S. HRG. 108–967

PRENATAL GENETIC TESTING TECHNOLOGY: SCIENCE, POLICY, AND ETHICS

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

NOVEMBER 17, 2004

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

U.S. GOVERNMENT PRINTING OFFICE
82–615 PDF WASHINGTON : 2013

For sale by the Superintendent of Documents, U.S. Government Printing Office
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Fax: (202) 512–2104 Mail: Stop IDCC, Washington, DC 20402–0001

SENATE COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

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PRENATAL GENETIC TESTING TECHNOLOGY: SCIENCE, POLICY, AND ETHICS

WEDNESDAY, NOVEMBER 17, 2004

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

The Subcommittee met, pursuant to notice, at 2:05 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. I call the hearing to order. Thanks for being here with us this afternoon.

I hope this hearing—I've called you here during the Lame Duck portion of our session, and I hope it starts a dialogue on an important topic that has, for too long, I think, been avoided, ignored, not delved into, and yet has profound impacts on our society and actually who we are as a people. And we hope to start that here today.

As Chairman of this Subcommittee, I called this hearing to examine the science, policy, and ethics of prenatal genetic testing technology and its impact on individuals.

On our first panel, we'll welcome Mrs. Cheryl Sensenbrenner, wife of Congressman Sensenbrenner, who I've had the great privilege to work with, and her sister, Tara Rae Warren.

On our second panel, witnesses will discuss the ethics and examine the scientific merits of prenatal screening and diagnostic testing technologies and their impacts on patients and doctors, parents and children.

And, as I said with this, I hope we start a dialogue, a much needed dialogue, on this important subject that I think has been swept under the carpet for too long and needs to be brought out in the open.

We have succeeded in mapping the human genome, a masterful scientific achievement. And tied to this achievement, we now have rapid advancements in technology for genetic screening tests able to detect over 450 fatal or debilitating conditions. I called this hearing because I am unsatisfied that we are doing our best here in the United States to ask the right questions in order to safeguard all human life.

The first "do no harm" principle of medical ethics should bind the rapid advance of scientific technology and its applications to patients. There is no question that this and similar topics are rever-

berating around the globe. Just listen to some of the following examples.

A recently released survey in New Zealand found that 1 out of 15 people who took genetic tests for hereditary diseases felt coerced into doing so by family members, insurance companies, or mortgage lenders.

In England, all embryos produced for IVF treatments are now being screened for cystic fibrosis and Huntington's disease, as well as for genetic predisposition to certain types of cancer.

The Estonian Government's health website proudly claims that since a hereditary disease program was instituted in 2003, 40 babies with Down's Syndrome have been, quote, "unborn" and the birth of, quote, "sick babies" prevented, with the help of prenatal diagnostic tests.

The Netherlands is discussing euthanasia for children up to 12 years old, targeting disabled children. Research suggests that, in the Netherlands, pediatricians make decisions in about a hundred cases each year that result in the death of babies with severe multiple handicaps.

And here at home, in the U.S., we seem to be finding that women diagnosed with an abnormal baby are coming under pressure to terminate their pregnancy. In 2001, the American College of Obstetricians and Gynecology recommended tests for cystic fibrosis to all Caucasian couples, even though Kaiser Permanente reported that among its Northern California patients, 95 percent of the couples who were carriers, and whose fetuses tested positive, terminated their pregnancies.

Insurance companies, both public and private, will have to make coverage decisions as genetic screening technology continues to advance. And such decisions must be made based on the ethical impact of the test on the primary patient: the unborn.

While I applaud our passage last year of the Genetic Nondiscrimination Act, we must assure that families receive full protection from discrimination on the basis of tests on the unborn. Health plans that do not normally cover surgical abortion may determine that it is cost effective to do so if the procedure occurs in concert with the genetic testing protocol.

It is my hope that this hearing will start a dialogue around some of these issues before healthcare providers and geneticists and possibly insurance companies start making these decisions for us.

As we consider the fast pace of scientific and technological progress in our modern world, we must not lose our moral compass. It would be devastating to replace our "First, do no harm" principle with a more utilitarian model based on collective economic viability. We don't want a world where parents feel driven to justify their children's existence.

In addition to the many abilities that persons with disabilities have which are equivalent to others, these individuals bring a beauty to our world that we don't want to miss. We learn compassion, heroism, humility, courage, and self-sacrifice from these special individuals. And their gift to us is that they inspire us, by their example, to achieve these virtues ourselves.

I look forward to the discussion, and I look forward to the panel's presentation on this important topic.

Senator Lautenberg, do you have an opening statement?

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

Senator LAUTENBERG. Yes. Thanks very much, Mr. Chairman.

And I agree with you that concern for children is a critical issue. I have four kids and ten grandchildren, and when I cast a vote in this Committee or on the Senate floor, I think about the effect that the vote will have on them. So I share your concern about children.

But this hearing isn't really about children. It's another attempt to advance an anti-choice agenda. And that's not the role of this Subcommittee.

Now, I've reviewed the hearings that this Subcommittee has held during the 108th Congress, and—this Subcommittee has jurisdiction over a number of issues—we've had 14 hearings on NASA, and a sprinkling of hearings on some other relevant topics. But the reason that we have Committees that have jurisdiction is so we can cover all of the subjects that are our responsibility, and there is no limit to the amount of the Committee concerns that we have.

But this Committee—and this is taken from our website—and I hope the witnesses will forgive me, because I don't differ with your being able to talk about the issues that concern you. We're proud to have both of you here. The question is whether or not we are taking time from this Committee when, in fact, we have other responsibilities. The Subcommittee on Science, Technology, and Space hearings in the 108th Congress subcommittee jurisdiction: National Aeronautic and Space Administration—we've had 14 hearings there; National Oceanic and Atmospheric Administration, one; National Science Foundation—we sat in this very room yesterday talking about—you talk about threats to children—we're talking about the climate change that we're witnessing these very days and the effect that this could have on families and children and communities being wiped out by flooding or atmospheric conditions that will not only not permit new life to begin, but end life as we know it; National Institute of Standards and Technology, not one hearing. Not one.

And I had mentioned the National Science Foundation. I went down to the South Pole to see what we're doing there about protecting our communities from being over—from being flooded because of changes in climate. Not one hearing—not one—in this Subcommittee.

Office of Science and Technology Policy, pretty important, one hearing. Fire administration—Lord knows we've had enough problems with forest fires and needs for being ready for any attacks that we might have on our country, fire. Federal R&D funding, one hearing. One hearing. We haven't really had a discussion of the need for stem cell research. Internet, not an important subject, I guess, in this committee, this Subcommittee on Science, Technology, and Space. Not one hearing on the Internet. Earthquake research problems and programs—we've had one hearing.

The Committee, I remind you—Subcommittee on Science, Technology, and Space. That's what our jurisdiction is.

Encryption. Are we talking about encryption today so we can find out what's happening before we send our kids into battle, to find

out how we protect our society? No, we're not doing any of that. International Science and Technology, one hearing.

Total, 19. This is over 2 years.

May I see the other? These are called extra-jurisdictional. The anti-abortion agenda—and people are free to make choices; I don't want to rob my colleague, Senator Brownback, from making his decisions about things, but this, again, the Committee on Science and—Subcommittee on Science and Technology. Media indecency and violence, two hearings. Marriage promotion, one hearing. Marriage promotion. Science and Technology. And now we're finding new ways to address the title, so we throw the word "science" in there to pretend that it really is a science interest. "A New Kind of Science." That's a whole other subject.

We've had, in the two years that we've been in business, 12 hearings in these extra-jurisdictionals, 19 hearings in the nature of our business.

I object to the hearings on—the 11 hearings on those issues that are beyond this Subcommittee's jurisdiction—hearings on divorce, abortion, stem-cell research—thinly veiled attempts to push the anti-abortion views. And, again, that's up to each individual. That's the wonder of our society, is that you can express yourself, express it in the proper forum. You can't hear—under the Freedom of Speech, you can't holler "Fire" in a theater, and, in this Subcommittee, we ought not to be reviewing things that don't belong in our jurisdiction.

It's telling that panels are always presented here with anti-choice witnesses to prevent a fair debate about some of the very serious topics. These 11 hearings promote a certain set of cultural values.

And I don't want to be misunderstood, I have no problem with holding these values or voting in any way that's consistent with them. That's the individual's right. But I do object to hijacking this Subcommittee, at taxpayer expense, to push an agenda that properly falls under the purview of the Judiciary and Health Committees.

And I reviewed these hearings that the Subcommittee held, and found it shocking as I looked at what we've accomplished. Fourteen hearings on NASA, a sprinkling of hearings, five others, on some other relevant topics. But when there are 11 hearings on issues that are beyond this Committee's jurisdiction—Subcommittee's jurisdiction, I am discouraged by it, and I am challenging the ability of this Committee to lead—this Subcommittee—to lead the agenda that we have an obligation to fulfil, and proceed with an agenda that pushes one person's—the Chairman's—view on what is moral and immoral.

There are other Committees to take care of this, Mr. Chairman. If this Subcommittee is going to be used in this fashion, then I propose that we hold hearings and get social scientists here to testify on the impacts that long-term childlessness has on families, whether or not we ought to be doing research on all kinds of illnesses and problems, and healthcare for children, until perhaps they're age 12, free of charge, regardless of family income. Those are the things that we might want to talk about. We can hold hearings to determine whether or not we are fully funding postnatal care, Head Start, and No Child Left Behind.

Those are the things that I think we ought to be focusing on, Mr. Chairman, and I raise my objection with all due respect and friendship, but total disagreement.

Senator BROWNBACK. Thank you.

Mrs. Sensenbrenner, thank you very much for joining us today. As you can tell in the Committee, we've had a lot of hearings the last 2 years, and we're delighted that you're here. We're delighted that you're here with your sister, and look forward to your presentation.

Be sure you get the microphone, if you can, close so that we can all hear your presentation.

Mrs. SENSENBRENNER. OK?

Senator BROWNBACK. Yes.

Mrs. SENSENBRENNER. Thank you.

STATEMENT OF CHERYL SENSENBRENNER, BOARD MEMBER, AMERICAN ASSOCIATION OF PEOPLE WITH DISABILITIES

Mrs. SENSENBRENNER. Thank you, Mr. Chairman and Members of the Senate Commerce, Science, and Transportation Subcommittee on Science, Technology, and Space.

Thank you for inviting me to testify on the implications of the new prenatal genetic testing technologies for people with disabilities and their families. I'm honored to have this opportunity.

My name, as you know, is Cheryl Sensenbrenner, and I am a Board Member of the American Association of People with Disabilities, AAPD. This is a national nonprofit, nonpartisan membership organization promoting political and economic empowerment for the more than 56 million disabled children and adults in the United States.

I am also here as a woman with a disability, and, probably most importantly, as the proud sister of a woman with Down's Syndrom, Tara Rae Warren. I am delighted that my sister, Tara, is able to be with us today for this important hearing.

Whereas my friend and colleague Andy Imparato will approach today's topic from a public policy standpoint, my comments today will be more personal.

Although we are currently making progress in public attitudes, there is still a strong tendency in American society to underestimate the positive contributions that people with disabilities are capable of making—if they're given a chance. I have seen people continually underestimate what my sister is capable of doing, and I have seen what can happen when people believe in her and give her an opportunity to shine.

Because Tara's mental disability is physically recognized, she is almost daily subjected to snide remarks, odd looks, and put-downs. Tara has faced many obstacles with no fear and total perseverance. Through her early education and with our family and my mom's support, and dad's, Tara has been able to support herself with various jobs. This financial independence has been a great sense of pride for Tara—or Tari, as we call her. She has been able to pay for her own car—that she drives—and her car insurance.

In the past few elections—and, indeed, in the last election—Tara has been a nonpartisan, paid poll-worker in Wisconsin. Tara has completed her high school education and taken a couple of college

courses. She has given speeches to student teachers of special education on the challenges of her disability. And, later, Tara would be most happy to answer any questions you might have—once she stops blushing—after me. I'm very proud of her.

Although I don't often encounter the same degree of paternalism that my sister has faced, I can tell you, from my own personal experiences living with a disability for all of my adult life, that people frequently underestimate or overlook my capacity—capabilities, as well. Many people assume that my injuries occurred after my marriage to my husband, Representative F. James Sensenbrenner, Jr. No, my husband got me in a wheelchair or, at my best times, on my Canadian crutches; and, today, often I function as I am with a cane, a leg brace; and sometimes, in bad times, in a wheelchair.

This has been a lifelong journey with me since I was 22 years old. For an example, I can remember when my father—he was the AG, Attorney General, in Wisconsin—we were going to a bank while I was working at the capital, sitting in the lobby, waiting for my dad, and a bank executive came in, looked at me, and stated, "People like that belong on the park benches out front, not in our lobby." He was holding the money in his bank that I was making in my job as a disabled person. I find it amazing that someone with a higher education would still think with such a closed mind. This is one small example out of thousands.

I can also remember back when the physically disabled were determined not-qualified to serve on a jury. I am curious to know whether they truly believed that I would be mentally unfit due to my physical disability or if it was simply an issue of handicap accessibility.

Being a disabled person can be difficult, but it's not impossible to deal with. On the positive side, with the support of my dear family and friends, only certain sports and pretty shoes with heels remain unapproachable to me.

When I had children, I didn't have to worry about prenatal genetic testing, because the science hadn't evolved to a point where that testing was widespread. Indeed, I was initially told not to get married or have children or a job. So, in those days—we have advanced somewhat from that time for people that are disabled.

I know that in recent years the science and practice of prenatal genetic testing has grown, so that now it is very common for pregnant moms to be offered screening tests to determine the likelihood that their baby would be born with conditions like Tara's—Down's syndrome—or spina bifida, which is similar, somewhat, to what I have now, or can be.

I'm concerned that expecting parents are being asked to consent to tests without really understanding the pros and cons of participating in this kind of testing. I am also even more concerned that expecting parents are being given the positive results of prenatal diagnostic tests for conditions like Down's syndrome—for instance, if they have a positive test and know they will have a Down's child—without giving good information about what it's like to raise a child with Down's syndrome, or what supports and programs exist in the community for people with disabled children.

When you couple the uninformed fears and concerns many parents are likely to have when they receive this kind of prenatal di-

agnosis, the pressures they perceive from their treating professionals, families, and friends to terminate the pregnancy, you have a recipe for uninformed decisionmaking that can dramatically reduce the numbers of babies born with Down's syndrome and other congenital disabilities.

As someone who can testify to the great joy and love that my sister has brought to me and my family—and, in fact, the community and the world—I am saddened and disheartened to think that the new genetic technologies would have this kind of impact.

As a parent, I'm deeply troubled by any efforts to use prenatal genetic testing to identify genetically "normal" or "healthy" children and terminate pregnancies that fail to pass this test. Our responsibility as parents is to love and nurture our children, whatever challenges they may face. As a society, do we really want to live in a world where children must pass genetic tests in order to be born?

I believe we have a moral and ethical responsibility to maximize the likelihood that children with disabilities will be welcomed into the world like other children, and that their families will be supported in their efforts to help their children thrive.

Science and medicine should be used to improve the quality of people's lives, not to encourage parents to try to engineer an advantage in the genetic lottery for their children.

If our experience with the prenatal screening and tests currently being used for Down's syndrome and spina bifida is a harbinger of what is to come, I'm very worried about how the new genetic technologies will be used, moving forward. I believe that God created a beautifully diverse human population for a reason, and we should be humble and proceed with caution as we develop tools that can be manipulated to threaten that diversity.

Thank you, Senator, for the opportunity to testify and for calling attention to this important topic.

[The prepared statement of Mrs. Sensenbrenner follows:]

PREPARED STATEMENT OF CHERYL SENSENBRENNER, BOARD MEMBER, AMERICAN ASSOCIATION OF PEOPLE WITH DISABILITIES

Mr. Chairman, Ranking Member Breaux, and Members of the Senate Commerce, Science and Transportation Subcommittee on Science, Technology and Space:

Thank you for inviting me to testify on the implications of the new prenatal genetic testing technologies for people with disabilities and their families. I am honored to have this opportunity. My name is Cheryl Sensenbrenner and I am a Board Member of the American Association of People with Disabilities (AAPD), a national non-profit, non-partisan membership organization promoting political and economic empowerment for the more than 56 million disabled children and adults in the U.S.

I am also here as a woman with a disability, and, probably most importantly, as the proud sister of a woman with Down syndrome, Tara Rae Warren. I am delighted that my sister, Tara, is able to be with us today for this important hearing. Whereas my friend and colleague Andy Imparato will approach today's topic from a public policy standpoint, my comments today will be more personal.

Although we are certainly making progress in public attitudes, there is still a strong tendency in American society to underestimate the positive contributions that people with disabilities are capable of making if given a chance. I have seen people continually underestimate what my sister is capable of doing, and I have seen what can happen when people believe in her and give her an opportunity to shine.

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Although I don't often encounter the same degree of paternalism that my sister has faced, I can tell you from my personal experience living with a physical disability for all of my adult life that people frequently underestimate or overlook my capacities as well. Many people assume that my injuries occurred after my marriage to my husband, Representative F. James Sensenbrenner, Jr. My husband, Jim, "got me" in a wheelchair, or at best on Canadian crutches. This has been a lifelong journey since I was twenty-two years old. I can remember when my father was the Attorney General of Wisconsin going to a bank and sitting in the lobby waiting for my father to conduct some personal business. I remember a bank executive looking at me and stating "people like that belong on the park benches out front and not in our lobby." I found it amazing that someone with a higher education would still think with such a closed mind. I can also remember back when the physically disabled were determined not qualified to serve on a jury. I am curious to know whether they truly believed that I would be mentally unfit due to my physical disability or if it was simply an issue of handicap accessibility. Being a disabled person can be difficult, but it is not impossible to deal with. On the positive side with the support of my dear family and friends, only certain sports and pretty shoes with heels remain unapproachable to me.

When I had my children, I didn't have to worry about prenatal genetic testing because the science hadn't evolved to a point where that kind of testing was widespread. I know that in recent years the science and practice of prenatal genetic testing has grown so that now it is very common for pregnant mothers to be offered screening tests to determine the likelihood that their baby will be born with conditions like Down syndrome and Spina Bifida.

I am concerned that expecting parents are being asked to consent to tests without really understanding the pros and cons of participating in this kind of testing. I am also even more concerned that expecting parents are being given the positive results of prenatal diagnostic tests for conditions like Down syndrome without getting good information about what it is like to raise a child with Down syndrome, or what supports and programs exist in the community for families with disabled children.

When you couple the uninformed fears and concerns many parents are likely to have when they receive this kind of a prenatal diagnosis with the pressures they may perceive from their treating professionals, family and friends to terminate the pregnancy, you have a recipe for uninformed decision making that can dramatically reduce the number of babies born with Down syndrome and other congenital disabilities. As someone who can testify to the great joy and love that my sister has brought to me and my family, I am saddened and disheartened to think that the new genetic technologies would have this kind of impact.

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I believe we have a moral and ethical responsibility to maximize the likelihood that children with disabilities will be welcomed into the world like other children, and that their families will be supported in their efforts to help their children thrive. Science and medicine should be used to improve the quality of people's lives, not to encourage parents to try to engineer an advantage in the genetic lottery for their children.

If our experience with the prenatal screening and tests currently being used for Down syndrome and Spina Bifida is a harbinger of what is to come, I am very worried about how the new genetic technologies will be used moving forward. I believe that God created a beautifully diverse human population for a reason, and we should be humble and proceed with caution as we develop tools that can be manipulated to threaten that diversity.

Thank you for the opportunity to testify and for calling attention to this important topic.

Senator BROWNBACK. Thank you very much.

And I would note, as you told me earlier, that you've testified here first before, on the House side, so I want that to get back to your husband——

Mrs. SENSENBRENNER. No, I haven't. I'm saying I'm waiting, sir.

Senator BROWNBACK. Oh. Well, we have taken this topic up first, and I thank you for your testimony.

You made a statement there at the end about—that you're afraid of the harbinger of what the testing for Down's syndrome and spina bifida will be on other genetic testing. What can we learn from our experience on testing, genetic testing, on spina bifida and Down's syndrome, relative to the new sets of testing?

Mrs. SENSENBRENNER. Well, I don't know if I can specifically answer your question. There are probably people that can do—What I can—what I am—I'm concerned about is that people—automatically, now, people are not given—automatically, they're tested, and they don't—they're—they see it as a closed door, and that this is horrible. They don't understand that it's just a child that has something different, and that you can deal with it.

I don't know—I don't quite understand how to answer your question, Senator. All I wanted to make clear was that having a child that has a congenital disability is nothing to—it's something to look at as a challenge, not as the end of opportunities for your parenthood.

Senator BROWNBACK. Yes, as it has been in your family. It's been a great gift of great joy.

Mrs. SENSENBRENNER. Yes. Matter of fact, when I was first hurt, we didn't always know if I would always be in the bed. And Tari was born, and as she—when she was young, I spent a lot of time with her, working with her. It's always best, if you have Down's—as I understand it, Tari—to get your education going a little early. And she functioned as my legs and my body to get things for me as I was working with her. And we got to be pretty close that way, didn't we, Sis?

Ms. WARREN. Yes, we did.

Senator BROWNBACK. Tari, welcome to the Committee. I'm delighted that you're here.

Ms. WARREN. Thank you, Senator.

Senator BROWNBACK. You give speeches to educational groups in the country. What do you tell them? What's the heart of your message?

Ms. WARREN. Well, the heart of the message is to tell the student teachers that I've been talking to—is to accept the people who have a disability and to help them when they are in trouble, and to be sure that they don't get teased or—try to be themselves in the class. They should mainstream them. I was mainstreamed. I was mainstreamed in—I did graduate with honors in 1989. I was mainstreamed through all my classes. And I did a pretty good job, except for one. But, otherwise, I encountered lots of people who weren't very nice to me, but I learned to live with it. And I think that people who have a disability like Down's syndrome should have—just to have, like, someone to be there for them in case—if people get rude and inappropriate to them in the middle of classes.

Senator BROWNBACK. You know, the—if you took a vote here in the Capitol of the most favorite employee in the whole Senate side

of the Capitol, I have a bet for who the winner would be. And I am certain I would be right on this. And his name is Jimmy. He operates the elevator on the Senate side. He's a Down's syndrome person, as well. And he is the most wonderful, kind, great—he gives me high fives and hugs like nobody else does. I love it. And he's just—he brightens my day in an incredible way. And I think of how much poorer we would be, as a world, or as a Senate, in particular, without Jimmy. And my guess is, Tara, for you, that—how much poorer people around your world would be without you.

I really appreciate you, and your showing the rest of us how to live. It's kind of you to do.

Ms. WARREN. Thank you, Senator.

Senator BROWNBACK. Mrs. Sensenbrenner, thanks for coming and being an advocate on this cause. As I said stated at the outset of the hearing, I don't think there has been another hearing in the House or the Senate on this topic, and yet it is on us as a topic, and we do have a set of tests that we've been doing. And we're going into a season where we're going to be able to test for hundreds of things.

Mrs. SENSENBRENNER. I know.

Senator BROWNBACK. And we really need to have a discussion, as a country, about, "OK, when—if you do these tests, now, what does this mean?" And let's not just say, "OK, we have to have the perfect child here." And having five children, there's no such thing as a perfect child, and every one of them are different. And that's the beauty of it. That's the real beauty of it. We need this discussion, and I'm hopeful that you can continue to have it with us, and that, Tara, you can continue to prod us to have this discussion, in all of its beauty and glory.

Ms. WARREN. Thank you.

Senator BROWNBACK. Thank you both for joining us here today.

I want to call up the second panel. Dr. John Bruchalski—he's a family practice practitioner in Virginia; Dr. Brian Chicoine, Medical Director of the Adult Down Syndrom Center of Advocate Lutheran General Hospital, in Park Ridge, Illinois; Dr. Kathy Hudson, Director of Genetics and Public Policy Center, Associate Professor of Bioethics, Department of Pediatrics, Johns Hopkins University—boy, I hope you get that all one business card——

Dr. HUDSON. I do.

Senator BROWNBACK.—Mr. Andrew J. Imparato, President and CEO of the American Association of People with Disabilities; and Mr. Andrew Kimbrell, Executive Director of the International Center for Technology Assessment, Executive Director for the Center for Food Safety, here in Washington, D.C.

This is an expert panel, a practitioners panel, that we wanted to talk about this same subject with this group, and I'm delighted that each of you were willing to join us today.

We will run the time clock, if we can get it going here, probably at five—we'll do it at 6 minutes. That's just a guide; although, if you can stay with that—and then we'll have—I'd like to have interaction and a dialogue afterwards, if we can.

Let's take the presentations in the order that they were introduced. Dr. Bruchalski—did I get that correct?

Dr. BRUCHALSKI. Yes.

Senator BROWNBACK. Thank you for joining us, and I look forward to your testimony.

STATEMENT OF DR. JOHN BRUCHALSKI, BOARD CERTIFIED OBSTETRICIAN AND GYNECOLOGIST

Dr. BRUCHALSKI. Thank you for this opportunity. It is, indeed, an honor to be on the same panel as Tara.

My name is John Bruchalski, and I'm a Board Certified Obstetrician and Gynecologist practicing in Fairfax, Virginia. I have practiced in the field of OB/GYN since 1987, which includes my residency. And I am very thankful for this opportunity to testify.

My career as a private practitioner has spanned the recent developments in prenatal genetic testing for Down's syndrome, spina bifida, and cystic fibrosis, and now cystic fibrosis at the clinical level. I have literally spoken to thousands of families about these diseases and these prenatal tests.

The emphasis of my testimony will be twofold—to show that the data we use for counsel is more confusing than clarifying, and, second, that the conversation generated may cause irreparable damage in the parent-child bond, with implications of how the family views individuals with disabilities, or, worse, how they view those who have had abnormal testing, but are completely normal human beings. More confusing than clarifying.

We are speaking today about maternal screening tests for conditions such as Down's syndrome. Screening tests are not diagnostic tests; they are meant to be preliminary tests, universally applied to those in low-risk populations, the results of which determining who will be counseled to undergo more accurate, but expensive and invasive—*i.e.,* riskier—diagnostics-grade testing.

In regard to Down's syndrome, the vast majority of mothers who give birth to Down's syndrome are under the age of 35. And so that these screening tests, such as the AFP or the triple screen, have, by their nature, an inherently in-built high false positive rate—the test is abnormal, but the subject may be normal—because the thresholds for declaring a screening test result positive is set to capture the most individuals who truly have the condition, at the expense of including some—or, in this case, many—who do not. It is in this expense that the sloppiness of these tests is exposed and, ultimately, the damage is done.

Parents are presented with these screening tests as a common, indispensable, accurate, and normal part of the prenatal evaluation. The results of these tests provide a statistical threshold, risk estimate, or likelihood—one in 150, one in a thousand, one in 50—that the blood taken from mom tells her the risk of—to her unborn child—her fetus has of carrying that disease, above the risk that her age predisposes her to, that the test—this is what the screening test is all about. Many moms are unaware that this a screening test, and not a diagnostic or definitive one. And even when explained thoroughly, we walk away—they walk away with—they walk away with other ideas of what we're trying to convey to them; they're walking away with wrong ideas. For someone like myself, who has had cancer, when someone says you have that, you begin to not hear very well.

Many moms are unaware that this is a screening test, and not a diagnostic or definitive one. Then the next step becomes a procedure that aims to obtain tissue or fluid for definitive diagnostic purposes, carrying a procedure-related pregnancy-loss rate of something around one in 200. This is very sloppy defensive medicine, as far as we're concerned. This data given to parents lacks any diagnostic certainty concerning the health or the genetic makeup of their unborn child. It's statistics.

Second, this attempt to mandate that all mothers have this test done, since 97 percent of children with Down's syndrome occur in families with no previous history of the syndrome, and 88 percent are born to women under 35 years of age, is an attempt to prevent the wrongful birth legal outcome, or any outcome which many feel should have serious consequences, including legal liability for the clinician.

This universal application for the screening test for Down's syndrome also lacks appropriate pre-test counsel, such as meeting with the families who have had children with such conditions. We attempt to do this with our patients. And after explaining the poor accuracy of these tests, including the high false positive, as well as false negative, rates and the need for invasive testing to determine the true condition of the baby—or the fetus, most women do not opt for this medical screen. In fact, we have had many patients who have transferred into our practice precisely because their prior obstetrical practice placed guilt and pressure on them to have this test that they truly did not want.

In reference to the present recommendation for universal screening for cystic fibrosis, being an asymptomatic carrier for the genetic mutation that causes CF is prevalent one in 25 to one in 30 in the United States, but this carries with it some major pitfalls. The gene for CF is very large, and the sheer number of mutations that are possible—over 900, to date—make all at-risk pregnancies not able to be identified. Therefore, the American College wants all OB/GYNs to offer, as you had mentioned, to non-Jewish Caucasians and Ashkenazi Jews this screening that only looks at 25 to 35 of the most common mutations. This is up for yearly review because of the science that's driving this.

This area of CF testing emphasizes the data currently with the best of intentions, and training is confusing and not clarifying for physicians or patients. With obvious lack of clarity in this area for prenatal testing comes a subtle, yet profound, undercutting of the unconditional parent-child bond.

Quote, "I spend an enormous amount of my time talking with mothers, trying to heal the damage that these tests do," one of my partners exasperatedly told me of his frustration from his last several practices that he's been involved with. Let's say the screening test is positive. The parent naturally asks, "Is my child okay? Is he or she normal?" Even if the tissue diagnosis comes back normal, these parents have not only been anxious about the health of their unborn child, they have been stripped of their joy about the pregnancy, because, seemingly, no amount of postprocedural counseling can erase all the anxiety in the minds and hearts of parents created by the abnormal screening tests.

"There must have been something to it." That's a common quote that we hear in our office. The anxiety and the lack of joy translates into a stigma attached to the child for the lifetime of the parent-child-family interaction. This stigma that sometimes had to have caused this test to be abnormal carries the life of the child with those parents. This is irreparable damage done to the family bond.

Also, in doing the definitive diagnostic procedure, such as amniocentesis and chorionic villus sampling, there is the very real possibility, if the screening test gives us a false positive, which encourages us to do the definitive test, and, while doing this procedure, the membranes that harbor the child rupture and a miscarriage occurs, or the chronic leakage of amniotic fluid occurs, resulting in severe developmental damage to the fetus, to the child, only to find out that the child investigated by the prenatal genetic screening test was, indeed, healthy. That risk has been documented to be somewhere between one-half to 3 percent for the rupturing of the membranes.

The loss of a healthy child due to a procedure done because a screening test was believed to be more accurate than billed causes a profound fracturing of the doctor-patient relationship. I know this, because I have personally experienced this issue in my own professional life.

So, in conclusion, the practical clinical application of this prenatal genetic testing technology is fraught with non-definitive relative risks. The unconditional love between parent and child, and the joy that this manifests, is destroyed with conditional, cautious stigmatization that lasts a lifetime. Because of the emotional and physical trauma that the Down's syndrome story has provided us, and the fact that I have family members with Down's syndrome, I strongly advise that this Committee continue to keep this conversation alive in regarding to these technologies and the future technologies.

Thank you very much.

[The prepared statement of Dr. Bruchalski follows:]

PREPARED STATEMENT OF DR. JOHN BRUCHALSKI, BOARD CERTIFIED OBSTETRICIAN AND GYNECOLOGIST

My name is John Bruchalski and I am a Board Certified obstetrician and gynecologist. I have practiced in my field since 1987, which includes my residency, and I am thankful for this opportunity to testify at this hearing on prenatal genetic testing technology: science, policy and ethics. My career as a private practitioner has spanned the recent developments in prenatal genetic testing for Down's syndrome, Spina Bifida and now Cystic Fibrosis at the clinical level. I have spoken to thousands of families about these diseases and these prenatal tests. The emphasis of my testimony, will be twofold: to show that the data we use for counseling is more *confusing than clarifying* and, secondly, that the conversation generated may *cause irreparable damage* in the parent child bond with implications of how that family views individuals with disabilities, or worse, how they view those who have had "abnormal testing" but are completely normal human beings.

More Confusing than Clarifying

We are speaking today about maternal SCREENING TESTS for conditions such as Down's syndrome. Screening tests are not diagnostic tests. They are meant to be preliminary tests, universally applied to those in low-risk populations, the results of which determining who will be counseled to undergo much more accurate, but expensive and invasive, *i.e.,* risky diagnostic-grade testing. Screening tests such as the AFP or the Triple Screen have by their nature an inherently high inbuilt high false

positive rate, (test abnormal, but subject is normal), because the threshold for declaring a screening test result positive is set to capture the most individuals who truly have the condition at the expense of including some, or in this case many, who do not. It is in this expense that the sloppiness of these tests is exposed, and the damage is done.

Parents are presented with these screening tests as a *common, indispensable, accurate, and normal* part of the diagnostic evaluation of the prenatal medical process. The results of these tests provide a statistical threshold, risk estimate or likelihood (*i.e.,* 1/150, 1/7,000, 1/50, etc.), that the blood taken from the Mom, tells her the risk to her unborn child, the foetus, has of carrying the disease that the test is SCREENING for. Many Moms are unaware that this is a screening test, and not a diagnostic, or definitive one. Then the next step becomes a procedure that aims to obtain tissue or fluid for definitive diagnostic purposes carrying a procedure related pregnancy loss rate of 1/200. (1)

This is sloppy, defensive medicine. This data, given to parents lacks any diagnostic certainty concerning the health or the genetic makeup of their unborn child. Secondly, the attempt to mandate that all mothers have this test done, since 97 percent of children with Down's occur in families with no previous history of the syndrome (2), and 88 percent are born to women under 35 years of age, is an attempt to prevent the "wrongful birth" legal outcome or any outcome which many feel should have serious consequences including legal liability for the clinician. This universal application of the screening tests for Down's syndrome also lacks appropriate pre-test counsel such as meeting with families who have children with this condition. We attempt to do this with our patients, and after explaining the poor accuracy of this these tests, including the high false positive as well as false negative rates and the need for invasive testing to determine the true condition of the baby, most women do not opt for this medical screen. In fact we have many patients who transfer into our practice precisely because their prior obstetrical practice placed guilt and pressure on them to have this test that they truly did not want.

In reference to the present recommendation for universal screening for cystic fibrosis asymptomatic carrier of the genetic mutation that causes CF is prevalent (1/25 to 1/30) in the United States, and this carries some major pitfalls. The gene is very large and the sheer number of mutations that are possible, over 900 mutations described to date, make all at risk pregnancies not able to be identified. Therefore the American College of OB/GYN wants us "to offer" to all non-Jewish Caucasians and Ashkenazi Jews this screen that only looks at 25 of the most common mutations and this is up for yearly review. (3)

This area of CF testing emphasizes that the data currently with the best of intentions and training is confusing, not clarifying for physicians and patients. With obvious lack of clarity in this area of prenatal testing, comes a subtle, yet profound undercutting of the unconditional parent child bond.

Irreparable Damage to the Family

"I spend an enormous amount of time talking with mothers trying to heal the damage that these test do," one of my partners exasperatedly told me of his frustration with these tests. Let's say the screening test is positive. The parents naturally ask, "Is my child okay? Is he/she normal?" Even if the definitive tissue diagnosis returns normal, these parents have not only been anxious about the health of their unborn child, they have been stripped of their joy about the pregnancy because seemingly no amount of post-procedural counseling can erase all of the anxiety in the minds and hearts of parents created by an abnormal screening test result. "There must have been something to it". This anxiety and lack of joy translate into a stigma attached to this child for the lifetime of the parent-child family interaction. This stigma that something had to have caused this test to be abnormal carries the life of the child with those parents. This is irreparable damage done to the family bond.

Also in doing the definitive diagnostic procedure such as amniocentesis and chorionic villus sampling, there is the very real possibility that the screening test gives us a false positive result which encourages us to do the definitive test, and while doing this procedure the membranes rupture and a miscarriage occurs, or a chronic leakage of amniotic fluid occurs, resulting in severe developmental damage to the fetus, only to find out that the child investigated by the prenatal genetic screening test was indeed healthy. The loss of a healthy child due to a procedure done because a screening test was believed to be more accurate than billed causes a profound fracturing in the doctor patient relationship. I know, I have personal experience in this regard.

Conclusion

The practical, clinical application of this prenatal genetic testing technology is fraught with sloppy, non-definitive relative risks. The unconditional love between parents and child, and the joy that this manifests is destroyed with conditional, cautious, stigmatization that last a lifetime. Because of the emotional and physical trauma that the Down's syndrome story has provided us, and the fact I have a cousin with Down's syndrome, I strongly advise this committee to continued study of these technologies and their implication for individuals with disabilities.

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Senator BROWNBACK. Thank you. I look forward to our question session when—we will have on that.

Dr. Chicoine? Did I get that correct?

Dr. CHICOINE. Chicoine.

Senator BROWNBACK. Chicoine, sorry. Delighted to have you here. Thank you for coming in, and I appreciate your willingness to testify.

STATEMENT OF BRIAN CHICOINE, MD,
MEDICAL DIRECTOR, ADULT DOWN SYNDROME CENTER,
ADVOCATE LUTHERAN GENERAL HOSPITAL

Dr. CHICOINE. Chairman Brownback, thank you very much for giving us the opportunity to testify about prenatal genetic technology testing.

I am Brian Chicoine, the Medical Director of the Adult Down Syndrome Center of Advocate Lutheran General Hospital in Park Ridge, Illinois. I'd like to share with you my perspective on genetic counseling and information provided to families prenatally, and how it relates to my work in addressing the health needs of adults with Down's syndrome.

I'd like to submit a more comprehensive written record for the—or statement for the record, as well.

Senator BROWNBACK. It will be in the record in full.

Dr. CHICOINE. Thank you.

If a literature search is conducting—researching Down's syndrome, one finds that the majority of citations deal with prenatal diagnoses. The focus is mostly on screening blood tests, characteristics or findings on ultrasounds, and other methods used to diagnose Down's syndrome prenatally. A small number of citations can be found on optimizing care for people with Down's syndrome. Little or no research can be found on prenatal counseling, particularly with regards to the issue of providing information about adults with Down's syndrome.

Healthcare professionals need to be sensitive to the needs of families for genetic counseling that is both supportive and balanced. Researchers should examine the individual experience of each family in order to determine how best to accomplish this goal.

At the Adult Down Syndrome Center of Advocate Lutheran General Hospital, we work to provide the best information and care for adults living with Down's syndrome. The Adult Down Syndrome

Center is a unique collaboration between the National Association for Down Syndrome, Advocate Medical Group, and Advocate Lutheran General Hospital. The center opened in January 1992, at the request of the National Association of Down Syndrome, which is the parent group that serves the Chicago Metropolitan Area. These parents identified a need to provide high quality health and psychosocial services for their adult children.

We have grown to a full-time center, and now serve more than 2,500 adults with Down's syndrome. In addition, we have published numerous articles and have presented many times at educational forums, including at the World Health Organization and the National Down Syndrome Society.

Down's Syndrome is the most common chromosomal cause of mental retardation. The incidence is approximately one out of 800 to one out of a thousand births. It affects all races, cultures, and nationalities. Generally, the risk of recurrence of Down's syndrome in a future pregnancy is 1 percent greater than the baseline, which was just discussed. And the baseline—again, the baseline risk for having a child with Down's syndrome increases with maternal age.

Blood testing, the maternal triple screening, which was discussed, is used as part of the screening process, particularly in younger women; and amniocentesis or chorionic villus sampling is required to make a definitive prenatal diagnosis, and are generally offered to women over 35 or those with a positive blood test.

It is difficult for me to paint an accurate picture of adults living with Down's syndrome. Trying to sum up a wonderfully diverse group of people is quite a challenge if you've not met them personally. On average, adults with Down's syndrome function in the mild to moderate range of mental retardation, but the range runs essentially the full gamut. However, increased level of function is clearly an area that is expected to improve with early intervention and other opportunities.

I tell young families that over time we may see what I call two syndromes. Our older patients often had little education and inadequate healthcare as children, and few opportunities as they reached adulthood. The younger people with Down's syndrome not only have better education, healthcare, and opportunities, but there are increased expectations for their success, and, as a result of that, we are seeing greater achievement and independence, as certainly was evidenced here a short time ago.

For years, families were told that their children with Down's syndrome would not survive into adulthood. This advice guided the family's expectations for their sons or daughters, it has caused families to lower their expectations, inadequately prepare for the full life span of their child, and left them unprepared to deal with health and other issues of their adult child.

During this time, the median age of death for a person with Down's syndrome rose from 25 years, in 1983, to 49 years, in 1997, and the life expectancy of a person with Down's syndrome is now 56 years.

Misinformation has been given to families prenatally. Families have shared with me some of their stories about the types of information they received when they were pregnant with a child with Down's syndrome. Some of the information was correct, but some

was incorrect, and some of the information overemphasizes the negative.

Some of the information provided during counseling is correct, such as: adults with Down's syndrome have a greater incidence of certain health conditions, such as diabetes mellitus, obesity, osteoporosis, celiac disease, and others. And some of the information presented is incorrect or misleading. For example, families are often told that all people with Down's syndrome develop Alzheimer's disease at a young age. While it has been demonstrated that people with Down's syndrome over the age of 35 or 40 do develop the microscopic changes seen in Alzheimer's disease, the incidence of clinical Alzheimer's disease may actually be similar to the incidence seen in the general population.

Unfortunately, many unproven—or much unproven information has been recited to families as fact, and has caused a great deal of confusion and concern. In addition, usually there's information about Down's syndrome that is not shared. The incidence of most types of cancer is lower in people with Down's syndrome. Hypertension is quite rare. And coronary artery disease, the leading killer of people without Down's syndrome, is almost nonexistent in adults with Down's syndrome.

Beyond what is said is the context of how the information is communicated. It is important to present a balanced picture of the strengths and challenges presented by these very special children and adults. There are a number of health conditions that are more common in adults with Down's syndrome. With improved healthcare and social and education and recreational opportunities, many of these problems are not inevitable, and the incidence can be reduced.

There is no question that adults with Down's syndrome face challenges. It is important that adults with Down's syndrome, their families, and healthcare providers have an appropriate and accurate information to help them work through these challenges. And it is important that this information be provided throughout the life span of a person with Down's syndrome.

I strongly recommend families who have a newborn with Down's syndrome, or are pregnant with a child with Down's syndrome, that they meet with other families who have a child with Down's syndrome. There is some research that is available on the experience of families with regards to how they were told that their newborn has Down's syndrome. The majority were disappointed with how the medical professionals told them that and how this information was provided. Referral to a support group did improve the experience.

In conclusion, people with Down's syndrome are living longer, living more independently, and reaching for new heights. With good healthcare, opportunities for achieving their potentials, and more realistic societal expectations, only greater accomplishments can be expected. Many of the people providing prenatal care or prenatal information about Down's syndrome seem to know little about adults with Down's syndrome. There is little research that has studied how information on children and adults with Down's syndrome is being provided to families in prenatal counseling. Families have shared with me many of their stories, and these stories,

as well as the studies, suggest that there is much to learn. Healthcare professionals need to be sensitive to needs of families for genetic counseling that is supportive and balanced. And researchers should examine lived experiences of families in order to determine how best to accomplish this goal.

Mr. Chairman, thank you, again, for this opportunity to speak with you.

[The prepared statement of Dr. Chicoine follows:]

PREPARED STATEMENT OF BRIAN CHICOINE, MD, MEDICAL DIRECTOR, ADULT DOWN SYNDROME CENTER, ADVOCATE LUTHERAN GENERAL HOSPITAL

Chairman Brownback and distinguished members of the Senate Commerce Subcommittee on Science, Technology and Space, I thank you for giving me the opportunity to testify about Prenatal Genetic Technology Testing. I am Brian Chicoine, MD, Medical Director of the Adult Down Syndrome Center of Advocate Lutheran General Hospital in Park Ridge, Illinois. I would like to share with you my perspective on genetic counseling and information provided to families prenatally and how it relates to my work in addressing the health needs of adults with Down syndrome. I would like submit a more comprehensive written statement for the record.

If a literature search is conducted researching "Down syndrome," one finds that the majority of citations deal with prenatal diagnoses. The focus is mostly on screening blood tests, characteristics or findings on ultrasounds, and other methods used to diagnose Down syndrome prenatally. A smaller number of citations can be found on optimizing care for people with Down syndrome. Little or no research can be found on prenatal counseling, particularly with regard to the issue of providing information about adults with Down syndrome. Health care professionals need to be sensitive to the needs of families for genetic counseling that is both supportive and balanced. Researchers should examine the individual experience of each family in order to determine how best to accomplish this goal. At the Adult Down Syndrome Center at Advocate Lutheran General Hospital, we work to provide the best information and care for adults living with Down syndrome.

Adult Down Syndrome Center at Lutheran General Hospital

The Adult Down Syndrome Center is a unique collaboration among the National Association for Down Syndrome, Advocate Medical Group, and Advocate Lutheran General Hospital. The Center opened in January 1992 at the request of the National Association for Down Syndrome, the parent group that serves the Chicago metropolitan area. These parents identified a need to provide high quality health and psychosocial services to their adult children.

We have grown to a full-time Center and now serve more than 2,500 adults with Down syndrome. In addition, we have published numerous articles and have presented many times at educational forums, including the World Health Organization and the National Down Syndrome Society.

Down Syndrome

Down syndrome is the most common chromosomal cause of mental retardation. The incidence is approximately 1 out of 800 to 1,000 births. It affects all races, cultures, and nationalities. Of the people with Down syndrome, 95 percent have an extra chromosome 21 and the other 5 percent have partial triplication of the 21st chromosome. Generally, the risk of recurrence of Down syndrome in future pregnancies is 1 percent greater than the baseline risk.

The baseline risk for having a child with Down syndrome increases with maternal age. Blood testing (maternal triple screening) is used as part of a screening process, particularly in younger women. This detects 60 percent of trisomy 21 pregnancies with a 5 percent false positive rate. Amniocentesis or chorionic villus sampling are required to make a definite prenatal diagnosis and are generally offered to women over 35 years of age and those with a positive blood test.

It is difficult for me to paint an accurate picture of adults living with Down syndrome. Trying to sum up a wonderfully diverse group of people is quite a challenge if you have not met them personally. On average, adults with Down syndrome function in the mild to moderate range of mental retardation, but the range runs essentially the full gamut. However, increased level of function is clearly an area that is expected to improve with early intervention and other opportunities. I tell young families that over time we may see "two syndromes". Our older patients often had little education and inadequate health care as children and few opportunities as

they reached adulthood. The younger people with Down syndrome not only have better education, health care, and opportunities but there are increased expectations for their success. We are seeing greater achievement and independence.

Information and Counseling about Down Syndrome

For years families were told that their child with Down syndrome would not survive into adulthood. This advice guided the families' expectations for their sons and daughters. It has caused families to lower their expectations, inadequately prepare for the full life span of their child, and left them unprepared to deal with health and other issues of their adult child. During this time, the median age of death of a person with Down syndrome rose from 25 years in 1983, to 49 years in 1997. The life expectancy of a person with Down syndrome is now 56 years. However, families have not been getting accurate information.

Misinformation has also been given to families prenatally. Families have shared with me some of their stories about the types of information they received when they were pregnant with a child with Down syndrome. Some of the information is correct but some is incorrect and the information often overemphasizes the negative.

Some of the information provided during counseling is correct. Adults with Down syndrome have a greater incidence of certain health conditions such as diabetes mellitus, obesity, osteoporosis, celiac disease, sleep apnea, hypothyroidism, atlantoaxial instability and other conditions.

Some of the information presented is incorrect or misleading. For example, families are often told that all people with Down syndrome develop Alzheimer's disease at a young age. It has been demonstrated that people with Down syndrome over the age of 35 or 40 develop the microscopic changes that are seen in Alzheimer's disease. However, the incidence of clinical Alzheimer's disease does not appear to be universal and may actually mirror the incidence seen in the general population, albeit on average 20 years earlier. There is much to be learned about Alzheimer's disease in people with Down syndrome. Unfortunately, much unproven information has been recited to families as fact and has caused a great deal of confusion and concern.

In addition, usually there is information about Down syndrome that is not shared. The incidence of most types of cancer is lower in people with Down syndrome. Hypertension is quite rare. Coronary artery disease, the leading killer of people without Down syndrome, is almost nonexistent in adults with Down syndrome. Asthma also seems to be less common in adults with Down syndrome.

Beyond what is said, it is the context or how the information is communicated. If every parent were painted a picture of only the negative possibilities for their expected child, perhaps no one would give birth to a child. It is important to present a balanced picture of the strengths and challenges presented by these very special children.

There are a number of health conditions that are more common in adults with Down syndrome. With improved health care and social, educational, and recreational opportunities, many of these problems are not inevitable and the incidence may be reduced. Obesity is a good example. It has been assumed that obesity was inevitable in adults with Down syndrome because of a slower basal metabolic rate. Research now shows that this is not true and the effects of healthier nutrition and an active lifestyle are now being investigated. One disease that is more common in adults with Down syndrome that would be expected to decrease with improved nutritional status and exercise and recreational opportunities is diabetes mellitus.

There is no question that adults with Down syndrome face challenges. It is important that adults with Down syndrome, their families and health care providers have appropriate and accurate information to help them work through these challenges. It is important that the information be provided throughout the lifespan of a person with Down syndrome.

I strongly recommend families who have a newborn with Down syndrome or are pregnant with a child with Down syndrome meet with other families who have a child with Down syndrome. There is some research that is available on the experience of families with regards to how they were told their newborn has Down syndrome. The majority were disappointed with how they were told or the information that was provided. Referral to a support group improved the experience.

Conclusion

People with Down syndrome are living longer, living more independently, and reaching for new heights. With good health care, opportunities for achieving their potentials and more realistic societal expectations, only greater accomplishments can be expected.

Many of the people providing prenatal information about Down syndrome seem to know little about adults with Down syndrome. There is little research that has studied how information on children and adults with Down syndrome is being provided to families in prenatal counseling. Families have shared with me many of their stories and these studies suggest that there is much to learn. Healthcare professionals need to be sensitive to the needs of families for genetic counseling that is supportive and balanced. Researchers should examine the lived experiences of families in order to determine how best to accomplish this goal.

This concludes my remarks. Mr. Chairman, thank you again the opportunity to speak about these important issues. I would be happy to answer any questions you may have.

Senator BROWNBACK. Thank you, Dr. Chicoine. And I was just sitting here thinking, myself, about the joy that I've met—that I've had of people that I know with Down's syndrome. And when you mentioned that about hypertension, I think, yes, you know, Jimmy drops my hypertension——

[Laughter.]

Senator BROWNBACK.—whenever I see him. I don't know if there's any way to quantify or measure joy, but I—there's certainly a large quantity that's there.

Thank you.

Dr. Hudson, thank you for joining us today.

STATEMENT OF KATHY HUDSON, PH.D., DIRECTOR, GENETICS AND PUBLIC POLICY CENTER, BERMAN BIOETHICS INSTITUTE AND INSTITUTE OF GENETIC MEDICINE, JOHNS HOPKINS UNIVERSITY

Dr. HUDSON. Mr. Chairman, good afternoon, and thank you for inviting me to testify on the science, policy, and ethics of prenatal genetic testing.

My name is Kathy Hudson. I'm the Director of the Genetics and Public Policy Center at Johns Hopkins University. The center was created by a grant from the Pew Charitable Trusts, and our mission is to provide objective information and analysis on genetic technologies and genetic policies. The center doesn't advocate for or against any technology, or for or against any policy outcome, but, rather, we help to provide information and analysis and policy options that are useful for public conversation and for decisionmakers as they consider these issues.

Over the past two years, the center has been investigating reproductive genetic testing, and we are about to issue two reports. The first, "Reproductive Genetic Testing, Issues and Options for Policymakers," presents a range of policy options that consider the potential effects, both good and bad, of different policy choices. Our second report, "Reproductive Genetic Testing, What America Thinks," presents the results of our in-depth and ambitious effort to assess what the public knows, thinks, and feels about prenatal genetic testing. It includes the largest survey of Americans' attitudes yet, as well as a very large-scale effort to engage the American public in a conversation—in a dialogue, as you mentioned—about these technologies.

In the next few minutes, I'd like to make five brief points.

First, genetic tests give information, information that, in the reproductive context, can provide great reassurance or precipitate a decision. I want to emphasize that the decision to have a genetic

test, to get the information, and the decision about what to do with the information raise separate, though interrelated, issues.

Second, I'd like to emphasize the importance of preserving the right to know and the right not to know genetic information. The philosophy of those providing reproductive genetic services is nondirectiveness. Simply put, that means that the implications of these decisions are so profound and so personal that the decision of whether or not to have prenatal genetic testing, and what to do based on the results, must reside with the prospective parents. And, indeed, the majority of Americans agree with this approach.

Third, I'd like to address the issue of test accuracy and quality of care. The decisions made based on prenatal genetic test results are weighty. And, thus, the accuracy and reliability of those tests are of paramount importance. While the prenatal tests that are in general, routine use today are generally of high quality, there's no government guarantee. There is no government review of the Food—by the Food and Drug Administration, or any other Federal agency, of genetic tests before they are marketed, and there are no proficiency requirements under the Clinical Laboratory Improvement Amendment for Molecular Genetic Testing, making it difficult to evaluate whether laboratories are performing the tests well. One possibility is to increase Federal oversight to ensure that genetic tests are accurate and safe.

I'd also like to just briefly mention that our report addressed many of the issues that have been raised here about the quality of care and the nature of counseling and the information, and how to enhance the quality of genetic counseling in the reproductive context.

The fourth issue I'd like to raise is whether we, as a society, need to draw a line delineating what tests are appropriate in the reproductive context and those that are not. There are many different genetic tests available, ranging—those for fatal childhood conditions—such as Trisomy 13, or Tay Sachs—serious disorders, risk of adult onset disorders, and, of course, tests for sex.

Some have raised the specter, even, that we will, 1 day, be able to test for and select socially desirable characteristics. There is considerable debate within our society about what the ethically appropriate uses are for genetic testing in the reproductive context. American support for reproductive genetic testing depends heavily on their intended use. A majority of the general public approves of genetic testing, in the prenatal context, for a fatal childhood disease, while a similar majority disapproves of that use for traits unrelated to health. So at the extremes, there appears to be some general agreement about the appropriateness, or not, of prenatal genetic tests, but that doesn't address who decides.

And that brings me to my final point. In closing, I'd like to share with you some insights into what the American public thinks is the appropriate role of the government in overseeing the development and use of reproductive testing.

While there is a remarkable diversity of views, most Americans in our surveys have said that the government should not regulate prenatal genetic testing based on ethics or morality. And a majority, 63 percent, feel that the government should ensure the quality and accuracy of prenatal genetic tests. Thus, the American public

expects that the government will make sure that when they choose to have a prenatal genetic test, the results are accurate.

Thank you.

[The prepared statement of Dr. Hudson follows:]

PREPARED STATEMENT OF KATHY HUDSON, PH.D., DIRECTOR, GENETICS AND PUBLIC POLICY CENTER, BERMAN BIOETHICS INSTITUTE AND INSTITUTE OF GENETIC MEDICINE, JOHNS HOPKINS UNIVERSITY

Mr. Chairman and members of the Subcommittee, thank you for inviting me to be with you today to discuss the science, ethics, and policy of prenatal genetic testing.

My name is Kathy Hudson and I am the Director of the Genetics and Public Policy Center and Associate Professor in the Berman Bioethics Institute and in the Institute of Genetic Medicine at Johns Hopkins University. Established with a grant from The Pew Charitable Trusts, the mission of the Genetics and Public Policy Center is to provide independent and objective information and analysis on genetic technologies and genetic policies. We hope our work provides useful tools for decision makers in both the private and public sectors as they consider and respond to the challenges and opportunities that arise from scientific advances in human genetics.

Genetic testing is undergoing tremendous changes. Scientists are identifying disease-causing mutations in humans at a remarkable pace and developing tests to detect them. There are over 1,000 genetic tests available or in development, all of which could potentially be used in prenatal genetic testing. The growing availability and use of genetic testing in the reproductive context presents a host of complicated social, legal and ethical issues. I applaud this Committee for its foresight in taking up this issue and welcome the opportunity to share with you the results of the Center's work and experience in this arena.

The Genetics and Public Policy Center has spent the past two years investigating reproductive genetic testing, which includes prenatal genetic testing, the topic of today's hearing, as well as carrier testing and preimplantation genetic diagnosis. We are about to issue two reports on the topic. The first, *Reproductive Genetic Testing: Issues and Options for Policymakers, aims* to help focus and facilitate the discussion about reproductive genetic testing by outlining key scientific and medical facts, considering ethical and social implications, and assessing both current and potential oversight for the development and use of reproductive genetic tests. It presents a range of policy options supported by expert analysis that consider the potential effects, good and bad, of distinctly different policy directions.

Our second report, *Reproductive Genetic Testing: What America Thinks,* presents the results from our in-depth effort to understand what the public knows, thinks and feels about genetic technologies. We undertook this effort so that policy leaders and other decision makers would have more nuanced and sophisticated information about public's attitudes towards these technologies than has previously been available to-date. This effort is the largest and most ambitious public opinion work to-date on this issue. We have surveyed over 6,000 Americans, conducted focus groups, and interviewed hundreds of individuals who have had personal or professional experience with these technologies. Recognizing that one of the drawbacks to both qualitative and quantitative public opinion research is that individuals are asked to comment on complex scientific and ethical issues which they may have had little prior opportunity to consider, we conducted an extensive public engagement activity this summer to obtain more informed, reflective opinions from the general public. Over 500 citizens in six cities across the U.S. (Sacramento, CA; Seattle, WA; Kalamazoo, MI; Fort Worth, TX; New York City, NY; and Nashville, TN) and over 100 citizens on-line took part in *The Genetic Town Hall: Making Every Voice Count.* Participants were provided with background information about the technology and issues, heard contrasting viewpoints from "the experts", and engaged in discussion with their fellow citizens about the issues of concern to them.

The Center does not advocate for or against these technologies or for a particular policy outcome. Rather we believe that policy makers should have access to objective analysis, comprehensive information about what the public hopes for and fears from these technologies, and robust policy options to guide the development and use of reproductive genetic testing.

Scientific Background

Genetic testing is the laboratory analysis of DNA, RNA, or chromosomes. Testing can also involve analysis of proteins or metabolites that are the products of genes. Genetic testing is done to predict risk of disease, screen newborns for disease, iden-

tify carriers of genetic disease, establish prenatal or clinical diagnoses or prognoses and direct clinical care. Testing can be done using many different biological samples, including blood, amniotic fluid (from which fetal cells are obtained) or individual embryonic cells.

Two forms of analysis are possible. *Cytogenetic analysis* is used to detect abnormalities in chromosomal number and/or structure. *Molecular genetic testing* examines the DNA sequence of individual genes.

In general, *prenatal screening* includes those tests and procedures used to assess fetal risk for an abnormality, including genetic disorders. It does not provide a definitive diagnosis of a genetic abnormality but indicates whether diagnostic tests are warranted. The advantage of prenatal screening is that a normal result provides earlier reassurance and an abnormal result allows the option of further diagnostic tests.

Prenatal genetic testing (or prenatal genetic diagnosis) is genetic testing of fetal cells obtained through procedures such as amniocentesis and CVS. Prenatal genetic testing of a fetus requires two steps: an invasive procedure (amniocentesis or CVS) to obtain fetal genetic material and an analysis of the material to identify genetic abnormalities or characteristics. Fetuses may be at increased risk for genetic abnormalities because of the mother's age (35 or greater at delivery), because the parents already have a child or other family member with a genetic condition, because one parent has a balanced chromosome rearrangement or because prenatal screening or carrier testing indicates an increased risk.

Amniocentesis is usually performed in the second trimester of pregnancy, at approximately 15–20 weeks gestation. A small amount of amniotic fluid is removed from the sac that holds the developing fetus. The fluid contains fetal cells that provide the material for genetic analysis. Amniocentesis is generally considered a relatively simple and safe procedure when performed by an experienced physician. Although miscarriage after amniocentesis is infrequent (one in 200–400 cases), it is a major reason the procedure is not routinely offered to all women. Infection and leakage of amniotic fluid are other rare complications of amniocentesis.

Chorionic villus sampling (CVS) is an alternative to amniocentesis, and can be performed during the first trimester of pregnancy. Fetal cells are obtained through biopsy of the chorionic villi—the cells that will become the placenta. CVS is generally done at 10–13 weeks gestation. Fewer physicians do CVS than amniocentesis, and as a result, it is not available in all areas. The risk of miscarriage after CVS is approximately 1 in 100, as compared with the 1/200–400 risk following amniocentesis. CVS can be used to determine all disorders that can be diagnosed by amniocentesis except the presence of neural tube defects, since CVS does not include analysis of amniotic fluid alpha-fetoprotein.

Prenatal Genetic Testing: Points to Consider

With that background in mind, I would like to make five main points about prenatal genetic testing.

1. Information and its use

Genetic tests give information—information that, in the reproductive context, can provide great reassurance or precipitate a decision. Before pregnancy, prospective parents may learn through carrier testing whether or not they are at risk of having a child with a genetic disease and may have to decide whether or not to try to have a baby. During pregnancy, prenatal genetic testing can rule out or diagnose a genetic disease in utero. When a genetic anomaly is identified, prospective parents make the difficult decision of whether to continue a pregnancy, or not. There are a host of issues related to prenatal genetic testing. Some of the issues relate to the information obtained from the testing, others relate to the profound decisions that prospective parents make based on the results. But I want to emphasize that the decision to have a genetic test—to get information—and the decision about what to do with the information, are two separate, but interrelated issues.

People differ in their desire to obtain information about the future. Since most genetic tests show no genetic problems, many find the information reassuring. Others want the information in order to have the opportunity to prepare emotionally, financially, and medically for the birth of an affected child. For these individuals, knowing as much as possible about the health of the fetus, as early in the pregnancy as possible, is of primary interest. Others, however, prefer to decline testing and welcome the child first, and then address any health problems the child may have. For them, prenatal testing may seem intrusive and unnecessarily worrisome. For couples who would consider abortion in case of a serious genetic condition, information about the condition and the prognosis helps them make the decision whether or not to terminate the pregnancy.

There are probably as many reasons to undergo prenatal testing—or to refuse it—as there are parents. Whether someone will ultimately accept or decline testing, and what course of action they will take based on the information testing provides, is impossible to predict. But as this Committee considers whether prenatal genetic testing is in need of Congressional attention, I would urge you to treat the information and the decision about what to do with the information as separate matters.

2. Preserving the right to know—and not to know

The philosophy of those providing, reproductive genetic testing is "non-directive" genetic counseling. Simply put, this means that, because the implications of these decisions are so profound and so personal, the decision whether or not to have prenatal genetic testing, and what to do with the test results, must reside with the prospective parents. Indeed there is strong support among Americans for this approach. A majority of Americans (64 percent) agree with the statement [1] "We ought to let people decide for themselves when it is appropriate to use reproductive genetic technologies because the consequences are so personal." Although most health care providers practice non-directive counseling in providing information about the risks and benefits of testing and the choices that may be faced depending on results, some observers have raised the concern that prospective parents may feel pressured to agree to prenatal genetic testing—pressure from their health care provider or from society at large.

Some fear that as testing becomes available for an increasing array of inherited diseases and conditions, couples will face growing medical and societal pressure to use all available technology—on the theory, perhaps, that if it is knowable, it should be known. Fear of liability—that they could be charged with failing to consider all potential genetic problems—could drive providers to seek as much information as genetic testing can provide. And as screening and testing become earlier and capable of detecting a broader range of conditions, the concern is that society will see reproductive testing as the "right" and "responsible" thing to do. Some believe that individuals will face growing medical and societal pressure to avoid the birth of a child that has not "passed" all the requisite genetic tests. On the other hand, some have argued that the more widespread genetic testing becomes, and the more each individual knows about his or her unique genetic makeup, the more society will be tolerant of human differences. Rather than expecting each fetus to meet some definition of genetically "normal," the knowledge that no individual is a "perfect specimen" may lead to greater acceptance of every individual and less pressure to use all available technology to have a "perfect" child.

Our policy report addresses these issues. Clearly, attention should be paid to preserving the rights of prospective parents *not* to use prenatal genetic testing. This can be accomplished by improving the counseling and access to information couples receive. Currently, information about prenatal testing is conveyed in a variety of settings and contexts. Sometimes it is a physician who discusses prenatal testing with the patient, sometimes a nurse or midwife and sometimes a patient is referred to a genetic counselor. Providers have varying levels of knowledge and comfort discussing these issues, and often very little time in which to cover all of the information adequately. Thus, patients may end up making decisions based on incomplete or inaccurate information. Some may proceed with testing without fully considering the decisions they may have to make depending on the results of the tests. Health care providers may present these tests as routine, just like all the other tests one gets during pregnancy, which may explain why patients sometimes report feeling pressured to agree to testing. Enhancing the genetic literacy of providers or providing better access to genetic counseling could help alleviate these concerns.

If a genetic condition is found during prenatal genetic testing, careful attention to how test results are conveyed and ensuring parents have access to the complete clinical picture can assist families in making informed decisions. Some disability advocates say that providers who discuss prenatal screening and testing describe conditions in the most extreme clinical terms and assume that parents will want to terminate an affected fetus. They believe that providers are predisposed to counsel in favor of that decision, without giving sufficient context to the prospective parents about what it would actually be like to raise a child with the particular disorder. One direct approach is to enhance the counseling available to parents by making sure that genetic counseling includes access to information from people living with genetic diseases and their families 'so that prospective parents may better understand the reality of having a child with the disease. Patient advocacy organizations working on behalf of people with the condition could work with providers to facilitate such interactions.

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[1] From Genetics & Public Policy Center 2004 Survey of 4,834 Americans.

Importantly, a more direct or holistic approach would be to ensure that society continues to support *all* prospective parents, including those who make the decision not to test, or not to end a pregnancy and that there continues to be a range of legal protections and support for people with disabilities and their families.

3. Ensuring test accuracy and quality care

The decisions made on the basis of prenatal genetic tests are weighty—if a prospective parent is going to decide whether or not to continue a pregnancy on the basis of a test result, the accuracy and reliability of the test is of utmost importance. The prenatal genetic tests routinely used have low false positive and false negative rates and are of generally high quality. But, right now government oversight of genetic testing is patchy at best. There are at least two issues here. The first is to make sure that a test is clinically valid before it goes to market. The second is to ensure that laboratories are performing the tests correctly so that the results are reliable. More attention needs to be paid to the role of Federal agencies in making sure that genetic tests being used by laboratories are accurate and reliable.

In our policy report we provide a detailed analysis of the current regulatory environment for reproductive genetic testing. Government oversight in this area is limited and fragmented. There is no government review of tests by the Food and Drug Administration (FDA) or any other Federal agency before they are marketed. *In* addition, although laboratories performing prenatal genetic testing are regulated by the Centers for Medicare and Medicaid Services (CMS) through the Clinical Laboratory Improvement Amendments of 1988 (CLIA), there are no specific requirements under CLIA to show proficiency in molecular genetic testing, making it difficult to evaluate laboratory performance of genetic tests. Interestingly, in our 2002 survey, we found that only 30 percent of respondents knew that the Federal Government does not review or approve reproductive genetic tests before they go on the market.

One possibility is to increase Federal oversight of genetic testing to ensure it is accurate and safe. FDA and CMS may have the authority currently to expand their role. *In* addition, Congress could pass legislation delegating additional authority to these agencies to ensure that prenatal genetic testing is done right.

Although professional groups have issued guidelines for providers for the appropriate use of some genetic tests, there are currently only a handful of guidelines for a genetic testing compared to the large number of genetic tests available. The number of genetic tests available is rapidly increasing, and there is no technological barrier to using them in prenatal genetic testing.

In the absence of government regulation, professional self-regulation is often a valuable tool. But the sheer number of tests and the speed with which they are developing, means that professional societies such as American College of Obstetricians and Gynecologists and the American College of Medical Genetics are hard pressed to keep up. In our policy report, we propose several options to address the need for more professional guidelines in the absence of more robust Federal oversight. One possibility would be that Federal funding could be made available through the agencies of the Department of Health and Human Services to help facilitate guideline development.

As mentioned previously, another approach to improving care is to improve the information that patients have. The quality of patient care would be enhanced if health providers were more knowledgeable about testing and prospective parents had all the information and counseling they needed to understand the choices they are making and the implications of those choices. Perhaps most importantly, counseling, screening and testing needs to be offered when parents are able to make the best use of the information. Most experts agree that genetic risk information and reproductive genetic testing options should be discussed with prospective parents *before* pregnancy during routine visits. The health care provider should take a family history and assess genetic risk based on family history, maternal age and ethnic background and discuss carrier testing options. Carrier testing done before pregnancy allows prospective parents to know their risks without having to make a decision to terminate a pregnancy.

4. For what purpose

There are many different genetic tests available, and questions abound as to whether, and how to regulate what people are testing for. There are tests for fatal childhood conditions such as Trisomy 13 or Tay Sachs disease. There are tests for serious disorders including Down syndrome, cystic fibrosis, and sickle cell anemia. Tests are also available for adult-onset disorders, such as Huntington disease, that would not affect the individual for many years, during which time a treatment may be discovered. There are also genetic tests that identify predisposition to, or increased risk of, developing a disease such as breast cancer as an adult. There is con-

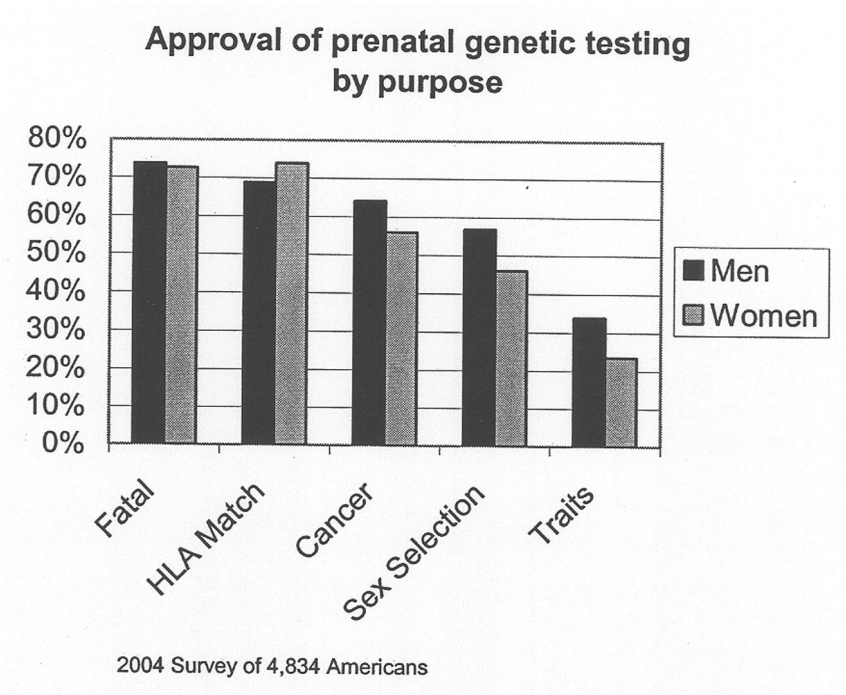
siderable debate about which of these tests are ethically appropriate for use in the reproductive context.

Many observers are concerned that the use of prenatal genetic testing will escalate to the point where it is used to test for what some call "designer traits"—characteristics unrelated to health such as intelligence or athletic ability. These most controversial tests, however, are not yet, and may never be, available in any context because these complex attributes result from the interaction of a host of environmental and genetic factors.

Americans' support for the use of reproductive genetic testing depends heavily on the circumstances under which it is being used. In a 2004 survey conducted by the Genetics & Public Policy Center, respondents were asked a set of questions about the appropriateness of using prenatal testing to find out whether a fetus will:

- develop a fatal childhood disease;
- be a good match to donate his or her blood or tissue to a brother or sister who is sick and needs a transplant;
- have a tendency to develop a disease like adult-onset cancer;
- be a certain sex; and
- have desirable characteristics like high intelligence or strength (hypothetically).

About two-thirds of the general public approved of the use of prenatal genetic testing for a fatal childhood disease and for tissue matching. A slight majority of survey participants approved of using reproductive genetic testing technologies to identify alterations associated with a tendency to develop an adult-onset disease like cancer. There was less support for using testing to identify or select sex and a majority disapproved of using hypothetical prenatal genetic testing to identify characteristics like intelligence or strength. Thus, a majority of Americans approve of prenatal genetic testing to identify health-related genetic characteristics and a similar majority disapprove of its use to identify traits. Attitudes towards prenatal genetic testing vary somewhat by race, education, religion, income and, as shown, by sex but follow the same general pattern with a majority of all groups supporting prenatal genetic testing for health-related uses.

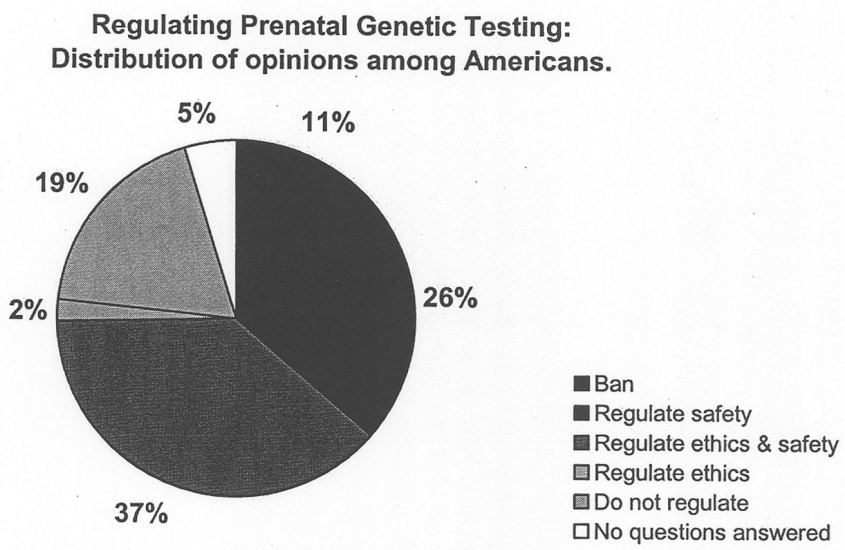


5. Diverse Views on Government Oversight of Prenatal Testing

Lastly, I would like to share with you some insights into what the American public thinks is the appropriate role of government in overseeing the development and use of reproductive genetic testing. In our April 2004 survey we asked 4,834 individuals whether the government:

- should regulate prenatal genetic testing based on quality and safety
- should regulate prenatal genetic testing based on ethics and morality
- should regulate prenatal genetic testing based on both quality and safety AND ethics and morality
- should not allow prenatal genetic testing at all
- should not regulate prenatal genetic testing at all.

Their responses are shown in the graph below and reveal the remarkable diversity of views present among Americans.



In conclusion, genetic tests provide information. There are a number of steps that could be taken to ensure that people have the right to know and the right not to know genetic information, to ensure that the information is accurate, and that society continues to support *all* prospective parents and their children. The Genetics and Public Policy Center would be happy to provide additional information and analysis as you consider prenatal genetic testing or other issues raised by advances in human genetics. Thank you.

Senator BROWNBACK. Thank you, Dr. Hudson.

And, Mr. Andrew Imparato, thank you for joining us—President and CEO of American Association of People with Disabilities.

STATEMENT OF ANDREW J. IMPARATO, PRESIDENT AND CHIEF EXECUTIVE OFFICER, AMERICAN ASSOCIATION OF PEOPLE WITH DISABILITIES (AAPD)

Mr. IMPARATO. Yes, thank you, Senator Brownback, for having this hearing.

And I am Andy Imparato. I'm the President of the American Association of People with Disabilities. We're a membership organization promoting political and economic empowerment for children and adults with all types of disabilities of all ages in the U.S. And I'm proud to say that Cheryl Sensenbrenner is one of our board

members, and I was delighted to—that you had her come and testify, as well, today.

Senator BROWNBACK. I might add, you had an intern in our office, this last year, who was just a crackerjack. I hope I can get her back, full-time employment, when she finishes college.

Mr. IMPARATO. Stacey Survasis. She had a wonderful experience——

Senator BROWNBACK. Yes, she's——

Mr. IMPARATO. I know you have another intern who's participating in the program that we're involved with, as well.

Senator BROWNBACK. Yes.

Mr. IMPARATO. You know, the real point that I wanted to make today is that the disability rights movement needs to be part of this discussion and part of this debate. And I'm delighted that you started with Cheryl Sensenbrenner, a woman with a disability, and her sister, Tara, giving their perspective on this issue.

One of the challenges that I think we run into is, if we let doctors and scientists control the debate, if you have to have a Ph.D. to participate in the debate, or an M.D., you're going to miss important human perspectives on what it means to have a disability.

My own personal connection to disability, I have bipolar disorder, or manic-depression. A lot of people have told me that there's a strong genetic link to that. If I look in my family, I can see that. I'm worried about what's going to happen in the future if people can do tests to find out that a child is likely to have manic-depression. If they've had a bad experience with somebody with manic-depression, is that going to color their decisionmaking? And what kind of a context are they going to be given when they're given the information from the test?

One of the most basic principles of the disability-rights movement is that disability is a natural part of the human experience that, in no way, should limit a person's ability to make choices, pursue meaningful careers, live independently, or participate fully in all aspects of society. When you hold that principle up against some statements that we hear from ethicists and from scientists—and I know you've got some blown up here in the front of the room—the statements are completely inconsistent with the notion that disability is a natural part of the human experience and does not equate to a negative, inherently.

A lot of people talk about a disability as if it were a tragedy, but disability need not be, and should not be, seen as a tragedy to be avoided, but as part of human diversity that can be accommodated and viewed as a source of strength, pride, and identity. Tragedies occur when our society artificially limits the ability of disabled people to participate fully in community life. When individuals are warehoused in nursing homes and other institutions because of a lack of funding for community-based support, when children are isolated and fall victim to the low expectations of teachers who lack the preparation or imagination to meet their needs, or when qualified workers seek employment and encounter prejudice that thwarts their career goals, that's where the tragedy occurs.

I think it's important, as we talk about new genetic tests and technologies, that we be cognizant of our history in this country of

eugenics and what we've done to people with disabilities in the name of eugenics.

In 1927, in the case of Buck versus Bell, Justice Oliver Wendell Holmes ruled that he thought it was appropriate to forcibly sterilize people who were classified as "feebleminded," so that they could not have a child. And this category included people with psychiatric disabilities, people with intellectual disabilities, and people with neurological disorders. In that decision—again, this was in 1927—Justice Holmes wrote, "It is better for all the world if, instead of waiting to execute degenerate offspring for a crime or to let them starve for their imbecility, society can prevent those who are manifestly unfit from continuing their kind."

Who decides who is manifestly unfit? This kind of ideology led to people with disabilities being one of the first groups that Hitler went after, and the Nazis went after, in the Holocaust, to exterminate as part of the T–4 program. And one would hope that the reactions to the holocaust and the advent to the disabilities rights and independent living movements in the U.S. and around the world would have put an end to eugenic efforts to eliminate people with disabilities. Certainly, the holocaust should have sensitized the medical and ethical communities to the dangerous potential of eugenic ideologies.

But, unfortunately, if we look at the rhetoric of some modern scientists and ethicists, we haven't put this issue to bed. Bob Edwards, the esteemed embryologist who created Britain's first test-tube baby remarked, at an international fertility conference in 1999, that the increasing availability of prenatal screening for genetic disease gave parents a moral responsibility not to give birth to disabled children. "Soon," he pronounced, "it will be a sin of parents to have a child that carries the heavy burden of genetic disease. We are entering a world where we have to consider the quality of our children."

Peter Singer, a bioethics professor at Princeton, has written that, quote, "It does not seem quite wise to increase any further draining of limited resources by increasing the number of children with impairments."

These kind of statements, to me, are examples of hate speech. They're examples of not understanding what people with disabilities are capable of achieving, how we feel about the quality of our own lives, and really, to me, harken back to the 1920s and to our ugly history of eugenics in this country and other countries.

I agree with a lot of the recommendations that have been made previously, and they're in my written testimony. I think it's critical, again, that people with disabilities be part of the public debate about what we do with these technologies. I think it's essential that families have an opportunity to talk to families that have children with disabilities when they're given diagnostic test results, and they be encouraged to do so.

I also think it's essential that people with disabilities be encouraged—and family members of people with gene-linked disabilities—be encouraged to go into genetics counseling as a profession, because they have personal experience with these conditions, and can convey that in their role as a counselor.

But, most important, I think that our public policy must be crystal clear that no family will ever—and I agree with Kathy's point on this—no family will ever be penalized for choosing not to have prenatal genetic diagnostic tests or for choosing to go forward with a pregnancy after a disability has been prenatally diagnosed. And no treating physician or treating professional should be penalized if their patient chooses not to have a test or chooses to go forward with the pregnancy.

And, last, it's critical that we build a network of support for families adjusting to the news that their baby is likely to have a disability, and that we expand programs like early intervention, affordable quality healthcare, respite care, accessible housing, and other forms of family support so that families can move forward with a pregnancy without having to incur severe financial and emotional hardships as they work to make their newborn is getting the best quality care possible.

Again, thank you for having this year. With all respect to Senator Lautenberg, I think this is an appropriate topic for this Committee and others. Kathy and I have testified in front of the Health, Education, Labor and Pensions Committee on the need for legislation prohibiting discrimination on the basis of genetic information, which she referenced. So, clearly, there are other committees that need to be involved, but, to me, this is, in part, an issue of science and technology policy. So thank you.

[The prepared statement of Mr. Imparato follows:]

PREPARED STATEMENT OF ANDREW J. IMPARATO, PRESIDENT AND CHIEF EXECUTIVE OFFICER, AMERICAN ASSOCIATION OF PEOPLE WITH DISABILITIES (AAPD)

Mr. Chairman, Ranking Member Breaux, and Members of the Senate Commerce, Science and Transportation Subcommittee on Science, Technology and Space:

Thank you for the opportunity to provide testimony regarding the important topic, "Prenatal Genetic Testing Technology." I am honored to have this opportunity. My name is Andrew J. Imparato and I am the President and Chief Executive Officer of the American Association of People with Disabilities (AAPD), a national non-profit, nonpartisan membership organization promoting political and economic empowerment for the more than 56 million children and adults with disabilities in the U.S.

With more than 100,000 individual members around the country, AAPD is the largest membership organization bringing together the diverse populations that make up the disability community. AAPD operates programs in the areas of leadership development, internships, mentoring and career exploration, civic participation, public policy advocacy, and member benefits. Founded on the fifth anniversary of the Americans with Disabilities Act (ADA), AAPD advocates for policies that are consistent with the goals of the ADA: equality of opportunity, independent living, economic self-sufficiency, and full participation in all aspects of society. My testimony today will address some of the disability rights issues that must be considered as the technology of prenatal genetic testing continues to develop.

As person with a disability that likely has a genetic link (bipolar disorder) and a civil rights lawyer, I am here today because I am concerned about the increasing potential of the new genetic technologies to be used in a manner that discriminates against individuals with disabilities. I am also concerned about the rise of a new eugenics that threatens to undo some of the important advances in how our society views children and adults with disabilities.

One of the most basic principles of the disability rights movement is that disability is a natural part of the human experience that in no way should limit a person's right to make choices, pursue meaningful careers, live independently, and participate fully in all aspects of society. Disability need not be seen a tragedy to be avoided, but as part of human diversity that can be accommodated and viewed as a source of strength, pride and identity. Tragedies occur when our society artificially limits the ability of disabled people to participate fully in community life; when individuals are warehoused in nursing homes and other institutions because of a lack

of funding for community-based supports; when children are isolated and fall victim to the low expectations of teachers who lack the preparation or imagination to meet their needs; or when qualified workers seek employment and encounter prejudice that thwarts their career goals.

As we examine the implications of prenatal genetic testing technologies, it is important that we remember the history of eugenics in the U.S. and the very real negative impact that this history had on the lives of people with disabilities, especially people with mental disabilities. In 1927, in the case of *Buck* v. *Bell,* Justice Oliver Wendell Holmes wrote a decision for the U.S. Supreme Court upholding the practice of involuntary sterilization of people who were classified as "feeble-minded" (a broad category that included not just people with psychiatric and intellectual disabilities but also people with seizure disorders and other neurological conditions). Writing for the Nation's highest court, Justice Holmes opined: "It is better for all the world, if instead of waiting to execute degenerate offspring for crime, or to let them starve for their imbecility, society can prevent those who are manifestly unfit from continuing their kind." *Buck* v. *Bell,* 274 U.S. 200 (1927).

In this now infamous ruling, Justice Holmes was supporting a world view that was in vogue among many American intellectuals at the time, and a view that became widely held among the Nazis in Germany. Physically and mentally "defective" people were among the first targets of the Holocaust, as Hitler's "T–4" program systematically exterminated disabled and chronically-ill Germans who were perceived as threatening the genetic purity of the Aryan race.

One would hope that reactions to the Holocaust and the advent of the disability rights and independent living movements in the U.S. and around the world would have put an end to the eugenic efforts to eliminate people with disabilities. Certainly, the Holocaust should have sensitized the medical and ethical communities to the dangerous potential of eugenic ideologies. Unfortunately, if we examine the rhetoric of some influential modern scientists and ethicists, we can see the emergence of a new eugenics tied to the rapid advances in scientific understanding of the human genome.

For example, Bob Edwards, the esteemed radiologist who created Britain's first test-tube baby, remarked at an international fertility conference in 1999 that the increasing availability of prenatal screening for genetic disease gave parents a moral responsibility not to give birth to disabled children. "Soon," he pronounced, "it will be a sin of parents to have a child that carries the heavy burden of genetic disease. We are entering a world where we have to consider the quality of our children."

Closer to home, Peter Singer, a bioethics professor at Princeton, has written that "it does not seem quite wise to increase any further draining of limited resources by increasing the number of children with impairments." Singer has even gone so far as to defend the ethics of a parent's choice to kill a disabled infant within a certain number of days after its birth. His Princeton colleague, molecular biologist Lee Silver, writes about a future in which the wealthiest in society will be able to pay for genetic modifications, resulting in a societal segregation between the "GenRich" and the "Naturals." In this society, according to Silver,

> "The GenRich—who account for 10 percent of the American population—all carry synthetic genes. All aspects of the economy, the media, the entertainment industry, and the knowledge industry are controlled by members of the GenRich class. . . . Naturals work as low-paid service providers or as laborers. . . . [Eventually] the GenRich class and the Natural class will become entirely separate species with no ability to cross-breed, and with as much romantic interest in each other as a current human would have for a chimpanzee."

From *Remaking Eden: Cloning and Beyond in a Brave New World* (New York, Avon Books, 1997, pages 4–7).

This kind of rhetoric, which should trouble anyone concerned about American ideals like equal opportunity and a just society, is particularly alarming for many of us in the disability rights movement. As Colorado disability activist and writer Laura Hershey has observed,

> The application of genetic knowledge to the repair of damaged genes, for the purposes of treating certain illnesses, may offer welcome benefits to some people with disabilities. But genetic research is likely to be put to other, more insidious, uses—such as denying health insurance, even jobs, to people whose genes predispose them to medical problems. Another threat is the implementation of eugenic policies to "weed out" certain types of people from the population. Thus, along with the much-heralded scientific advances offered by genetic research, disability activists nervously witness a resurgence of eugenic thinking.

"Will Genetic Research Lead to Eugenic Policies?," August 26, 1999, from Laura Hershey's online column Crip Commentary.

Because society continues to devalue the quality of life of people with disabilities, based on fears, myths and stereotypes that some people associate with particular disabling conditions, it is critical that people living with disabilities and their families play a large role in the ongoing public debates about how the new prenatal genetic testing technologies will be used. Equally important, the perspective of people with disabilities and their families should be incorporated into the education of physicians, genetics counselors, and other professionals who are interacting with expecting parents as they make choices about which tests to have and what to do in light of the results.

To the greatest extent possible, expecting parents who receive positive test results should be given an opportunity to meet with and talk to individuals and families who have experience with the particular disability that has been indicated. There is no substitute for this kind of first-person account of the joys and challenges that a child with a disability can pose for a family. This kind of exposure can demystify what the diagnosis means and begin the process of building a support network that will be critical for the family to develop as it prepares for the birth. One way to facilitate this outcome would be to create incentives for people with gene-linked disabilities and their family members to go into genetics counseling as a profession.

One of the dangers of the expansion of prenatal genetic testing technologies is that expecting parents will experience pressures to terminate their pregnancies from medical professionals and insurers. Doctors may want to avoid a complicated delivery and insurers may want to avoid expenses associated with the child's disability. Our public policy must be crystal clear that no family will ever be penalized for choosing not to have prenatal diagnostic tests or for choosing to go forward with the pregnancy after a disability has been prenatally diagnosed. Similarly, we need to protect medical professionals from being penalized or held liable in the event their patients elect to avoid prenatal tests or choose to move forward with a pregnancy where a disability has been prenatally diagnosed.

Finally, we need to work to build networks of support for families adjusting to the news that their baby is likely to have a disability, and to expand programs like Early Intervention, affordable quality healthcare, respite care, accessible housing, and other forms of family support so that families can choose to move forward with a pregnancy without having to incur severe financial and emotional hardships as they work to make sure their newborn is getting the best quality care possible.

As President Bush remarked when he introduced his New Freedom Initiative for people with disabilities in February of 2001,

> Wherever a door is closed to anyone because of a disability, we must work to open it. Wherever any job or home, or means of transportation is unfairly denied because of a disability, we must work to change it. Wherever any barrier stands between you and the full rights and dignity of citizenship, we must work to remove it, in the name of simple decency and simple justice.

Our challenge is to make sure that the growing technology of prenatal genetic testing does not erect new barriers to the full rights and dignity of citizenship, and that our values of simple decency and simple justice enable us to avoid the pitfalls of the new eugenics.

Thank you again for calling attention to this important growing technology, and for your desire to get a disability perspective on this difficult topic.

Senator BROWNBACK. Well, I obviously think it is, as well. And it's a key part, and it's on us, and I think it's something that we really need to have a good public discussion and a legal framework around it. Thank you very much for your testimony. There was excellent thought put forward.

Mr. Kimbrell, good to have you back with the Committee—Executive Director, International Center for Technology Assessment.

STATEMENT OF ANDREW KIMBRELL, J.D., EXECUTIVE DIRECTOR, INTERNATIONAL CENTER FOR TECHNOLOGY ASSESSMENT

Mr. KIMBRELL. It's good to be back with you, Mr. Chairman.

And, yes, I am the Executive Director of the International Center for Technology Assessment, and we do assess cutting-edge tech-

nologies in transportation, commerce, and science. I wish Senator Lautenberg were here, because my organization spearheaded litigation against the EPA to try and establish greenhouse gases as pollutants. We're joined by 11 states and five municipalities. And I certainly share his view that greenhouse—the greenhouse crisis is very important and does affect generations. But I would take issue with the Senator in his diminishing this extremely important issue that you've brought before us today; and I'm so glad you have, because it is so rarely discussed.

And I'm very, very pleased to be with Andy Imparato, who's done such great work here. And I'm looking forward to Kathy Hudson's work. I know many people who have been involved in that study, and I'm—I think it's going to be a very important addition to this very important debate.

And, having said that, I want to—I've submitted testimony on a number issues, but I want to follow up on what Andy Imparato said, because this is really important, to put this discussion in the framework of a hundred years of eugenic history in this country and elsewhere.

The eugenics that most of us are familiar with happened postnatally. They were based on political agendas or social efficiency. And the techniques that were used were sterilization. We sterilized over 60,000 people in this country, involuntarily, through 1958. Fifteen states still have those laws on their books, by the way, Mr. Chairman.

And, additionally, it was based on a kind of biological determinism and racial determinism that made people—biology was your destiny. And, therefore, if we didn't approve of your destiny, you didn't—you were unable to—sometimes not even survive. Often, we didn't allow you to have children, through forced sterilization.

We're not talking about that. The new eugenics is a little different than the old eugenics. But I think it's—it is just as threatening. And this eugenics is not happening postnatally, it's happening prenatally. And the techniques are no longer the rather blunt techniques of extermination or sterilization, but, rather, subtle techniques that we're talking about today, both in prenatal and now, with the new techniques, they're preimplantation genetic diagnosis, where we can actually try and create children.

And I think that what's very important to this Committee and, I hope, to this country, is, Are we going to begin a new era of commercial eugenics for the profit of a few corporations and the ability of scientists and corporations to patent genes—and even patent embryos—is going to be driving this new eugenics? But the result will be the same, as has been described by this panel.

So this is an extremely important question, Should we begin the commerce of eugenics? Should we begin the commerce where eugenics becomes a common practice? And it also is a very critical scientific question, because, just like biological determinism controlled the eugenics of the past, so genetic determinism is now controlling this new revolution.

I'm sure everybody on the panel is aware, as I am, that we have new results in the Human Genome Project, that you talked about in your opening remarks, Mr. Chairman. Originally, we thought we

were going to have about 130,000 genes, because that's the numbers of proteins, the number of traits of proteins, for creating human beings. It turned out we only had about 30,000 to 35,000 genes. And, just a week and a half ago, the International Human Genome Project said, "You know what? We only have about 20,000 genes." That's about as much as a worm. So we have as many genes as worms have, but at least some of us have more traits.

[Laughter.]

Mr. KIMBRELL. So where did all those traits—what's creating all those traits? If it isn't the gene, what's creating all those traits? We only have as many genes as worms. You know, we've been sold, kind of, a snake-oil thing here for several decades, that this genetic determinism was our biology and was our destiny. And what scientists are now saying is, that is simply not true. This genetic determinism is a triumph of orthodoxy over fact.

I just want to read, very briefly here, from the *Scientific American* of November 2003. "And they say, you know, the essential dogma is dead, this genetic determinism, and proven to be false by the Human Genome Project. And they say it will take years, perhaps decades, to construct a detailed theory that explains how DNA, RNA, and the machinery of all of life fit into an interlocking self-regulating system. But there is no longer any doubt that a new theory is needed to replace the central dogma that has been the foundation of molecular genetics and biotechnology since the 1950s." This is *Scientific American.*

In my testimony, I've included testimony by Dr. Richard Stroehmann, 25 years research director for the Muscular Dystrophy Association, where he says that less than 2 percent—less than 2 percent—of all diseases—less than 2 percent—are actually caused by a single gene, are monogenetic; the rest of caused by multifactual areas, including the environment, including the interaction of proteins, new discoveries they're making in RNA, and what they used to call junk DNAs—completely complicated, nothing to do with that simple model: one gene, one disease. Very small percentage of diseases.

And yet—and this is just by my count; I'd bet members of the panel have something to add to this—I have read that there is a gene for anxiety attacks. I have read that there is a gene for alcoholism. I have read that there is a gene for homosexuality. I have read that there is a gene for IQ. I have read that there's a gene for criminal behavior, a gene for obesity, a gene found, apparently, by some British researchers, for female intuition.

[Laughter.]

Mr. KIMBRELL. A gene for shyness. This was reported in the *Washington Post* last year, a gene for shyness. I thought the schools might be able to use that. And, of course, the gene for manic-depression.

And what makes this propaganda—and that's what it is, commercial propaganda for people who are trying to sell this—sell this new eugenics—because that's what this is about, commercial eugenics—is that, unfortunately, people believe it. The alcoholism gene became a joke. The homosexuality gene led to, actually, some indictments for fraud. But 60 percent of Americans still believe that alcoholism is due to a defective gene.

And in polls that we have seen—and these are just the ones that we've selected; I'd be very interested in Kathy's work—we have 1 percent of Americans said that they would abort for sex selection; 6 percent said they would abort a child that might be predisposed to Alzheimer's; 11 percent said that they would abort a child predisposed to obesity.

Senator BROWNBACK. Wow.

Mr. KIMBRELL. Now, the—unfortunately, this is not simply theoretical. That eugenics is occurring. We know sex selection is occurring in every one of the technologies we talked about today. Every one of the technologies already—including preimplantation genetic diagnosis—has already been used for sex selection, as the President's Council on Bioethics issued its report—reported. So it's already happening. This isn't theoretical. You know, we're behind the game on this one. And, you know, we've already tried to create a market where people don't want happy children, they want people that they're happy with.

And, as somebody who has appeared before you many times, Mr. Chairman, representing pro-choice groups, I do not want to see the pro-choice movement being used as a smokescreen for these new eugenics. I do not want a woman's right to choose to be transformed into a free pass to this new commercial eugenics. I think it would be a disaster for the pro-choice progressive movement for that to happen. And I certainly think if we prevent—and we should—if we could prevent sex discrimination in the workplace, shouldn't we prevent sex discrimination in who gets to live?

So, this is a very historic issue that we've brought up today, and I hope that our legislators are up to it, because we have to craft very important policy prohibitions right now on eugenics, while preserving the reproductive rights so many of us believe in.

This is going to be an enormous challenge, but, I think, by starting the discussion today, you've taken at least the first step in that direction. I thank you for holding these hearings.

[The prepared statement of Mr. Kimbrell follows:]

PREPARED STATEMENT OF ANDREW KIMBRELL, J.D., EXECUTIVE DIRECTOR, INTERNATIONAL CENTER FOR TECHNOLOGY ASSESSMENT

History does not repeat itself, but it does rhyme—MARK TWAIN

Preimplantation Genetic Diagnosis (PGD) is only one of many emerging genetic and reproductive technologies in need of broad public discussion and regulation, but we view PGD as a gateway technology. PGD, if permitted to continue unregulated, could pave the way to new eugenics, where children are literally selected and eventually designed according to a parent's desires and fears.

Recent rapid developments in PGD indicate that we are stumbling down a slippery slope toward this future rendering a policy response an urgent matter. Finally unfettered developments of PGD applications in the U.S. attest to the general failure of the U.S. policy regarding genetic and reproductive technologies. This policy failure must be corrected if we are to prevent a new eugenics in the U.S. and abroad.

Germany, Austria, Ireland, Switzerland, and Southwest Australia have banned PGD outright. Other nations, including the United Kingdom, France, the Netherlands, Belgium, Italy, and Greece have limited the use of PGD. Even in the US, until recently, PGD was used exclusively for medical purposes.

Today, two thirds of the 50 or so fertility clinics in the world offering PGD are in the US. Some clinics are blatantly performing PGD for selection.[1] Many other clinics have used PGD to avoid late-onset diseases like Alzheimer's. A growing number of couples are using PGD to select an embryo that would grow into a child intended to be a tissue match for its sibling. None of these applications were subject to formal regulatory review or public deliberation prior to their use. In the case of sex selection, the practice specifically violates the voluntary guidelines of the American Society of Reproductive Medicine.[2]

The U.S. lack of regulation has resulted in advocates of expanded PGD in other countries to push for more permissiveness abroad. Some of the advocates, including Robert Edwards, who 25 years ago performed the first successful IVF procedure in humans, explicitly promote the new eugenic approach. Edwards has predicted that "Soon it will be a sin for parents to have a child which carries the heavy burden of genetic disease. We are entering a world where we have to consider the quality of our children."[3]

In the United Kingdom groups have already organized protests against this new eugenics. People Against Eugenics[4] organized a September 30, 2004 protest at a British pro-eugenics conference at the Royal Society in London. The press release denounced the eugenics conference organizer, the pioneer of IVF, Robert Edwards as the link between the old-fashioned state sanctioned eugenics and the new free-market version. It notes that Edwards, who 25 years ago, performed the first successful IVF procedure in humans is the former President and a leading member of the British eugenics society.[5]

Today, twenty-five years after the birth of Louis Brown from Edward's IVF technique, some one million children have been born from the process of IVF. The paralleled development of genetic testing has resulted into the merger of genetic testing and assisted reproduction into preimplantation genetic diagnosis (PGD). Parents can now choose which of their embryos to implant in the mother's womb based on the outcome of more than 1,000 genetic tests that potentially could be performed on the embryos.

At birth, Chloe O'Brien seemed no different than any other healthy baby, but Chloe was the pioneer product of the new technology of PGD. Born in March 1992, she was the first baby to be genetically screened as an embryo for a genetic defect, cystic fibrosis (CF), before being implanted into her mother's womb.[6]

In the 12 years since Chloe's birth, up to 10,000[7] children have been born after a preimplantation genetic screening. Chromosome abnormalities such Down syndrome and single gene defects including CF, Tay Sachs, muscular dystrophy and sickle cell anemia have been screened with PGD.

These tests screen for some diseases like Tay Sachs, which disease results in short brutal lives for the children with the disease, but also for diseases like Downs where children can live into their 50s or later. Genetic testing for these diseases is not new in that many of them are already tested for through amniocentesis.

PGD accelerates trends begun through prenatal testing

While in the U.S. there are no national data on how many pregnancies are terminated as the result of prenatal testing, some regional results may highlight what decisions are being made through pre-natal diagnosis. Interestingly, some data suggest that more women may be carrying Down syndrome babies to term. A study at Harvard-Pilgrim Health Care found that while the incidence of pregnancies with Down syndrome in the HMO had increased from 2 per 1,000 in 1992 to 6 per 1,000 in 1996, there was a significant trend toward carrying fetuses with Down syndrome to term. In 1992, almost 100 percent of fetuses prenatally diagnosed with Down syndrome at the HMO were terminated; in 1994–95, this figure was 65 percent.[8]

Rates of pregnancy termination for Down syndrome vary considerably between hospitals and between ethnic and religious groups. A 2004 study by the CDC of

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[1] Aron Zither, "A girl or a boy, you pick," *Los Angeles Times,* July 23, 2002, A1.

[2] American Society of Reproductive Medicine,1999, "Sex selection and preimplantation genetic diagnosis," *Fertility and Sterility* 72(4):595–598.

[3] Edwards speaking at European Society of Human Reproduction and Embryology as reported in *Metro* July 5, 1999.

[4] E-mail from *peopleagainsteugenicsQhotrnail.com* on September 30, 2004.

[5] The Eugenics Society founded in 1907, changed its name to the Galton Institute in 1989.

[6] Larry Thompson, "Cell Test Before Implant Helps Insure Healthy "Test-Tube" Baby," *Washington Post,* April 27, 1992, A1.

[7] The President's Council on Bioethics, *Beyond Therapy: Biotechnology and the Pursuit of Happiness,* October 2003, p. 53.

[8] M.D. Macmillin and S.P. Parker at the American Society of Human Genetics, November 1, 1996.

Down syndrome in Atlanta women found a lower portion of elective termination among black women as compared to white women.[9]

A study of pregnancy terminations for Downs in Boston in 1996 found that rates of termination varied widely between the north and south shores of Boston even though both groups of women received genetic counseling from the same people. Apparently women with deeply held beliefs about abortion decided to terminate the Down syndrome fetus at a much lower rate than women who did not have the same beliefs. Improvements in societal attitudes and support services for children with Downs also seemed to change the numbers of women choosing not to terminate their pregnancies. Women who are better prepared for their child's condition may also be more willing to carry a pregnancy to term. Some researchers report, however, that most women carrying fetuses whose disorders are usually fatal at in early infancy choose to terminate those pregnancies.[10]

Many parents of children with Down syndrome consider them to be special children. A United Methodist minister from New England and his wife have a child with Down syndrome that he considers a gift from God.

> "We fluctuated between accepting and rejecting the Downs diagnosis . . . That day we also got word that the chromosomal test confirmed the Downs condition; by now the news was expected and absorbed . . . almost exactly a week after birth, we had our exit interview with our nurse in charge, wrapped baby up and buckled her into our inspected car seat, and gingerly drove back to our apartment and began the awe-some process of becoming full time parents.
>
> She is lovely. (She) is made in God's image. She is a letter from God that says, "I love you." As I began jotting down notes for today late at night, she was lying first on my shoulder, then on my lap, then on the bed between (her mother) and I. Her touch is wonderful. Her face testifies to God's glory."[11]

Unlike prenatal diagnosis, that might be used by a couple to prepare for child that has a genetic disease, preimplantation genetic diagnosis is likely to result in a decisions to exclude from implantation ANY embryo that has a suspected genetic disease or trait that might lead to disease in later generations. In this respect, preimplantation diagnosis, even more than prenatal diagnosis is a eugenics practice. By excluding individuals that might live with genetic diseases for many years, PGD is a form of negative eugenics. The designer baby wherein "positive" characteristics are selected for is not yet here, but it is a short step away.

PGD promotes both genetic discrimination and more IVF procedures

If we fail to pass legislation to prohibit all forms of genetic discrimination, parents may feel even more pressure not to have children with known genetic diseases. In these cases, they may choose to have IVF combined with PGD to avoid having a child with "avoidable" genetic diseases. If that happens, the brave new world of free market eugenics will have arrived.

Some argue that PGD should be a standard part of IVF practice. PGD is now performed routinely at one of the world's leading IVF clinics, the Reproductive Genetics Institute in Chicago. "It should be done for every IVF cycle, in my view," says Yury Verlinsky, the institute's director. "It doubles or triples the implantation rate, while decreasing dramatically the miscarriage rate." The overall effect, says Verlinsky, is to more than double the average success rate per IVF cycle, so that couples have a greater chance of conceiving a child and to do so sooner.[12]

PGD is still an experimental procedure. We do not know what long term health damage is caused to the early embryo as a result of removing one of its cells for genetic analysis. Furthermore, it requires a woman to use IVF, burdensome and risky procedure in order to have a child. Hormonal treatments required for egg extraction have caused long-term health problems in women. Low implantation rates and the high costs of the procedure[13] encourage fertility specialists to implant multiple embryos at the same time, resulting in high rates of multiple births. WF infants moreover have twice the risk of major birth defects than those conceived natu-

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[9] C. Siffel, A. Correa, J. Cragan, C.J. Alverson, Prenatal diagnosis, pregnancy terminations and prevalence of Downs syndrome in Atlanta. *Birth Defects Res Part A Clinical Mol. Teratol.* Sept. 2004; 70(9): 565–71.

[10] The Impact of Prenatal Diagnosis on Down Syndrome, Anencephaly, and Spina Bifida, Gene Letter, March 1, 1997 in *www.genesage.com/professionals/geneletter/archives/theimpact.html*.

[11] Letter from Rev. Tim Atwater to Jaydee Hanson, Nov. 2, 2002.

[12] Philip Hunter, Preimplantation Genetic Diagnosis: Studies begin to assess how screening might improve IVF success rates, *The Scientist* Jun. 21, 2004.

[13] M. Hansen, J.J. Kurincuzuk, C. Brower, and S. Webb, "The risk of major birth defects after intracytoplasmic sperm injection and in vitro fertilization," *New England Journal of Medicine* (2002) 346:731–737.

rally. Ironically, by encouraging more women to undergo WF as a strategy to avoid birth defects, the fertilization industry may be producing more birth defects.

Nonetheless, fertility clinics as promoting PGD for more than just the most awful birth defects. Mohammed Taranissi, who runs the Assisted Reproduction and Gynaecology Centre in London, says that the industry is considering promoting other kinds of PGD even more. It is possible to test embryos for the genes that will cause certain "late onset" diseases, such as a form of Alzheimer's, which can occur in middle age and some cancers. Doctors could identify and select embryos that would have a healthy childhood and youth, but are destined to die prematurely. "Is this something that we should do? That to me is a very important issue," said Mr. Taranissi.[14]

If IVF becomes still more common and more health insurers beginning paying for IVF, the combination of WF and PGD will likely mean the exclusion for the genetic pool of families having WF any of the genes that we are able to test for.

The absence of any real Federal regulation in this area will make it likely that parents will have to make difficult decisions with little guidance. There are only about 1,000 genetic counselors in the entire country, too few to effectively counsel an increased number of families seeking to use genetic testing. Moreover, only three states currently license genetic counselors and many health plans have dropped coverage for genetic counseling. Without independent counseling, the very people that have a financial interest in testing embryos will be advising couples on which embryos should be kept.

The New Eugenics as a form of "Cold Evil"

The fertilization industry has become like many of our other massive corporate and government bureaucracies wherein evil no longer requires evil people to purvey it. We are witnessing the "technification" of evil. Unfortunately, we have utterly failed to register the appropriate recognition and abhorrence of this new form of institutional evil brought about through our economic and technological systems. The tragic result of this failure is that this technological "cold" evil flourishes. If a totalitarian state were to propose eliminating all of its differently abled residents, we would rightly denounce that as the "hot" evil of genocide. If our society embarks on technological strategy of eliminating its future disabled members through a free-market technology should we be silent in the face of this "cold" evil of eugenics?

Recommendations for Regulatory Guidelines for PGD

Limit genetic testing of embryos to those conditions that result in early and painful death of children, such as anencephaly, Tay Sachs, Lech Nyan's Disease.

Prohibit negative eugenics in the case of all other genetic conditions.

Prohibit the use of PGD for selecting for non-disease characteristics such as height, weight, intelligence, personality traits, behavior or gender.

Implement a complete ban on the genetic modification of human embryos, including the introduction of synthetic genes or chromosomes.

Senator BROWNBACK. Thank you. This is an excellent panel and an excellent discussion.

Let me start on the issue of what we've learned from Down's and spina bifida testing. And Mrs. Sensenbrenner touched on this at the end of her testimony, that she doesn't feel like that we've started off with a very good track record with our ability to test on these two, and then now we're expanding into a field of four or five hundred, or maybe more, genetic tests that we can go with.

What have we learned from the practice of genetic pre-birth testing on Down's syndrome and spina bifida? Has it impacted, substantially, the number of children born with these two characteristics? What has it done, in practice, to those families? And I don't know, if one of the three doctors, who would want to—or do we know, from this country, or do we have better studies from other countries of what it's done?

[14] Sarah Boseley, Are we on the genetic slippery slope? *The Guardian,* July 22, 2004.

Dr. HUDSON. There have been studies that have looked at the number of Down's births in the United States since, apparently, we started marking whether or not a birth was a Down's birth on birth certificates. And so you can actually follow the numbers, over time, and there has been a reduction in the actual number of live Down's births, compared to what is the expected number, since the advent of testing. So there has been a decrease in the number of live-born Down births.

Senator BROWNBACK. By—do you know, Dr. Hudson, the numbers in this——

Dr. HUDSON. I could provide that for the record. I'd be hesitant to give you a number, because I'm bad with numbers.

Senator BROWNBACK. Yes. If you could, I would appreciate that, for the record. Because, what I have looked at, it's substantial. It's a substantial number. And my experience in other countries has been that this has really changed the number of Down's syndrome people in those societies.

[No information was provided at the time of print.]

Dr. HUDSON. I think it's important to keep in mind that when people—that screening does have a high false-positive rate, and that does cause anxiety among those women. When they get a screening test back that says, "You are at increased risk of having potentially a chromosomally abnormal fetus," they have this period of anxiety before they have the absolute diagnostic test. And some people will choose, potentially, not to have that diagnostic test if there's nothing that they would differently based on that information. But some people want the information, and they want the information in order to prepare medically, to prepare financially, to prepare emotionally for the birth of that child, or to make the always-difficult decision to terminate that pregnancy. So the information is, sort of—has a whole set of issues associated with making decisions and what kind of information. I think the other panelists have really raised some very good issues here about, How do we present information and what kind of information is presented about what the test will tell you and what the disease or disorder means for families and the children affected with those disorders?

Dr. BRUCHALSKI. Just to follow up on Dr. Hudson's comments on a practical, clinical level. Her comments are exactly right. Parents believe that a simple blood test can tell them the health of their child. That's how they approached this. That's how they're—oftentimes, that's the information given. And what they don't realize is, is that the screening test will—may provide an answer that then prompts a more definitive test—whether it's amniocentesis, or whether it's chorionic villus sampling, what have you—that carries with it a significant risk to terminating the life of their child, or the fetus inside of them. And what happens is, is that when mothers and fathers listen to this information, they're not fully—they're as confused about what is screening and what is diagnostic, and the anxiety that that provokes. Because they would never subject their child to an airline ticket that would crash one in 200 times. They just wouldn't do that. And yet that simple blood test, that statistic, then prompts further discussion and further decisions made by the parents. At least clinically, moms want to spend time with their sick or their children with disabilities. And I think Dr. Hud-

son's comments are correct, there are people who really use this information to try to prepare the family for the care of this individual.

I just know that I'm sick and tired—as a clinician, my profession has taken multiple hits over the last several years in reproductive issues. We put out—when it came to contraceptives and IUDs, we seem to put them out ahead of time. We're finding that there are side effects, whether it's with IUDs, what have you. And then we have the Women's Health Initiative, several years ago, that brought to light some risks to menopausal hormones. We're giving Viagra to the fathers and the husbands, but we're pulling away hormones from women because of further knowledge that has come to light.

Women don't trust us. "How dare you. You've let us down in the past," whether it's contraceptively or whether it's with peri-menopausal or menopausal hormones. And now I think it's coming to roost with prenatal genetic testing. "What you promised is not what we're getting." Because I know the difficulty that we spend, the time that we spend in our office talking to parents about false positives and false-negative tests, that they've come either from our practice or from other practices.

Senator BROWNBACK. Do we know anything from other countries, numbers, tests on Down's syndrome children?

Dr. Hudson, do you know anything on that? Mr. Kimbrell, do we——

Dr. HUDSON. I'm sure it's known, but I don't know it, off the top of my head.

I would want to make——

Senator BROWNBACK. Mr. Imparato, do you have a number on that? And I'll be happy to get back to you, but——

Mr. IMPARATO. I don't have a—I had another issue I wanted to raise that relates to the numbers, but—did you have something more directly——

Dr. HUDSON. I just wanted to make the point that, with first-trimester screening, while there are more positive results than there are actually affected pregnancies, it has had the effect of reducing the number of people who have had amniocentesis. Because if you get the negative results, which is good, back, then there's no reason, even if you have risk factors—advanced maternal age, et cetera—there's no reason for you to have amniocentesis. So the actual number of amniocenteses are growing down as a consequence of the number of pre-—first-trimester, non-invasive screening tests going up. So they have both some plus sides and down sides. But, ultimately, the number of amniocenteses is going down.

Senator BROWNBACK. Mr. Imparato?

Mr. IMPARATO. Yes, Senator, I just wanted to share a nuance on this question that would be interesting to look at. I don't know to what extent the researchers have. If you're talking about the context of parents who are expecting their first child, I think there's a lot of anxiety associated with the first child, and people are going to likely want to have all the information they can possibly get, because they feel that's part of being a good parent.

I know when my wife and I had our first son, I was working in disability rights. My wife wanted to have the test so she could pre-

pare. Second child, 5 years later, she didn't want to have the test because, as a parent, she realized that there are so many things that happen after the birth, you can't prepare for all of it. You roll with the punches as a parent. I mean, I think——

So I think it would be interesting to look at, What do, you know, people that have experience as parents opt for, and what happens in the context of the first pregnancy? And are people with that level of anxiety—relating to some of the other witnesses—are they in a really good position to hear that information and process it, given the anxiety that they have as new parents?

Senator BROWNBACK. Mr. Kimbrell, I want——

Mr. KIMBRELL. Mr. Chairman, I'd just quickly just jump in on that, which is that you mentioned spina bifida a couple of times, and I think it's a tremendous example of where genetic determinism failed. It was assumed that spina bifida was going to be either a monogenetic disease—and they said, "Well, we can't find that, so it's probably a multi-factual disease, a lot of genes involved." And actually they found it was a vitamin deficiency. If the 70 million women who can be pregnant in America were given folic acid, this would disappear altogether.

So, again, we—in this genetic determinism, you know, we have failed to look at the environmental factors and some of the economic factors that create a great many of these problems, in focusing on the very small number of diseases that actually are monogenetic. And I think it's an excellent of the larger reach we should be doing if we really want to protect children.

And, second, you know, we've talked almost solely about prenatal diagnosis. We haven't talked about preimplantation genetic diagnosis, PGD. And that's positive—that can be both positive and negative eugenics, but it also can be used as positive eugenics, where we can begin to select for certain traits before we have an embryo implanted, in IVF. So it adds a whole new element to this, which isn't just the negative eugenics of aborting a child, but actually, in the IVF circumstance, not going to an IVF center because you're infertile, but going there because you want to plan your child. A new commercial business in planning your children. And it brings up some very unique and, as I said, very important questions as to eugenics and commercial eugenics.

Senator BROWNBACK. Dr. Hudson?

Dr. HUDSON. I'd like to respond to the prior comments. The notion that anyone would want to go through in-vitro fertilization, which is expensive, painful, and uncomfortable, in order to make use of the extraordinarily limited number of tests that can be used in that context that are positively eugenic strikes me as only applying to an extraordinary rare individual.

The second is that, while my husband and I would love to have, perhaps you could imagine, a tall, blonde child, we could go through IVF, and there would be not a single embryo there that had those characteristics, because you can only pick from the characteristics that are present in the parents.

So I think we need to, sort of, have some realism, along with a "genetics are not destiny," in terms of thinking about what the possibilities are here, and keep them focused on the realistic, serious issues that confront us today, and not get too far afield.

Mr. KIMBRELL. Mr. Chairman, I just want to point out that in the report that the President's Council on Bioethics released, called, "Reproduction Responsibility," they report, with several footnotes, that over one-third of those who go through this process are not infertile.

Dr. HUDSON. But——

Mr. KIMBRELL. So that's not a very rare individual. And, also, it has already been used for sex selection and other non-disease cases. This is the President's page. I can submit this to the Committee for——

Senator BROWNBACK. We will put it in the record, and I appreciate the discussion back and forth on this topic.

[The information previously referred to is retained in Committee files.]

Senator BROWNBACK. I want to get back to Down's syndrome and what we've learned going through this. And there are quotes here that are really troubling to me. I think they're really troubling to Mr. Imparato, that he would note, and did note.

There's an article yesterday quoting a Dutch physician. This is in a Kansas newspaper. It says, quote—talking about the selection of a child—"Babies should be killed whenever some physical or mental defect is discovered, before or after birth." This is a Dutch physician.

It does seem like we're coming to an age or a point where we're going to have the ability to make a whole bunch more choices, and we're going to know a whole lot more ahead of time. And it does seem like we're trying to hone down into just, kind of, who we really want here, or not.

Dr. Hudson, do you see that in any of your research, where you're surveying and you're out, that—aren't you troubled by that? And, if so, where would you draw some limits around this, if you are troubled by it?

Dr. HUDSON. Well, I think you raised a really good point in your opening remark about starting a conversation. Because I think to the extent that people are having the conversation and thinking deeply about what is it that we want from this technology and what kinds of decisions that we want to make, that's going to help us all move along in this arena.

What we learned in our research was that where people draw the ethical line is along a very large continuum, and that people are anxious about other people making those limits or lines for them. And that comes from across the spectrum.

But there is this sense among a vast majority of Americans that there is a role that can be played by the government, in terms of safety and accuracy of genetic testing, as I mentioned. I think that we need to think long and hard, so that when people are in the situation of facing—making a decision about what tests to have, that they have as much information and as much thinking about it in advance.

And I'll give you one example. Someone else mentioned CF carrier screening is now the medical guidelines of the American College of Obstetricians and Gynecologists. But those tests, unfortunately, are most often being offered to parents to find out the parents' risks of having a child with CF after the woman is already

pregnant. That doesn't make any sense. We should be offering carrier testing and talking about genetics before people start having children, and not after.

So there's a lot that we can be doing to give people an opportunity—the worst time to be thinking about these things is in that anxious early pregnancy time. We need to think about these things ahead of time, collect information, have opportunities to find out, What is having cystic fibrosis like? What are the health conditions that you face? What kinds of medical situations, what kinds of social situations?

Senator BROWNBACK. Well, you know, Dr. Hudson, what about sex selection? Should people be allowed to pick, based on sex selection?

Dr. HUDSON. I'm not going to make a comment about whether people should or shouldn't. I will say that the most common means of determining, prenatally, what the sex of a child is, is not through genetic testing, but through sonography or ultrasound. So prenatal genetic testing is really, sort of, an offshoot. It's not directly relevant.

Senator BROWNBACK. You're seeing this take place in a number of countries, I believe. I've read articles—now, this is in an article—that India no longer allows the sonogram operator to tell the parents whether the child is male or female, because they've had a number of girls—you know, baby girls aborted. We're seeing some of this taking place in China. That's happening, and it has had an impact of skewing the population ratios of male to female within that society.

Dr. HUDSON. There's also——

Senator BROWNBACK. So, I mean, this is a very practical issue that's being expressed in many places around the world.

Dr. HUDSON. In this country, there's also technology prior to conception in which you can pick the sex of your offspring—called microsort—in which the sperm are separated based on whether or not they carry a Y chromosome, which would produce a male, or an X chromosome that would produce a female. And in this country—and we live in a unique culture, quite distinct from that in India or China—there is no preference toward males or females in the selection of which sperm to use in order to create a child. There are all sorts of other issues there, but a sex imbalance is not one of them.

Senator BROWNBACK. Where are we headed with this, as a practitioner? Dr. Bruchalski, I'd be interested in your and Dr. Chicoine's view on, Where are we headed, as a practitioner, in this field? Are you going to—now and in the future, are you going to have more tests that parents are going to be able to have ahead of time? They're going to be in your office, I presume, asking for these tests. They're going to know about, apparently, maybe factors—I don't know that they're going to know about obesity factors, but they're going to know about, perhaps, potential for certain types of cancer. What do you see as this thing—as this develops, moving on down the road?

Dr. BRUCHALSKI. As a clinician, I can tell that, over the last 15 years, we have moved from Down's syndrome to tubal issues to cys-

tic-fibrosis-carrier issues; and more and more, as we've been hearing today, have been coming to light.

What I'm afraid of is that our hands, right now, are being—I don't want to say "tied," but, to a sense, they are being tied to people who are getting on the Internet for information, where the data is out there, but it's unclear as to what understanding couples, as well as physicians, have on this. And we—when they talk about nondirective counseling, it's very difficult, at least from what my patients tell us, to have true nondirectional counseling. And I believe that that has been—because we are all called—as you asked Dr. Hudson about sex selection—we are all called to make judgments on this technology. And in the room, when you close that door and you begin to talk to parents, you're trying to take data that's statistical and apply it to their child, to their families.

And I'm very, very cautious as to what the future holds in regard to this, because we have already gone to preimplantation genetics. That's already happening. The production endocrinologists is where that's occurring. I'm a private practice, bread-and-butter OB/GYN in Northern Virginia, and what we're finding here is that we have to take incredible amounts of statistics, and translate that for parents, and make sure that they are fully aware of what choices they're making for their child and for their family—not just their immediate, but for their general family—because of these genetic issues.

It's hard for me to imagine what the future holds, because, over the last 15 years, we've made—we've now been pushed to cystic-fibrosis screening before it has come fully—before it has become fully accurate. And I think the data from statistics of risk to the actual disease, it's impossible to get. You can't translate that for the parent. And so nondirective counseling becomes "you do your best." And I think it's a noble and an honorable attempt, but I think it becomes harder and harder, because the questions become more challenging.

Senator BROWNBACK. Dr. Chicoine?

Dr. CHICOINE. I guess the concern I have is that so much of the focus now has gone on to the prenatal testing and the prenatal diagnosis that my question is, Are we going to lose the people that are already here? And are we going to lose the people that will still be born in the future, as well? Are we not going to be able to provide for them, because so much of the commerce and the economics is going in that direction, in not providing care for these people after they're born?

I guess the other question I have is—you mentioned, in your first statements, about just some of the things that you've learned from being around a person with Down's syndrome, and I think there are many things like that, that—and that's just one disability—many things we can learn from people. And you mentioned social things. But I think there are a lot of very scientific things that we have not taken the time to learn, as well. Why, out of more than 2,500 patients with Down's syndrome that I've seen, has one had a heart attack? Whatever it is that has—about people with Down's syndrome that prevents them from having a heart attack, I want.

[Laughter.]

Dr. CHICOINE. Why is it that we see almost no high blood pressure? I want some of that, too. You know, why do we see very little asthma? A number of conditions.

So I think there are a number of things about—you know, we—it's very interesting that we—that so much focus of genetics is now to limit genetic diversity, which we have been taught for hundreds of years—at least a hundred years—that that is the deal. Genetic diversity is what keeps us going. If we limit genetic diversity, we're going to lose ourselves as a species. We're going to—and that's how species get lost, because they don't have genetic diversity. And that, to me, I think, from a—I think it puts, right here in this arena, science—I think, to me, that's a very important piece that has been totally overlooked with regards to at least certain people with Down's syndrome. And I think that to—and I think certainly it's a social issue, as well, caring for them, caring for the people that are here. I think if you look at the number of studies—you know, I—just pull up Down's syndrome in the literature—the great majority talks about prenatal care, and very little about actually caring for the people that are here, and I think that's a mistake.

Senator BROWNBACK. This has been very informative.

Mr. Kimbrell, a final thought?

Mr. KIMBRELL. Yes. I think we do need to look also where we're going with this. You know, if you look, over the least couple of decades, and the "progress"—well, I'll put that in quotes—that has been made, there are things in the future that we're already looking at. For example, we saying, What about genetically engineering children to free them of certain diseases, certain characteristics, permanently changing their germ line? We already have the first one of these proposals before the NIH. And what about cloning embryos, cloning healthy embryos for infertility or for study? And it seems to me this is the next line. Right now, we're diagnosing. Now we're at the preimplantation phase. What about creating the genetic engineering? So——

Senator BROWNBACK. It might be to save your children. I've been reading about some, too, where you have a—save your sibling, where you try to get a genetic match for a child that's older.

Mr. KIMBRELL. Right. That's already happening, to a certain extent. But it seems to me, as far as policy recommendations, for goodness sakes, why can't we pass a ban on the germ line, genetic engineering of human beings? Why can't we pass a ban on the cloning of human beings and human embryos? Why can't we pass a ban at least on the patenting and the commercial patenting of human embryos and human life forms? It seems to me at least we can do that to stop any next phase that might be coming in while we begin this public debate that, in many ways, we started this discussion here today.

And, additionally, I do not think we—many states have prohibited surrogate motherhood, and there has been constitutional challenges to that have failed. You do not have a reproductive right to buy a child. And it seems to me that reproductive—this has zero to do with destroying a child, which is still happening in this country with many of the ethnic communities in this country—I've cited it in my book—many places where we literally are killing female

embryos because they're female. I don't—as a society, we need to discuss whether we want to make sure that doesn't happen.

So I think—in many of these eugenic areas, I think legislation is appropriate. And I would hate to—I hate to think back over a hundred year history where we failed to take that action with sterilization, and, all these years later, would fail again to save those children—who would be the victims of sex selection or because they were supposedly disposed to obesity—to save those children, again, I think would be a tragic error.

Senator BROWNBACK. Thank you all very much for joining us. The longer I've been around, the more I recognize that each and every person is unique and beautiful, no matter what their nature, no matter what they look like, no matter, really, anything. They're just—they're unique, they're beautiful, they're precious, they're a child. They're a beautiful gift from God. And I think we're the poorer when we don't welcome them in as much as we possibly can.

And it's also striking to me that, of societies, it is a big measure—what we do for the so-called "least" is a real key measure of what the health and welfare of a society is. And so we're really wrestling with fundamental questions on this one right here. I don't want to see us get to a point where we do lose diversity, because—out of some strange notion that we've got to have a perfect set here. And you see this happening, I think, in some other countries, you know, where you read about India, China—and Israel; I was visiting there, and they talk about Down's syndrome being a religious phenomena, that it happens mostly with very observant Jewish people, and not with others. And you want to know what impact does that have on a society, if that's the nature?

I do think this is appropriate for us to discuss. I think we really need to have a big discussion about it, as a nation, and not be scared of its implications in the overall abortion debate, but, rather, have a good discussion on it about what it means. Because we are upon the science right now. It is on us, and we need to have that good discussion.

I appreciate you opening up the debate about it. I look forward to working with each of you as we try to craft appropriate responses to it. And I'm sure we'll be talking more about this.

Thank you very much for coming. The hearing's adjourned.

[Whereupon, at 3:40 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

Mr. Chairman:

Concern for children is obviously an important thing. I have four children and ten grandchildren. When I cast a vote in this Committee or on the Senate floor, I think about the effect that vote will have on them.

So I share your concern about children. But this hearing isn't really about children. It's another attempt to advance an anti-choice agenda. That's not the role of this Subcommittee.

I've reviewed the hearings this Subcommittee has held during the 108th Congress.

This Subcommittee has jurisdiction over a number of issues. We've had 14 hearings on NASA and a sprinkling of hearings on some other relevant topics.

I object to the 11 hearings on issues that are *beyond* this Subcommittee's jurisdiction. Hearings on divorce, abortion, and stem cell research are thinly-veiled attempts to push anti-abortion views.

It's telling that the panels are *always* loaded with anti-choice witnesses to *prevent* a *fair* debate about some of very serious topics.

These 11 hearings promote a certain set of cultural values. Don't misunderstand me: I have no problem with holding those values, or voting in a way that is consistent with them. That is your right.

But I do object to *hijacking* this Subcommittee, at taxpayer expense, to push an agenda that properly falls under the purview of the Judiciary and HELP Committees.

If this Subcommittee is going to be used in this fashion, then I propose that we hold hearings and get social scientists here to testify on the impacts that long-term *joblessness* has on families. We can hold hearings to determine whether *not fully funding post-natal care, Head Start,* and *No Child Left Behind* is detrimental to children.

Thank you, Mr. Chairman.

Subcommittee on Science, Technology, and Space

Hearings in the 108th Congress

Subcommittee Jurisdiction	Number of Hearings
National Aeronautic and Space Administration	14
National Oceanic and Atmospheric Administration	1
National Science Foundation	0
National Institute of Standards and Technology	0
Office of Science and Technology Policy	1
U.S. Fire Administration	0
Federal R&D Funding	1
Internet	0
Earthquake Research Programs	1
Encryption Technology	0
International Science and Technology	1
TOTAL	*19*

Extra Jurisdictional	Number of Hearings
Anti Abortion Agenda	7
Media Indecency & Violence	2
Marriage Promotion	1
Science Behind Pornography Addiction	1
A New Kind of Science	1
TOTAL	*12*

WRITTEN QUESTIONS SUBMITTED BY HON. FRANK R. LAUTENBERG TO THE WITNESSES

For Andrew Kimbrell

Background. Andrew Kimbrell is the Director for the International Center for Technology Assessment (CTA). CTA is a non-profit that takes a negative and generally skeptical view of technology. Kimbrell writes that technology is "among the most powerful, and often destructive, agents of social change in modern times."

Question. Do you agree that there are situations where genetic testing can be positive, such as in families where there is a high risk for a certain disease? Wouldn't a negative test for a birth defect—especially one that is strongly predictive—provide an enormous sense of relief for the expecting parents?

For John Bruchalski

Background. Dr. John Bruchalski is the director of the Tepeyac Family Center in Fairfax, Virginia, an obstetrical and gynecological facility that "combines the best of modern medicine with the healing presence of Jesus Christ under the medical-moral guidance of the Catholic Church."

He states in his testimony that the data used for prenatal testing is "more confusing than clarifying and . . . that the conversation generated may cause irreparable damage in the parent child bond with implications of how that family views individuals with disabilities, or worse, how they view those who have had 'abnormal testing' but are completely normal human beings."

Question 1. It sounds to me like you are suggesting that prenatal genetic testing should not be done—is that your view? Shouldn't this be a decision that a woman makes with her doctor and not one that politicians make for her?

Background. Dr. Bruchalski has affiliations with the "Couple to Couple" league, and the "Family of the Americas," both organizations that oppose the use of any form of birth control. In addition,he is a board member for the Abortion Breast Cancer Link (ABC) that suggests there is a link between abortion and incidence of breast cancer. Such a correlation is false.

ABC's web page states:

> It cannot be said that all women who have breast cancer have had abortions. Similarly, not all women who have had abortions will get breast cancer. *Nevertheless, abortion is the most preventable risk factor for breast cancer.*

Question 2. Dr. Burchalski you are on the board of a group that has tried to line abortion and breast cancer. In light of the fact that the National Cancer Institute (NCI) contends there is no association between abortion and breast cancer, why do you continue to insist that such a link exists?

For Brian Chicoine, M.D.

Background. Dr. Brian Chicoine is the Medical Director of the center and on the Family Practice faculty at Lutheran General Hospital. Dr. Chicoine specializes in the area of adult Down Syndrome and has been with the center since its inception in 1992. Brownback has called Dr. Chicoine in to try to appeal to the disability community.

Question. Many prenatal tests can identify genetic disabilities such as Down Syndrome midway through pregnancy. In your work have you been able to use this knowledge in a positive way? For example, can you work with expecting mothers to educate and train them on how to effectively raise their child or put them in touch with parents that have developmentally disabled child to help them cope with some of the challenges that lie ahead?

For Kathy Hudson

Background. Kathy Hudson is the witness called to testify by the Democratic side. She should be friendly to our point of view.

Genetic tests provide information that can provide a diagnosis and guide treatment decisions, prognostic information that can help tell the course of a disease, or probabilistic predictive information about the future risk of disease. Some the birth defects that can be detected by prenatal diagnostic tests include: cystic fibrosis, sickle cell disease or Tay-Sachs disease; Muscular Dystrophy; Down Syndrome; and certain birth defects, such as spina bifida.

Question. Isn't it is unfair to layer guilt and shame on individuals honestly trying to make decisions that are based on the quality of life for the individual and the family—after all these decisions are not simple or entered into lightly?

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