



The Genetic Town Hall: Making Every Voice Count



Genetics and Public Policy Center • 1717 Massachusetts Ave., NW, Suite 530 • Washington DC 20036 • 202.663.5571 • Fax: 202.663.5992 • www.DNAPolicy.org

The Genetics and Public Policy Center is part of the Phoebe R. Berman Bioethics Institute at the Johns Hopkins University and is funded through a grant from The Pew Charitable Trusts

Copyright 2004

GENETICS & PUBLIC POLICY CENTER

Kathy Hudson, Ph.D.
Director

Audrey Huang, Ph.D.
Communications

Kristen Suthers, Ph.D., M.P.H.
Research Analyst

Joan Scott, M.S.,C.G.C.
Deputy Director

Andrea Kalfoglou, Ph.D.
Research Analyst

Rhoda Washington
Communications Assistant

Susannah Baruch, J.D.
Policy Analyst

Daryl Pritchard, Ph.D.
Policy Research Analyst

Sheryl Wood
Administrative Assistant

Gail Javitt, J.D., M.P.H.
Policy Analyst

Jane Solt
Office Manager

GENETICS & PUBLIC POLICY CENTER ADVISORY BOARD

Aravinda Chakravarti, Ph.D.
Institute of Genetic Medicine
Johns Hopkins University
Baltimore, MD

Ruth Faden, Ph.D.
Phoebe R. Berman Bioethics
Institute
Johns Hopkins University
Baltimore, MD

Thomas Murray, Ph.D.
Hastings Center
Garrison, NY

David Cox, M.D., Ph.D.
Perlegen
Mountain View, CA

Patricia King, J.D.
Georgetown University Law Center
Washington, DC

Mary Pendergast, Esq.
Pendergast Consulting
Washington, DC

Sharon Terry, M.A.
Genetic Alliance
Washington, DC

OUR RESEARCH PARTNERS

Jonathan Ortman
Public Forum Institute

Mark Marich
Public Forum Institute

Amy Eckenroth
Public Forum Institute

Holly Braly
Public Forum Institute

Note: The Genetics and Public Policy Center is grateful for the guidance and support of the Center Advisory Board and the contributions of our research partners in the design, conduct and analysis of the studies included in this report. The Genetics and Public Policy Center Advisory Board and research partners do not, however, necessarily agree with or endorse this report. The Genetics and Public Policy Center assumes full responsibility for the report and its contents.

TABLE OF CONTENTS

Acknowledgements	1
Preface	3
Genetic Town Hall Summary Report	5
Sacramento City Report	21
Seattle City Report	27
Kalamazoo City Report	33
Fort Worth City Report	39
New York City Report	45
Nashville City Report	51

The Genetics and Public Policy Center at the Phoebe R. Berman Bioethics Institute, Johns Hopkins University was established in April 2002 with a generous grant from The Pew Charitable Trusts. The Center is an objective source of information, research, analysis and policy options on reproductive genetics for the public, policymakers and the media.

The Genetics and Public Policy Center acknowledges and thanks The Pew Charitable Trusts for its generous support.

The opinions expressed in this report are those of the author(s) and do not necessarily reflect the view of The Pew Charitable Trusts.

Published December 2004. Copyright 2004 Genetics and Public Policy Center. All rights reserved. No portion of this paper may be reproduced by any means without written permission from the publisher.

Acknowledgements: Making the Town Halls Possible

The Genetic Town Halls would not have been possible without strong collaboration among several organizations and many individuals in cities across America. First thanks go to The Pew Charitable Trusts, whose generous grant established the Genetics and Public Policy Center in 2002 and supported the Town Halls. The Trusts recognized the power of genetic technologies to transform human experience and anticipated the struggle the public and our leaders will have in deciding how to best guide the development and use of these advances. Both the people of The Trusts – with special thanks to Maureen Byrnes, Leslie Tucker and Cheryl Rusten – and its financial support have been crucial.

The experienced group at the Public Forum Institute, an organization committed to developing the most advanced and effective means of fostering public discourse, was indispensable in guiding discussions, advising on content and format, and collecting and analyzing data. The Center especially thanks: Jonathan Ortman, who moderated each Town Hall and offered invaluable insight throughout the series; Mark Marich, who helped craft the Town Hall format and controlled data collection, analysis and communications; Amy Eckenroth, who directed the outreach and recruitment efforts in all six cities; and Holly Braly, who provided overall logistical support. The Center would also like to thank the Forum's team of regional coordinators who helped engage their communities in the dialogue: Nicole King (Fort Worth, TX); Patti Mindock (Kalamazoo, MI); Christi Ray Pugh (Nashville, TN); Tracy Saville (Sacramento, CA); John Williams (Seattle, WA); and Beau Willimon (New York, NY).

A special acknowledgement goes to Christopher Burke for his vision and creativity in making *Chosen Children: The Science of Reproduction Genetic Testing* and to 3 Roads Communication for the *Chosen Children* issues videos. The professionals who so generously gave of their time and expertise to making the *Chosen Children* issues videos - R. Alta Charo, J.D.; Francis S. Collins, M.D., Ph.D.; Amy Laura Hall, M. Div., Ph.D.; Leon R. Kass, M.D., Ph.D.; Patricia King, J.D.; Paul Steven Miller, J.D.; C. Ben Mitchell, Ph.D.; Robert F. Murray, Jr., M.D.; and Sharon Terry, M.A. - were indispensable in articulating the wide range of perspectives about the issues raised by reproductive genetic testing.

Medical experts, elected officials, clergy, scholars, industry representatives and parents with firsthand experience in reproductive genetic testing served as community panelists and generously shared their insights and perspectives in each city visited by Town Halls, and the Genetics and Public Policy Center thanks them.

And most importantly, the Genetics and Public Policy Center would like to thank the hundreds of interested citizens who devoted several hours of their personal time to explore these issues with us – and with one another.

Preface

In six American cities during the summer of 2004, a unique information exchange took place. From students to seniors, from medical professionals to people with disabilities, from the homeless to the well-to-do, people with all types of perspectives convened at Genetic Town Halls to learn more about a matter that affects the present and future generations — reproductive genetic testing.

Reproductive genetic testing, which will touch millions of people, give parents more options in having healthy babies, but they also raise troubling questions about future uses. Today, it is possible to test for serious genetic disorders; tomorrow, it may be possible to test for genetic contributions to characteristics such as intelligence.

The policy debate about these issues is often framed in the extremes. Yet the views of most Americans tend to be more nuanced. To better understand American opinions and attitudes about reproductive genetic testing and the values that shape them, the Genetics and Public Policy Center has undertaken extensive public opinion research through surveys, focus groups and interviews. A difficulty with these approaches, however, is that individuals are sometimes asked to comment on issues involving complex technologies about which they may have had little opportunity to consider in depth. Thus, the Center undertook a project to obtain more informed, reflective opinions by providing an opportunity for individuals to learn more about reproductive genetic testing, hear different perspectives about the issues and engage in discussions with fellow citizens.

The six *Genetic Town Halls: Making Every Voice Count* provided a setting for informed debate and discussion about the benefits and potential drawbacks of reproductive genetic testing. The Town Halls went beyond simple focus groups designed to harvest initial impressions; they instead set a process in motion, aimed at generating continued engagement and discussion about the complex issues surrounding reproductive genetic testing. From advance media coverage to personal conversations with family and friends afterward, the forums raised awareness and knowledge levels in the six communities involved.

Information about reproductive genetic testing and the range of issues it raises was provided at each forum in the form of videos prepared by the Genetics and Public Policy Center. Computer animation sequences offered an accessible grounding in the science, with an overview of the types of reproductive genetic testing: carrier testing, preimplantation genetic diagnosis and prenatal testing. Through interview footage, the videos also offered viewpoints about reproductive genetic testing from a variety of experts in fields ranging from medicine to theology. In addition, participants could ask experts on site to clarify issues or further explain the technologies at any point during the discussions.

Participants also had an opportunity to hear from members and leaders of their own communities. Theologians and clergy, parents with firsthand experience of reproductive genetic testing, medical professionals, community activists, elected officials and those in the biotech industry gathered as local expert resources for the forums in each community and shared their views with the audience during panel discussions.

As participants learned, debated and deliberated during the 3.5-hour sessions, they registered their opinions through a series of polling questions and during facilitated small- and large-group discussions.

The forums, free and open to the public, were supported by a grant from The Pew Charitable Trusts. All viewpoints were welcomed and sought. Outreach in each community emphasized attracting participants from all walks of life, all neighborhoods and all demographics. Some participants brought a blank slate and others, profound personal experiences with genetic testing or genetic disorders.

At the Town Halls, participants made it clear that they wanted information, discussion and input in the way these technologies are developed and implemented. Many expressed concern that with the dramatic advances in knowledge and technology in genetics, the Town Hall was not only critical, but on the edge of being too late. They pointed out that with rapid changes in the field, such discussions must be ongoing and widespread.

This report summarizes the issues brought up by the participants in the six Town Halls and their responses to questions posed. It looks at general trends, brings out points of agreement and presents issues about which individuals were divided. Also included are individual reports from each forum that allow for a glimpse at the attitudes and opinions in each of the six cities. As a whole, these reports offer an indication of the effectiveness of engaging the public in the policy debate about advances in genetics and a picture of the public's values and policy preferences for guiding the future use of these potent tests.

It is the hope of the Genetics and Public Policy Center that the informed discussion begun this summer will not end with the change of season, but that participants will expand these activities in their own communities and throughout the nation.



Sincerely,
Kathy Hudson
Director, Genetics & Public Policy Center



Joan Scott,
Deputy Director, Genetics & Public Policy Center

Genetic Town Hall Summary Report

INTRODUCTION

Three Highly Focused Hours

The public Town Halls were held in six cities during the summer of 2004. During the Town Halls, participants were asked to consider issues related to three types of reproductive genetic testing – testing that gives prospective parents information about their risk of having a child with a genetic disorder. The tests discussed included:

- carrier testing – genetic testing to determine if an individual carries one copy of an altered gene that causes a particular recessive disorder;
- preimplantation genetic diagnosis, or PGD as it is also called – genetic testing that is done on embryos produced through in vitro fertilization to select which embryos to transfer to a woman's womb;

- prenatal testing - genetic testing of fetal cells that is done during pregnancy to find out if the fetus has or is likely to develop certain inherited diseases or characteristics.

Participants were asked to consider three major issues about the uses of these tests:

- determining acceptable uses- should there be limits on what we test for, and if so, what are those limits and who should set them?
- examining safety and accuracy- are we doing everything we should to make sure reproductive genetic testing is safe and accurate?
- considering the effects of reproductive genetic testing – what is the impact on individuals, families and society of parents' ability to select the characteristics of their children?

The format of the Town Hall was the same in each city (Figure

Sacramento, California

June 29, 2004

Seattle, Washington

July 1, 2004

Kalamazoo, Michigan

July 19, 2004

Fort Worth, Texas

July 31, 2004

New York, New York

August 2, 2004

Nashville, Tennessee

August 4, 2004

1.1). After responding to a series of questions to obtain demographic information and to determine their initial views, participants were shown an informational video *Chosen Children: The Science of Reproductive Genetic Testing* that provided an animated overview of the basics of genetics and types of reproductive genetic testing. Then they viewed a video that

Strong Trends

Several issues got strong approval or disapproval:

- Eighty-nine percent of participants felt there should be limits set for acceptable and unacceptable uses of reproductive genetic testing.
- A high percentage thought that it was appropriate to test for a gene associated with a fatal childhood disease.
- But relatively few thought it was okay to test for a hypothetical gene associated with high intelligence or increased strength.



Figure 1.1 Genetic Town Hall Agenda

THE GENETIC TOWN HALL: MAKING EVERY VOICE COUNT	
9:00 a.m.	Welcome and Overview Kathy Hudson, Ph.D., Director, Genetics & Public Policy Center
9:10 a.m.	Overview of the Process Jonathan Ortman, The Public Forum Institute
9:20 a.m.	Initial Impressions: eFORUM Session Using keypads, participants responded to questions from the moderator on their opinions and values concerning reproductive genetic testing.
9:30 a.m.	The Science of Reproductive Genetic Testing: Video Presentation Participants viewed a video that explained the basics of genetic testing.
9:40 a.m.	The Ethics of Reproductive Genetic Testing: Video and Discussion Using keypads, participants responded to questions from the moderator, viewed a video on the ethics of reproductive genetic testing and then engaged in “table talk” discussion about setting limits on acceptable uses of testing. Using keypads, participants rated issues to consider when setting limits.
10:25 a.m.	The Safety and Accuracy of Reproductive Genetic Testing: Video and Discussion Using keypads, participants responded to questions from the moderator to gauge baseline impressions and then watched a video on safety and accuracy. The moderator then facilitated a question and answer discussion.
10:55 a.m.	Implications for Families and Society: Video and Discussion Following a video, participants engaged in more “table talk” discussion on the impact technologies can have on families and society. Using keypads, they rated their level of concern on the top responses developed at each table.
11:40 a.m.	Impressions: eFORUM Session Using keypads, participants responded to many of the same questions posed earlier on their opinions and values concerning reproductive genetic testing.
12:00 p.m.	Community Panel Discussion Regional leaders participated in a moderated panel discussion to reflect on the Town Hall themes that emerged from the discussions.
12:30 p.m.	Concluding Remarks Kathy Hudson, Ph.D., Director, Genetics & Public Policy Center

THE EXPERTS

The Genetics and Public Policy Center taped interviews with the following experts and incorporated their comments and perspectives into instructional videos that helped explain the technologies and define the range of viewpoints.

R. Alta Charo, J.D.

Professor of Law and Bioethics
University of Wisconsin

Francis S. Collins, M.D., Ph.D.

Director
National Human Genome Research Institute

Amy Laura Hall, M.Div., Ph.D.

Assistant Professor of Theological Ethics
Duke University

Leon R. Kass, M.D., Ph.D.

Fellow
American Enterprise Institute

Patricia King, J.D.

Professor of Law, Medicine, Ethics and Public Policy
Georgetown University

Paul Steven Miller, J.D.

Commissioner
U.S. Equal Employment Opportunity Commission

C. Ben Mitchell, Ph.D.

Associate Professor of Bioethics & Contemporary Culture
Trinity International University

Robert F. Murray, Jr., M.D.

Clinical Geneticist
Howard University Hospital

Sharon Terry, M.A.

President and CEO
Genetic Alliance

addressed one of the three major issues described above. Through interviews with a diverse group of people including medical

experts, policy experts, bioethics scholars and clergy, the videos provided an overview of the wide range of perspectives on that

topic. Prompted by the video and questions posed to them, participants broke into small groups for further discussion and to identify the issues most important to them. These were shared with the larger group who then ranked and discussed them. This process was repeated for each of the three issues.

An electronic keypad system allowed participants to respond to questions and register their opinions and then immediately see the views of the group as a whole. The responses provided valuable insight into the range of views held by those in the room – a picture participants filled in with their comments during the discussion that ensued. Participants were also encouraged to write comments down and submit them. In final evaluations, nearly all said they had had the opportunity to express themselves in the Town Hall.

The *Chosen Children* video series was also made freely available on DVD to Town Hall participants so they could share them with community groups or hold their own discussion groups.

Who Attended A Snapshot of Participants

Five hundred thirty-six individuals attended the Town Halls. All of the Town Halls attracted a broad range of participants.¹ Overall, about 40 percent were 50 years old or older, 34 percent were between the ages of 30 and 49, and 26 percent were younger than 30. Most forums were split roughly in thirds into



these age groups, except for Kalamazoo and Fort Worth, where about half of participants were in the 50 or older group and Nashville where 45 percent were between 30 and 49.

Overall, 59 percent of the Town Hall participants were women and about 80 percent of participants were White; Nashville and Kalamazoo had the highest percentage of Black participants, 14 percent and 16 percent respectively. Sacramento was the most diverse Town Hall with 10 percent Black, 10 percent Asian, 8 percent Hispanic and 10 percent “other.”

In general, participants tended to be well educated. Nineteen percent had some college or vocational education, 27 percent had a bachelor’s degree and 44 percent had some postgraduate education. Although income and occupation were not asked, it was noted anecdotally in each Town Hall that college, postgraduate or medical students were in attendance. The ability to take time off of work or to afford childcare to attend a Town Hall may also have reflected a higher educational level of participants.

Political and religious affiliations of participants varied greatly among each Town Hall. In Sacramento, Seattle and Nashville, about half were Democrats; in New York, 64 percent. The highest percentage of Republicans at any Town Hall was 34 percent in Fort Worth. About a quarter of participants at Seattle and Kalamazoo considered themselves Independents.

Overall, more than a quarter of all participants gave their religious affiliation as Protestant, 18 percent said they were Catholic, 16 percent said they were affiliated with another Christian religion and 7 percent said they were Jewish; about a quarter said they had no religion or preferred not to say. The religious identification of

participants in some forums varied substantially from this overall picture: in Seattle and New York, about 37 percent and 33 percent respectively had no religion or preferred not say; the Fort Worth group was 40 percent Protestant, and the New York group 7 percent Protestant.

Participants were asked whether they considered themselves either Born Again or Evangelical Christians. Overall, about a quarter identified themselves as Born Again; in Fort Worth and Nashville, 39 percent and 47 percent respectively said they were Born Again; in Seattle, 10 percent; and in New York, none.

When asked to choose among statements about abortion, overall,



Table 1.1: Town Hall Approval for Different Uses of Genetic Testing

	Carrier testing	PGD	Prenatal testing
Fatal childhood disease	95.1	80.4%	81.9%
Adult-onset disease	N/A	61.9%	56.4%
Tissue match	N/A	60.7%	54.7%
Sex	N/A	38.8%	43.8%
Intelligence or Strength	N/A	20.2%	21.3%

*All figures are percentage of Town Hall participants who responded to the question and answered “approve” or “strongly approve”. Community panelists and table facilitator responses are removed.

67 percent said the matter should be left up to individual women and 12 percent said abortion should never be permitted. In Fort Worth and Nashville, 21 percent and 19 percent respectively, said abortion should never be permitted. In Seattle and New York, 83 percent and 89 percent respectively said the matter should be up to individual women.

A Diverse Knowledge Base

Participants came to the Town Halls with varying levels of prior awareness of and personal experience with genetics. The knowledge level about genetics was somewhat higher than participants in a national survey conducted by the Genetics and Public Policy Center,² but not greatly so; 61 percent of participants had heard about carrier testing before participating in the Town Hall, 94 percent had heard of prenatal testing and 47 percent had heard of preimplantation genetic diagnosis.

This compares to 83 percent of participants in the national survey who had heard about prenatal testing and 40 percent who had heard about preimplantation genetic diagnosis.

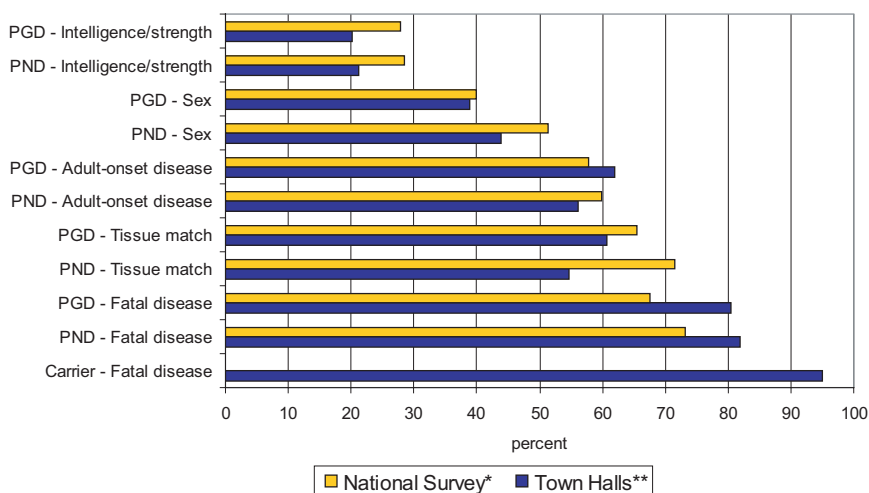
Twenty-three percent had either had a genetic test themselves or had someone in their family who had received one. Some parents at the forums shared personal experiences with testing and/or children with disabilities during discussion.

SETTING LIMITS

What Test, For What Purpose: Drawing the Line

After viewing a video on the science of reproductive genetic testing, participants answered questions measuring approval of the use of carrier testing – the testing of adults; preimplantation genetic diagnosis (PGD) – the testing of embryos; and prenatal testing – the testing of a fetus. They were asked to indicate whether they strongly approved,

Figure 1.2: Approval for Different Uses of Reproductive Genetic Testing



* Source: 2004 Survey, N=4,834. Non-respondents are removed.

** Source: Town Hall Data. All figures are percentage of Town Hall participants who responded to the question and answered “approve” or “strongly approve.” Community panelists and table facilitator responses are removed.

approved, disapproved or strongly disapproved of testing in five situations:

- testing for a gene mutation associated with a fatal childhood disease;
- testing for a mutation associated with a tendency to develop a disease such as cancer later in life;
- testing for a hypothetical gene associated with high intelligence or increased strength;
- testing for sex;
- testing to determine if the person will be a good tissue match for a sick sibling who needs a transplant.

Carrier testing – the testing of adults – was seen as the most acceptable, being the least invasive (Table 1.1). However, participants made it clear during the discussions that they did not want carrier testing done routinely without the parents being fully

informed of the impact of the choices that would have to be made based on the results.

While the majority approved of testing for a medical indication such as a gene mutation associated with a fatal disease, participants clearly drew the line at testing for hypothetical (currently unavailable) non-medical applications such as a gene associated with strength or intelligence. Participants were more divided on testing for sex. Figure 1.2 shows the overall results from the six forums, contrasted with a national survey conducted by the Center in April of 2004.² (Questions about carrier testing were not asked in the national survey).

Considerations in Drawing the Line: Where and How?

Participants were asked, “Do you think there should be limits set for acceptable and unacceptable uses of reproductive genetic testing?” An overwhelming

QUESTION:

What do you think are the factors to consider when setting limits?

number, 89 percent, said yes, there should be limits. Participants were then asked to discuss in small groups what factors are important to consider when setting limits. While many issues were raised, nearly all participants in the small-group discussions chose some variant of “test for serious disease, not just for a trait” as the major factor to be considered in setting limits.

Participants called testing for traits “trivial,” “frivolous,” “narcissistic,” and “elitist.” “When it gets to the point where it’s like picking out new clothes, it should stop!” one participant said.

But participants also acknowledged that it would be difficult to legislate against some uses. For example one participant said, “A mother could say, ‘I want testing for disease,’ but actually be thinking, ‘I don’t want another boy.’ Setting limits would be impossible. To find out the real reasons would be a huge invasion of privacy.”

Other participants pointed out that what constitutes a “serious” disability can also vary by culture or individual. Where the line is drawn will inevitably move as technology – both in terms of testing and in cures – progresses, participants said. Nearly all agreed that the key to making decisions on drawing the line is education.



The Online Genetic Town Hall

Concurrent with the Town Halls held in six cities around the United States, similar discussions were held on the same issues online. Fifteen groups, averaging about a dozen participants each, discussed the same three basic areas of reproductive genetic testing, but instead of meeting once for three-and-a-half hours, these groups “met” online for three, one-hour sessions held about a week apart.

Participants could use voice or text messaging. The sessions were moderated by a content expert so questions could be addressed immediately. Participants were sent copies of the educational videos and asked to watch them before each meeting discussion. They were polled on questions similar to, but in a slightly different format than those at the Town Halls.

The online format, whether due to anonymity or the slower pace of exchange, made for slightly more intimate discussion. Participants joked, argued and shared personal stories about their own families and experiences. It’s often the case with online forums that those who rarely speak up in groups feel freer to express their opinions. Yet the comments and concerns largely mirrored those at the face-to-face Town Halls.

The Role of Faith in Setting Limits

Many participants felt that their religious faith should be the guiding principle in setting limits. This was a prominent theme in Fort Worth and particularly in Nashville, where nearly half those participating in the Town Halls identified themselves as Born Again or Evangelical Christians. To some, reproductive genetic testing is seen as deeply offensive, an attempt by science to take on the role of God and “taking God out of the equation.” At all the forums, a few people made it clear that they cannot find anything beneficial about a technology that could result in a destroyed embryo or a terminated pregnancy. At the Nashville forum, “consideration for the sanctity and dignity of human

life” was named as one of the top things to take into account when setting limits on reproductive genetic testing.

Some participants said they worry that their belief system will be jeopardized or eroded in the future if a place is made in society for reproductive genetic testing. The top concern was that testing will begin to seem “normal” and “morally acceptable,” and it will become harder for people to choose not to test.

On the other hand, some participants objected to religious beliefs being used to set the agenda for the rest. Banning or limiting testing implicitly “imposes a single moral or ethical perspective,” a participant said.

The forums also made it clear that not all individuals of strong religious faith oppose all aspects of reproductive genetic testing. Some participants spoke of a religious and moral imperative to reduce suffering and research and scientific advancement plays a role in this, or how choosing an embryo through PGD to become a child that can help a sick sibling through transplant is allowing a child to do a great work.

The voices of those who feel strongly about these issues added a meaningful dimension to the discussion. At the Sacramento Town Hall, a few pro-life protestors outside the forum site were invited in to join the discussion. “I have religious feelings about genetic testing, but I don’t want to totally bash it just because of what I’ve been taught so far,” said one participant. “I want to learn more.”

Who Decides – and Who Enforces

A compelling question that surfaced in small-group discussion was not so much what the limits will be, but who will set them. In response to a question on the issue, 28 percent preferred that medical societies develop guidelines, 39 percent said the decision should be left up to individuals and their doctors, and 25 percent opted for federal or state legislation to establish acceptable uses for

QUESTION:

In general who do you think should set limits?

Information, Please

“It’s as if we expected the recruiting team of the Dallas Cowboys to determine all the players to be on the team in the future, on the basis of what we now know about the children in junior high school. Nobody, but nobody, will be able to come up with unerring recommendations in the absence of a firm knowledge base.”

Joe Leigh Simpson, M.D., president-elect of the American College of Medical Genetics, speaking at the Fort Worth forum about setting guidelines for the fast evolving field of reproductive genetic testing.

While participants got an introduction to reproductive genetic testing at the Town Halls, many spoke of wanting to learn more – and of wanting others to learn more. Government and elected officials were a particular target; reproductive genetic testing policy decisions would be suspect unless those formulating policy and voting had a strong foundation in the issues, participants said.

Who else needs more education? Participants named the following:

- Parents. “The public thinks testing is a pathway to a decision, when it’s really a pathway to information,” said a mother on the panel at Kalamazoo. “I just wanted to know what challenges were in front of me.”
- Religious leaders. One physician said his patients sometimes face frustration when going for pastoral counseling on reproductive genetic testing because their clergy don’t understand the technologies.
- Family physicians. Some participants noted that having a fully informed doctor was crucial to ensure informed decision-making and consent. Several participants noted that it is difficult for doctors to stay current in the rapidly changing field. A nurse practitioner noted: “We have incomplete information.”
- Genetic counselors. Genetic counselors, participants thought, should present the complete range of possible outcomes for a disorder to avoid showing bias when giving families the information they need to make decisions.
- Delivery and NICU personnel and pediatricians. A major benefit of genetic testing cited by participants is being able to prepare for the birth of a child with a disorder. Those who will care for such a child need to understand the nature of disorders, the range of possible severity and the benefits and techniques of early treatment.

Where are the gaps in knowledge? What topics need to be covered? Participants named the following:

- Risk assessment. “What are the odds?” participants wanted to know. Can a test accurately predict the chances of a disorder occurring or how severe it will be? “My understanding is limited regarding how absolutely a particular test result can predict what will happen vs. what could happen,” wrote one participant at the New York forum.
- Background on disorders. Several participants at the forums who work in health care fields mentioned the dearth of information on genetic disorders. Participants also stressed how important accurate and up-to-date information on disorders can be in making a decision. “If I had been told prenatally about my son’s condition, any decision I might have made would have been based on extremely negative case histories, which in fact turned out not to be an accurate description for my son,” said one participant.
- What it’s like. Those with firsthand experience with reproductive genetic testing shared the benefits of support groups and talking with other parents undergoing testing or similar procedures or facing possible disorders.

Following the Money

Who profits or could profit from reproductive genetic testing? That's what several participants at each forum wanted to know. "Doctors and clinics could potentially profit, and that could influence the way they advise patients. Ill-advised patients could make bad decisions," said a participant.

The most prevalent sense was that someone, or some company, would have a product to sell – a test – and that they would try to create a perceived need for it in the general public, pressing their services on the uninformed and undecided. One small group in Sacramento, for instance, listed its top concern as "the genetics testing industry may take advantage of people."

Other participants looked at broader industry issues, including gene patenting and intellectual property rights. "It is true that with intellectual property laws we're able to finance new discoveries," a Seattle participant said. "One of the reasons we have all this new technology is because of intellectual property." But another participant was concerned that those holding property rights or patents could become monopolies and restrict the public's access to the tests.

This issue was strong in Sacramento and especially in Seattle because of the biotech industry in the area, which one panelist said is "booming."

reproductive genetic testing. (When participants were asked about this again at the end of the Town Hall, there was some shifting of responses. See *Before and After: The Effects of Information and Discussion*).

In discussing the reasons for their initial responses, some participants said that because the medical community has not shown much success in establishing limits so far, it might be time for government to get involved. However, government officials attending the forums acknowledged that a lack of knowledge about genetics and the linking of genetic testing with abortion issues will make it

difficult to reach agreement on policy. Leaving the matter to the courts wasn't brought up as much, but when it was, it wasn't seen as a good path: "Will our elected officials decide on these issues, or will societal elites or the judiciary? The latter option is dangerous, in my view," commented a participant.

Some participants feared that "special interest groups" would step into this leadership vacuum. Some worried that those with a religious or partisan political agenda could have too much influence on setting restrictive limits, others that technology would run rampant if groups oppose establishing limits at all. Some wondered if these

decisions could be better made at a local level.

The influence of both insurance companies and corporate interests on setting limits was also debated by participants. On the one hand some felt that economic interests and the desire to protect against liability could be a powerful force in generating limitations. On the other hand, some thought corporate interests and the desire for free markets could lead to inappropriate uses of tests.

A looming question in all of the discussions dealt with who would enforce limits. If professional medical societies instituted limits, enforcement would be difficult, whereas federal or state government limits would come with the force of law behind them.

Ultimately, most participants expressed a wish that limits be set through a combined approach. An ideal scenario, some said, is that medical societies establish guidelines, the government ensures safety and accuracy and protects against abuses, and informed patients and their doctors make the ultimate decisions.

SAFETY AND ACCURACY

Weighing the Value of Government Review

Of all the issues discussed, a role for the government in ensuring safety and accuracy of reproductive genetic testing received the most clear-cut support. Overall, 90 percent supported government review and approval of tests before

TV Commercials for Genetic Testing?

Because commercials for drugs are now prevalent in television and print advertising, it was natural that participants would bring up issues of direct-to-consumer marketing of reproductive genetic testing. “We thought it was not a good idea,” said a participant after a small-group discussion at the Kalamazoo forum. “A medical provider should be involved in some way.” The group there picked limiting advertising of genetic tests as a major consideration in setting limits.

Regulating safety and accuracy would become even more important if direct-to-consumer marketing were to become prevalent, participants said in comments and discussion, because of the consequences of mistakes or misinterpretation. What makes the difference is that “a mistake could be fatal,” as one participant put it.

Additionally, for those who feel an embryo or a fetus is a life possibly in danger, advertising testing is a bad idea either because it means a person might not get appropriate counseling or because it could trivialize the nature of the test.

they go on the market, more than the 75 percent approval indicated in a national survey.³ During the discussion, some pointed to the FDA approval of prescription drugs and devices as being a model to apply to genetic tests. Many referenced a statement in the video voiced by Leon Kass, Fellow at the American Enterprise Institute: “It would be a terrible irony if, in the course of trying to select children who do not have terrible diseases, that you subject a perfectly normal embryo to tests that might harm them.”

Participants were questioned about several issues that could be seen as negative effects of increased

“The availability of testing should be as widespread as possible – but widespread testing without safety and accuracy, I can’t endorse,” said one participant.

regulation of the safety and accuracy of tests. None resonated particularly strongly. The top concerns were that regulation could increase costs of tests (51 percent were somewhat or very concerned), followed by the potential for delaying access (41 percent). “Cost is important, but if we have a choice, I think accuracy would be higher up on the list of priorities,” said a participant in Kalamazoo. However another participant said she didn’t want to see genetic testing end up “in the snarl like that surrounding psychotropic drugs – where regulation and clinical trials and FDA protocol is severely limiting the development of new medicines.”

Fewer were concerned about the potential negative effect of regulation on the biotechnology industry (34 percent) or felt that government regulation would be

ineffective anyway (35 percent). “I have yet to see the government be a positive force in regulation – it’s just too burdensome,” said one participant. “I think the biotech industry will regulate itself [based on] liability issues.”

IMPACT ON FAMILY AND SOCIETY

Participants were asked to consider in small groups the impact of reproductive genetic testing on individuals, families and society. Participants in general held positive views about these tests. They talked about how testing gives families choices; the option to avoid having an affected child or the opportunity to prepare for challenges ahead. They spoke of being able to access support groups, gather information, get counseling, contact specialists in advance of the birth and get a more realistic picture of what affect a disorder might actually have. They hoped that treatments would be more effective if diagnoses were made earlier instead of losing what can be precious time. Reducing suffering and stress, planning long-term care and reducing anxiety were also named as possible benefits. And while a little over half of the participants feared reproductive genetic testing will inevitably lead to “designer babies”, more (81 percent) felt that they

QUESTION:

What are the possible harms and benefits to individuals, families or society of parent’s ability to choose and select characteristics of their children?

Thinking Globally

Several participants at each forum brought up an international perspective on the issue. Participants referenced the current debate over crossing borders to get prescription drugs and drew a parallel to reproductive genetic testing.

“Eventually it will become an international issue,” said one participant. “Not all countries have the same limits. We have to protect our own folks to be sure what we’re getting is safe medically, that there’s counseling available, so people won’t run off to some other country and get it.”

But other factors might influence people to cross borders. “At some point, I would begin to worry that regulation will drive researchers overseas or underground,” a participant said. People might look elsewhere if insurance won’t cover testing, or if testing is too expensive, or if access is denied for another reason.

Others worried that other countries won’t have the same restrictions we might put into place here and will begin to select children having chosen traits. Not only might these people have an unfair advantage, but also they could become living “genetic outlaws” simply by crossing a border, one participant said.

helped families “make informed reproductive choices and have healthy babies”.

But some of the most animated discussions at all of the Town Halls arose when participants talked about their concerns about the possible impact on families and on society. Concerns about access, medical privacy, insurance discrimination and rights for people with disabilities vied for time with futuristic speculation about “genetic outlaws” and “designer babies.”

Equal Access

“Access remains the biggest health care issue in our country. Any kind of advanced technology will have to deal with the fact that our society has not chosen to allow all people to have equal access, and that will become more apparent as more selective technologies come aboard.”

Susan Hendricks, MD, maternal/fetal health specialist, Bronson Health Services, Kalamazoo

Economic factors were uppermost in the minds of participants during all discussions, but especially when considering the impact on families and society. Issues ranged from the toll caring for a child with a disability can take on a poor family to concern over

someday having a genetic “flaw” on one’s record making it hard to get or keep a job, to parents genetically engineering children who could make a lot of money in athletics.

Genetic testing is expensive; nearly all participants commented on this. Many related stories of insurance companies not paying for other types of medical care. What followed was a concern that access to tests would be limited to the wealthy and the burden of caring for people with disabilities would fall on poorer families, the line of reasoning continued – widening health disparities and deepening the spiral of poverty. Participants spoke of a number of barriers to equal access:

- **Geographic.** Some remote parts of the country and historically economically underdeveloped areas do not have access to health care workers who are familiar with and can administer these types of tests. Thus, some people and some areas are not even aware of testing as an option. Additionally, many in the U.S. do not have equal access to health care.
- **Economic.** Insurance companies, or the government for those who do not have private insurance, might not pay for testing. Only those who pay out-of-pocket would be able to afford testing.
- **Educational.** Access is also critical in being able to make informed decisions– if a patient doesn’t have full access to information and tests, he or she can’t make a good decision, participants argued.

Participants talked about the pros and cons of insurance coverage of reproductive genetic testing. On one hand, private or public coverage is important to be sure everyone has equal access to testing, but on the other hand, it can be a two edged sword if insurance companies were to require testing or use the information to the detriment of those tested.

“Why is the decision being left to individual patients and doctors, and no one’s talking about what the insurance companies will do?” asked a participant at the Seattle forum. Which is better – or which is worse – having insurance agencies deny coverage of testing, or having them require testing? Participants feared both scenarios in the future.

Many talked about stigmatization and about the cost of having a child with a disability, and some made the connection explicitly: someday, they feared, health insurers could force tests and refuse to pay for care of a child with a disability afterward if a parent chose not to terminate the pregnancy. Some even worried that the government might withdraw support one day for those with “avoidable” diseases or disabilities.

Additionally, if the government and insurance companies do decide to pay for genetic testing, many wondered if these institutions would then be entitled to the results of tests – and many worried about what might be done with these results.

“Will you have trouble getting a job because you have this gene that may cause cancer, whether or not you have cancer?” one participant asked. “Who should know the results? Should the government know? Should your brother know? These are big family questions,” said another. “Do we not allow you to tell your family?”

The government would want to look at results to shape future research and policy, and insurance companies, commented one participant, would leap at the chance to get this kind of data.

The Stepford Children

Although participants acknowledged the beneficial affects on a family of being able to test for genetic disorders, many shared concerns that parents would simply be too tempted to “design” a perfect child. Parents are under stress and in competition to have the best child and give their children the best of everything, participants said.

They worried that reproductive genetic testing could alter family dynamics and that children

would become commodified, like getting a new Mercedes, one said, comparing new families that might emerge to the movie “The Stepford Wives.”

Ultimately, children might even sue parents for not giving them the genes they want, many speculated. “Could someone say ‘I’m going to sue you because my IQ isn’t high enough?’” one person asked. “As parents you would now be responsible for the choices you made. There will be lifelong replaying of those choices,” another said. “Children would say, ‘Why did you choose me to be like this when you could have chosen me to be like that?’”

Children selected based on parents’ preconceived expectations could also either be demoralized by not reaching these expectations or never learn to think for themselves, an essential capacity in leadership and innovation, some participants worried.

The Biological Value of Difference

Although it sometimes sounded as if they were referring to agriculture rather than humankind, many participants noted “biodiversity” as something of value that could be threatened by reproductive genetic testing. In screening to eliminate disease, we may inadvertently destroy something we need in the future, goes this argument. Many participants mentioned the genetic mutation for sickle-cell anemia and its apparent connection to immunity to malaria. “Perhaps people with a certain food allergy are immune to diabetes and we don’t know yet,” said one participant.

Diversity, Disability and Discrimination

When asked about the possible harmful implications of reproductive genetic testing on society, Town Hall participants had plenty of science-fiction scenarios in mind. But overall, at each forum, the major theme expressed by participants was the need for diversity in our society. They feared the loss of diversity, in all its forms, and discrimination against any who aren't perfect.

Participants argued against allowing genes to determine our destiny. They pointed out that it would be impossible to know which genes, traits or disorders one would want to keep or eliminate, and that we should not have a limited perspective on what might be valuable traits in the future. As was most strikingly pointed out by a Kalamazoo participant, on the basis of genetic disease, serial killer Ted Bundy would have been saved as a fetus over physicist Stephen Hawking.

Others asked the basic question: What constitutes disability or severe disability? Participants feared a gradual narrowing of possibilities of what a human can be, what beauty can be and what intelligence can be. Many pointed out the dangers of imposing our present standards into the future. Many made explicit the fear of eugenics – that those who are “different” will be eliminated.

Another practical concern raised is that concentrating on reproductive genetic testing may

divert funding and brainpower away from treating and curing existing diseases. Treatments must still be sought, participants argued, to help the people already here with genetic disorders, and because of the nature of mutation, one can't guarantee that a disease can be entirely wiped out.

“We need to take care of the people already here,” said a participant. “Society doesn't take care of people in need.”

Further concerns about implications for society included:

- Gender imbalance. Participants referenced India and China and the results of sex selection there.
- Intolerance. People will “forget” how to accept differences if there are fewer differences to accept.
- Rare diseases will be neglected. Also, new diseases could be

created through tampering with genes.

- Creating “supermen.” Participants speculated that races of super soldiers or super athletes could be “created” to serve a family or a country, robbing people of autonomy and using them unconscionably.

In contrast to some of the futuristic fears people raised, many of the medical experts speaking at the forums stressed the inherent limits to the technology – it can be used only to identify, and in some cases select, genetic characteristics present in the parents, embryo or fetus; not to add traits. “It cannot create new genetic characteristics that neither parent has,” said one expert. And a life with testing doesn't mean a life without disease: “Not all diseases have a clearly diagnosable genetic component.”

Table 1.2: Do you think the government should regulate reproductive genetic testing?

	Before	After
Yes, based on safety and accuracy.	28.7%	39.9%
Yes, based on ethics and morality.	4.5%	3.8%
Yes, based on safety/accuracy and ethics/morality.	44.9%	44.1%
No, the government should not regulate reproductive genetic testing at all.	20.5%	9.6%
No, reproductive genetic testing should not be allowed.	1.4%	2.9%

Table 1.3: In general, who do you think should set limits?

	Before	After
Federal or state government makes regulations that determine acceptable uses.	25.2%	28.9%
Professional medical societies develop guidelines that determine acceptable uses.	28.2%	35.6%
Patient groups develop guidelines that determine acceptable uses.	7.7%	5.9%
Leave the decision to individual patients and their doctors.	39.0%	29.6%

BEFORE AND AFTER: THE EFFECTS OF INFORMATION AND DISCUSSION

A primary aim of the Town Hall project was to go beyond simply gathering off-the-cuff opinions or remarks as one might get in a survey or focus group and offer a forum for informed discussion and debate. Participants could learn more about the issues at hand, understand the various viewpoints, and hear from their fellow citizens. One measure of the impact of this approach is to see if opinions shift as a result of participation in the Town Halls.

At each Town Hall participants were asked a number of questions about what they thought about reproductive genetic testing before they viewed any of the informational videos or took part in any discussion. In addition, none of the questions were qualified in any way. So, for example, someone who answered yes to the question “Do you think there should be limits set for acceptable and unacceptable uses

of reproductive genetic testing,” could be thinking in terms of safety issues or in terms of moral issues. Many of same questions were repeated again at the end of the forums. Some interesting shifts in opinions surfaced.

Most felt that there should be limits set on acceptable and

unacceptable uses of reproductive genetic testing, and that did not change over the course of the Town Hall. In responding to the question “Do you think there should be limits set for acceptable and unacceptable uses of reproductive genetic testing?,” 89 percent responded yes at the beginning of the forum and 87 percent at the end. The most striking was a change in attitude about the basis for regulation. Overall, approval for regulating reproductive genetic testing on the basis of safety and accuracy went from 29 percent to 40 percent whereas support for leaving reproductive genetic testing unregulated fell, from 20 percent to 10 percent (Table 1.2).

A shift also occurred when participants were asked to consider who should set the limits. Acceptance for governmental regulations rose slightly from

Table 1.4: In general, do you agree or disagree:

	Agree before	Agree after
Parents should do everything technologically possible to prevent their child from suffering – including using reproductive genetic testing.	63.8%	59.4%
I am concerned about government regulators invading private reproductive decisions.	76.7%	72.0%
I am concerned about unregulated reproductive genetic testing getting out of control.	72.3%	84.8%
Reproductive genetic testing help parents make informed reproductive choices and have healthy babies.	81.5%	83.4%
Reproductive genetic testing will inevitably lead to genetic enhancement and designer babies.	54.7%	61.6%

25 percent to 29 percent and for professional guidelines from 28 percent to 36 percent, while support for individuals and their doctors making the decision fell slightly from 39 percent to 30 percent (Table 1.3).

People agreed that reproductive genetic testing helps parents make informed reproductive choices and have healthy babies, and this did not change over the course of the Town Hall, from 81 percent to 83 percent. But the concern about unregulated technology getting “out of control” did go up from 72 percent to 85 percent. And more expressed the belief that reproductive genetic testing inevitably would lead to genetic enhancement and designer babies – from 55 percent to 62 percent (Table 1.4).

Thus, at the conclusion of the Town Hall, there was more overall support for regulation, especially to ensure safety and accuracy. And although the view that reproductive genetic testing is potentially beneficial to families did not change, many have concerns about the impact of these technologies on our families and society.

INTO THE FUTURE

“I encourage you to speak up – speak up today at your tables, speak up with each other, speak up back at home, when the time comes. When you begin to see people in the private and public sector beginning to make decisions about these issues, it’s important that those people hear your voices.”
Maureen K. Byrnes, Director,
Policy Initiatives and the Health
and Human Services Program, Pew
Charitable Trusts

The Town Halls provided valuable information about what Americans’ hope for and fear from reproductive genetic testing. When asked, over 70 percent of participants felt that the forum had helped them clarify their own views and over 90 percent found the forums personally valuable. It is the hope of the Genetics and Public Policy Center that, armed with knowledge gained from the Town Halls, participants will continue to explore the social and ethical considerations of these advances and help ensure that their voices are heard alongside those of “the experts” during policy discussions. The Center, in turn, learned a great deal from the participants about how this model of public engagement can result in a rich and deeply textured view of how Americans from many walks of life view reproductive genetic testing. The results and findings from these Town Halls will be shared with policymakers at the federal and state level, adding the public’s voice to this important policy debate.

NOTES:

¹ For the purpose of this report, the percentages shown are for those participants from the general public who responded to the question. The responses from community panelists and table facilitators, who were often local expert resources, were not included.

² The Study of Attitudes Towards Reproductive genetic testing 2004 Survey.

³ The Public Awareness and Attitudes about Genetic Technology 2002 Survey.

Sacramento City Report

DEMOGRAPHICS

Who's Doing the Talking

The Genetic Town Hall in California's capital, Sacramento, took place the evening of June 29, 2004, in the Sheraton Grand Sacramento Hotel. One hundred twenty-nine people attended.¹ Participants' ages were divided roughly by thirds among those 18-29, 30-49 and 50 or older, with slightly more attending the 50 or older group (Figure 2.1). Fifty-eight percent were women. Sacramento was the most diverse of the Town Halls. Sixty-two percent of participants identified themselves as White, with the remainder fairly evenly divided among Black, Hispanic, Asian and "other".

Thirty-nine percent had postgraduate degrees, and all were at least high-school graduates. Politically, 46 percent identified as Democrats and 25 percent as Republican, with the remainder divided among Independent, other or non-responsive.

Twenty-four percent identified as Protestant, 20 percent as

Major Emerging Issues

Health insurance, employment and privacy: The Sacramento group's top-ranking hot button: How will the information from genetic testing be used? Concern about how genetic tests and their results could affect the basic issues of jobs and paying for health care rose from every small-group discussion. Their No. 1 concern when considering the societal implications of reproductive genetic testing: test results could result in employment and insurance discrimination. "Will you have trouble getting a job because you have this gene that may cause cancer, whether or not you have cancer?" one participant asked.

Cost and accessibility of genetic tests: Also high on the list was the fear of class stratification and harmful socioeconomic implications – the concern that families that can't afford testing would be more at risk to have children with genetic diseases and disorders.

Limits and who sets them: At the end of the session, 94 percent of participants supported limits on acceptable and unacceptable uses of reproductive genetic testing. Yet 70 percent agreed or strongly agreed that they were concerned about government regulation of private reproductive decisions.

Catholic, 16 percent "other Christian", and 27 percent identified as no religion or chose not to state their religion. Eighteen percent identified themselves as Born Again or Evangelical Christians. A leader and several members of a young persons' Evangelical Christian group attended. "I have religious feelings about genetic testing, but I don't

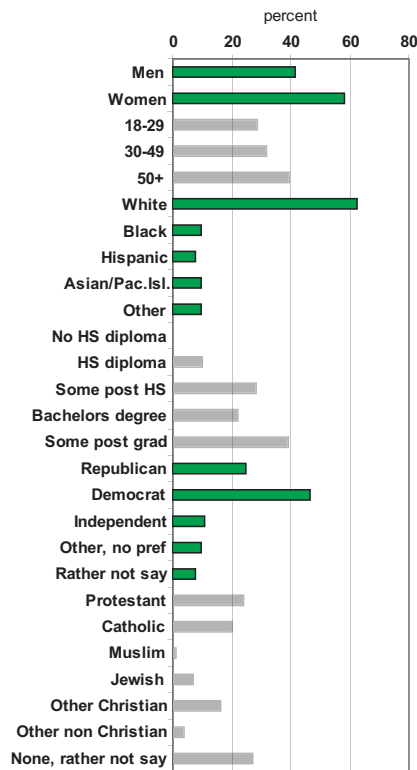
want to totally bash it just because of what I've been taught so far," said one participant at the beginning of the forum. "I want to learn more."

In reply to a question on abortion, 67 percent felt "the decision to have an abortion should be left up to individual women" and 10 percent disapproved of abortion for any reason. A few persons who oppose abortion protested outside the venue before the forum. Facilitators invited them to participate, and they added their voices to the proceedings.

A series of questions designed to measure knowledge of the issues revealed that 54 percent had heard of carrier testing and 48 percent of preimplantation genetic diagnosis. Nearly all (93 percent) said they had heard of prenatal genetic



Figure 2.1 Sacramento Demographics



testing. A quarter said they or a member of their family had had a genetic test, half said they had not and a quarter were not sure.

SETTING LIMITS

What Test, For What Purpose: Drawing the Line

Participants looked at a matrix of questions measuring approval of the use of three major reproductive genetic tests: carrier testing - testing of adults; preimplantation genetic diagnosis (PGD) - testing of embryos; and prenatal testing - testing of a fetus. They ranked their approval of testing in four situations: 1) testing for a gene

mutation associated with a fatal childhood disease; 2) testing for a mutation associated with a tendency to develop a disease such as cancer as an adult; 3) testing for a hypothetical gene associated with high intelligence or increased strength; and 4) testing for sex.

- Testing for a gene mutation associated with a fatal childhood disease was largely seen as appropriate. In this case, 94 percent approved or strongly approved of carrier testing, 73 percent approved or strongly approved of PGD and 72 percent approved or strongly approved of prenatal testing (Figure 2.2). Participants pointed out that knowledge of a condition wouldn't necessarily lead to an abortion or destroying an embryo but parents could prepare or initiate a treatment process.
- Testing for a gene mutation associated with a tendency to develop a disease such as cancer as an adult got slightly less approval. Fifty-seven percent approved of PGD; 49 percent approved of prenatal testing. Participants debated the role of environmental factors, the chance that a cure could be found for a condition as a person grows and the odds that a person would actually develop the condition. "If a test would show that you could get a fatal disease, why have that ax over your head to pollute the years you do have left - when you might not even get the disease?" said one participant. Others pointed to the advantage that advance knowledge could provide in initiating treatment:

"If you can stop some of these disorders as an infant, think of the quality of life later on," said a local Gray Panthers representative.

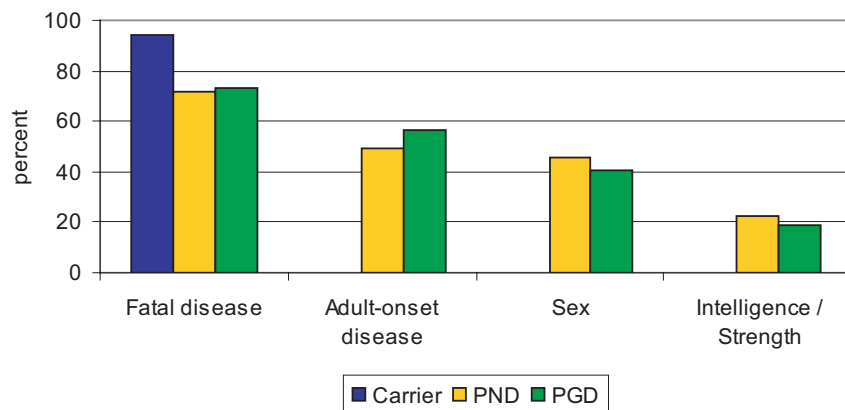
- While not yet possible, testing for a gene associated with high intelligence or increased strength was largely disapproved of. In this case, 81 percent disapproved of PGD and 77 percent disapproved of prenatal testing. This tied into participants' concern about designer babies and unfair advantages. "When it gets to the point where it's like picking out new clothes, it should stop!" one commented.
- Participants were more mixed on testing for sex. In this case, 59 percent disapproved of PGD and 55 percent disapproved of prenatal testing.

The group generally approved of using these tests only to detect disorders - and the more serious the disorder, the more the support for testing. The possibility of developing a disease, however, wasn't persuasive enough to garner strong support for testing. Participants drew the line at testing for characteristics such as intelligence and strength, but were mixed on testing for sex.

Who Sets Limits, and Why

Although 94 percent of participants answered yes to the question "Do you think there should be limits set for the acceptable and unacceptable uses of reproductive genetic testing?", the group was split regarding who should set the limits. Thirty-seven

Figure 2.2 Sacramento Town Hall Approval for Different Uses of Reproductive Genetic Testing



All figures are percentage of Town Hall participants who responded to the question and answered “approve” or “strongly approve.” Community panelists and table facilitator responses are removed.

percent said the decision should be left to individual patients and their doctors, 31 percent said federal and state governments should regulate unacceptable uses and 25 percent said professional medical societies should develop guidelines on what tests should be offered. At the beginning of the forum, “government regulators invading private reproductive decisions” was a concern for 77 percent of respondents; at the end, after the discussions and the video screenings, 70 percent were concerned.

Use of Information, Confidentiality Top Concerns

In small-group discussions, participants generated a short list of what factors they considered important to take into account when setting limits on the use of reproductive genetic testing. These were then shared with the full group, which ranked each concern.

Participants’ top concern when setting limits was the purpose of the test – in other words, whether testing was being done to prevent disease or to help or correct a condition.

“What’s our long-term vision for this?” asked one participant, saying that was the most important thing to consider. “To have a perfect society with no disease, no disabilities?”

Following closely behind was how the information would be used, meaning whether results would be available to insurers or employers, and whether tests would remain voluntary and confidential. “Who should know about the results?” a participant asked. “Should the government know? Should your brother know? These are big family questions. Do we not allow you to tell your family?”

Accuracy of tests was next on the list.

SAFETY AND ACCURACY

How Good Is the Test?

Most (89 percent) participants said the government should review and approve genetic tests for safety and accuracy before they are put on the market. About 63 percent believe, correctly, that the government does not currently do such reviews. In fact, those who held the view that the government should not regulate reproductive genetic testing at all fell from 21 percent at the beginning of the forum to 7 percent at the end. A little more than half present said they thought government policy on testing should be based on both safety and accuracy of the tests as well as ethics and morality.

Participants then ranked their concern about possible consequences of regulating the safety and accuracy of genetic tests. Safety and accuracy trumped speed of development, as only 32 percent of participants were concerned that regulation could delay access to tests or be burdensome to the testing industry (27 percent). Greater concerns were expressed that government regulation could increase test costs (51 percent expressed some level of concern) or that regulation would not be effective (50 percent expressed some level of concern). Comparisons with prescription drug regulations and the idea that government regulations can be “heavy-handed” and “inflexible” also were considered.

Training, regulation and licensing of technicians performing all aspects of the tests is essential to safety and accuracy, one participant pointed out. Participants also wondered who would enforce regulations and whether development of tests would be affected by interest-group funding. One participant asked whether the patent system would prevent development of cheaper or safer tests. “At some point I would begin to worry that regulation will drive researchers overseas or underground,” one commented.

Accuracy of tests also surfaced in small-group discussions as a factor in personal reproductive decision-making: If a test can’t be assured to provide complete and accurate information, how can an individual make an informed reproductive decision? One participant called for limits on direct-to-consumer

marketing of tests. “There’s so much wrong information out there, and that needs to be taken into consideration,” said one participant.

IMPACT ON FAMILY AND SOCIETY

Children as Commodities?

Testing’s potential impact on the parent/child dynamic brought out many interesting notions and a lengthy discussion. One participant spoke of creating a “Stepford mentality,” with people seeking perfect families.

“We always want the best for our children,” said one participant. “But we always want the best children, too,” another countered.

The top concerns expressed were that parents would not “use the information wisely” or that

testing would lead to designer children and that children would become another commodity, “like a Mercedes,” as one participant put it. Ranked next was a concept expressed as “human preferences creating the next generation.” What this meant to participants is that “designer” children formed by parents’ preferences would embody these as prejudices and perpetuate them in future generations, further narrowing diversity and increasing ignorance and intolerance about any other way to look or function.

Other interesting concepts emerged from small-group discussions. Would “choosing” children predispose parents to usurp a child’s free will? Children who have their blueprint, and, by implication, their life path chosen for them may not be able to lead or to cope with diversity, one group posited. Another participant’s observation resonated with the crowd: Could parents “design” super-athletes destined to bring in multi-million-dollar sports contracts, for instance? Participants were well aware of the affect a gifted child, or one with disabilities, can have on a family’s socioeconomic status and the impact genetic testing might have on family decisions.

About 64 percent initially felt reproductive genetic testing would inevitably lead to genetic enhancement and designer babies. By the end of the forum that rose to 72 percent. But 68 percent agreed that reproductive technologies help parents make informed choices and have healthy babies. Initially, 80 percent expressed concern that



reproductive technology could “get out of control”, by the end, 90 percent felt that way.

Will Information Affect Employment?

When asked about societal implications of reproductive genetic testing, the top concern among participants was down-to-earth and here-and-now: They worried that test results could be used to deny employment or health insurance. Ranking only slightly behind was the concern that the “genetic testing industry may take advantage of people”, meaning that the industry would promise more than what testing could really tell. Several participants referenced ubiquitous drug advertising and wondered if the same was ahead for genetic testing.

Ranking next were fears of further class stratification. Also important to participants was the preservation of diversity and tolerance for differences.

Participants also voiced a concern about “loss of humanity.” One participant put forward the idea that a race of “super soldiers” could be created by some nations.

While it wasn’t on the list of ranked concerns, the need for international regulations came up throughout the sessions. Participants foresee a situation similar to the current one with prescription drugs, where people would cross borders to get procedures they desired. “Don’t you think that eventually it will become an international issue?”

one asked. “Not all countries have the same limits. We have to protect our own folks to be sure what we’re getting is safe medically, that there’s counseling available, so people won’t run off to some other country and get it.”

But what participants in the Sacramento Town Hall feared most was losing health insurance. In her closing remarks, Center Director Kathy Hudson pointed out that the Center’s recent national survey reflected similar desire that insurance companies and employers not have access to genetic testing information.

THE PANEL: VIEW FROM THE EXPERTS

State Senator Dede Alpert D-San Diego (39th)

Sen. Alpert spoke of starting in 1995 the Senate Select Subcommittee on Genetics, Genetic Technology and Public Policy and how quickly technology has changed. The legislative process is “not designed to adapt” to fast-moving technology issues, she said. She recalled California’s history of eugenics in the early 1900s and noted that the original motive, to create “healthy, happy children,” had gone terribly wrong, even though some of the most respected people in society had created the programs.

“If we have proper discussions, these talks actually can be beneficial, but it’s going to be very difficult to get complete agreement. If these technologies are well used and well managed, it could mean

fewer abortions. That might be a positive, but it will be very hard to come to complete consensus.”

Where there is nearly universal agreement, she said, is on newborn screenings for genetic disorders to provide early treatment. “We can really make a difference in a child’s life. It’s not nearly as controversial as [other] testing.”

Thane Kreiner, Ph.D. Vice President, Corporate Affairs, Affymetrix, Inc.

Kreiner talked of the role of business in educating and providing information for consumers. He cautioned participants about buying into “genetic determinism” and reminded them that environment would always be a factor in development and that “the same genetic information can be used in a lot of different ways.”

“Regulation and control doesn’t have to be one-size-fits-all,” he said.

He also spoke of his company’s efforts to educate and provide a forum for discussion of issues. “We want to make sure we’re talking,” he said. “Industry associations can serve to channel information but don’t allow for the diversity of opinion we’ve seen here. How people are educated is a huge issue. We’re becoming literate as a society about technological changes going on, in ways that maintain our autonomy and choice.”

He expressed concern over tests offered over Web sites and the like tarnishing the reputation

of legitimate, accurate tests. In terms of genetic predisposition to disease, he said, it's going to be very hard for people to make decisions without quality assurance in testing.

Bert Lubin, M.D.
President, Children's Hospital
Oakland Research Institute

Dr. Lubin spoke of a disconnect between the families that could benefit from testing and the ones that actually get it. In his work with children with sickle-cell anemia, he said, he has found that many families didn't know testing was available, and it was never offered to them. "These are families whose priorities are putting food on the table and deciding what school their children will go to," he said.

He also called for regulations on medical advertising, saying it had adversely affected the cord-blood collection effort, and it could generate similar misinformation on genetic testing. Also, physicians in practice have insufficient experience with and knowledge of new reproductive genetic testing, he said.

And as important as offering tests is offering care for people with genetic disorders, he said. He spoke of his son, who has Down Syndrome, as enriching many lives with his perspective and values.

NOTES:

¹ For the purpose of this report, the percentages shown are for those participants from the general public who responded to the question. The responses from community panelists and table facilitators, who were often local expert resources, were not included.

Seattle City Report

DEMOGRAPHICS

Who's Doing the Talking

The Genetic Town Hall in Seattle, Washington, took place the morning of July 1, 2004, at the Bell Harbor International Conference Center, with 77 attending.¹ Several attendees had seen an announcement in the Seattle daily newspapers and business newspapers. A few were professionals in the medical field or a student in the field. Several had been attracted by a notice from Seattle Works, a volunteer organization for Gen Xers.

Participants' ages were divided roughly by thirds among those 18-29, 30-49 and 50 or older, with 65 percent women attending (Table 3.1). Eighty-eight percent of participants identified themselves as White, 8 percent as Black, and 2 percent as Asian.



Major Emerging Issues

Costs and counseling: These issues, not specifically referenced in the survey questions, emerged as important in discussion. Participants brought up the business side of reproductive genetic testing, including issues of intellectual property and patenting. Many also expressed the idea that counseling should be considered an essential component of the testing process.

Diversity: Participants expressed high regard for diversity, both in a reluctance to risk losing the contributions people with disabilities can make to society and on a larger societal level in a concern with maintaining biodiversity in the population.

Ambivalence about government regulation: Although most participants called for some kind of regulation of safety and accuracy of reproductive genetic testing, nearly all were unsupportive of involving the government in what they mostly felt were personal reproductive choices.

Forty-seven percent held postgraduate degrees and most of the rest had some college or a bachelor's degree. Thirty-four percent had children.

Politically, 22 percent identified themselves as Independent, half Democrat, 13 percent "other", 9 percent Republican and the rest declined to say.

A plurality (37 percent) either had no religion or chose not to say; 22 percent were Protestant, 16 percent Catholic, 8 percent Jewish, 8 percent "other Christian" and 10 percent "other non-Christian". Only 10 percent identified themselves as Born Again or Evangelical Christians.

None felt abortion should always be prohibited; 83 percent thought it should be a woman's choice.

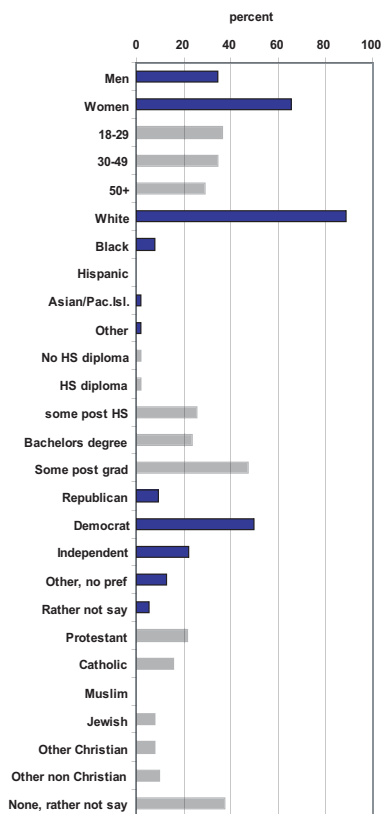
An initial series of questions revealed that the group had high awareness of the major types of reproductive genetic testing. Sixty-nine percent had heard of carrier testing, 61 percent knew of preimplantation genetic diagnosis and nearly all (96 percent) had heard of prenatal testing. Seventeen percent said they or a member of their family had had a genetic test, half said they had not and 31 percent were not sure.

SETTING LIMITS

What Test, For What Reason: Drawing the Line

Participants looked at a matrix of questions measuring approval of the use of three major reproductive genetic tests: carrier testing - testing of adults; preimplantation genetic diagnosis (PGD) - testing of embryos; and prenatal testing - testing of a fetus. They ranked

Figure 3.1 Seattle Demographics



their approval of testing in four situations: 1) testing for a gene mutation associated with a fatal childhood disease, 2) testing for a mutation associated with a tendency to develop a disease such as cancer as an adult, 3) testing for a hypothetical gene associated with high intelligence or increased strength, 4) testing for sex, and 5) testing for a tissue match for a sick sibling.

- Testing for a gene mutation associated with a fatal childhood disease was largely seen as appropriate. In this case, 98 percent approved of carrier testing, 93 percent approved of

PGD and 92 percent approved of prenatal testing (Figure 3.2). “They didn’t have the testing for couples when I got married,” said one participant, “and it might have been decisive on our having children.” Some participants pointed out that prenatal testing and PGD can place a burden on parents: “It’s another thing that singles out pregnant women and adds to their stress. Why put all that burden on a mother?” Another participant countered, “I think the benefits outweigh the psychological burden it puts on people.”

- Testing for a gene mutation associated with a tendency to develop a disease such as cancer as an adult got less approval. Sixty-two percent approved of PGD, and 53 percent approved of prenatal testing.
- While it isn’t yet possible, testing for a gene associated with high intelligence or increased strength was definitively disapproved of. Approximately 77 percent disapproved of PGD and 74 percent of prenatal testing for this purpose.
- Forty-six percent approved of testing for sex via PGD. Prenatal testing for sex got 55 percent approval. “I disapprove of people who keep having children until they get what they want, too,” said one participant.
- Sixty-seven percent supported testing an embryo to show if a person is a good tissue match for a sick sibling who needs a

transplant. Sixty-one percent approved of such prenatal testing.

The group generally approved of using these tests to detect disorders – and the more serious the disorder, the more the support. Participants drew the line at testing for characteristics such as intelligence and strength, but were generally OK with testing for sex.

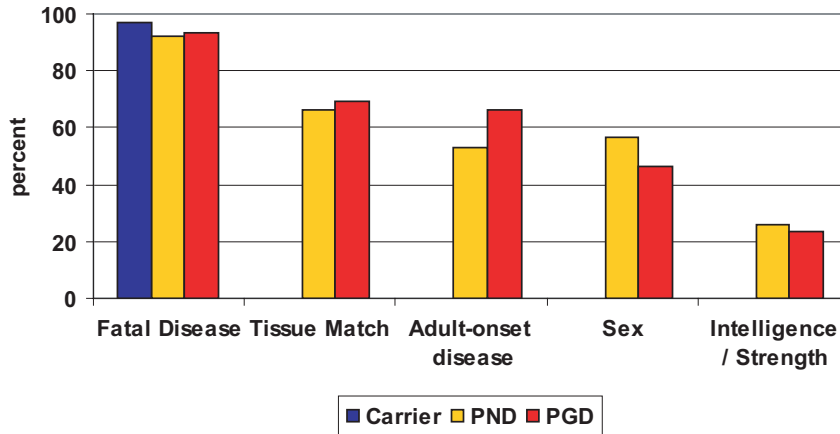
This group saw PGD as slightly more acceptable than prenatal testing when testing for disease-related conditions, yet those who disapprove of PGD because they disapprove of IVF spoke up as well: “I feel like the benefits are so far off that it’s a mistake to offer IVF and PGD on a widespread basis,” said a participant. “I have problems with the excess creation of embryos.”

Rules Wanted, But Who Makes Them?

In Seattle, 88 percent responded that limits should be set for acceptable and unacceptable uses of reproductive genetic tests. Yet few (16 percent) trusted the federal or state government to set such limits. Most (48 percent) said the decision should be left to people and their doctors, and 29 percent said professional medical societies should develop guidelines for what doctors should offer. Concern about government regulators invading private reproductive decisions dropped from 84 percent to 79 percent.

After the survey portion of the forum, panelists commented on this apparent contradiction. “We seem to want regulation, yet we’re

Figure 3.2 Seattle Town Hall Approval for Different Uses of Reproductive Genetic Testing



All figures are percentage of Town Hall participants who responded to the question and answered “approve” or “strongly approve.” Community panelists and table facilitator responses are removed.

afraid of it,” said State Rep. Shay Schual-Berke, M.D.

“Strangely, for all the distrust of government we have, we have high trust – or maybe we trust that there isn’t an alternative,” said fellow panelist and nonprofit activist Deborah Swets.

Participants sought a compromise or blended solution as to who would develop regulations.

“There are advantages on having folks at all those levels being involved,” one said. “I’d be concerned about only the government being involved.”

“Professional medical people actually develop the tests and know what’s appropriate,” said a participant. “Then federal and state government could take cues from those guidelines.”

“Why is the decision being left to individual patients and doctors, and no one’s talking about what the insurance companies will do?” said another, to general approval from the room.

A plurality of participants picked “who sets limits and how” as the most important factor to consider in setting limits.

“I don’t want people from any particular political administration to decide,” said one participant.

Several expressed concern that research on new technologies would also be affected by political or religious groups. “I’ve seen that the people who do genetic testing want to look at these questions, but they’re blocked by religious groups and other obstacles,” said a participant.

Another participant said he believes it’s “morally imperative to do [genetic] research,” because of the degree of suffering he sees as a volunteer in a nursing home.

Ranking behind the concern over who sets limits were two, sometimes conflicting, views. On the one hand, decisions should be based on “necessity, not vanity,” on the other, parental decisions should be respected. A participant articulated this conflict: “It’s easy to say testing shouldn’t be used for this reason or that reason, but who will decide which purposes are OK?”

Costs and Counseling Emerge as Concerns

In discussions on setting limits, Seattle participants brought up two issues: the business side of reproductive genetic technology policy and the role of genetic counseling. Participants generated a discussion of technology, research, funding and intellectual property rights, issues obviously of high interest in this region known for technological advances.

“The profit issue is one thing that hasn’t been mentioned,” said a participant. “Doctors and clinics could potentially profit, and that could influence the way they advise patients. Ill-advised patients could make bad decisions.”

Others brought up the issues of gene patenting and intellectual property. “It is true that with intellectual property laws we’re able to finance new discoveries,”

a participant said. “One of the reasons we have all this new technology is because of intellectual property.” But another participant expressed concern that patent holders could restrict and control access to tests individuals or the public would want.

“Patenting genetic information is a genie that should never have gotten out of the bottle,” said a participant. “If any of you have any idea how to get it back in, let us know. Nobody should own any part of your body, no way, period.”

Counseling in concert with reproductive genetic testing was another side issue that struck a chord with participants, several of whom said they are in the medical field. “I would be lying if I said I hadn’t encountered parents who made choices based on delusions and dreams,” said one nurse practitioner. “We’re not computers.

It’s not only factual, logical issues we take into account.”

“The availability of good counseling is a prerequisite for any of these decisions to be made,” said a participant. “It would be a travesty to ask anyone to make these decisions without good counseling.”

Yet several participants doubted counseling would be enough, calling for further public education on the issues: “We have incomplete information. I was brought up to believe medicine was infallible, and I’ve worked with doctors who have God complexes and act like they know everything. What if you find out your information was wrong?”

“People need much more education before they make a decision,” said another. “I have great respect for the profession of genetic counseling, but you can’t

help but give your own opinion when you talk to people. We need more information from more sources.”

SAFETY AND ACCURACY

How Good Is the Test?

Nearly all Seattle respondents (93 percent) believe the government should review and approve tests for safety and accuracy. “The availability of testing should be as widespread as possible,” said one participant. “But widespread testing without safety and accuracy, I can’t endorse. The potential for misuse overwhelms the notion that there shouldn’t be any regulation.”

At the beginning of the forum, 37 percent thought regulations should be based on safety and accuracy alone; by the end, after discussion and videos, 49 percent supported safety and accuracy alone as a basis for regulation. At the beginning of the forum, only 12 percent had called for no government regulation; by the end, that had not changed.

Did participants see any drawbacks in instituting government regulation of safety and accuracy of reproductive genetic tests? Forty-nine percent expressed some level of concern that increased regulation would increase cost of tests. Otherwise, 37 percent were concerned that regulation could delay access, be ineffective (33 percent) or burden the testing industry (40 percent).



IMPACT ON FAMILY AND SOCIETY

Help For Parents, Fears For Future

In small groups, participants were asked to formulate and rank major benefits for parents of reproductive genetic testing. At the top of the list was “preparation for challenges,” including getting ready for a child with a disability or preparing for termination of a pregnancy. The second- and third-ranked benefits brought out this dichotomy — testing could both mean early treatment for disorders and allow parents to avoid having a child with a disability. “Some of these things can be corrected before birth,” a participant said. “We could minimize that suffering.”

The top concern about allowing parents to select characteristics was “loss of diversity.” “These things are going on already,” said one participant, sharing a story about college-newspaper advertisements for egg donors that mostly seek women with a certain hair color, heritage and body.

Small groups also expressed concern over possible liability issues and parental burdens: “Could someone say ‘I’m going to sue you because my IQ isn’t high enough?’”

Concern about unregulated reproductive technology getting out of control also shifted, from 65 percent to 79 percent who agreed with the statement. The concern that genetic technologies

will inevitably lead to genetic enhancement and designer babies shifted only slightly from 41 percent to 44 percent. “As parents you would now be responsible for choices you made,” said one participant. “There will be lifelong replaying of those choices. Children would say ‘why did you choose me to be like this, when you could have chosen me to be like that?’” While there was much discussion of these issues, they did not rank highly with the full group.

Supporting Diversity as a Value in Society

Two issues tied for top-ranking concerns about the social implications of reproductive genetic testing — that they would be “used to push social, political or religious agendas” and that concentration on genetic technology would mean “ignoring more pressing global issues.”

“Loss of contributions of people with disabilities” and “potential elimination of something of value” were also cited by the small groups as concerns. But what ranked second to the diversity issue was “discrimination on many levels.” By this, participants meant discrimination by ethnicity, ability and income level, i.e., whether people could afford testing.

“Taken in the wrong direction, this is a potential technology for an alternative to ethnic cleansing,” said one participant.

Participants came out strongly with many personal statements about encounters with children

with disabilities and how these experiences bring value to life. People also pointed out that support systems for people with disabilities have improved and should continue to improve, which can minimize suffering.

Many others viewed diversity from a more biological perspective, arguing that our present perspective is limited and we may risk eliminating desirable characteristics along with currently undesirable ones. Some cited research linking a single sickle-cell gene mutation with resistance to malaria. “Perhaps people with a certain food allergy are immune to diabetes,” one said. “We don’t know yet.”

Also noted was the sense that concentrating on reproductive genetic testing overlooks the role environmental factors, some seen as correctable, have in causing disease and disorders.

PANEL: VIEW FROM THE EXPERTS

State Senator Rosa Franklin D-29th

Senator Franklin applauded the public dialogue on reproductive genetic testing, saying “I do believe very strongly that once the public is included and have the information, they are able to use that information in a very positive way. The more public debate, the more inclusiveness to bring this issue to the forefront for the public, will be helpful. I’m glad the ethical part of the debate is beginning.”

She pointed out that the science is moving so quickly that creating public policy is becoming a major concern, pointing to the slow progress of an anti-discrimination bill in the state. The education of policymakers on the issue is becoming a concern, she said. She also spoke of technological advances and policy formation in other countries and the danger of the United States being left behind: “We really aren’t keeping up, and I don’t think we will be able to keep up.”

**Dr. Roberta A. Pagon
Professor of Pediatrics,
University of Washington**

Dr. Pagon expressed concern that the discussion be focused on technologies currently available and not based in speculation. Also, she pointed out, “When the issue of limitations was discussed, we all spoke on terms of legislative limitations, but it’s really the dollars a health care provider will pay. If you had to pay for this yourself out of your paycheck or savings or vacation fund, would you want to put your money there?”

**State Representative Dr. Shay
Schual-Berke, M.D.
D-33rd**

Rep. Schual-Berke pointed out that the biotech industry in Washington state “is a booming piece of our economy. It makes it hard to have the sort of discussions that have happened here so naturally.”

She sees reluctance in legislatures to take on issues of

health-based discrimination and health insurance issues, she said. But “the train has long since left the station, and rather than let [legislation] happen by default, many would like to continue working on it.”

**Deborah Swets
Director, CitiClub**

Swets noted that the desire for choice and concern over how information is used is typical of the Seattle-area community. “Other than in terms of safety, we don’t want to hand the decision over to anyone else. That’s the most universal thing I felt was coming through.”

She also spoke of the group’s commitment to diversity. “How many exceptional people are afflicted with genetic disorders?” she said. “If by doing this, it means I’m missing having a Beethoven – boy, that just leaves me stuck.”

NOTES:

¹ For the purpose of this report, the percentages shown are for those participants from the general public who responded to the question. The responses from community panelists and table facilitators, who were often local expert resources, were not included.

Kalamazoo City Report

DEMOGRAPHICS

Who's Doing the Talking

The Genetic Town Hall in Kalamazoo, Michigan, took place on the morning of July 19, 2004, and attracted 91 people.¹ Ages skewed slightly older than in other forums, with 49 percent of the participants 50 or older, 30 percent 30-49, and 21 percent 18-29 (Figure 4.1). More women (61 percent) than men attended. Eighty percent of participants identified themselves as White, with 16 percent Black, 5 percent choosing "other" and none identifying as Hispanic or Asian.

Half (53 percent) had postgraduate degrees, and 27 percent had bachelor's degrees. Politically, 37 percent identified as Democrat, 28 percent as Independent and 9 percent as Republican. The majority (69 percent) said they have children.

Thirty percent identified themselves as Born Again or

Major Emerging Issues

Who sets limits: Perhaps reacting to today's "two Americas" climate, some participants expressed reluctance for the federal government or national medical societies to set regulations or guidelines, but wanted these to reflect smaller-community wishes. Direct-to-consumer marketing also emerged as a concern.

Framing a bigger picture: Participants brought up family and community issues often. Taking the entire family's welfare into consideration when doing testing and using information; whether to include the family in formulating regulations; and knowing your family and what it can handle as a factor in decision making all came into consideration. While participants at other forums brought up reduced suffering of a child as one of the possible benefits of genetic testing, many at this forum insisted that the issue needed to be the reduced suffering of the family. "You're not just choosing for yourself but affecting somebody else's choices," said one participant.

Evangelical Christians. Twenty-two percent said they were Protestant, 16 percent Catholic and 28 percent "other Christian."

In reply to a question on abortion, 62 percent felt "the decision to have an abortion should be left up to individual women" and 14 percent disapproved of abortion for any reason.

A series of questions designed to measure knowledge of the issues revealed that 63 percent had heard of carrier testing and that 43 percent had heard of preimplantation genetic diagnosis. Nearly all (93 percent) said they had heard of prenatal genetic testing. Twenty-one percent said they or a member of their family had a genetic test, and 63 percent said they had not.

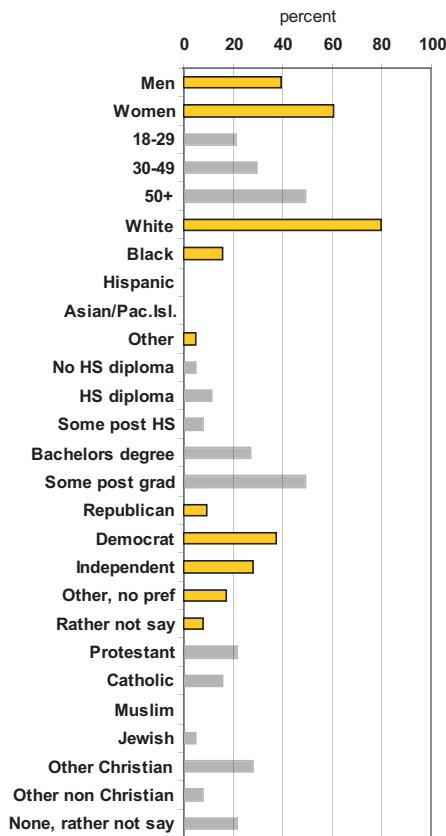
SETTING LIMITS

What Test, For What Reason: Drawing the Line

Participants looked at a matrix of questions measuring approval of the use of three major reproductive genetic tests: carrier testing - testing of adults; preimplantation genetic diagnosis (PGD) - testing of embryos; and prenatal testing - testing of a fetus. They ranked their approval of testing in four situations: 1) testing for a gene



Figure 4.1 Kalamazoo Demographics



mutation associated with a fatal childhood disease, 2) testing for a mutation associated with a tendency to develop a disease such as cancer as an adult, 3) testing for a hypothetical gene associated with high intelligence or great strength, 4) testing for sex and 5) testing for a tissue match for a sick sibling.

As in the other forums, carrier testing was seen as most acceptable. Likewise, the more serious the reason for testing, the more approval there was for testing. Testing for a gene mutation associated with a fatal disease was most approved of, with

participants drawing the line at testing for a gene associated with strength or intelligence. The group at this forum also showed less approval of testing for sex.

- Testing for a gene mutation associated with a fatal childhood disease was largely seen as appropriate. In this case, 95 percent approved of carrier testing, 85 percent approved of PGD and 88 percent approved of prenatal testing.
- Testing for a gene mutation associated with a tendency to develop a disease such as cancer as an adult got slightly less approval. Seventy-one percent approved of PGD; 65 percent approved of such prenatal testing.
- While not yet possible, testing for a gene associated with high intelligence or great strength was largely disapproved of. In this case, 78 percent disapproved of both PGD and prenatal testing.

Testing for sex was less acceptable to participants in this forum than in others. Only 32 percent approved of PGD, and 35 percent of prenatal testing.

However, 65 percent approved of PGD and 61 percent of prenatal testing to determine whether a person is a good tissue match for a sibling who needs a transplant.

Guidance vs. Regulation: Who Sets Limits?

Ranking high as a concern among participants at the Kalamazoo forum was the issue of

who decides who gets testing done and who decides how technologies will be regulated. “Will our elected officials decide on these issues, or will societal elites or the judiciary?” one asked. One participant commented on a “localization of power,” taking decisions away from communities. “We want to make sure that special interest groups would not be over-represented in the decision making,” said one small-group leader.

In a topic that generated some debate at this forum, nearly half (48 percent) said setting limits should be left to individual patients and their doctors, and a quarter each said federal and state governments should set regulations and 18 percent that professional medical societies should develop guidelines on what tests should be offered.

Panelist Dr. Susan Hendricks, a maternal/fetal health specialist, noted that physicians are currently obligated ethically and legally to follow certain standards of care established by medical societies.

Some felt that government regulations and medical guidelines raise significant issues of enforcement.

“The government makes regulations they don’t enforce all the time,” one participant said. “There’s always selective enforcement.”

Another said the medical community has not shown much success in establishing limits in the genetics field so far, so it might

be time for the government to get involved.

Not regulating testing leaves “too much power in a few hands,” one participant commented.

With a show of hands in discussion, about two-thirds demonstrated they felt a combination of groups should be in on the process of forming guidelines. Many commented that they felt the need for “balanced participation,” involving more than one sector of society.

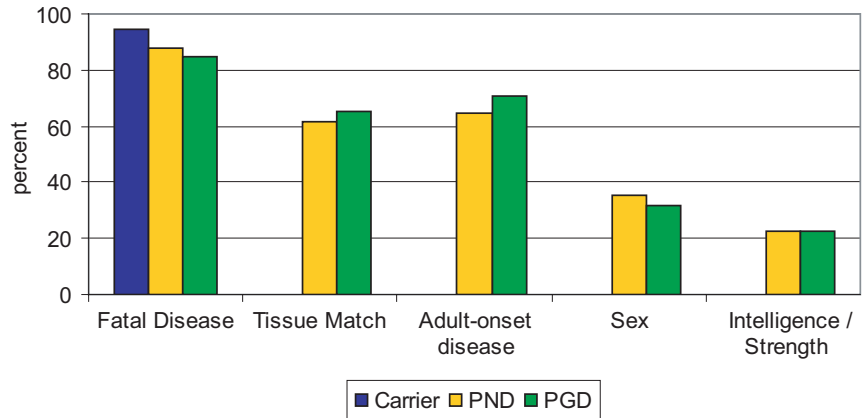
“The purpose of regulation is to provide genuine informed consent, so patient and doctor can make an informed decision,” said one participant.

Looking toward the future was the participant who brought up the aspect of creating flexible policy that can grow with the speed of changes in the field. “If there are controls, how will the controls be reviewed and revisited over time as the technology develops?”

Equitable access was also important to many at the forum. Cost as well as inequities in insurance coverage can affect access to tests, they pointed out. Government might play a role in ensuring equal access to these technologies, especially for those in remote or historically underserved areas of the country.

Some views on limits and who should set them changed from the beginning of the forum. At the start, 87 percent said they were concerned about government

Figure 4.2 Kalamazoo Town Hall Approval for Different Uses of Reproductive Genetic Testing



All figures are percentage of Town Hall participants who responded to the question and answered “approve” or “strongly approve.” Community panelists and table facilitator responses are removed.

regulation “invading private reproductive decisions,” but after the videos and discussion that figure dropped to 77 percent. Concern about unregulated reproductive genetic testing getting out of control also rose from 64 percent to 82 percent.

SAFETY AND ACCURACY

Call for Review of Tests

Nearly all (97 percent) participants said the government should review and approve genetic tests for safety and accuracy before they are put on the market. Half were correct in thinking the government does not currently do such reviews.

As at other forums, some concern was expressed that such reviews could increase the cost of testing and delay access, but neither concern was viewed as a reason

not to have government review. “Cost is important, but if we have a choice, I think accuracy would be higher up on the list” of priorities, said a participant. In small group discussion, safety and accuracy of tests came up as a concern as well, with one small group choosing it as their major issue. Another group reported, “We thought that direct-to-consumer marketing of testing was not a good idea. A medical provider should be involved in some way.”

Attitudes toward safety and accuracy showed a surprising shift after participants watched the educational videos and engaged in discussion sessions. The number of participants supporting government regulation of testing on the basis of safety and accuracy almost doubled from 26 percent at the beginning of the forum to 47 percent at the end. The number of those who felt genetic

testing shouldn't be regulated at all dropped to from 35 percent to 9 percent.

IMPACT ON FAMILY AND SOCIETY

Fear of Losing the “Essence of Humanity”

Top benefits of reproductive genetic testing to families mirrored those picked by participants in other cities: the ability to prepare for a child with a genetic disorder and to take steps to reduce children's suffering. Participants also pointed out that testing could be very reassuring to parents. By the end of the forum, more people “strongly agreed” (from 29 percent to 45 percent) with the statement “Reproductive genetic testing help parents make informed choices and have healthy babies.” In response to questions, experts at the forum offered some education on the false

perception that genetic testing can eventually wipe out hereditary diseases. The nature of recessive gene mutations and the common occurrence of new mutations make elimination of inherited disorders highly unlikely.

The prospect of being able to select characteristics in children raised concerns. Top among these was the loss of diversity in society. Comments spoke to the association of diversity with the “essence of humanity.” “It's the difficult things in life that make us who we are,” and being perfect would be a “loss of opportunity for personal acceptance,” participants said.

“What about someone like [physicist] Stephen Hawking? Someone might have chosen not to continue that pregnancy, and we would have missed out on a genius.”

“Where is the point at which ‘otherness’ becomes ‘disability?’” one asked.

“If we focus on the genes, we may lose the importance of nurturing” in raising children, said another.

Psychological pressures on parents and children also ranked as larger concerns. There were fears that children would be “commodified” and that those not “modified” would feel pressure to measure up. Parents could feel guilty no matter what decisions they made, participants said, and may be pressured by society to change their decisions or go against beliefs. The driving force of wanting children to be happy, healthy and successful is overwhelmingly strong, many pointed out. The concern that these technologies would inevitably lead to genetic enhancement and designer babies shifted only slightly during the forum, from 58 percent to 55 percent.

PANEL: VIEW FROM THE EXPERTS

The Reverend J. Louis Felton Pastor, Galilee Missionary Baptist Church

Reverend Felton said the church has a role in helping families work through the issues related to reproductive genetic testing and spoke frankly about the benefits and limits of medicine and fair access: “There are some things you'll never be able to plan. You can try to eliminate suffering, but



we all understand that sooner or later, we're all going to die.”

“There are some people on the right wing saying [reproductive genetic testing] shouldn't be available at all. I don't agree with that. The technology is obviously going to become more accessible. I don't think we should hide our heads in the sand. We should work together in trying to have the right response. I don't have a problem with the testing – the issue is, what is going to be done with the testing? If we don't have universal health care now, who is going to pay for this for certain segments of the population?”

**Susan Hendricks, M.D.
Maternal/Fetal Health
Specialist, Bronson Health
Services**

Dr. Hendricks spoke of how she has seen these issues play out in her practice. “Information can be power – but not everyone wants information. That's an individual choice.”

Dr. Hendricks also spoke of the importance of counseling and having a network of support for those who choose to use reproductive genetic testing. “We feel in our subspecialty that genetic counselors are one of the most important tools we have.” They can guide parents to support groups, specialists and information.

“Access remains the biggest health care issue in our country,” she said. “Any kind of advanced technology will have to deal with the fact that our society has not

chosen to allow all people to have equal access, and that will become more apparent as more selective technologies come about.”

**Amy Lance
Local daycare provider and
mother**

Lance spoke of her experience with reproductive genetic testing as a mother. “The public thinks it's a pathway to a decision, when really it's a pathway to information,” she said.

“I just wanted to know if I had some hurdles and what challenges were in front of me.” She spoke of a couple she knew who had a child with a genetic disorder and how “chaotic” the months after the birth were as they scrambled to find proper health care for their child, and how coping would have been improved with more information.

She also talked about the importance of developing tests for earlier in a pregnancy, saying it would be helpful for those who wanted to make choices as well as those who want to prepare.

**State Representative Alexander
Lipsev
D-Kalamazoo**

Representative Lipsey commented on the limitations of regulation, saying “the bottom line is that while government can provide some general framework, these decisions will be grounded on where our moral compass is and where our faith has taken us.” The discussion, he said, points out that “there are some things

we can and can't do and shouldn't do, and those issues really go back to our core, as opposed to being something imposed by our government.”

Yet he said the Town Hall, which he called a “policymaker's dream,” could help in these decisions. “There is the illusion that we sit in Lansing and Washington and come up with issues out of whole cloth. But we get little opportunity to find out what real people feel about real issues. Going around to these tables gives me a much better feel for the subtleties of the issues.”

NOTES:

¹ For the purpose of this report, the percentages shown are for those participants from the general public who responded to the question. The responses from community panelists and table facilitators, who were often local expert resources, were not included.

Fort Worth City Report

DEMOGRAPHICS

Who's Doing the Talking

The Genetic Town Hall in Fort Worth, Texas, took place the morning of July 19, 2004, at the Radisson Plaza Hotel and attracted 97 people.¹ Fifty-three percent were 50 or older, and 28 percent were 30-49 (Figure 5.1). More women (54 percent) than men attended. Ninety-seven percent identified themselves as White, with 22 percent Black and 2 percent Hispanic.

Thirty-seven percent had postgraduate degrees or bachelor's degrees. Thirty-four percent identified themselves as Republican; 27 percent were Democrats. The majority (66 percent) said they have children.

Thirty-nine percent identified themselves as Born Again or Evangelical Christians. Forty percent said they were Protestant, 22 percent Catholic and 12 percent "other Christian."

In reply to a question on abortion, 60 percent felt "the decision to have an abortion should

Major Emerging Issues

Evangelical Christianity: Slightly more than a third (39 percent) of participants identified themselves as Born Again or Evangelical Christians. This affected the issues raised, the attitudes and the language used. Words such as "trivial," "frivolous," and "cosmetic" came up in regard to certain tests. The frank "killing children you decide you don't want" was the top concern about genetic technology's possible affect on families, and other concerns mentioned giving parents "Godlike authority." Several people made it plain that their problems with doing preimplantation genetic diagnosis emanated from their belief that the embryo is a human life deserving of high respect and protection.

Who sets limits: The top issue at the forum was who would set and enforce limits. "I don't want someone else's religion limiting my tools and my choices," said one participant. There was also concern that regulations could become politicized, with representatives having an "agenda" that could affect what regulations are imposed. Questions extended to the point of wondering who would educate the people administering tests and counseling, and what effect that would have on individual decisions.

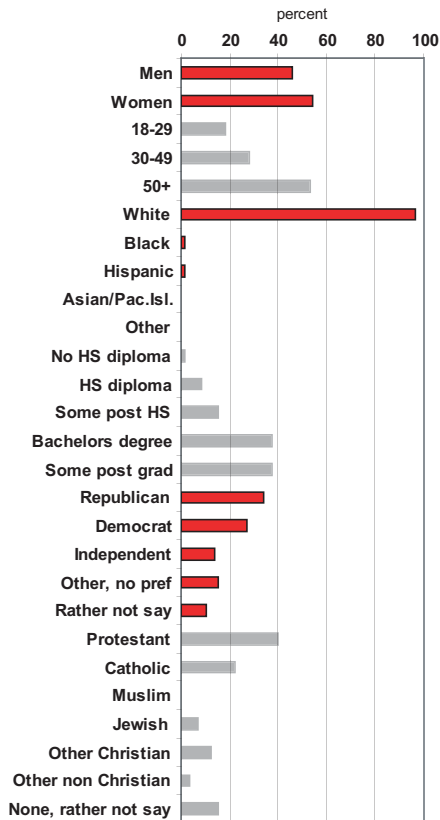
Confidentiality: After the group chose "who sets limits" as the top issue, some participants laughingly requested a "do over" to name "confidentiality," which had initially scored low, as their top concern. A show of hands showed the issue was indeed important to the group. Participants speculated on the impact of the confidentiality issue in the future: "Would the government [be entitled to] get results, either collectively or individually, if they fund or regulate a particular test?" one participant asked. "How would the government use those results to formulate future policy?" Another pointed out that if insurers paid for tests, they would want to know results, and these could affect what an insurer would be willing to cover.



be left up to individual women" and 21 percent disapproved of abortion for any reason.

A series of questions designed to measure knowledge of the issues revealed that 44 percent had heard of carrier testing and 33 percent of preimplantation genetic diagnosis. Eighty-nine percent said they had heard of prenatal genetic testing. Eleven percent said they or a

Figure 5.1 Fort Worth Demographics



member of their family had had a genetic test.

SETTING LIMITS

What Test, For What Reason: Drawing the Line

Participants looked at a matrix of questions measuring approval of the use of three major reproductive genetic tests: carrier testing - testing of adults; preimplantation genetic diagnosis (PGD) - testing of embryos; and prenatal testing - testing of a fetus. They ranked their approval of testing in four situations: 1) testing for a gene

mutation associated with a fatal childhood disease, 2) testing for a mutation associated with a tendency to develop a disease such as cancer as an adult, 3) testing for a hypothetical gene associated with increased intelligence or great strength 4) testing for sex, and 5) testing for a tissue match for a sick sibling.

As in the other forums, carrier testing was seen as most acceptable. Likewise, the more serious the reason for testing, the more approval there was for testing. Testing for a gene mutation associated with a fatal disease was most approved of, with participants drawing the line at testing for a gene associated with strength or intelligence. The group at this forum also showed less approval of testing for sex.

- Testing for a gene mutation associated with a fatal childhood disease was usually seen as appropriate. In this Town Hall, 92 percent approved of carrier testing, 80 percent approved of PGD and 71 percent approved of prenatal testing (Figure 5.2).
- Testing for a gene mutation associated with a tendency to develop a disease such as cancer as an adult raised discussion throughout the forum. Fifty-seven percent approved of PGD and 58 percent approved of prenatal testing. This was roughly even with ratings at other forums, but several participants wanted to factor in what would be done with the information. There was much approval for using such information to spur

treatment or change lifestyle to prevent or mitigate a later-onset disease. Participants also felt it was important to make clear that predisposition is not a definite diagnosis.

- While not yet possible, testing for a gene associated with high intelligence or increased strength was largely disapproved of. In this case, 86 percent disapproved of PGD, and 82 percent disapproved of prenatal testing. A few participants made the point that testing for developmental disabilities is in effect testing for intelligence.
- Testing for sex was also unacceptable to the majority. 75 percent disapproved of PGD, and 65 percent disapproved of prenatal testing. Several participants brought up worries over testing ultimately contributing to a gender imbalance in society.
- Participants were more split on using testing to determine whether a person is a good tissue match for a sibling who needs a transplant. Fifty percent approved of PGD in this scenario and 41 percent of prenatal testing.

The Specter of Outside Agendas

Ranking high at other forums as well, the question of who sets limits on reproductive genetic testing was the top concern here. The issue of enforcement was also added to the question at this forum.

Given the choices offered among who should set limits, 26 percent

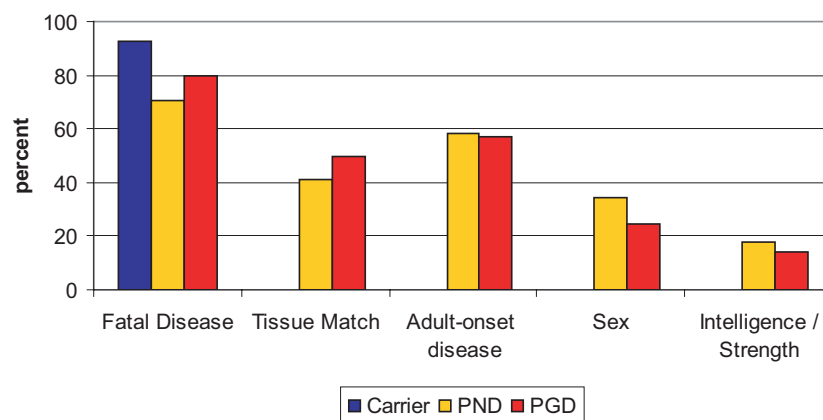
chose federal and state regulation, 44 percent professional medical society guidelines and 26 percent thought it was an individual matter between patient and doctor. This shifted slightly over the course of the forum to 31 percent support for federal and state regulation and 38 percent for medical professional guidelines. Nearly all (90 percent) said some limits needed to be set on acceptable uses of reproductive genetic testing.

In discussion, participants pointed to “agendas” on all sides that could creep into regulation at any stage, from creating regulation to enforcement. If a politician had a research constituency, for instance, one participant worried that this could affect how legislation would be shaped. Others were concerned that religious representatives would impose their views. “We need to go very slow and have many governing bodies to prevent problems: medical, government, judicial – checks and balances!” one commented. Several mentioned the learning curve on the part of the government and questioned whether public representatives have the background to craft regulation.

Not testing for “cosmetic” or “aesthetic” reasons was an important dividing line drawn by this group, as was how results would be used. Whether tests are done on an adult, fetus or embryo would also be a consideration.

Seventy-five percent said they were concerned about government invasion into private reproductive

Figure 5.2 Fort Worth Town Hall Approval for Different Uses of Reproductive Genetic Testing



All figures are percentage of Town Hall participants who responded to the question and answered “approve” or “strongly approve.” Community panelists and table facilitator responses are removed.

decisions, which was comparable with other forums and did not change substantially by the end (72 percent).

The confidentiality question, while important, didn’t trump these other issues. One participant said, “I agree that confidentiality is extremely important, but to me it’s secondary to having limits. It has to become part of the limits, not the reason for setting or not setting them.”

SAFETY AND ACCURACY

As in other forums, a high percentage (85 percent) said the government should review and approve genetic tests for safety and accuracy before they are put on the market. Fifty-six percent were correct in thinking the government does not currently do such reviews.

In written comments, many participants stated that FDA

approval would be satisfactory for reproductive genetic tests. While safety for the person being tested came up as an issue in the small-group discussions, it did not rank high in the group overall. As at other forums, mild concern was expressed that such reviews could increase the cost of testing and delay access.

Some questions were asked both at the beginning of the forum and after the discussions and educational videos. Using safety and accuracy as a basis for regulating testing went up in approval between the first and second round of questions, from 23 percent to 43 percent. Approval for not regulating testing at all dropped from 25 percent to 13 percent.

IMPACT ON FAMILY AND SOCIETY

Present Reality vs. Future Fears

Strong agreement that reproductive genetic testing will “inevitably lead to genetic enhancement and designer babies” went up from 62 percent to 71 percent between the first and second rounds of questions. Participants brought out many future scenarios, some on the fringes of possibility and some beginning to be dealt with now.

Tempering this was the reminder from many participants that our consideration of advances in genetics shouldn’t overshadow our current need to care for and treat people with diseases and disabilities. The strongest intersection of this refrain with the genetics discussion was the concern that focusing on preventing the birth of babies with diseases and disorders would somehow take away resources from developing cures. Within this discussion, these participants were up-front about the financial difficulties and stress of having a

child with a disorder or disease. “There is a tremendous savings if you don’t have to treat these diseases over a lifetime,” said one participant of the advantages of early diagnosis and possible treatment offered by testing. “The quality of life for people who grow up with disabilities is very poor,” another said. “Society doesn’t take care of people in need.”

But the top concerns about reproductive genetic testing were “killing children you decide you don’t want” and giving “Godlike authority perhaps parents shouldn’t have.” “Devaluation of life” and the “creation of a genetic second-class” were the top societal implications feared. “Loss of diversity,” an important concern elsewhere, was also one here, but ranked about in the middle.

In general, fears for the future centered on what participants perceived as happening in the present. “We already have a second-class society of people who are genetically different,” one participant said. “First we have to face reality: We’re already in the middle of this.”

Participants at the forum pointed out that a “perfectly healthy” society may be an untenable one.

Many participants used the word “elite” – both in reference to the concept of creating an elite and the idea that only an elite will have access to these technologies. A few participants brought up the question of a “profit motive” on the part of those in the genetic testing industry, but not in terms of profiting from gene patenting or new technologies as at other forums, but rather in terms of profiting from embryos or from pressing testing services and abortions on the unwilling or undecided. The possibility of a society-wide gender imbalance was seen as inevitable and undesirable by some participants, although this did not rank high among stated concerns. Some participants feared that parents would “create” siblings to treat problems of another child.

Another kind of fear for the future involved not having the right to the information or to the choices over what to do with it. Some participants said it was important to empower people with information and that they saw certain political and religious groups attempting to deny access to information or choices. Ironically, several speculated that what motivates these groups is fear.



PANEL: VIEW FROM THE EXPERTS

**Sandra Heaslet
Consumer/Patient**

Heaslet discussed her own process of decision-making in trying to conceive. She and her husband did seek advice from their pastor to help make decisions, she said. While she applauded the effort to discuss these issues, she said she had found it personally helpful that currently these matters are left up to the individual. Yet, she also said, “it’s going to be a wonderful tool to have, but we need to come together and figure out what the best is for everyone.”

**The Rev. Gilbert Marez
Pastor, Camino de Paz Christian Church**

Rev. Marez raised overall theological questions about creation and responsibility that, he said, the church could have a role in articulating. “We need to apply our faith to some kind of accountability, not just to the present but to future generations,” he said. “What does it mean to create something that in effect has always been God-given? And if we are to be co-creators, what is our responsibility to that, and how do we apply that given right?”

Another important issue is the education level of clergy on these issues. The mainline denominations, he said, tend to have a better background in the matter, but this raises a challenge when nondenominational

congregations are growing at such a rapid rate.

The church, he said, can offer qualities such as integrity, accountability and wisdom, as well as a model for the interworkings of God and community.

**Craig Mitchell
Instructor in Christian Ethics, Southwestern Baptist Theological Seminary**

Mitchell spoke of needing to get more information and the importance of the church dealing with the issue. “Ethics education is an important part for anyone in the ministry,” he said. “These kinds of issues are the kind you can’t run away from. Pastors will have to give advice on these. It’s a difficult one to cover simply because the technology is changing so fast.”

“Sometimes we don’t always make the right [policy] decisions. I look at prohibition, I look at slavery – what’s popular and what everyone agrees with isn’t always what’s right.”

**Joe Leigh Simpson, M.D.,
President-elect, American College of Medical Genetics
Ernst W. Bertner Chairman and Professor, Obstetrics & Gynecology, Professor of Human and Molecular Genetics, Baylor College of Medicine**

Dr. Simpson spoke of the fact that while many are concerned about technology moving too quickly to set regulation, very little is truly known about genetics and “the possibility of coming up with

meaningful and long-standing regulation is elusive at this time.”

“It’s as if we expected the recruiting team of the Dallas Cowboys to determine all the players to be on the team in the future on the basis of what we now know about the children in junior high school,” he said. “Nobody, but nobody, will be able to come up with unerring recommendations in the absence of a firm knowledge base.”

This doesn’t mean there’s not a place for some kinds of regulation, nor that such discussions shouldn’t be held. Quite the contrary — a “valid and reliable test with some defined predictability” is one goal. As for forums, “you have to look at what the public thinks and define the issue. Paradoxically, it’s an advantage that [the medical profession] is in a period of ignorance here...we can frame the argument for when the time to work out those details will come, which will be within five to 15 years.”

He also pointed out that sex selection to rule out sex-linked genetic disorders has been going on for several decades, “and we haven’t fallen to the ninth circle of Dante’s hell.” Many of the arguments heard at the forum had come up over the years about abortion and in vitro fertilization. The difference, he said, is that the medical profession “hasn’t shared these arguments in language that can be understood.”

“The real issue is paternalism vs. patient autonomy,” he said. “Are we

going to deal with a paternalistic system or allow each individual couple to decide, up to some level? I think [the latter] can work and should work and has worked.”

NOTES:

¹ For the purpose of this report, the percentages shown are for those participants from the general public who responded to the question. The responses from community panelists and table facilitators, who were often local expert resources, were not included.

New York City Report

DEMOGRAPHICS

Who's Doing the Talking

The Genetic Town Hall in New York City took place the morning of August 2, 2004, at the Lighthouse Foundation Conference Center. Many registered participants canceled because of a national alert that a neighboring building could be the target of a potential terrorist attack. Nonetheless, 42 people participated.¹ Thirty-five percent of participants were in the 30-49 age group, with about 35 percent younger and 33 percent older (Figure 6.1). More women (52 percent) than men attended. More than 82 percent identified themselves as White, with 7 percent Hispanic, 7 percent Black and 4 percent Asian.

Thirty-nine percent had postgraduate degrees, and 29 percent had bachelor's degrees. A majority (63 percent) identified themselves as Democrat; 15 percent as Republican. Not quite half (44 percent) said they have children.

The religious makeup of the group differed markedly from that of other forums. A plurality, 33 percent, said none or preferred not to give their religion. About a quarter were Catholic; there were a larger percentage of Jewish people (18 percent) than at other forums. No one at this forum identified as a Born Again or Evangelical Christian.

The highest percentage of any forum (89 percent) felt "the

Major Emerging Issues

Protecting choice: It was clear that participants at this forum were linking consideration of rights and limits on reproductive genetic testing with abortion. One participant spoke of the politicization that some people see as inevitably accompanying any government intervention: "A lot of people who work around reproductive issues are concerned about how political and ideological factors influence decisions." When asked who should set limits on reproductive genetic testing, 4 percent initially replied that this should be between individuals and their doctors. Sixty-eight percent initially were concerned about the government interfering with private reproductive decisions and this percentage increased over the course of the forum. Even the strong support for regulation of safety and accuracy of tests came with accompanying doubts about motivations of those who might determine limits.

Eugenics and discrimination: About half the group chose eugenics as their top concern when asked about possible harmful effects of reproductive genetic testing. "Who is deciding what is normal? What is considered a disability?" asked one participant. There was strong concern that a particular social class would be allowed to make decisions for all or to set standards for all. "The multicultural aspects of society should influence decisions, and society must allow individual decisions, even when they're unpopular," another said.

Insurance setting the agenda: Health insurance was brought up as a major factor in every facet of testing. A few participants said frankly that they felt insurance companies, rather than the public or government, would end up in effect setting regulations.

decision to have an abortion should be left up to individual women," and only 4 percent disapproved of abortion for any reason.

A series of questions designed to measure knowledge of the issues revealed that the highest percentage thus far (83 percent) had heard of carrier testing and that 46 percent had heard of preimplantation genetic diagnosis. Nearly all (96 percent) said they had heard of prenatal genetic testing. Thirty percent said they or a member of their family had had

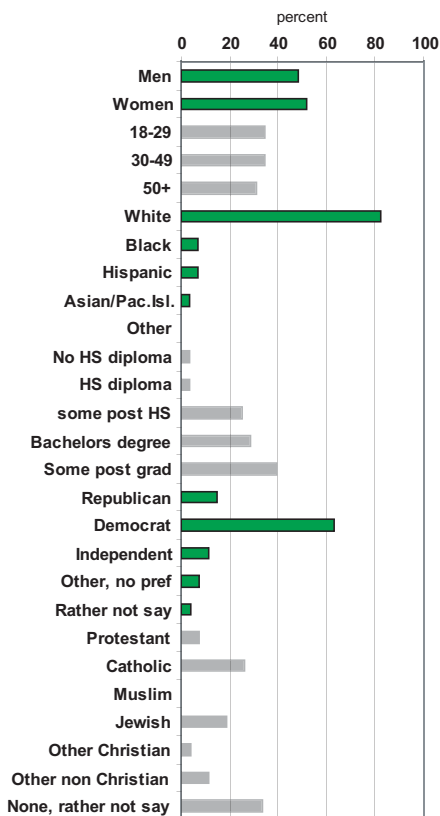
a genetic test; and 30 percent said they had not.

SETTING LIMITS

What Test, For What Reason: Drawing the Line

Participants looked at a matrix of questions measuring approval of the use of three major reproductive genetic tests: carrier testing - testing of adults; preimplantation genetic diagnosis (PGD) - testing of embryos; and prenatal testing - testing of a fetus. They ranked their approval of testing in four

Figure 6.1 New York City Demographics



situations: 1) testing for a gene mutation associated with a fatal childhood disease, 2) testing for a mutation associated with a tendency to develop a disease such as cancer as an adult, 3) testing for a hypothetical gene associated with high intelligence or increased strength, 4) testing for sex and 5) testing for a tissue match for a sick sibling.

As in the other forums, carrier testing was seen as most acceptable. Likewise, the more serious the reason for testing, the more approval there was for testing. Testing for a gene

mutation associated with a fatal disease was most approved of, with participants drawing the line at testing for a gene associated with strength or intelligence. The group at this forum also showed slightly less approval of testing for a tissue match or for sex.

- Testing for a gene mutation associated with a fatal childhood disease was usually seen as appropriate. In this case, 97 percent approved of carrier testing and PGD, and 87 percent approved of prenatal testing.
- Testing for a gene mutation associated with a tendency to develop a disease such as cancer as an adult was approved by 70 percent in PGD, and by 68 percent in prenatal testing. While generally in the forums approval rose with the severity of the disorder being tested for, one participant raised the question of who decides what disorder is a severe one, pointing out that this may be culturally determined.
- While not yet possible, testing for a gene associated with high intelligence or increased strength was generally disapproved of, no matter the testing method used. In this case, 70 percent disapproved of PGD or prenatal testing.
- Participants approved (61 percent) of testing for sex in PGD; 74 percent thought it was acceptable for prenatal testing.
- PGD to determine whether a person is a good tissue match for a sibling that needs a transplant

was approved by 65 percent and 73 percent for prenatal testing.

Rights and Limits: Who Decides?

Some questions were asked both at the beginning of the forum and at the end, after participants had been involved in discussions and watched educational videos. Concern that the government would invade private reproductive decisions went up over the session, from 68 percent to 83 percent. Yet 88 percent, a number comparable to other forums, said they believed limits should be set on acceptable and unacceptable uses of reproductive genetic testing. Support for setting no limits went down from 15 percent to 5 percent between the first and second round of questions.

The contradiction between wanting autonomy and wanting limits appears to emerge from the strength of two concerns at the forum — guarding reproductive rights and privacy and protecting against discrimination and eugenics. In the discussion groups, the top concerns to be taken into account when setting limits were the matter of who decides limits, whether a “genetic second class” is created and the safety and accuracy of testing – nearly a tie among these. Confidentiality and whether testing would be voluntary were also strong considerations in discussion.

At other forums, a consideration in setting limits was whether testing was to be done for a severe disease or for a trait, such as

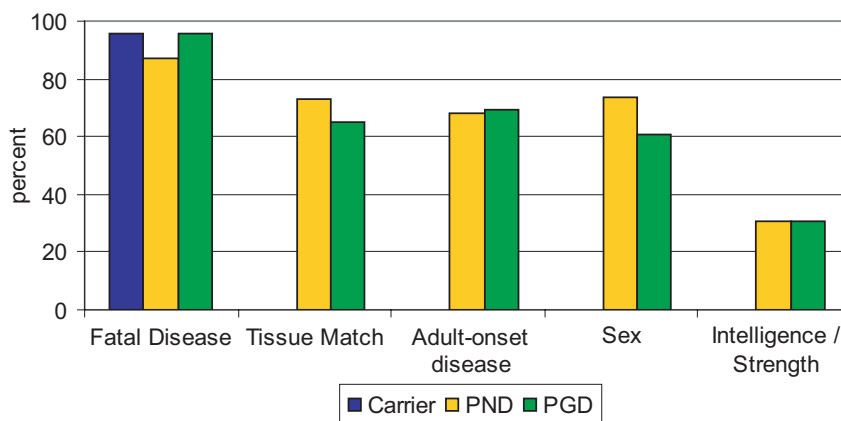
eye color. While this was also a concern in the New York group,

who would set the limits was of greater priority.

“Who should make the decision that a family should have to have a child?” one participant asked. Definitions of disability may be culturally determined, with families having vastly different senses of what constitutes a “serious” disability. By contrast, participants in other forums assumed a cultural consensus on the meaning of “serious” versus “frivolous” testing.

The key issue to this forum centered around who makes those “informed reproductive decisions.” Forty-one percent, more than in other forums, said they felt any limits on reproductive genetic testing should be a matter between individual patients and their doctors, with the rest split between opting for oversight by federal and state governments or medical societies. At the end of the forum, support for government regulation went up to 33 percent and the decision being left to individuals and families down slightly to 37 percent. “I would have liked to have two votes,” one participant said of the question, and a show of hands showed there were many who agreed with her. “I feel very strongly that as it’s in different stages of development, medical societies and even federal agencies would help inform the discussion and provide guidelines – and then I as an individual patient with my doctor would make the decisions.”

Figure 6.2 New York City Town Hall Approval for Different Uses of Reproductive Genetic Testing



All figures are percentage of Town Hall participants who responded to the question and answered “approve” or “strongly approve.” Community panelists and table facilitator responses are removed.

Government regulation might not be the best route, some participants said, raising questions of expertise and political agendas. Also, medical societies and doctors could be responding to profit motives, said another. And all have their own moral and ethical concerns that could influence decisions, a participant said.

SAFETY AND ACCURACY

Who Reviews Tests, and Who Pays?

Support for setting limits on the basis of safety and accuracy went up between the first and second rounds by more than 18 percentage points, from 42 percent to 60 percent. There was high approval for government review and approval of safety and accuracy of genetic tests (95 percent). As at other forums, there was not great concern that such

review and approval would cause major hardship; the possibility of regulation increasing costs and delaying access was a slight factor for about a third of participants. Ensuring safety and accuracy of tests was a major concern in the discussion groups as well.

As at other forums, the questions of reviewing tests for safety and accuracy led to a discussion of who pays for the test – which brought health insurance into the discussion.

Participants here articulated the fear that insurance companies will come to have an explicit role in reproductive genetic testing. Scenarios included insurance providers requiring testing, both broad testing and for specific disabilities. Another fear was that insurance coverage would implicitly guide reproductive choices through economics, i.e.,

they would refuse coverage for children with disabilities where the disability could have been detected through testing and the birth avoided. The other side of the matter was that insurance companies might determine that a disorder isn't serious enough to merit testing. One participant said her health insurance wouldn't cover a prenatal genetic test although she and her husband knew they had a gene mutation. "What are the costs of a lifetime of care versus the test?" she asked. Others wondered whether those with certain political agendas would push for government regulations that might either prevent testing for some disorders or limit choices in acting on test results.

One participant said that as tests become more common, safer and less expensive, insurance companies are likely to start recommending them. "If insurance companies do get involved, you'll have people at a general disadvantage," said another. "They'll have to pay more for insurance, and there could also be discrimination in terms of employment."

IMPACT ON FAMILY AND SOCIETY

Technology Out of Control

The top concern regarding family and societal impact was eugenics – this rated as of greatest concern for nearly half the participants.

Although the word and the concept was brought up early and



often, participants appeared to generally hold reproductive genetic testing in high regard, with nearly all agreeing with the statement that these technologies lead to healthy babies and informed reproductive decisions. However, the number concerned about unregulated reproductive genetic testing getting out of control went up from 73 percent to 90 percent. The concern that these technologies would inevitably lead to genetic enhancement and designer babies also went up from 38 percent to 45 percent.

The concern over insurance companies pushing decisions extended to government doing the same. Some participants feared that public support would be withdrawn for people with disabilities that could have been detected through genetic testing and that families would be penalized for choosing to have children despite a risk of disability.

There was a general sense in several of the small-group

discussions that minorities and the poor would fare badly in a world shaped by reproductive genetic testing. Concerns included whether these groups would have access to tests, lack of testing leading to a "genetic second class," the additional burden to a family of raising a child with a disability, the sense that certain traits will come to be seen as undesirable and that general intolerance of difference, not just of disability, would be exacerbated.

As stated, about half of participants worried about eugenics, or genetic discrimination. While in other groups pressure was seen as coming from parents themselves desiring perfect children, in this forum, participants also mentioned pressure from various outside factors. Even currently, an "inadequate infrastructure" leaves parents with limited choices and access to counseling about alternatives and choices, one participant said. "Who decides what is a disability?" another asked.

“The rich will be genetically enhanced, the poor genetically ‘challenged,’” wrote one participant.

Yet the top benefits seen in the discussion groups were the same as elsewhere — that reproductive genetic testing could lead to healthier babies and less disease, and that taking tests could prepare parents to deal with special needs their children might have. Reproductive genetic testing would strengthen the “ability of individuals to allocate their resources for their families in an autonomous manner, which will lead to happier people, more able to care for themselves and their families without government support and interference,” wrote one participant.

PANEL: VIEW FROM THE EXPERTS

David Hyman, M.D. Medical Director, The Genetics Center

While noting progress made, Dr. Hyman said health care professionals are still concerned about how much there is to be done. With the large number of rare conditions and the high number of couples at risk, he said, the industry has still not been able to improve the odds of people having a healthy baby beyond those that any couple has generally.

He addressed the difficult issue of sex selection, saying “most” in the industry have an informal policy of not doing sex selection. But there is not too much available

in the way of professional guidance on these issues, he said.

He praised funding for research, saying “the real beneficiary of support for science by government has been all of us. The genetic technology we’re working with is the product of research by incredibly dedicated scientists following their intellect in pursuing projects that didn’t necessarily have an economic benefit.”

Congresswoman Nita Lowey D-NY-18th

The House Appropriations Committee member and longtime advocate of biomedical research spoke to the practical reality of legislating medical procedures, reproductive ones in particular. “Anything Congress touches in medical decisions just gets bollixed up and causes real differences,” she said. She spoke of the enormous progress made in mapping the human genome, but added when research “gets tied to the abortion issue, people immediately begin voting on how they feel pro-choice or anti-choice...If some people could use this information to make a decision to terminate a pregnancy, I’m not sure it would go through Congress.

“There’s very little room for independent thinking in the Congress,” she said, speaking of “lobbyists who check your scorecard.” Yet though we know we won’t reach a consensus today, it’s crucial to have these debates and discussions, so that we don’t leave future generations “to wander an uncertain path,” she said.

Rabbi Edward Reichman, M.D. Assistant Professor, Yeshiva University Einstein College of Medicine

Rabbi Reichman spoke of the value of making decisions based on the “long, rich traditions” of religious leadership. “Man does believe he or she can do anything and create anything, but those of us of faith believe the ultimate creator is still God, and we have to answer to God.”

However, he said, there is no consensus on the use of reproductive genetic testing among world religions or even within the Jewish religion. There has been some discussion on where and how to provide guidance, he said, citing, for instance, that some leaders have approved of allowing PGD to be used to create children who could help others, as through a transplant.

“There are many different approaches to genetics and to the use of this extraordinary and wonderful technology,” he said. “I don’t think religion should impede the progress of science.”

Kevin Rogers Consumer / Patient

When his one-year-old daughter was diagnosed with Fanconi anemia, which will necessitate a bone marrow transplant, Rogers and his wife began IVF treatment to have another child and select through PGD the embryo that would be the best transplant match. Rogers shared his experience and

views on reproductive genetic testing.

“My overwhelming thought is that we’re wasting time,” he said. “My child is dying, other people are dying as a result of us being unable to make progress. We have to build on a foundation of science.”

“My own family can’t agree on some of these issues,” he said about the difficulty of reaching a consensus on policy. “We may be treading down a difficult path, restricting people from making their own decisions,” he said.

NOTES:

¹ For the purpose of this report, the percentages shown are for those participants from the general public who responded to the question. The responses from community panelists and table facilitators, who were often local expert resources, were not included.

Nashville City Report

DEMOGRAPHICS

Who's Doing the Talking

The Genetic Town Hall in Nashville, Tennessee, took place the morning of August 4, 2004, at the Nashville Renaissance Hotel and attracted 100 people.¹ More than 45 percent fell into the 30-49 age group – more than in any other city, with about 22 percent younger and 32 percent older (Figure 7.1). More women (61 percent) than men attended. Most, 83 percent, identified themselves as White, with 14 percent Black.

Fifty percent had postgraduate degrees, and 30 percent a bachelor's degree. A plurality (45 percent) identified themselves as Democrat; 24 percent were Republican. The majority (53 percent) said they have children.

Forty-seven percent identified themselves as Born Again or Evangelical Christians. Thirty-nine percent were Protestant, 14 percent Catholic, and 19 percent did not say.

In reply to a question on abortion, the smallest group so far (55 percent) felt “the decision to have an abortion should be left up to individual women,” and 19 percent disapproved of abortion for any reason.

A series of questions designed to measure knowledge of the issues revealed that 66 percent had heard of carrier testing and 51 percent of preimplantation genetic diagnosis. Nearly all (95 percent) said they had heard of prenatal genetic

Major Emerging Issues

Evangelical Christianity: Almost half of participants (47%) identified themselves as Born Again or Evangelical Christians, more than at other forums. Several participants limited their comments to statements to the effect that “this will cause more abortions.” Comments such as “we’re taking God out of the equation” and the importance of “preserving the sanctity and dignity of human life” were brought to the table. One small discussion group, for instance, stated that “there are no benefits” when asked to consider benefits of testing. Some participants, however, protested what they saw as a majority of conservative Christian viewpoints. Despite strong opinions on both sides, there was some shift in views in the before-and-after impressions about testing.

Discrimination: As one participant put it, “discrimination will arise from genetic testing.” This group shared concerns about discrimination on many levels: insurance discrimination, discrimination against children with disabilities and stigmatization of families who choose not to use reproductive technologies. Panelist and Vanderbilt political science professor Carol Swain appeared to sum up these concerns when she said, “I think poor people always lose out in these efforts.”

Harm inevitably arising from technologies: As at several other forums, the number of participants who strongly agreed with the statements that reproductive genetic testing would inevitably lead to designer babies and that unregulated technology would get out of control rose by the end of the Town Hall. Several participants said they support improving health and scientific advancement, but not enough to overcome their concerns that more testing might lead to more abortions. For instance, one participant approved of testing for a mutation associated with a tendency to develop a disease such as cancer as an adult, but only “so lifestyle can be planned” to lessen the disease potential. Yet the statement “Reproductive genetic testing help parents make informed reproductive choices and have healthy babies” got largely positive responses, with over 80% agreement in both rounds of questions.

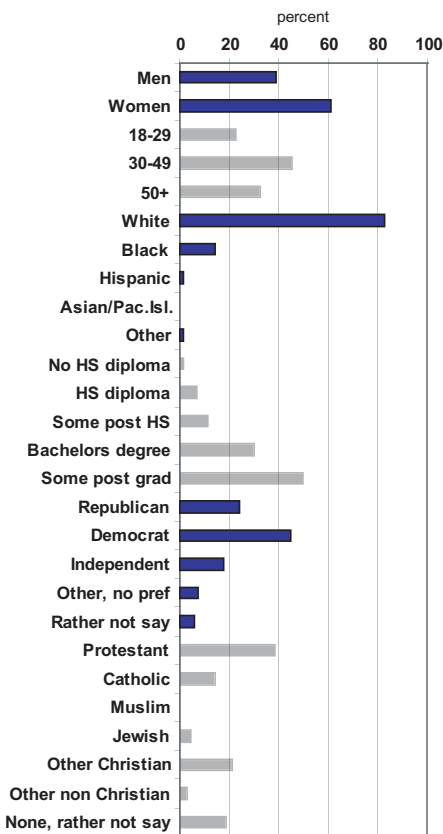
testing. Thirty-five percent said they or a member of their family had had a genetic test.

SETTING LIMITS

What Test, For What Reason: Drawing the Line

Participants looked at a matrix of questions measuring approval of the use of three major reproductive genetic tests: carrier testing, or testing of adults; preimplantation

Figure 7.1 Nashville Demographics



genetic diagnosis (PGD), or testing of embryos; and prenatal testing, or testing of a fetus. They ranked their approval of testing in four situations: 1) testing for a gene mutation associated with a fatal childhood disease, 2) testing for a mutation associated with a tendency to develop a disease such as cancer as an adult, 3) testing for a hypothetical gene associated with high intelligence or increased strength, 4) testing for sex and 5) testing for a tissue match for a sick sibling.

As in the other forums, carrier testing was seen as most acceptable.

“Couples planning to have children might as well know what each partner is bringing to the table in terms of genes for diseases,” one participant commented. Likewise, the more serious the reason for testing, the more approval there was for testing. Testing for a gene mutation associated with a fatal childhood disease was most approved of, with participants drawing the line at testing for a gene associated with strength or intelligence. The group at this forum also showed slightly less approval of testing for a tissue match for a donor or for sex.

- Testing for a gene mutation associated with a fatal childhood disease was usually seen as appropriate. In this case, 97 percent approved of carrier testing, 81 percent approved of PGD and 83 percent approved of prenatal testing (Figure 7.2).
- Testing for a gene mutation associated with a tendency to develop a disease such as cancer when a person is an adult won far less approval. Sixty-two percent approved of PGD, and 62 percent approved of prenatal testing.
- While not yet possible, testing for a gene associated with high intelligence or increased strength was strongly disapproved of. In this case, 82 percent disapproved of PGD, and 86 percent disapproved of prenatal testing. “We are barely able to measure IQ and predict much beyond academic skills, much less understand the genetic basis of the intellect,” one participant said.

- Testing for sex was also less acceptable to the majority. Forty-two percent approved of PGD, and 39 percent approved of prenatal testing. “Some cultures put major pressure on women to have a son,” one participant commented. “I’m not walking in their shoes, so I’m torn about this question.”
- Participants were slightly in favor (58 percent) of using PGD to determine whether a person is a good tissue match for a sibling that needs a transplant, while 47 percent approved of using prenatal testing.

Ethics and Morality Major Concern for Some

The group deftly and definitively named the top issues that they felt should be considered when setting limits on reproductive genetic technology — the “sanctity and dignity of human life” – when considering whether testing was to be done to diagnose a disease or simply identify a trait, such as eye color. The latter was a top concern in other forums as well. Participants said testing shouldn’t be done for “cosmetic” or “aesthetic” factors. Some said it would be acceptable to test for traits, but not to then alter them.

Considering whether the test was “morally acceptable to society, families and individuals” was named as important in setting limits. Another factor raised here and in other forums was ensuring education and counseling, and whether that would be part of creating guidelines or regulations.

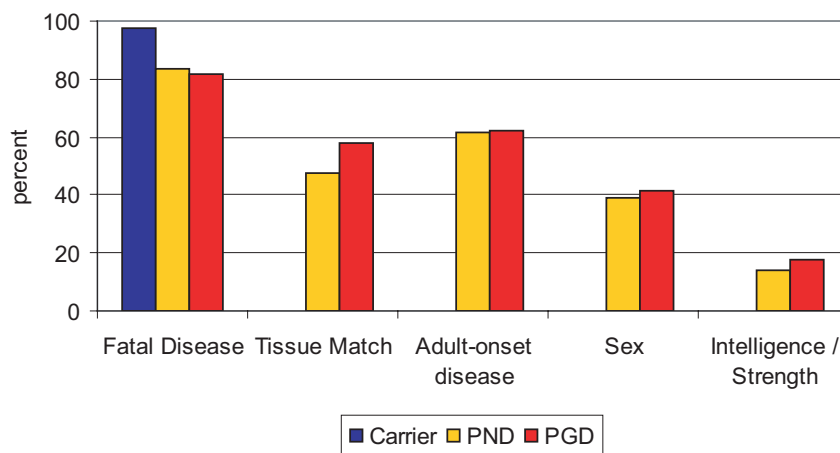
Regulation and Enforcement: A Question of Who and How

Some questions were asked both at the beginning and the end of the Town Hall, after the discussions and video presentations. Questions on who should set limits delved into the question of enforcement, as it had in other forums. When asked who should set limits, 29 percent thought professional medical societies should set guidelines, 20 percent supported federal or state government regulations and 36 percent preferred that the decision be left to individuals and their physicians. At the end of the forum the support for professional medical society guidelines had dropped a bit to 25 percent and federal or state regulations up to 28 percent.

Comments reflected concerns with enforcement and the desire to combine options in regulation. “There’s a difference between a regulation-type limit and guideline-type limit,” said one participant. “Different types of limits may need to be set by different entities.” A show of hands revealed participants were split on whether they preferred regulations or guidelines. One participant said that if tests are connected with health insurance, there would inevitably be state and federal regulation.

Sixty-three percent expressed concern that government regulators could invade private reproductive decisions but concern about designer babies rose from 50 percent to 59 percent. Limits

Figure 7.2 Nashville Town Hall Approval for Different Uses of Reproductive Genetic Testing



All figures are percentage of Town Hall participants who responded to the question and answered “approve” or “strongly approve”. Community panelists and table facilitator responses are removed.

and who sets them were not major concerns in small-group discussions, though one group did pick the necessity for flexible policy that reflects scientific advances as a top issue. Concern about reproductive genetic testing getting out of control rose from 73 percent to 84 percent.

SAFETY AND ACCURACY

Wanting to Be Sure is Deciding Factor

Opinions on the basis for setting limits changed over the course of the forum. Support for using safety and accuracy as a basis climbed slightly, from 33 percent to 40 percent. Eighty-three percent said the government should review and approve genetic tests for safety and accuracy before they are put on the market. A common argument for regulation was: “The government

reviews other aspects of the medical field – why not genetic testing?” Fifty-one percent were correct in thinking the government does not currently do such reviews.

Among the concerns listed, there was slightly more concern that instituting regulation might increase cost of testing. Participants had also raised issues of whether testing would be considered an entitlement for all and, if so, who would pay. The issue of regulations delaying access to testing was of less concern, but one participant commented that she didn’t want testing to get “in the snarl like that surrounding psychotropic drugs – where regulation and clinical trials and FDA protocol is severely limiting the development of new medicines.”

Great concern for accuracy surfaced – both over how accurate current tests are and how accurate testing has the potential to be.

Essentially at question was the matter of prediction and how it figures into decision-making. How sure could anyone be? One group cautioned that regulation would have to be reviewed as technologies evolve. If we test now for potential late-onset illnesses, what are the chances a cure might beat the illness in the race against time? Can testing pinpoint how severe a disorder might be? “If I had been told prenatally about my son’s genetic condition, any decision I might have made would have been based on extremely negative case histories,” said one participant, “which in fact turned out not to be an accurate depiction of my son.”

IMPACT ON FAMILY AND SOCIETY

Diversity, Discrimination Among Top Concerns

One participant struck a chord when she labeled a gene mutation “the ultimate preexisting condition.” But concern about health care discrimination was only one of the types of discrimination raised in the discussion of societal implications of testing. Narrowing diversity was the top concern here, followed by potential stigmatization of those with disabilities. (All panelists in the discussion after the forum called for strong support for people with disabilities and their families.) That testing could lead to an increase in abortions was another concern for this group. Several referenced sex-selection issues in India and China.

Reproductive genetic testing can “just make more pressure on children to be perfect, and they can’t possibly be,” said one participant. “Even if they’ve been designed to be perfect, they can’t possibly be.”

“This could redirect society’s values so that the way we decide who we value would move in a negative direction,” was the view of another participant.

The top benefit seen by the group was “prevention of disease.” Others included “early diagnosis” and “help for at-risk families.” Another group raised the point that the standard of health care could improve for all via testing; a participant commented that less genetic disease would mean more resources for people who need care.

PANEL: VIEW FROM THE EXPERTS

John A. Phillips, M.D.
Director, Division of Medical Genetics, David T. Karzon Professor of Pediatrics, Professor of Biochemistry, Medicine and Pathology

Dr. Phillips warned not to underestimate the capacity of people to care for and about one another: “I guess I’m sort of reminded of ancient Greece – you can judge a society by how well it takes care of its unfortunate,” he said.

When forming guidelines, he said, it’s important to remember that there are at least 5,000 genetic



diseases and some are very rare – making them hard to test for and to treat. “Most health care professionals would embrace the idea of improving tests.”

In his medical experience, he says, he has seen that simply offering the test and asking the question “what would you do?” serves to crystallize the issue for parents and make their decisions easier. “I can tell them about the accuracy of the test, but they need to consider how they’ll use it.”

He says he advises couples to talk to their clergy and family about the issue, but issued a call to the clergy to stay current. It’s difficult for couples under stress to go to religious advisors and then have to provide the clergy an hour or so of education on the subject, he said.

**The Reverend Kevin Shrum
Pastor, Inglewood Baptist
Church in Nashville
Past President, Tennessee
Baptist Convention**

Rev. Shrum referenced his observations of his own son and the competition among parents at football games to make the point that pressure for children to be the best is strong. “As a theologian, I want to embrace the best of what comes from the scientific method, but there’s another track of how we know things that is equally valid, and that’s the philosophical.”

“Most doctors I know are honorable men and women with ethics,” he said, but compared some in the scientific profession

to “a hound dog” who “goes along with his nose to the ground, and sometimes he’ll look up, and he’ll be in the middle of the road, about to get run over.”

**Carol M. Swain
Professor of Political Science
and Law, Vanderbilt University**

Swain referenced the Bible, the book “The Bell Curve” and the controversy it created, and a shameful history of forced sterilization in her comments. “We’re moving in the direction of eugenics if we’re not very careful,” she said. She said the dangers are not only aimed toward Blacks, “but poor Whites as well.”

“If we don’t have diversity, it’s hard to appreciate how much we’ve been blessed with health,” she said of what she perceives as the necessity of following God’s will.

**Carolyn Baldwin Tucker
Nashville Metropolitan
Councilmember-At-Large**

Saying that she “didn’t check her Christianity at the door” when she took office, Tucker spoke of having a “higher degree of responsibility... to look at what’s morally right” in the issue. “I have to be very aware of what is out there and what is being pressed on elected officials,” she said. She stressed that society needed to learn to look at and cultivate the inner self instead of concentrating on the visible.

A participant spoke out that she felt there was an overrepresentation of conservative Christian viewpoints on the

panel. Genetics and Public Policy Center Director Kathy Hudson explained that panelists were invited with attention to diversity of areas of expertise. Typically invited to serve on the Town Hall panels are physicians, elected officials, community leaders and parents with experience with the technologies. She went on to explain that the Center does not have information on the panelists’ religious beliefs or backgrounds, and those on the panel represent their own views and not those of the Center or any other involved organizations.

NOTES:

¹ For the purpose of this report, the percentages shown are for those participants from the general public who responded to the question. The responses from community panelists and table facilitators, who were often local expert resources, were not included.