

Overview and Background

“Genome Technology and Reproduction: Values and Public Policy” Project

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Project Overview

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I. Introduction

The project “Genome Technology and Reproduction: Values and Public Policy” is funded with a \$1 million grant from The National Institutes of Health; National Human Genome Research Institute - Ethical, Legal, and Social Implications Program (NIH-ELSI). The project, carried out by the University of Michigan and Michigan State University, will end July 31 of this year. The project grew out of discussions held by a community-academic-government group formed several years ago in Michigan to consider the societal implications of advances in genetic technology. One member of the group, an African American tenants-rights activist, voiced the perceptions of her neighborhood of genetic research being carried out by the University’s medical center, with the question “What are those people up on the hill getting ready to do to us now?” The project was formed with the intent of giving citizens, at the grass roots level, the opportunity to help shape the kinds of policies which will govern the use of genetic technology in the future.

II. Project Description

The two principal project goals were:

1. Utilizing “rational democratic deliberation” to develop recommendations for the three policy domains - laws, professional standards, and institutional policies - regarding the use and application of genome research and technology.
2. To disseminate the findings to the public, policymakers, health educators, and practitioners.

The project focus was primarily on issues related to reproductive decisions for several reasons:

1. In this issue area, people are likely to be personally affected by genetics.
2. It is an area in which people hold views closely related to and determined by their own values, religious beliefs, and moral principles, often in sharp conflict with the views of others.
3. It is an issue area which legislators are loathe to tackle because of its relationship to issues of abortion, embryo research, and when human life begins.

III. Summary of Project Phases

The project consisted of four phases: A. Focus Group phase; B. Community Dialogue phase; C. Policy phase; D. Dissemination phase.

A. Focus Group Phase

There were 9 focus groups, held in 4 Michigan communities. Each of the groups was different, with group composition varying by stage of life, demographic factors, and place of residence. The goal of the focus groups was to get an initial snapshot of peoples’ concerns related to genetics and reproductive technology.

B. Community Dialogues

There were 2 series of dialogues (Fall 1996 and Spring 1997) held in each of 7 Michigan communities, totaling 13 sessions per community, which were organized by Dr. Leonard Fleck of Michigan State University. The first dialogue series considered guidelines based on ethical and moral principles. There was a Policy Conference in between the two series. Participants at the Conference looked at recommendations coming out of the dialogues and their policy implications for government, professional organizations, and health care providers and insurers. The second series of dialogues concentrated on policy choices and options.

C. Policy Phase

The third phase of the project, headed by Edward Goldman, analyzed the recommendations of the dialogues in the context of case law, legislation, and professional standards. The result of this analysis was the policy report in the conference program. The draft of this policy report formed the basis for one final round of dialogues in all 7 communities to determine the extent to which the dialogue participants felt the report accurately reflected the discussions and recommendations coming out of the 2 series of dialogues.

D. Dissemination Phase

The final phase of the project is one of dissemination, this conference being one component of that phase. Several weeks ago we held a congressional staff briefing to share project findings with the staff of members of congress. We will also be writing a number of articles on the project both for scholarly publication and for policy makers. Members of the project team will be making presentations describing the project and its findings at a variety of conferences, institutes, and workshops. We will also be making available a number of reports on the various phases of the project.

IV. Principal Project Findings

A. Focus Groups

The focus group participants exhibited a fairly high degree of optimism about the potential of genetics research and technology to improve society through medical procedures likely to prevent pain and suffering and enable many people to avoid the consequences of disease and premature death. An exception was the focus group consisting primarily of African American participants who didn't share this sense of optimism, recalling a history which included the Tuskegee syphilis experiment, the serious problems caused by sickle cell screening, and the fear that we may be on the brink of a new period of eugenics that will likely further stigmatization of minority groups.

The focus groups also disclosed that while most participants felt optimistic about the potential of genetic technology, they were less certain of its potential in their own lives. The technology had a benefit in the abstract but people had a more difficult time imagining scenarios in which they themselves would want to be tested or to make use of the resulting information.

Focus group participants who had personal experience with genetically-related diseases were more supportive of early genetic testing than were those who had no such experience. The former group expressed the feeling that people needed to be made aware early of the likely consequences of genetic conditions to their future lives and to the lives of their children, so they could make childbearing decisions and prepare adequately for dealing with the onset of genetic disease in future years.

Finally, the focus groups disclosed a three-way split on issues related to genetic counseling. The lay public expressed the desire to be helped through the process of decision making on whether to get genetic testing and what to do with the information. In the professional focus groups, however, doctors voiced their hesitancy to provide that kind of support, partly because it was not their typical mode of operation, and partly because under a managed care environment they didn't have the time and weren't adequately reimbursed to provide it. Genetic counselors felt competent to help patients through the decision making process, but were concerned about the lack of sufficient numbers of counselors to satisfy the need for counseling, and the lack of reimbursement in most health plans to cover the extent of counseling patients seek. Genetic tests continue to proliferate. This disconnect between the expressed needs of the patient and the inability of health care providers to satisfy these needs will only be exacerbated. There will be an increasing demand on policy makers to address this growing problem.

B. Community Dialogues and Policy Phase

(See pages PP-QQ and XX-YY of the Proceedings.)

V. The Project Goals - Were They Satisfied?

By the end of the project we will have achieved the two project goals - the development of policy recommendations through the process of rational democratic deliberation, and the dissemination of our findings. There is also a more significant result of the project, as well as a significant limitation in having achieved the project goals which must be addressed by similar projects in the future. The most significant achievement of the project is the demonstration of the potential of the community dialogues process for developing policies in an issue area which is complex, divisive, and heavily laden with deeply held personal views, religious principles, and values.

We demonstrated that people are interested in learning about genetics issues, will invest time in discussing them, will carry on discussions in a calm, reasoned manner, reach consensus on many of the issues, and develop a respect for opinions which diverge from their own. This experience suggests that we don't have to leave policy making to the experts, to the lobbyists, or to the quick-and-dirty surveys which appear almost instantaneously following a media report of a genetic breakthrough. Public dialogue can help restore people's sense that they have a meaningful role to play in fashioning the rules and influencing the decisions which affect their lives. Citizens can in fact help determine just what "those people up on the hill" will be doing to them now.

While our project demonstrated that people at the grassroots level can help shape the policies affecting their lives, we also experienced a relative lack of involvement by people typically underrepresented in decision making, in spite of the fact that they are often most adversely affected by the policies which get adopted. Voices of communities of color, while present in the dialogues, were not heard with the kind of frankness and strength that they were in the focus groups. Voices of the less educated and those at the lowest economic levels were largely missing from the dialogues. In this respect we shared the same limitation that has been typical of dialogue projects in other issue areas. We clearly need to do a better job of inclusion of underrepresented groups if the dialogue process is to enhance the effectiveness of our democratic system of government. It is for this reason that we have submitted a renewal application to the National Institutes of Health, teaming up our two universities with Howard University. In the renewal, we seek to convene a new series of dialogues in communities of color and in those with lower socioeconomic status, and to change our methodology and project team to be more

responsive to the characteristics of these communities.

Audience Comments

40 BF: How were the minority groups put together? Did they represent lower socioeconomic status (SES) communities?

Eugenia Carpenter (project process consultant): They were put together through agencies in Ann Arbor seeing these populations, and other community outreach organizations. The minority focus groups were different from the community dialogues and the majority of the other focus groups, but they did focus on reproductive decision making. We sought a mix of lower SES and upper middle class participants throughout the focus groups.

40 BF: In your conversations with African American groups, what emotions—frustration, anger, fear, for example—did you get from these groups? Did you find they were sufficiently interested in reproductive issues, or others?

Eugenia Carpenter: Many of these participants had particular experiences with the health system and with health and social service agencies. The general feeling was not anger but a laid back “been there; seen that” degree of cynicism, or resignation about the likely benefits and costs of these breakthroughs. There were definite concerns about history, discrimination, and adverse use. Overall, though, the discussion was quite lively and focused on the issues.

Toby Citrin: There are three people at today’s conference who have particular expertise on and experience with these sorts of questions, relating to a conference they were instrumental in putting together held a month ago in Maryland. This was the National Dialogue on Genetics sponsored by Howard University and Sinai Hospital. Professor Marian Secundy and Ilana Mittman were the key conference organizers. Drs. Georgia Dunston and Pilar Ossorio were also active in it, as were several members of our project team. This conference was organized for the purpose of dealing with issues of inclusion in genetic policy making and development and in the clinical application of genetics. Dr. Georgia Dunston will share her insight on the issues of inclusion at her luncheon address tomorrow. The Maryland conference was very exciting, and came up with some very wonderful (and troubling) insights into the communities that have not always been heard from on this whole set of issues.

45 WM: Did you take into account the numbers of people in the groups, gender and age differences, variation in education, and pre- and post-session changes? Was a consensus claimed?

Eugenia Carpenter: The groups incorporated differences in life cycle. In this respect there were three types of groups: (1) single and married with no children; (2) those having a child and anticipating a second child; (3) parents of any age having a child with a genetic illness or condition.

Toby Citrin: Details are given in the conference report. There were 8-9 persons on the average in the focus groups. Variations in age and gender occurred over the different groups. We were not trying for consensus at this point, but to elicit attitudes and concerns for the subsequent project phases. A post-test was not relevant for them, but was conducted in the subsequent community dialogues.

Community Dialogues Phase

Leonard Fleck, Ph.D., Community Dialogues Phase Director

I. Introduction

Thomas Murray covered ethical issues in genetics and reproduction in terms of the family; we will be discussing these issues as they relate to community dialogues. We started off the dialogue process during the first series of sessions talking about ethics issues that we are committed to as a society. Public policy is rooted in deep social, moral values. Civil rights issues are an instance of this. The 60's legislation was not possible without prior moral dialogue in the community as engendered by Martin Luther King. Ethics does not focus on private issues, but social value-questions needing community dialogue and demanding community resolution.

II. Case Scenarios

In the dialogues we used the case scenario of Mr. H, a 26-year old male, whose father died of Huntington's disease at age 52. Mr. H knows he has a 50% chance of having the Huntington's gene, for which a direct genetic test is now available. We posed the question, "Does Mr. H have a moral right to NOT KNOW his genetic endowment?" If his diagnosis turns out negative, great! Mr. H will have a normal life expectancy. If he is positive for the Huntington's disease gene, he could have a disease onset 15 years after his 26th birthday. In that case, Mr. H deserves 15 good years, but he could be overwhelmed by depression insoluble by counseling. His conclusion is that he doesn't want to know if he has the gene. Dialogue participants responded to the question that he does have such a right so long as it does not affect anyone else. Suppose Mr. H wants to get married and have children of his own. Does he have a moral right to hide the facts from a potential spouse? Under the doctrine of informed consent, does the spouse have a moral right to know the risks to herself and their future children?

A further question: Should we have a law requiring individuals at risk for a serious genetic disorder to be tested to know their own genetic profile? (By "serious," I mean substantial compromise of length or quality of life.) Should we recommend that professionals have a policy requiring more directive counseling in these circumstances, i.e., strongly encouraging their patients to reveal these genetic facts to potential spouses?

To take an additional scenario, if Mr. H marries and chooses to have children, but wants to minimize risk to them, should we have a law that guarantees he will have access to pre-implantation genetic diagnosis (PGD), so that he can select unaffected 8-cell embryos, even if disability groups argue this is discriminatory? What if the cost of PGD is \$30,000 per successful pregnancy? Should we publicly subsidize such interventions at the 80% level? In another scenario, we also asked participants whether federal funds should be available for speeding-up research for germ-line genetic engineering.

III. Dialogues Description

The community dialogue goals were to:

- Test a model of rational community deliberation (RCD). (A viable alternative to shouting about abortion!)
- Identify through RCD the central ethical issues related to genetics and reproduction.
- Identify and articulate through RCD the ethical values related to genetics and reproduction.
- Propose through RCD morally permissible balancings of conflicting values related to them.

- Identify social values and public interests that should shape public policy.
- Frame policy options congruent with those endorsed social values and public interests.

I need to stress that the community dialogues process does not yield immediate final decisions. That takes 20 - 30 years, like the discussions on death and dying. National and local dialogues need to go on.

In terms of structure, we held the sessions in seven cities. There were six ethics dialogues in each city in the Fall, and six policy dialogues in each city in the Spring; 72 dialogues in all. 85% of the participants were Caucasian; 15% were non-Caucasian. We wanted more racial-ethnic diversification. Attendees were 56% female; 44% male. 17% were under 25 years old; 15% were 26-35; 27% were 36-45; 20% were 46-55; 22% were over 55. Educationally, at least 80% had a B.A. degree. These are the type of people who showed up; we could not have forced others into it. But we must correct the imbalance to better reflect the actual demographics of our society.

The dialogues were preceded by a long introductory letter. During the first session we conducted an initial computer survey. We put together readings for each evening, also a leader's guide with questions to start the dialogues. The sessions were two hours long, with a mix of large and small group discussion, each followed by an end-of-the-evening survey. At the end of the Fall and Spring dialogues we conducted a repeat of the initial survey by mail. The survey assessing process was also done by mail.

In the dialogue items that were used, we would vary the particular genetic disorder that was at stake. So, instead of having Mr. H, a 26-year old with the Huntington's gene, you could have Mrs. H who knew herself to be a bearer of the BRCA1 gene, a situation with very different implications. One could then ask, "Would Mrs. H have a moral obligation to inform a potential spouse of that fact if she did not want to reveal it?" The variables that went into the construction of the dialogue items included factors such as: physical or mental deterioration, age of onset (child/adult; mid-life/late-life), premature death vs. permanent disability, degree of compromise of quality of life, certainty vs. probability of bad outcomes (e.g., Huntington's disease vs. Alzheimer's disease linked to ApoE), medical ameliorability of the genetic disorder. At least 12 different relevant moral values, the cost of the intervention, and whether other individuals were affected also fed into the dialogue items.

The key ethical challenges of the community dialogues were:

- Articulating through rational community dialogue the primary moral values, judgments, and principles that ought to shape our social responses to a range of moral issues related to genetics and reproduction.
- Articulating through RCD the content of the moral and political concepts of genetic privacy, genetic justice, genetic and procreative liberty, genetic responsibility, and genetic discrimination.
- Articulating through RCD socially defensible balancings of conflicting moral values involving genetic and reproductive decision making.
- Articulating through RCD judgments of genetic ethics that can be the object of social agreement, stably endorsed as "reasonable enough" from multiple points of view characteristic of a liberal, pluralistic, tolerant society.

The goals of the policy dialogues were to:

- Identify social problem scenarios related to genetics and reproduction where policy response is and isn't necessary and reasonable.
- Identify public interests and social values that would justify or condemn a public policy response.
- Identify professional and broad patient values that would justify or condemn professional policy responses to specific genetic reproductive issues.
- Critically assess proposed policy responses by professional groups regarding specific genetic reproductive issues, given participant reluctance to endorse very much in the way of legislated public policy.
- Identify what kind of policy response is most appropriate:
 - *Prohibitions*
 - *Protections*
 - *Permissions*
 - *Promotions*

The key policy challenges of the dialogues were:

- Articulating through RCD a political concept of genetic responsibility for both individuals and society that is not eugenic. There are choices. As Philip Kitcher, author of *The Lives to Come*, said, we are moving away from an age of “genetic innocence” into an age of genetic moral responsibility. We must operationalize this.
- Articulating through RCD a political concept of genetic justice that allows us to assign an appropriate priority for funding genetic reproductive needs relative to other unmet health needs in our society.
- Articulating through RCD a political concept of genetic and procreative liberty that is suitably constrained by concerns for genetic justice, respect for nascent human life, and nondiscrimination with respect to viewpoints of the disabled. Should the Gina Kolata example mentioned by Thomas Murray, human cloning via somatic cell nuclear transfer, be within the domain of genetic liberty or should it be outside the bounds?
- Articulating through RCD a political concept of genetic privacy that does not compromise inappropriately the rights or interests of others who may not have the capacity to protect their own interests, such as future possible children.
- Determining the appropriate scope and role of religious values in shaping public or professional policy as it relates to genetic and reproductive decision making. (Disability and right-to-life group members were included in the dialogues.)

The tentative dialogue conclusions were:

- There is a range of moral judgments of varying degrees of specificity related to genetics and reproduction on which we can achieve a high degree of agreement.
- It is hard to detect large shifts in moral judgment from pre- to post-dialogue when complex balancing judgments are required.
- Large shifts in moral judgment are discernible from pre- to post-dialogue when initial judgments are heavily non-rationally determined, as in the cloning issue.
- Legal mandates for any kind of genetic testing are generally strongly resisted, even when the welfare of future children is at risk.
- Legally mandated premarital genetic counseling is acceptable to slightly more than half of participants.

- There is a broad acceptance of the political legitimacy of government protecting the genetic health of future children.
- 55-60% of participants endorse government-mandated educational approaches.
- 55-60% endorse government-provided economic incentives for genetic counseling and testing.
- There is significant concern about structuring economic incentives for genetic counseling and testing through employee health plans.
- There is a virtually even division of judgment on whether professionals should counsel more directly to elicit responsible genetic decisions.
- There is a virtual even split in judgment that we should have laws mandating insurance companies to pay for IVF when the intent is to avoid conceiving a child with a serious genetic disorder.
- There is strong opposition to any legal mandate for having children via IVF to avoid their being conceived with a serious genetic disorder.
- There is strong opposition to any legal ban on access to pre-implantation genetic diagnosis (PGD), or other alternative reproductive options.
- There is strong opposition to the idea that PGD represents invidious discrimination against the disabled worthy of a legal ban.
- There is strong opposition to permitting religious belief, e.g., that full personhood begins at conception, to shape public policy.
- Maximizing individual procreative liberty is politically the most legitimate way to allow religious values to shape individual reproductive decisions.
- There is fairly strong support for government regulation of the dissemination of genetic tests to protect consumers; even stronger support for professionals doing that.
- A strong majority (65% vs. 20%) is opposed to any laws that would ban the development of the capacity for germline genetic engineering. (Quite a strong level of support given the general opposition to the idea of human cloning.)
- There is strong support for federal laws that would ban insurance companies from using genetic information to price health insurance or deny it.
- There is very strong support for federal laws banning employers from using such.
- There is a virtual even split regarding a federal law that would ban prenatal testing for late-onset adult disorders.

Questions that remain are:

- Were the community dialogues a good model of rational community deliberation?
- What sorts of revisions of the process might be desirable? (These revisions are being addressed by the renewal grant proposal.)
- Is this format a most appropriate one for policy development when the questions address deep social values? (Indications are it was, but more analysis is needed.)
- What concept of representativeness should characterize the dialogue groups, one like our founding fathers that includes an elite group of persons, or one that goes after a diversity of viewpoint and grants all points of view a fair and respectful hearing?
- Are there any significant differences in moral or political judgments relative to demographics?
- How do we know that the post-dialogue judgments are any more “correct” than the pre-dialogue judgments?
- Why should policy makers care about this project as a model for policy making in genetics and reproduction?

Finally, the policy-making goals established by the project were to:

- Respond to genuine public concerns, such as genetic discrimination against Ashkenazi Jews or other groups.
- Respond to irrational public fears that may precipitate thoughtless policy.
- Protect space for responsible individual liberty in making genetic and reproductive decisions.
- Encourage broader public engagement in thinking through deeply controversial political issues.
- Shape just resource allocation policies regarding genetics and reproduction.

Audience Comments

40 WF: I think the dialogues provide us with some marvelous models. I am glad you included consumers in genetics. I just got back from a conference on genetics and public health but the public was not represented. There is a lot out there on policy making. Where should we start, at the “grassroots?”

Len Fleck: Yes. The renewal grant proposal stresses racial-ethnic diversity and working class America. We must alter some of the language to accommodate different groups, but the issues are generally appreciable by lay audiences.

Toby Citrin: The renewal grant represents a shift in methodology. It is not “top-down”. People are already engaging in their own community discussions. We are inviting communities to share their discussions with us.

65 WF: There are 3,030 people in my Massachusetts community. The people are enormously rigid about protecting their privacy. One town meeting covered the issue of whether we should provide condoms to high school seniors. All these people were turning out and voicing an opinion. Likewise, communities of African Americans might bring up the concept of sickle cell. This is a most poignant issue where discussion would make a difference.

Steven Vaughn, Len Weber (community dialogues facilitators): African American concerns such as Tuskegee were part of the discussions, but the primary focus was broader.

Toby Citrin: The renewal agenda has issues like this we shared with the dialogue participants. The question of why we are doing the research in the first place is also fair game. It is better to solicit participants’ questions rather than ones we present.

Policy Phase

Edward Goldman, JD, Project Policy Advisor

I. Policy Overview

The policy team - Sonia Suter, Rosemary Quigley, and myself - looked at the community dialogues as well as case law, current and proposed genetics legislation, and professional standards involving genetics, including analogous law (duty to warn, HIV, etc.). We wanted to see what policies could be crafted in response to the community dialogues. The team also wanted to create a process where policy could be reviewed by the community dialogue participants and by professional groups and legislators.

Policy was developed by looking at the results of the focus groups and community dialogues, law, etc. The team constructed draft policy recommendations, had them reviewed by community participants, and sought input from an expert advisory committee, which led to the final draft we have today. All of the groups had a chance to put these different areas under a microscope, to discuss “what’s broken,” what is an informed public law, what are the competing social goals, the legal and ethical considerations, and the political and economic implications.

These were the guidelines we followed:

In the United States everything is permitted except that which is forbidden.

In Germany everything is forbidden except that which is permitted.

In Russia everything is forbidden including that which is permitted.

In Italy everything is permitted including that which is forbidden!

We had to consider questions of: Whose policy is it? Will it be a governmental policy, state or federal? Should it be professional, should we wait and let the courts deal with these issues on a case-by-case basis, or should it just evolve through developments in science, like Thomas Murray sketched earlier?

The various policy responses we looked at included prohibitions, protections, promotions, and permissions:

- *Prohibitions*: cover those areas considered to be illegal or inappropriate. For example, “It is illegal to use genetic information to discriminate against any individual in employment decisions.”
- *Protections*: cover making sure that adequate privacy is provided to individuals. For example, “Genetic information cannot be shared with third parties without proof of patient consent.”
- *Promotions*: cover how to encourage certain behaviors. For example, “Genetic counseling will be available as a covered benefit.”
- *Permissions*: cover areas where several options are left open for the public. For example, “Parents are free to pursue all available technologies for reproductive issues.”

We examined in each case how policies could play out using each of these approaches.

A major touchstone was that policy had to emerge from informed community dialogue with due attention to existing legal rules and legislation, social implications, economic considerations, and professional standards. These recommendations are not final; there is a need for more analysis and feedback. The communities were asked for a sharpening of the policies, to revise them and suggest new ideas. We need a continuous feedback loop as part of this process. The recommendations are the result of ongoing reflection and education in the communities. Interest groups and legislators were included as well in the March 1997 Policy Conference.

II. Policy Issues

There was clear consensus in the communities that it is better to leave policy development to genetic professionals, but that we also need legislative action to prevent discrimination and to protect privacy and reproductive liberty. There is an ongoing need for education, both of the public and policy makers. We also recognize that substantial legislative involvement would be necessary to have our policy

recommendations adopted and we believe that legislative analysis should be responsive to the identified community concerns.

The policy report summarizes case law, legislative developments, community response, and ends with a series of recommendations. I will be covering important issues it highlighted.

A. Informed Consent

The notion of informed consent, or informed choice, involves making available, receiving, or declining information useful to professionals. These days this also includes discussing the nonmedical risks of genetic testing and the social risks, such as insurance denial and discrimination, and psychological reactions to test results.

B. Duty to Warn

This duty started with cases such as *Tarasoff v. Regents of the University of California* where there is a third party at risk of serious harm. (In this case the court ruled against a psychotherapist for failing to warn a third party about the patient's intent to kill.) The third party needs to be given information, but this would violate patient confidentiality. A "sphere of justice" or balance exists. Social value is deemed so important that it is trumping patient confidentiality in this circumstance.

There are other noteworthy cases beyond *Tarasoff*. In *Pate v. Threlkel* (Florida, 1995), a patient was treated for medullary cancer. Her daughter, who developed the same cancer, alleged that the physician was liable for failing to warn her mother of the risk to her children so that they could prevent the cancer from developing. The court could have ruled in favor of the mother's doctor, but the case proceeded otherwise. The court did recognize the parent could have been told of the risk to the family. In *Safer v. Pack* (New Jersey, 1996), the plaintiff's father died of colon cancer and the plaintiff herself developed colon cancer. She sued her father's doctor for failing to warn the family of the risk to his children. The court decided such a duty would be satisfied by taking reasonable steps to assure the information reaches those likely to be affected.

The court concedes that if the doctor knows the father will not tell, it may be necessary to breach confidentiality if it is very important that the information be shared with a third party and the doctor knows the patient will not tell. This is seen in HIV cases where the patient has sex often but does not want to tell. Some states say the physician has an obligation to inform the partner or the public health department for tracking purposes. The third party has a legitimate justice-based claim here - a right to the information.

C. The Question of Mandatory Testing and Mandatory Testing Legislation

In every state, newborn testing is mandatory where the condition is treatable. This is done to avoid injury to the child and where the child needs very quick attention to avoid injury. Phenylketonuria (PKU) is the classic example. If the newborn's diet is not quickly modified, there can be irreversible developmental disability. Every state has this kind of law, based on the notion that it can intervene on behalf of the child to protect the child's interest (somewhat like avoidance of abuse and neglect) where a demonstrable public health risk exists that can be reduced through testing. Conditions can be evaluated to see if they meet these criteria. Michigan tests for six newborn diseases of inborn metabolism plus a seventh condition - sickle cell. Public health asserts that if the parents know the child has sickle cell disease, when the first sickling crisis occurs doctors will know the child has the

condition and will be better able to anticipate and treat them. Some suggest getting consent for sickle cell disease first since there is no immediate treatment. For many states, though, newborn testing is mandatory—it is done without consent.

D. Prohibitions Against Insurance Discrimination

Such prohibitions apply to health insurance in most states, and to life and disability insurance and risk rating in some. In Maine, a new law prohibits discrimination in employment. Privacy laws cover many issues: newborn screening, paternity, identification of dead bodies, court procedure and forensic identification. The New York Times two months ago described an FBI database leading to three thousand “cold hits” of criminal suspects which could not have been done otherwise. This leads to the question of whether all of us want to put our DNA into a databank.

E. Effects on Research

One of the legislative approaches we looked at was the property-right approach.

The property-right approach stipulates that you own and can control your own DNA, and can get it back from anyone you have lent it to for a specific purpose. In effect it says, “You (the hospital) can have my DNA to test for genetic predispositions, but you must give my DNA back afterwards.” But other laws with different social policies exist. The CLIO (Clinical Laboratory) Act states that hospitals must keep the data for a period of time and do quality assurance studies on it. In malpractice cases, defense requires facts based on pathology slides, which are important to keep. It would be farfetched for someone to sue for return of everything the hospital has, slides included, just to get their DNA back. But competing social policies do exist in this area.

F. Genetics Exceptionalism

We also looked at the whole question of “genetics exceptionalism.” Should we treat genetic material and information any differently than other medical conditions? Should we not look at medical privacy and information as well? Often the question of privacy is broader than just singling out genetic material.

III. Summary of Policy Recommendations

(referring to pages 61-79 of the Policy Approaches / Recommendations Report)

A. Legislation, Definition of Genetic Information

Legislative bodies are to proceed slowly and to look carefully at language and definitions [p. 61]. Just as ethics speaks of “shared values,” policy makers will require “shared definitions”. We are particularly concerned about the definition of genetic testing. The question of “What is the genetic information?” is also important. Does it only refer to DNA or does it include radiographic information and sweat chloride results (cystic fibrosis)?

B. Role of Government, Reproductive Liberty

We recommend that any state or federal legislative involvement must preserve reproductive liberty [p. 62]. The communities were strongly against bans on childbearing. Participants felt newborn screening is all right on a mandatory basis, though. Voluntariness should be the touchstone. But the question remains, “Who should pay?” Should these services be like the abortion model? - “You want it—you pay for it?” Should there be money available for testing and research?

In addition, we would recommend that the government protect the privacy of confidential information and prevent discrimination. In looking at the issue of genetics, we are mindful that all medical information, not just genetic information, must be protected.

C. Genetic Testing

(1) Informed Consent

Informed consent is central [p. 64]. The legislatures should avoid articulating specific elements of informed consent, though. The area is moving too quickly, and is best left to the medical professionals. A 1985 Michigan Law required that physicians diagnosing breast cancer must relay to patient's alternatives to radical mastectomy, such as lumpectomy. Things have moved so quickly that law now needs amendment; it has misinformation in it. The legislatures should proceed slowly when it comes to new developments.

(2) Genetic Counseling

The community believed in the value of genetic counseling and our report emphasizes the importance of genetic counseling to help patients understand and deal with complex issues. There should be professional policies to insure counseling remains a part of genetic testing [p. 65]. Should genetic counseling be mandated or simply offered? We recommend that at the very least, laws hold providers obligated to make people aware of the availability of premarital genetic counseling. By analogy, the state mandates giving information about HIV testing. The question arises, "If genetic counseling is offered, who pays?" The communities recommended promoting but not mandating education. Providers should offer the opportunity for counseling should genetic testing occur.

(3) Disclosure of Test Results

The general consensus was that no disclosure to third parties should occur [p. 68]. Exceptions to doctor-patient confidentiality do exist, however, such as child abuse, patient abuse, duty-to-warn. The rule is absolute otherwise. There are rare instances where confidentiality must be breached to avoid serious harm. The professional should inform the patient in these circumstances. If the patient refuses to disclose, legislation may allow the physician the privilege to disclose together with professional protections. The professional has the discretion to report based on the prevailing standards. Disclosure is permissible to avert serious risk in certain very specific instances when no alternatives exist and all efforts have failed to get the patient's informed consent, e.g., when a relative or family member is at risk for colon cancer.

(4) Right Not to Know [p. 70]

We support policies that allow individuals to decide whether or not to receive genetic test results even if they have chosen to have genetic testing. This right is based on autonomy. It is straightforward except when third parties and children are affected.

(5,6) Testing of Minors, Newborn Screening

When looking at newborn screening, we believe that it should be limited to conditions where testing is necessary to provide immediate therapeutic benefits. In discussing testing of minors, we believe that courts and legislatures should defer to professional standards of care. We felt there is no need for mandatory testing in this area [pp. 70,71]. For parents who want to test a 12-year old, the provider must ask, "Why? What interventions can be performed? Can the testing wait until the minor is of legal

age (the exception being newborn screening where therapeutic benefits exist)?" There is still the question of consent before testing, especially if the data is used for other purposes. Every state has Guthrie cards, which are useful to epidemiologists. Data collection for one purpose, newborn screening, can be used for another purpose, e.g., forensics, which raises questions of consent. Thus the question is an important one to look at.

D. Protection of Research, Property Rights to One's DNA [p. 72]

We looked at questions of property rights not just in terms of competing laws but also research in general. The conclusion was that we must be really careful that laws do not inappropriately interfere with legitimate research. There are existing structures - human subjects review, institutional review boards (IRB's), consent processes. A further conclusion was that legislatures should avoid the creation of property rights on genetic samples and information. It upsets existing laws. Nobody has property rights on tissue up to this time. The implications of creating a property right are unclear; there could be an adverse impact on legitimate research and medical care. Consent questions also exist. Paragraph 7 of the University of Michigan surgical consent form says that "Any discarded tissue you donate to us, and can be used by the University." Steps that can be taken are to anonymize the genetic information and to build protections into informed choice.

E. Clinical Care

In the area of clinical care, we believe it is important to consider the costs that various policies may have in terms of clinical resources.

F. Discrimination

(1) Employment Discrimination

90% of the communities backed legislation to prohibit employers from requiring genetic testing or access to genetic information, with narrow to protect public safety [p. 75]. There is more benefit to employers protecting employees by cleaning up the workplace as opposed to genetic susceptibility testing. We also supported legislation prohibiting employment discrimination including discrimination on the basis of genetic information.

(2) Insurance Discrimination

For insurance discrimination we felt that specific attention must be given to distinguishing life, long term care and disability insurance from health insurance [p. 76]. The community response was unequivocal that legislators prohibit health insurers from discriminating based on genetic information. We believe that while it is easy to prohibit discrimination involving access to health insurance, we must also look at health insurance actuarial rate setting. The Huntington's disease life expectancy curve is different from the life expectancy average. Is it fair to rate them the same?

We believe that if legislators conclude health insurance is to be made available to those with predisposing disease genes then legislators must consider the powerful argument that it should also be available to those at risk for "non-genetic" conditions. We understand the important economic ramifications in this area and believe that legislation must address health insurance issues in the context of the larger problem in society of access to health care and insurance.

G. Professional Standards [p. 77]

If as we recommend society gives discretion to professionals to set standards for genetic policy, then we need appropriate mechanisms to ensure that professional standards are followed and meet

minimally acceptable criteria. Do professionals understand them? How carefully are they looked at, followed, and deviated from? A quality assurance mechanism should exist to see that professionals are adhering to the standards.

H. Education

There should be professional and public education on genetics on an ongoing basis [p. 78]. This includes seminars, on-line education, and newsletters. The legislature should also be included. Michigan drafted a bill stating that if you do human cloning, you will be fined \$10 million and there will be mandatory withdrawal of your license for life. But, if you kill a patient, you will only lose your license for three years! The cloning prohibition that was drafted is an overreaction in this regard. Education would have been useful in its framing.

I. State or Federal Legislation [p. 79] (J. in Policy Recommendations)

State legislation may result in many different sorts of policies, which could lead to confusion, but does establish a “laboratory” for determining which policies are most effective. On the other hand, federal legislation offers the possibility of uniformity in policy. We suggest a “federal floor” for common genetic policy areas, with room for states to work creatively. We emphasize that there is not one right answer emerging. Sometimes state legislation can help to work through the different approaches.

IV. Conclusion

The project methodology represents a very interesting way to approach creation of public policy. Lawyers typically sit in a room, close the doors, and ask each other what they think. The notion of actually talking to people is really exciting, especially to see how the various communities learned difficult genetic material and talked sensitively and intelligently about it, and to see how they could really give us a blueprint for policy development.

We believe that the policy paper shows how recommendations can be derived from a larger project intended to explore the role of the public in developing sound policy. We emphasize the need for continued study regarding these areas by researchers, genetic professionals, ethicists, lawyers, policy makers and, of utmost importance, the community.

Audience Comments

45 WM: Referring to page 79, has any similar rational community dialogue been conducted elsewhere in the country and if so, were any of the conclusions or procedures similar to that followed here? If the continuation comes through, dialoguing should be done in other geographic regions.

Stephen Modell (Project Research Associate): About 2 - 3 years ago Oregon held a Delphi group with genetics professionals as well as a focus group with public members to map directions and issues. This happened independent of us. Focus groups represent the first phase of our project. Vermont has a long history of discussing health care issues. They are preparing to hold town meetings on genetic issues. We promote models like ours being tested out in different states.

65 WM: I am a retired OB/GYN from the American Life League. In Dr. Thomas Murray’s iceberg example, the 90% below the water represented our shared values, with the 10% above being the disputed area. Rational democratic deliberation is destined to failure; we don’t have the wisdom to determine who shall live and who shall die.

Ed Goldman: A project like this will get a cross-section of viewpoints, the right-to-life included.

Blondeen Munson (Project Community Member): The Ann Arbor group did not achieve agreement on property rights and the ownership of DNA. Police collected DNA from young African American men in the Irwin Mitchell serial rape case in Ann Arbor. To get their samples back, the plaintiffs had to go to the Court of Appeals.

Ed Goldman, Sonia Suter (Policy Team Members): There is a difference between saying “You don’t have a property right to your DNA,” and saying that the police do not have a right to keep samples that were not disposed in a criminal case. The project recommendations dealing with property rights responded to legislation in the context of research, not forensics. It would be nice to go back and have more discussion with the community dialogues on this issue. The Governor’s Commission on Genetic Privacy and Progress concluded that it is inappropriate for the police to retain or coerce people to give samples. But this is separate from saying you have a property right to samples.

Dan Brock (Expert Advisory Committee Member): You mentioned a number of principles together with their exceptions. Did the exceptions come out from the community dialogues as thoroughly as the general principles, or are the exceptions an articulation from the policy analysis?

Shirley Bach (Community Dialogues Facilitator): Our group had exceptions to everything. To almost any question they had, the members wanted to write in the margins. We wondered, “How are we going to deal with this?”

Ed Goldman: Part of the beauty of using the scenarios is that you can work on a principle as well as the exceptions to it. It is a bit like Talmudic scholarship. There is the language of the bible in the middle of the page. To the right of it there’s a little note saying, “This is what I think it means,” signed a 6th century rabbi. Then from Maimonides there’s a note stating what they really meant, and so it goes down the page. This is like the process we were following.