REPORT OF THE WORKING GROUP ON

ETHICAL, LEGAL AND SOCIAL ISSUES RELATED TO

MAPPING AND SEQUENCING THE HUMAN GENOME

The plan to map and sequence the human genome has profound implications for the alleviation of human suffering due to genetic disease. Genes directly causing or predisposing to human disease will be placed on the map for all to investigate. Additionally, normal genes which may be involved in the pathways leading to the development of new treatments will be captured and fundamental biological lessons in genetic regulation and functioning will be learned through the Human Genome Initiative.[1]

Any scientific endeavor of this magnitude must be developed in concert with a plan to ensure that the public has access to the benefits in improved health care which should be a result of the research. It is also imperative to protect individuals and society from possible hazards which may be a consequence of our improved ability to detect and predict hereditary illness. The use of genetic information, for good or ill, has long been an issue in our society. But the quantity and complexity of genetic information which should become available requires that special precautions be taken.

Accordingly, the National Center for Human Genome Research is giving high priority to the development of a program to address the ethical, legal, and social implications of the Human Genome Initiative. This plan will attempt to anticipate the impact of the Human Genome Initiative and address what protections need to be in place so that the information generated can be of maximum benefit to individuals and society.

Although initially the Human Genome Initiative will produce information that will lead to the detection and diagnosis of genetic disease, the long range goal will go beyond this to providing improved treatment, prevention, and ultimately cure. The interim phase, before adequate treatment is available, is the one in which the most deleterious consequences can occur, such as discrimination against gene carriers, loss of employment or insurance, stigmatization, untoward psychological reactions and attention. Once effective treatment is available for an illness, most of these problems disappear. As the fruits of the Human Genome Initiative are realized, there will be an increased need for improved professional and public education to take advantage of the information gained.

In responding to the desires of the scientific community to understand the social, ethical, and legal implications of research on the human genome, the

---

[1]The Human Genome Initiative is discussed in detail in the National Academy of Science's 1988 report, "Mapping and Sequencing the Human Genome" and the Office of Technology Assessment's 1988 report, "Mapping Our Genes--The Genome Projects: How Big, How Fast?"

Office of Human Genome Research developed a program announcement which appeared in the March 3, 1989 NIH Guide to Grants and Contracts. Applications were requested to address questions such as: (1) What are the concerns to society and to individuals; (2) What questions in the areas of ethics and law need to be addressed?; (3) What can be learned from precedents?; (4) What are the policy alternatives and the pros and cons of each?; and (5) How can we inform and involve the public?

At its January 1989 meeting, the Program Advisory Committee on the Human Genome established the working group on ethics to develop a plan for this component of the human genome program. After considerable informal discussion within the group and with other scholars in ethics, law and related fields over subsequent months, the working group had its first formal meeting on September 14-15, 1989. A roster of the members is attached.

At this meeting, the working group began to define and develop a plan of activities to address the ethical, legal, and social issues arising out of the application of knowledge gained as a result of the Human Genome Initiative. Representatives of the National Science Foundation (NSF) and the National Endowment for the Humanities were invited to present their grant programs for research on ethics, science, and society and the working group noted that there was considerable opportunity for collaboration with these agencies, taking advantage of their expertise and experience in managing grants in this field.

The working group agreed that the purpose of the ethics component of the human genome program should be to:

- anticipate and address the implications for individuals and society of mapping and sequencing the human genome;
- examine the ethical, legal, and social consequences of mapping and sequencing the human genome;
- stimulate public discussion of the issues; and
- develop policy options that would assure that the information is used for the benefit of individuals and society.

The working group was strongly supportive of a program that would anticipate problems before they arise and develop suggestions for dealing with them that would forestall adverse effects. The approach to accomplishing these objectives should be several-fold:

- to stimulate research on the issues through grants;
- to refine the research agenda through workshops, commissioned papers, and invited lectures on specific topics selected by the working group;
- to solicit public input from the community-at-large through town meetings and public testimony;
- to support the development of educational materials for all levels; and
- to encourage international collaboration in this area.

A. STIMULATE RESEARCH

The working group is eager to encourage investigators in the research community to explore the wide range of issues pertinent to the human genome program. Outcomes of this research may be used to develop educational programs, policy recommendations or possible legislative recommendations.

In discussing the ethical, legal, and social consequences of the Human Genome Initiative, the working group deemed the following topics to be of particular importance and will strongly encourage research in these areas:

1. Fairness in the use of genetic information with respect to:

   - insurance (acquisition and maintenance of health, life, disability, catastrophic, long-term care, and automobile insurance coverage)
   - employment (equal access)
   - the criminal justice system
   - the educational system
   - adoptions
   - the military
   - any other areas to be identified

2. The impact of knowledge of genetic variation on the individual, including issues of:

   - stigmatization
   - ostracism
   - labelling
   - individual psychological responses, including impact on self image.

3. Privacy and confidentiality of genetic information regarding:
   - ownership and control of genetic information
   - consent issues

4. The impact of the Human Genome Initiative on genetic counseling in the following areas:.

   - pre-natal testing
   - pre-symptomatic testing
   - carrier status testing, especially for very common disorders such as cystic fibrosis
   - testing when there is no therapeutic remedy available, such as for Huntington's disease
   - counseling and testing for polygenic disorders
   - population screening versus testing

5. Reproductive decisions influenced by genetic information:

   - effect of genetic information on options available
   - use of genetic information in the decision making process

6. Issues raised by the introduction of genetics into mainstream medical practice:

   - qualifications and continuing education of all appropriate medical and allied health personnel
   - standards and quality control
   - education of patients
   - education of the general public

7. Uses and misuses of genetics in the past and the relevance to the current situation, e.g.:

   - the eugenics movement in the U.S. and abroad
   - problems arising from screening for sickle-cell trait and other recent examples in which screening or testing sometimes achieved unintended and unwanted outcomes.
   - the misuse of behavioral genetics to advance eugenics or prejudicial stereotypes.

8. Questions raised by the commercialization of the products from the Human Genome Initiative in the following areas:

   - intellectual property rights (patents, copyrights, and trade secrets)
   - property rights
   - impact on scientific collaboration and candor
   - accessibility of data and materials

9. Conceptual and philosophical implications of the Human Genome Initiative on:

   - the concept of human responsibility
   - the issue of free will versus determinism
   - the concept of genetic disease, particularly in view of the high rate of human genetic variability and the large numbers of people who will be found to have genetic vulnerabilities.

Most of this research can best be accomplished through the support of scholarly research and conferences. The working group recommended that support for conferences be limited to those that are highly focussed and produce a specific product such as recommendations or policy options. The types of research to be supported should be varied and involve many of the disciplines traditional to the humanities. General surveys for purposes of information gathering are not recommended at this time.

B. REFINE THE RESEARCH AGENDA

The working group is intentionally small so that others with specific necessary expertise can be recruited to join the effort as needed. To accomplish its task, the working group plans to invite individuals from a variety of disciplines to help refine the research and policy agenda. This activity will include small workshops, commissioned papers, and invited lectures by knowledgeable individuals. In an effort to gather needed information in a timely manner, the working group will convene two to three times annually to collect information and discuss how this new knowledge will be integrated into a plan to refine the research agenda and propose future action.

Initial plans for the first workshop are underway. The format of a focus group is envisioned. Participants will include prominent individuals from various occupations and professions on which the Human Genome Initiative will have an impact such as, insurance companies, industry, labor unions, geneticists, "consumers" of genetic information and services, constitutional law, media and the arts. The intent is to invite individuals who may not have been actively involved in the Human Genome Initiative or genetic research or services, but who can view the issues from a fresh perspective.

Participants will be provided background materials compiled by members of the working group and will be encouraged to discuss, on the basis of their experience and expertise, the most salient ethical, legal, and social repercussions of the plan to map and sequence the human genome and suggest areas of research, policy development or legislation which they feel should be in place. From these discussions, the working group will formulate specific recommendations to bring before the advisory committee.

C. SOLICIT PUBLIC INPUT

The working group unanimously agreed that a critical component of its mission is to inform the general public (in the broadest sense) about the Human Genome Initiative and to solicit from them their questions and concerns about human genome research.

The town meeting format was considered appropriate for soliciting public input. However, to be effective such meetings must be carefully planned, taking into consideration the need to reach a broad cross section of the public, and factors such as site, selection of participants, and wide publicity. A meeting of this type is tentatively planned for early 1991, or the end of the first year of this plan.

D. SUPPORT OF EDUCATION

The human genome program should include a strong educational component involving both formal and informal education targeted to all educational levels. It is suggested that NIH collaborate with NSF to develop model curricula that would be appropriate for the following groups: students at all levels, the media, medical practitioners, genetic counselors, scientists, teachers, and groups targeted for genetic services. Because NSF has

experience in curriculum development, the working group believes that co-funding of appropriate NSF programs would be an efficient way for NIH to accomplish its goals in this area. In addition, a program of individual postdoctoral fellowships, such as those funded in the scientific components of the human genome project, are recommended for support of individuals who have doctoral degrees in biomedicine and want to pursue studies in the ethical, legal, or social aspects of human genome research or vice versa.

Additional activities which should be pursued are:

- short courses in ethical, legal, and social aspects of human genome research for scientists; and

- short courses in genomics for scholars from the humanities who want to do research on the ethical, legal and social implications of the genome project.

E. INTERNATIONAL COLLABORATION

The working group supports the concept of international collaboration in this area under guidelines similar to those for biomedical research on the human genome. Collaborative projects should be supported by funds from all the participants in the collaboration. The Human Genome Organization (HUGO) could play an obvious role in this area, which would be welcomed.

The Human Genome Initiative will have a profound impact on the lives of people in all countries, including those without genome research programs. Ideally, representatives from all interested countries should participate in considering the issues that will arise. An international organization, such as UNESCO, could facilitate cooperation in this area.

Diseases and the suffering they cause respect no geographical boundaries. The sharing of results from the Human Genome Initiative across geographical barriers must be encouraged. Although differences exist cross culturally in the use of genetic information, the working group hopes that there are also sufficient similarities so that its efforts can be useful to all.

Ask Eric about this: "tell a story."

DRAFT

Add: to refine research a why get together, what when, why what conclude.

First Workshop of the
Joint Working Group on the Ethical, Legal and Social Issues
Related to Mapping and Sequencing the Human Genome

Williamsburg, Virginia
February 5-6, 1990

Summary

With 3 percent of the National Center for Human Genome Research's annual budget tagged for research on the social, ethical, legal, and economic implications of mapping and sequencing the human genome, the center will become the largest public benefactor of "bioethics" research in this country. To help identify areas where this money can be best spent, a working group of advisors met recently to discuss the genome project's bioethics research agenda with experts from sociology, history, ethics, genetic counseling, law, labor, the insurance industry, disability, and journalism.

The human genome project is an international research effort to decipher completely the entire set of genetic instructions inside human cells. Genome project research will inevitably give biomedical researchers new and powerful tools to identify disease-causing genes and to develop better treatments for the health problems they create. If misinterpreted or misused, these new tools could open doors to psychological anguish, stigmatization, and discrimination for people who carry these genes.

Issues raised by access to genetic information are not unique to the genome project. Nevertheless, new technologies

developed as part of the project are likely to increase the type and amount of information that can be obtained from examining genetic material. Because this may amplify the possibilities for misuse of genetic information, the working group is committed to identifying and addressing these issues before the technology is developed.

In the United States, the human genome project is spearheaded by the NIH's National Center for Human Genome Research (NCHGR) and the Department of Energy's (DOE) Human Genome Program. The NIH-DOE working group on ethical, legal, and social issues related to mapping and sequencing the human genome is made up of members selected for their expertise in ~~matters~~ those aspects — ethics, law, + social issues — relevant to the genome project ~~issues~~. The group has been given the task of identifying the ethical, legal, social, and economic issues raised by availability of human genetic information and the emerging powers to alter genes, and to help guide policy decisions in these areas.

[This is not great. I'm sure you can do better than my effort here.]

On February 5 and 6th, the eight-member working group, chaired by Dr. Nancy Wexler, of the Hereditary Disease Foundation and Columbia University, hosted ten outside experts at a Williamsburg, Virginia workshop. The meeting opened with a general discussion of issues considered important from the point of view of each participant's expertise and experience. These included:

1. Education. To facilitate informed public discussion of its social implications, factual information about the human genome project needs to

reach the lay public, students, and professionals. This information should clearly identify the limitations of the project and human genetics, as well as their promise. This may be done by developing school curricula containing genome project science and concepts and by tying into information outlets such as the mass media, religious institutions, health volunteer associations, and health professionals.

2. History. An awareness of the history of abuse of genetics is necessary to avoid the pitfalls of the past. In times of social or economic uncertainty, eugenic attitudes have emerged as intolerance certain individuals and states of health as being economic burdens on society.

? Thought is right but grammar isn't.

3. Privacy. How should the privacy of genetic information be protected? Present statutes concerning ownership of information or a patient's right to privacy do not guarantee confidentiality of medical information. ~~Such information may be exposed to several layers of access,~~ Several institutions and individuals may desire access to it, including the patient, the medical institution, and the state.

4. Medical insurance. New genetic tests may identify larger groups of people who carry genes predisposing them to common illnesses. How will this information ~~impact on~~ affect their

ability to obtain affordable insurance from a private carrier? Can reasonable new criteria and formulas for identifying who is insurable and for setting premium rates be generated?

5. Clinical Services. Availability of detailed genetic information will have tremendous impact on medicine. This may be particulary acute for latent, serious genetic diseases for which there are no cures. The recent development of a screening test for cystic fibrosis will provide an instructive model from which to study many of these issues. Genetic technologies are also likely to pave the way for the use of drugs such as hormones, growth factors, and immune system boosters, made by gene-splicing techniques. ~~Many~~ Some of these drugs are now approved for treatment of hormone-deficiency diseases, but have also been used illicitly by athletes as performance-enhancing drugs. The increasingly widespread availability of genetically engineered drugs to the general population raises many ethical questions about the use of such substances to enhance biological "fitness" of healthy people.

[I only know of 2 now for sale — hGH + EPO.]

Good!

6. Commercialization of Genome Technologies. As more genes are identified and screening tests developed, guidelines for technology transfer from research laboratories to the private sector need to be in place. Commercialization of screening tests also raises questions of quality control and

how these devices should be regulated by appropriate government agencies.

After consideration and discussion of those topics, workshop participants focused on developing priority areas.

1. **Tracking the cystic fibrosis experience.** The recent identification of the gene responsible for cystic fibrosis has paved the way for development and commercialization of methods to determine a person's carrier status and to identify affected fetuses. There is currently no cure for cystic fibrosis and treatments are mostly palliative; children born with this disease usually die in young adulthood. Because technologies developed as part of the human genome project will likely increase the number of disease genes identified (and the subsequent development of other testing methods), tracking and examining in detail the cystic fibrosis experience promises to provide an instructive model of the full range of issues of interest to the human genome project. These issues include:

i) transfer of technology from research laboratories to private industry for development and marketing;

ii) accuracy and quality control of genetic test ~~kits~~;

iii) the impact of information obtained from genetic tests on genetic counseling options;

iv) the role of insurance companies in covering medical costs of affected patients who were identified by prenatal tests;

v) ethical and legal responsibilities ~~liability~~ of clinicians ~~who fail~~ to perform genetic testing;

vi) confidentiality of information obtained from genetic testing;

vii) the psychological impact on patients and family members of information about one's medical fate, especially on for those predicted to develop illnesses for which there are no cures.

These issues may be examined through scholarly research, commissioned papers, workshops or conferences.

2. The effect of genetic information on insurance coverage. Because genetic tests may predict health outcomes, their use by private insurance companies to determine an applicant's financial liability has become an important issue. Increased availability of genetic tests may identify new and large groups of people who may be genetically predisposed to common disorders, such as heart disease, cancers, diabetes mellitus, immune disorders, etc. How will private insurers use this information to calculate the financial risk of insuring individuals who carry these genes? Studies are needed to identify how and which genetic information would be used to assess a population's insurance risk, to define a person as insurable, or to deny coverage ~~are needed.~~

In addition, the impact of so-called "good genes" on health insurance coverage may need to be assessed. Currently, reductions in premiums are given for health-promoting behaviors such as not smoking, exercise, and limited alcohol intake.

Should similar rewards be given to people who carry tumor-suppressor genes, toxin-resistance genes, or genetically hearty immune systems?

Most private insurers do not now use results of genetic tests to determine who they will insure. However, insurance companies feel they should have access to such information to offset its use by policy holders who might withhold adverse genetic information to receive lower premium rates. Because private insurance companies operate as for-profit businesses, people with genetic diagnoses may be forced to turn to other sources of affordable coverage. The working group suggested that research into alternate sources of health insurance for people with genetic diseases is needed. These alternatives may include government co-payment, employer benefits or self-insurance systems, or combinations of these. Such genetic testing may lead to more fundamental change in our system of health insurance.

3. **Education and outreach:** Clinicians, journalists, and other workshop participants who frequently deal with the general public observed that the public at large seems uninformed or to hold strong misconceptions about the powers of medical genetics and the role of genes in biology, disease, and behavior. ~~Formal~~ Careful assessments of public understanding of medical genetics and genome project science will help refine and target education and outreach programs. Resolving misconceptions is important so that informed debate and public discussion of the social implications of the human genome project can be grounded in fact.

Education efforts should be designed to demystify genetics and genome project science by bringing these topics into the public domain. In addition to underscoring the science and medical benefits likely to stem from genome project research, special precautions should be made not to hype or overpromise. Determining the complete sequence of human DNA will not produce immediate cures or knowledge of gene function. The genetic alteration responsible for sickle cell anemia, for example, has been known since the mid-1970s, ~~still~~ yet no genetic cure has been developed. Similarly, the complete sequence of human mitochondrial DNA is now known, but its function still remains a mystery.

The general public, health professionals, and genetic counselors, for example, should be made aware of the many factors aside from genetic makeup that influence human function and behavior. The ability to read a person's complete genetic makeup and make biological predictions may intensify the notion of "genetic determinism"--the idea that genes alone direct a person's biological (and perhaps social) fate. Education efforts should include discussions of the role of environment and other factors in social, behavioral, and biological development.

The opportunity to examine genetic material of large numbers of people will likely force a redefinition of the concepts of "normal," health, and disease. As knowledge about these concepts changes, it is important to adopt a value-neutral language in ~~order~~ be sensitive to the distorting effects of language

education, outreach, and counseling programs when referring to the wide variations in human genetic composition. Genetic difference does not equal genetic inferiority.

A first step toward education and outreach will require identifying organizations and institutions in place for dissemminating information to target groups. These may include decision makers in the mass media and school systems, as well as health volunteer associations, organizations for medical and allied health professionals, labor groups, policy makers, and religious groups.

Open dialogue between the working group and members of genetic disease and disability groups is essential to ensure that recommendations of the joint working group may best address the needs of people most likely to be affected by availability of genetic information.

Development of education and outreach programs may be funded in collaboration with genome project education programs of other agencies.

4. Confidentiality. As genetic testing technology becomes more widely availalble, access to genetic information by the individual, family, employers, insurance companies, and other institutions will have an increasing impact on personal privacy. Since laws protecting rights to privacy do not necessarily protect regulation or flow of medical information, areas should be identified where breakdowns in privacy are most likely to occur. Workshop participants identified three current levels of confidentiality of medical information: patient; medical

institution; and state. In addition, large, computerized databases now exist for storing "~~confidential~~" medical information, such as that gathered by insurance companies. Guidelines for responsible use of such information should be established. These guidelines should address: consent to be tested; the patient's right to know or not to know his/her test results; how information is used by physicians to make decisions about medical care; and how information may be used by a patient's family.

To implement working group recommmendations, NCHGR and DOE may fund projects initiated by the research community or invite applications from groups with appropriate expertise. Other mechanisms include contracts, which allow more oversight by the agencies, workshops, establishment of task forces, commissioned papers and reports.

A list of workshop participants is attached.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
Building : 31
Room : 4B04
(301) 496-xxx 402-0911

RJ

April 5, 1990

Benjamin J. Barnhart, Ph.D.
Manager
Office of Health and Environmental Research
Human Genome Program
ER-72
U.S. Department of Energy, GTN
Washington, D.C. 20545

Dear Dr. Barnhart:

Enclosed as promised, but a little later than promised, is a draft summary of the February workshop held by the Joint Working Group on Ethical, Legal, and Social Issues Related to Mapping the Human Genome. Please review it, remembering that it will be a public document in its final form. You may direct your comments to me by FAX, (301) 402-0837; by phone, (301) 402-0911; or by mail at the address listed above.

If I do not hear from you within two weeks from the above date, I will assume you have no changes.

On behalf of the working group, I thank all of you for your participation and thoughtful comments.

Sincerely,

Leslie

Leslie Fink
Chief, Office of Human Genome Communications
National Center for Human Genome Research

74/2

USDOE GTN COMM CTN TEL: 301-353-4767 Apr 13,90 12:13 No.023 P.02

DRAFT

NIH-DOE

RJ

First Workshop of the
Joint Working Group on the Ethical, Legal and Social Issues
Related to Mapping and Sequencing the Human Genome

Williamsburg, Virginia
February 5-6, 1990

Summary

With 3 percent of ~~the National Center for Human Genome Research's annual budget~~ this nation's annual budget for the human genome project tagged for research on the social, ethical, legal, and economic implications of mapping and sequencing the human genome, the ~~center~~ NCHGR at NIH and the DOE's Human Genome Program will become the largest public benefactor of "bioethics" research in this country. To help identify areas where this money can be best spent, a working group of advisors met recently to discuss the genome project's bioethics research agenda with experts from sociology, history, ethics, genetic counseling, law, labor, the insurance industry, and journalism.

is this true? I should we say "a major"

The human genome project is an international research effort to decipher completely the entire set of genetic instructions inside human cells. Genome project research will inevitably give biomedical researchers new and powerful tools to identify disease-causing genes and to develop better treatments for the health problems they create. If misinterpreted or misused, these new tools could open doors to psychological anguish, stigmatization, and discrimination for people who carry these genes.

Issues raised by access to genetic information are not unique to the genome project. Nevertheless, new technologies

74/3

USDOE GTN COMM CTN TEL: 301-353-4767 Apr 13,90 12:13 No.023 P.03

developed as part of the project are likely to increase the type and amount of information that can be obtained from examining genetic material. Because this may amplify the possibilities for misuse of genetic information, the working group is committed to identifying and addressing these issues before the technology is developed.

In the United States, the human genome project is spearheaded by the NIH's National Center for Human Genome Research (NCHGR) and the Department of Energy's (DOE) Human Genome Program. The NIH-DOE working group on ethical, legal, and social issues related to mapping and sequencing the human genome is made up of members selected for their expertise in matters relevant to genome project issues. The group has been given the task of identifying the ethical, legal, social, and economic issues raised by availability of human genetic information and to help guide policy decisions in these areas.

On February 5 and 6th, the eight-member working group, chaired by Dr. Nancy Wexler, of the Hereditary Disease Foundation and Columbia University, hosted ten outside experts at a Williamsburg, Virginia workshop. The meeting opened with a general discussion of issues considered important from the point of view of each participant's expertise and experience. These included:

1. Education. To facilitate informed public discussion of its social implications, factual information about the human genome project needs to

USDOE GTN COMM CTN TEL: 301-353-4767 Apr 13,90 12:13 No.023 P.04

reach the lay public, students, and professionals. This information should clearly identify the limitations of the project and human genetics, as well as their promise. This may be done by developing school curricula ~~containing~~ concepts and science projects related to the genome project ~~science and concepts~~ and by ~~tying into~~ utilizing information outlets such as the mass media, religious institutions, health volunteer associations, and health professionals.

2. History. An awareness of the history of abuse of genetics is necessary to avoid the pitfalls of the past. In times of social or economic ~~uncertainty~~, eugenic attitudes ~~have emerged as intolerance~~ toward certain individuals and states of health ~~as being~~ which may be regarded as economic burdens on society.

3. Privacy. How should the privacy of genetic information be protected? Present statutes concerning ownership of information or a patient's right to privacy do not guarantee confidentiality of medical information. Such information may be exposed to several layers of access, including the patient, the medical institution, and the state.

4. Medical insurance. New genetic tests may identify larger groups of people who carry genes predisposing them to common illnesses. How will this information impact on their

USDOE GTN COMM CTN TEL: 301-353-4767 Apr 13,90 12:13 No.023 P.05

ability to obtain affordable insurance from a private carrier? Can new criteria and formulas for identifying who is insurable and for setting premium rates be generated?

5. Clinical Services. Availability of detailed genetic information will have tremendous impact on medicine. This may be particulary acute for latent, serious genetic diseases for which there are no cures. The recent development of a screening test for cystic fibrosis will provide an instructive model from which to study many of these issues. Genetic technologies are also likely to pave the way for the use of drugs such as hormones, growth factors, and immune system boosters, made by gene-splicing techniques. Many of these drugs are now approved for treatment of hormone-deficiency diseases, but have also been used illicitly by athletes as performance-enhancing drugs. The increasingly widespread availability of genetically engineered drugs to the general population raises many ethical questions about the use of such substances to enhance biological "fitness" of healthy people.

6. Commercialization of Genome Technologies. As more genes are identified and screening tests developed, guidelines for technology transfer from research laboratories to the private sector need to be in place. Commercialization of screening tests also raises questions of quality control and

USDOE GTN COMM CTN TEL: 301-353-4767 Apr 13,90 12:13 No.023 P.06

how these devices should be regulated by appropriate government agencies.

After consideration and discussion of those topics, workshop participants focused on developing priority areas.

1. **Tracking the cystic fibrosis experience.** The recent identification of the gene responsible for cystic fibrosis has paved the way for development and commercialization of methods to determine a person's carrier status and to identify affected fetuses. There is currently no cure for cystic fibrosis and treatments are mostly palliative; children born with this disease usually die in young adulthood. Because technologies developed as part of the human genome project will likely increase the number of disease genes identified (and the subsequent development of other testing methods), tracking and examining in detail the cystic fibrosis experience promises to provide an instructive model of the full range of issues of interest to the human genome project. These issues include:

i) transfer of technology from research laboratories to private industry for development and marketing;

ii) accuracy and quality control of test kits;

iii) the impact of information obtained from genetic tests on genetic counseling options;

iv) the role of insurance companies in covering medical costs of affected patients who were identified by prenatal tests;

USDOE GTN COMM CTN TEL: 301-353-4767 Apr 13,90 12:13 No.023 P.07

v) liability of clinicians who fail to perform genetic testing;

vi) confidentiality of information obtained from genetic testing;

vii) the psychological impact on patients and family members of information about one's medical fate, especially on for those predicted to develop illnesses for which there are no cures.

These issues may be examined through scholarly research, commissioned papers, workshops or conferences.

2. The effect of genetic information on insurance coverage. Because genetic tests may predict health outcomes, their use by private insurance companies to determine an applicant's financial liability has become an important issue. Increased availability of genetic tests may identify new and large groups of people who may be genetically predisposed to common disorders, such as heart disease, cancers, diabetes mellitus, immune disorders, etc. How will private insurers use this information to calculate the financial risk of insuring individuals who carry these genes? Studies are needed to identify how and which genetic information would be used to assess a population's insurance risk, to define a person as insurable, or to deny coverage ~~are needed~~.

In a addition, the impact of so-called "good genes" on health insurance coverage may need to be assessed. Currently, reductions in premiums are given for health-promoting behaviors such as not smoking, exercise, and limited alcohol intake.

Should similar rewards be given to people who carry tumor-suppressor genes, toxin-resistance genes, or genetically hearty immune systems?

Most private insurers do not now use results of genetic tests to determine who they will insure. However, insurance companies feel they should have access to such information to offset its use by policy holders who withhold genetic information to receive lower premium rates. Because private insurance companies operate as for-profit businesses, people with genetic diagnoses may be forced to turn to other sources of affordable coverage. The working group suggested that research into alternate sources of health insurance for people with genetic diseases is needed. These alternatives may include government co-payment, employer benefits or self-insurance systems, or combinations of these.

3. **Education and outreach:** Clinicians, journalists, and other workshop participants who frequently deal with the general public observed that the public at large seems both uninformed and to hold strong misconceptions about the powers of medical genetics and the role of genes in biology, disease, and behavior. Formal assessments of public understanding of medical genetics and genome project science will help refine and target education and outreach programs. Resolving misconceptions is important so that informed debate and public discussion of the social implications of the human genome project can be grounded in fact.

Education efforts should be designed to demystify genetics and genome project science by bringing these topics into the public domain. In addition to underscoring the science and medical benefits likely to stem from genome project research, special precautions should be made not to hype or overpromise. Determining the complete sequence of human DNA will not produce immediate cures or knowledge of gene function. The genetic alteration responsible for sickle cell anemia, for example, has been known since the mid-1970s, still no genetic cure has been developed. Similarly, the complete sequence of human mitochondrial DNA is now known, but its function still remains a mystery.

The general public, health professionals, and genetic counselors, for example, should be made aware of the many factors aside from genetic makeup that influence human function and behavior. The ability to read a person's complete genetic makeup and make biological predictions may intensify the notion of "genetic determinism"--the ~~idea~~ misconception that genes alone direct a person's biological (and perhaps social) fate. Education efforts should include discussions of the role of environment and other factors in social, behavioral, and biological development.

The opportunity to examine genetic material of large numbers of people will likely force a redefinition of the concepts of "normal," health, and disease. As knowledge about these concepts changes, it is important to adopt a value-neutral language in

USDOE GTN COMM CTN TEL: 301-353-4767 Apr 13,90 12:13 No.023 P.10

education, outreach, and counseling programs when referring to the wide variations in human genetic composition.

A first step toward education and outreach will require identifying organizations and institutions in place for dissemminating information to target groups. These may include decision makers in the mass media and school systems, as well as health volunteer associations, organizations for medical and allied health professionals, labor groups, policy makers, and religious groups.

Open dialogue between the working group and members of genetic disease and disability groups is essential to ensure that recommendations of the joint working group may best address the needs of people most likely to be affected by availability of genetic information.

Development of education and outreach programs may be funded in collaboration with genome project education programs of other agencies.

4. Confidentiality. As genetic testing technology becomes more widely available, access to genetic information by the individual, family, employers, insurance companies, and other institutions will have an increasing impact on personal privacy. Since laws protecting rights to privacy do not necessarily protect regulation or flow of medical information, areas should be identified where breakdown in privacy are most likely to occur. Workshop participants identified three current levels of confidentiality of medical information: patient; medical

USDOE GTN COMM CTN TEL: 301-353-4767 Apr 13.90 12:13 No.022 P.11

RJ

institution; and state. In addition, large, computerized databases now exist for storing "confidential" medical information. Guidelines for responsible use of such information should be established. These guidelines should address: consent to be tested; the patient's right to know or not to know his/her test results; how information is used by physicians to make decisions about medical care; and how information may be used by a patient's family.

To implement working group recommmendations, NCHGR and the DOE program may fund projects initiated by the research community or invite applications from groups with appropriate expertise. Other mechanisms include contracts, which allow more oversight by the agencies, workshops, establishment of task forces, commissioned papers and reports.

A list of workshop participants is attached. 2

My correct name and address:

Benjamin J. Barnhart, Sc.D.
Manager, Human Genome Program
ER-72 GTN
Office of Health and Environmental Research
U.S. Department of Energy
Washington, DC 20545
(301) 353-5037 FAX: (301) 353-5051

7/12

USDOE GTN COMM CTN TEL: 301-353-4767 Apr 13,90 12:13 No.023 P.12

RT

MINUTES OF THE NIH-DOE WORKING GROUP ON ETHICAL, LEGAL AND SOCIAL ISSUES RELATED TO MAPPING AND SEQUENCING THE HUMAN GENOME

Second Meeting

Williamsburg, Virginia
February 6, 1990

Working Group Members: Jonathan Beckwith, Robert Cook-Degan, Patricia King, Victor McKusick, Robert Murray, Thomas Murray, Mary-Lou Pardue, and Nancy Wexler, Chairperson. Government Representatives: Benjamin Barnhart, Elke Jordan, Eric Juengst, Bettie Graham, and Leslie Fink.

The Working Group (WG) met from 2:00 p.m. to 5:00 p.m. following the conclusion of its first workshop to discuss what actions were required as regards the workshop and what should be the WG's next order of business. Below is a summary of its deliberations.

Follow-up Discussions from Workshop. The WG briefly reviewed the major topics discussed which were education, the media, confidentiality issues, and insurance. Education and insurance issues were considered to be of high priority. Regarding education, the WG agreed that there was a need for education at all levels including using popular magazines, television programs which try to weave public information messages into their plots, such as L.A. Law, television talk shows and PBS presentations. It ~~would~~ also be important to have meetings with decision-makers in the media, e.g. science and general reporting editors in addition to reporters. The WG also felt that individuals with high visibility such as Dr. James Watson and Admiral James Watkins could be encouraged to talk about the human genome project to a broader audience, with emphasis on education.

There was also a consensus that the WG needed more information about how insurance companies make decisions, such as which risks and what levels of risk are acceptable in insuring individuals. The WG also felt that without having an economist as a member, the WG would not have the expertise to make recommendations or evaluate how insurance companies calculate risk. One suggestion was to have a geneticist and actuary work together in predicting which genetic tests are likely to become available within the next five years and what effect this would have on actuarial

Also we should invite Stacy Lewis Sullivan to the Soc of Human Genetics meeting? It seems more likely that others like Charles Cantor could benefit the project? - discuss

7/1/13

data. Tracking the "CF Experience" was also considered important. The Institute of Medicine's proposed study on genetic services might address some of these issues and be considered a possible model for such a study.

Working Group as an Organization. The WG discussed in some detail its mission, selection of members, its name, and expansion to include additional expertise, interaction with interest/consumer groups and liaison with the European Community.

(1) Mission--Several members expressed concern that they did not have a clear understanding of the WG's mission. Was the WG a deliberative body or involved with outreach or strategy? The first report of the WG states that the group is responsible for defining and developing a plan of activities to address the ethical, legal, and social issues arising out of the application of knowledge gained as a result of the Human Genome Initiative. Thus, its role is one of planning and not doing, with the exception of activities that will assist the WG in refining the research agenda, such as putting on workshops and commissioning papers.

(2) Working Group's Name. The WG's name is often shortened to "Ethics Working Group." Some members felt that "ethics" was too narrow a definition of the WG's role and that this shortened name does not convey to the public the broader role and interest of the WG and the human genome program. Thus, some members suggested that the name be changed to reflect the true role and responsibilities of the program and ergo the WG. It was decided that the full title of the WG was appropriate and every effort should be made to use the full title when referring to the WG and the research grants program.

(3) Expansion of the Working Group. The WG discussed expanding the WG to include additional expertise. It was decided that two additional members would be desirable. The expertise areas considered were members of affected groups, theology, labor, industry, and economics. Members were asked to send suggestions, including names, to Dr. Graham.

(4) Interactions with Interest/Consumer Groups. There were several issues raised with respect to potential users of information resulting from the human genome project: (a) identifying these groups and inviting dialogue; (b) identifying a liaison who would receive on a regular basis information about the human genome program and be an appropriate participant at some meeting; and (c) being more proactive in dealing with interest/consumer groups. Some of the groups that may be interested in and need information about the human genome program include affected groups,

professional societies, American Colleges of Obstetrics and Gynecology and Pediatrics, insurance companies, theological groups, minority community, labor groups, and genetic counselors. The WG was asked to send to Robert Cook-Degan by February 28 the names of relevant interest/consumer groups. The WG also agreed that the next two workshops would be targeted to exchanging information with (a) several interest groups, in particular the Cystic Fibrosis community and the National Institute of Diabetes, Digestive, and Kidney Diseases and (b) representatives of the media and educational community.

(5) Liaison with the European Community. The WG agreed to have a representative from the Ethical, Legal and Social Aspects Working Party (ELSA), Human Genome Analysis Program of the European Community attend future WG meetings as an observer and the WG would have observer status with ELSA.

The meeting was adjourned at approximately 5:00 p.m. The time and place of the next workshop will depend on the availability of interest/consumer groups to meet with the WG. Efforts would be made to have another workshop within the next three to four months.

ETHICS WORKING GROUP

Jonathan R. Beckwith, Ph.D.
Department of Microbiology and
Molecular Genetics
Harvard Medical School
200 Longwood Avenue
Boston, MA 02115
617/732-1920 432-1920
617/738-7664 (FAX)

Robert Cook-Deegan, M.D.
National Center for Human
Genome Research
National Institutes of Health
Building 38A, Room 201
Bethesda, MD 20892
301/869-0066
301/869-2156 (FAX)

Patricia King, J.D.
Georgetown University Law Center
600 New Jersey Avenue, N.W.
Washington, DC 20001
202/662-9084
202/662-9444 (FAX)

Victor A. McKusick, M.D.
Division of Medical Genetics
Johns Hopkins Hospital
600 North Wolfe Street
Blalock 1007
Baltimore, MD 21205
301/955-6641
301/955-4999 (FAX)

Robert F. Murray, Jr., M.D.
Department of Pediatrics, Medicine,
Oncology, and Genetics
Box 75
Howard University College of Medicine
Washington, DC 20050
202/636-6340
202/745-3731 (FAX)

Thomas H. Murray, Ph.D.
Center for Biomedical Ethics
Case Western Reserve University
2119 Abington Road
Cleveland, OH 44106
216/368-6196
216/368-3128 (FAX)

Mary Lou Pardue, Ph.D.
Department of Biology
Room 16-717
Massachusetts Institute of Technology
Cambridge, MA 02139
617-253-6741

Nancy S. Wexler, Ph.D.
Hereditary Disease Foundation and
Department of Neurology and Psychiatry
College of Physicians and Surgeons of
Columbia University
722 West 168th Street, Box 58
New York, NY 10032
212/960-5650
212/960-5624 (FAX)

Scotch® 7664 "Post-it" Routing-Request Pad

ROUTING - REQUEST

Please
- ☐ READ
- ☐ HANDLE
- ☐ APPROVE

and
- ☐ FORWARD
- ☐ RETURN
- ☐ KEEP OR DISCARD
- ☐ REVIEW WITH ME

Date _____

To Benjamin J. Barnhart, Ph.D.
Manager
Office of Health & Environmental
Research
Human Genome Program
ER-72
U.S. Dept. of Energy, GTN
From Washington, D.C. 20545
301-353-3683

PARTICIPANTS FOR ETHICS WORKSHOP
FEBRUARY 5-6, 1990
WILLIAMSBURG, VIRGINIA

INVITEES

CLINICAL MEDICINE

Elena Gates, M.D.
Assistant Professor of
Obstetrics & Gynecology
University of California
Medical Center
400 Parnassus
San Francisco, CA 94143-0346
415/476-4492

ETHICS

Ms. Adrienne Asch
Associate in Social Sciences
and Policy
New Jersey Bioethics Commission
CN061
Trenton, NJ 08625-0061
609/275-8714

JOURNALISM

Dr. Thomas Goldstein
Dean, School of Journalism
Northgate Hall
University of California - Berkeley
Berkeley, CA 94720

LAW

Steven P. Goldberg, J.D.
Professor of Law
Georgetown University
600 New Jersey Avenue, N.W.
Washington, DC 20001
202/662-9034

INSURANCE

Robert J. Pokorski, MD, FACP
Second Vice President
Medical Director - Lincoln National Life Ins.
300 S. Clinton Street
P.O. Box 1110
Fort Wayne, IN 46801
(219) 427-3034

SOCIOLOGY

Dorothy Nelkin
Professor
Department of Sociology
School of Law
New York University
269 Mercer Street
New York, NY 10003
212/998-8347

EUGENICS

Dr. Robert Proctor
The New School for Social Research
66 West 12th Street
New York, NY 10011

LABOR

Sheldon W. Samuels
Executive Vice President
Workplace Health Fund
Industrial Union Department
AFL-CIO
Washington, DC 20006
212/842-7830

Dr. Robert Nussbaum
Department of Human Genetics
University of Pennsylvania
School of Medicine
Clinical Research Building, Room 475
422 Curie Blvd.
Philadelphia, PA 19104-6145
215/898-1012

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Memorandum

Date: 13 March, 1990

To: Nancy Wexler FAX TO Venezuela [redacted]

From: Leslie Fink, Office of Communications, NCHGR

Subject: Workshop summary and other items

Nancy:

Finally a reasonable draft (I think) summary of the Williamsburg workshop for your review. Eric Juengst has had a look at it, and I've incorporated his comments.

Two other items:

1. I mentioned before you left that ABC is doing a "documentary" (or as close as you can get on network television) about medical technology, the information it gives us, and how we make decisions based on that information. They are including the human genome project and want to focus on genetic information and how it is used. They are enchanted that we have an ethics working group and are interested in including our approach in their documentary. As I mentioned, they would very much like to interview you [Barbara Walters will interview Jim Watson.] in this context. Please let me know if you are so inclined and if you will be able to fit it into your April calendar.

2. Also, WNET, Channel 13 in New York is on to another series about "The Future of Medicine." It's being put together by the same folks who did The Brain and The Mind. We are working with them to see how we would fit into their 8-part series [and whether and how much money we want to give them]. As you know, WNET produces educational materials in conjunction with their series, and we feel we could get a lot of bang for our educational buck if things turn out to be mutually agreeable. They are also interested in chatting with you about our ethics component. Their producer, Stefan Moore indicated that you might get a call from Richard Hutton when you return.

I hope all is going well for you there. We are slogging through as usual.

Leslie

The Potential Impact of Genetic Testing on Private Insurance

Robert Pokorski, MD, FACP

Contents

002 SOS TNT 18:28 05/05/90

INTRODUCTION

Good afternoon. I am Dr. Robert Pokorski, a medical director of Lincoln National Life Insurance Company. I would like to thank the Gannett Foundation and The Foundation for American Communications for co-sponsoring this meeting and providing me with an opportunity to visit with you today.

My primary focus on a day-to-day basis concerns the medical aspects of life insurance. This will be reflected in the prepared remarks that follow. I have, however, been accompanied by representatives from the American Council of Life Insurance and the Health Insurance Association of America who will be able to provide additional information in answer to questions that extend beyond my field of expertise.

Before addressing some of the specific concerns that will arise as a result of genetic testing, I would like to make a few general comments regarding insurers' perceptions of genetic tests at the present time.

From an underwriting point of view, insurers wish that genetic tests had not been developed. The current risk selection practices used by insurance companies have generally been accepted by the medical community and insurance-buying public, and these practices have permitted millions of people to purchase private insurance protection at an affordable price.

But diagnostic and therapeutic advances in the practice of medicine are both inevitable and desirable. Genetic testing represents such an advance. It will be thrust on a society that has had little experience in dealing with many of the complex ethical, medical, and social issues that will arise. Many facets of society -- including the private insurance industry -- will need to study the potential impact of this new technology and adapt.

Insurers have no current interest in nor enthusiasm for using genetic tests. Why? In the near future, these tests will probably deal with fairly uncommon impairments and/or the use of genetic tests will be reserved for selected situations in which the individual is thought to be at significant risk for developing a genetic disorder.

But at some point in the future, genetic testing may become standard practice within the medical community. Having a panel of genetic tests performed may be as routine as having a cholesterol or blood sugar done. If and when this occurs, insurers will be forced to consider ordering genetic tests themselves. Such an action might be taken to enhance the risk selection process but even more likely it would be a defense against insurance applicants' use of significant knowledge about their potential health and longevity.

PRINCIPLES OF INSURANCE AND RISK CLASSIFICATION

A great deal of the present concern regarding future use of genetic tests by insurers stems from a lack of knowledge of the basic tenets of private, voluntary insurance. For this reason, I would like to briefly overview some of the fundamental principles of insurance before directly addressing issues associated with genetic testing.

Insurance is intended to provide financial protection against unexpected or untimely events. In particular, life and health insurance are purchased not in anticipation of imminent death or illness -- although it's understood that death is inevitable and serious illness is fairly common. Rather, life insurance is obtained to protect dependents or business associates from the financial disadvantages that can occur in the event of unexpected death and health insurance is meant to provide protection in the event of a significant financial loss associated with an unanticipated illness.

How does private insurance work? Basically, policyholders pay a relatively small, affordable amount into a common "pool" and the benefits of that pool are distributed to the unfortunate few who die (life insurance), become disabled (disability insurance) or develop a serious illness (health insurance). In this way, the financial loss attendant to these events can be mitigated even though the events themselves cannot be prevented.

But not all people are alike. The likelihood of occurrence and magnitude of loss will vary. Some people will apply for large amounts of insurance and others for small amounts. Some *will be young* and others elderly. Occupations and avocations will modify the likelihood of unexpected death or

illness, as will health enhancing activities such as exercise, proper diet, and nonsmoking. And some applicants will already be in poor health or at known significant risk of developing poor health in the future.

These different factors are evaluated by the insurance company through a process known as "risk selection and classification." The more common term for this is "underwriting." By means of this process, the insurance company determines the appropriate contribution to the risk pool by an individual policyholder.

The fundamental underlying goal of the underwriting process is equity: policyholders with the same or similar expected risk of loss are charged the same. The higher the risk, the higher the premium. The lower the risk, the lower the premium. Note the distinction between equity and equality. With equity, premiums vary by risk; with equality, everyone -- young/old, healthy/ill, and with/without associated factors that significantly increase the likelihood of experiencing an early claim -- would pay the same price.

During the underwriting process, risk classifications are created that recognize the many differences that exist among individuals in order to place applicants into groups with comparable expectations of longevity and health. Although the risk presented by any single individual cannot be determined with absolute precision, if people are assigned to groups with reasonable accuracy and the total number of insured persons is large, then the estimate of the risk of the entire group of insured people is likely to be accurate.

Traditionally, characteristics of importance for risk classification have included factors such as age, gender, health history, physical condition, occupation, the use of alcohol and tobacco, family history, and serum cholesterol. These factors serve to identify individuals that have a greater or lesser likelihood of premature death or illness in the future. Because of this process, costs are held down for the great majority of insurance applicants since premiums more closely match the risks taken on by the insurance company.

Adverse selection, also known as antiselection, is a consideration that is of great importance to insurers. Adverse selection is a well known phenomenon in which people with a likelihood of loss greater than what they are charged for tend to apply for or continue insurance coverage to a greater extent than do other people. It occurs when applicants withhold significant information from the insurer and/or choose amounts and types of insurance that are most beneficial to themselves. For example, someone with a history of heart disease is more likely to apply for insurance and/or apply for a greater amount of insurance coverage than he would have otherwise done because he knows that he is likely to experience a claim in the foreseeable future. If he fails to mention this important information on his insurance application and the insurer does not otherwise become aware of it, the premium charged by the insurer will be insufficient to cover the risk involved. This premium deficit would be made up by the others in the pool who have paid their fair share.

Adverse selection also occurs if the insurer is not permitted to obtain or use information that is pertinent to the risk being considered. In the example above, the premiums charged would be insufficient to cover the risk involved if the insurer was not permitted to ask the proposed insured and his attending physician about the nature and severity of the heart disease, or if this information could not be used after it had been obtained.

What would happen if the insurance company was unaware of important unfavorable information that was known to the applicant? In these instances, serious errors in risk classification would occur. Certain individuals would receive their insurance at unreasonably low cost. More claims would be filed than were expected. And if a significant number of these risk classification errors were made, the financial status of the entire insurance pool would be adversely affected.

But couldn't premiums simply be increased across-the-board to cover the payment of these unanticipated benefits? Where permitted, an insurer could increase premiums to reflect these revised claims expectations. But this would encourage potential insurance applicants who are at lower risk to either buy from a different seller or exit the insurance market altogether. And with the exodus of the lower risk insureds who were subsidizing the individuals who had knowledge of their unfavorable

Higher overall premiums to offset effects of high-risk pts may drive healthy people from risk pool

By denying insurance to high-risk folks, costs are held down for entire pool.

premiums $\downarrow$ only sick stay in pool.

risk status -- individuals who had adversely selected against the insurance pool -- a further escalation of premiums becomes necessaary. More potential applicants then decide not to apply for insurance.

Eventually, a point is reached in this upward spiral where the desired coverage becomes unavailable on any reasonable premium basis or the insurer becomes financially unsound. This "assessment spiral" phenomenon is not a theoretical possibility. It actually occurred in some companies during the 1880's and early 1900's because of poor risk classification practices.

TYPES OF GENETIC TESTS

Conceptually, genetic disorders can be divided into two broad groups: (1)diseases with a genetic predisposition, and (2)genetic diseases.

Diseases with a genetic predisposition (or a genetic component) are those in which the presence of a gene confers an increased tendency to develop a certain disorder. The disorder may or may not develop depending on a variety of associated personal and environmental factors such as geographic location, diet, exposure to harmful chemicals or toxins, exercise, obesity, tobacco use, heavy alcohol ingestion, and so on. A genetic predisposition is often a factor in the development of common impairments such as cancer, coronary heart disease, hypertension, diabetes mellitus, and epilepsy. Together these disorders are responsible for much of the morbidity and/or mortality that is experienced by the insurance pool.

Genetic diseases are disorders in which the genetic component is so overwhelming that it is expressed in a predictable manner without a requirement for environmental interaction. For example, an individual who inherits the gene for Huntington's disease, cystic fibrosis, or Duchenne muscular dystrophy will eventually develop the disorder regardless of other socioeconomic factors or preventive health measures. Individual genetic diseases are rare compared to diseases with a genetic predisposition but collectively they are an important cause of morbidity and mortality.

Attending physicians will probably begin to use new diagnostic tests that can identify genetic diseases and diseases with a genetic predisposition shortly after they are developed. As mentioned above, insurers have no current interest in ordering such tests themselves. But although they may prefer to avoid ordering genetic tests, it could be very important that insurers have access to prior test results. Why? If this information were unavailable to the insurer at the time of underwriting, then applicants who already knew via tests performed by their attending physicians that they were likely to experience early death or illness could buy large amounts of insurance coverage at prices that failed to reflect this increased risk. In the aggregate, this could involve disproportionately large numbers of applicants and/or very significant amounts of insurance. The ensuing claims would markedly exceed projected losses and everyone within the insurance pool would suffer.

Consider the following scenario.

Suppose that a man who applies for an individual life or noncancelable disability insurance policy has had a genetic test performed in the past by his attending physician, the results are unfavorable, i.e., the test suggests a significant likelihood of premature death or disability, and the insurance company does not learn about this result. If no other unfavorable risk factors are known in this case, the policy is issued on a standard class basis.

What has happened? Essentially, the principle of equity has been violated. This applicant with an above average claim risk has obtained insurance at standard rates. This situation is very analogous to that of an older person who misrepresents his true age and obtains insurance at the rates of a much younger person. It is important to note that he has not suddenly become a standard insurance risk because he was issued standard insurance. Rather, he is a substandard risk who has nonetheless obtained insurance at standard rates because of a failure of the underwriting process.

Although the applicant would be pleased with this arrangement, the other policyholders would be very unhappy with this sequence of events. True, he currently seems in good health. But his unfavorable genetic test clearly identified a significantly increased risk. And since his insurance coverage cannot be canceled once it has been purchased nor can the premium be increased relative to other policies issued to individuals with similar coverage, it is

05/30/90 16:07 LNL 505 005

likely that he will be paid benefits from the pool that are disproportionate to the premiums he has paid.

PRIVATE AND PUBLIC INSURANCE

Many people have come to expect that private life insurance and, to a greater extent, private health insurance, is an entitlement, i.e., that all citizens have a right to expect that affordable insurance protection will be made available to them regardless of age or health. This expectation is based to a considerable degree on misconceptions regarding the nature of private and public insurance programs. A brief discussion of these two different types of insurance will help clarify their relationships.

PRIVATE (VOLUNTARY) INSURANCE

Participation in a private commercial insurance plan typically is voluntary. You choose whether or not to belong and determine how much insurance protection you would like to purchase. Since all of the funds used to pay future claims against the insurance pool are derived either directly or indirectly from premium payments, risk classification is essential in order to ensure that the premium charged is proportionate to the risk assumed. The potential for adverse selection is very real and an important concern of the insurer. Finally, private insurance companies are businesses that are accountable to their policyholders and stockholders. They must generate a profit for those who have invested in the company. If insuffient premiums are collected, a private insurance company, like any other business in which liabilities exceed assets, will cease to exist.

PUBLIC (INVOLUNTARY) INSURANCE

American society has used private means to fulfill certain general social welfare needs such as payment for health care. But private health insurance has never been a completely adequate or universal method of providing access to the health care system, nor has it been a perfect mechanism for covering all diseases. The poor, disabled, aged, or seriously ill cannot always be covered by private means. For this reason, society has supplemented private insurance with publicly supported programs such as Social Security, Medicaid and Medicare.

Participation in a public insurance plan is typically not voluntary. You do not choose whether or not to belong nor do you determine how much insurance protection you will have. Rather, participation is mandatory and benefit amounts or entitlements are determined by the law establishing the program.

Since everyone -- good risks, poor risks, even those suffering from a severe or terminal illness -- is automatically insured and there are no options regarding the amount of benefits that will be paid, adverse selection is not a concern. Premiums are charged in the form of income and social security taxes, or so-called "insurance premiums", but they are not and need not be proportionate to the risk assumed. Risk selection is not required and no profit motive exists.

Even given these fundamental differences between private commercial insurance and public insurance, couldn't legislators or regulators simply mandate that private insurers provide coverage -- at rates appropriate for lower risks -- to those individuals who have learned from their attending physicians or an insurer that a genetic test has identified a higher likelihood of premature death or illness? Or, in an action having the same consequences, couldn't insurers be prohibited from asking applicants and their attending physicians for the results of prior genetic tests or ordering their own tests?

There seems little chance that this would work a private, voluntary insurance industry. This mandated subsidization of unfavorable risks by good risks would be tantamount to an indirect governmental tax levied solely against insurance policyholders and stockholders. The impact of such an action may not appear significant at the outset but its cumulative effects would be dramatic.

Under such a scenario, many potential policyholders -- primarily favorable risks who would be asked to subsidize the higher, underpriced risks, and people with other health impairments such as cancer and heart disease who pay a premium commensurate with their increased risk -- would realize that they are being overcharged or treated unfairly, and choose to not buy insurance because coverage has

SDO SDS LNL 16:41 03/05/30

now become unaffordable for them.

Why? Wouldn't the premium increase be relatively small? Although such a plan for mandated benefits probably wouldn't result in significantly higher costs at first, premiums would gradually and progressively rise as more and more favorable risks decide not to purchase insurance. The relatively large base of good (standard) risks is progressively eroded, it becomes increasingly difficult to subsidize the poorer risks, and premiums increase again. The situation worsens even more as some companies decide to stop writing this type of insurance coverage altogether since a profit can no longer be expected.

Such a legislative or regulatory mandate would force insurers to provide coverage for a large (because of the effects of adverse selection) group of people at a price that would be insufficient to cover the claims that would occur. These additional costs would be passed directly to other policyholders with a subsequent decrease in insurance affordability and availability.

GROUP INSURANCE

The use of genetic tests by employers is an important topic that will be vigorously debated in the future. Although this is yet another issue not directly related to the use of genetic tests by insurers, it has nonetheless raised concerns that people who are insured through their place of employment (commercial group insurance) may find their coverage jeopardized. A brief overview of the differences between individual and group insurance is provided below in order to addresss this issue.

For individual life, disability, and health insurance, an applicant applies for whatever amount of insurance coverage that he or she feels is needed (within broad guidelines established by the insurance company). An application form is completed, medical questions are asked, tests may be ordered, and an attending physician's statement may be requested. The premium charged is based on factors such as age, gender, health history, general physical condition, and occupation.

Group life and health insurance is generally divided into two categories: medium to large size groups containing 10-25 or more employees, and small groups.

Under a medium to large size group life and health insurance plan, an employer buys a single policy for his employees. All employees can elect to receive coverage if they so choose. Benefit amounts are fixed by formula and individuals are normally not subjected to the underwriting process described above with the possible exception of those who choose not to participate in the program when they first become eligible and those who withdraw from the plan and later request reinstatement. Rather, the entire group is underwritten according to factors such as the number of employees, age and gender distribution, area of the country, and prior health care costs for the entire group. Once a rate is established, it is typically adjusted ("experienced rated") on a yearly basis depending on claims experience. If claims exceed expectations, rates increase. And vice versa. With such a large group, it is expected that some workers will be poor insurance risks. But the majority who are good risks tend to offset these few, thus allowing the insurer to offer coverage to the entire group at an affordable rate Typically, payment by the employer of part of the cost provides adequate incentive for the good risks to join the insured group.

Small group life and health insurance is different. Since these groups do not have the benefit of a large number of employees among whom the less healthy risks can be shared, claims experience is strongly dependent on the health of the small number of individuals within the group. For example, if one individual in the group was already ill or at significant risk of becoming ill in the near future, and the insurer was not aware of this information, then the claims submitted by this one individual could far exceed the claims expected from the entire group. To guard against this possibility, in the absence of underwriting, the insurer would have to increase the premium rates for all small groups. The increased premium rates would induce groups with more good risks not to buy coverage. An assessment spiral much like that described earlier for individual insurance would develop. And if such a practice occurred with any regularity, the cost of insurance to small groups would soon become unaffordable. For this reason, the underwriting of small groups shares

400 SOS TNT 16:42 05/05/90

many similarities with that used for individual insurance, e.g., the need for application forms, medical questions, and sometimes tests and attending physician's statements.

What will be the possible effect of genetic testing on group insurance? Approximately 90% of commercial group health insurance and perhaps a similar percent of group life insurance is sold to medium to large sized groups. The employees within these groups are eligible for insurance coverage as a benefit of their employment. There is no individual underwriting or testing of those who sign up for the program when the group plan goes into effect or when new employees begin work. For this reason, the overall impact of genetic testing on group insurance coverage will probably be minimal. For small groups, the ramifications are less certain. The effects may be more similar to those experienced in individual life and health insurance.

GENETIC TESTS AND RISK CLASSIFICATION

Insurers, like the rest of society, are just beginning to consider the impact of genetic testing on the private insurance industry. There are still far too many uncertainties to permit firm conclusions or projections for the future. With this caveat in mind, five points regarding the use of genetic tests to classify risks will now be discussed.

POINT #1. A MAJORITY OF INSURANCE APPLICANTS MAY BENEFIT DIRECTLY FROM THE USE OF GENETIC TESTS

Some critics of the use of genetic tests by insurers to classify risks assume that the results of these tests will generally be unfavorable, the affected applicants will be summarily declined, and insurance availability and affordability will diminish. Such a belief is ill-founded. In fact, the converse may be true. Genetic tests may very well increase the number of individuals who are eligible for insurance coverage due to the superior predictive value of these tests and the resultant improvement in risk classification. Many tests will indicate a very low probability of premature death or illness related to a particular genetic feature. This knowledge may permit insurance companies to lower the premiums for this quite sizable group of people and increase or at least maintain the same high percentage of people who are granted insurance at standard rates because their level of risk has now been more accurately estimated.

It is true that tests for genetic diseases (as opposed to diseases with a genetic predisposition) will be able to identify some people who will most certainly experience premature death or illness. Knowledge of such test results may lead to adverse underwriting decisions by insurers, i.e., extra premium payments or a declination. But at other times, these tests will offer significant benefits. For example, consider insurance applicants with a family history of Huntington's disease who have no manifestations of this disease themselves. Because it is not yet known if they have inherited the disease, they pose risks to the insurance pool that are very difficult to insure at reasonably low rates. But if a genetic test indicates that they are not carrying the Huntington's disease gene, then insurance coverage could be offered.

POINT #2. INSURERS SEEK TO MAINTAIN A BROAD MARKET

Insurers are acutely aware of the potential problems that might arise if the results of genetic tests were used to prevent significant numbers of insurance applicants from obtaining insurance at affordable rates. There are the obvious public and governmental relations concerns. But financial factors will exert an even greater influence.

Private insurance companies are in business to sell rather than deny insurance. Since this is a very competitive business, insurers have absolutely no incentive to use new tests unless by doing so they can operate more efficiently and offer a lower cost product to the consumer. Even with the advent of genetic testing, the economic necessity of generating new sales will act to ensure that the potential market for insurance products remains as large as possible.

It is worth noting that it was the private insurance industry that was responsible for initiating studies to determine the insurability of individuals with health impairments who had traditionally been unable to obtain insurance coverage. Insurers

800 SOS TNT 18:43 06/30/89

concluded that insurance protection could be offered to many of these individuals as long as the risk could be adequately evaluated and priced appropriately.

POINT #3. GENETIC DATA WILL BE EVALUATED IN THE CONTEXT OF OTHER RISK SELECTION PARAMETERS

Genetic test data will represent only one of the many factors that must be considered when insurers attempt to arrive at reasonable estimated probabilities of if and when premature death or illness will occur. This point is in sharp contrast to the mistaken belief that these tests will often be the sole or primary determinants of insurability.

Consider the case of a man who has had a series of genetic tests performed and a heightened risk for the occurrence of a certain type of cancer was identified. Does this automatically necessitate a declination or extra premium payments? No! Many other factors must be evaluated. Is he currently in good physical condition? Are there favorable considerations such as regular physical exercise or avoidance of tobacco and excessive amounts of alcohol? What is his occupation? Is there a history of health problems? How often would such a genetic test abnormality be anticipated in the average person? Is the type of cancer for which the predisposition was identified a common or uncommon cause of mortality or morbidity relative to other illnesses that occur in a large group of insured persons? Does this type of cancer develop so rarely that an adverse underwriting decision may not be necessary even if a significantly increased likelihood of its occurrence has been detected? And how old is he? Has he already passed the age at which the cancer would probably have developed if it was going to occur?

Given all of these considerations, such an applicant who was in otherwise good health might still receive insurance coverage at favorable rates because he is known to be an excellent risk except for a genetically increased likelihood of developing a certain type of cancer. And since he has been alerted to this heightened risk, he can take whatever precautions are possible such as avoiding other factors that may further increase his risk, having regular medical checkups, etc.

POINT #4. ADVERSE SELECTION IS A REALITY

The reality of adverse selection by insurance applicants is apparent from almost any publication dealing with the social, ethical, and economic ramifications of genetic testing. For example, authors discussing the utility of a genetic test to identify the gene responsible for Huntington's disease speak openly about the importance of "acquiring disability insurance" and the need to "buy extra insurance -- before testing." (1). Others write that an important factor in deciding if a test for Huntington's disease should be performed is whether or not the individual is "adequately insured" before the test is ordered (2).

A common theme of critics of the use of genetic tests by insurers is that such a practice would lead to inappropriate risk distinctions among those with genetic diseases (3,4,5). Such comments highlight the mistaken impression that such distinctions by insurance companies are somehow bad or unfair. They also indirectly express the belief that, although it is acceptable to differentiate risks among insurance applicants with a history of cancer, diabetes, or heart disease -- disorders that, like genetic diseases are usually not someone's "fault" -- by requiring that they pay an insurance premium appropriate for their increased risk, it is unfair to ask the same of people with genetic diseases or diseases with a genetic predisposition.

It is not well understood that differentiating risks is precisely what insurance companies must and in fact are expected to do, i.e., identify good and poor risks and charge premiums commensurate with those risks. In fact, such risk distinctions are the underlying reason why insurance coverage can be offered to so many people at affordable rates.

POINT #5. RISK CLASSIFICATION IS A SOUND BUSINESS PRACTICE

The current levels of insurance affordability and availability are as good as they are because of risk classification and the principle of equity: policyholders are charged equal premiums for equal risks. If insurers were unable to use the results of genetic tests during the underwriting process because "risks

600 SOS TNT 16:43 03/09/90

should only be classified on the basis of factors that people can control", then equity would be seriously impaired and private insurance as it is known today might well cease to exist.

But risk classification is not only a matter of fairness. It is also a sound business practice that enables insurers to offer a wide array of insurance products at attractive, affordable prices. With private insurance, people decide if and when they'll purchase insurance, from whom they'll buy it, and in what amounts. Would people be willing to pay more for insurance than what they perceive as their fair share? Would they be willing to make premium payments over and beyond what is needed to cover their own risk so that others at higher risk could get the same type of coverage at a disproportionately low rate?

And where would the line be drawn? If two people of different ages purchase life or health insurance coverage at the same time, would the younger person be expected to contribute the same amount to the pool as the older person? Would a healthy person be asked to pay the same premium as a person who is already ill as a result of a disease that is beyond his control? And if two people have a genetic test performed and one test is favorable and one is unfavorable, would they both be forced to make the same premium payments into a common insurance pool even though the likelihood of an early claim is markedly different? The answer to each of these questions is clearly "NO". In a voluntary insurance market where people can freely choose the timing, seller, and amounts of their insurance purchases, the need for risk classification is more than a matter of fairness. It is an economic reality.

CONCLUSION

In conclusion, I would like to reemphasize a few of the points I made earlier.

Insurers are very supportive of advances in genetic research that will one day lead to earlier treatment and/or prevention of disease. But they have no particular interest in nor enthusiasm for using genetic tests. Their current risk selection practices have generally been accepted by the medical community and insurance-buying public. They have no desire to initiate new screening tests rife with uncertainty and controversy.

But at some point in the future insurers may be forced to consider using genetic tests if their use becomes standard practice within the medical community. This action would be taken to enhance the risk selection process. But even more importantly it might be necessary in order to provide some protection against the significant adverse selection that would otherwise be certain to occur.

At this time insurers are no more able to answer the difficult questions concerning future use of genetic testing than is any other facet of society. In fact, most of the questions themselves are still unknown. We will continue to study the issues and await further developments. This can be our only reasonable course of action until significant technologic advances are made and the nature and use of genetic testing becomes more apparent.

FOOTNOTES

1. Alan Newman, "The Legacy on Chromosome 4," Johns Hopkins Magazine, April, 1988, p. 30-39

2. Sally Squires, "Do People Really Want To Know Their Medical Future: DNA and Destiny," Washington Post, October 4, 1988, p. 14-16

3. Joseph Martin, MD, et al., "Predictive Testing For Huntington's Disease With Use of a Linked DNA Marker," New England Journal of Medicine, 1988, Vol. 318, p. 535-42

4. Peter Gorner, "A New Genetic Test Can Foretell Agonizing Death: Would You Take it?," Chicago Tribune, Aug. 4, 1988

5. Amy Virshup, "The Promise and the Peril of Genetic Testing: Perfect People," New York, July 27, 1987, p. 26-34

010 EDS INT 16:44 05/05/50

SUMMARY
(suggested changes in caps)

With 3 percent of the NATIONAL CENTER FOR HUMAN GENOME RESEARCH'S annual budget tagged for research on the social, ethical, legal and economic IMPLICATIONS OF MAPPING AND SEQUENCING THE HUMAN GENOME, the CENTER will become the largest public benefactor of "BIOETHICS" research in this country. To help identify areas where this money can be best spent, A WORKING GROUP OF advisors TO THE CENTER met recently TO DISCUSS THE RESEARCH AGENDA with EXPERTS FROM SOCIOLOGY, HISTORY, ETHICS, GENETIC COUNSELING, LAW, LABOR, THE INSURANCE INDUSTRY, AND JOURNALISM.

The human genome project is an international research effort to decipher the entire set of genetic instructions inside human cells. Genome project research will give biomedicine new and powerful tools to identify disease-causing genes and to develop BETTER treatments for THE HEALTH PROBLEMS THEY CREATE. If MISINTERPRETED OR misused, THESE NEW TOOLS COULD open doors to PSYCHOLOGICAL ANGUISH, stigmatization AND discrimination for people who carry THESE genes.

SENT BY:Xerox Telecopier 7021 : 3-12-90 ; 1:25PM ; 3014802170-
301 402 0837:# 2

Issues raised by access to genetic information are not unique to the genome project. Nevertheless, the new technologies developed as part of the project are likely to increase the type and amount of information that can be obtained from examining genetic material. Because this may amplify the ~~potential~~ possibilities for misuse of genetic information, the working group ~~has taken a~~ is committed ~~[illegible]~~ to identifying and addressing these issues before the technology is developed.

In the United States, the human genome project is spearheaded by the NIH's National Center for Human Genome Research (NCHGR) and the Department of Energy's (DOE) Human Genome Program. The joint NIH-DOE working group on ethical, legal, and social issues related to mapping and sequencing the human genome is made up of members selected for their expertise in matters relevant to genome project issues. The group has been given the task of identifying the ethical, legal, social, and economic issues raised by availability of human genetic information and to help guide policy decisions in these areas.

On February 5 and 6th, the eight-member working group, chaired by Dr. Nancy Wexler, of the Hereditary Disease Foundation and Columbia University, hosted ten outside experts at a Williamsburg, Virginia workshop. The meeting opened with a general discussion of issues considered important from the point of view of each participant's expertise and experience. These included:

SENT BY:Xerox Telecopier 7021 ; 3-12-90 ; 1:25PM ; 3014802770-
GAMO PRINTING SERV.
301 402 0837:# 3
P03

1. Implementation of working group recommendations. To gather the information needed to evaluate policy options, NCHGR and DOE may make grants to projects initiated by the research community or invite applications from groups with appropriate expertise. Other mechanisms include contracts, which allow more oversight by the agencies, workshops, establishment of task forces, commissioned papers and reports.

Is this our "charge?" Why is this here? Is this data or rationale intro to the workshop? If so, incorporate above

In order to facilitate informed public discussion of its social implications

(1). Education. Factual information about the human genome project needs to reach the lay public, students, and professionals. This information should clearly identify the ~~promises~~ limitations of the project and human genetics, as well as its ~~limitations~~ promise. This may be done by developing school curricula containing genome project science and concepts and by tying into information outlets such as the mass media, religious institutions, health volunteer associations, and health professionals.

Good

3. ~~Eugenics~~ History. An awareness of the history of abuse of genetics is necessary to avoid the pitfalls of the past. In times of social or economic uncertainty, eugenic attitudes have emerged as intolerance toward ~~older people and the chronically ill and emphasis on~~ certain individuals and states of health as being economic burdens on society.

SENT BY:Xerox Telecopier 7021 ; 3-12-90 ; 1:26PM ; 3014802770→ 301 402 0837:# 4 P04

How should the privacy of genetic information be protected?

4. ~~Confidentiality and~~ Privacy. Present statutes concerning ownership of information or a patient's right to privacy do not guarantee confidentiality of medical information. Such information may be exposed to several layers of "privacy," including the patient, the medical institution, and the state.

This sentence is unclear

5. Medical insurance. ~~The private insurance industry is a for-profit business, the motives of which may run counter to the insurance needs of people who have been given genetic diagnoses.~~ New genetic tests may identify larger groups of people who carry genes predisposing them to common illnesses. How will this information impact on their ability to obtain affordable insurance from a private carrier? ~~Perhaps~~ Can new criteria and formulas for identifying who is insurable and for setting premium rates ~~need to~~ be generated?

6. Clinical ~~Issues~~ Services. Availability of detailed genetic information will have tremendous impact on medicine. This may be particulary acute for latent, serious genetic diseases for which there are no cures. The recent development of a screening test for cystic fibrosis will provide an instructive model from which to study many of these issues. Genetic technologies are also likely to pave

SENT BY:Xerox Telecopier 7021 ; 3-12-90 ; 1:27PM ; 3016802770-
301 402 0837:# 5

the way for ~~"gene therapy" through~~ the use of drugs such as hormones, growth factors, and immune system booster, made by gene-splicing techniques. Many of these drugs are now approved for treatment of hormone-deficiency diseases, but have also been used illicitly by athletes as performance-enhancing drugs. The increasingly widespread availability of genetically engineered drugs to the general population raises many ethical questions about the use of such substances to enhance biological "fitness" of healthy people.

7. Commercialization of Genome Technologies. As more genes are identified and screening tests developed, guidelines for technology transfer from research laboratories to the private sector need to be in place [how would these be different from the tech-transfer mechanisms already in place?]. Commercialization of screening tests also raises questions of quality control and how these devices should be regulated by appropriate government agencies.

After consideration and discussion of those topics, workshop participants focused on developing priority areas.

(1) Tracking the cystic fibrosis experience. The recent identification of the gene responsible for cystic fibrosis has paved the way for development and commercialization of methods to determine ~~not only~~ people's carrier status ~~but also~~ and to identify affected

fetuses. There is currently no cure for cystic fibrosis and treatments are mostly palliative; children born with this disease usually die in young adulthood. Because technologies developed as part of the human genome project will likely increase the number of disease genes identified (and the subsequent development of testing methods) tracking and examining in detail the cystic fibrosis experience promises to provide an instructive model of the full range of issues of interest to the human genome project. These issues include:

i) transfer of technology from research laboratories to private industry for development and marketing;

ii) accuracy and quality control of test kits;

iii) the impact of information obtained from genetic tests on genetic counseling options;

iv) the role of insurance companies in covering medical costs of affected patients who were identified by prenatal tests;

v) liability of clinicians who fail to perform genetic testing;

vi) confidentiality of information obtained from genetic testing;

vii) the psychological impact on patients and family members of information about one's medical fate, especially on for those predicted to develop illnesses for which there are no cures.

SENT BY:Xerox Telecopier 7021 ; 3-12-90 ; 1:28PM ; 3014802770-
301 402 0837:# 7

These issues may be examined through scholarly research, commissioned papers, workshops or conferences.

(2) **The effect of genetic information on insurance coverage.** The publin holds an "entitlement mentality" with respect to health insurance, which extends to both government-sponsored insurance programs and private companies that sell insurance for profit. Private insurance is intended to cover untimely, unknown, or emergency health crises, and not chronic or anticipated health needs, such as those that arise in people who have genetic diseases.

Because genetic tests may predict health outcomes, their use by private insurance companies to determine an applicant's financial liability has become an important issue. Increased availability of genetic tests may identify new and large groups of people who may be genetically predisposed to common disorders, such as heart disease, cancers, diabetes mellitus, immune disorders, etc. How will private insurers use this information to calculate the financial risk of insuring individuals who carry these genes? Studies are needed to identify how and which genetic information would be used to assess a population's insurance risk, to define a person as insurable, or to deny coverage are needed.

In a addition, the impact of so-called "good genes" on health insurance coverage may need to be assessed. Currently, reductions in premiums are given for health-promoting behaviors

SENT BY:Xerox Telecopier 7021 ; 3-12-90 ; 1:29PM ; 3014802770-
301 402 0637:# 8

such as not smoking, exercise, and limited alcohol intake. Should similar rewards be given to people who carry tumor-suppressor genes, toxin-resistance genes, or genetically hearty immune systems?

Most private insurers do not now use results of genetic tests to determine who they will insure. However, insurance companies feel they should have access to such information to offset its use by policy holders who withhold genetic information to receive lower premium rates. Because private insurance companies operate as for-profit businesses, people with genetic diagnoses may be forced to turn to other sources of affordable coverage. The working group suggested that research into alternate sources of health insurance for people with genetic diseases is needed. These alternatives may include government co-payment, employer benefits or self-insurance systems, or combinations of these.

(3) Education and outreach: Clinicians, journalists, and other workshop participants who frequently deal with the general public observed that the public at large seems uninformed or to hold strong misconceptions about the powers of medical genetics and the role of genes in biology, disease, and behavior. Formal assessments of public understanding of medical genetics and genome project science will help refine and target education and outreach programs. Resolving misconceptions is important so that informed debate and public discussion of the social implications of the human genome project can be grounded in fact.

SENT BY:Xerox Telecopier 7021 ; 3-12-90 ; 1:28PM ; 3014802770-
501 402 0687:# 9 P08

Education efforts should be designed to demystify genetics and genome project science by bringing these topics into the public domain. In addition to underscoring the science and medical benefits likely to stem from genome project research, special precautions should be made not to hype or overpromise. Determining the complete sequence of human DNA will not produce immediate cures or knowledge of gene function. The genetic alteration responsible for sickle cell anemia, for example, has been known since the mid-1970s, still no genetic cure has been developed. Similarly, the complete sequence of human mitochondrial DNA is now know, ~~for example~~, but its function still remains a mystery.

The general public, health professionals, and genetic counselors, for example, should be made aware of the many factors aside from genetic makeup that influence human function and behavior. The ability to read a person's complete genetic makeup and make biological predictions may intensify the notion of "genetic determinism"--the idea that genes alone direct a person's biological (and perhaps social) fate. Education efforts should include discussions of the role of environment and other factors in social, behavioral, and biological development.

The opportunity to examine genetic material of large numbers of people will likely force a redefinition of the concepts of "normal," health, and disease. As knowledge about these concepts changes, it is important to adopt a value-neutral language in education, outreach, and counseling programs when referring to the wide variations in human genetic composition.

SENT BY:Xerox Telecopier 7021 ; 3-12-90 ; 1:30PM ; 3014602770-
301 402 0837:#10 P 10

A first step toward education and outreach will require identifying organizations and institutions in place for dissemminating information to target groups. These may include decision makers in the mass media and school systems, as well as health volunteer associations, organizations for medical and allied health professionals, labor groups, policy makers, and religious groups.

Open dialogue between the working group and members of genetic disease and disability groups is essential to ensure that recommendations of the joint working group may best address the needs of people most likely to be affected by availability of genetic information.

Development of education and outreach programs may be funded in collaboration with the [National Science Foundation's genome project education program.] Is there such a thing?

(4) Confidentiality. As genetic testing technology becomes more widely availalble, access to genetic information by the individual, family, employers, insurance companies, and other institutions will have an increasing impact on personal privacy. Since laws protecting rights to privacy do not necessarily protect regulation or flow of medical information, areas should be identified where breakdown in privacy are most likely to occur. Workshop participants identified three current levels of confidentiality of medical information: patient; medical institution; and state. In addition, large, computerized databases now exist for storaging "confidential" medical

SENT BY:Xerox Telecopier 7021 ; 3-12-90 ; 1:31PM ; 3014802770→ 301 402 0837:#11 * 1

information. Guidelines for responsible use of such information should be established. These guidelines should address: consent to be tested; the patient's right to know or not to know his/her test results; how information is used by physicians to make decisions about medical care; and how information may be used by a patient's family [redacted].

A list of workshop participants is attached.

SENT BY:Xerox Telecopier 7021 ; 3-12-90 ; 1:31PM ; XEROX PRINTING SERV. 3014802770-
301 402 0837:#12 P 12

physician obligation to warn 3rd parties.

~~Give guidance to physicians~~

OUTLINE DAY I

(1) Mechanisms of Actions.

I. Grants
   A. Community at large
   B. Fund redundancy
   C. Invite applications from relevant groups

II. Contracts
   - More control, oversight

III. Workshops/ Task Forces and Working groups

IV. Commissioned papers and reports

V. Interagency agreements

Issues, Implementation Priority, Agent.

Insurance:

II. Implementation
   A. Working group - jointly with insurance industry. Combine scientific expertise with actuarial expertise predict which tests would have ~~most~~ which effects.

Fund studies to determine effects

NORD (Nat'l Organization of Rare Disorders) worried that HGP will take away funds from their diseases.

(2) Education

I. Issues
A. How to "innoculate" a curriculum
B. How to identify target audiences for educators who, in turn, ? education providers?

II. Implementation
A. Educational system K-college
B. Media: target those responsible for media. Science press, lay press. broadly defined: TV, radio,
1) editors
2) reporters.

~~Educational content~~

~~I. Issues~~
~~A. Media tends to.~~
C. Religious Institutions
2-way educational process
D. AFL-CIO
1. workshops for labor leaderships.
2. courses for work force.
E. Health voluntary organizations and disability groups (NORD)
F. Medical + allied health professionals
G. Civil Rights / Disability Rights groups

(3) Educational Content

longer discussion

I. Issues
   A. Media tends to sensationalized, focus on cures, or controversy, progress or peril.
   B. Danger of overpromising - overblowing what can be done will rebound negatively.
   C. Genetic determinism, environment and free will; "does genetics = fated?" If genetic, is it immutable?
   D. Genetic Variability
      1. A continuum of function and dysfunction
      2. Value-neutral vs. value-laden language. "defect, disease, v. difference.
      3. How beliefs of counselors may influence reproductive decisions of clients
      4. Implications for disability groups.

II. Implementation
   1. Development of shared curriculum or materials.

III. Human Origins and other Good stuff.

④ Eugenics

I. Issues

A. In times of social or economic uncertainty there can be an emergence of eugenic thought and attitudes (like Germany)

B. Linkage develops between certain groups "elderly, infirm, genetically "defective" and financial burden.

C. Stigma opens the door to abuse.

History of genetics - bad rap. History of genetic abuses in mid 20th century.

1 Behavioral Genetics (Jonathan Beckwith)

A. Institutional aspects

B. Evaluation criteria for.

eg. "criminality" dangerous tremendous potential for harm in labelling.
alcoholism.

~~Outline Part I~~

Add to longer discussion

(5) I. Confidentiality and Privacy

A. Privacy law will not protect

B. Ownership law not protect

C. Law "ambiguous" and ??

D. 3 levels of privacy. (See notes)

G. Systems of records

1. Medical Info Bureau

2. Nat'l Library of Medicine

F. Anticipating future use of files (screening rans at plants)

G. Consent to testing in the first place.

(6) I. Insurance

A. Current private insurance operates on the equity ~~egal~~ principle (The rate matches the principle) Up to 500% risk insured

B. Private insurance governed by profit motive which may be antithetical to justice.

C. genetic diagnosis of certain groups are likely to impinge on private insur. protection to "middle risk groups" with genes predisposing to common disorders.

Funnel studies to determine ratio to insurable (unreliable groups).

D. Alternatives to private insurance

1. Nat'l Health Insurance. 2. Employers as Insurers 3. Self-insuring groups 4. Gov't subsidy of uninsurable.

Alliance of Genetic Support Groups - R. Murray. VT

CIVIL RIGHTS

A. Equality of opportunity in employment, housing, etc.

B. Disabilities Act legislation - sparing disability; how to live with disability.

C. Relevance of equality - difference debate.

D. Where to put fetus - genetic counselling training. Abortion-related issues.

E. Parental obligations to fetus & genetically different fetuses). e.g. AIV+ (directed vs. non-directed counselling)

CLINICAL ISSUES

A. Therapeutic lag

B. Cost trends

C. Psychological issues
   1. Stigma, self-identity. Psychology of knowing test results

D. Follow CF testing to see how that plays out.

E. Gene therapy - modifying human kind. Through production of recombinant gene products (HGH, erythropoeitin, lymphokines).

F. Professional liability for failure to do genetic tests, refer to counselors.

Studies to Seek

A. Historical perspectives
B. Interdisciplinary studies of insurance issues regarding middle range of people genetically predisposed.
C. Projections of Potential (impact assessments
D. Track of experience as "model" of genetic screening issues.
E. Cross-cultural perspectives on handling genetic information.
   1. within USA
   2. international

Commercialization

A. University - industry relations / transfer
B. Quality control of screening tests, other genetic technology.
C. Guidelines for practice

D. Regulation of genetic devices, tests (FDA?); moral picture regarding whether a device should be approved. Not based on whether it works, but on whether it should be used.

PRIORITIES:

1. Keep track of C.F. experience — President's Commission on Ethics report.
2. Influence Americans with Disabilities Acts.
3. Make coalition contacts - outreach. Use Watson as intro leader / door-opener also Watkins.

4. What is Project about? (Define links with disease or not). Define message. Project has impact on many areas of our lives. Economic, social, health. "Grand Design."

4. Track public perceptions, advocacy groups. Evaluate public understanding. Target groups to educate.
5. Address:
   Insurance issues
   Clinical services
   Deep issues

Longer discussion of education.

Needs:
Materials to explain what genetics can and cannot do. Address diseases, disability groups, biological determinism.
Dispell misconceptions. Awareness of genetics history.

Good ethics relies on good facts. Ground public in facts.

Risk/benefit: what are real benefits from HGP and what are risks?

"De-esoteric" issues of HGP.

Genome Project is not magic bullet to resolve societal ills. Determinism, people at social level don't take

responsibility for their social roles.

Elhe: position paper to James Mason talking about NIH taking on studies of social implications of research. New opportunities to expand social ~~research~~ impacts of.

Williamsburg Mtg

*Working Group Report - send to all members

*13.12

- (1) key issues
- (2) priorities
- (3) strategy - how address issues ; (4) process ; (5) to whom should be directed
- Record - not public - a summary - and consensus
- Dinner - 7:00 - meet 6:45
* - March - DOE will have an announcement on ethics - (would like copy & PA)
- normal vs. optimizing people

What are the most pressing issues

- Educating the public about what genetics can offer
  let's ground work - through press on TV

- how can press be involved -
  newspapers have science section & viewers generally; TV behind
  - bring in science reporters from - editors - big & mid-level papers for briefs - a school should be doing Chic. TV news directors; this is what you should be thinking about how can be done visually
  - journalists don't seem to be in business of education
  - how - work through editors + they make decisions
    > papers do not have science writers - people do not advertise in science section - per O.

select where their ads are placed
- basic ed. vs. puzzs - a good way to introduce the topic is through the social questions
- responsible reporting & contributions are good
* - parenting magazines, gen. curriculum, obligation - just line
- scientific issues are legal issues, political - don't need a science writer to do this.
- if scientists can't translate their knowledge - then don't know what they are doing
- being > narrow - Glamour regularly gives readers a chance to give their views - go after the "institutions" - not NY Times - it's must be multicultural - public schools, schools of journalism - (> journalism schools have a science program now)
- lot of effort to train science writers - focuses on cures & controversies; lot to be understood about media -
- How should deal w editors?
- invite them to conference - tell them what you are doing
- editors don't get invited to many places
- demarcation between science & non-science is false question - don't have problem w regulation - as long as it is truthful

equally impt.

* • What should be said? – danger of overblown (the implications of what is going to be found out. Rockland's article – "to help poor, homeless" – overstep the premise that leave to sensationalism – raised expectation (math gene, manic depressive – some caution is necessary). Nuclear + Solar energy are examples of overblown

Basic education – genetics = thus as focus

* • Educate > receptive members of society – children (elem. + junior high) – BSCS in Colorado – sickle cell + Tay Sach – money was deleted + program ↓; model curriculum – under Clarice Reid – teaches in science + health attended – not able to follow-up; gets around "what' hot", sensationalism, etc.

? given the scope of the Center – have the efforts "scratched" the surface of interested parties.

If want to reach Congress – present to staff + they will give info to legislatures

fearful of press + lack of control you might have

• what data is yielding powerful info – prediction is impt – want to minimize risk; – planning, accountability possible

Have deep seated concepts about - have mysteries -
* info - should not have; - ~~is~~ there info we should not have

What should press
- Misunderstg about carrier states
- interaction between genetics + environment
- scientist miscommunicate -
- genetics = fated
- bothered by the HGP will give us "the info" there ~~is~~ is research ongoing that will contribute to effort - (HGP is narrowly focused; entire efforts will go beyond this)
- what are the ramifications of having this info?
- once you know you have a condition -- you know what life is going to be like - A > narrow description of essentially)

- Education / outreach
  - out reach - ↑ awareness re genetics
  - areas where lack agreement - what is normal
* - organized religious groups - another that needs to be educated - usually considered to be antagonistic - would help us understand the tough philosophical issues
  redundancy important

Institutional out reach
media
schools
religion
or

~~3rd~~ 5 outreach group

1 Primary care physician – organized medicine

4th

1 Insurance industry – should be able to tell them story

NEJM – > people ī private insurance would have covered CF test. – indicated that they declint.

* What are the institutional arrangement to handle this new info?

no code of ethics has an arrangement ⅁ an institutional arrangt

- fear of technology
- historical baggage
- racial hygiene + eugenics movement – creature of science
- genetic determinism – > knowledge = > employed view of world

Genetic determinism is 20th cent. invention; modern determinism culminates in 20+30 – ↓ in 50s and ↑ 70's – worry about contagion – in economic crisis – ; stigmas on differences make a difference ī financial burden – defects + risks become invidious. In Carter years – memos to encourage elderly to make living wills – as a way to ↓ financial burden.

> people think that as soon as we have info – we will know everything – what is happening ī what we know now – is impt.

will not have to wait until project is complete

U.S. has a history that individual is "property" + is owned by the individual.

- Discussion on determin - what we know now encourage what Jonathan is concerned ~ - we talk always about predictions - ~ assurance - how get disability, hope benefits to people - assurance is limit on predictive risk - (AIDS - a test of knowledge → outcome)

  X-cultural - how genetics handled - looking at mind-set in x-cultural settings

  Integrate info into genetic services

  - determinate
  - limitations of testing
  - how used in courts, schools to shape public policy
  - what are consequences

  Doctor - patient relationship
  language of comm - difference vs. defect

Monday P.M.

- Insurance - Pokorski
  - Private commercial insurance - pay claims - financial compensation for untimely, unexpected situations - "pool by risk categories"
  - private insurers are voluntary; risk selection - claims come from money paid by insurers;
  - equity vs. equality

What not allowed to discriminate -
cannot use Race, ethnicity; can use gender, geographic differences, can be used for health insurance

Insurance companies do not want to use genetic test - public will use them - + then will request insurance for a variety of reason - health, life insurance, etc.

how good test is - etc. - will be used to decline groups of people - describing CF_1^{+HD} - will be > interested in cardiovascular, hypertension. (not interested in CF or HD because not insurable any way). HIV - test for life insurance - (people know - informed consent need --

- Models for insurers
  netherland - $ x amt okay - above that require tests
  in U.S. pools for special purpose - flood insurance, car insurance - uninsurables

- industry is "bladdicity" - need to develop uncertainty,

- stereotype & not fact is being used by insurance companies - Sensory, disabilities - actuarial data not factual (Colombians, deaf and company had data to show Colombians had extra mortality - denied to eliminate

Medical Info. Bureau - ~300 ins. comps - info exchange for insurance companies - to detect fraud - companies suspecting excess claims - (self protective mechanism)
(sharing of info -)

* - ? a) if private competitive market when genetic tests becomes available - where do the companies draw line between asymptomatic HIV or smoking - what judgments go into that - then we can figure out how much of a problem; (b) level of info such - no need for private -

can't answer - don't know when tests will be available - talking about coronary heart disease - not CF

* - Insurance ≅ social security; ~~concepts~~ education role ~ what insurance can do; learn to articulate what / how insurance decisions are made.
gen. public -> neutral group of people
how, decisions are made above coverage of conditions in advance

· Have insurance – risk not been ~~insured~~ pooled; corporations will not insure rich; part of social research – need for a replacement of private insurers if not can

\# – alternatives models of national health ins to predict

* role of employers as insurers

? Why is it that industry will not charge premium per people ↓ rich; # of variables – genome project – "good genes" – should not be charged same as lower rates.

(ans. real potential that people will be found to have good genes – may be possible –

Procter – new knowledge about genes will not change things for the insurance industry –

Can have access to info – just as one cannot have access to race

* insurance companies must maximize profits – and part of that is to maximize justice

– shouldn't dump on insurance companies or private employers – have to accept the bottom line + deal ~~c~~ issue

I. Insurance

A. Grants

B. Look at mid-range - rest group

C. Alternatives

1. National health insurance

2. employers as insurer

3. self-employed

4. Poor - subsidized & high risk groups

D. Working Group - (geneticist + actuarial develop a paper that realistic states what genetic info is available within next 5 years + how would this info affect insurance industry

II. Confidentiality -

3 levels -

1. family

2. institutional, courts, employers)

3. State

* -Have someone in genetic dimension + actuarial people to illuminate gray zones - know what test would actually be available within 5 years
- look at policy options to ask - what would happen - what if?

* What will happen if people are not insurable?

(in OTA report - looked at devices for which gene therapy was available - had n 10 - did not affect > people)

not only genetic structures but class of occupations are also problematic - markers are becoming available - will also be used (genes + environment)

~~Privacy~~
~~Who Pays for Test~~

Constitutional right to privacy -

Ownership - does not necessarily mean that you have control of it - (not constitutionally protected

3 levels of ~~Privacy~~ Confidentiality
Individual - how affects family
Institution - employers, courts, insurers
State - (NY has demanded names of individuals in certain genetic dimension)

(Public Health Model - another way of handling issues)

"Society is genetic - you get it from the children"
Margery Shaw -

Storage of genetic/medical info in computers

Medical Insys. Bureau - venture that worse would be to code people;

- Largest genetic file was in Nazi Germany - based on public health implications - in 1920's info collected w/ any knowledge that it would have been used for another purpose in 1930s. (Collection & files Probably would have had no effect on what happened - would have happened anyway).

- Can see an analogy in 20 years about asking presidential candidates for genetic profile.

(PKU testing - a very different issue - because you can do something about it)

Are there provisions for patients people who do not want the info?
* → what, the instance for breaking confidentiality -

Destruction people use - prospective parents should have a moral duty to know whether they should place an unborn at risk - do not compel - how many wrongful life cases before the court - does the threat of litigation ↑ coercion

Individual vs. other - has potential for breaking down trust in genetics
- mother + HIV test +; should father also know

Obligation to know - in sickle cell - some people do not return to get test. write letters; visit homes - coercion - trying to make people know; some think this is in the hands of God -

~~1 Standard to physician about~~

** → Appropriate standards must be laid out by the professionals - ~~same~~ usually if there are standards legal profession will abide by them.

Malpractice will drive the encentive to set standards

Tuesday A.M.

Mechanism

I. Grants
- community-at-large
- fund redundancy
- invite applications from relevant groups

II. contract

III. Workshops / tasks forces + working groups

IV. commissioned papers + reports

V. Interagency agreement

(issues, implementation, priority, aspects)

Education

I. Issues

A. How to "inoculate" curriculum

B. Identify target urgent for ed.; who in turn can be educational providers

II. Implementation

A. Education system - K - college

B. Media - target those responsible for media - broadly defined - (1) editors - (2) reports, (3) scientific press, (4) lay press - Planned

C. Religious institutions (2-way educational process

D. AFL-CIO

1. workshops for labor leaders

2. courses for work force

E. Health vol. organizations ~~disability groups~~

F. Medical + allied health professionals

G. Civil Rights / Disability Groups

Education Content

I. Issues

A. media tend to sensationalize - focus on cures, controversy, progress or peril

B. Danger of over promising - overlooking what can be done - well released negatively

C. Genetic determinism, environment + free-will; does "genetic fate" - if genetic - is it mutable

D. Genetic counseling
- a continuum of function and dysfunction
- value-free (neutral) or value-laden language
  " defect, disease, or difference
- How beliefs of counselor may influence reproductive choice / decision of client
- implication for disability groups

II. Implementation

development of shared, core curriculum / material

Eugenics

I. Issues

A. In times of social or economic uncertainty, there can be an emergence of eugenic thought + action - U.S. + Germany - worldwide

B. A linkage develops between certain groups - elderly, infirmed, genetically "defective" - and feminized gender

C. Stepping open the door to abuse

D. Behavior genetics
- constitutional aspects
- evaluation criteria
- [illegible] of O.C.D.

Insurance

I. Issues

A. Current private insurance operates on the equity principle - rate = risk; up to 500% risk insured (500% - Recent MI) beyond that - No (cancer, HD, CF)

B. Private ins. governed by profit motive which may be antithetical to justice

C. Social Role of industry

D. Genetic diagnosis of certain groups are likely to impinge on private insurer practices - "the middle risk group" with genes predisposing to common disorder

E. Alternatives to private insurance

1. National health insurance
2. Employers as insurers
3. Gov. subsidy & unsurables

II. Implementation

work group - jointly ∈ insurance industry - combine scientific expertise ∈ actuarial expertise predict which tests (in next 5 years) would have what effect

Confidentiality

I. Issues

- privacy law will not protect
- Ownership " " " "
- Law "ambiguities" and case contingent
- Levels of privacy
  - personal / clinical / family
  - institutional (courts, employers)
  - State

over

Sheldon – values & researchers – term – error, fault, difference,

– van drives up at plant & takes blood (blood) from workers – screened for many things – workers do not know what being tested for & no feed-back – (should get informed consent) additional tests only few cents more

Proctor – Historical consciousness – genetics text book – no reference to misuse of genetics in text book – history of HGP also important – how something emerges

Pat – Insurance – friend studies & middle group – where insurers is likely to extend coverage – may be genetic or not – economics – language / decisions fear that many people have no knowledge & insurers – need independent perspective

Nussbaum – fall out from HGP – genetic loci for disorder – designing long before therapy – initial design expensive – ? & how to treat will still be open

R. Murray – Help rich individuals – put in a pool & distributed to insurance companies to share risk

– ? documents on screening – (Hastings, Commission, need to review & add-on instead new)

- behaviors - some have strong genetic component - potential for eugenics is dangerous. (violence, alcoholism)

Goldberg - apply for job - don't get it because won't provide genetic profile on some certain characteristics (equal employment) → cannot take into account as a factor in employment

Asch - states & strong laws for. American & Disability Act - should include genetic disability - B. Cook-Deegan - appears not to have any resistance

T. Murray - History should be given a segregant place in what we study
- it would be helpful to have projections based on reasonable & legislate - what kinds & how many tests will we have, cost, (clinical genetics, consumers, industry, researchers [Newborn - one can identify major list -

Sheldon - Pre-employment agree & Goldberg; workers' compensation.
use of technology that could influence long term mating pool - make a change in genetic pool -
stigma - workers who flunked the tuberculin test - created a social stigmatized group - not desirable mate isolated

Relkin - if look at various models - x-cultural studies would be important; economic stress of health care & re-enforcement, nature of legal system, nature of legislature structure -

B. Cook - Allegan - ① good report coming out of WHO coming out which speaks to alive
② where we can do a lot of good is to follow the CF testy - how work it way into system generate data about process

Kenig - ① stronger preference to x-cultural studies in U.S.; make enormous assumptions that we all act alike;
② Seema - in NY Times - re CF - if we don't do empirical work on use of screen test -
③ theoretical problem - Stevens comment - equality model under severe attack - original context - black-white - people no longer accept that assumption - in an area where it matters - new born - [concept of fairness is changing - significant debate going on]

Asch -
Bates - Private industry is going off in zone of controls we are talking about - in profit motive - moving ahead

Weyler - Mentioned CF study.

Beckwith - Technology done to implementation should be discussed - DNA fingerprinting as well as CF (guidelines developed)

Proctor - + implications - human origins -> done on mitochondrial DNA - (may not be so good - religious views)

T. Murray - Gene therapy - control, production, distribution
Sheldon - commercialization - what is private responsibility for public health + to whom
- ~~Not~~ genes - gov. agencies - trade assoc. / unions - gov. regulated
need to be controlled ↓ not gov. regulated

T. Murray - commercialization may need to consider not only the test itself, but what a result means and counseling.

Provider

1. Tracking CF experience
2. influencing disability acts
3. most organizations have a secondary level - liaison (a) - identify person / committee you want to interact w
4. Education issues - Watson can get into editorial boards he will be asked to sell ethical + social implications can get a certain coverage - work as a team
"opening doors"

- Elke - the "admiral" is also interested in genome project.

Samuels - PR best left to professionals - we need to know what message

- need a model to identify how make up can be changed by new findings vis-a-vis environment - environmental
- industry concerned that won't have to be concerned by environment - if can get right genetic make-up

- what is HGP project actually + potentially

Cook-Deegan - ? whether there is a model -
concerned re global premises lead to wrong conclusion

Kevin - creation of public policy ≠ education
public should know about effects, implications for both vs in several areas - economic, medical,
Elena - as develop policy - have ongoing conversation re institutions etc. IOM will do a study on delivery of clinical services - may not be broad enough to cover - "deep thought - ethicality vs. diffusion; determinism,

Nolan - public understanding - people, organization
tracking disputes -

Samuels - is some overall view - will build opposition out of fear, misunderstanding

Baldstein - would you have a 2-5 page article about what the HAP is about.

Insurance -
Beckwith - what's going on now, plans,

Proctor - different ways to set priorities - WA - acts as a moral conscious - biological determinism - only adds fuel to fire - "need to set up warnings" - needs to get out soon.

T. Murray - education re HGT is a part of the ethical concern
Re " - need "informed consent of public"; - education - evaluate - have a referendum -

Barnhardt - target groups to be educated -

Nussbaum - sharing risk - study of pharmaceutical companies + orphan drugs may be worthwhile

T. Murray - insurance an important issue scholarly + practically -
(insurance companies)
Eleana - input of results - what are they willing to cover

P. King - > issues laid out - kinds of insurance - BC/BS was left out - what WA needs is an economist - a sustained interaction -

Adrienne – "deep thought topics" – document that would lay out facts + why issues are impt + how personal they are – how much should cost to society matter in terms of personal reproductive decisions, – genetic connections & psychology also – need to create materials – do not exist.

T. Murray – have been created – say news media – may not be best

Sheldon – There are gut issues that could destroy project – the Genome Office may be picketed – Asch on to something – need to head off misunderstanding.
Al Fritz – Jesuit – physician + works c̄ these kinds of issues – leaders who need to be brought on board.

Nelkin – 2 separate issues –
① "deep thought" – predict use of a prediction tool – a course trying to work out
② approach – ~~training~~ used – setting up capacity to respond – ways to handle/anticipate

Beckwith – what is relationship to science project – people doing/supporting work may disagree c̄ these discussions –
* shouldn't we have papers to generate interaction c̄ scientists – yesterday said researchers have made statements made about what HGP will do – could be

person if we come out w a different statement - should anticipate

Civil Rights /

Elena - fetus - Parental obligation toward unborn children

Ruth - psychological / civil rights / abortion issues -
(CF - talk w teenagers w CF to discover what their thoughts are about children)

Protection - (Katherine)

Diana Walsh - Boston U - Testing -

~~Elaine~~ King - There hasn't been a great deal of thought about parental obligation - what do we owe our children - ~~Roe~~ Re vs. Wade - very little - we don't know how to think about it; it's a problem of delivery of clinical service. ~ 900 counselors - who will do it & who will train, - certification, issues have to be revisited - directive vs. non-directive counseling - (black & w HIV do not abort - may have real implications) -

Elaine - ob/gyn - do not have training in counseling - cannot be included in group of reasonable counselors -

Nussbaum - directive vs. non-directive is always an issue -
- this group has to get message - genome project - only / national dedication - * cannot cure societal ills -

- irresponsible to generate info + train people to provide information + ~~train people to dissemin info~~ info in public

R. Murray - A.S. Hum. Gen - strategy to include human genetics in curriculum
a lot of literature on (churches are strong on directive counseling)

Samuels - Employee assistance counselor - + several others ~~will~~ have "peer counselor" - do drugs, genetics, + a variety

Gates - Professional liability will encourage medical specialist to refer cases to genetic counselor.
Types of counseling - as it involves the individual - do they ~~need need~~ want the info and how will it be used

---

Gate
- Ability of ob/gyn to deal c onslaught of info
- pressure brought on PC women for pre natal tests - especially if lead to abortion of fetus c genetic defect

Goldberg - ① issue of determinism - make clear that HGT will not ↑ role gene play in behavior
② politically touchy - lead to c work on environmental and social issues

Samuels - determinism is getting a bad rap; hyperbole could have been used > precisely

Nelkin - a lot of issues - public mind set - how people assimilate info;

Asch - all issues impt

Baldstein - media not monolithic - not all sensationalize - Wexler - what would you want your students to know about - Baldstein - dozen of stories floating around

T. Murray -
- ethics ed. in genetic issues in med. sch.
- use of genetic testing in employment + insurance
- x-national study - why different nations deal w genetic info in different ways

Erie - sense of job ahead of them; - a whole list of projects will be pursuing

Purdue - used to conf. where there is a lot of data - hope we will get some "data" soon; examine issues impt.

R. Murray - a lot of work would be employed by collecting what has been done - Hastings had a script dealing w similar issues x 10 yrs. ago - cut when NEH lost $ + funding. Also concerned w NIH's peer review system "old boy network."

T. Murray - major ethics program in past were not in place where NIH had major resources - Chem. and

McKusick – ① impressed ↑ Baltimore comments – "get to the Editors" – 2nd week of Feb course – have reporters attend Bar Harbor course. – a lot can be done ↑ this – need to include editors
② must pursue HUGO activities
③ clinical services – CT-paradigm is tremendous + timely
④ Alliance of genetic support groups – have been involved for > years; emotionally + social satisfying – they always know > about disease than > doctors – keep investigator "feet-to-fire" (founded by Joan Weiss – used to be McK's genetic counselor)

[redacted]

Working Group Meeting

Mailing lists

- List of names / ideas – different groups + target populations
- – where / when have annual mtgs – give talk
  - problem ↑ credibility (inclusion); need ↑ group – if many organizations are asked to give you info about what interested in; (outreach) – to be invited – elements arena of suspicion –
  - mission of working group – clear – do not have a commonly understood of mission; role of group varies ? deliberative, strategy; outreach ?? should stop calling ourselves "ethics" WG – in the

world - ethics not simple; how many economist know this group exists - if interested in insurance - then
- NIH grant making agency has dealt best w scientists -

Hearing - invite groups - may learn something -
(Pat - accomplish outreach - let people know where we have come to date - invite people/organizations -
⇒ How to change our perception on the outside -
(someone from disability group should come to us soon)
physicians + disability groups - health care specialists - what should we be working on
"grant groups ??"
Just "Stake Holders" - theological groups, disability groups, medical groups (phy. genetic counselors)
very tough to find "all groups" - those not well represented
hard to identify
Pat - (not interested in making this a public hearing)

[Late April - mtg of 2 groups

Education - Future topic - can weave some issues about the Human Genome Project - i.e. LA Law - mentally retarded person

- information sharing - astute chair - deflect back to statement (letter of invitation would spell out what expectations are)

Envoy

- Perception/kin community about a small group that is trying to shape whole project.

Kay - "CF experience" - introduction of new technology - have documented, empirical study - screening, insurance, privacy (Case study)
- how process gets affected - how can there be intervention to make process work - should think carefully about intervention - actual strategy - (intervention at individual - WG) ← ? decision ?

Wexler - mid-ground - invite those who are making policy re CF to next mtg - ? what criteria would WG take

Nancy's Charts

- System of Records
  - medical info bureau
  - NCM
- anticipate future use of files
- consent to testing

Civil Rights

- equality of opportunity - employment
- Disabilities Act legislation
- Relevance of equality - difference debate

Clinical Issues

- therapeutic lag
- cost trends
- family as Pt/client?
- psychological issues
  - stigma + self-identity
- CF-testing issues / guidelines
- gene therapy / gene product
- prenatal diagnosis criteria

Priorities

- tracking CF experience
- " public perception
- influence disability act
- find out outreach contacts
- develop materials
- address consumer issues (impact

- Institute of Medicine – Economist
- OTA –
- HCFA –

* suggest have an economist on working group — sometimes are difficult to work w but are useful

Barnhart – ent to include people on DOC's mailing list & put in copy of summary

1st Ethics Joint Working Group

Participants, consensus

DOE 270 million dollars to study genetic damage caused by radiation or other energy chemicals; environmental mutagens.
- Develop technology to detect genetic mutations in human DNA.

(?) DOE to release RFA soon

N. Wexler - Hereditary Disease Foundation. Santa Monica, CA.

Johnathan Beckwith - Science for the People XYY. socio-biology; mathability of women being genetically based. Behavioral genetics.

NIH now largest funder of bioethics grants by government (Bob Cook-Deegan). First time NIH has gotten out to support ethics research.

Bob Pohorski, MD. Lincoln National Life Insurance Company.

Thomas Murray: use of performance (recombinant DNA) based enhancing drugs in sports. Metaphor for larger society. Performancing enhancing drugs in use by general populations. [Case Western Reserve]

Gates: public is misinformed about what genetics can offer. Don't understand gene level.

Goldstein: editors, middle-level editors. Bring in for enlightening sessions. Glamour.

Asch: articles in parenting magazines, genetic counselors etc.

[Dorothy Nelkin: NYU.; Robert Murray, Howard]
Council for the Advancement of Science writers.

Proctor: be careful not to over-estimate benefits of HGP.

R. Murray: teach genetics to younger audiences. Congressional staffers

Pat King: bring in religious groups. Clergy. Groups can help us understand what issues are.

Samuels / ASCh: "Is there knowledge we shouldn't have?"

Beckwith: Lack of understanding of what genetics is. Fate. Can't be change. Nature / nurture. Reductionist view. Reinforces the view that genetics is fated.

Applications of information vs generating information how to use that info. HGP - not part of gene function. (Going on outside the HGP).

Sammels:
What is disease? What about susceptibility to exposure to environmental contaminants.

"normal is mathematic fiction."

R. Murray:
Genetic variation in a population. "There are no normal people, we'll all have genetic defects."

"Genetic determinism". Counselling is for range of options for genetic diseases.

Education

King, Nelkin
Need to assess the public mind set. What they understand. What they can deal with.
- bring in religious institutions
- organized medicine. - internist, family practice.
- insurance company
- others in report of working group.

What are the institutional arrangements to handle the information that is coming out?
- Should scientist attempt to develop a neutral language

"Human ecology."

Cook-Deegan: people ~~in ago~~ will learn genetics because of the issues raised here.
1. fear of technology, info we can't handle.
2. historical baggage, racial ~~hygiene~~ hygiene. bad historical track.
3. Genetic determinism vis a vis genetic information will HGP information underscore genetic determinism.

Many steps between the gene and the phene. HGP info may ~~xx~~ indicate that there is so much we don't know about human behavior. Multifactorial influences on human function and behavior.

[Daniel Goleman - Behavior writer NYT].

Education

determinism becomes more important issue when there is social and economic climate. "Burden of Alzheimer's" on society. "Cost savings" becomes coercive. Economic climate may become coercive.

misconception:
As soon as we have the sequence we will know how humans work. eg mitochondrial genome. Now have sequence. Don't know what it does.

Will understand bits of information all along. Issues are currently with us. With come up all along.

tion

Nichols:

May need to look at cross cultural studies about effect of economics on genetic determinism.

"Western society accepts certain systems." Is HGP one of them?

Explanation of Private Insurance Industry

LUNCH

Bob Pokorski - Lincoln National Life Insurance (Private Insurance Industry)

Industry does not want to do tests, but would potentially benefit from information.

Private insurance provides protection for untimely, unknown, emergency health needs (not for sick people)

other chronically ill people should get into fed. sub. insurance programs.

Do risk assessments - adverse selection.

People have "entitlement" mentality. Feel they are entitled to to insurance coverage.

For-profit business

(Selling Science: Science and the Public)
Dorothy Nelkin

When healthy people drop out of pool, high-risk steps in, risk gets higher for those remaining. Premiums go up. Payout goes up.

Description of what kinds of things ins. companies use to disqualify applicants.

Not close to using genetic tests to disqualify.

Do not insure HIV+ tests.

Goldberg: Competition among ins. companies may foster variation in test requirements.

Cook-Deegan: need to reassess public policy about private v. public insurance. public policy needs to fill in gaps where private insurance leaves off. (Samuels also).

Tests that ins. companies use may not be reliable as disease predictors. Are people who are sensory impaired at higher risk for premature death.

Medical Information Bureau ~~Agency~~: sharing of info from one agency to the next. May pre-empt competitiveness.

King:
Bifurcate insurance system:

Private Sector	Govt
healthy people (least need it)	sick people (most need it)

↓ Is there a middle group?

Insurance Confidentiality

Wexler:
Having insurance cover genetic tests then gives them access to info. Do we want them to have info.

[Elke, Pam, Me - lobby for new health insurance policy. Public policy on health insurance.]

Samuels
look at impact on insurance industry of genetic testing.

Alternative models of national health insurance

Maybe should get grants to focus on

"middle group" and alternate forms of public health insurance, employer ins.

R. Murray:
HGP can find "good" genes and lower disease risk → insurance risk.

e.g. regular exercise, no smoking
lower premiums.

Individuals have pre-knowledge and then buy higher ins. coverage. Unfair to ins. companies.

insurance

May not have to have genetic tests until they start to buy high-level insurance premiums. (e.g. over $100,001 → then have tests)

Goldberg:
"government subsidy" – "partnerships with industry. Private companies that take on higher risk patients.

Cook-Deegan:

grants — Need info on what happens when insurance is denied.

RFA's — Genetics and actuarial process. Marriage of these two. What are outcomes.

longer discussion

CONFIDENTIALITY of GENETIC INFORMATION

Steven Goldberg:

Federal privacy act - means you're allowed to see what info gov't has on you. You can assume that it's accurate

Ownership - doesn't mean information can't be regulated, bought, etc. Doesn't limit access to information

patient level (clinic)
employer, institution level
state level
} levels of confidentiality

computer storage of genetic information

Marjorie Shaw:
Genetic information is ~~communicable~~ contagious -
passes vertically from person to person

[Comprehensive genetic information collected in Germany in 30s. → then used for sterilization and euthenasia program. Could not predict at first how the files could be used.]

King: How to think about genetic information in the context of families..
(genetic diseases as public health issues eg. PKU).

Uses vs. confidentiality. Confidentiality is impossible. Then must figure out how to use info rather than to keep it confidential.

{Genetic screening in public health policy.

To what degree does litigation drive moral values? Malpractice worry will drive use of genetic tests.

"Individual" ownership of ~~Gene~~ information model may breakdown first for cases of genetic disease. eg. HIV+ mothers. does father have right to know. Also physician obligation to warn 3rd parties.

Second Meeting
Working Groups - Afternoon · 6 February 1990
Nancy Wexler
Ellie Jordan
Eric Jeungst
Mary-Lou Pardue
Robert Murray
Victor McKusick
Bob Cook-Deegan
Jonathan Beckwith
Bettie Graham
Patricia King
Ben Barnhardt
Tom Murray

✓ Contacts with genetic disease networks.
Bob C-D:
- say we're open to receiving ideas from various interest groups; find out where they have annual meetings; speak to groups; exhibits (?)

P.K.
- groups should not become enemies. Have groups come talk to HGP groups Increases HGP credibility, knowledge of issues. Eliminates suspicions ~~Rabbit testimony~~.
- Generate a mission statement of ethics working groups: deliberate, ~~do~~ out reach?

Nancy - talk to Chris Joyce. Set him straight.
Victor McKusick has photographs.

abandon "ethics" name in group name.
have broader role. - economic, social, legal, etc. "Ethics" not understood by lay public, media.
- emphasize other roles of committee.

1. Advise NIH-DOE about how it will spend "ethics" money.

→ ELSI - Ethical, legal and Social Issues.

R.M.
2. Call together groups to have "Consensus Development" conferences.
[develop policy options].
★ "provide information that could be used to develop policy options."

T.M.
3. Public hearings on categories brought up in morning session.

labor groups
genetic counselor groups

Being in disability groups, human genetics society, ACOG, Pediatric Society, insurance company, theological groups. [World Council of Churches - position statement on genetics] Minority community. Ct community genetic disorders groups. Behavioral genetics groups.

Also go to their groups. Dialogue.

BC-D: put together a list of groups to invite to next meeting. Have ready by end of month.

4 Educational Meeting. At later date
outreach
Journalists, editors, high school biology teachers (Assoc. of ~~High~~ Science Teachers). Television producers (?)

Work with NSF on educational grants.

Cystic Fibrosis -
Elbe: NIH have conference in early March about test kit technology (lead = NIDDK). Consensus development about desirable course of action at this time.

IOM study (Bob CD)
1. Who should carry out tracking "CF experience." Introduction of new technology and related issues: reimbursement, confidentiality, etc. counselling, technology transfer

Should check in with NIDDK to see if they are doing similar things.

2. Intervention strategies in CF. Activists oriented. Does this group play a role in intervention? Do not sanction or censor. Have anticipatory role to anticipate ELSI issues re. CF.

What will HGP do after meeting with CF community?

BCD: Can take steps to fill in gaps that allow policy decisions can be made.

PK: Find out what is not covered at CF Conference and move on getting gaps filled. Invite NIDDK, Establish common and separate needs. Have two days next session:

↗ CF - day 1
↘ other interest groups - day 2

Education.

Need mailing lists for philosophers, economists, history of science, history of medicine, genetic counselors. To keep updated on our program plans. IOM uses economists on their committees. Ask them for lists.

Also OTA, HCFA

Need to stimulate grants in combined interests of medical genetics and development of actuarial data. What effect will genetics testing have on actuarial data?

European Community has subgroups called ESLA and would like to send representative to NCP meeting. Send as observer and vice versus.

[Bernadet Modell, Malcom Ferguson Smith WHO Report on Ethics of Genetic Testing]

New Committee Members:

MD. connected to Hatch, former director of HERSA. Connected on Hill. Expertise in congressional relationships, health care services. Suggested by Anne Hamson Clarke of March of Dimes.

Needs: two slots max

✓ Disability Groups – Adrianne Asch

✓ Theology

Labor — Larry O'Connell, President of Rank Ridges Trust (?)

Industrial groups
✓ Economist

People close to community interests
Disability
Labor / Industry

GOVERNMENT REPRESENTATIVES

NATIONAL INSTITUTES OF HEALTH

Elke Jordan, Ph.D.
Deputy Director
National Center for Human
Genome Research
Building 1, Room 201
Bethesda, MD 20892
301/496-0844
301/496-4843

Bettie J. Graham, Ph.D.
Chief, Research Grants Branch
National Center for Human
Genome Research
Building 38A, Room 613
Bethesda, MD 20892
301/496-7531
301/480-2770 (FAX)

Eric Juengst, Ph.D.
Special Expert on Ethics
National Center for Human
Genome Research
Building 38A, Room 613
Bethesda, MD 20892
301/496-7531
301/496-2770 (FAX)

Ms. Leslie Fink
Public Affairs Officer
National Center for Human
Genome Research
Building 38A, Room B2N13
Bethesda, Maryland 20892
301/402-0736
301/480-2770 (FAX)

Ms. Michelle Coleman
Committee Managment Officer
National Center for Human
Genome Research
Building 38A, Room 613
Bethesda, MD 20892
301/496-7531
301/496-2770 (FAX)

DEPARTMENT OF ENERGY

Benjamin J. Barnhart, Sc.D.
Manager, Human Genome Program
Office of Health and Environmental
Research
ER-72, GTN
Washington, DC 20545
301/353-3683
301/353-3884 (FAX)

PARTICIPANTS FOR ETHICS WORKSHOP
FEBRUARY 5-6, 1990
WILLIAMSBURG, VIRGINIA

INVITEES

CLINICAL MEDICINE

Elena Gates, M.D.
Assistant Professor of
Obstetrics & Gynecology
University of California
Medical Center
400 Parnassus
San Francisco, CA 94143-0346
415/476-4492

ETHICS

Ms. Adrienne Asch
Associate in Social Sciences
and Policy
New Jersey Bioethics Commission
CN061
Trenton, NJ 08625-0061
609/275-8714

JOURNALISM

Dr. Thomas Goldstein
Dean, School of Journalism
Northgate Hall
University of California - Berkeley
Berkeley, CA 94720

LAW

Steven P. Goldberg, J.D.
Professor of Law
Georgetown University
600 New Jersey Avenue, N.W.
Washington, DC 20001
202/662-9034

SOCIOLOGY

Dorothy Nelkin
Professor
Department of Sociology
School of Law
New York University
269 Mercer Street
New York, NY 10003
212/998-8347

EUGENICS

Dr. Robert Proctor
The New School for Social Research
66 West 12th Street
New York, NY 10011

LABOR

Sheldon W. Samuels
Executive Vice President
Workplace Health Fund
Industrial Union Department
AFL-CIO
Washington, DC 20006
212/842-7830

Dr. Robert Nussbaum
Department of Human Genetics
University of Pennsylvania
School of Medicine
Clinical Research Building, Room 475
422 Curie Blvd.
Philadelphia, PA 19104-6145
215/898-1012

ETHICS WORKING GROUP

Jonathan R. Beckwith, Ph.D.
Department of Microbiology and
Molecular Genetics
Harvard Medical School
200 Longwood Avenue
Boston, MA 02115
617/732-1920
617/738-7664 (FAX)

Robert Cook-Deegan, M.D.
National Center for Human
Genome Research
National Institutes of Health
Building 38A, Room 201
Bethesda, MD 20892
301/869-0066
301/869-2156 (FAX)

Patricia King, J.D.
Georgetown University Law Center
600 New Jersey Avenue, N.W.
Washington, DC 20001
202/662-9084
202/662-9444 (FAX)

Victor A. McKusick, M.D.
Division of Medical Genetics
Johns Hopkins Hospital
600 North Wolfe Street
Blalock 1007
Baltimore, MD 21205
301/955-6641
301/955-4999 (FAX)

Robert F. Murray, Jr., M.D.
Department of Pediatrics, Medicine,
Oncology, and Genetics
Box 75
Howard University College of Medicine
Washington, DC 20050
202/636-6340
202/745-3731 (FAX)

Thomas H. Murray, Ph.D.
Center for Biomedical Ethics
Case Western Reserve University
2119 Abington Road
Cleveland, OH 44106
216/368-6196
216/368-3128 (FAX)

Mary Lou Pardue, Ph.D.
Department of Biology
Room 16-717
Massachusetts Institute of Technology
Cambridge, MA 02139
617-253-6741

Nancy S. Wexler, Ph.D.
Hereditary Disease Foundation and
Department of Neurology and Psychiatry
College of Physicians and Surgeons of
Columbia University
722 West 168th Street, Box 58
New York, NY 10032
212/960-5650
212/960-5624 (FAX)

GOVERNMENT REPRESENTATIVES

NATIONAL INSTITUTES OF HEALTH

Elke Jordan, Ph.D.
Deputy Director
National Center for Human
Genome Research
Building 1, Room 201
Bethesda, MD 20892
301/496-0844
301/496-4843

Bettie J. Graham, Ph.D.
Chief, Research Grants Branch
National Center for Human
Genome Research
Building 38A, Room 613
Bethesda, MD 20892
301/496-7531
301/480-2770 (FAX)

Eric Juengst, Ph.D.
Special Expert on Ethics
National Center for Human
Genome Research
Building 38A, Room 613
Bethesda, MD 20892
301/496-7531
301/496-2770 (FAX)

Ms. Leslie Fink
Public Affairs Officer
National Center for Human
Genome Research
Building 38A, Room B2N13
Bethesda, Maryland 20892
301/402-0736
301/480-2770 (FAX)

Ms. Michelle Coleman
Committee Managment Officer
National Center for Human
Genome Research
Building 38A, Room 613
Bethesda, MD 20892
301/496-7531
301/496-2770 (FAX)

DEPARTMENT OF ENERGY

Benjamin J. Barnhart, Sc.D.
Manager, Human Genome Program
Office of Health and Environmental
Research
ER-72, GTN
Washington, DC 20545
301/353-3683
301/353-3884 (FAX)