DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

MAR 13 1990

March 12, 1990

The NIH-DOE Working Group on Ethical, Legal and Social Issues Related to Mapping and Sequencing the Human Genome met recently in Williamsburg, Virginia for a combined workshop and working group meeting. I am enclosing the minutes of the working group meeting. The workshop report is currently being prepared and a copy will be sent to you as soon as it is available. If you would like additional information, please contact me at (301) 496-7531.

Bettie J. Graham

Bettie J. Graham, Ph.D.

File ethics WG

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 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
Building : 1
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January 29, 1990

Nancy S. Wexler, Ph.D.
Hereditary Disease Foundation
Department of Neurology and Psychiatry
College of Physicians and Surgeons of
Columbia University
722 West 168th Street, Box 58
New York, NY 10032

Dear Dr. Wexler:

I am pleased that you are able to attend the upcoming workshop of the Ethics Working Group in Williamsburg on February 5th and 6th, 1990. As I emphasized before, this is to be an informal workshop with no set agenda. We are eager to learn your views from your professional and personal perspective regarding the impact of the Human Genome Initiative. We look to you for guidance with respect to the activities of the National Center for Human Genome Research and the role of the community at large in responding to the challenges of this major biological research undertaking.

The workshop will take place from 9:00 a.m. to 5:00 p.m. on Monday, February 5 and from 9:00 a.m. to 1:00 p.m. on Tuesday, February 6. The Ethics Working Group members who are participants in this workshop will be staying until 5:00 p.m. on Tuesday. They are meeting to plan the implementation of ideas raised at the workshop, as well as make plans for public hearings which will be scheduled in the Summer or Fall.

For those of you who arrive early enough on Sunday evening, please join us at the Williamsburg Inn (room to be announced) to get acquainted.

Some of you have already sent to the office a brief biography or curriculum vitae. If you have not already done so, we would very much appreciate receiving this information prior to the meeting. Also, if you have an article that would be helpful for us to read before the meeting, or suggestions for a bibliography, we are compiling a list of articles pertinent to this area and would be pleased to receive your recommendations.

Enclosed is a list of participants who are attending the workshop and some additional reading materials for your interest. If you have any questions or suggestions, please do not hesitate to contact Dr. Nancy Wexler (212-960-5650), Dr. Bettie Graham of my staff (301-496-7531) or me (301-496-0844).

Sincerely,

Elke Jordan

Elke Jordan, Ph.D.
Deputy Director
National Center for Human Genome Research

Enclosures

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

INVITEES

CLINICAL MEDICINE

Elena Gates, M.D.
Assistant Professor of
[redacted] Gynecology
alifornia

practise + ethics
ACOG ethics [illegible]ittee

ETHICS

Ms. Adrienne Asch
Associate in Social Sciences
and Policy
[redacted]ssion

JOURNALISM

Dr. Thomas Goldstein
Dean, School of Journalism
[redacted]erkeley

press ethics

LAW

Steven P. Goldberg, J.D.
Professor of Law
[redacted].W.

law + science

SOCIOLOGY

Dorothy Nelkin
Professor
[redacted]

EUGENICS

Dr. Robert Proctor
[redacted]ial Research

historian/science
Medicine under the Nazis

LABOR

Sheldon W. Samuels
[redacted]

Health/biology + environment + occupational [illegible]

Dr. Robert Nussbaum
Department of Human Genetics
[redacted]
n 475

[illegible]

Dr Robert Pokorski MD internist
Lincoln National Life Insurance Company

ETHICS WORKING GROUP

Jonathan R. Beckwith, Ph.D.
Department of Microbiology and
Molecular Genetics
[redacted]

Robert Cook-Deegan, M.D.
National Center for Human
[redacted]

Patricia King, J.D.
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Robert F. Murray, Jr., M.D.
Department of Pediatrics, Medicine,
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Thomas H. Murray, Ph.D.
Center for Biomedical Ethics
Case Western Reserve University
[redacted]

Mary Lou Pardue, Ph.D.
Department of Biology
[redacted] of Technology

Nancy S. Wexler, Ph.D.
Hereditary Disease Foundation and
Department of Neurology and Psychiatry
College of Physicians and Surgeons of
[redacted]

GOVERNMENT REPRESENTATIVES

NATIONAL INSTITUTES OF HEALTH

Elke Jordan, Ph.D.
Deputy Director
National Center for Human
[redacted]

Bettie J. Graham, Ph.D.
Chief, Research Grants Branch
[redacted]

Eric Juengst, Ph.D.
Special Expert on Ethics
National Center for Human
Genome Research
[redacted]

Ms. Leslie Fink
Public Affairs Officer
National Center for Human
[redacted]

Ms. Michelle Coleman
Committee Managment Officer
National Center for Human
[redacted]

DEPARTMENT OF ENERGY

Benjamin J. Barnhart, Sc.D.
Manager, Human Genome Program
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[redacted]

JAN 30 1990

PENNSTATE

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FAX copy to 2/2
Bettie – return
to me

January 24, 1990

Elke Jordan, Ph.D.
Office of Human Genome Research
Building One Room 201
National Institute of Health
Bethesda, MD 20892

Dear Elke:

It is my understanding that the upcoming Ethics Working Group workshop is to be primarily an opportunity for the members of the Group to begin hearing different views on 1) the ethical/social implications of the HGI and 2) the most urgent research and outreach needs for the Center's ELSI program.

Nancy's plan is to have our guests first speak informally on the first topic and then, after discussing the substantive issues that emerge with the Working Group, turn to the question of programmatic priorities (perhaps during Tuesday a.m.?).

I agree that it is better not to organize the meeting around a topical or thematic framework, since that may inhibit what emerges from the discussion. However, it may be useful to have some back-up discussion questions for the group. Here are a few suggestions, organized by guest (mainly for convenience, since most questions can benefit from multiple perspectives):

Elena Gates (medicine)

1) How has California's AFP screening program affected the physician's job in providing prenatal care to obstetrical patients? Are there lessons in that experience for other forms of prenatal predictive genetic testing?

2) How should clinicians respond to parental requests for prenatal tests for genetic traits that are highly variable (e.g., neurofibromatosis) or treatable (PKU), or non-pathological (cutaneous melanism), when such tests become available?

Robert Nussbaum (genetics)

3) Does the advent of family-based linkage map diagnostic tests place new pressures on the tradition of client-centered, non-directive genetic counseling? How should counselors allocate their allegiances in these circumstances?

4) By what criteria should new proposals for routine neonatal genetic screening be assessed? Is CF screening a candidate?

Robert Proctor (history)

5) What are the closest contemporary American analogues to the sort of social/scientific movement that supported America's eugenic policies during the 20's and 30's?

Ian Rolland (insurance)

6) Could the private health insurance industry survive if its underwriters' access to predictive genetic test results were restricted? Are there lessons to be drawn for genetic testing from the industry's experience with HIV testing?

Sheldon Samuels (labor)

7) Should there be social (i.e., government-run) programs designed to protect susceptible workers from genetic hazards in the workplace, even if mandatory genetic screening and monitoring of workers are necessary for their success?

Steven Goldberg (law)

8) Who has the best legal claim to "own" particular pieces of genetic information, like the identity of an informative RFLP marker in a particular family? The geneticists who identify the marker? The family members that carry it? What legal theories of property would one turn to in this case?

Dorothy Nelkin (sociology)

9) What models exist for thinking about the social impact of predictive knowledge about individual members of a community?

Adrienne Asch (social policy)

10) What sort of public policies might be effective in curbing unjust social discrimination against carriers of particular genes?

Thomas Goldstein (journalism):

11) In the face of the mix of commercial interests, scientific competition and clinical confidences that may all be involved in the development of diagnostically useful map and sequence data, how should the flow of news about new advances be controlled?

The Working Group may be well beyond these questions, of course, and I certainly would not want to tie them to this agenda. However, I think that these are questions that will come up naturally during the discussion, and they do indicate where my own curiosity currently points! I hope they are what you had in mind.

I will be glad to talk with you, Nancy and Bettie about these suggestions at your convenience.

Sincerely,

Eric Juengst

Eric T. Juengst
Assistant Professor of Humanities
(Philosophy)

ETJ/kkg

cc: Nancy Wexler