UNITED STATES NATIONAL BIOETHICS ADVISORY COMMISSION
NATIONAL INSTITUTES OF HEALTH

THE INTERNATIONAL SUMMIT OF NATIONAL BIOETHICS ADVISORY BODIES

Parc Room
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San Francisco, California

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8:30 a.m.

International Summit of National Bioethics Advisory Bodies

MICHAEL ABRAMS
CDBI, United Kingdom

JOHANNA KITS NIEUWENKAMP
CDBI, United Kingdom

JOHN H. BRYANT
CIOMS, USA

KAUSAR S. KHAN
CIOMS, Pakistan

ROBERT LEVINE
CIOMS, USA

STEFANO RODOTA
Membre du Groupe de Conseillers
Fondazione Basso, Italy

BARTHA KNOPPERS
HUGO, Canada

DANIEL WIKLER
International Association of Bioethics, USA

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MARTINE ROTHBLATT
Bioethics Subcommittee
International Bar Association, USA

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UNESCO, France

JUAN CARLOS TEALDI
Argentina

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Australia

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Brazil

CRISTINA BONTEMPO DE FREITAS
Brazil

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Brazil

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Canada

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China

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France

JEAN-PIERRE CHANGEUX
France

ALAIN POMPIDOU

France

NORIO FUJIKI
Japan

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DARRYL MACER
Japan/New Zealand

TAKASHI FUJIMOTO
Japan

IKUFUMI NIIMI
Japan

HIRAKU TAKEBE
Japan

SONG SANG-YONG
Korea

MANUEL VELASCO-SUAREZ
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Spain

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Spain

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Sri Lanka

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United States

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Yugoslavia

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STEVEN HOLTZMAN
BERNARD LO
LAWRENCE MIIKE
DIANE SCOTT-JONES

A G E N D A

A G E N D A

AGENDA ITEM: PAGE:

Morning Session (Continued)

Luncheon Address

Afternoon Session

P R O C E E D I N G S

8:42 a.m.

Welcome

DR. SHAPIRO: Good morning, ladies and gentlemen.

I'd like to introduce myself. I am Harold Shapiro, President of Princeton University, but, more importantly for today, Chairman of the National Bioethics Advisory Commission, which was appointed in the U.S. relatively recently.

I want to extend a warm welcome to all our guests, particularly our guests from abroad. It's a great pleasure to have you here today, and we are very honored that many of you have taken an extra day to spend some time with us, so that we can learn from each other, and speaking at least for our National Commission, so we can learn from you.

Many of you are very active in organizations that have been studying the issues for a very long period of time, and we consider it a great honor to be here with you today, so that we can learn from you, and hopefully we can make some contribution to each other's work.

Now, given that there are so many commissioners from the National Bioethics Advisory Commission, this, in addition to being a joint meeting of all of us together, is also an official meeting of the National Bioethics Advisory Commission.

As a result of various federal laws regarding the openness and nature of these meetings, we do have to start this meeting with a formal announcement. For those of you that may find this a little unusual, this just is to satisfy the requirements of the NBAC members here.

So, let me turn to Rachel Levinson to make the appropriate announcement.

Rachel?

MS. LEVINSON: Thank you very much, Dr. Shapiro.

I am Rachel Levinson. I'm the Assistant Director for Life Sciences at the White House Office

of Science and Technology Policy. Closer?

DR. SHAPIRO: Start that again.

MS. LEVINSON: For those of you who couldn't hear me, I am Rachel Levinson. I'm the Assistant Director for Life Sciences at the White House Office of Science and Technology Policy.

I am, for the purposes of the Federal Advisory Committee Act that Dr. Shapiro referred to, the designated federal official for the National Bioethics Advisory Commission and the liaison to the White House.

I'd like to add my welcome to all of you, to Dr. Shapiro's, and say that I'm very pleased to be here and take part in this meeting, and that it is an open public meeting as was mentioned, but I'm informed at this point at least that no one from the public has registered a desire to make a formal presentation to the meeting. I'm sure that that opportunity, should someone make -- make that decision later, that we'll -- we'll try and accommodate it.

And with that, I would like to -- to open this meeting.

DR. SHAPIRO: Thank you very much.

I think it's going to be necessary for those

of us when we speak to use the microphone to speak pretty closely to it. Otherwise, I think it is difficult for everyone to hear.

As I mentioned just a few moments ago, the National Bioethics Advisory Commission here in the U.S. has only recently been appointed. As a matter of fact, this is our second meeting. We had one meeting in Washington a month or six weeks ago, and this is only our second meeting.

I want to issue an apology to all our guests. I know we have already misspelt some names. We even put some people in the wrong country, and I want to apologize for that. It's because we did get this meeting together as quickly as we could. We ourselves are just getting our staff mobilized, and I hope that none of you are unnecessarily offended. It just was honest mistakes.

I also want to apologize that we, for this meeting, do not have any simultaneous translation for those of you that aren't as fluent in English as in other languages, and I think we would have preferred to have that. Just given the constraints of time, we were unable to arrange it. I ask for your understanding of that, and I apologize to you in

advance for that.

Well, what draws us all together here, of course, is that we share a common concern with the ever-new social and moral dilemmas that are generated by both the advancing frontiers of science and changing moral sensibilities in the societies which we serve.

It's always been a startling thing to me as an economic historian, interested in technology and science, that all advances seem on the one hand to be both awe-inspiring and appalling at the same time, and that we deal with those problems, all of us are dealing with those problems, as they arise in the area of -- in the biomedical area.

As I said just a moment ago, NBAC was very recently appointed. I think as many of you know, however, there have been previous commissions in our country, most notably the National Commission which really worked in the mid-'70s, I think 1974 to 1978, followed by the Ethics Advisory Board, and, very importantly, the Presidential Commission, the President's Commission, which worked in the end of the '70s/beginning of the '80s, roughly 1978 to 1983, here in the U.S.

However, since that time, since those early '80s, there has been no body at the national level for the on-going deliberation of these issues, no official national body, and, so, that's been, I think, missing in our country for the last 15 years or 12 to 15 years, and, of course, many of you -- for many of you, that's been a period when your own countries and your own areas of concern have been very, very active.

There have here in the United States been, of course, many efforts at the state level dealing with issues and the regional level, and, of course, at the professional level.

Indeed, I think it's fair to say that in the scholarly area, there's probably been a boom, if one could use such a word in relation to this subject, there's kind of been a boom in bioethics, and, so, there's a whole literature that's been established not only here but, of course, abroad.

All of us together have established a brand-new literature in this area which has very much enriched the understanding and our capacity to deal with these problems as we go along.

Now, what I would like to do right now is introduce a few colleagues who also want to extend a

few words of welcome and perhaps a few words of what they hope our discussions will accomplish today, and after that, I will go back and just briefly review the agenda so we know where we're headed during the day, and then just proceed directly on.

So, let me now call upon Jean-Pierre Changeux, President, Comite Consultatif d'Ethique from France. We're very privileged to have him here today, and let me turn to him right now.

Mr. Changeux?

Statement of Jean-Pierre Changeux, President
Comite Consultatif National d'Ethique

MR. CHANGEUX: Mr. Chairman, ladies and gentlemen, it's a privilege for me to say a few words of introduction to this International Summit of National Bioethics Advisory Commission in San Francisco, and I wish to express my special thanks to Professor Harold Shapiro for this invitation.

The gathering of more than 50 representatives of ethical committees from all around the world makes this a unique opportunity to listen and to debate the many ethical issues raised by the progress of scientific knowledge and its application to medicine.

On one hand, the ambitions of scientific progress is to be objective and universal. On the other hand, as pointed out by the French philosopher George Canguilheus, science does not decide the destination of the facts it produces at the level of society. This is indeed a moral issue.

Yet, the diversity of morals does exist from one part of the world to another or even within a given country, and as a consequence, the differences in cultures, history, religious traditions. Moreover, political and economical factors must step into debates primarily aimed at ethical recommendations.

Ethical committees at the national level, at least from the experience we had in France during the past 13 years, do help define solutions, even provisional, in such difficult situations.

However, a number of recommendations need to be satisfied. First of all, the committee members should include people with different interests and backgrounds. For example, people who belong to the main philosophical and spiritual families, who have shown in the past competence and interest for ethical issues or who are members of the scientific or medical research community.

Thus, a diverse understanding of moral issues and a variety of scientific and technical competencies has to exist within the ethical committees.

Secondly, the condition should be such that open and public debates, many of them sometimes for months, to finally led to an agreement. In French, we say accords ethique, rather than a consensus on a minimal solution.

Creativity in the debate is essential to find an original solution which resolves the conflicts in the course of an ethical debate.

In France, the Comite Consultatif National d'Ethique, which was founded in 1983, has no legislative power, but only produces advice or recommendations in a consultative manner.

In 13 years, up to 50 recommendations have been made public. Some of them are translated in English in this book that I can make available to anybody.

These recommendations were on topics as different as assays of drug and experimentation in humans, tissue transplantation, medical assistance to procreation, research on embryos, genetic tests and

predictive medicine, and also on toxicomania, behavioral sciences, contraception in mentally-handicapped persons or voluntary sterilization.

Most of the recommendations given by the Commite Consultatif National d'Ethique were incorporated in a Law of Bioethics which was voted finally by the French Parliament in 1994.

In the course of these debates, a number of common ethical principles emerged. I would simply say a few words about them.

They include, first, the respect of the dignity of the human person, Kant, a universal value which excludes that any singular individual be treated as a thing, or as a piece of merchandise, or as a pure mean.

This requires in particular the informed consent of all those who participate in any given research with the written condition that they fully understand that they decide to contribute in a freely and autonomous manner.

The principle of maximal good or welfare, which is significantly more than what usually the medical community thinks the primum non nocere of the Hippocratic medicine.

Third, the principle of justice, which in the case of bioethics, relies on the recognition and respect of scientific knowledge first, but give equal opportunity to anybody throughout the world to benefit from the progress of science and technology.

The debates in bioethics thus aim at the discovery of complete and practical solutions which conciliate the progress of objective knowledge with the respect of human dignity, of solidarity for all of us, of liberty for each of us.

I feel certain to learn from each other about these issues during this meeting, and again I want to thank Professor Shapiro for this opportunity.

DR. SHAPIRO: Thank you very much.

Let me now call on Michael Abrams from the Steering Committee on Bioethics Council of Europe.

Statement of Michael Abrams
Steering Committee on Bioethics

MR. ABRAMS: Thank you, Dr. Shapiro, for your Commission's very kind invitation for me to attend on behalf of the Steering Committee of the Council of Europe.

It is an enormous privilege and pleasure for me to be here today, and I would like to say how

grateful I am for two reasons.

First of all, for personal reason, my wife and I spent a year in San Francisco some 33 years ago at the expense of the Rockefeller Foundation, and now we're able to revisit the city at the expense of the Council of Europe. That may or may not be an ethical approach to take. Of course, my wife and I are particularly delighted by this invitation.

The -- those from Europe will well know the composition of the Council of Europe, but from those outside that continent, perhaps I could just point out that it consists of governmental representatives from virtually every European state, from Iceland in the north to Malta in the south, from Portugal in the west to Russia in the east, and I had the good fortunate to be present when Russia signed the European Convention on Human Rights very recently and undertook that all the habitants of Russia would have access to the Human Rights Court in Strausbourg, which was clearly a hallmark date in the history of ethics in Russia.

I very much am looking forward to hearing the various discussions around the table today. The Steering Committee on Bioethics has been tackling ethical issues for a great many years, and you have

some of our documents in your papers, including one which I have been personally involved with for something like seven years, the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine. In short, the Convention of Human Rights and Biomedicine, colloquially known as the Bioethics Convention, though I think I'm not breaking any secrecy of the meetings saying that we changed the name from Bioethics to Convention on Human Rights and Biomedicine because there was some doubts among member states about the precise meaning of the word "bioethics".

So, I'm sure that that will be further illuminated in the discussions today.

I am very pleased to be able to tell you that the word "draft", which is in your papers, can now be canceled because the Committee of Ministers of the Bureau just two days ago formally adopted this convention, and they will be opening it for signature very shortly. There are one or two very minor drafting changes in the text compared to what you have, but there is nothing of any substance that has been altered in any way.

So, that, too, is a further milestone in spreading ethical behavior in treating human beings in biology and medicine throughout the Continent of Europe.

When the then-Secretary General of the Council of Europe first invited work on what I still am going to call the "bioethics convention" for short, her aim was that throughout the Continent of Europe, the same ethical standards would apply.

You can judge for yourself from the document as to what extent we've been able to achieve a high enough ethical standard, but what I can tell you from the difficulties of the drafting committee, which I chaired, was the great problems in reaching agreement among some 39 states on the precise wording and the precise content of an international ethical communiqué.

So, my particular interest in being here today, apart from listening to the very detailed discussions of various items, is an important international issue.

To what extent internationally, that is globally, can we agree on common ethical principles in the treatment of human beings in biology and medicine,

so that throughout the world, we can have a common ethical baseline for the way we practice?

I therefore look forward, Mr. President, to a very enjoyable day, and thank you again for inviting me.

DR. SHAPIRO: Thank you very much, and congratulations on getting the word "draft" removed. That is an accomplishment and very much appreciated.

Let me now call on Norio Fujiki, Vice President, International Bioethics Commission of UNESCO.

Mr. Fujiki?

Statement of Norio Fujiki, Vice President
International Bioethics Committee, UNESCO

MR. FUJIKI: On behalf of International Bioethics Committee of UNESCO, especially President and Madam Lenau, I would like to say something for the conversation of your wonderful meeting, and, of course, I'll bring back this information, and then I would like to add some of our new discussion in the next -- next years. We will have a meeting, and, so, I would like to just make a short story about International Bioethics Committee in UNESCO.

In 1993, we have started, after the

consultation with the Director General, we have established the new Division of Bioethics, which the director is now here, over there, Dr. Kutukdjian, and, so, that means we have three science, education and United Nation scientific, cultural and the educational, and then to add one in social consequences. That means the bioethics in there, and then now we have started on our international debate among the 40 members of the different countries, and then 10 members of the bioethical organizations, and now have started for the discussion on the international instrumentation for the protection of the human genome, which will be in 1998, at the time of the 50th -- United Nations 50th Anniversary, and, so, in this time, we have discussion of bioethics in brain research and embryo research, population genetics diversity project and teaching of bioethics and so on, and then otherwise, the Commission presented a draft of the declaration of the protection of human genome.

And we have been happy to have last draft of the declaration on the protection of human genome right will be discussed in this meeting, and we're very happy to have it, and then otherwise we have now

a little bit talked about the -- our -- the studies in Japan and of the International Bioethics Seminar in Fukui we have in 1987. We have a first time to welcome the professors to Fukui, and then to have a meeting of the -- this is the first meeting of the bioethics medical, and then to have five times to have it.

And then I just wanted to say -- to make propagandas for the next session will be in Japan, in the UNESCO Bioethics Commission Conference, which will be held in Kobe, in the next year, November, and some of you have already received our invitation, but then at this time, I'll extend my gratitude to have this meeting, and then also to -- to Japan to discuss on the bioethics problem occurred in especially in Asian and Pacific regions.

Thank you.

DR. SHAPIRO: Thank you very much.

Let me just, before we go on to our agenda proper, let me just get one or two logistical items out of the way.

First of all, despite the formality of our setting here, given that as a kind of burden we have to carry, I do hope that we'll keep our discussions as

informal as possible, although we have -- all have these large names in front of us, I can't read them all from here, and I don't know you all personally. So, I hope you won't mind as the discussion goes on if occasionally I find I have to point or nod, you will not take that in any inappropriate way.

Second of all, I do want to remind all the delegates that we do have a lunch in which we are very fortunate to have Professor Amy Gutmann, who will speak to us today on some reflections -- Deliberating About Ethics in a Democracy is the -- is the -- the title of her talk. Some Reflections on Commissions.

Most of us are members of commissions, most of us are interested in how one goes about deliberating matters of ethics within democracies, and I think you'll all enjoy that very much.

Now, what is being passed out right now is an important ticket. If you fail to have this ticket, lunch costs $30. If you have it, that's all you need. So, please put these tickets in your pocket or elsewhere where they are safe because we look forward to the lunch. The lunch, I believe, will be just in the room next door to us, just down the hall, just -- just after we break.

Alex, do you have anything further to say about the lunch? Is there any --

PROF. CAPRON: For anyone who doesn't have a ticket, we'll get them one.

DR. SHAPIRO: If you don't have a ticket, see Alex or see the registration desks out in front, but we want -- we're trying to hand one out to each one of the delegates here. So, I'd just ask you to -- to keep hold of that.

Self-Introductions of Delegates

DR. SHAPIRO: Now, while I know that many of you have been friends and colleagues for many years, and though there are quite a few of us here today, I do want to take this opportunity to allow us to introduce ourselves to each other.

So, I'm going to start with Alex on my left, if we could just go around the table, everyone just tell our colleagues who you are and one other sentence that you might want to say about yourself, and we can go around the table, then we'll begin our discussions.

Alex?

PROF. CAPRON: I'm Alex Capron from the United States, a member of the National Bioethics Advisory Commission and was previously the Executive

Director of the President's Commission and Chairman of the one commission that the -- Dr. Shapiro forgot to mention, which was another official United States commission that existed for a couple of years to advise the United States Congress, and then controversy in the Congress put us into the deep freeze like a frozen embryo, and we never issued any reports, which is why we're so unknown, in the mid-1980s.

MR. CHANGEUX: I'm Jean-Pierre Changeux from Paris, France. I am the Chairman of the National Consultatif D'Ethiques Committee for Health and Life Sciences, and, professionally, I am a neuro-biologist.

MR. ABRAMS: Michael Abrams, representing the Steering Committee of the Council of Europe. I come from London, where I have retired from being Deputy Chief Medical Officer in the Department of Health, where, among other things, I was responsible for all the bioethics and consent and research issues that we're going to be discussing for the rest of the day.

MR. LEVINE: I'm Robert Levine. I'm here representing CIOMS, the Council for International Organizations of Medical Sciences, and I'll have a

chance to speak about their work later this morning.

I'm a Professor of Medicine and lecturer in Pharmacology at Yale University, School of Medicine.

Thank you.

MS. SCOTT-JONES: I'm Diane Scott-Jones. I'm a member of the National Bioethics Advisory Commission. I'm a Professor of Psychology at Temple University, and I've chaired or served as a member of ethics committees for the professional organizations I belong to, such as the Society for Research and Child Development in the American Psychological Association.

MR. LO: I'm Bernard Lo. I'm a member of the U.S. National Bioethics Advisory Committee. I'm a Professor of Medicine at the University of California here in San Francisco, and I guess I'd like to welcome all of you to our city.

MR. BRITO: I'm Arturo Brito, a member of the National Bioethics Advisory Commission, an Assistant Professor and pediatrician out of the University of Miami, and my primary interests involve the provision of health care to under-privileged and minority children.

MR. KUTUKDJIAN: My name is Georges Kutukdjian. I'm Lebanese. My training is in Cultural

Anthropology. I'm presently the Director of Bioethics at UNESCO and the Secretary-General of the International Bioethics Committee. Formerly, I was responsible at UNESCO of the Program on Human Rights.

MR. BRYANT: My name is John Bryant. I'm Emeritus Professor of Community Health Sciences at the Aga Khan University in Kharachi, Pakistan. I'm President of CIOMS, which Dr. Levine just mentioned, and currently we are -- CIOMS is working with the World Health Organization on the Ethical Content of a Renewal of the Health For All Strategy.

Thank you.

MS. KNOPPERS: Bartha Maria Knoppers, Professor of Comparative Law and Ethics, University of Montreal in Canada. I chair the Canadian Medical, Ethical, Legal, Social Issues Committee, the MELSI Committee, of the Canadian Genome Program, as well as the Ethics Committee of HUGO, to which I will be speaking shortly.

MR. CHALMERS: Hello. I'm Donald Chalmers. I'm the Chair of the Australian Health Ethics Committee, and as I'll be talking with you shortly, I won't go on very much. I am a Professor of Law, and I have to confess that I'm always very embarrassed when

I describe myself as a lawyer.

MS. DeFREITAS: I'm Corina DeFreitas. I'm from Brazil, from the Health National Council, that's now with Executive Group, that's working about research involving human subjects, and we would have here now two our chairmen, Dr. Hessne, he couldn't be here, but we have another member of this group here with us.

Thank you.

MR. PESSINI: I am Leo Pessini from Brazil. I am a member of the Executive Working Group of the National Health Council of Brazil, and I am here with Corina, and I am involved in the bioethics field for several years, and I'm directing a Center of Bioethics in St. Camillus College in Sao Paulo, Brazil.

MR. QUI: My name is Ren-Zong Qui, Professor of Philosophy. I'm responsible for a program in bioethics in Chinese Academic Social Sciences.

MR. MACER: Hello. I'm Darryl Macer. I'm from two countries to the west of here in the Pacific, Japan and New Zealand, and I'm also a member of UNESCO Committee, and I'm interested in the -- what this Commission representatives can say for the countries of Asia and Pacific who -- especially Asia, who don't

have national commissions.

Thank you.

MR. NIIMI: Good morning. My name is Ikufumi Niimi from Japan. I'm a member of the Association of the Bioethics and Medical Law in Japan, and I am a law professor, and my main interest is informed consent.

Thank you.

MR. VELASCO-SUAREZ: I am Velasco-Suarez from Mexico. I'm an Emeritus Professor of Neurology at the National University of Mexico, and now President of the National Commission of Bioethics in Mexico.

MR. YUDIN: My name is Boris Yudin. I'm from Russia, from Moscow. I'm Vice Chairman of Russian National Committee on Bioethics, which is a non-governmental independent organization.

MR. LADISLAV: My name is Ladislav Soltes. I am Professor of Pediatrics from Slovak Republic in Bratislava, and head of the Institute of Medical Ethics and Bioethics in Bratislava.

Thank you.

MR. GELZER: I'm Justus Gelzer from Switzerland, pediatrician, and formerly in

pharmaceutical medicine, now Secretary-General of the Swiss Academy of Medical Science, a member of the Central Medical Ethical Commission, elaborating guidelines for the Swiss Medical Corps in Medical Ethics.

MR. GILLON: I'm Raanan Gillon. I'm physician part-time, that's general practitioner, and a Professor of Medical Ethics at Imperial College, London. I'm on the Institute of Medical Ethics Board, the Royal College of Physicians Ethics Committee, and the CIOMS Ethics Advisory Committee, and I'm Editor of the Journal of Medical Ethics.

MS. CHADWICK: I'm Ruth Chadwick. I'm from the University of Central Lancastershire in the U.K. I'm here representing the Nuffield Council on Bioethics, and I'm also Coordinator of the European Project Euro-Screen on the Ethics of Genetic Screening.

MR. JONSEN: My name is Albert Jonsen. I'm Professor of Medical Ethics at the University of Washington in Seattle. I was -- I'm here representing -- as the recently-retired Chair of the National Advisory Board on Ethics and Reproduction. My successor would be sitting next to me here, Ruth

Macklin, were she here.

I was a member of both the President's Commission for the Study of Ethical Problems in Medicine and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and I'd just like to call to President Shapiro's attention the fact that the last meeting of a commission here in San Francisco that I know about at any rate was a meeting of the National Commission for Protection of Human Subjects that took place probably in 1978, which was disrupted by protestors against a bioethical issue. That was the San Francisco of the eras when those things took place. So, better watch out.

DR. SHAPIRO: We'll be careful.

MR. DONNELLEY: I'm Strachan Donnelley. I'm President of the Hastings Center in Briar Cliff Manor, New York. I'm trained in Philosophy and Research in Biomedical and Environmental Ethics, and previously headed the International Bioethics Program at the Hastings Center.

MR. WIKLER: I'm Dan Wikler. I'm the President of the International Association of Bioethics, which is the organization within whose

general program this event is occurring, and as President of the IAB, I welcome all of you to our sessions.

I know that the participants in the IAB program will benefit greatly by having the chance to talk to you, and I hope that we will have a long on-going association.

MS. NATHANSON: I'm Vivienne Nathanson from the United Kingdom, where I'm head of the professional side of the work of British Medical Association, including its Bioethics work.

MR. HLACA: I'm Nenad Hlaca from the Lowe School, University of Freaca. I was Director of the Course of Human Rights in Medicine from the University Center for Post-Graduate Status in Dubrovnik, and from 1994, I'm the member of the Lowe Commission from the New Croatian Family Code.

Thank you.

MR. HARRIS: I'm John Harris from the United Kingdom. I'm Professor of Bioethics of the University of Manchester, and I'm also sitting on the Ethics Committee of the British Medical Association, and I'm a member of the newly-established U.K. Government Advisory Committee on Gene Testing.

MR. HUG: I'm George Hug, pediatrician of Switzerland the United States.

MR. WELLIN: Yes, I'm Stellan Wellin, Director of an independent Center for research Ethics in Sweden. I'm a philosopher by training, and we have been involved in a number of studies, one about the setting up of Ethics Committee on Gene Technology in Sweden. That's included in your package here.

MR. TRONTELJ: I'm Joze Trontelj from Slovenia. I am Professor of Neurology and Chairman of the National Medical Ethics Committee.

MR. BENATAR: I'm Solomon Benatar from South Africa. I'm Professor and Chairman of Internal Medicine at the University of Capetown. I'm also the founding director of a multi-disciplinary Bioethics Unit at the University of Capetown and a member of the Medical Research Council, Committee on Ethics on Human Research.

I've recently been appointed Chairman of the University of Capetown Research Ethics Committee.

MR. DONDORP: My name is Wybo Dondorp. I work as a scientific staff member with the Health Council of the Netherlands, which is an advisory body to the Government, the Dutch Government, and I

represent the Standing Committee on Medical Ethics and Health Law.

MR. SANG-YONG: Song Sang-Yong from Korea. I am a Historian and Philosopher of Science at Hiland University. I have been active in bioethics since the East Asian Conference on Bioethics in Beijing last year. I hope to organize a Korean Society next year.

MR. SAKAMOTO: Sakamoto from Japan. I'm Professor of Philosophy at Nehoma University, and currently I am the President of Japanese Association for Bioethics and also East Asian Association for Bioethics.

MR. BINAME: George Biname from Belgium. I am President of Belgium Association of Bioethics and member of International Association of Law, Ethics and Science.

DR. SHAPIRO: Thank you.

I just want to say that that was one of the mistakes we made. We had our colleague here noted as France on his little card, and he asked me if we were making any predictions regarding the further unification of Europe or something of that nature. No. It was just a mistake.

MR. HOLM: I'm Soren Holm from Denmark,

member of the Danish Council of Ethics, which is the standing advisory body for the Parliament, and I'm -- when I'm not a member of that Council, I'm working at the Department of Medical Philosophy at the University of Copenhagen.

MS. LYNCH: I'm Abbyann Lynch, the President of the National Council on Bioethics and Human Research in Canada. I'm an Associate Professor of Health Care Ethics at the University of Toronto.

MR. FABRI: I'm Arcia Fabri from Brazil, a member of the National Committee, Ethics Committee on Research Involving Human Subjects. I'm also President of the Society of Theology, Science and Religion.

MR. TEALDI: I'm a Professor of Ethics in the University of Contanias, Sao Paulo, Brazil.

MR. RODOTA: My name is Stefano Rodota. I am Professor of Law in University of Rome, Italy, and I am a member of the Group of Advisors of the European Commission on the Ethical Implication of Biotechnologies as well as member of the Ethics Committee of HUGO.

MS. KHAN: My name is Kausar Khan. I am from Pakistan, here representing the CIOMS Group, along with Dr. Bryant and Professor Levine, but I'm at

the Community Health Sciences Department of University in Kharachi, and I teach biomedical ethics but also train government people in primary health care, and as part of the health system and introduce or try to integrate health and human rights issues there, and also part of the Human Rights and Womens Rights Lobbying Groups in Pakistan, and last but not least, I'm coming from a country where democracy again nose-dived and crashed, and, so, I'm really looking forward to the luncheon session because in a country where democracy keeps stumbling the way it does in Pakistan, the issue of ethics and human rights becomes a very central and burning issue.

PROF. BACKLAR: I am Patricia Backlar, and I'm a member of the National Bioethics Advisory Commission. I'm a Senior Scholar at the Center for Ethics and Health Care, Oregon Health Sciences University, and Senior Research Associate in the Department of Philosophy at Portland State University.

My principal work has been concerned with ethical issues that concern persons who have serious cognitive impairments.

MR. CASSELL: I'm Eric Cassell. I'm a member of the National Bioethics Advisory Commission.

I'm a Professor of Public Health at Cornell University Medical College and a practicing physician for many years.

I've also been a Fellow of the Hastings Center for 25 years or so. I'm -- I'm particularly interested -- my particular interest in -- in ethics is the nature of persons, particularly sick persons, and what it means to be a person in a world of others.

I just must say I look around the room, and I'm stunned by what has come about in the last -- really the last decade or so and what that really means for the rights and welfare of persons.

MR. CHILDRESS: I'm James Childress, a member of the U.S. Bioethics Advisory Commission and also a member of its predecessor body that failed, the one that Alex mentioned.

I teach in the Department of Religious Studies in the Medical School at the University of Virginia, where I also co-direct the Virginia Health Policy Center.

MR. HOLTZMAN: My name is Steven Holtzman. I'm a member of the U.S. National Bioethics Advisory Commission. I wanted to say it's an honor and a privilege to be sitting at this table with all of you.

I'm the Chief Business Officer of Millennium Pharmaceuticals, a Cambridge-based biotech -- Cambridge, Massachusetts,-based biotechnology company engaged in genetics and genomics research, in order to develop therapeutic and diagnostic products directed to the underlying cause of human disease.

I co-chair the U.S. Biotech Industry's Organization's Bioethics Committee. My personal interest in bioethical issues go back some 20 years to my undergraduate and graduate training in Philosophy.

MR. MIIKE: My name is Larry Miike, and I'm having an exercise in dexterity here. My name is Larry Miike. I'm a member of the United States Commission. I'm currently Director of Health for the State of Hawaii on leave -- is this thing on? On leave from the School of Medicine, where I'm a Professor of Community Health.

DR. SHAPIRO: You already have been introduced, but perhaps just once more to make the record.

MR. FUJIKI: This is Dr. Fujiki. I'm a medical geneticist, and, so, we have faced many implicit experience to have discussion with the genetical conferees, and, so, we move to the intention

to the bioethics and then after we have, as I told you before, we have had the International Bioethics Seminars several times.

Thank you, and my background is in Emeritus Professor of Fukui Medical School.

Thank you.

MS. LEVINSON: Again, I'm Rachel Levinson from the Office of Science and Technology Policy in the Executive Office of the President.

I'm especially pleased that the United States has a group to be able to join this distinguished international group. That was not true a little more than a year ago when the President established the National Bioethics Advisory Commission.

MR. DOMMEL: I'm Bill Dommel. I'm Acting Executive Director of the National Bioethics Advisory Commission. Although trained in the law, I have focused on ethics for the last two decades, and I am the drafter of the federal-wide Common Rule for the Protection of Human Subjects in the United States.

DR. SHAPIRO: Thank you all very much.

I know we took a little bit of time to introduce ourselves to each other, but since I hope

this meeting will just be the first of many times which we will spend with each other in the future, it really was very helpful certainly to me and my colleagues to put names together with faces, and, so, thank you very much for your patience.

Let us move now on to our agenda. The agenda is really broken up into three or four different segments. We'll begin with the discussion which really centers around the use of genetic information, the various aspects of that.

We will then move on to -- we will break at the end of that discussion, and then we will move on to the human subjects protection. We'll spend some on that.

Then we'll break for lunch, in which I've already told you about Professor Gutmann's remarks, and after lunch, we will assemble back here to try to see if we can help each other understand which commissions have been successful, which ones not so successful, and perhaps identify some of the characteristics that make these kinds of advisory bodies useful to the societies which -- which they serve.

If we have time, we might spend some time discussing what we might do at future meetings, if we

should be able to assemble again together some time -- some time in the future, and at the very end, since this is a public meeting of NBAC as well, if there are members of the public who wish to address at least those NBAC members who are here, we will have some time to do that.

So, let's now go on to the first aspect of our agenda, that part which is dealing with genetic information in various ways, and we've asked four or five of the delegates here to begin our discussion.

So, let me turn first to Mrs. Knoppers from Canada, as you've heard before, to begin our discussion.

What Have Commissions Done About Genetic Information and Technologies? Reports on Gene Mapping, Screening, Diagnosis and Patenting

Statement of Bartha Knoppers, Chair
Ethics Committee of the Human Genome Organization

MS. KNOPPERS: Thank you, Mr. Chair.

For those of you who are not aware of what or who HUGO is, it's not Victor Hugo or Huge Grossius. It's the Human Genome Organization, an international organization of scientists involved in the Human Genome Project, the global initiative to map and

sequence human genome.

HUGO was established in 1989 by a group of the world's leading genome scientists to promote international collaboration within the project.

HUGO carries out a complex coordinating rule within the Human Genome Project, and its activities range from the support of data collation for constructing genetic and physical maps of the human genome to the organization of workshops to promote the consideration of a wide range of ethical, legal, social and intellectual property issues.

HUGO fosters the exchange of data and bio-materials, encourages the spreading and sharing of technologies, provides information and advice on aspects of human genome programs, and serves as a coordinating agency for building relationships between various government funding agencies and the genome community.

Finally, it provides an interface between the Human Genome Project and the many groups and organizations interested or involved in the human genome initiative.

HUGO currently has over a thousand members from 50 countries and has six subcommittees, including

not only the HUGO Ethics Committee, which I will speak to, but also one on Human Diversity and another on Intellectual Property, and so on.

It maintains three regional offices, HUGO Americas, HUGO Europe, and HUGO Pacific.

With your permission, Mr. Chair, I'd like to say two words about what the Human Genome Project is as well as the Human Genome Diversity Project.

The Human Genome Project, the HGP, is an international research program designed to construct detailed genetic and physical maps of the human genome, to determine the complete nucleotide sequence of human DNA, to localize the estimated 50,000 to a 100,000 genes within the human genome, and to perform similar analyses on the genomes of several other organisms used extensively in research laboratories as model systems.

The Human Genome Diversity Project came under the auspices of the Human Genome Organization in January 1994. The Human Genome Diversity Project is a collaborative research project being developed on a global basis under the auspices of HUGO.

The overall goal of the project is to arrive at a much more precise definition of the origins of

different world populations by integrating genetic knowledge derived by applying the new techniques for studying genes with knowledge of history, anthropology, and language.

More specifically, the Human Genome Diversity Project aims (1) to investigate the variation occurring in the human genome by studying samples collected from populations representative of all the world's peoples, and (2) to create a resource for the benefit of all humanity and for the scientific community worldwide.

The resource will exist as a collection of samples that represents the genetic variation in human populations worldwide, and also as an open long-term genetic and statistical database on variation in human species that will accumulate as these samples are studied by scientists from around the world.

This latter project is the focus of discussion of a special session on Monday morning to which you are cordially invited.

I will now turn my attention more specifically to the Ethics Committee itself. In order to bring you up-to-date on the HUGO Ethics Committee, I thought what I would do is to read to you the actual

operating rules and procedures which the Ethics Committee will be discussing on Monday afternoon.

The principles suggested for this committee are the following: recognition that the human genome is part of the common heritage of humanity; adherence to the international norms of human rights; respect for the values, traditions, culture and integrity of all persons and populations; and the acceptance and upholding of human dignity and freedom.

The specific aims of the HUGO Ethics Committee are as follows: to promote discussion and understanding of social, ethical and legal issues as they relate to the conduct of and knowledge derived in the human genome initiative.

This includes consideration of research directions, practices and results, the issues of human diversity, privacy and confidentiality, intellectual property rights, patents and commercialization, disclosure of genetic information to third parties, the non-medical use of information about genetic susceptibilities, and the medical, legal and social aspects of testing, screening, accessibility, DNA banking and genetic research. As you can see, our aims are quite wide.

We also aim to act as an interface between the scientific community, policymakers, educators and the public. We aim to foster greater appreciation of human variation and complexity, to collaborate with other international bodies in genetics, health and society with the goal of disseminating information, to act as a consultative body in order to advise, consider and issue statements where appropriate.

What have we been doing? The HUGO Ethics Committee has 11 members from 10 different countries, and in its last deliberations at a meeting held in Bethesda, 1995, set out the guidelines for genetic research based on a paper entitled "Ethical Issues and International Collaborative Research on the Human Genome", published in Genomics, June 1996.

This paper led to deliberations within the committee and the adoption by the committee of a statement on the principle conduct of genetic research. This statement is meant to look at international collaboration and research in the Human Genome Project and Human Diversity Project.

This statement was published in the May 1996 issue of the Genome Digest, and I would be pleased to make it available to anyone here present.

Rather than go through the statement, I will read to you the underlying principles which give way to the statement. The statement itself will be presented at the session on Diversity on Monday.

The concerns that gave rise to the adoption of this statement by the HUGO Ethics Committee were the following: the fear that genome research could lead to discrimination against and stigmatization of individuals and populations and be misused to promote racism; loss of access to discoveries for research purposes, especially through patenting and commercialization; reduction of human beings to the DNA sequences and attribution of social and other human problems to genetic causes; lack of respect for the values, traditions and integrity of populations, families and individuals; and inadequate engagement of the scientific community with the public in the planning and conduct of genetic research.

I will not read to you the statement at this time because we don't have much time. I would like to inform you that HUGO Council has asked the committee at its session this year to begin to study the control and access of human genetic material and information.

Since the Human Genome Project and Diversity

Project are international endeavors, they asked us to examine from an international comparative perspective and to look for what was addressed by Dr. Abrams, common international values and norms that can be used in the research community with a view to the ethical, legal, and social issues surrounding the issue.

Thank you.

DR. SHAPIRO: Thank you very much.

Let me now turn to Donald Chalmers, Chair of the Health Ethics Committee from Australia.

Statement of Donald Chalmers, Chair
Health Ethics Committee, Australia

MR. CHALMERS: Thank you, Mr. Chairman.

If I may perhaps dispense with some of the courtesies of introduction as I only have 10 minutes, but to say this, that in the last 10 years of my involvement with the Australian Health Ethics Committee and other national bodies in Australia, the one thing which I think binds us all together is the international aspects of the work which we all carry out.

May I say there's hardly a person sitting around this room whose work I have not used in some of our deliberations or not exchanged correspondence

with, and I welcome this opportunity, Professor Shapiro, to meet with my colleagues.

May I very briefly let you know a little bit about the Australian Health Ethics Committee. It has an unusual background in a country which, as you all probably all know, has had many debates about in vitro fertilization and embryo experimentation.

There was a short-lived national bioethics consultative committee which was later brought together with the Medical Research Ethics Committee of the then National Health and Medical Research Council. After some debate within our Commonwealth Federal Parliament in 1991, it was decided that this committee, the Australian Health Ethics Committee, would be placed on a statutory basis. It exists through the National Health and Medical Research Council Act of 1992.

It is a multi-disciplinary committee, but, interestingly, although the members are appointed by the Minister, they are nominated by various bodies throughout the country. For example, the doctor, medical practitioner, is appointed by the learned colleges, the lawyer is appointed by the various law societies, the philosopher is again appointed by deans

of philosophy schools.

Interestingly, it's the sole authority in matters of health and medical research guidelines. Those guidelines are not only passed by the Australian Health Ethics Committee, they are then laid before the Commonwealth Parliament.

There was a feeling that, I think, in our country, that ethics was not to be something which was simply to be contained within a group of so-called experts.

More than that, before the learning procedure before the Parliament, any set of guidelines must be presented for two stages of consultation. I believe this is rather unique internationally, but not only must opinions be sought from the public at large to ensure that there is a proper public accountability, any guidelines themselves that are drawn up must again be presented for consultation to ensure, in other words, that the committee has played due regard to the public consultation process.

Finally, the Australian Health Ethics Committee is responsible for the national auditing and accountability of our system of institutional ethics committees, the equivalent of the institutional review

boards in this country.

In other words, the AHEC or the Australian Health Ethics Committee is in itself a new committee with a new statutory basis, and I believe there will probably be some occasion this afternoon to tell you a little bit more about that.

Secondly, may I say that I've tabled, and I make my apologies, that I've put on a white folder on to everyone's desk. I'm sorry that there was insufficient of those, but inside, you will find a small account of the Australian Health Ethics Committee, and you'll find a copy of the current statement on human experimentation.

As I did not have enough copies, Mr. Chairman, I decided to positively discriminate against all the American delegates, and I've distributed them amongst all the international delegates, and there are a very few for your country. I apologize for that.

The statement, as you will see, is one of the older in the world. It was actually first drafted in 1973 and subsequently in '76, and its latest redraft is 1992. It is, I suspect, quite akin to most of the national statements of similar variety.

It sets up a code of practice for research

requiring all research projects on human subjects to be presented for consideration by a committee.

It may be interesting to note that in 1995, in my country, because of concerns about the international clinical trials on the abortifacient drug RU-486 and also because of some concerns of research which had been carried out some 20 years before on women by the introduction of hormones derived from human pituitaries, which had resulted in some cases of Creuzfeld Jacobs Disease, that there was a view from the Minister, that's the Commonwealth Minister, that the system of IACs, Institutional Ethics Committees, should be reviewed.

That review having been completed, there is at the moment a public review and a public consultation being conducted which is very likely to lead a substantial revision on many aspects of that document.

If I was to look into the crystal ball, I suspect the most likely things which are going to change will be procedures, composition, especially concerns about international multi-centered trials, and the proper review of those.

I believe I've been asked, Mr. Chairman, by

you to say a little bit about what is happening with the Australian Health Ethics Committee and human genetics.

At the beginning of this year, the new federal government has asked the Australian Health Ethics Committee to take a comprehensive view about human genetics and human genetic research.

` In our country, as I suspect in most countries, there has been a piecemeal and case-by-case response to matters of human genetics. For example, we have some legislation on human embryos. We have some legislation on privacy. We have some legislation or guidelines in relation to genetic registers.

What the Minister has asked our committee to do is to make a comprehensive review of guidelines, legislation, professional practice in the area of genetics, to draw up advice over the next three years in the spectrum of human genetic research, genetic testing, the use of genetic information, the collection and storage of human tissue for genetic testing, access to human tissue for later testing, genetic screening, privacy and confidentiality, and advice about the implications of the storage of genetic information for future generations.

This, may I say, Mr. Chairman, has been an extremely challenging and exciting invitation. It is within the terms of the Act establishing the AHEC that our Minister can in fact give references directly to the AHEC, and we've been very happy to take that responsibility.

May I, in closing, say that you have looked to the future to say that we may meet again. Wearing another hat, as a law reform commissioner, I have had the occasion to meet with colleagues in that area on a couple -- on a biennial basis.

May I encourage this group and under your chairmanship to meet again because there is much which we can learn from each other and much that we join, and may I, on behalf of my organization and my Minister, say that if you wish, we would be most welcome to host such an organizational meeting in Australia in a couple of years.

Thank you very much.

DR. SHAPIRO: Thank you very much, and thank you very much for your generous invitation.

Let me now turn to Abbyann Lynch from Canada, who has a few remarks.

Statement of Abbyann Lynch, Chair

Consent Panel Task Force of the
National Council on Bioethics in Human Research, Canada

MS. LYNCH: Thank you, Mr. Chairman.

In terms of the National Council on Bioethics in Human Research, many of you will have received a folder which describes that particular group, and it's that to which I want to speak as well as to the new effort in Canada, which is called the Code of Conduct for Research Involving Humans.

In terms of the National Council on Bioethics in Human Research, which was founded in 1989, its mission is to advance the protection and promotion and well-being of research participants and, second, to foster high ethical standards regarding conduct of research.

Its particular activity is directed to the assistance of the Research Ethics Boards, the REBs, which are somewhat analogous to the United States' groups of the IRBs.

The National Council has also asked to foster dialogue among those concerned with research, to work with funding groups regarding needs in research, and to assist in the development of ethics

expertise regarding new questions.

This particular group is funded by the three government-granting councils, that is the Research Council involving Medicine, the Natural Sciences and Engineering Group, and the Social Sciences and Humanities, as well as by the Government Health Group.

It is also given space in lieu of funding by the National Physicians and Surgeons Accrediting Body, and it's accountable to those sponsors.

It has a membership at the moment of 15 persons. These have normally been assigned and appointed by the Royal College of Physicians and Surgeons in Canada, but recently the group has the right to nominate and to appoint its own members.

It works by way of four smaller committees. All of these people are volunteers. The four committees are concerned with consent, with evaluation of the research ethics review process, with research design and with communications and education.

It works by way of query response; that is, direct questions arising from the Research Ethics Boards. It has publications, and you have three of them included in your particular package just in front of you.

The journal called Communique. The topics are varied in that particular journal, ranging from conflict of interest, ethics and epidemiology, ethics and clinical trials, ethics and genetic research, and most recently a report of site visits to all of the Canadian medical REBs in the country.

It has a number of discussion documents to its credit. One of them, Research on Children, which is included in your package, one on Consent, which is just to be discussed next week, and one on REB Surveillance, which is again to be discussed at its meeting next week.

The National Council sponsors workshops and conferences as well as site visits to the various REBs.

The National Council is moving to the Worldwide Web in terms of publications, education and discussion, and will start to include within the next year the non-medical REBs as the area for site visits.

I spoke about that particular group first because I'm here as the President of the group, but in terms of the interest of this particular section of the discussion, you would perhaps be more interested in the Code of Conduct for Research Involving Humans,

which has just been prepared by three councils in Canada.

I'm not really the person to speak about that. That's an absent colleague who should be sitting here, but this particular Code of Conduct is unusual in Canada in that it has brought together the three major research funding groups, the Medical Research Council of Canada, the Natural Sciences and Engineering Research of Canada, and the Social Sciences and Humanities Research Council of Canada.

This has been an effort on-going for the last two years, and in particular, with reference to the work of this group, it has a section on genetics, and I'd like just to point out the major headings there, which are the subject of on-going debate in Canada because this is the Code of Conduct to which the REBs, the Research Ethics Boards, will refer when there are questions about genetics and genetic research.

As you may understand, there's no legislation as such in Canada about the Research Ethics Board, and, so, we differ significantly from the United States and from other groups around this table, but it is this Code of Conduct which will be

referred to in terms of the approval or non-approval of research ethics protocols and particularly in the area of genetics.

And, so, you'll find within that code still under discussion, not finally approved, a section on informed consent, a section on the responsibility of the Research Ethics Board to speak to investigators, Research Ethics Boards granting groups, educational bodies, education in terms of the ethics of genetic research.

There's a very clear statement there that this group is recommending that in Canada at least, research in genetics be limited to research involving somatic cells in tissue, and that there will be no particular non-therapeutic use of gene therapy.

It speaks as a fourth point about the duty in terms of the Research Ethics Boards to advance knowledge, to ameliorate disease and not to engage in the area of genetic enhancements. There's a small section on banking, and then finally a section very specific saying that the researcher must discuss commercial use in terms of any genetic research.

So, to summarize what's been said here, the National Council on Bioethics in Human Research is

made up of volunteers. It is a group which is responsible and accountable to the various research councils.

Genetic research has not been a large part of its activity. It's been much more focused in the area of direct response to Research Ethics Boards and does have a number of what I perceive to be distinguished publications to its credit, not the least of which is the particular publication on research involving children, and you have a copy of that in the collection of materials.

Thank you.

DR. SHAPIRO: Thank you very much, and thank you for bringing those materials with you.

Let me now turn to Manuel Velasco-Suarez from Mexico.

Statement of Manuel Velasco-Suarez, President
Comision Nacional de Bioetica, Mexico

MR. VELASCO-SUAREZ: First of all, I want to thank Dr. Shapiro for the invitation to be with you this morning.

Bioethics has moved the scientific community around the world. As we can see now with this fortunate meeting, which is meant to push forward the

moral inter-disciplinary revolution between biomedicine, law and the social science in general, to save in the first place man from himself, as we are in danger to be the object of experimentation with insulting tests and even torture, to being false and non-voluntary confessions, for instance, and in addition, sometimes, far from the cultural considerations or religious beliefs, without voluntary consent.

Sometimes the answers are imposed by false and immoral services that compromise the dignity, autonomy and even the human destiny.

Medical, law and other professionals in ontology should contain principles of respect for the living being from its very conception, birth and life until its extinction.

It is also of a bioethical concern the duty of environmental and ecosystem protection, to prevent damage to nature, wherever life exists, and to avoid other damages negatively opposed to the common well-being.

Being conscience of the rapid development of the life science, we should encourage the use for the well-being of the individual and society. We need to

respect both the human being as an individual and as a member of the humankind.

Equity in natural science out of platonical reasons is present and should be present in the relationship between knowledge and perception of practical values. In the interrogative human phenomenon, which from different ontologic and teleologic approaches, are attenuate now than ever before science to bioethics in respect of human rights without gender, distinction, color, social state, etc.

Nevertheless, taking into account realities arising from the technical issues and scientific discoveries, sometimes equality is not widely available to all people.

There are some emerging issues related to the advances of the Human Genome Project with implication of human subjects, able to create a revolution even more impressive than the industrial revolution, with great challenges for justice and the universal rights of humanity.

The expenditure of hundreds of millions of dollars every year in different programs, but especially in the one which now is helping to know the human genome, probably it will prolong the expectation

of better life of the inhabitants of developed countries.

However, we think that the very difficulty this program will help the less-developed countries that represent almost 80 percent of the planet population still victims of misery and ignorance.

Here again, the practical biomedical field should be determinated by justice and equity.

The Human Genome Project and its subsequent implications is discovering new fields of great importance, but with the eventual resulting human inequity, thus it should be necessary to open an international debate about justice, natural science and solidarity, taking into account philosophical, religious and cultural aspects close to the human being, revitalizing the declaration of the human rights.

Also, it's occurring, something with discrimination with patients with HIV and the AIDS patients.

Another insidious problem occurring in the selection of human embryos fertilized in vitro. In this case, it appears like the humans from which the germinal cells were taken did not pass through embryo

stage. Without any respect for life, they select one being given death to all others.

From the respect to other people's rights comes the universal right for a dignified human society, from the very beginning of life to destiny of our species when they are adulterated.

Some medical doctors and lawyers seems to have forgotten the moral principles, synthesizes not only in the Hippocratic Oath, which represented the paternalistic ethics, but even with the bioethics and after some of the declarations of Nuremberg and the Helsinski document and many others.

For the brilliant minds, like the ones which created the atomic bomb, bioethics could appear an inquisition against science. Lawyers, economists and politicians also have the obligation of recovering the ethical codes of personal value, to translate them into the social right. Without them, it is impossible to conceive man which also remarks its life through the fulfilling of the rights and obligations in harmony with the scientific freedom and responsibility, preventive of the prevailing behavior.

Biomedical behavior in its human environment are enhanced with all that is related with human

rights and legal protection of the dignified life, related to the spirit of the law, and the anthropological, psychological and social respect of the human subjects, especially when the restrained of the freedom sometimes is accompanied with the impossibility to be defended.

With these criteria, the National Commission of Bioethics in Mexico, it was a matter of discussion for more than five years. Fortunately, we founded it in 1993, and since then, we have been the advisors for the chambermen and senators in reviewing some aspects of the law, and also in the universities, organizing congresses, like the First International Congress of Bioethics that we organized in Mexico three years ago, and we think that the importance of legal institutions should avoid the violations of human rights and condemn torture, also, that it is inflammatory to those who practice it, and especially to the decision to survey the vital science of the unfortunate victims.

Human gene ethics, gene ethics, gives the key for its origin, gene, and the ethics, moral, of the human species.

Thank you.

DR. SHAPIRO: Thank you very much.

Finally, before we proceed to our general discussion, let me call on our colleague from Slovenia, Mr. Trontelj.

Statement of Joze V. Trontelj, Chair
National Committee for Medical Ethics, Slovenia

MR. TRONTELJ: Ladies and gentlemen, Mr. Chairman, I am really grateful for this honor to be able to speak at this distinguished gathering.

I am representing the Slovenia National Committee on Medical Ethics, which I have chaired during the last two years.

Slovenia is a small Central European country with a population of just two million, an old nation with a strong West European culture heritage, but also a 50-year long history in the former Socialist Yugoslavia.

This ethics committee has a respectable tradition of uninterrupted work of over 20 years. This and the preceding committee have in the 30 years of their existence considerably shaped the ethical atmosphere in medicine and health services in Slovenia.

Although a sizable amount of medical

research has been going on in the recent decades, virtually no study involving human subjects was possible without the previous approval by the committee since the early '60s.

As a result, we have not seen any significant cases of unethical research on human patients, and Slovenia has enjoyed early and effective legislation in the ethical and legal aspects of medicine.

Let me now briefly touch on the situation regarding ethical aspects of gene technology in my country.

I have participated as a member of the working party in drafting the new law on gene technology which is just now ready for entering into the parliamentary procedure.

As a basic model, we took the new Austrian law, which deals with the application of gene technology on micro-organisms, plants, animals, and humans, a rather complex piece of legislation indeed.

I am happy that we were able to accommodate the principles recommended in some four documents issued in the recent four years by the Council of Europe.

In addition, I have had the privilege of attending for the last two years the Steering Committees on Bioethics of the Council of Europe, where we worked on Conventions on Human Rights of Human Beings with respect to the application of biology and medicine.

So, we could also rely a great deal on the provisions of the Convention as well as on the discussions that led to the development of the chapter on human genome.

By the way, I was a little unhappy as it was decided in the really last stage to omit one article out of the Convention that was restricting the non-medical use of genetic data, but as I understand, this will be possible to do in the protocol that is going to be elaborated on the basis of the Convention.

In the Slovenia Gene Technology Law, the special sensitive nature of genetic information is recognized and its privacy and confidentiality is rigorously protected.

Employers and insurance companies are not allowed to access personal genetic data. Interference with genome of the human germ cell line for the purpose of modifying any transmissible genetic traits

is forbidden.

A human genetics commission is established at the national level with responsibility to review, approve and to monitor all research projects as well as new applications of gene technology that might affect human health and human rights.

Among other principles, let me mention just a few. A particular emphasis is placed in the law on the obligatory offer of pre- and post-test counseling to the persons undergoing gene testing as well as a continuous support whenever needed.

In addition to the person's right to be informed, the law also enshrines his or her right not to be informed. In pre-natal genetic diagnosis, also the partner of the pregnant woman must be involved in counseling and decision-making. The information must be given in a neutral way, and counseling must not be of a directive nature. In case of a severe gene disorder, the couple must have complete freedom to either keep the pregnancy or have it terminated.

The pre-natal genetic screening is limited to cases of suspected serious conditions. The relatives of the tested person are informed only with his or her permission, but advice must be given to

this effect whenever indicated.

Creation of embryos for the purpose of research is prohibited.

In conclusion, also in Slovenia, the lay public is watching the developments in biology and medicine with increasing concern, and I certainly expect some difficult public discussions when the new law will be introduced and presented to the public.

However, we are all aware of the importance of public openness and the understanding and acceptance.

Thank you.

DR. SHAPIRO: Thank you very much, and let me thank all those who have presented this morning.

Discussion Among the Delegates

DR. SHAPIRO: We now have probably at least three-quarters of an hour for general discussion, and I know it is very difficult to separate issues because these issues, all the issues, in many of these areas are related in subtle and sometimes very direct ways, but, nevertheless, if we could try to focus our questions and/or comments on issues dealing with genetic information, again broadly speaking, what kinds of problems people have addressed, what kind of

problems they have, what kind of questions they have, and in particular how your commissions or other groups that have been studying this, what kinds of recommendations you have come up with as have just been summarized quite well in the case of Slovenia.

So, let me just open the floor for questions. Let me turn to my colleague, Alex Capron.

PROF. CAPRON: I hope you will understand that one of the reasons for the questions I am going to ask is that our National Commission is charged with looking at this subject, and we hope that through the process of looking abroad and hearing what has happened, we will have the benefit of the conclusions that have been worked on.

One very basic question about genetic information is the one just mentioned by Dr. Trontelj, and that is the question of the special nature of that information, and this is a phrase that is very often used.

I would like to have some advice from the groups that have directly addressed this question. Why they concluded that genetic information is special, if they did, and, if so, how they define genetic information?

Because the attention to this field has been driven by the development of molecular tests for the DNA -- for the genes and eventually for the DNA mutations, and yet "genetic information" has long been part of both biomedical research and clinical care, family histories and the examination of patterns.

And, so, the question is, why should it be treated specially? Is this simply a reflection of the fact that ordinary medical information has not enjoyed the protection of confidentiality that it ought to, that doctors and hospitals and so forth have been a little too lax in holding confidential ordinary medical information, or is there something that the commissions and groups have decided is in some ways unique to this information as opposed to information about other diseases and conditions, mental illness or HIV infection and other sensitive matters?

Why is this special, and, if so, if you're treating it as special, how do you define genetic information, and is there a distinction between the traditional sorts of information that was derivable in clinical practice and research, and that which is derived through the molecular technology?

Thank you.

DR. SHAPIRO: Is there anyone that would like to address this question? I'm sorry. Did you have your hand up? Yes, please.

MR. HOLM: Well, --

DR. SHAPIRO: Would everyone please just give their names so the people recording your remarks can know who it is? Because we're trying to make a record of the meeting.

MR. HOLM: Soren Holm from Denmark. This issue about whether genetic information is special was discussed fairly extensively when -- in a commission preparing a law on the use of health information in employment in Denmark, and they decided that in the end, you couldn't claim genetic information to be special, but that you should have the same protection for all kinds of health information in employment decisions, which means that as the law currently stands, a Danish employer cannot ask for any kind of health information, and there are obviously public safety restrictions and things like that which could give access to health information.

But on the other hand, a newly-proposed Danish law on genetic information in insurance has been forced to take account of the fact that insurance

companies sort of have used health information for at least the last hundred years when they put out life insurance policies.

So, there you've had to keep a distinction between "ordinary" health information and genetic information, so that the law in that area is going to say that genetic information is special, and you cannot ask for it, whereas ordinary health information, whatever that might be, is not special.

DR. SHAPIRO: Can I just ask a follow-up question before turning to Ms. Knoppers here?

Professor Capron asked and perhaps also, when you do want to make a difference as in the insurance case in Denmark and many other countries, is there any way of deciding what falls into one category versus another category? What falls into the category of things that you can use and what falls in the categories you can't use for the insurance company case?

MR. HOLM: Well, in this proposed law, I think the distinction is supposed to rest on just information being genetic information. Whether that also goes for the color of your eyes, I'm not certain, but I'm sure that Danish lawyers will have a field day

trying to find out what it actually means.

DR. SHAPIRO: Well, we'll stay tuned.

Mrs. Knoppers?

MS. KNOPPERS: Professor Knoppers from Canada. I'd like to speak to Alex's last point first. The Social Issues Committee of the American Society of Human Genetics sent yesterday to the Board of the American Society of Human Genetics, which now numbers about 5,000 members across the United States, a statement on familial disclosure of genetic information by professionals of the members of the Society, and in there, there is a statement that says the committee -- the preamble discusses the arguments about the sensitivity, the specificity, the unique historical context, the stigmatization and so on of genetic information, like psychiatric information in the past, like cancer information in the past, and comes to the conclusion that while sensitive, genetic information should be considered as medical information.

It does, however, call -- it's not in the mandate of the committee, but it's in the text and the body of the text for exactly what you mentioned, Alex, which is stronger laws, reinforcing regulatory

articles and so on and sanctions, for medical information rather than specific to genetic.

I'd like to mention in my other hat, which is my Canadian MELSI hat, that the Canadian MELSI Committee on Sunday of this week sent an open letter following a workshop with the volunteer organizations and associations with genetic diseases across Canada, an open letter to the insurance industry of Canada, albeit we usually end up being sort of a filial of North American insurance, an open letter asking that the Canadian Life Insurance Disability and Additional Health Assurance Companies set up a task force in Canada to look at the specifics of a country such as ours, which, like European countries, has a universal health care system, and therefore does not consider itself to be bound by the kind of trade-offs that go on in its neighbor to the south.

That report, which will be presented at the Insurance Symposium at this meeting, indicates various routes that we've been looking at, the Belgium route, which is a legal prohibition, though I'd like to hear from our Belgium members how that is working, how to distinguish as you mentioned between the legitimate discrimination of insurance companies under law as

private companies offering a service to the public where they have always had access to information, to questionnaires or other ways, and how to provide a minimum amount of insurance to all Canadians, life insurance, as a social good in a modern society where you need insurance in order to have or acquire other social goods.

So, that is the first recommendation, and asking insurance companies to check whether their actuarial tables, where they calculate the risk of the genetic risk information, whether those tables are up-to-date, whether they are specifically sensitive enough to handle the information on susceptibility, pre-symptomatic, probabilities, risk factors, late onset, and all the other nuances that come from genetic factors and common diseases.

So, we're looking for a statement from them as to whether they are scientifically, actuarially, legitimately discriminating.

Finally, the Canadian MELSI Committee is also working on a policy statement on genetic screening and information at the level of populations, which is another interesting -- we always think of information as persons, belonging to persons, but when

you're doing population screening, you're moving it to another level of -- of discourse and different policy and ethical-legal concerns may apply.

DR. SHAPIRO: Thank you.

Professor Cassell?

MR. CASSELL: I'm Eric Cassell from the United States. Following on that, I think one of the things we're seeing is the failure to protect persons from -- from revealing their information that does them harm.

In ordinary medical circumstances, that failure, by calling it special will somehow make this really -- this time, we'll be able to protect people from genetic information, but as Professor Knoppers points out, there is no difference really. It's medical information, and it brings up the question of insurance, all kinds of insurance, beginning to think the unthinkable, which is moving back a step as to what information they really require to be equitable in a free society, and that is going to take a lot of pressure, but the pressure has to be there.

There is nothing special about genetic information, except that it brought up this question and opened it up again for public discussion.

DR. SHAPIRO: Thank you.

Ms. Scott-Jones?

MS. SCOTT-JONES: I have a question of a different sort. I'm Diane Scott-Jones from the United States and part of the newly-formed National Bioethics Advisory Commission, and as we begin the work of the commission, I have a question for those of you who are on commissions that are longer-standing than ours.

How is it that you've taken into account the diversity of opinion that exists among professionals and among the lay public in the issues that you address? How do you ensure that as a -- in your bodies, that you're sensitive to diversity of opinion?

DR. SHAPIRO: Could I -- could I just make a suggestion here? That seems to speak directly to the issue we're bringing up this afternoon, that is, how these commissions work.

MS. SCOTT-JONES: Okay.

DR. SHAPIRO: Would you mind if we postponed that question?

MS. SCOTT-JONES: Not at all.

DR. SHAPIRO: We'll take it up immediately when we get to that -- that session. A very important question, but something that I always think works on

how commissions operate and so on. Is that all right?

MS. SCOTT-JONES: Great.

DR. SHAPIRO: Okay. Thank you.

Yes?

MR. GELZER: Mr. Chairman, Gelzer, Switzerland. I wanted to point out that we in Switzerland consider genetic information definitely separate from medical information for the main reason that it impacts on multi-generation of an individual, of his offspring.

In terms of the insurance companies, there is a moratorium for the next three years that this issue will be evaluated, but for the time being not applied.

As documented in the papers on the table, we feel very big desire to limit the genetic testing of currently-commercially-available genetic test kits in our society because the physicians are inadequately informed about the impact, and therefore we suggest that we have a central agency controlling in Switzerland the commercial testing kits for the patients.

DR. SHAPIRO: Thank you.

Yes?

MR. MACER: I would like to just add a point of a case of positive discrimination that's used in the Japanese health care system.

The Japanese health care coverage covers everybody in the community because once you are born, you are covered. There is normally a different scheme from 10 to 30 percent of coverage you must pay yourself for your family.

However, if you suffer from a certain listed hereditary disease, you are guaranteed 100 percent coverage for life of any medical condition. So, there can be certain positive benefits of genetic screening or testing.

DR. SHAPIRO: Thank you.

MR. MACER: It depends on the health care system.

DR. SHAPIRO: Yes. Let me turn to -- once again, to Mr. Changeux.

MR. CHANGEUX: I want to say that the French Bioethics Committee has been very much concerned about this issue in the Chapter of Medicine from Prediction to Prevention, and I think it's something special.

First of all, we have to say that detail means the phenotypes and not converse. So, it has

really some --

DR. SHAPIRO: Closer to the mike.

MR. CHANGEUX: -- central role in the way the organism is set up, and also as it was said, of course, it's transmitted from generation to generation.

But I think the fact that it means the phenotypes and not the reverse is something important because it creates some kind of predictive character in the way it is understood, and to that sense, I think it may create very important ethical issues in the fact that the knowledge of this information may or may not lead to some decision before birth or even to decision about taking care of people after a certain age.

And this is the reason why in France, we have said that the use of these genetic information for insurance company and employment is prohibited, and even if the test may have been requested by the person consent or even with their consent, because I think there is, of course, the argument that somebody can say look at my map, it's a clean one, and I want to have a cheap pie, and this is, I think, an important point.

The second thing deal with the diffusion of the tests by companies, and there is very strong pressure on this because, of course, we would like to ask individuals to make their own genetic test, and say, well, we feel in good shape in 10 years on that and so on and so forth.

And there is a potentially-enormous market on this diffusion of genetic tests. The reason why we said that there should be approved by the drug agency, which may be -- I don't know -- the Food and Drug Administration, and that's -- the genetic test protocols should be restricted to a very strong supervision by not only the doctors but also on the laboratories themselves because, of course, there are possibility of mistakes in many of these tests, and this is an important ethical issue concern.

And this is also the reason why there is a program of information of the patients about these tests, and most definitely we have found that even the doctors do not know about very much what they mean, and there is not only an education of the patients but also of the medical staff, and in these aspects, we propose is that there always should be a dialogue between the patient and the -- the doctor who -- or

small commission which should include in particular geneticist, but also a psychologist, because revealing to somebody the circumstances of some kind of genetic effect may seriously affect the mental status.

And the question of confidentiality, all this is in this document, it is a 46 opinion, and concerning the confidentiality, I think this is an issue, and there is in France a law and a commission for the protection of stored informatized information, and, of course, this information sooner or later is going to be stored in data banks, and in this aspect, the condition of access to these banks is something which creates a very serious concern.

In addition to not only the insurance company but also the employment, it may be under the power of political forces, and in this aspect, I ask Dr. Knoppers how she views the protection against political use of genetic information among different populations throughout the world, which may unfortunately, and we see it still presently, could be used for discrimination on political basis.

And I think this is a real danger for human rights, and I just say one thing, that this aspect, I think, we consider that there is a real issue for

humankind on these studies on genetic information, which I still think I don't like the word "special case". I don't think it means much.

We have just to -- to look at what it is really harmful and where are the dangers, and I would ask her the question, if, Mr. Chairman, you think it is the time or later on.

What are the safeguards that you have for this access on different populations, which may lead, of course, to racial discrimination?

DR. SHAPIRO: Now's an appropriate time if Professor Knoppers wishes to answer.

MS. KNOPPERS: Professor Changeux, you are no doubt aware that the UNESCO International Bioethics Committee in its report of 1995, on populations and genetics, looked at this very issue. This was brought to the International Bioethics Committee and is a continuing concern, but I will let the director speak for the IBC itself.

Stemming from this report and from the fact that the conclusions were -- the original report was highly critical of the diversity project, and yet in its deliberations, the committee realized that the issue was one of population genetics and the

possibility, as you have just mentioned, of testing of populations, whether commercially or government or however sponsored, could lead to the use of that information for political purposes.

That report, which was drafted -- I should say the committee was chaired by Darryl Macer here, has made an official overture to the HUGO Ethics Committee to together set up or discuss the possible creation of an international ethics committee particular -- particularly focused on the issues of population genetics, discrimination and political use or misuse.

While we all know, those of us who have by osmosis, speaking for myself, or by knowledge, speaking for the scientists here present, learn that genes know no national or political boundaries, the historical precedents are there for us to need to look at the possibility of misuse.

So, we will be looking at our HUGO Ethics Committee on Monday on the possibility of the creation of such a committee.

Thank you.

DR. SHAPIRO: Thank you.

I really have quite a few people who want to

speak. I'll try to get you in some kind of rough order when I first saw your hands.

Let me turn to Mr. Miike here first.

MR. MIIKE: I'm interested in the question of since we have multi-committees on different nations looking at the issue, they all seem to arrive at the same general issues, and they all seem to be reaching the same types of conclusions.

Is that by design? Is that by serendipity? Is that included in the formal analysis? Are you trying to make culture-free judgments, and then, in other words, trying to stay away from either the cultural or political climate in which you operate and trying to reach some, what I would try to call, some value-free conclusions, and then put out into the real world and see what happens? That's my basic question.

For the HUGO rep, my understanding is that you give recommendations to, say, research that are multi-national trials-types of situations or you have research which will be done in different countries, so you want to make recommendations.

Is that -- is that driven by -- which side is being driven? Is that driven by the need for some uniformity in research protocols or is that driven by

the side that says we must have common values when we do research in multi-national trials?

DR. SHAPIRO: Very interesting question. Does anyone want to answer this particular question or respond to Mr. Miike? Because I think it is a very intriguing question.

In fact, if I didn't misinterpret it, Mr. Abrams really raised it in a little different way before in claiming that we should be looking for some common set of values that could cover people of very different kinds of cultures, and, so, if I understood you correctly.

Does anyone want to answer that question as to what's pressing what here? Yes?

MR. HOLM: Holm from Denmark. I don't know whether it's an answer to the question, but at least in the three years I've been a member of the Danish Council of Ethics, the Council has only agreed on a policy recommendation once.

So, I don't think we -- at least we're not looking for any value-free solutions. We might end up having to do that if we decided that we had to agree, but at least our mode of work is that we tried to discuss the issues until we sort of see that we cannot

agree, and then we'd try to sketch what the positions are.

DR. SHAPIRO: Yes?

MR. CHALMERS: Could I -- Donald Chalmers, Australia.

DR. SHAPIRO: Yes.

MR. CHALMERS: Could I perhaps just reply to your -- the question in the corner? I don't necessarily believe that there's such uniformity. I think there is some areas in which we need international uniformity.

I think there's no doubt whatsoever that we live in a quintessentially international community, where I think drug trials are now being conducted internationally, a great deal of research is being done internationally, and I think that one prime principle, the protection of the interests of those who are being the subjects of research, predominates, and I think that will probably be one of the things which will leave us with some doubts about the Human Genome Diversity Program.

There may be some circumstances in which we suspect or we may not have sufficient proof that those people being the subject of the research are giving an

informed consent, the reason being that I think we all agree internationally now that consent is not a signature. It's a process, and it has a cultural context.

On the other hand, if that's the one thing which I think binds us together, I would, just as a matter of information, say that I think when we start looking at different regimes around the world in relation to privacy and confidentiality, I think we'll probably find that there are very many different regimes.

I think there are some countries which basically trust governments and have reasonably often. I think some other countries, and I'm aware of my colleague across at the Danish Council of Ethics have -- have different views.

So, I think there's a lot of difference when it comes down to privacy and confidentiality.

DR. SHAPIRO: Could I perhaps take the privilege of sitting where I am and just try -- I hope, Larry, I don't make matters more confusing, but I want to ask a specific question, I believe directly related to the question you asked.

That is, can people imagine a medical

experiment in biomedicine so important, so pressing on us, that we want to carry out international trials and getting some kind of uniformity of approach would dominate all other considerations?

Can someone -- I don't know if that's imaginable. I'm just asking if that's imaginable to anybody, those of you who have thought about this a lot more than I have, or would it never be the case anything could be that -- that important?

Yes, Mr. Changeux?

MR. CHANGEUX: I would like to say that we have a concern in France with assays being carried out in countries which have not the same economical development as other countries. That's the first point.

And, of course, this is a very sensitive issue because sometimes people from these countries feel that they are, sometimes justified, exploited by occidental countries for their assays, which -- and the condition which often would not be accepted in our occidental countries.

And as safety, we suggested that, of course, there should be some kind of mixed supervisory group which would first assess that there are no cultural

problems with the country in question, which would oppose the study in question, and, second, that there should be consultation of ethical committees on both sides.

In addition, because there might be possibilities that look at committees in these countries accept things that would not be necessary acceptable at the world scale. So, this is something which I wish to mention.

The second point, I think, deals with the point you mentioned, which is to make assay of the world scale. We have been faced in France by a problem concerning these drugs, these anti-potaise agents, and the companies which have these compounds in limited amounts started to make, I would say, some kind of discrimination between countries in the sense that at least in our country, the amount of compounds which was available for, I would say, assay was not sufficient to make a very large-scale thing.

Anyway, this -- there is a political issue behind it, as you may imagine, and this is also a question of what is the power of international companies in this aspect, and I think, personally, that this kind of thing that we are doing is extremely

important, and I would strongly support your view which is to have some kind of international discussion where all these aspects should be discussed, and I support wholeheartedly these debates in particular the material necessity of doing these kinds of things in addition to other aspects which are more local and concern cultural traditions.

DR. SHAPIRO: Okay. I'm going to try to recognize people who haven't spoken yet, since there's getting to be rather a long list, and I want to give as many people an opportunity as possible.

Yes? Right at the very end, alongside. Yes. I'm sorry. I can't --

MR. HARRIS: That's all right. Thank you. John Harris from the United Kingdom.

I wanted to return to the question of what genetic tests or whether genetic tests should be permitted, and, if so, to what extent.

I mean it seems that very often, a principle of caution is accepted as being the right approach, particularly, for example, on the question of home testing or on the question of late-onset conditions and so on.

But I think there's a big issue, and it is

that if it's -- if it's my genome, if it's information about me, then it's unclear what the grounds for denying me access to that information about myself are.

In other words, I'm -- I'm unclear that people have a right to operate a principle of caution to stand between me and information about myself, particularly when we so often accept that things like self-awareness are goods and indeed are necessary conditions of autonomous choosing.

Then it becomes very problematic to think that I may not be entitled to test myself. So, I am challenging the assumption that we're actually entitled to operate a principle of precaution at least insofar as the individual's access to private information about their own genome is concerned.

DR. SHAPIRO: Thank you.

Maybe -- does anyone want to address that particular issue which has been raised? Are there conditions under which one could imagine denying someone access to information about their own -- their own genetic make-up?

Yes?

MR. RODOTA: Rodota from Italy. I'd like to

go back to the special nature of the genetic data, and I think that if we have to take into account the fact that in front of traditional health information that are peculiar of a single person, of a single individual, genetic data are shared with other members of the familial group.

It means that we are in front of a change of also the legal nature of this data. In some international documents, like a draft recommendation, new draft recommendation of the Council of Europe on health information -- health information, these kind of data are indicated and defined and as property ownership of the familial group.

It means an obligation to communicate this data to other members of the group. Also, if the single individual opposes to the knowledge of this information by himself, this is very important change in the idea of personal health information.

DR. SHAPIRO: Thank you.

Professor Levine would like to address an earlier question I raised. Let me turn to Professor Levine now. Then we'll come back to this side over here. I know Ms. Chadwick has a comment.

MR. LEVINE: Thank you. Is this thing

working? You can hear me? Oh, now it's working.

The earlier question I wanted to address was whether anybody could envision something so important that -- in research, that it would override all other considerations, and it interested me that there was no response to that because it's hard to imagine such a thing.

I do want to say that I'm aware of at least two sources of -- or two places in which such considerations have been brought up.

In the Nuremberg Code, I think that's what they were thinking of when they wrote the principle that has to do with research in which there is a priori reason to anticipate that death or a disability could occur as a consequence of the research, and one of the mistakes Nuremberg made was to say that would be permissible only in circumstances in which the experimenter -- the experimenters would be willing to serve as subjects.

I think they were implicitly thinking that or implicitly saying that no one so rationale as an experimenter would ever subject himself or herself to deadly experiments unless it were terribly important.

The other very thoughtful article in which

this issue is raised is in one of the early articles by Hans Jonas, called "Philosophical Reflections on Experimenting with Human Subjects", and in this article, he clearly argues that research -- the goals of research are almost invariably option goals, and therefore the need to do research would have to yield to other more important priorities, except, said Hans Jonas, except in circumstances where the survival of the civilization was at stake, and I think, although he didn't say, I think he might have acknowledged the legitimacy of overriding some other considerations in a setting like during the Great Plagues, the Black Plague in Europe, the Small Pox Epidemics and so on, that we might then do some things without informed consent.

Thank you.

DR. SHAPIRO: Thank you.

I believe there was a hand down here. Yes? That's right. Further down. That's right. Excuse me. I don't know everyone's name, and I apologize.

MR. WELLIN: Yes, Stellan Wellin from Sweden. There has been many issues. Let me just start by saying to John Harris that I think the issue is not whether individuals should be allowed to use

the genetic tests, but whether the genetic tests should be allowed to be sold on the market in the same way as we do with all medical issues.

Then going back to the issue of -- that had been discussed earlier on genetic information and medical information, it seems to me that it is as bad to be discriminated against in insurance on medical grounds being already sick, than it is to be discriminated on genetic grounds. There would be a risk to be sick. So, I think it's just that we are used to the other one.

On the other hand, I think the insurance companies has some logic in saying that they need to have access to the same information as the person who takes the insurance has, and that talks for they should be allowed to ask, in my opinion, to ask for genetic information which the individual already has -- has access to. But this is not the official Swedish position.

On the other hand, there is another question. What should the role of the insurance companies be, which is very, very important? I'm coming from a country where we have the National Health Insurance Company, and this makes the issue

very small indeed, and I think that the issue of genetic information really press home the point that one should have a national health insurance company, and I feel very sorry for the Americans.

DR. SHAPIRO: Thank you.

Ms. Chadwick?

MS. CHADWICK: Thank you. Ruth Chadwick. Your screen group is from the arguments for the special nature of genetic information to be that it has four characteristics.

The one that's already been mentioned quite a bit that it should be shared between family members, then it's independent of tissue, it's independent of age, and it's independent of clinical state, but those who agree that these characteristics make genetic information something special don't agree on what the implications of that are, and some people have argued that if it's special, it requires stronger protection of confidentiality and privacy, but, on the other hand, some have argued that it requires less protection of privacy and confidentiality, and similarly some have argued that this special nature, the predictive nature of genetic information, leads to arguments for a right not to know it, whereas against

that there is the argument that because it's shared, people should share the information and display solidarity, and be less worried about other people having access to their genetic information.

In the U.K., the Nuffield Council on Bioethics, which published its report on genetic screening in 1993, argued that the questions of confidentiality and insurance-needed review and recommended that the government seek early consultation with the insurance industry.

The select committee set up by the government endorsed this and asked the insurance industry to consult with geneticists and other relevant persons and come up with recommendations.

This process is still going on, but the current position of the Association of British Insurers is that they will not ask people to undertake genetic tests, but they do think that people should be required to disclose information resulting from genetic tests that they have as a matter of fact had.

Thank you.

DR. SHAPIRO: Thank you.

Eric Cassell?

MR. CASSELL: I think your question about is

there something so important that it would override our usual protections and the genetic information is right on one thing, that there are values or are there values greater than whether people stay alive or not, individual persons are alive or not? Are there values greater than just life and death, and what happens in the technological pursuits is that seems like the only important value, is that somebody lives.

For example, we could conceive of a test for a head injury where something looks so promising that it would change the death rate dramatically. On the other hand, it would also involve people having lost their protection against their participation, voluntary participation.

So, the issue at the bedside, which is are there things more important than just staying alive, which none of us have quite figured out how to resolve, is back in the center of these deliberations, also, and it is a really central question that we keep bouncing off because for scientists, there are many things more important than individualized, except, of course, their own.

DR. SHAPIRO: Let me just say that there are quite a few people I want to recognize. The question

I asked, when I asked it, I hadn't quite been thinking of life and death matters but simply overcoming, for example, cultural issues, just ignoring cultural differences for the perspective of a particular procedure, something a little less dramatic than -- than the life and death which is hard enough. I understand.

But let me now ask Mr. Wikler.

MR. WIKLER: Speaking to the question about self-ownership of genetic information, John Harris has asked why would we ever be -- why we would ever hesitate to ensure that individuals have maximum access to the information about their own genes.

I'd like to place before your attention a couple of considerations that came up in the deliberations of a group which has been meeting for three years composed of academics and members of the American and Canadian life insurance industries. Alex Capron is the director of this group.

The first, I think, is one which is evident to all, which is that unbridled access, immediate and complete access to this information, doesn't necessarily provide access to the education needed to understand the significance of this information.

Significance not only for the individual but for other -- for related individuals, and this might have an important impact on this person's planning and beliefs about their own future.

Secondly, there is a more subtle factor, which only applies to private insurance markets, but even in countries as advanced as Sweden, I believe life insurance is still delivered on the private market, and that is the fact that if there is a means for individuals to gain information about their own genes through some kind of testing which they administer, either through anonymous testing in laboratories or even through some kind of home testing, an important ethical consideration is what use will be made of this information, and a couple of the representatives of the insurance companies put before us the proposition that one important use of this information would be to commit fraud, commit fraud by an individual who finds out that they have a genetic condition and then applies for life insurance to a company who either by law is forbidden to ask or which for marketing reasons has decided not to require a further test of individuals who are applying for a given kind of insurance.

Now, this individual will know that they are at much greater risk than other people who are applying for the insurance, but because they've done this anonymously or themselves, they will feel that they are in a position where they do not have to disclose this risk, and the insurance executives put to us the question, if you believe this is unethical behavior because it is fraud, then how could an ethics group decide that this is a right of individuals?

DR. SHAPIRO: Okay. Professor Childress?

MR. CHILDRESS: This is an area you haven't addressed. I'd be interested in whether any of the commissions, who are a mix of private and public, a mix of audiences, whether directed toward governmental group or -- or professional groups or some other groups, so I know we have a large variety, but I'd be interested in whether any of the commissions have addressed issues involving state-mandated genetic screening, particularly of newborns, and what kinds of limits have been proposed, what kinds of guidelines and restraints.

DR. SHAPIRO: Specific question regarding state-mandated testing, particularly of newborns.

Professor Knoppers?

MS. KNOPPERS: Professor Knoppers, Canada. As I mentioned earlier, we are the MELSI Committee of Canada looking at population screening, including newborns, which are systemically and systematically screened in all Canadian provinces, though the number of diseases may vary according to local or provincial incidence.

We are looking to reaffirm classical principles of screening in terms of the guidelines set out by the WHO as well as by the New York Academy, and at the same time, in that reaffirmation, avoid the simple add-on of new diseases that do not meet those criteria, which I will not elaborate upon here, but we want to distinguish between those screening programs that have a proven benefit to identify populations for immediately-treatable conditions where those asymptomatic persons who are at risk would not otherwise be found, and where, if and when they were found, the treatment would be too late.

So, those are the -- so, we're looking to reaffirm as well as what do we do then with all the new other add-ons, like CF and so on, we are looking at that issue.

Mr. Chair, may I answer the question

directed me earlier?

DR. SHAPIRO: Yes.

MS. KNOPPERS: The question had to do with the fact of whether international guidelines in their homogeneity in a way either undermine or may not respect cultural diversity in the communities that are a part of that international community.

It's an absolutely beautiful question. The HUGO Council, when they asked HUGO Ethics Committee to look at the elaboration of a principled statement of conduct, was not to facilitate research, though perhaps that could be one of the spin-offs of such a code of conduct should its members be sufficiency inculcated and respect the code of conduct, but rather because a lot of international research in collaborative studies through disease families around the world or through collaborative mechanisms between individual researchers escaped REB review or even if there had been initial REB review at the local level at the initial sampling stage, the uses or the testing or whatever being done is on -- is for other purposes.

So, the idea was to have an international statement that would be prospective and principled in nature. The usual route for international statements

has always been to sort of work towards consensus after individual nations and ethics committees and commissions have either adopted codes or laws or directives or principles with the result that like with organ transplantation and with new reproductive technologies, 10 years after the fact, when nations already are sort of frozen into their positions, we have a very hard time looking for commonly-held, and I think the Council of Europe experience is proof in point, to provide guidance that doesn't become too homogenous and bland and generalities and so on.

With the Human Genome Project, we have a unique opportunity to take a prospective principled approach and then allow for cultural differences in the interpretation of those principles at a national level.

Thank you.

DR. SHAPIRO: And what do you expect would happen if that's achieved, if in fact when you allow for those cultural differences, the feedback is that the protocol itself doesn't look so effective from the scientific point of view?

MS. KNOPPERS: I take as a given that scientific validity is an ethical prerequisite.

DR. SHAPIRO: Okay. That's interesting.

Last question because I'm going to have to break. Yes?

MR. HARRIS: Can I go back to what I take to be your big question, and that is entitlement to ignore or override cultural considerations?

It seems to me that we have a precedent in most societies already for this, and that is compulsory post-mortem examination, where there are often many cultural objections to tampering with the body after death, but it is accepted that there is a public interest argument for finding out the cause of death.

Now, if we ask how powerful in many cases that public interest argument for violating those cultural beliefs is, I think it's actually not a very strong one, yet we still accept it.

So, it seems to me that we already accept, most of our societies, that there are public interest considerations which override cultural differences. We accept it in post-mortem. It may be that that benchmark, if it is one, would provide something that we could extend, and if I may, just to respond to Dan, Dan's points, the entitlement to receive information

is not the same as the entitlement to use it fraudulently.

You can object to fraud, but still allow people to receive the information. I don't see that those two have to be tied together.

Thank you.

DR. SHAPIRO: Thank you very much.

I know there are still others who want to speak, but I think we've been here three and a half hours now, and it's time for us to break.

PROF. CAPRON: Two and a half.

DR. SHAPIRO: It only seems. Two and a half. Thank you, Alex.

We'll take a break. Let's try to reassemble in about 20 minutes, about 25 after the hour.

Thank you very much.

(Whereupon, a recess was taken.)

DR. SHAPIRO: Colleagues, if we could assemble, we'd like to move on with our agenda, please.

(Pause)

DR. SHAPIRO: If we could call the meeting to order again, please, so we could proceed.

(Pause)

DR. SHAPIRO: Can everybody out there hear me? Is this working? I'm glad because I can hear everyone else at the same time.

This hour, we are going to spend between now and approximately 12:30 continuing our discussion with the focus, perhaps even more focused somewhat on the question of research with human subjects as opposed to genetic issues surrounding genetic material, once again acknowledging that these aren't easy matters to completely separate.

In any case, we've asked two of our colleagues to begin our discussion by addressing us. The first would be Professor Levine, who has introduced himself before, but to remind you, he's a member of the Council for International Organizations of Medical Sciences, also Professor and so on and physician.

Professor Levine?

What Have Commissions Done About Research with Human Subjects? Reports on Protecting Human Subjects, consent, and Review Processes

Statement of Robert Levine, Council for International Organizations of Medical Sciences, CIOMS

MR. LEVINE: Thank you, and as a physician,

of course, -- is this working? No? Help.

As a -- tell me when this is beginning to work? I'll just say things you don't need to hear until the microphone goes on.

DR. SHAPIRO: It's working.

MR. LEVINE: Okay. Thank you. All right. We've got it.

As a physician, of course, I find it necessary to use slides. I'm very pleased to have this opportunity to present the guidelines that were put out by CIOMS, the Council for International Organizations for Medical Sciences, in collaboration with the World Health Organization, in 1993.

A word about the Council. This is an international organization. The members of this are organizations that are both international and are concerned with medical sciences.

The organization has its offices at the World Health Organization in Geneva. Its project in international guidelines for biomedical research resulted in its first publication in 1982 of a document called "The Proposed International Guidelines".

Because the word "proposed" is in the title,

many people thought incorrectly that it was intended as a rough draft. It reflects instead the fact that CIOMS was proposing to the governments and to the institutions of the world that they might want to consider their guidelines in drafting their own policy statements, and to a large extent, this happened.

CIOMS then, for reasons that I'll go into later, if you wish, decided to undertake an extensive revision of these guidelines, and I have the wrong date on this slide. It published these guidelines in 1993.

Now, along the way, CIOMS recognized the need for separate guidelines in the field of epidemiology, and these guidelines were discussed at an international conference in 1990 and published in 1991.

What the guidelines concentrate on, though, are the international ethical guidelines for biomedical research involving human subjects. I had the good fortunate to be co-chair of the Steering Committee for this project. The other co-chair was Dr. Jack Bryant, who you heard from briefly this morning.

The first problem we encountered as we began

to think of guidelines that might apply around the world was the centuries' millennia-old problem of ethical universalism and its opposition in cultural pluralism.

Universalists very briefly are those who believe that there is a set of correct ethical principles out there, and that the reason our perception of them seems to change from time to time is that we just are getting better and better at identifying them.

The -- so, they would hold that the same ethical principles would hold in every place and in every period of history.

Cultural pluralists, by contrast, point to the fact that all ethics are developed in cultural contexts and necessarily reflect the histories and traditions of particular cultures, and it's for this reason that cultural pluralists acknowledge the legitimacy or the inevitability and legitimacy of differences in ethics across cultures.

These debates were carried out in philosophy journals until not too long ago, and as we became more and more aware of the necessity to have multi-national research, especially biomedical research, the debates

over this moved out of the philosophy journals and into other publications, including the New England Journal of Medicine, and it's at this point that you begin to see the participants in the debate called names.

The pluralists call the universalists ethical imperialists, who would say yes, we'll try to develop a treatment for your children's diseases, but, first, you must allow us to replace your ethics with our own, and the universalists on -- by contrast, call the pluralists ethical relativists, and say what they subscribe to is just whatever is right. There would be no way to evaluate whether one set of ethics was to be preferred to another.

What CIOMS was striving for was global applicability, which is different from universalism. This would be something that could be applied across cultures in 1993 with the awareness that as time went on, it would have to be revised to build into it revised understandings of ethics, and as you will see, also, whenever one aspires to global applicability, the guidelines become less and less substantive and more and more procedural.

The document that was produced recognizes

the legitimacy of cultural pluralism within limits, and it also recognizes some ethical principles which it refers to as transcending moral rules.

Now, it's also necessary to remind ourselves that there have been a series of international documents, international codes of ethics, for research involving human subjects.

I see these as a progression. Each of the writers of these documents was aware of the work of its predecessors, thought it detected errors that needed correction, and began its own project with the aim of correcting the errors of its predecessor.

Nuremberg, being the first International Code of Ethics, was intended by its authors to be limited in scope. They were asked by their consultants to put in something for trying out new therapies or new diagnostic modalities, and they said no, we have been given a specific charge, and this is not part of our charge.

They were also asked to contemplate the need for proxy consent in the event of legal incompetence, and they said no, we are not asked to review that kind of research.

Another problem with Nuremberg is that it

didn't define research, but it was very clear that research was perceived as something that was done to particular -- the bodies of particular persons, and that it could be harmful -- it -- it could result in death.

Our perception of what is called research has evolved in the last 50 years, and now we include such activities as looking at people's medical records as research.

It's bizarre, but when we describe projects of looking at people's medical records without informed consent, there are some people who say this is in direct violation of the Nuremberg Principle Number 1, and therefore this activity is to be analogized to the work of the Nazi research physicians. I for one think that's preposterous.

The other thing we have to deal with in looking back at Nuremberg is that the public perception of research has changed dramatically since the 1940s. I snipped out two sentences from publications in the 1960s to show you the prevailing mindset that informed the writing of the codes and regulations through the 1960s and indeed through the 19 -- early 1980s.

Here we see the language that's used by Hans Jonas in his first seminal essay, "Experimentation: Philosophical Reflections on Experimentation with Human Beings".

He refers to conscription of subjects who sacrificed themselves in the service of the collective. Jonas is not making this up. That's the way people thought about research when he wrote in 1968.

Another, the next passage is from the International Covenant on Civil and Political Rights, and it says no one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical experimentation, and from this, you can see that in the 1960s, the United Nations' perception of medical research is that it was a subset of an activity that could be characterized as torture or cruel or inhuman punishment. This is not the way we look at research in the 1990s.

The World Medical Association looked at the Nuremberg Code and said that this is not for us. They said this is a document crafted by lawyers with the aim of establishing standards for criminal

prosecution, and what we need instead is a set of guidelines written by physicians for physicians.

One of the improvements that they made over Nuremberg is that they recognized that there are some experiments in new diagnostic and therapeutic methods and some other experiments that are undertaken to serve other purposes than simply to cure the individual, and this recognition by their Committee on Medical Ethics in 1953 gave rise to their classification of all research as either therapeutic or non-therapeutic.

This is logically unsound, and it leads every agency that has used this dichotomization, for some reason this gadget doesn't work anymore, every agency that has used this dichotomy in its ethical codes or otherwise in its reasoning has developed some -- it has in effect painted itself into a corner ethically.

So, Principle 2.6 is taken from the justification of therapeutic research. It says that the objective must be the acquisition of new medical knowledge, but that it's justified only to the extent that -- or only to the extent that medical research is justified by its potential diagnostic or therapeutic

value for the patient.

Principle 3.2 comes from the non-therapeutic research passages, where it says that if there is no therapeutic or diagnostic value, the subjects must be volunteers, either healthy persons or patients for whom the experimental design is not related to the patient's illness.

This effectively rules out all placebo controls. It outlaws the fields of epidemiology, and it says if you ever want to study the pathogenesis or natural history of a disease, you can only study patients who don't have the disease you're interested in. That's the sort of logical problem I mean.

As CIOMS put it in its '93 publication, Helsinki was not designed to provide guidance for controlled clinical trials; rather, it assures the physician freedom to use a new diagnostic or therapeutic measure.

DR. SHAPIRO: Your slide didn't advance.

MR. LEVINE: Sorry. It did now. Thank you.

In other words, what Helsinki's clinical research category corresponds to is what we in the United States have come to call compassionate use.

Now, the CIOMS guidelines were developed by

a group that was heterogeneous with regard to gender, race and nationality. There were members from both developed and developing countries, and diversity with regard to profession, ministries of healthy, medical and other health-related professionals, health policy-makers, ethicists, philosophers, lawyers, and others.

This is different from Nuremberg, which was developed by American white male lawyers, and from Helsinki, which, as they said, was developed by physicians for physicians.

I don't mean to say that something is incorrect merely because it did not have a diverse membership, that a document is incorrect merely because its designers were not diverse in, you know, these categories, but in 1996, we would insist upon having a more diverse group participate in developing ethical guidelines of such importance.

Now I'm not going to present the entire 52-page document. I will tell you that there are in it 15 guidelines with extensive commentary on each of them. I'm just going to provide some samples of these.

Informed consent in under-developed communities. It says that all reasonable efforts

should be made to obtain individual informed consent, but when, because of communication difficulties, the investigators cannot make prospective subjects sufficiently aware of the implications of consenting, the decision should be elicited through a reliable intermediary, such as a trusted community leader.

It also recognizes that there can be very different material inducements from one culture to another, very different material inducements could be legitimate, depending upon the gift exchange traditions of the culture.

It points out that in some cultures, women's rights to self-determination are not acknowledged. In general, women in these cultures should not be employed as research subjects, unless there is some very strong reason to do so. However, they should not be deprived from chances to receive investigational therapies.

Efforts must be made to let them decide, even though the formal consent must be obtained from another person, usually a man. It recommends that the invitations to participate in these activities should be extended by women who are sensitive to culture-specific cues of whether or not they really want to

get involved with this.

It even makes provision for circumstances in which formal clinical trials can be justified in pregnant and nursing women when you're attempting to be directly responsive to the health needs of the women or the unborn babies or fetuses that they are carrying.

I'll spend my last couple of minutes on some of the standards for ethical review. As of 1982, CIOMS says that the ethical standards should be no less exacting than if the research were carried out in the country of the sponsoring agency, but it adds the provision that the goals of the research should be responsive to the health needs and priorities of the host country.

This is an attempt to avoid exploitation of the sort that we saw when industrial sponsors from developed nations would go into developing countries in order to recruit subjects for the trial of drugs that would only be marketed in the developed countries.

It sees the job of reviewing research has something that can be apportioned between committees in the developed nation and other committees in the

developing nation, especially when the research that's designed in a developed country will be carried out using subjects in a developing country.

In the country of the sponsoring agency, primary responsibility is assigned for three categories of activity. The first two of these are judgments that we believe are universal. For example, the science must be sound.

As Professor Knoppers mentioned earlier today, it's one of the first ethical criteria for a justification of research that there has to be sound scientific design.

Also in the developed country, there can be a review of drugs for their safety, vaccines for their safety, and so on, and in general, the developed countries should see to it that there is no violation in principle of the agreed ethical standards.

Now, in the developing or in the host country, we would have the REC, Research Ethics Committee, in the host country primarily responsible for determining the responsiveness of the research to the priorities of the host country, and they would also look to the details of informed consent, the legitimacy of monetary inducement, and the procedures

to guard against invasions of privacy and breaches of confidentiality.

It says that the Research Ethics Committee members or consultants should include persons who are thoroughly familiar with the customs and traditions of the community in which the research is to be done.

The obligations of the sponsors are generally put as prima facie obligations. In other words, this is the starting position. You are expected to do this unless you can advance good reason to do otherwise.

So, when doing research in a developing country, the -- if it's designed to develop a product, there should be some provision to make the product reasonably available in the host country at the conclusion of the research.

There should be an effort to train and employ local personnel to assist in the development of independent ethical and scientific review committees, when indicated, to make the necessary health care facilities available, to provide free medical therapy and compensation for research-induced injury, and borrowing from the anthropologists, to leave the communities no worse off when the researchers go away

than they were when the researchers arrived.

My last slide, to show that I don't think that the CIOMS '93 document is the final answer, I want to mention a few problems that I see in it.

There are no provisions. It announces reasons why they could not put provisions in it for genetics and fetal research. In my view, it insists too much on informed consent in what the document calls "under-developed communities".

It -- it calls upon the investigators to recite all of the elements of informed consent even though they're working in a community where not going along with what the community leadership decides to do is almost literally unthinkable.

The document should explicate its "transcending moral rules". It states that there are such, and it only implies what they might be, and, finally, I would call for an increase in its responsiveness to the legitimate requirements of cultural pluralism.

Thank you very much. Thank you for your attention.

If somebody could turn that off, thank you. I always try to leave people in the dark.

DR. SHAPIRO: Well, thank you very much for that very thoughtful and lucid presentation. I appreciate all the effort that went into preparing it. Thank you very much. We'll certainly come back to it in our discussion.

Let me turn now just before we go our general discussion to Mr. Hlaca from the Law Commission of the Family Code in Croatia.

Bring the microphone closer to you, it will be a little better, I think.

Statement of Nenad Hlaca, Law Commission for the Family Code and Transsexualism, Croatia

MR. HLACA: It's okay now or not? Okay.

(Pause)

MR. HLACA: Bioethics was imported in Croatia during the last decade with the new medical technologies. In the same time, there was strong influence of socialist regime in which collective rights were more important, and in which there was no place for individualistic approach in the protection of the human rights.

Historically important step in the development of the bioethical approach was the first course of human rights in medicine organized at the

University Center for Post-Graduate Studies into Dubrovnik in 1984.

In 1990, it was organized the first East-West Bioethical Conference by the Hastings Center from New York, and this was also a very important step to bridge between the East and West on bioethics.

In the last 12 years, even during the war, the courses in Dubrovnik were dealing with the human rights issues in medicine and health care. In the multi-disciplinary approach, the participants from Croatia and from all over the world discussed the ethical dilemmas and protection of human rights raising from the modern medical technology.

Tragic events in the former Yugoslavia during the war focused our interests of the participants on the problems of the war victims, displaced persons, and refugees as well as on the ethical and legal aspects of the family dysfunction on the 1994 course, for example.

The principle of the health care reform now in Croatia as a sovereign state is a flexible step-by-step process based on realism with necessary changes based on the good experiences from the former socialist system.

The health care reform is oriented towards more efficient resource management and more professional autonomy. There is a risk of just changing from a governmental order to a command system or to a professional or industry system. Equal accessibility and quality of the health care for all the population is still an aim of the health policy in Croatia.

It is welcomed that the Medical Chamber has received extensive competencies in the Croatian health care system in the fields of medical ethics and sanctions, protection of citizens rights in terms of quality and defining standards of health care services.

In the Croatian medical practice, there are introduced in the form of autonomous norms bioethical commissions as decision-making bodies for the specific medical treatments. Examples are rules of ethical committee from the clinical hospital center in Zagreb for medical treatment and transplantation of bone marrow, rules on organization and work of ethical committee from hospital, Sveti Duh in Zagreb, and the a very interesting and important rules of the ethical committee of the Medical School University of Zagreb.

Next step should be the unification of the bioethical standards on the national level.

The situation now in Croatia dealing with the bioethics is the vacuum in the public policy. The biomedical ethics is introduced in the policymaking structure through the participation of the independent academic experts in the law commissions. This is an example of the ad hoc topic-specific bioethics commissions.

The discussions in the mass media related to the draft of the abortion code are example how is the urgent need of serious bioethical research as a method of transforming medical and biological chaos into the order of moral principles.

The UN General Assembly adopted in 1989 the UN Convention on the Rights of the Child. It is very interesting and important to stress that until now, we have more than 180 ratifications of the document, and its succession procedures of former Yugoslavia Croatia has through an act of notification adopted this Convention into its legal system without any restriction.

With accession to international collectives, the state delegate, a part of their sovereignty, so

that the legal system has to be in accordance with the international standards.

It's an interesting and important to stress that the Constitution of the Republic of Croatia and the Articles 164 explicitly prescribes that international agreements which are concluded and confirmed in accordance with the Constitution and proclaimed became a part of the internal legal system of the Republic of Croatia, and their legal force is over the laws.

The Ministry of Labor and Social Affairs nominated in 1994 the Law Commission for the new Family Code and soon the draft will be under the debate in the Croatian Parliament.

The draft will be completely in accordance with the standards from the United Nations Convention and especially which Article 12 of the Convention and will take care about the rights to express its thought on all matters that concern him or her and to attach importance to them in conformity with the child's age of majority.

The draft of the new Croatian Family Code, according to the United Nations Convention, established the parent-child relationship on three

basic premises: the child's rights, the child's greatest interests, and parental responsibilities.

Parental responsibilities as a new legal concept replace the institution of parental rights enabling a new system of legislative and ethic evaluation of the child as a legal entity. The theoretical basis for the new legal approach to the child's legal status is in the child's autonomy which in relation to the degree of its maturity enables it to make independent decisions.

Parental rights originate from duties and exist only as they are necessary for the protection of the personal rights or property rights. Children's rights must be reflection of the development of human nature and social changes. Parental rights are developing into the children's rights to independently make decisions when they are sufficiently reasonable and intelligent. The legal validity of the children's decisions should be evaluated from case-to-case.

The new Croatian Family Code will be a modern code which will contain norms related to the marriage, parents and children relationships, adoption, guardianship and property-related norms. Related to the status of the mentally-disordered the

new concept which will be introduced in the practice will take care about the preserved capacities of the people to whom the guardian will be nominated.

The changes are radical because in the positive legal system, we had old approach by which the legal status of the mentally-disordered people was generally reduced in the court proceeding.

With the new approach in the court decision, which is a legal presumption for the nomination of the guardian, it should be expressly declared for which decision-making processes the person is incapable. For all the other legal situations, his or her capacity will be no restricted.

In the practice of the Croatian administrative organs, there were in the recent time few cases related to the legal effects of the sex-change interventions.

In Croatian legal system, there is not yet accepted special law on the sex change, so the comparative sources legislation from the European and decisions from the European Court of Human Rights should be considered.

The problem is how to achieve a fair balance in these delicate situations. The fair balance should

be achieved through the special act and the legal aspects of the sex change. Special act is extremely important because of the numerous personal relations in which the sex is important as a biological fact.

Court procedure with effects of the authorization of the sex-change surgery should be the basic exemption for the legalization of the sex-change interventions.

It is also important to impose the severe critics the practice in which the sex change is legalized only through the administrative procedure for the changes of the names.

As in the practice of the European Court of the Human Rights, in the Family Code of Croatia, there is a norm by which is void the marriage if there is no diversity of the sexes of the spouses.

In the practice of the Croatian courts, there was no yet judgments related to the right to marry of the persons after the sex change. The future of the Croatian legal standards should be close to the standards of the European Commission and the European Court of Human Rights because recently and finally Croatia has become the member of the Council of Europe.

Thank you for your attention.

DR. SHAPIRO: Thank you very much.

Discussion Among the Delegates

DR. SHAPIRO: We now have some time to open the floor for general discussion. Let me turn since it's the first hand I see to my colleague Professor Childress.

MR. CHILDRESS: A number of questions that emerged for me, but let me focus on one directed, first of all, to Bob and then to people from other countries.

One of your guidelines is the right of subjects to compensation for research-related injuries, and this is stated as a very strong right with the obligation to provide such compensation, and yet in the United States, at most, we've only recognized the duty to inform research subjects as to whether we will have such compensation available for them in case of injuries.

I wonder if you could sort of comment on your sense of what has happened, and then if others would tell me whether in other countries, there really is a duty to compensate a research-related injury.

This may be another area where we've been --

lagged far behind in our skills in developing this area.

Thank you.

MR. LEVINE: Is this thing working? No. Jim, thank you very much for picking up on that point. I -- I just snipped that point out of a larger paragraph.

Just as we said in some countries, women's rights to self-determination is not acknowledged. We also said in some countries, the injured subject's right to compensation and free medical therapy is not acknowledged.

It's my belief that in the developing world, the United States is one of two countries that doesn't make provision for providing at least free medical therapy. The free medical therapy, of course, being related to the fact that they have national health plans, so they didn't have to set up a special program to treat injured research subjects.

Thank you.

DR. SHAPIRO: Yes, Mr. Chalmers?

MR. CHALMERS: Donald Chalmers, Australia. Just in a factual response, we have a universal Medicare system. In addition to that, the National

Health and Medical Research Council has issued compulsory guidelines four years ago about the requirement for insurance, and as of this year, the international -- an international firm has introduced a no-fault compensation for clinical trials notification, and that's a pre-condition to carrying out that work.

So, we're quite serious about the insurance.

DR. SHAPIRO: Are there any other comments on that particular issue? Yes?

MR. YUDIN: Boris Yudin from Russia. My comment will be about problems which are related to Professor Levine's presentation.

Earlier this year, in Russia, was very sharp system of research of human embryos, and there were post-operative problems related to this issue. I can now just only name this problem.

First, the problem of status of embryos. Do we have research with human subjects or not in this case?

The second problem, problem of informed consent. That was consent from -- from women who were aborted, but it is unclear how valid is this concern in principle because the women, so to say, they do not

want to have childs.

Second problem is problem of local ethic committee. There was such committee in the institute which made this research, but it was composed from -- only from members from staff of this institute, and the former chairman, it gives -- it approves -- approved this issue, but it means that unethical decisions can be approved by ethical committee.

The fourth problem, problem of lack of international regulations in this area, and you know that in our situation in Russia is such that we are very receptive to international regulations, and the lack of them is -- creates a very difficult situation in this field at least.

And next problem, problem of international sponsorship. Russia, I think, is not developing country, but because of scarcity of financial resources, many developed countries involved in the research in Russia because Russian hires professional specialists can earn money with this way, and the problem is problem of who in the sponsoring country must -- who -- who must seek for implementation of standards.

And the last problem, the problem of

scientific soundness of this research. It's rather unclear scientific soundness to my opinion of research on transplantation of fetus tissues.

Thank you.

DR. SHAPIRO: Thank you very much.

I want to now turn to our colleague from South Africa, who's had his hand up all morning, and I seem to somehow always skip by him. Solomon?

MR. BENATAR: Thanks, Mr. Chairman. Is this not working?

DR. SHAPIRO: Yes.

MR. BENATAR: It's on now. Thank you, Mr. Chairman.

DR. SHAPIRO: Sort of about a 13-second delay apparently.

MR. BENATAR: I'd like to comment, if I may, on -- on Bob Levine's presentation, and say that in 1993, the South Africa Medical Research Council wished to update for the country our guidelines for ethics of research on both humans and animals.

We had previously a very flimsy document that clearly needed to be very extensively updated. We had the choice of either adopting a document produced elsewhere, and the two we favored most was

the CIOMS document or the document from the Royal College of Physicians of London, but we felt that neither were most user-friendly for our country and neither would on their own serve the kind of educational purposes that were necessary at the particular phase of development of ethics in South Africa.

And the point I want to make is that it was very generous of both CIOMS and the Royal College of Physicians to allow us to use their documents verbatim in many parts to construct what we hoped would be a user-friendly document for our country, and I think there's a lesson in that for other countries in that without having to reinvent the wheel and without having the resources to do so, it is possible for less-resourced countries to produce reasonably-adequate guidelines for themselves which clearly in time would need to evolve.

The major issue we've had, and it hasn't been addressed here, is how one traverses the gap between producing guidelines, ensuring that they're read by the people who submit documents to ethics committees for research subjects, and that determining whether they remotely live up to what they claim to do

to in their experimental work.

We found that despite the recommendation that all research workers should read the relevant sections of the report prior to submitting their applications to the ethics committee, there's reasonable evidence to suggest that many of them don't or do so very skimpily, and from limited auditing tests by just sticking a needle into the odd research project, it's clear that there's a very large gap between the recommendations and what people do, and I think that's the concern that the public at large have, is that the profession and professional people may produce wonderful documents, but what do they do to ensure that those ideals and principles are put into practice?

That's the comment I'd like to make at this stage. There is a broader comment that I wanted to make as the only representative from the African Continent here, and it's related more to the earlier issue.

I'll make now if you'd like me to, but I'm happy to hold it to a later point, should you prefer me to do so.

DR. SHAPIRO: Please. Please go ahead.

MR. BENATAR: Mr. Chairman, what I wanted to say was that I feel very privileged to be the only person from the African Continent at this meeting, and what I want to say I say with considerable reluctance for two reasons.

The first is my doubt that speaking off-the-cuff without any prepared statement, I can really adequately affect some of the concerns felt very broadly throughout Africa by Africans themselves.

My second concern is that in saying what I want to say, I may sound offensive, but that's not my intent. My intent really is to enlist the kind of support that I believe is necessary from this kind of committee and understanding the issues of a continent like Africa.

So, with those provisos, and if I don't tread carefully enough as an African or if I offend you, I hope you'll forgive me for not doing it properly.

What I want to say is that the African Continent is a marginalized continent. In many ways, it's a dying continent, a continent out of sight of the industrialized world, except for the tragedies of Rowanda and Somalia and the like that hit the

headlines and the television.

There's a very inadequate exploration of why these issues are like they are in Africa, and very little understanding of the legacies of imperialistic impositions which continue on the African Continent on the future of the people there.

Lack of attention to the way in which a debt which can never be repaid was developed in Africa, lack of exposure of the collusion of governments with despotic leaders, and the use of AID money to buy military equipment, military equipment which is now being used to massacre people in genocidal proportions, a lack of an understanding of the cultural imperialism on Africa, a lack of understanding of the way in which many of the adverse events taking place on the Continent reflect a legacy of a relatively-recent past.

And the concern that many Africans feel is that for all the high-flown intentions described in various documents relating to the Human Genome Project in the same way as we noticed them in the -- in the Guidelines for Ethics of Research, is that these are in some way camouflages for protecting the interests of the most developed nations in the world, and that

discrimination and marginalization will continue to ensure that the lives and the human dignity and the rights of billions of people are ignored.

Yesterday, Jonathan Mann said in one of his presentations that when the word "poverty" comes up, it's a paralyzing term, and that everybody says, well, this is all due to poverty, and they throw up their hands in horror.

My suggestion is that we shouldn't be paralyzed by the word "poverty", but we need to reflect back on how that poverty arose, and we need to get away from victim-blaming, and we need to get away from the idea that we can only look at the up side of industrialization and recent developments and compare that with the down side of what's happened in Africa.

We have to look at the down side of the one and the up side of the other as well, and my concerns that I want to express not for myself, because I'm a Westerner and much like you deeply embedded in the ways and traditions but have become sufficiently Africanized through my involvement in resistance to apartheid and trying to move into a new South Africa, to appreciate the feelings of Africans about the need to see the world, if possible, to some extent, through

their eyes, even if only an understanding what needs to be done for their continent.

So, there's an element of skepticism, an element of concern that the discrimination that's taken place in the past will continue once the genetic code is unraveled, and no amount of reassurances on paper will, I think, help the people of Africa to feel they're not marginalized and unloved by the rest of the world, and this, the practical attempts to make an impact on the lives of people in that country.

If I may say so, perhaps the events in South Africa, the transition peacefully to a new power structure reflects something that Africa might be able to teach the Western world.

Whether that dream can become a reality will depend on as much support for South Africa and Sub-Saharan Africa and the role it could play in the African Continent as there was admonishment for the aberrant apartheid policies that characterized that country in the past.

So, my appeal, Mr. Chairman, if I've managed to do so, as an African, is to help you to view more adequately, if you can, through the eyes of others what these developments might mean, even if those

fears are unfounded, and to put in place some mechanism for practically ensuring that the spirit of the declarations and the concerns about genetic research will not further marginalize people in Africa.

Thank you.

DR. SHAPIRO: Thank you very much for those thoughtful remarks.

I've got a long list of people who want to speak. I'll try to do my best, again trying to recognize first those who haven't yet had a chance to participate.

Mr. Holtzman?

MR. HOLTZMAN: This is somewhat of a question to Bob, but from a practical perspective, thinking about the actual conduct of international genetic research, and how to do the right thing when you want to do the right thing, my company currently is conducting genetic research studies in the U.S., Canada, Costa Rica, the Azores, Sweden, Finland, Israel, China, Portugal, Ireland, and a number of other countries. Those are the ones that came to mind.

We have to do that in order -- and cast the

net very broadly if we're going to identify genes that can lead to drugs which have broad applicability.

We find that the paradigm for, for example, informed consent we start with is the U.S. paradigm, and this is a country which puts -- places a tremendous emphasis on individualism and autonomy, and then we go to another country, and as I think you noted, you can find yourself trying to do the right thing, and what you're doing is undermining the authority structures of that culture or society.

But meanwhile, if you then turn around and don't do it the way we do it in the U.S., you then say I'm subject to criticism that in fact you're not paying appropriate attention to individual rights.

So, my question is really a reflection of how can we, and maybe it's the group around this table, put together perhaps guidelines which would allow for the progress of this research in a manner in which everyone could feel that in fact it is possible to do the right thing?

DR. SHAPIRO: Thank you.

Bob?

MR. LEVINE: Yes?

DR. SHAPIRO: Please respond.

MR. LEVINE: It's because of difficulties of the sort you identified that I said early on that as you strive in guidelines for global applicability, you lose more and more of the substance of your guidelines in favor of procedural guidelines, and, so, what we emphasized is how deliberative bodies set up in one country or another handle various aspects of the problem.

I also want to take this -- so, I don't have the answers and maybe never will.

I also want to respond to one point that the doctor from Russia brought up. It's not only -- although we focus so much on informed consent as being the peculiarly-Western concept, everywhere we looked, we saw vast differences across various cultures, and I recently had some discussion with our American National Aeronautics and Space Administration, who's attempting to do research in collaboration with Russia on their astronauts, and they're having terrible problems collaborating because of the very, very different perceptions of confidentiality in the two countries.

The Russians think that if you're an astronaut, everything we know about you is public

information, and that's an anathema to the American way of thinking, and, so, this one point -- and Russia and the United States are not as far apart culturally as the United States is from some of the countries that Sol Benatar was talking about in Sub-Saharan Africa, and yet we see these vast differences.

DR. SHAPIRO: Thank you. Ms. Lynch?

MS. LYNCH: I wanted to go back to the very general question of the gap between the guidelines and the review of -- which takes place because of those guidelines, and to speak a little bit or to ask others to speak a little bit about the way in which that kind of review is audited.

In other words, in Canada, you have included there an issue of communique which describes the site visits to the 16, and we have only 16 medical faculties, to the REBs, the Research Ethics Boards, and we find a tremendous difference among those research ethics boards.

We -- we don't need to go international to find that difference, and the question then becomes for a country like Canada and perhaps others, where we're not inclined so far to move into the legislative framework which has been applied to the IRBs in the

United States, how it is that we can not only educate in the area of ethics, research ethics review, but how we can bring about some consensus.

There is, for example, moving from the gap between the guidelines to the research ethics board, and in terms of differences among research ethics boards, it's not uncommon to find in the National Council that people are research ethics boards shopping because we can find different perspectives in terms of the cultural differences in our country.

So, one might say if you do it at the University of Toronto, then automatically you ought to be able to do it at McGill, and others will say if you can do it at Lavalle, then why can't you do it at Delhovzy.

So, some comment, please, on how we're auditing research ethics boards, and how we're trying to come together in terms of the observation of the guidelines that have been so carefully crafted.

DR. SHAPIRO: Seems to me that's a very interesting question, whether these guidelines are enacted and legislation or not, the auditing issue remains; that is, after you've announced what you'd like to do, the question is, what happens, and is

there any experience around this table on mechanisms, effective mechanisms of auditing these kinds of committees, which will have different form, of course, in different places?

Anyone have any observation on that? Your colleague right next door has and then Marcus.

MR. HOLM: Yes, Soren Holm Denmark. Well, I think actually as a bioethicist, I find sort of making new ideas and making small detailed changes in guidelines very interesting, but I think that if we want to actually get better ethical research, we would do much better in putting our effort into auditing, first of all, the research ethics committees, but then, also, the actual consent process because at least the few Danish studies we have show that researchers do not always do what they tell the committee they do.

So, even if, as in Denmark, we have committees which are fairly similar, we can be certain that there's quite a large gap between the protocol and what is actually taking place when consent is being sought.

So, I think for many developed countries, we would be better off putting our effort into auditing

both committees and researchers rather trying to develop new guidelines. I think that we have guidelines which are fairly good and could be interesting to find some which are slightly better, but I think that in the interest of the public and in the interest of research, we could use our efforts better elsewhere.

DR. SHAPIRO: Let me ask a question directly in this area. I guess a query of some kind. That is, one of the unfortunate things that plagues all of us is that accountability and bureaucracy go hand-in-glove; that is, the more accountability, the more sure you want to be, the more checkers we have, the more checkers on the checkers and the checkers on the checkers and the checkers on the checkers and so on, there really is no end to that in principle, and striving therefore for a certain level of accountability could in the end -- I'm just -- I'm not sure, but could in the end be quite counterproductive.

Would it be better to ask the question, rather than what kind of auditing we should have, would it be better to ask the question, what evidence exists today that current practices aren't working? That is, that somehow whatever the researchers are

doing, whatever IRBs we have or other ethics committees, what evidence is there today, research that is going on today, whether it's in Canada, the U.S., elsewhere, that they really don't work?

Now, I haven't conducted that investigation. I don't know the answer. But perhaps some of you do know the answer. That is, do you find not work gone on in the '70s and the '80s, but today, that really there are serious problems?

We haven't heard from you, Mr. Jonsen.

MR. JONSEN: Al Jonsen, United States. You just changed the quality of my answer, President Shapiro, when you said not things that happened in the '70s and the '80s. I'm going to say it anyway.

I just recommend that as the new commission undertakes this subject, that they return to the transcripts of the National Commission's work, which, at one point early on, did a very extensive discussion of the question of accountability and auditing.

We had long -- and these would not really be manifest in the reports, but only in the debates that are recorded in the transcripts. We -- we assessed almost every different point of view on auditing of -- of the research enterprise, and I think almost every

consideration that could be brought up was at least reviewed and thought through.

The substantial report that -- that did result from that was the report on institutional review boards, which is, of course, a public document.

I'd like to make one comment also about the consent process in relationship to the history of the National Commission; that is, there is one area of the National Commission's work which I believe was -- was substantially sound work which never became part of public policy for a number of reasons, which I won't go into here. That's the report on the institutionalized mentally-infirm.

One of the most difficult areas in research is dealing with persons with psychiatric illness or mental retardation, and the Commission did a study of that, which -- which met a great deal of opposition, and therefore was never accepted by the government, even though the President's Commission requested that it be implemented.

It seems to me that it is crucial to go back to that area of extreme difficulty, which affects very large numbers of persons, to revisit the questions, to analyze them again and to make sure that this gap in

our public policy relative to research is rectified.

DR. SHAPIRO: Well, thank you very much for that remark. I'm really glad that you made it because I did want to get us at some stage to the issue of vulnerable populations, and you mentioned one extremely-important one, and that's very helpful, and I'd like to come back to that. I appreciate that remark.

But let me now turn to Mr. Abrams who has been waiting patiently, and I have others on the list, also. I hope to get to everyone.

MR. ABRAMS: Thank you very much. Do I have the microphone? How about now? Okay. How's it going?

DR. SHAPIRO: Apparently if you start talking, it comes in.

MR. ABRAMS: Okay. I'll start. It's this -- it's the question of how much uniformity you can get from various countries when you're, as indicated by our colleague on the right here, when you're doing international trials.

I think there's a basic philosophic point almost about how you should approach this; that is, do you intend to go for the highest common factor that

you think is ethically acceptable, or do you intend to go for the lowest common multiple that most people are willing to sign up to?

Now, in the Council of Europe, we determined quite early on that we would adopt the first approach, that if we were not able to say anything useful on the subject, it was better to say nothing than to say something that was too wishy-washy.

You can decide for yourself whether we've achieved that, but what is interesting is that the 39 member states of the Council of Europe have all signed up to the concept of informed consent, and they have all signed up to certain basic principles about how research should be undertaken.

I know it's taken a long time to get there, but I think it shows that if you put the effort into discussion and to convincing people, you can make substantial and worthwhile progress on very difficult ethical issues, but I for one do not agree with the idea that you go along with the lowest factor that everyone would agree to. That may be very unsatisfactory in the long run.

But if I might turn to your question, Chairman, on audit. I think you're absolutely right.

You don't want to create a bureaucracy of accountability. I think what you want to do, as you indicated, is to try and develop some system of exception reporting to identify the bad cases.

But I think we do actually have a very strong international instrument for ensuring that scientific research in the medical field is now ethically acceptable; that is, that the vast majority of scientific journals now require that all articles that are published are based on research that has been ethically approved by the relevant body, and I think the more that that can be spread, the more the education spreads around the world, that ethical acceptability is the absolutely primary requirement for any form of medical research.

I hope therefore that we can persuade all scientific journals to make that an absolute requirement for acceptance of scientific articles.

DR. SHAPIRO: Thank you.

Professor Knoppers, you had your hand up a long time ago.

MS. KNOPPERS: Yes, I'd like to speak to the issue of the International Convention on the Rights of the Child, because I think it serves as an example of

what our colleague from South Africa was raising, the issue of guidelines or principles that stop at well-meaning, well-intentioned and sometimes commonly-shared values, but then stay at the level of principles and never make it down to the area of procedure.

And even though we have over a 180 countries who have signed that International Convention on the Rights of the Child, the actual misa en verve or the actualization, if you like, of that convention depends not on countries accepting it in principle as they might ethical guidelines or CIOMS guidelines or whatever, but in putting into place the procedures to activate those principles, and perhaps more substantive justice would be done to children and to their rights or to subjects of researcher -- participants, I should say, in research, if more attention was paid as our Danish colleague said to the actual procedures that accompany and translate the principles than to constantly modifying the principles themselves, because the Convention is an example of a well-meaning document which to date is missing countries such as yours which has adopted a law making it a part of their internal law has not seen any

change in the condition of the child or respect for children's rights.

DR. SHAPIRO: In that connection, just an anecdotal remark, ever since being appointed to this Commission, every time I'm close to a hospital, I walk in, and I ask -- or a medical center, I ask for their informed consent forms and just look, and I've just been accumulating a little file. I have about 30 of them now, and they're all from this country. So, it's all operating under the same system, same set of guidelines, and the variance is staggering. The variance in these forms. I don't know what it means, frankly. I haven't analyzed it carefully, but just at that level, just a very practical every-day level, what do you actually right down for people to see and to think about?

I've really been rather stunned by -- by the variance at that very practical level.

Yes?

MR. GELZER: As has been said, one could increase quality control and auditing and quality of trials through stipulation that publishers of journals would not accept publications without this followed up.

Now, in Switzerland, there are even more pragmatic points. The Science Foundation would not even allocate grant money if there is no evidence that it has come through an ethical review mechanism, and I think that is pragmatic and very effective way to increase quality.

DR. SHAPIRO: Thank you very much.

Yes?

MR. HOLM: Well, you asked for data from the '90s showing that there were problems in the process. Well, first of all, it's an almost universal finding from every country where you study the written information the patient gets that it is so hard to read, that it's unreadable for the general public, and that's at least one problem.

There's also one American study, not from the '90s but from the '80s, I think, which shows that it gets worse during the IAB approval. That's the consent form which are passed more unreadable than the ones which go into the process.

So, at least there we have a problem because we cannot -- well, not all our research subjects are college graduates. So, there's one problem. Most of the research done on the written -- the oral

information part also shows that there are huge problems there.

So, I think it's well documented from a number of developed countries that there are huge problems in the actual process of getting consent.

DR. SHAPIRO: Thank you very much. I did not mean to imply that I thought there were no problems. I just meant to imply that it's good to put that against a template which looks at other issues as you're considering them, but I agree completely with you. There are certainly problems.

Yes, please?

MR. QUI: Thank you. I think that the CIOMS guidelines are very good document, but the chapter on the under-developed countries, I think, still not adequate.

I would like to -- I think -- I suggest that we should have a special meeting or a special project to how to apply the principle of the uniform consent in the developed countries.

I -- I would like to make two points. One is in China, for example, if you mention the research -- research or experimentation, the Chinese will be scared because they have a bad experience. They have

in the past, they have tested by like the -- the -- the -- Japanese occupation, they have tests in the very cruel and inhuman way. Also in some hospitals, some with the doctors, like American doctors, also tested them, tested them poor patients without any informed consent in four days or three days.

So, they are scared. So, if you mention the research expectation, they -- they -- if -- they would think that they would be treated as a guinea pigs. So, it's a problem.

But now I think it's good that because in China, we have many projects and cooperative studies between China and the United States or European countries, and the sponsor countries require that. You have to obtain from the human subjects of the informed consent. You should have ethics committee. So, it's very good. So, it's -- it's -- I think it's good.

The second point I would like to make is because it's different culture, because there's a concept of the person who is -- in the developed countries, it's quite different.

The -- the -- the person who -- in developed country, less independent than that in Western

countries. They are -- they are -- live in the close relationship with family member, with the committee member. So, also there's also more complicated because we are more variable because we just have research and subject and family and community.

Sometimes even the -- another aspect, even the -- after the help of the committee leader and family leader and the -- the -- the -- the subjects, the possible subjects, agreed, consent, then they don't even -- they are not willing to sign the form, because in practice in China, if -- in -- in the clinical setting, the form, the informed -- the consent form is signed by family member, not the patient himself or herself, and in the village, if you do some massive preventive intervention research, then because we have a program -- a project of the use of folic acid to prevent the neural defect, it's a very successful subject.

Even consent, they don't -- they don't -- they're not willing to sign the form. So, it's a problem. So, we talk about this. Some improvement -- some are not good because in this project, the village doctor signs the form. This means the community consent, but the subjects agree to give consent.

So, some colleagues and the media think it is not good to practice because if have some legal dispute, it's very difficult because the signing is agreeing to it, not to the human subject himself.

So, how to -- how to apply the principle of uniform consent in the developed countries is still much work to do. So, I -- I -- so, I -- so, I suggest is we have special project or special meeting to talk about this.

DR. SHAPIRO: Well, thank you very much. Clearly, we do have -- there are very special circumstances you described, and it's very useful to hear that articulated so carefully.

Yes, the colleagues from Brazil.

MS. DeFREITAS: Please. We -- I think we have some special problems with informed consent, but on the contrary of China, we -- we are concerned about the vulnerability of persons, of subjects, in that -- that make the -- the -- the assignment of the informed consent, but for reasons of access and compensation are considered vulnerable.

This is the case of the -- the patients from the public health system, from the university hospitals, and from some -- some kind of -- of -- of -

- some kind of people, such as HIV-positive, that if they -- they -- they enter a research program, they can have the access to the treatment, and this is our great problem about informed consent, and to -- the thing of vulnerability is the great deal that we have to -- to specify and to -- to research about to -- to make sure that the informed consent is -- is -- is a -- it's true. It's a supportive thing.

DR. SHAPIRO: Thank you very much.

Well, there's a lot of issues in this area we haven't had time to fully talk about, but our schedule now calls this part of our meeting to end.

Let me just remind you about what's ahead of us. First of all, lunch will be available, I understand, right next door, just beyond those walls, at 12:45, just about now. So, we can adjourn and reassemble for lunch.

As I mentioned before, we will have a luncheon address by Professor Gutmann on Deliberating about Ethics in a Democracy: Some Reflections for Commissions.

When we reassemble here this afternoon, we should try to reassemble about 2:15, approximately at 2:15, and we'll be looking at the characteristics of

advisory commissions and others, what characteristics seem to make for success and which don't.

Of course, if we have any extra time, we can review -- we can return to a lot of the subjects which you've only begun to deal with.

Let me just speak to Bill and see if there's anything else we need to -- I'm sorry.

For those of you that would like to hear Professor Gutmann's talk and will not be joining us for lunch, they will be on the TVs in this room. For those members of the public who may not be joining us for lunch, the address itself can be seen in this room.

Okay. Anybody short of luncheon tickets, you can speak to Professor Capron, who is just on my left.

Thank you very much.

(Whereupon, at 12:45 p.m., the meeting was recessed, to reconvene this same day, Thursday, November 21st, 1996, at 1:30 p.m., for the Luncheon Address.)

LUNCHEON ADDRESS

1:32 p.m.

DR. SHAPIRO: Well, I've been looking forward to this moment to introduce Professor Gutmann, Dean Gutmann, for a few weeks now. However, even though I introduce many, many people every week, I've been a little worried about this introduction, been a

little nervous about it, for a couple of reasons.

First of all, Dean Gutmann and I work as colleagues at Princeton. We've known each other for a long time, and I have come to have such enormous respect for Amy, not only in her work in political philosophy but in her work as Dean of the Faculty at Princeton now and her work as the founding Director of our Center for the Study of Human Values, that I was wondering whether anything I could say would give an adequate indication to you of how much I have valued working with her, how much I have learned from her, and how fortunate we are that she has agreed to speak to us at our lunch here today.

Amy is, as some of you know, the Lawrence Rockefeller University Professor of Politics and Dean of the Faculty at Princeton University.

Her education, she received her B.A., not surprising to any of you who know her, magna cum laude from Harvard, and received a Master's degree from the London School of Economics, and a Ph.D. also from Harvard.

Her work, both the work that she has done on education, on liberal equality, on discrimination, work she has done not only herself but work she has

done with her colleague, Dennis Thompson, have truly informed our national discourse on how it is that democracies think about and talk about issues that really matter.

She has also headed a program, Ethics in Public Affairs of Princeton. "Democratic Education". I don't remember, Amy, if that was your first book or not. I think that was your second book. I don't remember. Is a book which I have used extensively myself in my own classes at Princeton, and her books on Liberal Equality, Democracy and the Welfare State, Ethics in Politics, which is forthcoming, and many other publications have established her as one of the important thinkers in America and indeed one of the important thinkers anywhere dealing with issues in liberal democracy.

So, I think we are all very privileged to have her with us today to speak to us at lunch, and it is my great pleasure to introduce a colleague, a friend, a teacher, and hopefully as we go along a collaborator, Amy Gutmann.

Dean Gutmann?

(Applause)

Deliberating About Ethics in a Democracy: Some

Reflections for Commissions

Amy Gutmann, Ph.D., University Center for Human Values, Princeton University

DR. GUTMANN: Thank you, Harold, very much, and it's a pleasure to be here.

I was talking to Alex Capron and Dan Wikler reminiscing, asking them when it was that they were so centrally involved in the President's Commission on Health Care, and it was 1979 that that commission was formed, and I was thinking back then because they had asked me -- they had commissioned an article from me, and I wrote an article on for and against equal access to health care, and at that time, there were so few articles in this area, that it got -- it's been reprinted more than anything else I've ever written, but that was because there was nothing else there to -- to reprint, and there's a sea change.

There has been a sea change over a 15-year period in this country in the intellectual, moral and political understanding of health care and bioethics, and I just want -- I was just thinking about that and marveling about it because it's not -- not only because it's a sea change, but because it's a very positive sea change, and the amount of understanding

that we have now, because of commissions such as the one President Carter formed and then went on during President Reagan's term in this country has been quite astounding.

Now, as you know, commissions in this country and probably in many of your countries are created for many different purposes. They are created to address a dazzling array of issues, from taxes to trade, from baseball to bioethics.

Now, despite their diversity, well-constituted bioethics commissions can serve a purpose that transcends their particularity, and I want to focus on that purpose, deliberation, which is both moral and practical.

It is also the centerpiece, that is deliberation is the centerpiece of what I take to be the most promising conception of contemporary democracy. A conception that has come to be called, not surprisingly, deliberative democracy.

Deliberative democracy is the opposite of sound bite democracy. Sound bite democracy suffers, and our society, I believe, is suffering at this very moment, from a deliberative deficit. People talk a lot about the economic deficit. Our economic deficit

is actually decreasing. Our deliberative deficit seems to be increasing by the day or by the expansion of our mass media.

In a sound bite democracy, the din and deadlock of public life, where insults are traded, slogans proclaimed and self-serving deals are made and unmade, that din and deadlock reveal the deep disagreements that pervade public life.

But a sound bite democracy does nothing to resolve those disagreements on mutually-acceptable grounds, and it does still less to help citizens live with on-going disagreements in a mutually-respectful way.

Democracies cannot avoid disagreement. Indeed, no society can avoid disagreement. So, the problem with sound bite democracy, the problem with the absence of deliberation, is not disagreement. The problem is that we can deliberate about our disagreements in a way that contributes to rather than detracts from the health of our societies, if we actually engage in good faith deliberations.

Now, I want to focus today on four important social purposes that are served by deliberation, and I will draw four corresponding lessons for bioethics

commissions from those purposes.

The four purposes and the lessons for bioethics commissions flow from, indeed they respond to, four ineradicable sources of moral disagreement in society, and those four sources are scarce resources, limited generosity, those were the two sources that Dave Hume highlighted, third source is incompatible values or, if you will, the moral disharmony of the universe, if you want to be lofty about it, and the fourth source is incomplete understanding.

Now, I'll begin with an old airplane joke, actually an airplane story. You can determine whether it's a joke. An old airplane story which I think illustrates all four of these sources of disagreement, and the story goes as follows. It's actually a revised version of a story my mother told me about 15 years ago, actually coming up on the airplane from Florida. So, I always think of the story when I'm on airplanes, which I was this morning.

There are four people aboard an airplane which is about to crash, and there are only three parachutes on the airplane. The four people are the president of the United States, the most famous philosopher in the world, no doubt a member of Harold

Shapiro's Bioethics Commission, a parish priest and a hippie.

So, there are four people on the airplane, three parachutes, the airplane's about to crash, and the president of the United States gets up, and he says, I'm the leader of the most powerful country in the world. The world depends upon us for peace and prosperity, and he takes a parachute, and he probably also grabs a Big Mac, and he jumps off -- he jumps off the plane.

The most famous philosopher in the world looks at the parish priest and the hippie, and he says, the Bioethics Commission of the United States depends upon me for the success of its deliberations, and he grabs one, and he jumps off the plane.

At that point, the parish priest looks at the hippie, and he says, son, I have devoted my whole life to doing the right thing. I really think that this is a time where you should take the last parachute and bail out. Please, son, do that, and the hippie looks at the parish priest, and he says, hey, man, don't worry, the most famous philosopher in the world just took my knapsack and jumped off the plane.

Well, not -- not all -- not all conflicts

that are based on scarce resources and limited generosity and incompatible values and incomplete understanding, which this one certainly was based on all of this, are resolved so neatly, so readily, by the stupidity of a philosopher, although there's another lesson to this story.

When I tell this story to my students, I use it as a story to tell my students because I teach ethics. Why? When you teach ethics, it's not only principles that count, but the facts matter as well.

Okay. The first source of our moral disagreement is scarce resources. We would not have to argue about how best to distribute health care or who should receive organ transplants were these goods unlimited.

Deliberation in the face of scarce resources has a great value, and this is the value I will focus on that corresponds to the first source of our disagreement, which is scarce resources, and that is the value of contributing to the legitimacy of decisions made under conditions of scarcity.

In the case of organ transplants, as in many other situations of scarcity, some people will not get what they want or even what they need. The hard

choices made by public officials and professionals in these circumstances of scarcity should be more acceptable even to those who receive less than they deserve, if everyone's claims have been considered on their merits rather than on the basis of wealth, status or power.

Even with regard to decisions with which I disagree, I take a different attitude towards those decisions that are adopted merely by virtue of the relative strength of competing political interests and those that are adopted after careful consideration of the relevant moral claims.

Careful deliberation that yields moral justifications does not, of course, make up for the organ transplant that a desperately-sick person might but fails to receive. But deliberation does help sustain the legitimacy that makes possible our collective efforts to secure more resources in the future and to live with each other civilly in the meantime.

To serve this legitimizing purpose in the face of disagreement, deliberative forums like bioethics commissions should take account of as many excluded voices as possible, the interests and

preferences of people whose power alone would not enable them to be heard.

Such inclusion carries with it the risk of temporarily intensifying moral conflict; that is, when you bring more voices in, when you understand the preferences and interests of more people, you may actually at least temporarily increase moral conflict. You make the problem of scarcity all the more vivid.

But it seems to me that the benefit of taking this risk far outweighs the costs, and the benefit is that an inclusive deliberation brings into the open legitimate moral dissatisfactions that are suppressed by more power-oriented ways of dealing with disagreement.

Deliberation by bioethics commissions therefore does not seek consensus for its own sake. It seeks a legitimate consensus, one that can be justified on reciprocal rather than sectarian terms, on more inclusive rather than more exclusive terms.

So, scarce resources are a problem that we can't overcome, but bioethics commissions can give legitimacy, if they deliberate, to the decisions made in the face of scarce resources, even if people don't agree with the conclusion and people won't always

agree or, I should put it more starkly, all people will never agree with these conclusions.

The second source of our moral disagreement is our limited generosity. Few, if any, of us are as altruistic as the parish priest in the airplane story, and people who are altruistic are rarely bailed out as -- as easily as the parish priest is.

Deliberation in well-constituted bioethics commissions actually also can respond to our limited generosity. How? By creating forums in which we are encouraged to take a broader perspective on questions of public policy than any of us alone would otherwise be inclined to do.

Now, John Stuart Mill presented one of the most cogent accounts of such a deliberative process. Participating in public discussions, he said a citizen is called upon to weigh interests not his own, to be guided in the case of conflicting claims by another rule that has partial particularities, to apply at every turn principles and maxims which have for their reason the existence of a common good.

Now, the practice of deliberating on bioethics commissions or any place else for that matter will not suddenly make most of us public-

spirited when we were previously alienated individualists. It's not going to convert scoundrels into saints, but bioethics commissioners rarely start out as scoundrels. So, that's not a problem.

What is a problem is what the background conditions are in which bioethics commissions are formed and who is put on bioethics commissions. Limited generosity as a source of moral disagreement bares a lesson for the creation and constitution of bioethics commissions. It alerts us to pay attention to the conditions under which those commissions operate, and those conditions include, for example, the level of competence of the deliberators, how well informed are they, the distribution of resources, are they equally situated so that some deliberators don't have more power over others, and also, frankly, their openmindedness. What kind of arguments are they likely to take seriously? Is the commission created in a way that the widest range of reasonable arguments are likely to be taken seriously?

All these factors will make a difference in how successful a commission's deliberations are, but all we need to assume in defending deliberation is that most people are more likely to take a broader

view of issues, to consider the claims of more of our fellow human beings in a process that is deliberative than in one that puts a premium on power politics, on bargaining, or on mere negotiation.

The lesson here -- the lessons here are multiple. Let me just mention two. One is that it's not only the number and diversity of voices that are heard and arguments made that count, but it's also the willingness and ability of the deliberators to take a broader perspective in light of differing perspectives.

In other words, it also depends on deliberators not believing that they alone possess the truth, the whole truth and nothing but the truth.

If people begin and end with that intuition, deliberation is very likely to fail. Nothing else will succeed either. Deliberation holds out the greatest promise for this success, but the conditions under which the commission is created and the kinds of deliberators who are put on the commission will make the difference.

The second lesson is that it's important that commissions are at least partly shielded from power politics; that is, if a commission is set up in

a way that it's continually -- its deliberators are continually pressured in the same way that an elected official can be continually pressured, this kind of deliberation is simply not going to take place.

The third public purpose of deliberation responds to the third very-often neglected source of moral disagreement, and that is incompatible moral values. There seems to be a tendency perhaps in human nature to believe that all good things come together, and that if we pursue one -- one good, everything else will come instead, and this always is bewildering to me that there's a tendency for people to believe this because our daily lives belie this.

We're continually making hard choices and not often between good and bad, but between good -- good things. Even totally altruistic individuals who are trying to decide on the morally-best standards for governing a society of abundance would not be able to reconcile some moral conflicts beyond a reasonable doubt. They would still confront, for example, the problem of abortion, which pits life against liberty, or the problem of fetal tissue research or the problem of whether individuals should be held responsible for health problems that are partly the product of their

own choices or the problem of whether children who cannot give informed consent should be the subject of medical research which promises good to come of it.

We value informed consent, but we also value the good that comes of medical research. We value the protection of individual children, but we also value the possibility of medical research coming up with goods for future children, maybe even for the child who is being subject to research but who can't herself give informed consent.

Well, deliberation cannot make incompatible values compatible. Some philosophers think it can. So, I'm not telling you a self-evident truth. There are philosophers who think if you think long and hard enough at the end of the day, you'll get all the values to be compatible. They, of course, believe that at the beginning of the day. So, that makes me suspicious that they're -- of the proofs at the end of the day this is going to happen.

But deliberation can clarify the nature of such moral conflicts. It can help us sort out self-interested claims from public-spirited ones, and it can help us identify the public-spirited claims that have greater weight. Through a deliberative process,

a bioethics commission can begin to isolate those conflicts, such as abortion, that embody genuinely-moral and incompatible values on both sides, and those conflicts that do not may then turn out to be more easily resolvable.

We might discover that some conflicts are the result of misunderstanding or lack of information or we might now see ways to settle some issues by bargaining, negotiation and compromise.

In this way, deliberation helps us put moral principle and moral compromise as well as bargaining in their place.

Deliberation in the face of incompatible values recommends what I call actually in a book that I co-authored with Dennis Thompson called "Democracy and Disagreement: An Economy of Moral Disagreement". By economizing on our moral disagreements, we manifest our mutual respect as we continue to disagree about morally-important issues and politics.

Now, this economy of moral disagreement is actually manifest in several commissions that many of you may be familiar with. For example, the Warnock Commission in Great Britain, the Fetal Tissue Research Commission in this country, all manifest the economy

of moral disagreement. They focused ultimately on trying to find where their common ground was, and they built on that common ground without actually ever ultimately resolving the incompatible values with which they began.

The potential for mutual respect among citizens that this economy of moral disagreement manifests is an important part of the deliberative perspective that I think the bioethics commission should seek as it proposes resolutions to problems that are bound to remain controversial.

A bioethics commission therefore might focus on issues on which it can reach some reasonable consensus rather than on issues that are more likely to remain polarizing, or if it chooses to focus on highly-contentious issues, the quality of its analysis, how well it recognizes the competing values at stake, will be at least as important as the bottom line that it reaches.

So, incompatible values, the recognition of incompatible values, holds out a lesson, I believe, for bioethics commissions and for deliberators in general to try to strive for an economy of moral disagreement.

Now, the fourth and final public purpose of deliberation that I want to discuss with you today responds to the fourth source of disagreement, which is incomplete understanding. This is the source of disagreement that intellectuals are least likely to acknowledge, but it seems to me as obvious as all the others.

Indeed, it seems impossible that it not be the case given that intellectuals disagree, if anything, more vehemently and often more completely than any other group of people you could put together.

Incomplete understanding characterizes almost all of our conflicts and is vivid in the case of many conflicts in bioethics.

Well, deliberation carries with it an obvious virtue. It carries with it the incentive to bring more knowledge and greater understanding rather than less to bear on difficult problems. That may seem obvious, but lots of other processes carry with it the opposite incentive, which is to shield, to keep more information out of the picture, to make bargaining easier, for example.

Well-constituted bioethics commissions are an excellent example of how deliberation can

contribute to making more justifiable decisions by responding constructively to our necessarily-incompatible understanding, incomplete understanding.

Through the give and take of argument, commissioners can learn from each other, come to recognize their individual and collective mistakes, and develop new views and policies that are more widely justifiable.

When all we do is bargain, we learn how better to get what we want. When we deliberate, we expand our knowledge and understanding, including our self-understanding, as well as the understanding of the public interest.

Now I want to focus on one particular aspect of the virtue of deliberation. In a deliberative process, majorities are obligated to offer reasons to dissenting minorities. All commissioners must expose their positions to criticism. Majorities thereby give minorities their most effective and most fair chance of persuading others of the justice of their positions.

The hope that views -- the hope here is that views better than those held by either the majority or minorities at the outset will emerge from such a

process.

Now, I've talked a lot about the virtues, the benefits of deliberation; that is, its virtues and benefits from the perspective of justice and from the perspective of the pursuit of the public good.

But the emphasis might be placed elsewhere; that is, let me consider a critic of deliberation for a moment, who says that doesn't the emphasis on moral deliberation create occasions for high-minded statements, unyielding stands, doesn't it arouse moral fanaticism? After all, the art of politics and commissions are in the political world is the art of compromise. Morality seems to be often, if not always, opposed to compromise.

Well, my response to this criticism is not to deny that focusing on moral issues can arouse moral fanatics nor to deny that morality does have to do with taking principled stands, but this criticism, I think, rests on one misconception, and that is that taking a moral stand commits you to be against compromise.

Theories of justice that have pointed towards a democratic society have always advocated forms of compromise, moral compromise. The virtue of

deliberation is that it addresses moral views on their own terms. Addressing morally-charged issues on moral terms is the only justifiable way to deal with moral conflict without suppressing it. But addressing morally-charged issues on moral terms does not mean being against compromise.

No deliberative process can avoid the risks of intensifying moral conflict, but the alternative ways of dealing with moral conflict, I think, are far worse. Moral extremists assume that they already know what constitutes the best resolution of a moral conflict without deliberating with their fellow citizens, who will also, by the way, be bound by any resolution, and this assumption of knowing the truth before we hear from others who will also be affected by our decisions is the height of arrogance.

If I refuse to give deliberation a chance, I forsake not only the possibility of arriving at a genuine moral compromise, but I also give up the most defensible ground for maintaining an uncompromising position, and that is that I have tested my views against those of others.

This is not to deny that there are problems that should be held -- there are positions that should

be held uncompromisingly. There are such positions, but people who engage in moral reasoning in a deliberative forum, I think, are likely to see that those positions are few and far between.

I'm reminded actually of one of my favorite New Yorker cartoons, which shows a little boy tugging at the coattails of Thomas Jefferson and looking up at Thomas Jefferson and saying, "If you take these truths to be self-evident, then why do you keep harping on them so much?"

Well, the answer, I realized, the answer, which is not given in this cartoon, might be because they can only be self-evident if they stand up well against counter-arguments and alternative understandings, and that's why you keep harping on them, and you harp on them in public because if they don't stand up, then they're no longer -- you should no longer hold them as self-evident, and indeed -- I mean this is what I supplied to Jefferson in his response, but it's actually true that what Jefferson believed because Jefferson favored periodic constitutional conventions, partly for this reason.

He actually wanted to make sure that the truths that were held, that he held as self-evident,

would be self-evident 20, 50, you know, generations past. Now, I'm not sure we want periodic constitutional conventions, but maybe we want periodic bioethics commissions appointed to test the results of previous bioethics commissions, and here I'm actually serious.

One of the lessons of our incomplete understanding is the importance of reiterating our understandings, of testing previous decisions of previous bioethics commissions, to see how they have stood up against criticism, and as importantly, whether they have yielded the benefits that they promised or expected.

Deliberation that is reiterated contains the means of its own correction, and the lesson here is that bioethics commissions should not think of their decisions as once and for all, but rather as provisional, to be tested and retested at later dates.

The contribution of bioethics commissions to social welfare is probably greatest when the bioethics commission itself advocates accountability for the results of its recommendations.

We were talking earlier about holding other people accountable, but one of the lessons of our

incomplete understanding is for bioethics commissions to hold their own recommendations accountable, to arrange for the testing of results, the testing of understandings in the future.

The contribution of the best bioethics commissions is therefore unlikely to be the certainty of their conclusions, but rather, as I have argued, first their legitimacy, second their breadth of understanding, third their recognition of and respect for competing values, and fourth their capacity to be re-evaluated in the foreseeable future.

And that's true, I think, for most of the questions that bioethics commissions ask. When, if ever, can medical experimentation be justified in the absence of informed consent? Whose permission, if anybody's, does a doctor need in order to perform genetic research on the genetic material of a dead person? When, if ever, should a person be informed of the results of scientific research on her genetic material? What rights of privacy, if any, do people have to the results of medical testing or genetic research?

I don't think the answer to any of these questions is obvious. I don't think an answer can be

avoided, but neither do I think that any bioethics commission should fool itself in thinking it can give the clearly-correct answer once and for all.

Gather the wisest philosophers and physicians together, and they will surely disagree, as will even the best bioethicists. But if disagreement about public policy per se is not the major problem to be overcome in any free society, then bioethics commissions have a great deal to contribute to the making of public policy.

A major problem of contemporary societies is the absence of adequate deliberation in the face of moral disagreement. Deliberation is by no means a panacea. But deliberation is an essential means to move forward constructively in the face of our most profound moral disagreements, and well-constituted bioethics commissions, I think, can play a critical role in decreasing our deliberative deficit.

Thank you.

(Applause)

DR. SHAPIRO: Amy, thank you very much. You've given us all a lot to think about, and I'm sure we'll think about it over and over again as at least this Bioethics Commission and, of course, the others

that are represented here carry on their work in the years ahead.

Thank you very much. I know that Dean Gutmann flew out here this morning and is flying back this afternoon. So, thank you very much for going to that extra effort to be with us today.

(Applause)

DR. SHAPIRO: I think we can take a moment to stretch. Let's try to reconvene in about 15 minutes in our last room.

Thank you very much.

(Whereupon, a recess was taken.)

A F T E R N O O N S E S S I O N

2:33 p.m.

DR. SHAPIRO: Ladies and gentlemen, if we

could assemble, we will get this afternoon's session underway.

(Pause)

DR. SHAPIRO: Dan, you're the first on the agenda, so we're going to need you at the table.

(Pause)

DR. SHAPIRO: Ladies and gentlemen, I'd like to begin this afternoon's session.

What we'd like to do for the next hour or so, depending on the enthusiasm and vitality of the discussion, is to look on what characteristics of commissions or other similar bodies really help -- really take them to a successful conclusion of one kind or another; that is, what makes some successful and others less successful, and there's an awful lot of experience sitting here around the table, and we thought it would be interesting if we shared our particular perspectives in this area.

As this morning, we'll have one or two people begin our discussion, to give us their perspectives on this issue, and then open it to general discussion once more.

I do want to remind everyone that at the conclusion of the more formal part of this meeting,

since this is also an NBAC meeting, there will be an opportunity for members of the public to address at least the NBAC members, everyone is welcome to stay for that, but at least address the NBAC members. Anyone wishing to do so should sign up just outside. There's a sign-up list outside right next to this room. I think so far, we have one person who's signed up. There may be others by that time.

All right. Let me turn to Daniel Wikler, President of the International Association of Bioethics.

Dan?

What Characteristics of Commissions--Such as Scope,

Sponsorships, Memberships, Functions, and Relationship to Health System, Government and the Public--Contribute to Success or Failure?

Statement of Daniel Wikler, President, International Association of Bioethics

MR. WIKLER: Thank you. I'm honored by having been asked to speak briefly, I know.

DR. SHAPIRO: To speak or briefly?

MR. WIKLER: I'm honored by both because it's very difficult to speak briefly. So, I take this

as a compliment, to speak about methodologies on bioethics commissions, and I would like to first say where I'm drawing some of the -- my remarks from, aside from my own experience as a -- with the wonderful title of staff philosopher for the President's Commission, which gave me a business card, as I was telling Harold Shapiro earlier, with the presidential seal on one corner, and then my name, and then under that staff philosopher, and in Washington, D.C., there's a mating ritual when you meet somebody is to hand your card over, and I would hand my card over, and they would look at it and break out into gales of laughter, and then ask to see my real card.

So, I will draw on that experience a bit. Also, I was for a couple of years a member of a working group which Alex Capron was also a member of. There may be others here, too, who were in, at the National Academy of Sciences under the direction of Harvey Feinberg of the Harvard Public Health School, which set out to accomplish this task of understanding how bioethics commissions work, and what the characteristics might be of the ones that work the best, and also of those that worked very badly.

Finally, I was a consultant to the Office of

Technology Assessment Report of a couple of years ago, which had a very similar mission. That report was requested by members of Congress because they were interested in setting up the National Commission that Professor Shapiro is the chair of, and the OT asked me to be a consultant on international bioethics commissions, and that resulted in part in a mailing list and a list of consultants which ultimately resulted in the presence of some of you today.

I'm not going to be reporting on the findings of any of these groups, but rather giving my own idiosyncratic understanding of at least some of their ideas, and others who are members of these groups, including Alex Capron, might have a very different menu of suggestions to make.

The National Academy of Sciences group, as far as I know, is the only study committee which has over a sustained period of time attempted to gather information about these commissions and to determine which features of commissions augur well and which ones predict failure.

That group drew on several different sources of information. First of all, they commissioned a number of studies, and these studies were printed

along with the final report of the National Academy of Sciences committee under the title of "Society's Choices", and that became a significant title, and I'll indicate a little bit later why, and that is available to all of you through the National Academy Press in Washington, D.C.

DR. SHAPIRO: And can be ordered on the Net.

MR. WIKLER: And can be ordered on the Net, NAP.EDU, I believe.

Secondly, we drew on a number of international consultations. Some of you have -- were polled both by OTA and indirectly by the National Academy study to find out what, in your own experience, has worked well, and, thirdly, we drew on our own experiences and also our own theoretical views about the proper methodology of a commission of the sort that was so eloquently expressed by Amy Gutmann at lunch.

Now, we had hoped originally to be quite specific. For example, we had -- there's a perennial question, where should a bioethics commission be situated? Should it be a freestanding commission? Should it be in the health ministry? Should it be part of the legislature? Should it be in the office

of the president or the prime minister? And we hoped that by looking at the outcomes of some of these commissions, we could say, well, the ones that were in such and such a location did better than the others.

But it became -- it turned out almost immediately to be very difficult to draw any such conclusion. Part of the problem is that there is a wide variety of views about what constitutes success on a commission, indeed what a commission is for, and until you know what constitutes success, of course, you can't begin to state what predicts that success.

We found out immediately that in our own discussions, that we differed over what would count as a criterion of success, and let me mention a few which are not entirely consistent with each other, and these remained at the forefront of our attention throughout our study.

The most tangible evidence of success is impact, and the most tangible sign of that is impact on law and regulation. Now, I'll draw most of my examples from the American experience because that's what we were up -- that's what we were studying, but I'll have one or two illustrations from the international experiences.

In the American experience, perhaps the commission that had the most important impact on regulations was the National Commission for the Protection of Human Subjects, which Al Jonsen here was an important member of, and this commission issued law-like regulations which have virtually formed the bedrock of human subjects review in the United States ever since. Almost everything that's come since has been a revision of the work of the National Commission.

So, there was no question that that commission was successful from the point of view of impact.

The President's Commission brokered, although it did not formally write, a definition of death and even a means of diagnosing death, and this was negotiated with the American Medical Association, the American Bar Association, and other groups, and that had immediate impact, too.

The definition of death in the United States is a matter of state regulation rather than national law, but 49 states now have used the President's Commission definition of death. So, the overwhelming majority of Americans, when they die, will be declared

dead according to the definition proposed by the President's Commission, and that's a grisly sign of success, but it is certainly a tangible one.

Now, a second kind of impact which is probably more important but much harder to measure is in the realm of public education. The President's Commission produced not only judgments about what might or might not be undertaken, in fact there were relatively few of these judgments, what the President's Commission mostly did was to produce very long and, I think, well-researched reports, and the reports exhibited both the results of data collection, for example, the commission bought the services of one of the leading polling companies to ask Americans in your capacity as patients, do you want doctors to tell you the truth, and this was some of the first polling that was done on these questions of obvious relevance to medical ethics, which in the past people had more or less estimated or made up based on their sense as clinicians or as patients, here was some hard data.

So, these were reported in these -- in these volumes, but also the reports gave a -- the fruits of extended moral deliberation, just the sort of thing that Amy Gutmann was talking about at lunch, and if I

may say so, I believe that these reports represented for one of the very first occasions in the American experience the public use of deliberative moral reflection, in which long stretches, 20 to 30 pages at a clip were filled with extended moral arguments, trying to dissect moral issues, to make the proper distinctions, to offer reasons pro and con, and finally come to some kind of tentative conclusions, and these were useful both for their substance and also, I think, as examples, and one indication of the impact was, for example, I think with one of our most important reports, which was the -- the report on deciding to forego life-sustaining therapy, that the -- not only the conclusions but, more importantly, the reasoning, the reasoning has been reported over and over again in judicial opinions, at local levels, all the way up to the national level, and it won't surprise me at all if the Supreme Court, which is now reviewing two landmark decisions of lower courts on physician-assisted suicide, quotes also from this volume.

Now beyond the question of impact, an important criterion of success had to do with democracy, and there are several ways in which

democracy can be furthered and embodied in the work of a -- of a bioethics commission.

One way is through public involvement. Now, Professor Shapiro has said that this meeting is open to the public, and there will be an opportunity at the end of this meeting to -- for the members of the public to speak their mind and before the assembled commission, and this is a matter of law.

Now, this is an indication that the work of this commission as with all of its predecessors is entirely out in the open. There was some concern that the openness of this procedure would inhibit discussion, and that on something as sensitive as bioethics, questions of life and death and sexuality and other very, very private matters, if members could not speak their mind without worrying about the press overhearing and without the pressure groups attending and so on, then the actual process of deliberation would be attenuated.

Nevertheless, it makes it more democratic, and there are other ways that the public can be involved, also, and another criterion is whether or not as Amy urged so eloquently whether or not all voices are heard in the works of the report as opposed

to the voices of a small elite.

Now, a further criterion which, as an academic, I have to say is the one that comes first to my mind, I'm not arguing for that, just reporting that, is very hard to assess, but that doesn't make it any less important, and that is the soundness of its findings and its reasoning.

Here, the basic benchmark is this, if the report were submitted to a top-level academic journal, would it pass peer review? Now, this is not something we ask of government reports very often. Government reports are written with an eye towards politics and for satisfying various interest groups, but if we're supplying something that is simply more than a sum of the inputs but does as Amy urged us to do, produce reasoning and thinking, which perhaps no one would have been able to produce without the kind of deliberation that went on in this exercise, then that won't do, and, so, then we have to ask about this product. Is this sound? Does this meet our highest intellectual standards?

And I think it's important to emphasize that although the subject matter of a bioethics commission is morality itself, is ethics, that the academic

standards for reasoning in ethics and morality should be no lower than they are in any other subject, and that's a very difficult standard to meet.

Well, these are a few of the criteria which were held out as benchmarks by members of the groups that I'm speaking of. What about the conclusions? Well, it turned out that conclusions are almost impossible to draw on the basis of the data that we were able to collect.

We do not have natural experiments. We don't have a long series of commissions. The commissions we looked at were very few in number. They differed in various ways in terms of being located in the legislative branch or in the Office of the President and so on, but it was not possible to say that this or that good outcome or bad outcome was a result of that.

What the National Academy of Sciences panel instead offered was something like a reflective essay on how society in general might accommodate advances in medicine and biology, and I'd like to just sound a very few points before closing from this essay and from other work being done on the same subject.

The first thing is, and I think I've already

alluded to this, that the conclusions of a body, yes, we should or should not permit doctors to assist suicide or whatever, the conclusions are probably much less important than the arguments in the data that are adduced for those conclusions.

There's a danger in the notion of a bioethics commission, that the commission will act on the model of the oracle, that a group of people who are thought to have some kind of special insight will have a vote on an issue, and the vote will be communicated to the public, and that will be the end of it.

But no one on these commissions, of course, has anything like the divine insight that the oracle is supposed to provide. We're all composed just of ordinary human beings. We have to earn our moral authority. We don't simply get it by virtue of being appointed to a commission, and, so, the oracle model, which is a very thin report which simply states how the commission voted, is, it seemed to most of us working in this group, of relatively little value.

The important thing is to lay out at great length the reasons for that judgment, and to be fair, also, the best argument that could be made for the

opposite judgment, even if that judgment is rejected.

Now, one thing I think about the structure of a commission does follow from this finding, if it's a finding, which is that having a large and professional staff is the key to success or a key to success or at least a sine qua non.

The President's Commission had success, I think, in part because it used academics rotating through the commission staff on -- on one-year loans from university, each of whom could bring many years of research that were done on precisely the topics chosen by the commission for its report, which it could then lend by way of expertise to the commission reports.

But there are other ways of doing it, too, with career civil servants, but a professional staff of significant size rather than simply a recording secretary is a key.

Secondly, that the engagement of the public is valuable for a number of reasons, and this cannot be stressed too strongly.

First of all, it lends legitimacy. The report itself may have olympian wisdom, but unless it's accepted, unless it's believed, it won't have any

impact, and legitimacy is a very important consideration.

Engagement with the public lends this, and, secondly, engagement with the public improves the intellectual quality of the commission's report. I think that the openness requirement for the American commissions that have been created have -- has been an important factor in their success in both of these regards.

I believe also that there are models abroad to which American commissions and other commissions might look with favor. Denmark's, I think, is worth pointing out in particular. The Danish Commission has made an extraordinary effort to reach out to the public and to involve the public in its deliberations.

In one of its exercises, for example, the Danish Commission prepared a high school curriculum, I believe it was on resource allocation, and high schools all around the country were given hypothetical examples in which choices had to be made and which people had to specify the grounds on which it would decide to allocate resources one way or another way, and this public education campaign was a way of bringing the gravity and the importance of ethical

deliberation home to the population in a way I can't -- that I don't believe could be duplicated any other way.

Another issue. The Danish Commission convened a meeting of newspaper editors and convinced them to carry a series of feature articles that I believe were prepared by commission staff in their newspapers on exactly the same days, and by doing this, they created a national debate in Denmark on some of these grave ethical questions which most people simply don't approach with the requisite degree of information.

Now, I'll close with the -- the main point, I think, that was made by the National Academy of Sciences commission, which was to widen its focus. In the end, the choice of the title "Society's Choices" for the Academy publication was -- was fastened on because the emphasis here is that the choice is not a choice by a group of appointed experts. It is in fact a choice by an entire society, and following on this, the study group decided that it would be a mistake to present a book that would simply talk about bioethics commissions.

Bioethics commissions are a part of a much

larger process. It's a process by which society accommodates to advances in medicine and biology, and also in which medicine and biology accommodate to changes in society. Both of them require rethinking, accepted traditions in ethics and medical practice, and this occurs not only through the deliberations of an expert body but as the philosopher Michael Oakshott has -- has termed it, in the conversation of mankind. It occurs at the barbershop and at the grocery store, and in the churches and in family -- over family kitchen tables, everywhere people are talking about these issues, and at the organizational level, at the group level, family level, people are -- are advancing our understanding of these -- of these issues.

So, it's important to look at bioethics commissions not only internally, how they operate, what their structure is and so on, but how they fit into the conversation of mankind and on how their work can be furthered by coordinating the work of the commissions with the many other avenues for conversation on these issues in a society.

And just to give the last punch line to the study, the Academy study ended up with the one recommendation which all study commissions feel is

very important to make, and that is that more study is needed.

Thank you.

DR. SHAPIRO: Thank you very much.

I'd now like to turn to one more person before we go to our general discussion, and that's Mr. Stefano Rodota for the European Commission.

Mr. Rodota?

Statement of Stefano Rodota

European Commission

MR. RODOTA: Thank you, Mr. Chair.

The group of advisors of the European Commission on Ethical Implication of Biotechnology has a unique characteristic in the very complicated world of the ethics committee. It is a body working at the national level, the community of 13 states of the European Union.

You know maybe that the Union at the beginning has been conceived as a purely economic community, as a single market, but in the last two years, all members of the Union became aware of the impossibility to build up a true community of people on a purely economic basis. So, they became concerned with the citizens rights, with common shared values.

On the way of widening the horizons of the European Union, we encountered the group of advisors that was established at the '92 and is now ending second term.

The group is now composed of about nine members and is chaired by a theologian jurist, one of the three women members of the group. We are appointed by the European Commission, the Government of the European Union, as persons representing different scientific areas and intellectual attitudes.

It means that the selection is basic on purely technical and not political grounds. The group is composed by two journalists, one biologist, several diverse theologians, two jurists, and one expert in health policies.

Because this kind of appointment, are we truly independent? Of course, my answer is self-defensive and is yes, but independence is strictly connected with the way in which a body works, and I will try to give you some information about that.

The group's terms of reference are to identify and define the ethical issues raised by biotechnology, to assess from the ethical viewpoint the impact of the community's activities in the field

of biotechnology, to advise the commission in the exercise of its powers on the ethical aspects of biotechnology, and to ensure that the general public is kept properly informed.

First of all, it's very important to know that the opinion of the group are not binding for the commission, and that we can decide to investigate an issue on our own initiative. It implies a mutual condition of freedom, but on the side of commission and the side of the group.

Second, we don't work only in camera, but we organize always hearings with the groups, with the interest groups everywhere in Europe involved in issues we are dealing with.

It means that we try to integrate some excluded voices into the decision-making process, and this openness is also a mean for the group for defending itself for some pressures by economic powerful groups, and it means that we speak not only to the commission but to the European public opinion.

For that, we try to give maximum publicity to our opinions. During the first term, our opinions were restricted, but now they are in principle presented in press conference. Also, before to be

communicated to the European Commission and until now, the group has published eight opinions in very different areas, this folder may be, and you can find the least and some of the eight -- seven -- of the seven opinions because the last one on the patentability of biotechnology opinion invention has been published after the issue was published.

And all opinions have been approved unanimously. Only in the last opinion on the patentability of biotechnology invention, we had a dissent on a specific point.

If you look -- so, the group is acting at two levels. If you look at the content of the opinions, you can see that we are trying to introduce into American-oriented community some fundamental ethics principles and to develop a number of these principles which are indicated as guidelines not only to the Union as a whole but also to the governments of each state of Europe.

We have three main points of reference, dignity, equality, information, as grounds for choices and collective actions, and the special position as stipulated to the group to deal with the problem of cultural, economic and social environment, and with

the role of government in providing or promoting some basic social services and in controlling some activities in the field of bioethics.

In this broad perspective, the group has the ambition to be a bridge between bioethics and biopolitics, but at this point, we encounter a crucial and critical question common, I think, to the great majority of these bodies, which is our legitimacy, our democratic legitimacy.

Why I have been chosen and appointed and not another Italian? Are we confronting with an embryo of a perspective government of learned people in the moral sensitive areas of organization of our societies? I think that the future of the ethics committee highly depends to the capacity to give democratic answers to these questions.

Thank you.

DR. SHAPIRO: Thank you very much. Thank you very much indeed.

Discussion Among the Delegates

DR. SHAPIRO: I think now we can open our -- up to the period of just general discussion. I want to turn to my colleague, Mrs. Scott-Jones here, who asked a question earlier this morning, and I

preemptively said that would be better off this afternoon.

So, I want to turn to you first, so perhaps you could ask your question now.

MS. SCOTT-JONES: Okay. I'll repeat the question. The question is how in the ethics commissions that have already existed or in the past or in existence now did you take into account the diversity of opinion that exists on the topics that you addressed, the diversity of opinion within the profession and in the public? How did you make sure that you were accommodating diversity of opinion?

DR. SHAPIRO: We got some eager answers. Yes, Professor Knoppers?

MS. KNOPPERS: It's Bartha Knoppers. I'll answer that question after making one comment on Dan Wikler's. When you said one of the ways to measure, I don't know if you said measure success, but perhaps measure the impact of commissions was to see whether their findings or final conclusions were followed by law, I think we could turn that around and say equally how bad laws were avoided by the presence of commissions' resolutions, which I think bad laws are a greater danger than anything else.

As to the consultative process, I can speak to one instance or actually two. In 1992, in Canada, there was a Royal Commission appointed on new reproductive technologies. This was a freestanding commission, i.e. not answerable to any department or ministry federally or provincially but only to the prime minister, thus meant to set it away from the usual turf wars that can go on in biopolitics.

However, this commission, because of the very subject matter, and I think you've had like experience in the United States, included prenatal diagnosis, fetal research, use of tissues as well as embryos and everything else related to new reproductive technologies, and so immediately came under very heavy public scrutiny as well as that by interest groups well organized as they were.

In its travels across the country, I think we did 18 cities, every city was preceded -- in order to get the public to come, you have to do quite a mass of radio and television fore-running, if I can say it, in order to make sure that they will come.

The public hearings -- and every person, no matter the most eminent scientist or the most knowledgeable person involved in reproductive

technologies, and then I'm talking about the patients themselves, were given the same amount of time, and these deliberative procedural rules also drew criticism because those who had the real facts, of course, wanted more time, and those who had the real ideologies that they wanted promoted wanted more time.

So, there were problems, and we need to have an open deliberative public process, but it is a very expensive one, and it's also extremely stressful on commission members. I can tell you that.

I think the success of this commission, one was its independence, which I hope you have, but also the fact that our -- our conclusions didn't please anyone. If that's a measure of success, I'm not so sure. There are 17 volumes of research and two volumes of findings and summary volumes, and currently in Canada, we do have a bill of which about 80 percent reflects our conclusions.

The -- last year, actually probably about 18 months ago, the Prime Minister of Canada convened a national forum on health to look at health care structures in a country that is a confederation where health is a provincial affair, something akin to the German situation of Landers and so on.

How in a country with universal health care system to look at the future of our health care in Canada. This forum commissioned a paper of which the principal author, I think is here present, Terese Larue, sitting over there, and looked like Dan's work at commissions around the world in about 15 different countries and presented it in tables divided by the very issues you're concerned, composition, mandate, budget, impact, and so on, and that was presented and is available in both French and English from the Canadian Government.

One of the conclusions of this report was that, as Dan said, that there is nothing more important than your ensuring a proper infrastructure to do your work. You can have the experts, you can have the good will, you can consult the public, but you need to have an infrastructure. You need to have however you do it, methods already described by -- by Dan, you must have a budget for commission papers, for commission staff, how -- or whatever, and I think similarly for the Canadian MELSI program, and I'll close there, we are using both a free research approach in a research program, but also commissioning papers to prepare us in our deliberations.

Commission experts are usually extremely busy people and when asked to draft things on the spot, irrespective of their experience and learning, are not necessarily the best persons to do that, and that drafting should never be done on the spot anyway.

Thank you.

DR. SHAPIRO: Thank you very much.

Alex?

PROF. CAPRON: I wanted to respond to Diane's question by saying that clearly there are two levels of diversity. One is the diversity of views expressed by your witnesses or experts who are called, and the other is the diversity in terms both of views and of characteristics of the commission, and needless to say, in the United States, with the diversity of population that we have, a very non-homogeneous, very heterogeneous population, I think our experience would indicate that for legitimacy and recognition, it's important to have both of those, and I just tell you, I think much of our experience is similar with the National Commission and the President's Commission, to what Bartha described happening with your Canadian Royal Commission in the sense of taking public commentary when we had hearings both in Washington and

elsewhere and constantly being covered by the press. All of our meetings were in the general press, sometimes on national television when we were reaching conclusions, but always covered in the press and -- and followed by -- by some people.

The diversity of views to me was illustrated right from the beginning of the President's Commission when we were looking at the issue of the determination of death, and this is something on which there's a very broad consensus issue as you know in the medical-neurological field and among people who deal with these issues, both in terms of patients in intensive care units and those who are potentially organ donors, but where there had been some disagreement in other quarters, and the witnesses that we invited included one protestant theologian, and then two Catholics here because there wasn't a lot of -- the protestant theologian came and said basically protestants have no particular religious perspective on the determination of death, and then we had two Catholic priests, both from St. Louis, both priests, taking the diametrically opposite points of view.

On the one hand, that death occurred only when there was basically putrefaction of the body, and

then the other that the brain-based determination of death was an acceptable view, and then finally we had two orthodox rabbis, both of them professors of religious studies at -- in New York, and one of them, also a Ph.D. biologist, who also taught biology, and they also took the opposing views, and I should say that the discussion was so heated that the rabbis at point started arguing in Hebrew with each other, and because all these commission hearings in the United States have to be taken down in transcript, at that point the poor transcriber, who was not someone using a recording machine but was a court reporter, threw up her hands in dismay, and the chairman of the commission had to insist that as vivid as the debate would be, it would have to be conducted in translation, in English, for us.

So, I think that that -- the diversity view is absolutely essential. That was something that we sought out with that commission.

If I may comment on the way in which controversy can turn bioethics into biopolitics, having experienced that with the commission that did not last long and was caught up in congressional politics, my sense is that one of the debates that we

have about methodology is whether a commission is better suited to its task when it has a single task.

The Warnock Commission in Great Britain, for example, looking at reproduction, the new reproductive technologies, or the commission, the Royal Commission in Canada, looking at one topic, versus a commission that has many topics, and it is clear to me that some of the commissions that have had a single topic have in some ways had an easier time of it because they don't get caught up in all the other issues that may complicate their lives, but in another way, my experience with the President's Commission was that if a commission could establish its credibility in the public eye and with those groups that would have some concern about whether it was doing a good job in -- in -- among the politicians or whatever, if it could do that in one field, it could build on that base as it approached other topics, and, furthermore, that a group of commissioners who worked together on one topic can come to trust each other and learn how -- which insights they can draw from each other from their different perspectives and backgrounds as they go on to additional topics.

And I would be very interested in this

discussion with a variety of groups we have around this room to know whether in your own countries you have had experience with one type of commission or the other, and if there was any of this gaining of credibility, this accretion of legitimacy over time as different topics were addressed well.

So, that -- that is a question. Having made my comment, I also end up with a question, but I do think that the diversity issue is not only what you hear but who you are when you hear it.

DR. SHAPIRO: Well, I think there's an increasing portfolio of questions out here. So, I'm hoping those people we call on will address at least one of them, so we could have some kind of parity here.

If you want to -- you have to answer a question in order to ask a question. That way, we'll keep some kind of balance here.

Mr. Changeux?

MR. CHANGEUX: I would like to just share with you experience in France about this issue which I think is a very basic issue.

First of all, in our ethical committee, we have people belonging to the main political and

spiritual families, which are all named by the presidents of the republic. They are the Catholics, Protestants, Jews, Muslims and Marxists, still, and I wish to say that these persons -- I was careful to say belonging to not -- these family of thoughts.

In other words, they have not to defend what is the basic opinion within their group, and I think this is a very important issue because they feel free to discuss as themselves, to argue sometimes.

So, the other aspect -- and I wish to say that this is working quite well, and viewing many of the discussions, nobody identify himself as belonging to a given group, a given family.

This never happened during the past four years, and nobody says I am a Marxist, and therefore I take this position. I am a Catholic, and here's my view. They always use rational arguments, and if the argument is good, then it convince the others and so on and so forth, as it was explained at lunchtime.

Now, there are nevertheless some issues where there are dissident opinions inevitable, that happen, very few times. I must say that most of the time, we all agree unanimously. We have no vote. We never vote, and -- but, nevertheless, we have some

people -- we had opinion on drugs, which is something which maybe you will have to debate in this American committee, I don't know, but this is, of course, in France a very important issue, and at the political aspect at this level is very poor.

But the opinion outside was, I think, quite positive, but nevertheless I want to say that there, it was one person who said I don't want to share the view, and, so, there was a dissident opinion which established together with the actual recommendation of the committee which sometimes is 20 to 30 pages.

So, this is, I think, what is being done by the Supreme Court in the United States, and this is a thing which has to be done.

Now, there is negative aspect of it, I wish to say, is that when one person singularize himself or herself at the end, then its opinion takes a weight which is almost equivalent to that of the majority opinion.

So, the question was whether or not the dissident opinion should be put, of course, written but anonymous. It's an issue which we have to debate. We have not yet debated on that point in the committee, but I want to say that we have to, and I

think it's a good point to publish the dissident opinion, but whether it should be nominal or not, I think, -- until now, they were nominal.

Now, I have two further points. The question of the basic dissident on moral issues, which was debated at lunch, is, of course, a very important point, but since you are a psychologist, I may mention the work of Elliott Turiel, who is a Californian psychologist, and he has done experiments which I think are of great interest for us with children and with different -- belonging to different religions.

I think one set was from Amish, and the other from Orthodox Jews, and he asked the children whether they would accept that the other group deviate from his traditional moral views, and what is interesting is that the child accepts that there is non-follow-up of church day, wearing the hat, the beard, reading the traditional books and so on and so forth, but not basic moral issue, which is to create pain of suffering on the others and so on and so forth.

So, they make a clear distinction with what Elliott Turiel called social convention, which is linked to a given philosophical or religious or

culture tradition, and basic ethical principles, which is not to kill, not to lie, and so on and so forth.

So, I personally think that to many different cultural groups can agree on some basic ethical issues. That's -- but I want to make -- I wish to say that by experience, this happens.

And last, two things, very brief. We have every year a day of ethics. Journee National d'Ethique, a national day for ethics, where I think several of you have been there where we expose publicly. It's widely open to public, and this is a way to at least publicize and also discuss with people with different views.

And the last point I want to make, which I think is also something that I don't know what is the position of the American committee on this issue, is who is going to ask questions to the committee. What kind of party of personal -- so on and so forth.

So, in France, we can be formally asked by ministers, by the government representatives and so on and so forth, but we can also be asked by anybody, if he wants to have an answer to a question. Of course, we select them, then they are worked out, but we are open to receive questions, and I must say that two

years ago, there was protests by deaf people because in France, the sign language is -- is not systematically given to deaf people to enter this thing, but just to say that there was a poster on the back of the -- of the room, and I asked them why don't you like the statements, and there was no opinion about it.

Thank you.

DR. SHAPIRO: Thank you very much.

Mr. Chalmers?

MR. CHALMERS: Thank you. Donald Chalmers, Australia. I would be very disciplined, Chairman. You have said that we've got to answer the question. I will answer --

DR. SHAPIRO: You want to ask one, yes.

MR. CHALMERS: I am not going to ask a question. I'm going to answer Professor Scott-Jones, but in answering it, I'm going to change the question around.

The question is how do we handle diversity of views? I suspect we have to start thinking of how we obtain that diversity of views. I was particularly mindful of the comments of the two speakers about the great effort that all commissions take around the

world to obtain public opinion.

I suspect if we're quite honest, I don't think we're particularly useful. I think we can quote some examples from the Danish Council of Ethics, but I think it really is a problem. The legitimacy of these bodies is based upon their public independent consultation.

Our committee, for example, has been required by law to not only conduct a public consultation but to carry to this second-stage exercise in presenting the guidelines themselves to the public for further comment. That process is in fact supposed to produce accountability because my committee would then be required to give reasons of how the particular consultation has affected the product of the guidelines.

We're a country which has freedom of information, and therefore the record of debate could be audited. That's all very fine on a procedural level, but my worry is how do we actually get people to give their views?

In Australia, there is no doubt that there is very organized medical, academic, professional organizations. It's very easy to write. We have an

address. We would expect because of their professional organizations to hear the view.

Similarly, there's -- there are some human rights groups. There are some health consumer groups, and there are other public bodies which are reasonably well-organized.

May I say, however, that in the three public inquiries which we've conducted, each of which have received hundreds of submissions, I can say with confidence I am sure we had the professional voices. I am very sure, however, we did not hear the people's voices.

Simply if you look at the exercise of the number of submissions which have been presented, I don't think we're very efficient in putting ads in newspapers, using community radio, using mailing lists and so on and so forth.

I still think, for example, the subjects of research, there are no organized voices for the subjects of human research, yet we expect to hear their voices.

I think what I'm saying, therefore, is that I hope perhaps if we meet again in a couple of years' time, it might be something fruitful for all of us

together to try and investigate what ways have worked and what ways we can improve, to ensure that we have that legitimacy of hearing the voices of those that we are supposed to serve, for after all, if we do in fact do that, not only are we acting ethically, it's much more likely that our opinions will be heard by the politicians.

Thank you.

DR. SHAPIRO: Thank you.

Dr. Abrams?

MR. ABRAMS: Thank you, Chairman. I, too, am not going to ask a further question. So, I hope I get what we call a brownie point for that in England, but I do wish to speak from the United Kingdom point of view, just to throw a different sort of perspective on the question that you asked, Professor Scott-Jones, because I think it's a very important and very difficult question.

I agree very much with what Dr. Chalmers has said about the importance and method and techniques of getting a variety of views. One can somewhat cynically observe that members of commissions in my experience tend to pick on the views that they like as representing the public.

So, but it's pretty difficult to decide which are the real public views, but there's no problem getting them, but what I wanted to touch on is our experience in England of the Warnock Report on Human Reproduction which Dr. Capron has already mentioned.

Yes, that was an excellent report that was published in the early '80s, but the fact that it was an excellent report is not the same thing at all as saying that it was widely accepted because after it was made public, there was very intense discussion by the public at all levels, scientific, academic, newspapers, all sorts of pressure groups, and very strong and conflicting views on what was in that report.

The government, perhaps I have to have some responsibility for the way it behaved at that time, took several years to decide how to handle this report. The result was that when it presented the -- what is now the Human Fertilization and Embryology Act to Parliament, it went through in 1990, something like six years after the report was published, there was virtual unanimity in Parliament about the right way to legislate.

So, the perspective I would like to put on it is that the publication of the commission's report may itself be the start of a process that then leads to legislation which is non-contentious.

I must say that is one possibility. There are obviously some areas, such as abortion and euthanasia, where I think it's extremely unlikely that any process of public consultation is going to lead to any form of unanimity, but that doesn't mean you don't have to tackle it, but I just wish to point out that the final process of consultation and discussion before legislation is a very legitimate way of concluding a commission's work.

DR. SHAPIRO: Thank you.

Dr. Brito?

DR. BRITO: Arturo Brito from Miami. I just want to continue with the theme that Dr. Chalmers expressed about hearing the voices of the -- of -- of the public and how it seems that previous committees and commissions, etc., have not done a wonderful job of -- of that.

One of my concerns is that the biggest challenge is to provide a voice for the most vulnerable group of people, and in -- in under-

developed countries, in countries that -- where there's a lot of poverty or even in countries that are considered to be industrialized or developed, where the populations that are poverty-stricken, where the illiteracy rates are high, my concern, and I think this is something we need to tackle on our commission is -- is how are we going to assure that these populations are ethically served in all types of research, and the populations I'm talking about go beyond the poor and the illiterate, the children, the mentally disabled, and communities where voices aren't heard from certain segments of the population; for instance, women in certain countries and in certain situations.

So, I guess what I'm saying is just I'm -- I get a little concerned because even in this room and even anyone from the public that later on is going to express an opinion, it's doubtful that it can be from these groups.

So, somehow in our deliberation and in our -- as we go through the process, we need to keep these groups in mind.

DR. SHAPIRO: Thank you very much.

Professor Cox -- Oh, I'm sorry. Yes?

MR. PESSINI: A brief note about the Brazilian experience, a recent one. In Brazil, I think a little over one year, we was formed an executive working group of the Minister of Health to -- to draw some guidelines about research with human subjects, and a multi-disciplinary group was formed by distinguished professionals from research, philosophy, bioethics, theology, law and medicine areas, besides representatives of the public health system, users, women's groups, pharmaceutical industry and governmental services, health policies, science and technology.

The group were consulting the society and reading literature. I think that the issue that was raised here about legitimacy of the committee, and here, we have some interesting figures.

The consulting part involved correspondence to any 300 institutions and experts, asking for suggestions. The distribution of 25,000 sets of international rules of CIOMS at national level. Organization of regional meetings, participation in the Brazilian Congress of Bioethics and, finally, collecting proposals in a public audience in June of '96.

So, this was a search for legitimacy, and from another perspective, well, as a result of this consulting the society, we received 119 suggestions from research institutes, universities, human rights organizations, professional associations, a public ministry and civil society organizations, all together conforming a meaningful number of opinions.

From this was one aspect. Now, the other one was the bibliographic review and analyzing the legislation of many countries of Latin America, particularly Canada, here in the United States, and European Community and Rules of International Organizations.

So, the process resulted in the Brazilian rules approved by the National Council of Health last month, October 10th, which will be continued to develop a specific rules in areas such as human genetics, assist reproduction, international cooperation among others.

So, the basic document was just this year, and I think that the hard -- the hard discussion will be -- is about to start when we -- we will be dealing with the specific items, such as indigenous populations, projects involving biosafety,

pharmaceutical products, human reproduction and human genetics.

DR. SHAPIRO: Thank you.

Professor Childress?

MR. CHILDRESS: This is a very illuminating discussion, and I'd like to connect it with one of Dan Wikler's points. I found Dan's discussion to be very helpful in getting at particularly criteria of success, but, Dan, you admitted that there might be some inconsistency or possible tension in the criteria presented, and I'd like for you to reflect, if you would, on the possible tension between our interests in public participation, our justification of proposed policies to the public, our involvement in public education, as a commission.

Tension between that on the one hand, and on the other hand, the requirement that the materials meet academic standards, because quite often it seems to me that this might go in the direction, say, of a very technical understanding of rationalize reasoning that might strip away metaphors, symbols, stories and so forth, and how -- how in terms of your examination of -- of different commissions, how did you see this possible tension dealt with? Any suggestions for us?

MR. WIKLER: Badly. I -- I needn't point out that you've touched on one of the -- the key tensions in that list of desiderata, and, of course, there is no easy way to or even practical way to find a path through that minefield without getting blown up at some point.

I would -- I don't think that the -- the commission -- the group that worked at the Academy came up with a satisfactory answer. It just urged the maximum of both, even though they do conflict, and the only thing I would throw out personally, just as -- as a -- a philosopher, I suppose, is that the ideal very hard, if not impossible to realize in practice, is that one be able to separate that which one knows as a result of research and data collection and like from that which one feels to be knowledge simply because that -- those are one's own beliefs, and, so, to the extent that one can be attentive to the voices of a wide variety of viewpoints, cultural inheritances and so on, that make up one's society and be sure to give equal respect for each of these voices, you can separate this out from the -- that part of one's presentation which can be anchored more objectively, let's say, in the kind of research that one has done.

Now, I say that knowing how fatuous it sounds, but that would be the ideal, and it would probably be a -- a product in which there was some attempt to label the findings of the commission, either as the product of research which can be defended as objective knowledge on the one hand, and the more culture-bound or personal perspectives.

Now, in the end, a decision has to be made. The commission will come down on one side or the other, and, so, it's not simply enough to lay out five different points of view, one of these has to be endorsed, but I don't -- I -- and to that extent, of course, it's impossible to give equal voice or equal emphasis to all of these different points of view.

But in my own view, I don't think that's such a problem simply because I don't think that the conclusions of the commissions are all that important. What's important is the arguments they give in favor of them, and these can reflect all of these different viewpoints.

DR. SHAPIRO: Thank you.

Professor Lynch?

MS. LYNCH: It's Professor Abbyann Lynch from Canada. I'd like to go back to a comment that

was made by Dr. Rodota earlier on about independence, and I think it's reflected in the comment that was made over here, about the council that was formed in Brazil under the direction of the Department of Health, and, generally, to ask for other experience about how independence of such a commission can be maintained.

I think independence in terms of those who provide the budget or independence in terms of those who name the people who are going to be on the commissions is a very important feature. We can judge legitimacy in terms of public participation, but surely there's a prior question, and that is, how free is the group to go on and to explore what needs to be explored?

What are the limitations on the substance, whether they're going to be controlled by budgetary considerations or by the naming of certain personnel, it seems to me, is a very important feature that we haven't discussed here.

DR. SHAPIRO: Thank you.

Dr. Holm?

DR. HOLM: Yes, Soren Holm, Denmark. First, Professor Childress's point. If you look at what the

Danish Council of Ethics has published in its nine years of existence, you would find a couple of books of poems, I think three books of short stories, and one novel, all intended to foster public debate on these issues. Some of the poems on genetics, the novel is also on genetic screening.

So, I think you can -- you can find ways of raising public awareness, which sort of does not require deep philosophical thoughts or analysis.

The other point is, of course, that when we talk about representation and consultation, I think there's one great problem which I think is true of all bioethics commissions I've ever come across; that academics are hugely over-represented.

There are good reasons for this in the subject matter, but I think in a way, this is a very -- it is a problem also for the way such commissions work.

Finally, on the point of consultation, the Danish Council of Ethics also does these formal consultation exercises, and I find them extremely unfruitful. The representative of the Danish association of this, that or the other, who might not -- well, who is employed to be the representative of

this association, stands up and gives the party line, then the representative of some other association.

I think that in Denmark, we have had -- we get much more information by what you would call informal consultation, which we can do because we are a small country. So, we have the system that if anybody wants to have a member of the Danish Council of Ethics come talk about something, they can get the expenses paid, and they can get -- get the expenses paid for advertisements, which means that the members of the Danish Council of Ethics do between 20 and 30 of these things a year per member, and I think we get a lot more of the public voice in those than when we call for formal consultations.

DR. SHAPIRO: Thank you very much.

Mr. Kutukdjian?

MR. KUTUKDJIAN: Thank you, Mr. Chairman. Georges Kutukdjian from UNESCO. The International Bioethics Committee has been right from its inception imagined as a forum of discussion. It does not adopt opinions, and therefore the debate, it prints its reports it has, are more conceived as an inspiration for legislations in the member states of UNESCO, and also it's a fairly large group of at present over 55

members, and the principles that we followed right from the beginning were cultural diversity, of course, a multi-disciplinary composition, which has already been referred to here, but specially the members that have been requested or invited to serve on this committee, have been invited to do so in tuito personae, that is to say, in their private capacity, and they sit in that private capacity.

They do not represent any corporate interest or any national view or position, and I believe that also right from its inception, it was conceived as extremely important to include public participation and involve the views of international non-governmental organizations, a number of which constantly participate in the discussions of the International Bioethics Committee.

This includes the public because all the sessions have been conceived as being open to the public, including the press, which has followed very closely all the debates of the International Bioethics Committee.

Now, I think that we were in a position to propose to the General Conference of UNESCO, which has endorsed this at the -- in November, it invited all

member states of UNESCO to create consultative ethics committees, based on the following three principles: cultural diversity, multi-disciplinary composition, and independence.

Of course, independence, this was discussed, has various meanings and can have different connotations, depending on the socio-cultural context of a given country.

The two further roles which have been stressed at UNESCO are the importance to stimulate public debate, and in order to do so, have an active role in education and information because it's extremely important to interact with the society at large.

These principles, I would like to stress, have been also endorsed and adopted by the 93rd Inter-Parliamentary Conference, which met in Madrid last year, and they had on their agenda bioethics. This inter-parliamentary conference, I'd like to remind, is composed of more of parliamentary groups that meet from over a 120 countries throughout the world.

These principles have also been adopted by the last heads-of-state summit of the African -- of the Organization of African Unity, which met in July

1996 in Yauonide, Cameroon, and they had on their agenda bioethics as one of their -- of the topics, and the resolution they adopted include these principles as being guiding principles for the future ethics advisory committees, which they urged all member states of Africa to set up.

Thank you.

DR. SHAPIRO: Thank you very much.

Professor Chadwick?

MS. CHADWICK: Thank you. The Industrial Council on Bioethics is not, of course, a national official body in the U.K. It's an independent body and only one of several bioethics bodies, but its method of working is to set up working parties to look at specific issues, and the membership of these working parties is determined by two broad criteria. One, to assemble a range of expertise on that issue, and, secondly, to gather together a variety of viewpoints, and the working parties undertake public consultation.

But I think that going back to Dan Wikler's presentation, one of the criteria of success for the Nuffield Council would see as its own is to anticipate a public concern as well as to respond to it, and it

will shortly begin work on a new project on genetics of mental disorders, such as schizophrenia. Well, in fact, the working party is already setting its terms of reference, and in December, there will be a public consultation and information packs will be sent out, and if anybody here would be interested in an information pack, that will be available from the Council next month.

The other thing I wanted to say is that the Euro-screen Group, which I coordinate, has a subgroup specifically looking at the issue of how to raise public awareness, and one of the things that we'll be doing as an experiment over the next year is opening a genetic information shop, which will be audited as a research tool to see how successful this kind of way of involving the public is, and a report on that should be available after the end of next year.

DR. SHAPIRO: Thank you.

Professor Levine?

MR. LEVINE: Thank you. I wanted to make two comments that are not -- is this working? Oh, good. Two comments.

The first has to do with a topic we discussed very much earlier, and that is whether or

not to include minority reports in the reports of a commission, and one of the adverse effects of doing that is that very often, you spend months trying to develop a consensus statement, and then at the last minute, one or two individuals want to depart from that and write a minority report.

What gets lost in the final publication is that all of the others, if they knew they were developing their own report, without these one or two members, would have developed something that was much more strongly on the opposite side of what the minority report says.

I've been in a number of groups where that has happened. So, maybe if you can get people who think they're going to not be included in the majority report to identify their concerns early, at least it could be possible to do something about that. I've never been part of a group where that worked.

The second thing I want to say has not been discussed this afternoon, but I think it has a lot to do with whether or not the recommendations of a commission are followed.

This is something that the CIOMS group identified as an issue and dealt with -- was aware of

it, conscious of it, as we went along, that all too often, guidelines and particularly international codes contain expressions of lofty ideals that are very, very different from what anyone really expects anyone will do, and when these highly-idealistic statements are included among recommendations that you expect people to do, the very idealistic ones will become identified as unattainable, and, so, the people who are supposed to be guided will say, well, they can't possibly think that we can do that, and it gives them license to pick and choose which of the guidelines they're going to follow.

I could give plenty of examples of that, but the main thing I want to say is that in writing guidelines or recommendations, try to make them as pragmatic as you can, and put the idealistic statements about where you hope society will be a generation from now, put that in the commentary or in an appendix.

Thank you.

DR. SHAPIRO: Thank you.

Professor Jonsen?

MR. JONSEN: I -- Al Jonsen, United States. I'll be talking about a United States experience, but

it took place now so long ago, that I feel like it's a different country.

The National Commission for Protection of Human Subjects that the Congress established sat from 1974 to 1978 and was followed in 1979 with the President's Commission, which sat till 1982.

In those early years of -- '83. Thanks, Alex. Well, I went off in '82. So, it ended -- it ended when I left.

During those years, that decade, we saw, I think, really vast changes. When the National Commission began, it was an age of happy innocence about ethics. There had never been an experience of this sort before in the United States, and I think there was a general belief that one could let ethics be ethics, and that it would work well, and it did.

That commission came into being largely because of two very powerful incidents that had strong political implications. One was the use of research -- was a research project that took place in the American South for a number of years, in which American -- African Americans were left untreated for syphilis. That became a public issue in -- in the early 1970s, and the second was an issue that had to

do with the use of fetuses for research, and by a strange coincidence, an issue which had strong civil rights overtones and appealed to the liberal members of the Congress was matched with an issue that had strong abortion overtones and appealed to the conservative members of the Congress.

So, the solution to the problem was -- this is a word that's been much used in the United States in the last couple of months, was -- was a non-partisan approach. The commission was conceived of as being non-partisan.

I could not tell you the political affiliation of any of my colleagues on that commission, and as a result, there was a very -- it was possible for ethics to be ethics because the politics were not obvious.

Over the course of the seven years that I sat on these two commissions, I could see the innocence degenerate, and as we reached the end of the President's Commission work, there was already an attempt to insert very powerful political opinions into the commission process.

It seems to me that every country has its own experience with -- with the way in which

commissions inter-relate with, as Professor Rodota said, biopolitics.

I am sure each one of you has had very, very different experiences in that regard, but in my experience, the most successful of the commission experiences were those first few years of the National Commission relative to its -- its attempt to work out guidelines for human experimentation.

That leads to a second point in this regard. I think another feature of the success of that commission was its concentration upon specific questions. We -- we spent very little time discussing moral philosophy in general. We spent very little time arguing at the level of speculative principles, but, rather, we had a number of very specific cases of research that we felt needed to be dealt with, and the more specific cases tended, I think, to -- to generate more agreement and less diversity, so that the less-speculative and the more-concrete the commission remains in its -- in its work, I think it's -- it's the -- it's more successful.

Thank you.

DR. SHAPIRO: Thank you very much.

Since the next person I'm going to call on

is a member of NBAC, I feel free to say at this moment that this list I have is certain to get unstable, it's growing faster than -- than it's -- than we're managing to shorten the list.

So, I would really ask people in view of the time to be as succinct as possible.

Now, I can turn to Professor Cox.

MR. COX: David Cox from the United States. The -- I'm very interested in this aspect of public input into commissions because my own personal views are, as has already been stated eloquently by others, that that validates the commissions, and the -- I don't really -- so, I'm going to make a statement and that's that I don't really see it as a difficulty that the commissions themselves are over-balanced with academics. It's always the case.

But I really think that if -- it's only a difficulty if those academics in the commissions don't have vehicles for bringing the public into the deliberations, as has already been discussed, and, so, I think the challenge is what the clever ways are to bring the public in, and I was struck by the comments from our Danish colleague of the clever ways that the Danish Commission has done this, and I'd be very

interested to hear from other people in other countries if -- if they don't do similar things, why not, because it strikes me that that's the real key.

We can't get under-represented groups commenting if we don't, as commissions, put something before them. Specific questions, as Dr. Jonsen just said, for people to comment on, and I think that clever vehicles to get people to comment on them are -- are extremely important.

If people don't comment on the issues, then I think perhaps the academics on the commissions aren't dealing with issues that are the important ones.

DR. SHAPIRO: Thank you.

Ms. Khan?

MS. KHAN: Kausar Khan from Pakistan. The question I'd like to raise is initially, I thought it was perhaps more pertinent for any international bioethics commission, and I was thinking of UNESCO, but then, on the other hand, I also thought that this would -- the question is also relevant for any bioethics commission from one of the more developed countries, like the U.S. or the European Union, because of the implications these countries have for

countries like Pakistan, countries in the Nation of Africa.

And -- and the question has to do with the use of research. I would like to know whether there's any commission which has also tried to see whether there can be or tried to prevent the use of research for the production of weapons of mass destruction, because I think when we are looking at even at biomedical ethics, it is not only an issue of insurance company industry or pharmaceutical industry. We also have an arms or military industry complex in the world.

So, especially in the context of research that is going on genetics, is there -- what chances or risks there are for the use of this research for making weapons of mass destruction, especially when we see today in the world armed conflicts are -- are immense, and I was just looking at some data of 1995.

U.S.A. had arms exports worth $15 billion, followed by Britain, which was $4.8 billion, and France, $3.8. So, we do see that these countries which are very powerful, they have powerful commissions on biomedical ethics, on bioethics, but the question is then, are these commissions also

ethically bound to think about the impact of omission -- I'm not saying of commission, of omission of certain concerns on the use of knowledge?

And, so, as -- I mean who's -- I mean how are the parameters being kept for these commissions, and whether these commissions can also raise issues vis-a-vis the implications for countries outside the fold of these powerful blocs?

DR. SHAPIRO: Thank you very much.

I'm not going to -- I have a lot of names written down. I don't think I'm going to take any more because we're going to have to -- the time is running short, but I still do have quite a few people who want to address some issues.

Obviously we're not going to be able to take up each question that's been posed, although we will make a careful list of those, and at least speaking for the NBAC members, we will come back and look at all the questions that are raised, although we obviously aren't going to be able to deal with them here this afternoon. I regret that, but given our time, I don't think that's possible.

Mr. Holtzman?

MR. HOLTZMAN: Another question. Is it on?

DR. SHAPIRO: Just keep talking. It goes on.

MR. HOLTZMAN: Okay. Steve Holtzman from the United States. I suppose it's in the nature of ethical discourse from the 10 Commandments forward with its thou-shall-nots, that it tends to focus on negatives, that it's more important to articulate what one ought not do, and that commissions often arise in response to an abuse or an anticipation of a potential abuse.

And the question I had is to what extent do we have an ethical obligation to be thinking of our role in a positive sense, in terms of creating the enabling conditions for advances in biomedicine, biotechnology, and its potential benefits to be realized?

DR. SHAPIRO: Thank you.

Mr. Harris?

MR. HARRIS: Thank you. A couple of very brief points. I think it's worth reflecting on the question of what commissions should try to do, and indeed the form that their reports should take.

To take up Dan's point earlier about meeting academic peer review standards, I mean one thing that

commissions are never very big on, indeed possibly could not be big on, is originality, and if that's a normal requirement of peer review, then they would clearly fail.

I mean if you take some of the recent U.K. reports, the Warnock Report, the Clothier Report, some of the Nuffield Council reports, they're very thin on moral argument or indeed on reasoning of any sort or indeed on evidence of deliberation.

What you get are phrases like members strongly felt or a majority were convinced, but you don't get the detail of what convinced them or of what the basis of their feelings were.

So, I think a real question is should reports actually articulate the sort of deliberations that we heard so eloquently phrased at lunch time, and which would be a required part of academic peer review?

The other quick point I wanted to make, I agreed with what Michael Abrams said earlier, tracing the history of the aftermath of the Warnock Report, and it seems to me very important that commission reports should be the start of public debate, not the end of it. They shouldn't be regarded as having

settled things but, rather, having laid out the parameters for a necessary public debate before any legislation should issue, and that leads me really to the final point, which is Ruth Chadwick mentioned that the Nuffield Council tried to anticipate public concern rather than respond to it.

I think another question is whether commissions should try to lead public opinion rather than follow it. The Warnock Report, for example, in the U.K. stated explicitly that it was attempting to follow public opinion, and one of the bases on which I criticized it at the time was there's no point in gathering the great and the good together to deliberate lengthily on ethical issues, if they feel constrained simply to follow public opinion.

It's surely their job to lead it, and to give reasons for leading it in particular directions.

Thank you.

DR. SHAPIRO: Thank you very much.

Ms. Macklin?

MS. MACKLIN: Thank you. I'm Ruth Macklin from the United States. I wanted to speak briefly to a couple of points. I was a member of the Presidential Advisory Committee on Human Radiation

Experiments that completed its work a little over a year ago, and those of you who saw Friday's New York Times saw the implementation of one of the recommendations that came out of the work of this commission.

Now, perhaps this commission differs from some of the general commissions that are being discussed because it was charged, among other things, with a historical task; that is, to study what happened when the United States Government conducted radiation experiments often unwittingly on citizens of this country during the Cold War era. It was a very -- the charges were quite specific to the committee.

Nevertheless, there are a couple of things that are relevant to the discussion that we're having here. One is that when there are stakeholders on any particular point that's being discussed by a committee, it will be impossible to satisfy those stakeholders.

The committee was created by President Clinton and the working group from different agencies in the Federal Government in the United States. It was created precisely not to be a stakeholder committee and that stakeholders were, too, people from

the radiation community and the Los Alamos Laboratories and other federal organizations that had hands in the actual research that had been conducted, and the victims, and they were mostly family members of the -- of the victims.

These groups were not satisfied with the provisional recommendations on findings. They were not satisfied at the conclusions that were allegedly factual conclusions, not ethical recommendations but what happened and when and who did what, and from the beginning to the end, one group of stakeholders, the victims of the radiation experiments, complained that the committee did not have a member of the victim community on it, and therefore anything it said would not be credible to that community.

Well, the 900-page document was a consensus document, only one member of the committee chose to write not a minority report but a statement, and it turned out not to be in very strong disagreement, but despite the fact that the stakeholders on the outside of the committee continued to criticize the committee not only for failing to have a victim or a family member of a victim on the committee, they also criticized the membership of the committee, saying

there are radiation specialists on here, and there's a radiation specialist who published an article 15 years ago with one of the people who was charged with doing some of these allegedly unethical experiments.

You can't win on everything, and therefore satisfying the community, particularly stakeholders, can never be viewed or should never be viewed as a criterion of success.

A final point about what John Harris said. We did strive in the report to include an ethical analysis and arguments in support of the -- of the conclusions, both the findings and the recommendations. Perhaps those arguments did not satisfy everyone, but we thought it was important to give a basis, especially for a public that may be unacquainted with academic bioethics, to give them a feel not only on who said what and who voted -- how many members voted for what, but what were the reasons that the committee came to the conclusions that it did, and I think it was able to be done in a way that was accessible to the general public.

Thank you.

DR. SHAPIRO: Thank you.

Mr. Cook, do you have something to say?

Excuse me. I'm sorry. I got your name wrong. I apologize. Mr. Macer?

MR. MACER: Darryl Macer.

DR. SHAPIRO: I'm so sorry.

MR. MACER: In this case, from New Zealand. I would like to make a comment about New Zealand. Regarding the role of the public on making submissions to the committee, in fact, the law in New Zealand on the membership of health ethics committees states that the majority must be lay members, the chairperson must be lay. So, actually more than half the committee are members of the public, not academics.

So, I think this would be one way to guarantee the participation of the public in bioethics committees. However, those committees are a little different from the commission, which -- in their responsibilities, but still I think it's an interesting challenge for other countries.

DR. SHAPIRO: Thank you.

Mr. Pompidou?

MR. POMPIDOU: Thank you, Mr. Chairman, and I must apologize for arriving late, but it's a problem of scheduling.

So, I would like first to underline one

point that's of increasing importance of biomedical engineering and of biotechnology in our society, and there are financial and economic states, and in regard with that, it is necessary position and a necessary mandatory position, is -- is great diversity of the -- of the concerns and working of the public opinion with also the context.

So, my question would be, how to build a stronger participative democracy, and what would be the role of the ethics committee, and, of course, the scientists have their own specific approach and expertise in bioethics of their research areas and positions that is from their own experience.

But my question is, how to better involve the decision-makers and politicians? There are very few politicians here. I am from France. I am also from European Parliament, and I am a member of the Ethics Committee and the HUGO Ethics Committee. I have been a politician. I am a candid hybrid politician because the European Union is a teaching member state, and I'm not in jail.

So, how to better involve decision-makers, and I think that a good example is -- is -- is a group of advisors on European Commission, where scientists

who are expert in law and in bioethics and where member -- they are -- they are member of the European Parliament, too.

So, I think that it's very important in order to have a better representation of public opinion, not -- not only to -- to follow the public opinion, but also to listen to this opinion, to have this kind of -- of -- of decision-makers and politicians.

Thank you.

DR. SHAPIRO: Thank you.

Dr. Bryant?

DR. BRYANT: Yes, my question comes from the fact that several of us here have been asked to work with WHO in defining the ethical content of a new global health charter.

I wanted to pick up on the comment of Dr. Brito who was -- actually to extend his question. He said he wanted to be sure that poor populations are ethically served in research, and then I wanted to extend that to say, and what about the application of those findings through public systems, and this raises the question then of equity of access, and I'm just wondering then how the National Bioethics Advisory

Commission would look at that divide between research-related decisions and the application of those decisions, where it becomes entwined then in the health care system?

Thank you.

DR. SHAPIRO: Thank you.

Professor Gillon?

MR. GILLON: Yes, I'd -- Raanan Gillon, London. I just wanted to add a simple suggestion about the involvement of the public; that certainly looks very promising in the U.K. at the moment, and I think it started actually in Germany and -- and in the States, and that is the notion of the citizens' jury, and certainly we have found it in our local area very revealing in the context of mental health care, but I think the underlying assumption is entirely consistent with Amy Gutmann's advice to us all at lunch time about the importance of deliberation in the area, and it was found -- in fact, I think this is quite a widespread finding, that the citizens, whether randomly chosen or stratified random sample, actually tend to look at the issues that they are confronted with very thoroughly indeed, much more dispassionately than might be anticipated, and indeed are quite open

to change, and I think that's a system that is well worth at least acknowledging and experimenting with.

DR. SHAPIRO: Thank you very much.

Yes?

MR. GELZER: I have a brief question to Dr. Wikler's talk. In our country in Switzerland, currently there is a debate about the ratio between ethicists and scientists or experts in a corresponding commission.

Now, in our view, we are not a state ethical commission. We think the scientists should have -- should be a larger number of scientists compared to the ethicists, but this is being debated, and there are free voices that this should be opposite way around.

The second issue which is on-going is the ethical question of stipulated quota for women. Now, as a matter of fact in the current proposal for a new law, for a human ethics commission, it is stipulated that there shall be 50 percent women ratio should be achieved.

In our opinion, this is not a very good idea, but we will find out what the Swiss will do. It would have been interesting to know from this

competent group, particularly from Dr. Wikler or from Changeux, what they think about fixed ratios.

DR. SHAPIRO: Does anyone want to answer succinctly about fixed ratios? The colleague from Denmark wishes to answer.

MR. HOLM: The Danish Council of Ethics has a fixed ratio, and it works excellently.

MR. GELZER: What fixed ratio?

MR. HOLM: Well, given that there's an unequal number of members, there will always be one more of a given gender, but otherwise it's 50/50.

DR. SHAPIRO: That's men and women. What about scientists and ethicists, which was the other part of the question? You may not wish to answer that.

MR. HOLM: Well, if I can get a definition of a scientist and a definition of an ethicist, I can answer the question.

DR. SHAPIRO: In that case, I leave it to the two of you to discuss.

Alex has some insight on this issue.

PROF. CAPRON: I just want to note one problem with the expression of this idea. Our rules for institutional review boards, which are human

subjects committees at a local level, when the rules were written in the late 1970s, they stated that not all members of any such group shall be of a single sex, and the reading in English suggested that we needed some hermaphrodites on every commission.

DR. SHAPIRO: There's always a new problem. I want to draw this part of our meeting to a close, but there are two more people I want to call on.

Mr. Suarez first, and then the colleagues from Brazil.

MR. VELASCO-SUAREZ: I think that all of us agree that this meeting has been very inspirating, and that the deliberations have been with great freedom.

So, I think that we are going back home with more solid ideas, but at the same time, we think that we cannot globalize ethics and bioethics. So, the collaboration, international collaboration should be the great extent that we choose to exchange with the commissions, to exchange ideas, but never to ask the people, even the Congress, to announce the participants because they think that they have certain beliefs to belong to some practice.

So, if we ask them to renegotiate of that beliefs, we are not really acting as good

bioethicists. In my opinion, the great advantage and the hope of this meeting will be to start a very close collaboration, to have certain section in our commissions to exchange all of the production we have, and then to make a special criteria for each country and for each group, and especially for the problems, very different from the ones from one country to other.

DR. SHAPIRO: Thank you very much.

Yes, colleague from Brazil?

MS. DeFREITAS: I would like to make some reference from the speech of Mrs. Lynch about the indefiniteness and the preoccupation of the group concerned about the indefiniteness.

We have some mechanism to try to assurance the indefiniteness, some of them, the composition -- about the composition of the group, multi-disciplinary group with our representative of the users, and the nominating process that is -- is from -- and half of the group -- half of the members are drawn up by the members of institutional committees, review committees.

On the other hand, the group, the national -- National Commission is linked to National Health

Council, that is social control organization, and so is not really governmental organization. It has a mixed mission, and I think that this way, that some -- some mechanism is assured, and -- but we -- we try, too, to -- to guarantee that the opinions and the -- the deliberations of the commission -- National Commission are delegated and is not submitted to National Council. The National Council delegated the -- the -- the mission, and all deliberations to be free to this -- to this National Commission.

DR. SHAPIRO: Thank you.

This is the last comment here before we move on.

MR. TAKEBE: Hiraku Takebe from Japan. I wish to say a few words on behalf of my Chinese colleagues, but, unfortunately, he left.

During last two or three years, there have been very strong opinion at the Chinese law, that actually mother and child health law, and that has been denounced at length by -- particularly by jurists and international federations have been trying to relocate the congress which is to be held in 1998 in Beijing, and because of that law, but, fortunately, Chinese agree to discuss that openly, and meeting will

be held.

But I wish to ask you to listen to Chinese at least because that is pending, this congress, and also we'll discuss human genome organization committee after this congress, and I -- as an Asian, I wish to say we must be -- there is some at least difference in under-lying philosophy and religion or different concept and also Chinese are only country, I should say, who are trying to suppress population explosion by so-called one-child policy.

Of course, human rights is involved, but still Chinese appreciate the citizenry tying to suppress human population explosion, and I wish to say one point and the last. For example, you may not know that Downs Syndrome children in China live about only one year on average. That's mainly due to very, very poor medical and health condition.

I guarantee they are not kidding because they do have law to prohibit killing of baby which was a custom for many years, very unfortunately. So, I wish to say in China. I'm not saying -- I'm not quoting Chinese policy, but I wish to say please listen to whatever the Asians say. We are not accustomed to speaking English. So, this is a good

opportunity.

Thank you.

DR. SHAPIRO: Thank you very much. It was very clear what you had to say.

Future Means for Collaboration and Topics Needing Consideration

DR. SHAPIRO: Let me now call an end to this particular aspect of our discussion because I want to spend the last few minutes of our meeting -- I have my own internal rule that I never like to finish a meeting late, and I certainly don't want to finish this one late. We've been here a long time.

But I wanted to have some discussion regarding whether there was either appropriate or enthusiasm or ideas regarding any future collaboration that might take place, that we might imagine, between groups, such as those that are represented around this table, and, of course, possibly others.

This is not by any means an exclusive or complete universe of important groups that are addressed in these problems, and I know Dan has some ideas about that.

So, why don't I turn to you, Dan, again and see if you could begin our discussion?

MR. WIKLER: Thank you, Professor Shapiro. There are any number of ways that commissions who are represented here could find avenues for future collaboration, and I'm going to offer one and put it before you, and it's, of course, your decision whether to use this or some other route.

Let me say a word for those of you who are not familiar with the International Association of Bioethics, about this organization. It was created about five years ago, simply in order to create a forum for international exchanges on bioethics. It's a non-governmental organization, primarily academic, although it has had many forms involving policymakers, and as an organization, it takes no positions on any stand except for academic freedom.

The organization, the International Association of Bioethics, has two main functions. One is to hold a world congress every two years, and this is the third. The first was held in 1992 in Amsterdam with the -- the National Health Council of the Netherlands as the host, and the second was held in Buenos Aires. This is the third.

The fourth will be held in Tokyo. Professor Sakamoto, who was here earlier, will be the president

of that congress, according to an action of the Board just last night.

The second function, besides the world congresses, is the sponsoring of over a dozen issue-oriented networks. For example, there's a network on brain death, there's a network on resource allocation, there's a feminist approaches to bioethics network, and on and on, and each of these operates as a pretty much-supporting and semi-autonomous society.

The link they have with the IAB is that they draw on members of the IAB for membership in their own organizations, and they tend to schedule their meetings in conjunction with the IAB. So, two of the post-congress sessions here in San Francisco will be run by networks. One is the feminist one, and the other one is the brain death network, and then other symposia that are occurring within the regular IAB program have been handed over to the networks for them to set up as they wish.

So, these operate as semi-independent organizations. As they say at Harvard, every tub on their own bottom. They're independently supported, but they're also independently run.

Now, it seems to me that if this group

wishes to continue to meet and even to expand, and if it wishes to have some activity in between biannual meeting, that this -- both of these frameworks for the IAB could offer a solution.

You could choose the site of the -- of the IAB congresses as a -- the site for your own meetings, which I think would offer a couple of advantages. One advantage is that those of you who would be going to these meetings could be recruited to appear on the -- the regular sessions of the IAB congress, offering your expertise and offering others the chance to hear from you. It would also offer you the chance to attend sessions of interest to you, and, secondly, because the IAB congress is three days long, you could -- instead of trying to pack everything into one grueling day like today, you could schedule sessions over three days, and it would be up to you whether these sessions would be open to the public or would be closed so that they're only open to you or a combination of the two.

And, secondly, if this group chose to incorporate itself as an IAB network, I think there would be several advantages, too. One thing is that, as was noted by the -- the National Academy of

Sciences committee is that at the moment, every commission that begins a study of these issues reinvents the wheel. They begin from nothing.

There is no place where reports from other commissions are deposited for easy reference. You have to know hundreds of fax numbers which probably have changed by the time you get a hold of them. So, it's virtually impossible to find out what other commissions may have done on a topic in which you want to launch a study, and there's no bulletin board. There's no central scheduling office that can tell one commission to -- that might inquire whether any of the commissions are -- are engaged on -- in a study of this issue or plan to in the near future, and therefore no sharing of resources and insights.

If this group chose to incorporate itself as a network, I -- as long as there was enough energy put into the project, it would be possible to maintain a listing of on-going projects along with names, telephone numbers and fax numbers of responsible parties, whereby commissions could keep in touch with each other, and this could be put on the World Wide Web.

So, the -- I'm offering the services of the

IAB on the grounds that it is a kind of a framework that's already in existence. It's a fledgling organization, five years is not a long time to get established, and it will change over time, but I think we can expect that over many years, it will continue to have congresses every two years and will have flourishing networks in the meantime, and I invite you to consider this framework as a -- as a site for your own energies.

DR. SHAPIRO: Thank you very much.

Let me just say something, of course, with respect to what you have referred to as this group. I mean this group is only a group in the sense that we all came here today. There's no others, and we share some common interests, but -- and you were kind enough to respond to our invitation to come, to which we are very grateful, but I don't want anyone to feel that there's some decision been made that this is all of a sudden now a group, yet another group, that you belong to and so on.

But I think it would be interesting to know, we don't -- and I don't propose that we reach any decisions of any kind right now, but it would be interesting to know whether you think a meeting of a

group composed this way, not necessarily a whole day, but on issues of common interest is a useful thing to happen once in awhile, perhaps once every two years, and, secondly, to pick up another suggestion that was made, whether it would be useful, for example, if we maintained, we meaning some undesignated person or somehow was maintained, a Web site of some kind as an example, where reports would all appear, and where our schedules might all appear, so that we could keep in touch in that way. That would have to be -- we'd have to think about how that might be done, but the real question right now is, if you feel something -- things like that are worth thinking about further, and if they are, we will certainly give it some effort and so on, but I'd really like to get some initial response, and let me thank Dan for his remark.

Yes?

MR. CHALMERS: Don Chalmers, Australia. Let me take -- take it in two parts. The first, I think, is absolutely clear, that I think it utterly desirable, Mr. Chairman, that we do meet on a two-yearly basis. From personal experience over the last years, there is nothing quite so frustrating as having to write to all of you each time we start the new

inquiry, reinventing the wheel, defining the work. It is absolutely critical, I think, to the future success of bioethics commissions which have now formed part, I think, of the international scene, that there is some form of organized collaboration. I think that's unquestioned in my view.

The other question of whether it should be under IAB -- IAB, I think that's something which I suspect none of us would want to commit ourselves to immediately. I think it would require discussion with our own committees.

I would perhaps ask you a question. I know, Chairman, you're trying to prevent these at great lengths, but, for example, there are other organizations, such as your own, such as UNESCO, and there may be other organizations which could form the umbrella organization to organize some of this and perhaps other organizations may be able to give some advice whether they'd be willing to act as it were as the coordinating central focus, the hub of the wheel, so that that can be facilitated because I think in my view, it's a worthwhile project.

DR. SHAPIRO: Thank you.

Are there other feelings about this? Yes,

Mr. Changeux?

MR. CHANGEUX: Thank you, Mr. Chairman. What I think we cannot commit ourselves in any -- as chairman of ethical committee, to any kind of particular organization. That's fine. But the main emphasis is that I think there are many partners now raising -- which concern the international aspects.

We had in France the question of drug availability, the question of genetic tests throughout the world were mentioned and so on and so forth, and my suggestion would be that not only we meet every two years, but that we try to find an agenda where we could discuss some issues, which are prepared by commissions before.

DR. SHAPIRO: Thank you.

Any other views or comments? Yes?

MR. HOLM: I think that meeting every two years will be enjoyable and important, but I think that it is more important to get some kind of structure which also functions in between because -- well, I think that what is really needed is the information interchange, and we cannot do that on a biannual basis.

So, what -- I think what somebody has to

give some concentration into how that could be done, and the question is, of course, since we're not now a group as defined by the Chairman, how we then decide to -- somebody is to be.

DR. SHAPIRO: I'll come back to that in a minute.

Mr. Benatar from South Africa?

MR. BENATAR: I'd like to make a provocative suggestion, if I may. We've been talking about bioethics commissions today, and clearly the impact of these are very important on individual health and the concerns about individuals which should be universal.

Yesterday, the point was made that the human rights approach could supplement the bioethics approach to be concerned about the health of populations as well as the health of individuals.

It strikes me that during the course of today's discussions, the word "bioethics" has been extended into the word "biopolitics" which tells me that some of the things that we hope to achieve through discussing bioethical issues and human rights issues have a global context that go beyond the interests of any particular nation.

So, what I want to suggest is that if we are

really concerned about bioethical issues at the global level, which indeed we are if we're concerned about the human genome, and if there is indeed a link between bioethics and human rights, perhaps what we should also be doing during the course of having these commissions is holding up nations' foreign policies as mirrors against which we should look at our bioethical and human rights concerns, to determine the extent to which it really would be possible to make these universal and applicable to people across the world.

DR. SHAPIRO: Thank you.

Mr. Pompidou?

MR. POMPIDOU: Yes, I -- I agree with the term of "biopolitics", but I will extend this term to biogeopolitics with diversity and opinion, and this was a problem of how to link with -- with UNESCO. UNESCO did a very good work, you know, and is represented at most of the countries of the world.

So, how is this -- this group, and the national -- United States committee could -- could organize links with the UNESCO?

DR. SHAPIRO: Thank you.

Yes, go ahead.

MR. KUTUKDJIAN: Thank you very much. Very

briefly, I would like to say that I had a discussion with the Director General of UNESCO, and in fact, he indicated that in 1998, he would like very much to call a meeting of the presidents of national ethics committees throughout the world, a very international and global gathering of the sort, but to discuss specific points of an agenda on -- on certain issues that are considered as being important to both the North and the South and to the East and the West.

Thank you.

DR. SHAPIRO: Thank you.

Any other comments?

MR. ABRAMS: Thank you, Chairman. The Council of Europe has organized and acted as the secretariat for meetings of national ethics committees within Europe. The point I would like to make is that there has been some dissension among the European countries about whether that is a good or a bad thing to do, and it is also quite clear that there's great diversity about how national ethics committees are formed, their responsibilities and their legal status, and indeed some member states of the Council of Europe do not have national ethics committees in the sense of the commission that is sitting here.

But one of the critical features of the discussions about whether to hold such meetings has been about what should be the umbrella organization. I think therefore it very important to follow Dr. Chalmers' wise comments that members around the table may well wish to discuss with their own bodies before coming to any conclusions on this.

DR. SHAPIRO: Well, I certainly don't want to suggest that we have any intention of coming to a conclusion here. Just we're trying -- my -- my objective is simply to get some initial reactions. If it seems to be interesting enough, we can then follow up and take a lot more discussions.

I've got a few people on my list already. Mr. Rodota?

MR. RODOTA: Yes, I think there is consensus about the utility to have some periodical meetings, but two problems we have now is to a continuous information about the work of the national or super-national committees, and Professor Changeux asked -- stressed the point of the agenda.

It's -- it's useful when a national committee and ethics committees working about its own agenda to know if the same problems are at work at

others. I have seen in many -- there is the initiative -- it's Web site with the support of international association, it's possible to organize a Web site for the ethics committee. I think that's not so difficult and so expensive initiative.

DR. SHAPIRO: No. That's right. A Web site -- everything requires effort and focus and administration of some kind, but it's not a big -- it's not a big issue.

Ms. Khan?

MS. KHAN: I'd like to briefly comment on this -- the national ethics committee and especially since you mentioned UNESCO is thinking of calling the presidents of national ethics committees.

I mean I can speak for Pakistan. We don't have any national ethics committee. The way any committees get formed when the government is initiative is it's like announcing a decree. For instance, at the village level, there was to be committees in order to get the family education. Illiteracy is very high there, and this was declared, and somebody went and hand-picked a couple of people and said here's your committee.

So, it will be -- in countries which are not

-- don't have a democratic tradition, especially where the power structures are organized the way they are organized, very despotic governments, then there is no process of the formation. So, there is really no people's representation, and on the one hand, there is, I think, a need to have an international body where countries are represented, but not in terms of presence of committees which don't even exist.

So, I think we need to address this issue of how a large number of countries who are really vulnerable because of the chaos that prevails there, and then how are they to be involved in this larger process.

DR. SHAPIRO: Thank you.

Any other comments before we conclude?

(No response)

DR. SHAPIRO: Well, let me just -- let me just say that -- excuse me. Let me just say by way of concluding this part of our meeting that once again, my great gratitude I would extend to all our visitors, especially those visitors from abroad, who have joined us and shared your expertise and experiences with us.

Speaking for the NBAC group, that is the National Bioethics Advisory Commission here, we're

enormously appreciative and enormously enriched by -- by your comments and are very grateful to you.

We will continue to think ourselves and be in touch with you regarding what some possible next steps might be, if any; that is, I recognize everybody's very busy. You don't need yet another group just for its own sake. It has to have a real function. That might bring some of us together periodically. We might establish a Web site or other form of communication.

We'll get -- we'll give that some thought and, of course, consult with you before actually doing anything. So, there's quite a lot to be done before we'll take the next step.

I do want to respond to one question which was asked directly about NBAC, and I think it may have been Dr. Bryant, but I apologize if I've associated the question with you incorrectly, as to whether we're going to take on the issues of the health care system, the ethics behind it, and so on and so forth, which obviously is an extremely important issue. The ethical principles on which anybody rations health care is obviously a big issue.

I just want to point out as a matter of

information that in the Executive Order which established our commission, we were asked to take on two issues initially, and those will be the ones that we take on initially.

I can't speak for how the commission will eventually determine its own agenda. One is a broad area of human subject protection, which we had some discussion today. The other is probably even broader area of genetic information, its handling and its status and so on, and, so, those will be the two main areas that we address in the coming year, and I think it's premature for me to speculate much further than that since the commission has had -- our commission has only had one meeting. We'll have our next one in January of '97.

We do, as I understand it, have a broad capacity to choose our own agenda. So, it really will be the commission that will structure that in the next five-six months, and we'll have a better answer to Dr. Bryant's question next year than we do this year.

So, unless there is any other question, we'll just end this part of the meeting. The next part of the meeting, at least for those NBAC members that are present, is the public comment session.

Anyone who wants to is sort of -- certainly welcome to join that, but it's not necessary.

As of a few minutes ago, we had only one person who had requested to speak to us. I don't know if there will be any others. That person is John Cavanaugh O'Keefe.

MR. DANIELS: Yes, I wonder if we'll be able to --

DR. SHAPIRO: Do you want to identify yourself, please?

MR. DANIELS: Yes, I'm Norman Daniels from the United States. As someone who is interested in a lot of the issues that the commissions in different countries are addressing, I would like to just speak on behalf of other researchers in this group who are not seated at your table, to endorse the idea of a Web site in which there would be an opportunity to have access to this information.

This is an opportunity to enable and empower discussion that takes place on a larger scale than what happens in each particular commission, and I think that every commission would benefit from that -- the existence of such a Web site into which perhaps comments and other kinds of remarks from a much larger

group of researchers and interested parties could be addressed.

DR. SHAPIRO: Thank you very much.

Let me now introduce our -- or ask Mr. John Cavanaugh O'Keefe from the American Life League, I believe, who wants to address the members of NBAC.

Just -- I should have mentioned this before Mr. Daniels spoke, but we do have a regulation we use, five minutes is the amount of time we allow each speaker.

Public Comment

MR. O'KEEFE: About two minutes is fine. Thank you very much, Mr. Chairman, and members of the commissions for your attention. Time presses, and I will be brief. I -- I don't mean to give sound bites rather than deliberation, but I -- I'll blame the clock and just push ahead.

In -- in 1961, I stood on a sidewalk by Pennsylvania Avenue at the time of John Kennedy's inauguration and listened to his address, and the magic of that moment still lasts at least for me.

He said that we, Americans, are heirs of a revolutionary belief, "the belief that the rights of man come not from the generosity of the state but from

the hand of God".

It seems frequently that bioethical reflection at least in this country and perhaps around the world requires avoiding religious language, and it seems to me that from -- from Kennedy's perspective, that would be counter-revolutionary, and I wonder if we're back in the business of funding Contras.

I'm troubled that the commission includes physicians, lawyers and academics of many kinds but does not include clergy. Most Americans include input from the clergy, some clergy, at some point in their moral decision-making.

It seems to me fair to say then that this committee does not represent the normal ethical reflection of this nation. Your fierce commitment to cultural sensitivity should perhaps include a sensitivity to American culture.

My criticism is not simply procedural. Pope John Paul II has written two encyclicals or open letters on bioethical issues in the past three years, but I haven't heard any allusion in any way to his thought from anyone here, not just citations but -- but even an awareness of his thought, except from Professor Velasco-Suarez from Mexico.

Please, read the encyclicals. If anybody here on this commission or any other commission wants them, I will get them to you. I'd be glad to do that.

Finally, one of your chief concerns, as you said, is protection of human subjects or the subjects of human research. Please be aware, please remember that many people consider human embryo research to be involuntary destructive human research, carried out on our brothers and sisters.

We consider it to be worse than the abuses in radiation experiments or in Tuskegee. To ignore this view or to skip past it too fast can undermine your credibility on all other issues protecting all other human subjects.

Thank you, Mr. Chairman, for your attention.

DR. SHAPIRO: Thank you very much for your remarks.

Before we break, I do -- did promise someone an announcement, and let me turn now to Dr. Golden who wants to, I think, announce the creation of another commission in Great Britain.

MS. GOLDEN: I hope -- can you hear me? Thank you, Mr. Chairman. Amanda Golden. I'm from the U.K. Office of Science and Technology, and I just

wanted to bring to the attention of participants here that in June, the U.K. Government announced a new advisory commission. This is the Human Genetics Advisory Commission, and to let you know that we hope to be announcing the membership of that commission very shortly, and if people do want to have further information, please do get in touch with me.

DR. SHAPIRO: Thank you very much.

I think we have someone else who would like to address the commission. Just want to introduce yourself, please.

MS. BISHOP: Yes, thank you. My name is Laura Bishop, and I work with the National Reference Center for Bioethics Literature in Washington, D.C.

I just wanted to take this opportunity since you were gathered here from many places around the world to say that your frustration in attempting to obtain information about what other commissions are doing and -- and what topics they're discussing is -- is one that the National Reference Center shares.

We have tried to provide at least a place in the United States where there is information from commissions in the United States and around the world, and, so, if you would think of the library whenever

you are preparing a document or asking for comments or have any other information that you'd like to make available, we do make that available to people doing research, and we have tried very hard to ask for that information, but simply because you don't receive a letter or a request doesn't mean we're not interested.

It takes time to find out what is happening and to make contact with the right person. Sometimes the letters go to anonymous people, and we don't know who to contact. So, please -- please keep that in mind.

And one other comment. Your question about how to ensure diversity and how to ensure comments from groups that might not otherwise be heard from, I know the President's Commission, there was a lot of information contained in -- in the hearings that were not part of the reports, and there certainly was an opportunity for public comment, but a setting like this is not a -- is not a forum that's accessible to many people, and I would echo the -- the request for thinking of creative ways to invite public comment.

Some of them may be -- and I recognize part of it is limited by the need to make comments part of the public record, but bioethics car washes or running

a laundromat or walking the dog in the park would certainly bring a lot of comment from people who might not be prompted to come to a very formal hearing with microphones and people sitting at tables in formal attire.

I don't know how you approach that problem, but thank you.

DR. SHAPIRO: Thank you.

Anyone else like to address the commission that's here this afternoon?

(No response)

DR. SHAPIRO: In that case, thank you all very much.

MR. CHALMERS: Could I just -- before you leave, I suspect that I'm going to speak for all of us in thanking you for the courtesy and for the way in which you've conducted the proceedings today. They've been quite exemplary.

I apologize on behalf of everyone who asked too many questions, but we can be forgiven. So, perhaps may I ask my colleagues to join in the traditional way in thanking you and your committee.

Thank you.

(Applause)

DR. SHAPIRO: Thank you very much.

We are adjourned.

(Whereupon, at 4:58 p.m., the meeting was adjourned.)