Human Genetics Commission, United Kingdom
Philip Webb
Member, Human Genetics Commission

DR. McCABE: Well, good morning, everyone. I hope everybody had a restful evening last night.

We're very pleased this morning to be able to welcome two honored guests from the United Kingdom and Australia. We're delighted that Philip Webb, a member of the U.K. Human Genetics Commission, and David Weisbrot, president of the Australian Law Reform Commission, have journeyed so far to be with us today to tell us about some of the work that their commissions have produced and relevant policy developments in their countries.

We recognize the global nature of the issues we are addressing and how important it is to build bridges between our country and other nations who are grappling with similar questions. These ties can be mutually beneficial, and I'm certain that they will be of great benefit to us to learn from their experiences in an effort to enhance our own endeavors.

After the presentations, we will have a roundtable discussion with our guests which Chris Hook will lead us in.

First, let me introduce Mr. Philip Webb. Mr. Webb is a member of the U.K.'s Human Genetics Commission and the Board of Trustees of the Genetic Interest Group. Mr. Webb has also served as a member of the former U.K. Advisory Committee on Genetic Testing, the ACGT, where he worked on issues associated with genetic tests sold directly to the public, paternity testing, prenatal diagnosis, and preimplantation genetic diagnosis.

In addition to his public service, Mr. Webb currently is a management consultant in the health care industry. His previous professional positions were with AstraZeneca Diagnostics, Glaxo, and Imperial Chemical Industries, where he helped to establish a new genetics diagnostic business.

Mr. Webb, we really do appreciate your being here. Welcome and thank you so much for traveling so far to be here. Please.

MR. WEBB: Well, good morning, everybody, and thank you, Dr. McCabe, for that introduction and your kind invitation to talk to you this morning.

You're absolutely right. There are many similarities between our two committees or commissions, and I'm sure you'll see that in the presentation this morning.

What I'm going to do this morning is to give you an overview of the Human Genetics Commission came about, what it has done so far, how it operates, what its future work plan is, so that you get a good feel for the overall position, and then you'll also see some of the details.

So the Human Genetics Commission was formed in 1999, following on from the Advisory Committee on Genetic Testing, which was the predecessor body which was there for three and a half years, and I was a member of that before the Human Genetics Commission. We've been operating now for three and a half

years and I guess we must have done a reasonable job because we got our mandate renewed for a further three-three term.

We're there to provide the U.K. government with advice on the big picture of human genetics and the advances that are coming down the track and what the implications may be for society. Our brief is particularly to look at the ethical, social, legal, and financial implications as well as the technical.

All of our members are appointed by open advertisement. Ads are placed in the major U.K. newspapers and interviews are conducted with a three-person panel: somebody from the Department of Health, somebody from the Department of Science, and an independent observer. People are chosen on their ability and the fact that they want a balanced commission with different people from different aspects of life, as you've got here on your committee.

One of the first decisions the Human Genetics Commission made was to work in public. We didn't want to be seen to be making decisions behind closed doors. Everything we do is either in public or all of our newspapers and agendas and minutes are all put on our website.

So there's a fine picture of genetic diversity. That's the Human Genetics Commission outside the city hall in Cardiff last month, where we held our last major commission meeting.

The commission is chaired by Baroness Helena Kennedy, who is a member of the House of Lords, and she also is a barrister and a human rights lawyer.

Our vice chair is an interesting person, Sandy McCall Smith. You may have seen recently some books in the bestseller list, one called "Tears of the Giraffe, and another, "The No. 1 Ladies Detective Agency." Alexander McCall Smith is a bestselling author. He's also a professor of medical law at Edinburgh University.

The rest of our commission is made up of a mixture of scientists, clinicians, researchers, and we have somebody from GlaxoSmithKline sitting on our commission to give us the commercial perspective. We also have lay people, consumer issues, lawyers, ethics, and we also have representatives from the chief medical officers of the four countries of the U.K. So they all have input there, what you would call ex officio members, and we have the chair of the Human Fertilization and Embryology Authority that regulates all assisted reproduction technologies in the U.K.

So our remit is to advise health and science ministers on issues of human genetics and the advances, and how those advances may impact society and health care in the future.

Part of our remit is to engage with the public and we think that's very important. We like to get the public views. It's not just a matter of us educating the public. The public can educate us and we very much want to hear their views.

We do also have a remit to look ahead because government doesn't want to be caught on the back foot as it was over GM crops. That caught U.K. government ministers in a difficult position. They weren't prepared for it, and so they want us to ensure that we're thinking ahead of the game and we're giving them good advice in good time.

So what have we done so far? Well, the first thing we've done is to produce a report called "Inside Information," and that report is on the storage, protection, and use of personal genetic data. I was going to bring six copies with me, but when I realized how heavy it was, I just decided to bring the one, which I

will leave with you. It runs to 182 pages. If you can't manage that, we've put a small version together which is 32 pages, half-size, but in that there are something like 38 recommendations, and I'll tell you a little bit more about that in just a second.

The second one, "Genes Direct," is about the offering of genetic testing services direct to the public. That's a review that I chaired, and I'll tell you more about that as well in a few minutes.

The MORI survey. We felt it very important early on to get a feel for what the public were concerned about and what their thoughts were about the new genetics. So had a survey done of 2,000 members of the public and we had some very interesting feedback from that which helped us greatly to understand the concerns of the U.K. public.

The way we work is that we agree a work plan with government ministers. So one of the first things we did was put together our ideas of what we thought was important to give ministers advice on. So we have a rolling work plan. We just agreed a new work plan with ministers so we're clear on what it is we're going to be working on over the next two years, but we also have to have some capacity left in case we need to work in a reactive manner as well.

But we work through subgroups because with a commission of 18 members -- I'm sure you're aware of this yourselves -- it's very difficult to get actually to conclusions and get works done. So the Genetic Services Subgroup is the largest subgroup and it's the one that I chair. It looks at everything to do with genetic services in the U.K.

The consultative panel that we have is made up of people affected directly or indirectly by a genetic disorder, and we value that group because they have firsthand experience and can help us to really understand better what the issues are for them.

The sort of meetings we have are twofold. We have information gathering sessions, which are perhaps similar to what we saw here yesterday, where people come and make presentations. Then we have our public, what we would plenary, meetings, where the business side of the commission's work takes place in public and where we make decisions and carry on with work.

We are also charged with advising the government on whether its regulatory frameworks are right. So we could decide that the Human Genetics Commission is no longer required, but I think we've got plenty of work to be going on with for the time being, so we won't be doing that just yet.

This dialogue that I mentioned earlier with the public, the picture you see there is one of our members, Professor John Burn, engaging with a group of 17-year-olds who are all studying science before going on to university. This was at one of our meetings in Birmingham, and we are keen to get the views of young people because they're not necessarily going to be easy to get their views if we do surveys and ask questions. They not necessarily very forthcoming. So we wanted to get a group of them together and really tease out what they think about genetics and what they think are the important issues.

We are keen to ensure that the public engages with us and as often as we can, around our meetings, we want to get the feel for what the people want us to be looking at, and that helps to form our work plan as well, but we recognize that that takes time and money to get it right.

Our consultative panel. We now have over 100 people who are volunteers who have decided that they would like to help us with our work, and we value their experience because they either are personally suffering from a genetic condition or a member of their family is, and they can give us real input about

what the issues are, particularly about genetic services and how the health care system is looking after them.

So we ask them to comment on our draft reports, on our work plan, and they work mainly by correspondence, but when they first of all came on board, we had an introductory meeting which many of them attended, but we are cognizant of the fact that many of these people do find it difficult to travel, because of their disabilities in some cases, and therefore we work largely by email and correspondence. But we do value those people and their comments and that's very useful to us.

One of the issues that came out of our MORI survey was that the public were very concerned about the use by insurance companies of genetic testing information. Now, when we reviewed this in detail, we put a recommendation to the government that there ought to be a moratorium on the use of genetic testing while we look at it in more detail and see how it should be handled in the future. So there is currently a five-year moratorium in place where insurance companies have agreed that they won't look for genetic information on any policy less than 500,000 pounds in value.

We're talking here about life insurance. I know over here health insurance is a much bigger issue, but because of our National Health Service, we don't have that as an issue, but believe me. We have life insurance as an issue because many of these policies are linked to house purchase and mortgages.

So what we've agreed to do is during that moratorium period, do further work and research to advise government on what we think ought to be in place after that moratorium.

One of the things we want to do is to look at family history because family history, one could argue, is genetic information. That's why they want it. They ask you questions like "Have either your mother or father died of any of the following diseases and at what age?" That is very often genetic information. So that's what we're doing on genetics and insurance.

Now, the report that I showed you, "Inside Information," that was a piece of work that took us about 15 months to produce. It's a report that was sent to ministers in May, 2002. There was a lot of interest in it. We carried out a big consultation exercise. We had a document called "Whose Hands on Your Genes?," which caught people's imagination, and we had a tremendous response from groups and members of the public who wanted to give us their opinions, and they were very useful to us.

We had a number of public meetings and this was the first time we'd used our consultative panel to make sure that the things that we were thinking about were the things that were important to them and they were very helpful in guiding us in that.

Now, we came up with a set of general principles, and we were trying to get a balance between respect for persons and privacy of the individual against the common interest that we all have in advancing genetic science and health care. So we drew up a set of principles in that report based on the overarching idea that there should be respect for individuals and those individuals should be entitled to genetic privacy. We don't think anybody should have their genetic information obtained without their consent.

I remember when your ex-President Bill Clinton came over to one of our quaint little English pubs and drank some of our wonderful warm beer, but after he finished, one of the big guys in black coats came and took the glass and put it under his coat. He didn't want anybody testing Bill Clinton's DNA. I can't imagine why.

(Laughter.)

MR. WEBB: But that's something we think is important, though, that people shouldn't take others' DNA and have it tested without their consent, and we have seen examples of that.

Obviously, personal genetic information can be extremely sensitive, and therefore should be treated with the utmost confidentiality, and we, like we heard from you yesterday, think that discrimination should not be based on people's genomes.

So our key recommendations -- there were 38, but I'm not going to bore you will all 38 of those now. The key one was that there should be a new criminal offense to prevent people deceitfully obtaining your DNA and testing it and publishing results of it.

That came to light in the case of Steve Bing, who had allegedly had an affair with Liz Hurley and produced a child, and somebody rummaged in his trash can and got his dental floss and tested his DNA and showed that he was the father of Liz Hurley's child. So that is the sort of thing that we're trying to avoid in the future.

We think that there may be a need for separate U.K. legislation to prevent genetic discrimination. We heard here yesterday about what's happening here in the U.S. and that was very interesting to hear, and we have recommended to the government that they should be looking at something along those lines in the U.K. We've also recommended that we need to be careful of that balance between the individual's rights and the general interest of society.

Now, genetic discrimination can come in all sorts of areas, in employment, in insurance, in education, and in health care, which is a particular issue here. What our public poll showed was that genetics and insurance provoked a really strong negative reaction with a large majority of people disagreeing with the insurance companies using our genetic information to raise their premiums, but we did note that it was a major concern among the public, and hence our moratorium.

Now, very recently, the U.K. government has produced a white paper on genetics. Now, a white paper in government terms is a statement of policy of what it intends to do, and this policy statement is about realizing the value of genetic advances through our National Health Service. Additionally, 50 million pounds additional money has been put into clinical labs, training of staff, getting more people up to speed with genetics and understanding the importance of it in medicine and health care.

This white paper was produced by the government. The forward was by our Prime Minister, Tony Blair, and he recognized the importance of the Human Genetics Commission in ensuring public debate and advice to the government.

So the government's response to our first report, "Inside Information." The government has committed to developing the new offense that we recommended. That's fairly important for us, for our credibility and for the public seeing that government does take notice of what we do, and not only are they going to produce a new statute in that respect, they are going to consider the evidence for legislation on unfair discrimination and how to deal with that. They welcome our input to the debate and in developing policies for the insurance industry and they have committed to publishing a revised code of practice on patient confidentiality, which is another of the recommendations we put forward.

For those of you not familiar with the U.K. Biobank, that is a project being funded by the U.K. Department of Health, the Wellcome Trust, and the U.K. Medical Research Council to take 500,000 DNA samples from individuals between the ages of 45 and 69 to try and work out what links there are between various genes and certain health disorders.

Now, we suggested that that U.K. Biobank needed to be completely separate from anything that the police wanted to use for the DNA database, and the government has accepted that the police would only ever have access to any research database in very exceptional circumstances.

Now, the "Genes Direct" report, this was the review that I chaired looking at over-the-counter, as we would call it, direct genetic testing without the involvement of medical practitioners. We think that that's likely to increase. As I think you said in your debate yesterday, with faster, cheaper technologies and more and more genetic tests becoming available, it's likely to become a big issue.

We already know that a lot of testing is being offered over the Internet and we've even seen it in the U.K. in the High Street, people offering genetic tests to test your genes to tell you what your personal diet ought to be. Well, I'm not aware of the links between genes and diet and the interactions between those two as being well-proven science at this stage.

However, as you said yesterday, people increasingly want to take control of their own health care and not necessarily always to go through physicians and the traditional health care system. So we're trying to balance those two things, but we did find that in our consultation a great number of people were concerned that vulnerable people should have some protection from overzealous commercial organizations trying to sell them whatever genetic tests have come out this week.

So our key recommendations were that we didn't think there ought to be a ban on direct-to-consumer genetic testing, but we think there ought to be stricter controls on it.

Predictive genetic tests, where it comes to taking samples at home or even testing samples at home, we think there could be a serious problem there, and that comes back to this taking DNA and testing it without consent because if it is done at home, how does the lab know where that DNA has come from and whether or not there is informed consent? It's very easy to tick an Internet box, but it doesn't really tell you whether that person is, A, informed, or B, has consented.

So we think that most genetic tests should still be carried out in the context of the medical referral system and there should, in the U.K., be a well-resourced National Health Service Genetics Service that can properly manage and allow access to the latest tests and technologies. The white paper has confirmed that that will be the case.

How would that be carried out in practice? Well, the MHRA is the Medicines and Healthcare Products Regulatory Agency. It's the equivalent of your FDA. It was only formed in April of this year by the coming together of two former bodies, the Medicines Control Agency that controlled pharmaceutical products and the Medical Devices Agency that controlled devices and diagnostics. So those two have now come together and we think that the formation of that body is an opportunity to further develop the regulatory system for genetic tests, and we have asked them to do that.

There's been a lot of debate in the U.K. about human tissues and the storage of organs taken without people's consent. You know, they've found huge numbers of organs stored in hospitals that were taken 20 and 30 years without people's consent, and that's become a big issue. So there is going to be an organization called the Human Tissue Authority that regulates the taking and storage of human tissues in the future. That may have a role to play in the taking and storage of DNA which, after all, is a prime human tissue.

We're also concerned about the Internet and we want to ensure that people are educated or at least they know where there is a reliable source of information, and we think our website, that I'll give you details of

later, could be a reliable, independent source where people can find out information about genetics and genetic tests and what they ought to be aware of and what they ought to be looking for before going ahead and having a test.

So what about our future work? Well, our work plan covers genetics and discrimination. We need to have, in good time, advice to government on what ought to be the next steps when the moratorium on genetics and insurance runs out.

The main piece of work in 2004 is going to be on genetics and reproductive choice. Now, that is sure to be a hot topic conversation, and we know already that there are strong views on one side and strong views on the other and a big gap in the middle. It's going to be quite a challenge to produce a report and recommendations that will be signed off by the commission as a whole, but it's going to be an interesting piece of work.

I'm chairing a review into paternity testing and that's even going to cover genealogy testing as well. It's starting off as a short review, but I have a horrible feeling that it will take a little longer than some people think. But we're just in the process of producing a consultation document which will go out to groups and individuals who we know have an interest in those subjects and we will get some public debate going as to what the issues are. We have concerns about men testing children without the mother's consent or even knowledge, and we also, on the reverse side, have concerns about mothers testing other men who aren't necessarily the perceived father of the child without his consent. So there are a whole number of issues that we need to look at there and come up with some recommendations.

One of the other things that we've been asked to do in that genetics white paper by the government is to work with the National Screening Committee, which is another body that controls all national screening programs in the U.K. We've been asked to work with them to look at is there a case for offering genetic profiling of every child at birth? So we will be starting that piece of work in the next few months.

Then we have the ongoing of the monitoring of all of the things that we are keeping a close eye on, such as discrimination, gene patents, and those sort of things, and engaging the public.

Just before I finish, the genetics and reproductive choice, it has been identified as a key piece of work that we ought to do. Ministers do want advice on it. Every week in the newspapers, they use the words "eugenics" and "designer babies," and this does create a lot of concern for the public.

So we do want to come up with some advice in this area to how things ought to be carried out because there are new technologies, there are commercial interests driving more screening, and we all know about the gene chips, where it may soon be possible to test a child at birth for every gene that's known.

We need to work with others, such as our Human Fertilization and Embryology Authority and the National Screening Committee, but you'll see from that pie chart there that when the question was asked what people think about the use of genetics to decide whether or not parents ought to make decisions about the birth of children, 57 percent agreed that that was a reasonable thing to do, 26 percent thought it was unreasonable, and 16 percent were neither strongly for or strongly against. But it just shows how the opinion is split.

So then in summary, the Human Genetics Commission is a well-established, well-respected body that has produced some key reports that government has acted on. Our role is to advise government and we are doing this by producing those reports, which are getting attention. We are promoting and participating regularly, weekly, in public debate. We are working in a very open, transparent manner, and we hope you

will all take the trouble to have a look at our website and I'm sure you'll find some interesting things on there. We want to work with others to seek socially sustainable policies.

Thank you for your attention.

(Applause.)

DR. McCABE: Well, thank you very much, Mr. Webb. I think we'll forgo with any discussion at this time and leave that to the roundtable.