

*Australian Law Reform Commission*  
**David Weisbrot, J.D.**  
**President, Australian Law Reform Commission**

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DR. McCABE: I'm now extremely pleased to introduce Professor David Weisbrot, who is president of the Australian Law Reform Commission, where he is currently involved in an examination of gene patenting and human health issues and the protection of human genetic information.

Professor Weisbrot's past professional experiences included dean of law at the University of Sydney, foundation pro vice chancellor of the College of Humanities and Social Sciences, a commissioner of the New South Wales Law Reform Commission, and a member of the law faculties of the University of New South Wales and the University of Papua and New Guinea.

Professor Weisbrot is admitted to practice law in California and New South Wales and earned a law degree from the University of California, Los Angeles.

So it's a pleasure to welcome another Bruin to the podium today. Thank you very much for traveling so far.

MR. WEISBROT: Thank you. It's a pleasure to have been invited to speak. We've been admirers of the work of your predecessor committee and very pleased that the committee has been reestablished in this forum to do ongoing work.

I apologize for not being here yesterday. I really would have liked to have been, but I was sitting actually in Ed McCabe's chair at a similar sort of forum in Australia, and then had to make a made dash to the airport. I said something I never thought I would say in my life to a cab driver, which is "Do you think you could drive a little bit faster?"

(Laughter.)

MR. WEISBROT: And fortunately, have made it here.

As the introduction said, we completed a major review of the protection of human genetic information in Australia just over a two-year period. It was a joint reference, one to the Australian Law Reform Commission, of which I'm president. It's essentially the federal government's legal think tank on big picture issues. We get project work from the Attorney General and there are things that require detailed research and a high degree of public consultation and public engagement, and then we provide recommendations to the government afterwards. We've been in existence for about 28 years now.

We did this in partnership with -- and as it happened, it was a very personally and professionally productive partnership -- the Australian Health Ethics Committee, which is a principal committee of our NHMRC, the National Health and Medical Research Council, which is more or less the equivalent of your NIH.

The inquiry said "The Protection of Human Genetic Information" in lawyer, bureaucrat, ability. It had three pages, I think, of terms of reference. They really boil down to three very simple propositions.

That is, in relation to human genetic information and the samples from which that information is derived, how in Australia do we best protect privacy and how do we protect against unfair discrimination. I've got that italicized because it is a tautological concept. We do allow many distinctions lawfully to be drawn among individuals and there are others we decide are invidious ones.

Then finally, how do we ensure the highest possible ethical standards, and although to a lawyer ethics essentially means the things that we impose on doctors and researchers, it was useful to have the Australian Health Ethics Committee remind us that that ethical dimension had to carry into all of the other areas we looked at as well, including law enforcement, insurance, and a whole range of other activities.

When we started, I don't think we realized the breadth and scope of the inquiry. We did have to go back to the government and say we needed a little bit more time. Well, partly that was because of the very high level of public engagement and we wanted to give people a meaningful opportunity to participate.

But going down the left side, you can see the things that were in the medical/health camp, and those are the things in blue I'll predominately be talking about this morning that I've been asked to speak about.

So we looked at issues of oversight of medical research, and that's primarily the Health Ethics Committee's role. We looked at issues of clinical genetic practice, at systemic health care issues, and at the emerging large numbers of genetic databases, tissue banks, and registers, because as we came to see, almost every collection of medical things, of tissue, blood, and almost anything else, can be systematized into a genetic database.

One thing, for example, is that every child in Australia who has been born since 1960 or so has been subject to a Guthrie test. I think you probably have the same thing here -- that's not real blood -- and these are all over, literally, Australia. They're stuffed in filing cabinets in pretty much every hospital where children are born. It's only now that we realize that there is in fact an unsystematized or an unorganized national genetic database and some real issues about how that's to be treated. Of course, issues about genetic privacy in relation to cancer blocks, blood and pathology labs, and whole range of related issues. I'll talk a little bit more about that in a moment.

Going down the other side are things I won't spend much time on here. You probably will talk about them at other parts of this conference or in the future, but we looked at issues of employment discrimination, where genetic testing can be an issue. We don't have major problems in this area at the moment, but that's not to say that there won't be significant problems in the near future.

It seems that every Australian has seen the film "Gattaca," in which we have a highly geneticized future, children are tested at birth, streamed into different occupations, and streamed out of others. We actually had to show the film to our staff because they kept hearing about it at every meeting that they went to. That's the sort of future, of course, we want to desperately avoid.

We did also look and spend quite a bit of time on the area of insurance. As in the U.K., this is primarily in relation to life insurance. We don't have a problem in relation to health insurance, essentially, because we also have a comprehensive medical system that covers almost all the things that people want. You can also get private top-up insurance, but even that is community-rated in Australia, so you just choose from a menu of services whether you want to include dental, whether you want to include visits to the gym and shiatsu or whatever, and you get your price. It is not individual risk-rated.

So the key issue for us was simply life insurance, and we don't in Australia tie mortgages to life insurance either. The property in Australia is secured by the title to the property. So it's a lesser-order issue, but nevertheless quite an emotional one, and so we did spend quite a deal of time on that.

We took different approaches in relation to employment and insurance, I should say. In the employment area, our recommendations are highly interventionist. Essentially, we said genetic testing should not be a feature of employment decisionmaking, with some rare exceptions, and those are exceptions where you can show that there's a very clear occupational health and safety reason -- if you're running a beryllium mine -- and there won't be many of those examples because everybody keeps using the beryllium mine example. So there's not likely to be many, many others.

Or if it's a circumstance in which you're putting lives at risk. So it may be that for professional pilots, you have slightly more of a reason to look at genetic testing if there's a rational scientific basis to do so, but basically we said don't do it in that context.

In the insurance area, where it's essentially based around the interchange of information and actuarial practice requires accurate and material data, we were a little bit more open to the idea that it should continue to be used. We also had some empirical studies done of the insurance industry which they were cooperative in and found that over the last two years, there were only about 100 applications a year that contained genetic test information. So it is still not a major feature. In fact, it's hardly a feature at all in actuarial decision making.

However, family medical history, of course, is a feature in almost every application. So we actually focused a bit more of our attention on trying to get the industry to deal intelligently with family medical history, not to overreact to labels, not to overreact to information, to try to get actuaries that are trained in genetics, so that they're assimilating the latest medical and scientific knowledge, rather than relying on what they might have studied many years before in first-year biology before they did their actuarial studies.

We also spent quite a lot of time looking at law enforcement because, of course, now genetic testing is a standard feature of all metropolitan police forces. That was driven home, I think, to the Australian public recently in relation to the Bali terrorist disaster in which nearly 100 Australians died. Most of those people were identified positively by genetic tests because there was no other effective means of identification, similar to the World Trade Center disaster here.

There are real problems in law enforcement in Australia in terms of harmonization of laws. We have nine different police forces, six state and two territory, and federal. They all have different rules and regulations relating to genetic testing. They essentially operate in two different planes.

There are the ones that rely on recommendations that came out of a major task force in Australia, and those only collect DNA in serious crimes. They only store it as necessary. If someone is acquitted or charges are dropped, their DNA profile is destroyed. So it's, you might say, the civil libertarian model of collection.

On the other side, we have the states in the Deep North, which is the equivalent of your Deep South, as you'll appreciate from the geography, and those places want to collect everybody's DNA for every reason and keep it in perpetuity. The only exception they make are for other police officers because there have been some industrial issues. One of the few employment disputes we've had has been in relation to police officers who have been asked to provide a sample because they're investigators and there's a possibility of their DNA being intermixed in crime scene samples. There have been a couple of threats of industrial

action and the authorities in the various jurisdictions have backed down from asking the police to provide compulsory samples.

We also look at issues of kinship and identity, a broad grab bag of some very different but complex issues. The extent to which genetic testing might be used in immigration, for example. It is used now sometimes for identity. So our immigration authorities tell us, using their soft voice, that sometimes there are people who come from countries where there aren't good records and they want to show that they are related to an Australian who's sponsoring their application for immigration, and this will give them an opportunity affirmatively to establish that they are the parent, son, or daughter of the person who holds Australian citizenship and can sponsor them.

They don't do health testing, predictive health testing, at the moment. That could come in the future. At the moment, they tell us it's tough enough just to do sort of TB testing around the world on people who are applying. But it's something we've asked them to look at in much more detail and to come up with protocols on.

Parentage testing, paternity testing, is something we didn't think would be a big issue in the inquiry. It turned out to be a very big issue. There are a lot of very angry dads in Australia, it seems, or putative dads. So I would say the bulk of the submissions we received were in that area. They were all very angry ones. They usually started off with a denunciation of the Australian Law Reform Commission for no particular reason other than we were government or people who had some authority. Then it proceeded into stories about how this an area in which men are again being disadvantaged by the state and by our family court.

There's a lot of advertising going on around that now. That's something I'll talk a little bit more about in a moment, but almost any doctor's or surgery office has these kind of things in it and they're all over the place. "Are You My Daddy?" In fact, our experience is little children never ask that question, but angry dads certainly do.

We also made recommendations that were disappointing to those groups because we said we didn't think that surreptitious testing should be allowed in those circumstances, non-consensual testing, without an order of the relevant court.

We looked at issues of Aboriginality with the most sensitive concerns. It was an area where, when we did our original brainstorming, we said what would happen if somebody denied or challenged someone else's right to describe themselves as an indigenous person of Australia, an Aboriginal person? Would genetic test come up? We thought, well, fortunately, we don't have to deal with that question.

About mid-inquiry, there was an election of ATSIC, the Aboriginal and Torres Strait Islander Commission, which is our vehicle for self-determination of indigenous peoples, and one activist in Tasmania challenged the ability of 800 people in Tasmania to be on the roll of electors. He said, "I know you. You're not Aboriginal."

A lot of those people came forward with genetic tests that said, "Here's a document from the 1800s that shows this is an Aboriginal person. Here's the chain. Here's how I fit into that family."

Very, very difficult issues, but real-life ones at the moment. In the end, we didn't make positive recommendations in that, other than to say it was primarily a matter for Aboriginal people to determine as a matter of self-determination and we provided a lot of history and comparative data, and also some of the

guidelines on how the law currently operates, but we didn't feel we had done the proper consultation with Aboriginal communities to make positive recommendations in that area.

Then we looked at a grab bag of other services and entitlements. We had some people come forward to us to say that they were not allowed into government job retraining schemes because they had predictive health information that indicated that they would not be good candidates for that in the views of the government. People from Huntington's families, for example. We had people raise with us the issue of whether the education system might ever debar students from coming into schools or certain schools because they shared a predisposition to ADHD. People were concerned about nursing homes using testing for early-onset Alzheimer's.

We had issues already in sport. The State of Victoria's Boxing Council has been talking about the idea of having professional boxers genetically tested before they would issue a license to see if they had the marker for punch-drunk syndrome. It's not clear whether you would need it or not have it to get the license. But they're starting to talk about those issues, and you may have read in the paper that the Australian Institute of Sport, which is a very high tech operation in Canberra, has now identified the genetic markers that are found in 95 percent of the world's elite sprinters. It's fast-twitch muscle fiber.

So we have talked to them about whether there is any ethical dimension in there or whether they're talking about gene "therapy" as the next doping issue in world sport, or whether they will do the "Gattaca" thing and say to the promising young sprinter, you're winning all your age groups, you're the best young sprinter in Australia, but your genetic marker is just not showing it, so why should we invest hundreds of thousands of dollars in your development?

Sport is like religion in Australia. In fact, much more important, and so this is an issue that we looked at in some detail. I have to say that I'm pleased that the Australian Institute of Sport, which hadn't been looking at the ethical dimension overmuch, is now starting to take that very seriously.

The inquiry processes I think were very important in shaping how our ultimate recommendations were found. The commission itself consists of a few of us lawyers and judges and we have ultimate responsibility, legally and morally, for the report and the recommendations, but our standard modus operandi is to set up an expert advisory committee, a steering group, for every project that we do.

In this one, we included some of Australia's leading genetic researchers, people who have been talked about as potential Nobel Prize winners. We had people who headed up clinical genetic testing services, bioethicists, health consumers, indigenous health consultants, the head of state and territory public health systems, actuaries, privacy discrimination commissioners, and so on. Lawyers, human rights lawyers, forensic scientists. It was to make sure we were being steered in the right direction and we gave the proper weight to the different issues.

We engaged in the usual extensive literature review, which took us to the work that SACGT did previously, and also of course we were heavily reliant on some of the groundbreaking work that the U.K. Human Genetics Commission has done.

We produced two consultation documents which were in heavy demand -- those are just the acronyms for them -- and issues paper and a discussion paper, and that was to help the public work through these issues in stages and to help us work through in stages.

We conducted 15 major public forums around Australia. They were in all of the capital cities and most of the major regional centers. They were quite well attended. They got a lot of media coverage, which also helped the attendance at these things.

We received more than 300 written submissions, and these ranged from the big, well-researched, computer-produced ones that you'd expect from the Australian Medical Association, the insurance lobby, the employers groups, the major cancer research labs, and so on, but most of them were individual heartfelt letters from people saying, "This is what we're going through. We have a child who has this genetic condition. We don't want other families to have to go through this same sort of thing in the future." They were very, very important. Many of them were very moving.

The 300 is probably a very conservative figure. We have some people who wrote to us every day for two years and they continue to do so. We counted those as one continuous submission.

We also had over 200 targeted meetings. These were with genetic support groups, clinical geneticists, GPs, rotary clubs, anybody who wanted to talk to us either to get information from us or to provide information to us about the issues. So it was a pretty thorough national process.

The final report that we lodged in this inquiry we called "Essentially Yours," and it is meant to be kind of a double entendre. On the one hand, we argue very strongly against ideas of genetic essentialism. That is, how people should be dealt with is simply by a reading of their genetic code. On the other hand, we talked about it being essentially up to the person to control their own genetic information and genetic destiny.

The report was launched by the Attorney General and the Minister for Health in our federal Parliament in May, 2000. It again received quite a bit of media coverage.

Given the breadth of subject areas I talked about earlier, you'll appreciate that we had 144 recommendations, but these were not all -- in fact, maybe not even primarily -- directed to government, and I think it's a complexity of the modern world that ensured that we had to make recommendations directed at all layers of government -- federal, state, and territory -- but we also made recommendations aimed at regulators; at educators because we found that our Australian doctors are not terrifically skilled up in genetic issues, and we heard that consistently from people in the public forums; we talked more generally about health professionals, genetic counselors, and others; and then recommendations directed at insurers, employers, law enforcement agencies, and all of those I talked about before.

I've been delighted to keep verbalizing, as we say in Australia, Dr. Francis Collins, who, when he spoke at the International Genetics Congress in Melbourne just a month or two ago, talked about this report as "a truly phenomenal job, placing Australia ahead of what the rest of the world is doing." We thought that was very nice of him to say and we hope it's accurate.

Our recommendations are not self-executing, of course. We're an advisory body. However, we're fairly optimistic. We have a very good track record of having our advice turned into action, whether that's legislation or administrative or other action.

You can see there that about 58 percent of our recommendations are implemented. Most of them get in. There are another 22 percent that are partially implemented. The nil implementation block we hope will continue to narrow because that includes three or four of the most recent reports, including "Essentially Yours," that the government and others are still working through. So there's a only a small proportion of cases where government actually rejects our advice or puts it in the too hard basket.

In our public process, we found, not surprisingly, the same sort of things that American and European commentators have talked about, and that was a real ambivalence about genetics. On the one hand, there was tremendous optimism, maybe even overoptimism, about the medical breakthroughs. So there's not a day goes by where the Australian media now don't have some story about a remarkable so-called discovery of a so-called gene for something and that that's going to lead to tremendous clinical breakthroughs either in gene therapy or smart drugs or one of those sorts of things.

Almost all of those, when you track them back, of course, come from the pharmaceutical company or from the lab that's doing it, and there are good reasons for them to do that in terms of getting funding and so on, but it also maybe creates a little bit of overoptimism in the community, or at least not a sense of how far away we are still from some of these therapies. On the other hand, there are some remarkable breakthroughs happening every day.

On the other side, there is this still kind of a gut anxiety about loss of control. So we had people talked to us about is this more mad science? Is it possible for us to regulate? There are people in the indigenous community and other communities who have fears about eugenics.

I remember one meeting in which we talked about a Tay-Sachs screening program in the Jewish school system in Sydney and Melbourne, and a woman came up to me afterwards and said, "My grandchildren have been tested in one of these schools and I guess it's okay. I think it's probably important. I do have some serious reservations, though," and she paused a moment and pulled up her sleeve and showed her number from the concentration camp, and I didn't have to ask her why she had some lingering concerns about that.

There are interesting fears about commercialization, too. Again, there's a gut instinct. I notice that the latest John Le Carre novel, now that the old evil empire has fallen, is about big pharmaceuticals. You know, is this the new evil empire?

We found that, continuously in meetings, it was at almost every meeting we had that there would be somebody who would get up and make an impassioned plea and say, "I'm a good citizen. I'm happy to give my genetic material to research to help find cures for Parkinson's disease and diabetes and so on, but I don't want those big drug companies making a profit on it," and especially those big American drug companies." The Swiss and French and other ones seem to be getting off fairly lightly, but there was a real fear -- again, a gut fear -- and particularly of genetic material being taken out of Australia, taken offshore, where there might be lesser controls or at least an inability to track what was being done with it.

The data is interesting, though, in that all of our public opinion surveys show that Australians have not -- and we hope won't have to say not yet -- lost faith in the possibility of effective regulation of biotech in the public interest. If you look at some of the surveys in Europe, they're fairly dismal, and maybe for good reason. We haven't had in Australia Chernobyl and foot and mouth disease and mad cow disease and so on, and areas where public authorities have shown themselves singularly unable to cope or unable to show how they're coping. So Australians still are exhibiting some good will and openness in this area.

A threshold issue for the commission, of course, was is genetic information exceptional? Do we have to come up with whole new regimes, a genetic privacy law, a genetic discrimination law, and other kinds of qualitatively different protections? We went through the usual litany. In this group, I think I need not talk about all of those issues in any detail at all.

But our conclusion was we need to recognize the special features and challenges of genetic information, but not to embrace genetic exceptionalism as a guiding principle for public policymaking. I think we've

moved through, in the world that's thinking about these issues, the cycle of first the future shock and being struck by the new genetics and the need to regulate heavily to deal with it and then more to an inclusivist approach which says, well, we've already developed all kinds of sound principle and practice in relation to other challenges to our public health system -- HIV and others -- and really we can just build upon that and then deal with the different features of genetic information.

This is something we use to explain to the public, I think, more about the process than I need to talk about here, but it's a scientist looking at the 3 billion piece puzzle and the one on the right saying, "I think I found a corner piece." So this is trying to say don't rush too far ahead in thinking where we are with the science, although it is moving remarkably quickly.

I guess, partly in our esteem for the U.K. Human Genetics Commission and other similar bodies, our central recommendation in "Essentially Yours" was that we needed to something similar in Australia and we recommended the establishment of a Human Genetics Commission of Australia. Again, this is recognizing the rapid pace of change and the need for a continuing independent, authoritative voice that could talk to government, that could talk to the public, and so on. So in order to keep that level of public content up, so that people thought we're not being lied to, there are people who are giving us the cutting edge information, and it's open process, we needed to establish this sort of body.

We have had since quite a lot of groups come to us -- genetic support groups, scientists, and others -- and say there's almost a post-review depression in the community. When you were operating, when the Law Reform Commission inquiry was going for two years, we had somebody to come and talk to and share all these ideas and concerns, and now that you've stopped, we've got nobody to talk to. So I think it is important for our government to move quickly to establish a Human Genetics Commission to be able to capture the concerns, the ideas, and so on.

As with the U.K. commission, we recommended broad-based membership. So on the one hand, we need people who understand the cutting edge science. On the other hand, we need also the ELSI dimension, the people who understand the ethical, legal, and social implications, and of course, people from affected communities, and that idea about providing a national forum.

We assign some specific responsibilities to the HGCA. One is in the insurance and employment areas, to keep a watch and brief over that, and to provide high-level advice to those industries. The other I'll talk about more in a moment, which is looking at genetic tests in terms of access and equity.

I was asked to talk particularly about our approach to regulating access, and so the next bunch of slides deal with that. One role we assigned to the HGCA was to identify certain sensitive genetic tests that might require restricted access and counseling, and to advise our regulator, which is the Therapeutic Goods Administration, kind of the equivalent of the FDA, accordingly.

We used an analogy with the approach to HIV/AIDS testing. In Australia, this testing can only be done at certain public hospitals that do a lot of the testing, so they have the highest possible quality assurance and analytical regimes, and they are also very, very sensitive to issues of privacy and non-stigmatization, and they also are very good on counseling. So if you limit the number of suppliers of the testing, you can also ensure that the counseling regime is appropriate.

The technology exists, of course, to have an AIDS test kit in every doctor's office, but the Therapeutic Goods Administration, on advice from our public health system, has restricted access, and we've said there may be some genetic tests that are in that category, that people really shouldn't have them without the ability to have the appropriate counseling and other kinds of infrastructure in place.



On the other hand, there are going to be other genetic tests that are really just replacing other kinds of biochemical tests, and if it's just another generation, if it's a test that used, for example, for hemochromatosis, rather than a liver biopsy, well, then maybe you don't need to go through a whole lot of that process. But there are going to be some that do have that extra sensitivity.

We also ask the HGCA to look at request pathways. That is, in Australia, to say who can order a genetic test. Should general practitioners be able to order every one? Should some only be orderable by clinical genetic specialists? If they are ordered, should that trigger some sort of counseling thing on a computer? Should they be rebatable through Medicare, which is our comprehensive national health scheme similar to the NHS in the UK? So those are issues we asked the HGCA to look at.

We also looked at the lab side and said that any DNA testing for health purposes where there's a reportable result should only be done by accredited labs that have been accredited specifically to do that sort of genetic testing. So wanted to raise both the quality assurance side there and also to make sure that those labs had the appropriate ethical regime and also were sensitive to the appropriate counseling needs.

On the regulating illicit testing side, from remarks that were made earlier, I take it that you looked at this yesterday, but we predicted the obvious, that as the technology increases and improves, that there will be increasing availability and decreased cost. There will be a lot of direct marketing. There are financial and other incentives for people to, or think they need to, have genetic testing done.

So we predicted increasing pressures for, for example, non-court, non-consensual paternity testing. That's already evident in Australia. As I showed you, there are leaflets available. There are ads on late night television in similar terms and they usually involve do-it-yourself buccal swabs, which you then put in a little plastic bag and send offshore because Australian labs, by and large, won't do their testing now on that basis.

We were concerned about surveillance testing of partners and children because there already are groups that market non-genetic tests in those areas. You know, we can tell you whether your children are taking drugs or are there going to be the equivalent of those genetic tests?

Then we were concerned about the illicit testing that Philip talked about earlier. Will journalists and private investigators try to get Nicole Kidman's DNA for a front page story? Why is Russell Crowe so angry? You know, he's got the gene for anger.

Then on the more serious side, will we have employers doing that kind of illicit testing that we saw in the case here, the Burlington Railway case handled by the Equal Employment Opportunity Commission.

We also followed England in recommending the creation of a new criminal offense, and I should say I spent 30 years in law reform trying to avoid the use of criminal law in regulating most areas, but we thought this was serious enough and compelling enough that we would create an offense in very similar terms. That is, knowingly or recklessly -- recklessly is advertent to the consequences, but not really caring about them -- submitting another person's genetic material for testing without their consent or without other lawful authority. So a court can order a paternity test, even if the person doesn't want it, the police have statutory authority to take DNA in certain circumstances, and so on.

There are also questions about regulating curiosity, in a way. We thought that there is probably going to be more and more of these "genetic health" test kits available. One of the most famous is Sciona's test, the Philip Smiley, and they were marketing these through the Body Shop until very recently. I guess they could look at your genes and tell you whether you should get the raspberry bath balm or the passion fruit shampoo or indeed both to improve your genetic health. They were only 120 pounds, so widely

accessible, and I'm sure a lot of people gave them as Christmas gifts. After some adverse publicity, the Body Shop has stopped distributing them and I know quite a few of the major pharmacies in Australia have refused to stock it as well.

But when the controversy started, the CEO of Sciona was asked what do people need this for? Why would they want to do it? I thought the quote is worth looking at in full. He said, "There's already a lot of information out there recommending, for example, a diet high in fruit, broccoli, and grains and low in char-grilled red meat, smoked and preserved foods, and alcohol. Consumers find this advice daunting, as they are not sure to what extent it pertains to them as individuals."

So I guess that means you could either have lots of fruits and vegetables and exercise and eat grilled fish or you could lie on the couch and have a lot of hot fudge. If you're not sure, what you really need is a genetic test to make your mind up for you.

We thought, well, how do we regulate these areas? The best responses involve a high degree of consumer education, obviously, and we assigned a major, major role for the Human Genetics Commission in promoting public education about genetics. Also, providing some financial incentives and disincentives. In Australia, again, with our comprehensive health scheme, not putting a genetic test or genetic test advice on our schedule of things that are covered for free is a substantial financial disincentive for people to engage in it. It becomes expensive otherwise.

We looked at some areas of formal regulation. As I mentioned earlier, our Therapeutic Goods Administration could restrict access to certain sorts of test kits, and we recommended the introduction of criminal law in one area.

Then some extent it really is probably buyer beware. Those Sciona tests, it seems to me, are probably the genetic equivalent of mood rings. I'm not sure whether we want to use the full force of the state and criminal law to crack down on them. On the other hand, we hope that consumer education will be sufficient that people won't waste a whole lot of money and, even more, a whole lot of anxiety on them.

Some systemic health care issues. We wanted the system to start gearing up now for the time when, and this is very loosely, but all medicine will be genetic medicine. There will be a genetic component in most sorts of medical tests and medical advice. So we asked the Australian government to start looking at strategic planning issues, at cost issues, training needs, and so on.

We asked family doctors to start taking this more seriously because, as I said earlier, a consistent message we heard from affected families was "Our doctor didn't know anything," and of course, the more rare the condition, the less the doctor knew. Of course, the older and more experienced and better the doctor in many ways, the less they knew about genetics as well, by and large.

So we heard it over and over again about a lack of knowledge, about a lack of communication skills, and it's not easy to communicate ideas about probability and risk. The literature in that area is quite frightening, actually, and in a country where gambling is a passion -- gambling on sport is probably the national religion -- you understand very quickly that people have no idea about probability and risk when it comes to many areas of their life and they should have a better handle on it when it comes to important aspects of their own physical well-being.

So we talked about the need to develop an integrated program of medical professional education -- not just for doctors, but for other health professionals -- starting at the medical schools and working through.

A very close friend of mine is the dean of a leading medical school in Australia. He's also a fairly defensive person, and so when I approached him with all of this criticism, I sort of stood back and waited for the response. He thought about it for a moment and said, "Yes, that would be right." So there is a recognition that we need much more in that way.

We also need more resources and backup for genetic support groups because, again, the lesson from the families was, yes, it was good talking to a doctor, but things really started to fit into place when they talked to other families, and sometimes that meant families around the world through good linkages on the Internet and they told us how they were coping. They often had very practical, down to earth, kind of day-to-day solutions for things, good advice, and so on.

So we need to support those people as well as medical professionals. It's a very, very cost-effective way of assisting the affected community, but one that doesn't seem to figure into government budgeting as often as it should.

Genetic counselors were, in many ways, we thought the heroes of the revolution and our inquiry because, again, people said to us, here's what happened. There were some symptoms or some family history. We went to get a genetic test. We got a result. Our doctor didn't know much about it, so we went home and, in the way of the modern world, we typed it into Google and then we scared the wits out of ourselves when we looked at all of this information. We're all going to die. We're all going to die very soon.

But 99.9 percent of the time, they were greatly reassured after visiting the genetic counselor. Now, it may have been that they still had some serious issues to deal with, but at least they were given perspective, they were given an entre into social and psychological counseling, they were given some good concrete information, they were put in touch with genetic support groups, and so on.

So we thought this was really, really a key to the development in this area, and we made some recommendations that would try to facilitate this about more funding, about recognizing genetic counselors as a distinct profession in Australia, and this has financial implications because if you're a professional in the health area, you get a provider number and you can bill Medicare, which is again our national comprehensive system, and so there's some resistance to increasing the number of people who have the ability to bill the system. On the other hand, if you're going to limit it, I don't think it should be starting with genetic counselors.

Then we wanted to improve the articulation among the various clinical geneticists, GPs, public health officials, and counselors.

This is, from the New Yorker, I thought a perfect comment on issues of genetic counseling, which is the doctor is saying, "There's no easy way I can tell you this, so I'm sending you to someone who can."

One of the controversial issues that we dealt with, and which will continue to be one of the big issues, I think, is how health professionals deal with shared genetic information. It's the other side of that. When we first started the inquiry, our idea, well, this is really sensitive, personal information. So we're probably going to have to beef up our privacy laws to protect individuals.

Part of the way through, we started saying, well, in some areas for sure, but in other areas, the shared characteristic, the familial dimension of genetic information, is going to require moving away from some of that idea of individual privacy and protection. We heard that from genetic counselors, from family cancer registries, and so on, and increasingly an idea that there was a real problem around individual confidentiality, the individual doctor-patient relationship.

So many genetic counselors, many people at the cancer registries, clinical geneticists, said to us, you know, what I have all the time is somebody coming in and getting a positive test for breast cancer, colon cancer, FAP, one of those, and I'm not at all confident they're telling their genetic relatives that they maybe need some screening, that they're sharing that information, and what I live in fear of is the phone call from somebody who rings up and says, "You know, two years ago you tested my sister. She was positive for BRCA1. She never told me. We haven't spoken in many years since that terrible Christmas night some time ago. All you had to do is phone me and I would have gone and got my screening, but I didn't know anything, and now I've got an advanced cancer."

So they're saying what can we do in that area? Sometimes we're not confident from body language and sometimes we're not competent because the person says "I haven't spoken to my family for years," and sometimes they say -- you know, the perversity of it -- "Well, good. Here's my vengeance on all of those people who made my life miserable for all these years. I know something important and I'm not going to share it." What do people do in that circumstance?

It's a very tough one. What we did was recommend to our NIH equivalent -- which does set medical standards, doctor-patient standards, in many areas -- we ask you to develop a rule through more thorough consultation in this area that will allow health professionals to disclose information, even where the individual has not given that consent, where a patient's genetic relative would be at serious risk of harm. We know that there are very difficult and complex issues around that, especially in English-speaking countries, according to all of the cross-cultural data.

I know those of you who have seen Dorothy Wertz' very impressive cross-cultural work, which is confirmed by our own international consultations, is that in the English-speaking countries, and it's consistent across Australia, New Zealand, U.K., U.S., and Canada, the individual doctor-patient relationship is the prime one. It's very difficult to get people to budge off that.

If you look across Asia -- I was just at a national bio symposium in Korea -- people had much less difficulty with the idea that this is shared familial information and that, of course, other family members should be an integral part of the decisionmaking and of the information flow.

I think it's in my next slide. Yes, this was one I was given by a Korean geneticist friend, and he said he thought that genetics was proof of Confucianism. So here's the idea that it is all shared. It's all family. It's not individual. These ideas of shared genetic information fit perfectly into his world view, into his personal and religious views.

Issues about managing genetic databases. I mentioned that earlier and Philip mentioned that. I won't spend much more time on that. We don't have in Australia an equivalent of BioBank or Iceland's DeCODE or the Estonian one, the name of which escapes me just this moment.

However, we have vast numbers of inchoate or unorganized databases; a national "collection" of Guthrie cards; of course, genetic information that could be taken from pathology labs and blood banks and tissue banks and familial cancer registries; and then thousands and thousands of research projects all over the universities, the biotech companies, and so on.

So we need to look more carefully at it. We asked our, again, NIH equivalent to provide a new chapter of our national statement on ethical conduct in research involving humans, to develop a chapter specifically on the ethics of how to manage these databases. These included issues relating to more effective oversight by ethics committees, human research ethics committees; better consent and disclosure protocols, and we provided some model prototypes in our report; and more thought given to issues of

deidentification or use of gene trustees, independent mediaries. Then controversially, and it got our privacy commissioner upset, but that's okay, is extending the Privacy Act beyond data to cover samples, genetic samples from which genetic information can be routinely got. We said that if those things don't work, then we might move to a more heavier regulatory system involving actual licensing or registration of databases, but we didn't move that way yet.

We looked at issues of population genetics and screening. You know, are these sensible programs that we've got? There are a whole lot of them out in the community. Are we appropriately targeting at-risk populations or are we doing genetic testing to satisfy grant applications and researcher interests? We have the issues of the neonatal testing. There are school-based programs.

Then there's a program starting to emerge in the workplace. There's a HaemScreen initiative in Australia in which employers fund hemochromatosis screening. It's an entirely voluntary program, but it's done at the workplace level, and the employers have said and the insurance industry has said if people volunteer for this and they then do the right thing, which is give blood to the Red Cross and keep the hemochromatosis in check, then we won't discriminate against them either in the workplace or in terms of risk-rated insurance.

I don't know. It's an interesting collaboration. I'm glad those various sectors are talking to each other, but I have some concerns about the program and also whether, just epidemiologically in Australia, that's the program in which we want to invest lots of money.

So we've asked for kind of better balanced decisionmaking there and also some thought about how we use these databases. Do we use the Guthrie cards in an epidemiological way, even if it's got no individual consequences? Would it be appropriate for the Australian government to say let's test all the cards from 1960 for diabetes markers to see if we need to have a better education program in that area? I mean, are those the sorts of things we would want to do?

I would mention just briefly that we've moved on to the next stage or a second inquiry, which is looking at the intellectual property aspects of genetic materials and technologies. Many people urged us to do this within the context of the previous inquiry, but it really wasn't possible.

But we have now moved into it and our terms of reference talk about the need to balance encouraging innovation and investment, on the one hand. In other words, support the current intellectual property registration regimes of granting of patents and, to some extent, copyright without harming further research or reasonable access to clinical genetic services.

In Australia, as here, a lot of these issues arose out of concern about access to breast cancer testing, for example, about the relationship between Myriad and our public health system. Myriad has since licensed an Australian company, GTG, to provide those services in Australia. So there's a very direct and lively public debate in Australia about those issues.

Of course, we are ultimately bound by our international obligations in these areas as well under the TRIPS agreement, although I guess part of what our inquiry is looking at is whether there is significant enough wiggle room in there for us to take some steps in Australia that will provide a better balance than may be done in some other countries.

Again, those are the issues that we're looking at, which I won't spend much time on now, but they're there.

It's probably worth saying there are some important differences from the U.S. situation. We have a comprehensive public health care system with subsidized community-rated private health insurance top-ups. Most of our genetic testing occurs within the public system now, although there will be an increasingly significant private element, including the company GTG is now moving to develop very high-tech labs that will provide much quicker turnaround than our current public testing labs do. So there will be more and more pressure to shift things from public to private.

We have a question about whether there is less active, less aggressive, enforcement of patent rights in Australia. It's just an empirical issue that we're looking at at the moment. We've done the usual establishing the advisory committee for that program, we're doing our usual consultation program, but I think significant in this area is that we're looking at collecting empirical material about these issues in Australia. So we've admired the work that Mildred Cho and others have done at Stanford on looking at the actual practical effect, day to day, in clinical genetic services and research labs, and we've got some mirror studies that are being done in Australia.

Some possible approaches to reform in that area, we're looking at how to use existing law and process more effectively and issues about compulsory licensing and Crown use. We're looking at our fairly vigorous competition laws, and there's a tension in the intellectual property area where the grant of a patent gives someone a monopoly right. On the other hand, we have very vigorous competition laws and a very active Competition Commission. So what's the interplay there?

Then in Australia, again more so than here, there's a key issue about government purchasing power. We effectively have a monopsony in this area. That is, that all the testing is done through public health systems and drugs are almost all purchased through our PBS system, Pharmaceutical Benefit Scheme, which is subsidized by many billion dollars by the government and keeps the cost of drugs down. So our government has very strong purchasing power.

This has been a key issue in the free trade agreement discussions that are going on now between Australia and the U.S. in which U.S. authorities have said, well, those billions of dollars of subsidy are harming the interests of our pharmaceutical companies, and the Australians are saying, well, a lot of things can be on the table, but PBS and MBS, the medical side of it and the pharmaceutical side of it, are things that are very, very important. You'd be a very brave politician in Australia to talk about weakening either of those things.

Some other reform options. Possibilities of looking at statutory exceptions for medical research or clinical practice, and maybe some altered criteria for patentability, but I think we're not likely to go that way because of the locked-in structure of the international rules and practices.

Further information. Everything we do, we do in public, and all of our publications are on our website. The report that we did, which I shared a slide of, I can't carry because it's that thick, 1,200 pages. It does go nicely on a CD, however, and we're happy to provide those for people who contact us. All of our issues papers -- for example, the one now in the gene patenting area -- are available on our website.

I'd also just like to say that I hope this next little period won't be the end of the dialogue. So if you've got issues or concerns or want to find out more about what we're doing there or have suggestions about any of our papers or wish to make a submission, then please do contact us in any of those ways. Probably electronically is the most efficient way, given the time zone difference.

Thank you very much for your attention.

DR. McCABE: Thank you very much, Professor Weisbrot.