Roundtable Discussion with Philip Webb and David Weisbrot

DR. McCABE: I'd like to acknowledge Ms. Lynn Mainland from Health Canada, who is in attendance, and wish you a warm welcome. I'd also mention that the SACGT heard and benefited from the Genetics Commission of Ontario, and we appreciate your attending the meeting here.

I'll now turn it over to Dr. Hook, and we should go until 10:25 and then we'll just take a 10-minute break.

DR. HOOK: Well, I'd like to begin by thanking both of you gentlemen for outstanding presentations, and also, please take back to your various groups our acknowledgement and thanks for the tremendous work that you're doing. I hope that we can continue the dialogue.

I'll just begin with a question in that are there areas that either of you would see as important for all of our various committees or commissions to be directly collaborating on? I know we could learn a great deal from each other and we often have similar thinking in various areas, but are there areas that you would identify, perhaps the direct marketing or Internet sales of genetic testing, which we should be explicitly working together on?

MR. WEBB: Yes. I think that the Internet testing services that are offered are of concern and nobody has the answer individually as to how we can best deal with those matters. We do want to enter into dialogue with other nations about how best to use sites for education because we all recognize that education is probably the easiest answer, rather than legislation, and so we would certainly like to have dialogue about how to regulate, as far as possible, Internet testing.

DR. BEMENT: Arden Bement from the Department of Commerce. I also echo Dr. Hooks' comment about your lucid and very informative presentations.

My question has to do with measurement uncertainty. Microarrays and gene chips are still relatively new technologies and still have rather high error budgets. So questions of statistical significance and validity enter in and also protocols to analytically resolve legal challenges, especially in forensic applications of genetic determination.

The other thing that is often misconceived is that accreditation equals conformity to standards, which it does not. So accreditation by itself is probably necessary, but not sufficient.

I'm curious to know whether your commissions have gotten into these issues and, if so, what you have concluded to date.

MR. WEISBROT: I can talk about some of those things. I think we tried to discuss the issue of accreditation in those terms. We certainly heard lots of criticism of the accreditation system as one in terms of pro formas and so on and occasional inspection, rather than routine analysis. There seemed to be a clear correlation, though, in Australia, and I'm sure elsewhere, between labs that do a vast number of tests in a particular area and ones that do it occasionally in terms of getting their quality assurance right and being able to provide all of the double-blinds and all the other tests you need to do to ensure quality. So that was another reason for our trying to centralize somewhat the sensitive tests, to say let's have these done in places where you have a lot of testing done and where you have people who are expert and consistent in analysis.

We also made quite a few recommendations to our two bodies that do accreditation -- there's a national accreditation body and there's also the Royal College of Pathologists -- about lifting their game in terms of accreditation. So we said we want to improve the processes. We want much more guidance in the protocols. We want much more attention paid to ethical concerns and counseling concerns, as well as quality assurance ones.

But on the other side of that, I think we probably simply need to resource the people who keep them in check, the consumer health groups, medical practitioners, public health authorities, and so on, the people who are consumers of the labs, to make sure that they're sufficiently up to date with the issues to provide the challenging environment for those people to do their job very well.

On the evidentiary side, we did discuss in some detail and there are several chapters and lots of recommendations relating to the use of genetic information and genetic test information in the courts. This has been a big issue in the U.S. and there has been some collaboration there across Australia and the U.S. and some other common law countries in terms of EINSHAC's, the Einstein Institute, initiative for educating judges. Just a few weeks ago, there was a major program in Australia that involved about 60 or 80 Australian judges and a number who had come from the U.S.

So there's a need in that area. We've identified a number of cases in Australia where certainly the science was very bad, the lawyering was pretty bad, and there's a need to lift the game in both those areas.

DR. BEMENT: Thank you.

DR. WILLARD: Hunt Willard. That was terrific. Thank you both very much.

Just a point of information as I sort of balance the output that both your commissions have generated and try to see where we're going on this committee, can you give us some idea of the frequency of your meetings and also the number of full-time staff that were presumably behind you gentlemen so that you would have time for other pursuits?

MR. WEBB: Yes, certainly. That's a very important question because we can't work without adequate resources, and as I understand it, you are trying to do that.

The way we work is that we have three main meetings a year. We then have working groups who may meet on a monthly basis to produce specific reports with the backup of a secretary out of five full-time employees. So the review that I'm chairing at the moment into paternity testing, I have a subgroup of six or seven people who are working with me. We meet once a month with Department of Health officials who act as the secretariat and at the end of each meeting they produce the minutes, they draft reports, and circulate it electronically to us. I believe our budget is somewhere around half a million pounds a year.

MR. WEISBROT: The Australian Health Ethics Committee is similar in terms to your organization. It has 17 members. It's a formulaic composition. It has a lawyer familiar with health issues, a minister of religion or equivalent in the community, a scientist, a medical doctor, and so on.

I think one of the things that emerged through the process was that they were pretty amazed at what we could do by not being like that, by being a full-time commission with full-time staff and resources. So we really were the ones who drove the project, but with their very considerable informed input.
The Australian Law Reform Commission has a budget of about $3 million a year Australian, about $3.5 million, close to $3 million U.S. This was a major project for us. We had two commissioners working on it, full-time commissioners working on it full-time, myself and another, and we had about six to eight

researchers and then a few support staff. So I'd estimate over the two years we would have spent about a year's equivalent budget.

We also got a grant of another half million dollars from the Department of Health to do the extensive public consultation program. So, of course, money to rent hotel rooms and travel around and talk to people and produce a lot of literature, which we did as well, like the HGC, at all different levels. So we have the big thick reports, but then it distills all the way down to one-page brochures and we even tried that thing where you give out the free postcards in coffee shops to tell people to contact us if they were interested in further information.

The experience of dealing with AHEC and the Law Reform Commission, the differently comprised and resourced ones, led to our recommendation that the Human Genetics Commission should be established on the same basis that the Law Reform Commission is.

I should say that the Health Ethics Commission unanimously endorsed that recommendation. So we said it should be a full-time body. It should contain permanent staff, although the commissioners would rotate over time, of course, and that it should be given an adequate budget. We even did some discussions of similar bodies, like the Human Rights Commission and the Law Reform Commission, to get a principal idea of what the budget would be, and we said it looked like about $8 million Australian a year would be appropriate.

DR. LEONARD: Debra Leonard. This is a very targeted question, which is, David, you say that DNA testing won't be done by accredited laboratories, and you include with QA ethics, consent, and counseling. So is it going to be, in your image of what should be done, the laboratory's responsibility to do the counseling in place of the physicians?

MR. WEISBROT: No, definitely not, but if they were going to on a fee-for-service basis do this, then they should have in place a regime that naturally referred people to genetic counselors. So it's not that they do it themselves, but that they worked in association with genetic counselors or with family doctors or whatever was relevant in the circumstances.

DR. LEONARD: Both in the pre-analytical consenting phase as well as in the post-analytical genetic -- I mean --

MR. WEISBROT: Probably. Again, it would depend upon the particular test, but by and large, yes, pre- and post-test counseling. Again, we used HIV/AIDS as the model for that, and so we're also conceptually dealing with the most sensitive kinds of tests, but genetic tests, that would not be the case with things that were determined by the Human Genetics Commission to be more routine sort of tests that could be handled by a doctor or by the provision of literature, for example.

DR. LEONARD: One other. Have you determined how you would define "serious risk of harm" when you're allowing physicians to communicate results to -- or not results, but recommend certain types of genetic testing to relatives of a patient? How will you define "serious risk of harm"?

MR. WEISBROT: Well, there is some detailed discussion of that in the material, and of course, it's very difficult. One of the problems was in the concept of imminent risk, and so there are protocols around now that allow moving past the normal strictures when there's an imminent risk of harm. When you're dealing with genetic information, by and large, you're not dealing with that kind of imminence.

So that was one principal question. In general terms, it would be more or less what you would guess we said. We asked the NHMRC, the NIH equivalent, to do a more detailed study of this in association with doctors organizations and so on to try to get a handle on it. Our brief to them was to give them general terms of reference, saying this is what the community and the specialists are telling us needs to happen. We haven't done enough work to come up with a rule that we would recommend to government, but we think you should do that after you've done the appropriate level of consultation.

DR. TUCKSON: First of all, David, again, it's amazing for you to get on that cab and get here and be this fresh, and we really appreciate it.

Philip, I was wondering, given how closely you're working with the government and all the various ministers, and you made that plural, what is your sense of how organized or how it is organized in the U.K. in terms of the Cabinet or the government leaders in terms of their interaction together around these issues and focus? Are you dealing with them one on one and by one or is there some central mechanism that helps the country to focus on priorities or are you sort of discovering those priorities on your own based on those?

Secondly, how soon do you think you'll have that website for consumer information and education available and can you share that with us as you develop it? Because I think that's something that we learned yesterday that we may want to model.

MR. WEBB: Yes, certainly. As regards our interactions with government ministers, the British Civil Service, as it is known, is well-established and we report both to health and science ministers. Now, it is very helpful to us that our secretariat is provided by the Department of Health. So the five full-time equivalents are actually employees of the Department of Health seconded to work for the Human Genetics Commission. So they have all the right contacts within the Department of Health for making our recommendations go to the right places and the people.

Secondly, they also have the right contacts in the Science Department. So the channels are already well-established, they're already existing, and the people who support us have the right contacts. So I think that's tremendously helpful.

As regards to website, we would like to think that that is going to be ready and set up and operational midway through next year, and we would be delighted to share that with you.

DR. TUCKSON: Is there one coordinator for those four different categories or do they, again, work independently or co-equally? I mean, is there any coordinating mechanisms for the government leaders?

MR. WEBB: Well, certainly, there are cross-government initiatives, and too often in the past there have been accusations of being in silos and not talking to one another. Now, since this government has been in power, the concept of, as they call it, joined-up government is becoming much of a reality, with health and science ministers and even Department of Trade and Industry ministers regularly meeting to discuss issues of common interest.

DR. WINN-DEEN: Okay. I'll keep the question brief. I'm not making any comments on how long the answer is.

I want to know what the trick was to get the government to specifically target 50 million pounds towards improving the education of the health care workforce in genetics, so that they could be informed and

intelligent about how genetic services are provided, because in the U.S. this is apparently mostly a grassroots effort and not a coordinated government initiative.

MR. WEBB: Well, this is something that we have been saying for the last five years. So it's not an instant turn out of 50 million pounds.

We've also worked through such groups as the Royal College of Physicians, Royal College of Surgeons, Royal College of General Practitioners, and the nursing organizations. They all recognize that they need better education and that genetics is infiltrating every part of medicine. So with their help -- and the Department of Health recognized that that is important, too.

If I put my cynical hat on, I would say that perhaps some government ministers think that genetics is a sexy subject and that if they are seen to engage with it, it may be good for their image and ensure their longevity in office.

DR. McCABE: Well, thank you very much. On behalf of the Committee, I would to thank both of you for coming to visit with us and tell us about the exciting things that you're doing in both Australia and the U.K. I hope that we can use this as just the beginning and keep lines of communication open, share reports, and continue to have dialogue, and also, with our past history with Canada, I hope we can do the same. So we look forward to continuing to talk with you, and thank you again for coming to visit with us.