

**Human genetics : the Government's response : third report / Science and Technology Committee.**

**Contributors**

Great Britain. Parliament. House of Commons. Select Committee on Science and Technology

**Publication/Creation**

London : H.M.S.O., 1996.

**Persistent URL**

<https://wellcomecollection.org/works/bsqsku2h>

**License and attribution**

You have permission to make copies of this work under an Open Government license.

This licence permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

Image source should be attributed as specified in the full catalogue record. If no source is given the image should be attributed to Wellcome Collection.



Wellcome Collection  
183 Euston Road  
London NW1 2BE UK  
T +44 (0)20 7611 8722  
E [library@wellcomecollection.org](mailto:library@wellcomecollection.org)  
<https://wellcomecollection.org>

SCIENCE AND TECHNOLOGY  
COMMITTEE

Third Report

HUMAN GENETICS: THE GOVERNMENT'S RESPONSE

Volume II

Minutes of Evidence and  
Appendices

---

*Ordered by The House of Commons to be printed  
3 April 1996*

---

LONDON: HMSO

£10.60

HC 231-II

LIBRARY
General Collections
P
6491



22501698393



# SCIENCE AND TECHNOLOGY COMMITTEE

## Third Report

### HUMAN GENETICS: THE GOVERNMENT'S RESPONSE

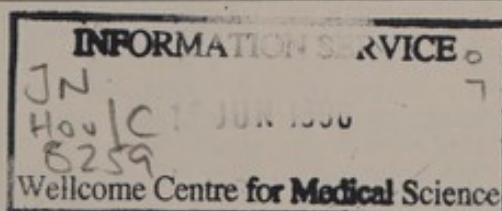
#### Volume II

#### Minutes of Evidence and Appendices

---

*Ordered by The House of Commons to be printed  
3 April 1996*

---



LONDON: HMSO

£10.60



The Science and Technology Committee is appointed under Standing Order No 130 to examine the expenditure, administration and policy of the Office of Science and Technology and associated public bodies.

The Committee consists of 11 Members. It has a quorum of three.

The Committee has power:

- (a) to send for persons, papers and records, to sit notwithstanding any adjournment of the House, to adjourn from place to place, and to report from time to time;
- (b) to appoint specialist advisers either to supply information which is not readily available or to elucidate matters of complexity within the Committee's order of reference;
- (c) to communicate to any other such committee and to the Committee of Public Accounts and to the Deregulation Committee its evidence and any other documents relating to matters of common interest; and
- (d) to meet concurrently with any other such committee for the purposes of deliberating, taking evidence, or considering draft reports.

Unless the House otherwise orders, all Members nominated to the Committee continue to be members of it for the remainder of the Parliament.

---

The following were nominated Members of the Committee on 13 July 1992:

Mr Spencer Batiste  
Dr Jeremy Bray  
Mr Malcolm Bruce  
Mrs Anne Campbell  
Cheryl Gillan  
Mr William Powell

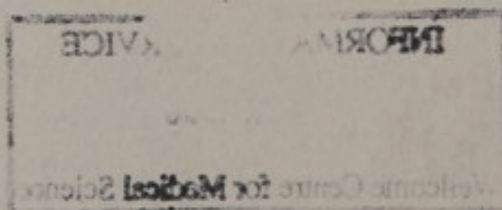
Sir Giles Shaw  
Sir Trevor Skeet  
Dr Gavin Strang  
Sir Gerard Vaughan  
Dr Alan W Williams

Sir Giles Shaw was elected Chairman on 15 July 1992.

On 9 November 1992 Mr Malcolm Bruce was discharged and Mr Andrew Miller added to the Committee.

On 16 November 1992 Dr Gavin Strang was discharged and Dr Lynne Jones added to the Committee.

On 7 November 1995 Cheryl Gillan and Mr William Powell were discharged and Mr Ian Bruce and Mr Patrick Thompson were added to the Committee.



## LIST OF WITNESSES

page

*Wednesday 14 February 1996*

Professor Martin Bobrow and Professor Sir David Weatherall	...	...	...	...	1
Professor Sir Kenneth Calman, Chief Medical Officer, and Professor Sir Robert May, Chief Scientific Adviser	...	...	...	...	8

*Wednesday 28 February 1996*

Rt Hon Stephen Dorrell, MP, Secretary of State for Health...	...	...	...	...	16
--	-----	-----	-----	-----	----

*Wednesday 6 March 1996*

Mr Ian Taylor MBE, MP, Minister for Science and Technology	...	...	...	...	30
--	-----	-----	-----	-----	----



LIST OF MEMORANDA INCLUDED IN THE MINUTES OF  
EVIDENCE

	<i>page</i>
1. Memorandum from the Department of Health (HGRD13) ... ..	26
2. Memorandum from the Office of Science and Technology (HGRD11) ... ..	30
3. Memorandum from the Office of Science and Technology (HGRD15) ... ..	44

## LIST OF APPENDICES TO THE MINUTES OF EVIDENCE

	<i>page</i>
1. Memorandum from Professor Peter Harper and the Royal College of Physicians Clinical Genetics Committee (HGRD1) ... ..	47
2. Letter to the Clerk of the Committee from Professor Peter Harper (HGRD2) ... ..	47
3. Memorandum from the Association of British Insurers (HGRD3) ... ..	47
4. Memorandum from SmithKline Beecham (HGRD4) ... ..	48
5. Memorandum from the Nuffield Council on Bioethics (HGRD5) ... ..	49
6. Letter to the Chairman of the Committee from the Alzheimer's Disease Society (HGRD7) ... ..	52
7. Memorandum from the Genetic Interest Group (HGRD8) ... ..	52
8. Letter to the Chairman of the Committee from the Genetics Forum (HGRD9) ... ..	53
9. Letter to the Clerk of the Committee, enclosing a memorandum from the British Society for Human Genetics (HGRD10) ... ..	56
10. Memorandum from the Royal Society (HGRD12) ... ..	57
11. Letter to the Clerk of the Committee from the Association of British Insurers (HGRD14) ... ..	58



# MINUTES OF EVIDENCE

WEDNESDAY 14 FEBRUARY 1996

Members present:

Sir Giles Shaw, in the Chair

Dr Jeremy Bray  
Mr Ian Bruce  
Mrs Anne Campbell  
Dr Lynne Jones

Mr Andrew Miller  
Mr Patrick Thompson  
Sir Gerard Vaughan  
Dr Alan Williams

## Examination of Witnesses

PROFESSOR MARTIN BOBROW and PROFESSOR SIR DAVID WEATHERALL, examined.

### Chairman

1. You were kind enough to come to the Committee before right at the commencement of our inquiry into human genetics. I do not think that you will be entirely surprised that the Committee thought that it might have a brief revisit to the subject in the light of the Government's response with a view to providing advice to the Committee as to how we might ultimately respond on this particular issue, a fascinating and substantial issue which you have had such experience of in your period with MRC and now you are speaking as an alumni in that regard. Sir David, you were very kind to the Committee, inviting us down to visit you in Oxford. You have given us a great degree of assistance in our inquiry but in this particular case we are asking both of you to come and discuss some of the issues which we see arising out of the Government's report to our inquiry with a view to helping the Committee perhaps distil its own response given a little bit more time in which to do it. We are very grateful that you should come. If we may, we will ask questions to you both to which no doubt you will each or severally wish to respond. Could I start off by saying the Government reply says: "through the Human Genome Project most of the important human disease genes are likely to be identified within the next five years". We take it that these "important disease genes" are those implicated in multifactorial disorders. Is the Government's statement in that regard accurate, do you think?

(*Professor Sir David Weatherall*) I think that is a bit optimistic. Probably what is more likely is that within the next five years or so many of the simple inherited disorders, the monogenic disorders, will be sorted out in that way. The commoner diseases like heart disease, diabetes and psychiatric disease, the genetic component of which is only part of the story because there is also a big environmental component, may be partially sorted out but I think five years is much too optimistic. There is an enormous complexity in some of them. Even if we identify some of the genes involved, sorting out their abnormalities and abnormal actions in common diseases which have a big environmental component will I suspect, take quite a bit longer than five years.

2. Do you broadly agree with that, Professor Bobrow?

(*Professor Bobrow*) Yes, I think that is right but there will be major inroads during that period of time. This is not going to be one of sudden cataclysmic revelation. There are already pieces of information coming to light which are starting to fill in the jigsaw puzzle. I do not think we are going to see anything approaching an end game in the next five years, perhaps ten to 15.

3. Could I ask, within that rough timescale would you also be able to come to an accurate assessment of the risk of developing a particular condition if one possesses a particular genetic variation?

(*Professor Bobrow*) Yes, I think we are already in that position for some diseases and in some genes. What will happen is that there will be a numerical incrementation of the number of tests that do give predictive information. In some of those the information will be of a large enough effect to be useful and in others it will be rather small and we will look at it and we will throw it away because it is not very important.

### Mrs Campbell

4. I wonder, Professor Bobrow, if you feel that the Government reply pays enough attention to the likely consequences of this time lag between knowing that a gene is implicated in a disease and being able to judge accurately the increased risks of possessing such a gene? I think you have referred partially to that but do you think there is going to be some confusion there in the Government's response?

(*Professor Bobrow*) I think that there will be a particular form of difficulty in preventing screening programmes if I follow the gist of your question, in that when one has basic scientific information which implicates a gene in a disease process you can make estimates of how good the predictive information might be and you can make estimates of how effective strategies for changing that right might be by advising people to change their lifestyle or putting them on pills or whatever. To really validate how accurate your estimates are requires longitudinal studies and it will take many more years before they really stand rock solid.



14 February 1996]

PROFESSOR MARTIN BOBROW  
AND PROFESSOR SIR DAVID WEATHERALL

[Continued]

[Mrs Campbell Cont]

5. So the implications are that although important human disease genes are likely to be identified within the next five years the implications of that are not likely to be understood for many years following that?

(Professor Bobrow) If I could have one more go at that and then pass it on to an expert. I think there is a danger of saying that because we will not understand everything in five or ten years therefore we can afford to let the problem rest for a while. My feeling is that there are already extant examples of specific genes which do give predictive information which raise most of the problems of application that we will face in the future. My view is that we need to have a developed framework very soon for dealing with the examples that already exist even though the major flood may be some years down the road. Those examples are well rehearsed in the report.

(Professor Sir David Weatherall) I think it is just worth recapitulating what we are talking about this evening. There are genetic diseases due to one defective gene that runs through families in a highly predictable way. There are about 4,000 of those but fortunately most of them are very, very rare. There are a number in the community which added together make up an important part of paediatric practice. Those diseases are easily definable and most of them will be diagnosed within a highly predictive way; many of them are now and within the next five or ten years most of the important ones will be. That is absolutely clearcut. The second issue we are talking about is genetic susceptibility to common killers of Western society, basically heart disease, stroke, psychiatric disease, diabetes, and soon. I think there is still a little bit of confusion between the two. What we are talking about in this five, ten, 15 year plan is getting closer and closer to reasonable accuracy in trying to predict a person's risk of having heart disease or diabetes and so on. I think it is very important that we keep these two issues quite separate because they are totally different. For the second group it is much more difficult to say when we will be able to predict susceptibility with accuracy.

6. Would you expect the price of genetic testing to fall in the future?

(Professor Sir David Weatherall) The price?

7. Yes.

(Professor Sir David Weatherall) Yes, I think so because a lot of the technology is still new and by and large the more a test is used, as you know, the more the price does tend to fall. I think the technology will get simpler all the time.

Sir Gerard Vaughan

8. Going back to the first part of that question from Anne Campbell, there are likely to be time lags. I think we are all agreed on that, and during that time public anxiety and misconception of what is going on is likely to build up very quickly. Would you agree with that?

(Professor Sir David Weatherall) Yes.

9. Do you think that there are sufficient, adequate bodies, if I can call them that, to keep this sort of information in perspective and to see that public anxiety does not run wild at times?

(Professor Sir David Weatherall) This is a very difficult question. I think perhaps one of the easiest approaches is to give you an example of what happened in the past in this field. Somewhere round about ten years ago there was quite a bit of anxiety about gene therapy, in other words transferring genetic material, but there is no doubt that there was quite a lot of difficulty activating anybody to do anything about this. First of all we got the Medical Research Council to set up a review group, and they established some simple ethical and clinical guidelines. They were taken up by the research councils in Europe but then there was another major delay before the Department of Health was persuaded to set up a review body to look at gene therapy. It was a very long time lag. We just got there in time actually, the first gene therapy protocols came in just when the Clothier Committee had about finished. My concern during that time was that if there was a major advance in the field we would, in this country, be caught unprepared and there was always a chance that this would happen. There was a lot of work going on in the States; people had moved gene therapy abroad because they could not do it in States. I think in a very fast moving and complex field like this where there is a lot of unpredictability probably one does want a body of some type that is constantly monitoring it because of the uncertainty of the speed of advance. It was very like this with gene therapy, we knew it was going to happen but we were never quite sure when. It took an enormous amount of work to get the appropriate body into place and we just about made it in time in this country, but only just. That is my concern.

10. Can you tell the Committee if you are satisfied we now have the mechanisms in place to prevent wild speculation and anxiety spreading?

(Professor Sir David Weatherall) Well, we have the Nuffield Bioethics Committee which I belong to. It is excellent but of course it has got a very limited kind of brief. Then there is the new body which has been suggested in the Government's reply. I feel a little bit uneasy, I must confess, that we have not quite got the mechanism in place for monitoring what I think is going to be quite a difficult period, a period of uncertainty, and the kind of body that could actually reassure the public.

Chairman

11. Any comment on that or are you in broad agreement, Professor Bobrow?

(Professor Bobrow) I certainly agree. I would add one personal whinge perhaps if I might.

12. How splendid.

(Professor Bobrow) It is quite often said that scientists and doctors tend to take decisions upon themselves and make policy on the hoof and of course that is a well justified criticism. Geneticists in general have fallen over themselves for the past 20 years in several different ways not to be socially irresponsible but to recognise that the development of technologies and the application of discoveries requires a dialogue between the professionals on the one hand and the public on the other hand. The difficulty is that at the moment I think the



14 February 1996]

PROFESSOR MARTIN BOBROW  
AND PROFESSOR SIR DAVID WEATHERALL

[Continued]

**[Chairman Cont]**

professionals do not have a body with whom they can engage in dialogue. In addition to the points that Sir David has made I do feel quite strongly myself that we would have a much more open and constructive dialogue in this country if there were a focus of policy advice of some sort, rather along the lines that was suggested in your report, that could fulfil that role.

**Mr Miller**

13. Sir David, in response to Anne Campbell you said that you detect some confusion. Can I just press you on that. Do you detect that confusion in the Government's reply?

(Professor Sir David Weatherall) Slightly, yes. This is not being critical because I think these issues are very complicated and in fact they have not always been put over awfully well by the scientists when talking to the public. The gene for diabetes immediately raises all sorts of thoughts in one's mind. There is one gene that runs through the family and if you inherit it you get diabetes. I do not think that this confusion is anybody's fault. I just hope tonight that we can get these two totally separate types of genetic disease separate in our mind because if you keep pressing us as to the rate of progress, they are totally different for the two groups.

*The Committee suspended from 4.58 p.m. to 5.07 p.m. for a division in the House.*

**Dr Jones**

14. I gather from your replies so far that you are as concerned as this Committee is to ensure that we take advantage of the full potential that knowledge of genetics and human genetics gives us, and we actually have public confidence in this area of science. I gather that you have some reservations about the current arrangements which include various, I think there are five, bodies at the moment and the Government proposes the new body on genetic testing which is set up under the auspices of the Department of Health. The Government has rejected our recommendation for a Human Genetics Commission even though it acknowledges that this field of science is advancing, it says "rapidly developing". We will shortly be seeing representatives of the Government and the civil servants responsible for drafting the reply, what sorts of questions do you think we should be asking them?

(Professor Bobrow) Can I have a team to draft a response!

**Chairman**

15. You could easily plead an amendment of some kind, I cannot think of the number.

(Professor Bobrow) I cannot think of a good answer to that that would go down on television. As I read the response I could not quite understand why there was a desire not to have a reasonably co-ordinated single focus of policy advice. I can entirely see the need for specialist technical advice in a number of fields literally dealing with the nuts and bolts of how things operate. My concern was, for example, in trying to imagine a body which would advise on the ethics of screening but that could not

consider the possibilities of employment discrimination against those screened just lacked reality because that would seem to be one of the major ethical issues that one would come across in weighing up some types of screening programmes. There are any number of other examples where it seems to me that the policy issues are closely interdigitated and I can see no particular purpose in separating them, nor can I see that it would be workable.

(Professor Sir David Weatherall) I think that is right. There are two parts to that question and I think Martin has answered the first part extremely well. In other words, because there are so many complex issues moving so fast in genetics I think both our concerns are that the remit of a committee just to monitor screening is really too narrow. I think that would summarise my main concern. The second issue that you raised is equally important. I am not sure there is any kind of committee that is going to solve the problem of public anxiety in a field that is moving this way. Perhaps the existence of one, if it is properly constituted with a wide-based membership, may go some way but I think that the issue is much broader. It is a problem of communications in science, about which I am not sure the Government can do very much about.

16. Just to come back on that, the Department of Health press release does say that the advisory committee will need to be reassured as to the arrangements for the protection of personal genetic data, so it could be that that could be expanded to take on board employment and insurance issues but the problem then is that it is a committee that reports to the Department of Health rather than the DTI. Do you think there is a solution to that problem? Is there a seed there of hope in that remit that has been given to the advisory committee?

(Professor Sir David Weatherall) Yes, I just do not think it is broad enough.

**Dr Williams**

17. I do not know how much time you have spent studying our report but it did elaborate some of the areas we would want the Human Genetics Commission to cover, was the position as we recommended it broad enough to take charge of these areas?

(Professor Sir David Weatherall) If it is not we ought to really try to define which areas it is not broad enough in. Which particular areas were concerning you?

18. We took in employment, insurance, public understanding, acceptance as well as the functions of genetic testing, screening, recommending widespread screening programmes. It was a very broad umbrella body. Generally yourselves and within the scientific community that you represent do you feel that this is the kind of formulation that you were looking for?

(Professor Sir David Weatherall) It really does need to be able to be broad ranging. There is a lot of public concern, particularly in North America, at the moment, and when it happens in North America it will happen here tomorrow, about the whole question of investigation of the genetics of the



14 February 1996]

PROFESSOR MARTIN BOBROW  
AND PROFESSOR SIR DAVID WEATHERALL

[Continued]

**[Dr Williams Cont]**

nervous system, IQ genetics, mood, trait genetics, and so on. There is enormous movement in the United States to ban all this kind of research altogether, "we should not do it, we do not want to know". I think we do need some kind of group that is continually debating this and many other concerns about human genetics. If you argue that a screening committee has a remit to talk about almost any aspect of human genetics and genetic activity then fine. It just came over to me as a little bit narrow, that was all.

**Dr Bray**

19. Is there a problem about the different combinations in which problems can arise from different areas and the speed with which things are moving? May I draw attention to a headline in *Nature* this week which I am sure you have not yet had a chance to read. "Fertilization without sperm" is the headline. It is a method of in vitro fertilization that has not only worked: "Patients producing vanishingly small numbers of spermatozoa could be helped, and the pregnancy rates obtained were as good, if not better, than most centres achieve with in vitro fertilization..." It is not without sperm, it is with a sperm pre-cursor and the ovum is fertilized. It points out: "the new techniques are not without critics, on scientific as well as ethical grounds. For example, although the health of children concerned ... is broadly reassuring, some legitimate concerns have been raised. The disruption of spermatogenesis in some infertile patients with non-obstructive azoospermia will have a genetic origin involving, for example, microdeletions in the Y chromosome." I have not got a clue what that is all about but it does seem to me to involve the interaction of different aspects of genetics and embryology in a way which is immediately clinically applicable. These procedures have been carried out, children have been born according to this. If there were a public demand for more efficient in vitro fertilization somebody is going to come along and say "Can I have one of those?" In the present set-up there seems to me to be no body to which the public or the medical profession or researchers can go with a question like that and say: "Hey, what is going on?"

(*Professor Bobrow*) I think, as David said earlier, setting up committees probably does not in itself allay anxiety out there. What I think does carry the case forward is where there is a reasonable amount of well informed public and open discussion. In order to have a discussion you need to participate at least. For that reason the sort of organisation that was suggested in your initial report seemed to me to be sufficiently broad ranging and flexible to act as that focus of discussion.

20. Specifically it is a function which has to address the interactions of the different areas between screening and therapy and social effects?

(*Professor Bobrow*) Yes, I think inevitably so.

21. Separate bodies do not address the issue even if they are comprehensive.

(*Professor Bobrow*) There must be a point at which the expertise of the body is simply not adequate and there will be a spectrum of interactions between

genetics at one end and the ground covered by fertilization and embryology authority at the other where I suspect there would be a partition but there must be an overlap, it cannot be a cut off point.

**Sir Gerard Vaughan**

22. Pursuing really the same line, last night there was yet another television programme on this field, this time talking about stem cell research. In some people's eyes that is a very alarming kind of thing to know about but not really understand what its implications are going to be. Our worry is that work will go on which is either undesirable or not understood or misunderstood and there will be no body with the authority to step in immediately and keep some control over it and see that it is explained in a responsible and intelligible way. It is my understanding that you rather agree with this, that the present mechanisms are not going to be adequate?

(*Professor Bobrow*) I agree that the present mechanisms for discussion do not seem adequate. I am not sure that I would agree that there is a need for a body which monitors the research that is permissible if that was part of what you said. I think that there are other reasonably robust mechanisms for monitoring what research is done. The point at which that research becomes applicable is the point at which I think there is a need for a much more cogent and unified view of biological science.

(*Professor Sir David Weatherall*) I think this is very difficult. There has been constant change in medicine over the last 50 years and if you argue that you are going to set up a commission every time there is a new advance that would be absolutely farcical. I think the concern at the moment is that genetics, the technology of modern genetics, is so all pervading in medicine and goes in so many different directions, it is difficult to decide where the goal lies in terms of control committees. I think screening was a very sensible thing to do. I think the only concern is the breadth of the subject. There are concerns in the hinterland in relation to reproductive physiology of germ line therapy and many other topics which may be quite useful in the near future. There is a whole host of other issues. I think there is a feeling, certainly among the scientific community, that at this particular time in the development of this field it might be valuable both for the community and for the scientist if there was a body with a broader remit to keep an eye on that field. This field is unlike other medical advances in that it affects every branch of medicine, and in a rather unpredictable way for the immediate future. I think that it is a very complex issue.

**Mr Thompson**

23. I am a newcomer to the Committee and my background is in the physical sciences rather than the biological sciences and therefore my impression is that this is a very difficult subject. I hear what you say already and I think you are saying this is not just any advance in science, this is a rather special new advance in science and therefore has to be addressed specially. The Government, as we know, has



14 February 1996]

PROFESSOR MARTIN BOBROW  
AND PROFESSOR SIR DAVID WEATHERALL

[Continued]

**[Mr Thompson Cont]**

established this rather modest advisory committee on genetic testing to tackle something on which—it is a long time since I read *Brave New World* by Aldous Huxley but I think we are probably going to see a little bit of *Brave New World* in all this, so although this question may be slightly repetitive—I think we have got a long way to go before we get public confidence in all this. Is the mechanism that the Government suggests going to be sufficient? If not, is there any other mechanism which will help to create that particular confidence? In particular I am thinking of an issue which we may come back to later, the issue of privacy for example. What I am really saying is is there a worry about this out there? Is the Government's new committee going to be a sufficient mechanism or not?

(*Professor Sir David Weatherall*) I think we have both said as much as we can about that. It is a start. I think our concern is that it probably does not have quite a broad enough remit to cover the current complexity of the field and to have the kind of expertise in depth which it would need, and the breadth of people on it to deal with the problem as it is now. I hate any form of committees and I hate any form of bureaucracy, particularly in anything to do with medicine or science. But I think one needs a debating chamber at the moment in this field.

24. But you agree with me that this field is not just like any other advance in science?

(*Professor Sir David Weatherall*) It is different.

25. It is special?

(*Professor Sir David Weatherall*) Yes, it is special.

**Mr Miller**

26. In the Government's response they say that: "The Department of Health has set up mechanisms to ensure that any proposal for screening is subject to careful evaluation before introduction". Professor Bobrow, in your experience are these mechanisms more satisfactory than when you produced the report of the Genetics Research Advisory Group?

(*Professor Bobrow*) I would have to say that I am not aware of any important changes in those mechanisms at least in so far as they apply to genetic screening over this period of time. I have heard talk of things that are to come but nothing exists as of yet.

27. Is there now a forum for developing national policy guidelines for genetic screening programmes as you recommended? Do you believe that the Advisory Committee on Genetic Testing will ensure that these programmes are satisfactory?

(*Professor Bobrow*) My difficulty in giving you the straight answer you deserve is that what I have seen of that committee is basically a press release. Its terms of reference are rather broadly stated. I do not think I know enough of how it will function or who is on it to be able to give a sensible answer to that. Others in the room presumably know much more.

**Chairman**

28. Could we turn now to the question of ethics or one of the questions of ethics. At the moment there are these Local Research Ethics Committees, is it your view that they are able to deal with the fairly

large genetic research programmes that are currently under way? Can they deal with these programmes satisfactorily?

(*Professor Sir David Weatherall*) For the vast majority of things that come up in any kind of major research centre they deal with extremely well. In this particular field I think we were worried, for example when gene therapy was starting out, that there would be difficulty with the totally new technology although you could argue ethics are ethics and technology is technology and when one weighs up particular procedures for patients you cannot dissociate the two. There are complexities in modern genetics which I think probably make it quite difficult for a local ethics committee to deal with. This is why the Nuffield Ethics Committee has been so valuable in producing guidelines in these complexities as they have developed, for example, in genetic screening. The answer is yes, they are absolutely first class, the Local Ethics Committees. Occasionally when you get a rapidly moving field like this you probably need a bit more central expertise to thrash things around because a Local Ethics Committee cannot do this; its job is highly pragmatic, it has got to make quick decisions, many of them across innumerable fields. Therefore I think you need both mechanisms, particularly when something new and exciting like this is going on.

**Sir Gerard Vaughan**

29. Are the arrangements for providing genetic services satisfactory at the moment? For example, are there any genetic services which could appropriately be devolved to GP fundholders?

(*Professor Sir David Weatherall*) Over to you!

(*Professor Bobrow*) There is a degree of ambiguity in the Government's response on that. It obviously depends on what you mean by "genetic services". I think that the field is too specialised and too few of those practising as GPs today have any training in their background of genetics for that to seem to me to be a sensible way forward unless there is some form of administrative mechanism of which I know nothing that could be set up to make sure that the system does not depend upon individual GPs really understanding what it is that they are supporting because they plainly do not and cannot be expected to. Genetics was not taught in medical schools for practical purposes, it is hardly taught now but ten years ago there was virtually no teaching.

**Mr Thompson**

30. What kind of genetic services are we talking about? It sounds a bit horrifying to me.

(*Professor Bobrow*) No, not at all. It is perfectly simple and straight forward.

31. I am just taking my new boy line.

(*Professor Bobrow*) There are about 15 or 20, a bit more than that, regional centres, regional with a small "r", more or less covering patches based on the old health authority regions which provide specialist laboratory diagnostic tests and genetic counselling for the areas surrounding them.

32. We are talking about diagnosis?



14 February 1996]

PROFESSOR MARTIN BOBROW  
AND PROFESSOR SIR DAVID WEATHERALL

[Continued]

[Mr Thompson Cont]

(Professor Bobrow) We are talking about diagnosis and counselling.

Sir Gerard Vaughan

33. We talk a great deal about counselling and the need for it, and it is absolutely paramount, but who counsels the counsellors? Where are they going to get all this advice from or are they just people with an interest in the field?

(Professor Bobrow) The people we speak of as genetic counsellors are really people who work, either doctors or nurses with a special experience of and increasingly with a formal training, in genetics who work in centres with a special expertise in genetics. Increasingly, although that was not true until recently, they also have training in counselling as a topic and they have a variety of support mechanisms appropriate to that.

Mr Thompson

34. The Department of Health, does it in your opinion provide adequate leadership on developments such as genetic testing, or the provision of national screening? Are they doing a good job in this area? Do you want me to rephrase the question or withdraw the question altogether?

(Professor Bobrow) There are two separate issues, one of which is the National Health Service which is not, to my naive way of thinking, quite the same as the Department of Health. The National Health Service has not as yet, I think, seriously demolished any of the structures of genetic services that have been built up. I am optimistic that that state of affairs might continue.

Chairman

35. Very good. Sir David, have you any comment?

(Professor Sir David Weatherall) What Martin has said is terribly important. If you look at the provision of genetic services in the United States it is certainly not as effective under that rather kind of fragmented insurance-based system. I think the Health Service has the organisational ability to have a first class genetic service incorporated into it. I can speak easily because I am not a professional medical geneticist. The regional centres give an absolutely excellent service. I think maybe the DoH has been a little bit slow in moving some of the screening programmes into the community. But it has got the organisation based on the regional services. I am really not pessimistic about that at all.

Dr Williams

36. Can I tie that in with your earlier comments on GP fundholding. Do I understand you to be saying that any move towards devolving to GP fundholders at this stage is going to threaten a deterioration in the service or kill off the service and perhaps the right form of organisation is by top slicing the regional health authority budgets and asking those departments of clinical genetics to provide primary health care, to go into the communities so the service then becomes widely available?

(Professor Bobrow) I can only give a geneticist's viewpoint on this. I am not an expert in health service management and would not wish to be so. I think our concern is that genetics is only a very small part of the Health Service, it is so small that it more or less disappears below the horizon of visibility of anyone who is seriously engaged in looking at the totality of health services. Even within a region a geneticist almost always lands up in practice discussing the size and configuration of service with one or at most two people who have taken the trouble to learn something about that. Our fear, and it may be a groundless fear but it is a fear until it is explained away, is that the more this is devolved out there the less likely we are going to be able to find those people with whom to engage in dialogue so there will be an attrition of service not through malice but just through no-one actually knowing we are there.

Mrs Campbell

37. Are you aware how far the contacts between insurance companies and geneticists have gone? We understood that they were making quite satisfactory progress but since the Government's response was published this may have been somewhat, shall we say, diminished?

(Professor Bobrow) I actually was sufficiently entertained by that phrase in the Government's response to phone around half a dozen of my colleagues who I know at various times have had discussions with people from the insurance industry. I asked any of them if they recognised the description of current strong ongoing talks and they universally said no. There have been sporadic talks from time to time and occasionally it has looked as though they were making headway. We have all found a noticeable lessening of enthusiasm over the past three or four months.

Dr Jones

38. Do you think that has anything to do with the Government's rejection of the 12 month deadline?

(Professor Bobrow) How could I speculate?

Dr Jones: I would like to just raise the issue of patenting of genes which is quite important. As you know, the Committee recommended that genes should only be patented in the context of a particular utility and we also recommended that the European Patent Convention should be amended to allow patents to be challenged on the grounds that they were drawn too wide. That has been rejected by the Government. Do you agree? What are the implications of that for medical or genetic research?

Chairman

39. Let us put it this way, you could answer in relation to what is your view on patents currently but certainly the Government have made that proposal.

(Professor Sir David Weatherall) We talked about this at some length, did we not?

40. Yes.



14 February 1996]

PROFESSOR MARTIN BOBROW  
AND PROFESSOR SIR DAVID WEATHERALL

[Continued]

**[Chairman Cont]**

(*Professor Sir David Weatherall*) This is a very difficult issue. I think the feeling that I have and that of a lot of my colleagues is that for this field to advance it has got to be possible under certain circumstances to patent genetic material. I think where we have all been concerned is on blanket patents of any form of DNA. A patent should only cover the novel utility of genes or DNA sequences. The big concern for the field has been any kind of blanket patent over any form of DNA of unknown function. Just finding a gene should not make it patentable. You really do need to have either a novel mechanism for getting that gene or a completely novel use and then I think one has to talk about patenting otherwise much of the use of this whole field for medicine and humanity will be lost because industry will not be able to develop it.

Dr Jones: I think the Committee was unanimous in agreeing that point. What we were saying was that the patent should only cover the specific utility, the patent of the gene. We have had a comment from Smith Kline Beecham, for example, which says the public has interpreted that in one way and the Government in another. Obviously the pharmaceutical companies want to interpret it in the same way that the Government has. Our view was, I think, heavily influenced by the scientific community. There is a lot of public concern about the issue of patentability of genes and certainly within the House of Commons there was an Early Day Motion which got a lot of support against any kind of patenting of human life. It is absolutely important if we are going to have public confidence that this should be clear and yet the Government seems to think that genes should be treated no differently from any other discovery.

**Chairman**

41. Perhaps, Professor Bobrow, you might give your view.

(*Professor Bobrow*) I thought that the suggestion that came through in your report was an extremely good balance in the sense that there clearly has to be a mechanism for patenting things of value. What I think we are seeing at the moment is an absolute epidemic of defensive patenting where people are patenting things where the discovery lacks novelty in the sense that once the first 50 genes have been cloned the mechanisms for cloning the next five or ten thousand are rather repetitive. There is a feeling that everything must be patented because nobody knows

how the patent lawyers will eventually interpret the extent to which you can control your little discovery. They do not know whether they are going to say there is nothing novel in the cloning of the four hundredth gene or whether they are going to say it is a novel sequence and you can have full rights to it. This is leading, I think, to a lot of totally spurious activity patenting things which do not have any real potential for valuable application and I think no-one benefits from this other than presumably patent lawyers who must be enjoying it a great deal. I myself as a sort of practitioner, and I think many others who recognise the need for patenting, really also recognise the need for a certain amount of moral guidance as to how we are supposed to handle what at the moment is just a free-for-all with everyone saying that one day a test case will be decided but who knows when.

**Dr Bray**

42. May I ask you about one sentence from the Smith Kline Beecham comment. They say: "The express rejection by the Government of any suggestion that the scope of gene patenting should be limited would add clarity to the Committee's useful report." What it is saying is that provided there is a utility which is serious and the gene is patented then that should cover all other possible utilities of the same gene. They are asking for that clarification, is that clarification which you would be happy with or not?

(*Professor Bobrow*) Me personally? Absolutely not. It seems to me that is making presumptions about unknown discoveries far off into the future. It is a moral rather than a scientific issue. If they argue that all future as yet unforeseen uses should be covered then what is the rationale for demanding that there should be one use to start the process off? You could have any old gene and say: "I anticipate unforeseen uses".

**Chairman**

43. I take it you agree with that?

(*Professor Sir David Weatherall*) Absolutely.

Chairman: Thank you very much for coming. I do apologise for the interruption. I am most grateful for the time you have been with us. Thank you.



14 February 1996]

[Continued

## Examination of Witnesses

PROFESSOR SIR KENNETH CALMAN, Chief Medical Officer, and PROFESSOR SIR ROBERT MAY, Chief Scientific Adviser, examined.

## Chairman

44. Sir Kenneth, you are most welcome. You are welcome to the Committee because you have been before and you are welcome because we like to have you again. You know precisely why it is you are here and you had the good fortune to hear the previous session. I understand that it may be your wish to say something in general terms to the Committee before we proceed with our questioning. I apologise again for the late arrival of your turn, if I may put it that way.

(*Professor Sir Kenneth Calman*) Thank you very much. First of all, I would like to say how much I welcomed your report and how much I enjoyed reading it. Secondly, I would like to say how much I enjoyed the last session because many of the issues which came up and the responses were very helpful. I think part of the reason that we are here today is to be in listening mode and indeed not only to take your questions but to listen to the general comments. I think you should be in no doubt at all that genetics is seen by us as being very important indeed in terms of the development of clinical practice and indeed the comments Sir David Weatherall made about this being something rather special is something I would certainly agree with. It is not only important for the individual but, of course, for the population. The impact however, and I think much of the discussion has been about testing and screening, will be much greater than just that and will be on gene therapy, on our understanding of disease, and that may happen faster than the gene testing bit. I think that is important to bring up. On the classification of disease, on new methods of therapy which are not gene therapy but other forms of new therapy which our understanding takes us into, new pharmacologies, prevention, etc., it is also about risk and also about the exclusion of risk. Finally, if I may just distinguish, because I am not sure you did in the last section, between testing which is about testing individuals and screening which is about the population. The Genetic Testing Committee is about the testing of individuals. That really is quite an important distinction. Genetics is something which is of very real interest in the Department. The response, I hope, will reflect the very considerable discussions we have had on the implications of the new genetics. We take a considerable amount of time to get advice and evidence ourselves and we have consulted widely. The issues, however, are complex and do need a lot of thought which is why we welcomed your report. Perhaps two examples are relevant. The first relates to the breast cancer gene which I think a couple of years ago sounded as if it might be the way into genetic testing for breast cancer. We now, in that first gene, have something like 200 mutations and there is now a second gene so it does become more complex. Secondly, in relation to gene therapy which was initially very promising, I think again as Sir David has said that might be slightly further off than we might have thought. Since I gave evidence in April 1995 we have continued to respond to the changes,

the very rapid changes, and have been developing some of the infrastructure to support these changes. There are three specific things that I might just comment on. First there is the establishment of a national screening committee and that is not just about genetic screening. This was foretold in a paper which I produced in January 1994 in relation to the development of screening services. Secondly, as part of the Bobrow Committee, whose report you have seen, there was a suggestion that that advisory committee should continue and that will continue and we hope Professor Bobrow will chair that. Thirdly we have, as part of our thoughts on the development of cancer services, a wish to set up a cancer genetics service which will be a subset of Professor Bobrow's Committee chaired, we hope, by Professor Harper because we thought that would be a very useful way of looking at how you develop a service, in other words is it cancer related or is it genetic related? In fact, for each of the diseases there are many slightly different models. The importance of the regional services, which again my two colleagues before me have identified, are I think very important, the academic service and clinical and molecular bits working together. These models of service are being developed. The service that we do have in this country is I think admired across the world. There is a very real need to integrate the research on the clinical side of things as clearly as possible. Of course, the Government did respond to your comments about fundholding general practice I thought very clearly in the report. Finally, if I could emphasise, as I did the last time I appeared before this Committee, three things. First of all, the importance of public understanding of genetics and the need for public confidence. Secondly, the importance of professional education, again raised by my two colleagues before me. Thirdly, the importance of the ethical base to take these developments forward.

## 45. Sir Robert?

(*Professor Sir Robert May*) I did not have the opportunity to speak to you earlier in the first round because I was not here, as it were, then. I particularly welcome the opportunity not least because I have, dare I whisper it, continuing research interests in the subject. It is clear that human genetics and biotechnology more generally offer a great deal to society both to understand ourselves and understand our place in it; and also in application of that understanding to make life better for everyone. We are very grateful for the very full and comprehensive inquiry you put together and at the same time that is why we took it very seriously and consulted very widely. OST co-ordinated the response from some ten Government Departments, which also partly made it a bit time consuming. When we speak of human genetics, the science and its consequences, it seems to me we speak of unravelling the genetic map, reading the code of life at the most fundamental level. We also speak of the consequent application of that—the genetic testing, gene therapy—which



14 February 1996]

PROFESSOR SIR KENNETH CALMAN  
AND PROFESSOR SIR ROBERT MAY

[Continued]

**[Chairman Cont]**

promises much for improved health care; and I would emphasise, taking us just a bit wider, we speak more generally of biotechnology which offers, I hope, even more in the way of more efficient and more sustainable food production, cleaner technologies and methods of improving the environment. In all of these areas we have got world class scientists doing world class research. In 1992-93 the research councils spent more than £100 million in biotechnology research construed broadly. We are well placed, I think, to capitalise on sensible applications of this basic research. I can even offer commercials for Foresight Groups that have identified genetics and biomolecular engineering as key priority areas for the new Link Programmes that have been established as a principal mechanism for taking some of the biomedical work forward. Having said all that, and as you so clearly pointed out in your report, common to all biotechnology research and application is the need to bring the public along with us, to ensure public understanding and acceptance on the basis of that understanding. That is nowhere more true than for human genetics, as you have observed, with all the potential concerns that can arise. I could again, and will, abbreviate a commercial for OST efforts in the public understanding of science generally but I would emphasise the research councils, particularly the Medical Research Council and the BBSRC, have done a lot and are continuing to do a lot in a very focused way in trying to promote public understanding of genetics in particular. We come to you far from complacent. I can see the dangers. On the one hand what we do not want to see is a public backlash against applications of genetic science. On the other hand, what we do not want to see is inappropriate inhibition or an over-regulation of legitimate research and sensible application. It is just essential to get the balance right. Again I welcome this continuing dialogue and I am here essentially to listen constructively to try and make sure we get that balance right.

46. Thank you both for that. Let me ask Sir Kenneth Calman, I detected from you a willingness to consider public education and public confidence as being an essential ingredient in the successful application through the Health Service and no doubt through genetic therapy, genetic testing and so on. Why is it, therefore, that you felt disinclined to accept the breadth of the Committee's proposal for a commission which deliberately included in its remit those sorts of aspects, ie to cultivate public confidence through education, through standards of counselling, through preparation, so that the anxieties might be reduced before they reach critical level?

(Professor Sir Kenneth Calman) I do not think there is any disagreement between us in relation to the objective. The issue is what is the correct mechanism and that, I think, is part of the reason why today I am certainly in listening mode to hear other options which are available. Regarding the questions which you asked the two previous speakers, I think their responses were very interesting because simply setting up a commission may not be the only way to develop public confidence in this area. It may not be the only way to develop greater public understanding. I think the objective is the

same, the question is whether there is a better mechanism to do that. It may well be that there are other ways of ensuring that the public become aware of these issues and are indeed involved in the discussions too, some of the initiatives that Sir Robert has mentioned with OST in terms of a general public understanding of science.

47. But the Commission composed of a wide range of persons, many of them drawn from the laity if I may put it that way, and it was part of our perception really that it would be seen at arms' length rather than a committee appointed by and responsible to the Secretary of State for Health.

(Professor Sir Kenneth Calman) I understand that, I am just trying to say there are a number of ways in which you do it. It seemed to me that the discussions on the Commission, as set out in the report, may have moved a little bit, certainly in the discussions I have heard today, it being more about the public confidence issue and public understanding. I think that is an important way of thinking about that Commission which is perhaps not the way I read it initially. I think your development of that theme is very helpful today.

(Professor Sir Robert May) Can I just say one thing by way of supplement to that. Obviously public understanding of science is part of the general remit of the Office of Science and Technology and in particular human genetics. We are aware of the sensitivities surrounding the issues; it is just that we do feel that we think we have in place an adequate set of procedures to carry that out. I could give you a catalogue of things like the information pack for schools and so on. I would more broadly emphasise that both the Medical Research Council and the ESRC have done projects on ethical, legal and social aspects of the subject. One of the ESRC's identified priority areas for future funding is social implications of technology, including new medical technologies. The BBSRC, you will be aware, funded a consensus conference that drew a set of lay people together to explore ways of raising public awareness of genetics and initiating that debate. We resonate with your concerns here, it is just that we are not fully convinced that we are not doing a pretty good job already.

**Dr Williams**

48. I just have one question on the GP fundholders. I listened carefully to what Sir Kenneth Calman was saying and it sounded very reassuring and tied in with the earlier comments, but in the Government's response when I first read this paragraph 56 was very dismissive of any devolution to fundholders. In paragraph 59 it left things fairly wide open over a period of time so that GP fundholders would be in discussion and collaboration with NHS provider units as to what services would be developed. I was in a debate last week where the Minister for Health in advocating GP fundholding seemed to attribute all innovation at GP level to the fundholders, as it were, as if all other GPs were not interested in innovation. It was very much a two tier kind of approach so I am quite concerned



14 February 1996]

PROFESSOR SIR KENNETH CALMAN  
AND PROFESSOR SIR ROBERT MAY

[Continued]

**[Dr Williams Cont]**

here in the Government's mind that maybe in 56 versus 59 of their response you are saying one thing and doing another thing?

(*Professor Sir Kenneth Calman*) I do not agree with that. 56 is pretty clear, it is not about fundholding. I think if you were to think about the development of genetic services generally, and that is what 59 says, it is important that those involved in purchasing should actually be involved in some of the discussions but it does not mean to say GP fundholders would purchase them. There is quite an important distinction between the two. I think we also have to be quite careful not to exclude general practice from the importance of genetics. We made the point when I was here last time that in terms of family histories and counselling and follow through general practice is important in that. I also do not think that Professor Bobrow was saying that GPs should not have a role in that at all. What I think it makes clear in 56 is that it is not about GP fundholders actually purchasing services. What it is about in 59 is involving general practice, including GP fundholders, in developing the kinds of services required. For example, with Professor Harper's interest in this area he will, I hope, be looking at cancer genetics services and it will be very difficult to do that without involving the primary care teams to see how best that service could be developed.

**Chairman**

49. Could I just quote from your response on this: "There is no intention to devolve funding for all the functions and elements, or the collaborative and co-ordinating roles, of the genetic services to GP fundholders".

(*Professor Sir Kenneth Calman*) Yes, I thought that was fairly clear. I understand the confusion in 59 but I hope I have clarified that.

Dr Williams: I see the role of health commissioning and a fairly strong role for GPs within health commissioning but I would be very concerned if any part of the budget on genetic services was not determined centrally. At this stage it has to be determined by regional health authorities and directors of health.

**Dr Jones**

50. It does imply that some funding could be delegated. It says there is no intention to devolve all funding. Is that just a liaison arrangement?

(*Professor Sir Kenneth Calman*) I am happy to take this very much further. I hope we have answered it properly. Supposing, just supposing, in relation to cancer services you thought that counselling was important, it may well be that there are parts of that which might be relevant and could be delivered at a local level through a GP fundholding base but that is not quite the same as actually purchasing a genetic service.

51. Should that not be the role of the GP anyway, to counsel his patients?

(*Professor Sir Kenneth Calman*) It seems to me that this is an important issue and I hope I have answered it but there must be other big issues.

**Dr Bray**

52. Can I ask Sir Robert against the background of his own research interests a question on risk. Do you think it is foreseeable that genetic tests could be used to enable insurers to lower the risk of their insurance including medical insurance or for employers to select a healthier workforce? In other words, can you use genetics to reduce the risk of insurance?

(*Professor Sir Robert May*) Yes. As in any other form of insurance the more knowledge you have the more you can balance things out.

53. People who are genetically vulnerable would either face very high insurance or would not be able to get insurance at all?

(*Professor Sir Robert May*) Stepping aside from genetic testing for a moment, the insurance industry as I understand it has uniformly taken these kind of things into account. If you are already pregnant, certainly in the United States, it colours the relation you have to that form of insurance. That is to say, as I understand it, an underlying principle is insurance is meant to cover risk not certitude. If you have something where you know you have a claim you cannot then subsequent to that knowledge take out the insurance in a way that is not coloured by that knowledge. There are two different aspects to all this. One is whether insurance companies have a right in this area, as in all others like motor car insurance, to have access to prior knowledge on the part of that person claiming insurance as distinct from whether they may put precautionary conditions on it. I would see the latter as something that is very much an issue for dialogue with the insurance industry because that would be rather different from the more commonplace thing of prior knowledge.

54. Can I draw your attention to paragraph 104 of the Government's reply where it says: "The Government notes the Committee's view that genetic information may limit the scope of medical insurance in the medium to long term. It has yet to be persuaded by any evidence that such problems may occur in the foreseeable future." Is that not an outright denial of what you have just said?

(*Professor Sir Robert May*) I am reluctant to offer a parsing of the intent of a paragraph like that.

55. But it reads as an extraordinarily complacent reaction.

(*Professor Sir Robert May*) Perhaps it would be helpful if I outlined what I understood to be the position which is to say the Government welcomes the continuing dialogue with the insurance industry and genetic experts on a code of practice for the industry with respect to genetic information.

56. So it is highly foreseeable that problems may occur?

(*Professor Sir Robert May*) Indeed.

57. Thank you.

(*Professor Sir Robert May*) What one wants to work to is a code of practice that deals with these issues and deals clearly with the distinction of the issues between prior knowledge on the part of the person seeking insurance and the attempt to screen out all risks in a way that transcends prior



14 February 1996]

PROFESSOR SIR KENNETH CALMAN  
AND PROFESSOR SIR ROBERT MAY

[Continued]

**[Dr Bray Cont]**

knowledge. I, speaking personally as I am now allowed to, would expect that to be part of the dialogue that unfolds.

58. I think that is very welcome.

(*Professor Sir Robert May*) I think we were all in agreement in relation to what we need round the difficult set of issues that come up here, many of them, however, parallel issues in other areas of insurance that cover different people being at different degrees of risk; our car insurance depends on where we live and we often have little control over that, but we felt we shared the concern that this code of practice moved towards. We differed in feeling that it would not be constructive to draw a line in the sand on a specific date.

**Mrs Campbell**

59. Sir Robert, you have listened to the comments from our two expert witnesses and I wonder in view of their replies to some of our questions whether you still feel that the Government's reply will allow an orderly development of the science and application of genetics?

(*Professor Sir Robert May*) I am sorry, we have moved off the insurance issue?

60. Yes, we have. I am looking now at the whole report and the reply which many of us felt was very unsatisfactory from the Government. What I am saying to you is you have heard the comments from our two expert witnesses today and in view of some of the replies that they gave are you still completely satisfied that the policies in the reply have your unshaken confidence?

(*Professor Sir Robert May*) First let me paraphrase what I heard by way of their reply so we are sure we are talking about the same thing. I heard them say that there is a variety of technical issues here, some of them covered by existing committees, some of them more directly addressed by the new Advisory Committee on Genetic Testing, of which we are the first country in the world to set up such a thing; but they are nonetheless worried about things, interfaces among them, and they are worried about other things that may unfold as we go down the road. I heard them say that they thought in the substance of managing the technical and scientific issues that come up we have a pretty fair coverage. What I heard them say was a worry, was that when bringing along public opinion and reaching a wide forum of debate there may be a role for some central co-ordinating committee that transcends this collection of other things. That is possibly a gloss upon what they said but in so far as they said that, I think that was a very reasonable thing for someone to say.

61. The Human Genetics Commission, which we proposed in our report, would actually satisfy some of those criticisms, would it not?

(*Professor Sir Robert May*) In some respects and in some respects it would go quite a bit further.

62. Can I just ask you a further question. You mentioned in your opening statement that there were a very large number of departments involved in formulating your reply. Did the large number of departments involved involve you in compromise in any way?

(*Professor Sir Robert May*) It is unavoidable when you get opinions from ten different departments each representing a different perspective. You, after all, have a Cabinet style Government in which people have different views which then come to a collective decision; so too if you have the civil servants that try and execute the initial policies it would be amazing if ten different departments were identically congruent on every point initially. I think they had a fair airing, a fair hearing of all the points of view. I do think it is reasonable to say that in respect of the question of considering the substantive issues that genetic research implies in biomedical science, there was general confidence that there is co-ordination among the existing committees, that it is unlikely that issues are going to slip through that net, and that looked like a sensible way forward bearing in mind one is always trading costs and benefits—searching always to minimise bureaucracy while maximising the protection of public interest.

63. I am sorry to interrupt but could I just put it to you that in fact a Human Genetics Commission which will span a number of different Government Departments is something which is quite difficult to accommodate within the present structure of Government and this is one of the reasons why the reply implicitly rejected that.

(*Professor Sir Robert May*) I would not think so.

(*Professor Sir Kenneth Calman*) Not at all, I think that is quite a wrong assertion. There are a number of issues, the drugs issue for example would be a very good one, where there is a multi-Government, multi-department involvement in that. I saw this response not as a series of compromises but actually as an agreement between a variety of departments. I would have thought that that is perhaps the best way to put it. I am quite sure that the inter-departmental bit was not the issue against any kind of commission at all, the issue was the one that Sir Robert has very clearly stated.

**Dr Bray**

64. On the drugs precedent specifically there is a Medicines Commission and it does have committees.

(*Professor Sir Kenneth Calman*) No, that is medicines as opposed to the abuse of drugs which is the one I meant, not the Medicines Commission.

**Dr Jones**

65. On that one, Professor May mentioned that there are co-ordination arrangements, could he say what those are and how effective they are in feeding back to the different departments?

(*Professor Sir Robert May*) You have embarrassed me. I could not give you chapter and verse of the detailed arrangements.

(*Professor Sir Kenneth Calman*) One very good example of that: there is a thing called the Interdepartmental Group on Public Health chaired, as it happens, by the Chief Medical Officer which brings together about ten Government Departments and can raise a wide variety of issues that concern the work of public health for general discussion.



14 February 1996]

PROFESSOR SIR KENNETH CALMAN  
AND PROFESSOR SIR ROBERT MAY

[Continued]

[Dr Jones Cont]

66. Obviously with the tremendous progress that is being made in science there is going to be an increased demand for health services. Are you satisfied that the health service will be able to meet these demands when already the regional centres are expressing concerns at their ability to cope with the current situation? In the Government's response it does say that some of these services are having difficulties establishing themselves in the internal market arrangements.

(Professor Sir Kenneth Calman) This is a very important issue. From what I hoped I said at the beginning we have very good regional centres. It is important that these regional centres are appropriately funded. I think the issue, however, is how genetic services are to develop. There are at least two ways in which they can develop. One is to remain as regional services and gradually expand or they could be outposted in other areas such as an oncology centre, a neurology centre. That is one of the reasons why the Sub-Committee on Cancer Genetics really has to look at that kind of model. There are different ways in which they might expand and develop. I think that we should be pretty flexible to ensure that happens. If you remember, right now most of the services are at the single gene end, most of the services are for children and related to that kind of area. If we develop it into cardiovascular disease, diabetes, cancer, it actually changes things. What I am really quite excited about is how we will be able to take that forward and continue to provide a very high quality genetic service for the population as a whole.

67. Who is responsible for advising Government on the development of the service?

(Professor Sir Kenneth Calman) On the development of the genetic service? I think there are several ways in which that is done. One is that following Professor Bobrow's report we will be reconstituting that committee, chaired by Professor Bobrow, which will have not only science but management as part of that. Secondly, I do have a consultant adviser in genetics, Professor Pembrey who spoke to you last time, and thirdly, because we work in the National Health Service and in this country we have access to any kind of advice that we need. Indeed, one of the joys of working in the United Kingdom is the ability to get access to Professor Weatherall if we need to, to contacts in the MRC, we have that advice and we can get that advice any time that we wish.

Mr Miller

68. In your introduction, Professor Calman, you described I think a future where genetics will become very important in clinical medicine. I think you will agree that at the sharp end application it is a relatively small component part. At the same time, of course, looking around the world there are some pretty large financial institutions bankrolling some very large parts of research so somebody out there has got some confidence that it is going to be fairly big in the next few years. How important do you expect genetic medicine to become in the next 15

years? Do you agree that within the foreseeable future most people will have some contact, directly or indirectly, with genetic screening?

(Professor Sir Kenneth Calman) Just the last few words I take issue with.

69. It is a question, you do not need to take issue with a question.

(Professor Sir Kenneth Calman) The answer to your question is genetics and genetic medicine I think is, as Sir David said, really at the heart of a whole series of changes that are going to go on. Again, as I have tried to say, that is within the foreseeable future. It may not be all at the screening end and that is the distinction I would make. In other words, the development of our understanding of disease, the way in which we treat patients, may not all require a genetic element, it may be non-genetic because we understand the disease better. Therefore, in terms of whether everybody will get into some kind of screening programme is a slight side issue to that. It may happen but I am not sure about that.

70. I said directly or indirectly.

(Professor Sir Kenneth Calman) Yes.

71. Most people will have.

(Professor Sir Kenneth Calman) I think if you look 20 years ahead at the impact of genetics as opposed to genetic screening, genetics will be very considerable to the population as a whole. I make that point very clearly.

72. So against that background you are still arguing that current mechanisms that were established around science being a speciality area for a handful of people and only applying to a handful of client groups, those mechanisms will be adequate in the future?

(Professor Sir Kenneth Calman) No, I did not say that at all.

73. That is how some of us read the report.

(Professor Sir Kenneth Calman) I think that is taking it a little step too far. What I have said, and will continue to say and said the last time I was here, is that genetics and the way in which genetic medicine will impact on individuals in the population will be very considerable. Within the National Health Service, for example, we have recognised that and will continue to recognise that and we will have to find ways in which we can deliver an increasing amount of genetics. The issue, however, is whether that is in a genetics centre or whether that is within general medicine as a whole. That is quite an important distinction. I am not quite sure which way it will go. You will have to ask Sir David that issue. Indeed, when you did ask him I think he said it could go either way too. I think neurologists will get interested in that, cardiologists will get interested in that, oncologists will get interested in that, maybe that is where we should put the resource and the development rather than in a genetics centre. That is a service delivery issue which needs quite a lot of discussion.



14 February 1996]

PROFESSOR SIR KENNETH CALMAN  
AND PROFESSOR SIR ROBERT MAY

[Continued]

**Sir Gerard Vaughan**

74. Do you agree that greater public knowledge will lead to greater confidence in what is going on and therefore enable people more easily to determine whether they wish to have genetic testing and in turn may lead to less counselling?

(*Professor Sir Kenneth Calman*) I think the answer is quite clearly yes to that and I think both of us have said very strongly that the public understanding of science generally and of genetics in particular is a very important component in all of this. The public do have to have a greater understanding of what is going on.

75. We thought that a very important benefit from having a Commission would be that this would enable greater public understanding and would increase the confidence in what was going on. Do you feel that you and research councils will be able to do this? Do you think you will have sufficient resources to carry out this huge task?

(*Professor Sir Kenneth Calman*) I think at the resource end we already put a considerable amount in. We are, again as Sir Robert said, very much at the leading edge of a lot of genetic developments anywhere and I would hope that we would stay there. What I have got out of the discussions, both in the previous session and this session, is a slightly different view of the Commission. It seems to me to be more related, and maybe I am wrong on this and it would be helpful to hear, to the development of public understanding and confidence. That I think is interesting because it is not quite the way in which I had read it before.

**Chairman**

76. We took a view, Sir Kenneth, and this was a view particularly recorded when we went to the United States and took evidence there. There is a point at which these issues of lost public confidence in testing of this kind and the flapping that goes on about patenting on the one hand or insurance in the United States are the sorts of issues where the public are hugely involved in relation to insurance but are not quite sure that they want to know what all these things are going to be about. It came to the Committee as a clear recommendation that the speed with which the science is shifting is probably far faster than the speed of public acceptability of what in many cases is known as genetic engineering. They are sometimes misled. That is why we felt it necessary to lift and carefully prepare the ground before too many more years have passed.

(*Professor Sir Robert May*) Can I just add a footnote to that. I regard public involvement with science, and a public understanding of the every day nature of the way it shapes our lives, as one of the most important things for us all to be trying to do, in this area predominantly. I do not think that can be accomplished from the top down. I do not think that any one central body, whether it is the Committee on Public Understanding of Science, the British Association, the Royal Institution, or the efforts of local consortia run by school teachers, is the one single mechanism. What we need is many different avenues and many of them from the bottom up. We will do more to educate people about medical

genetics by weaving threads about it into *Eastenders* than we will ever do by having meetings at the Royal Society. That is another larger issue that we should all be working on together. I do not regard the existence of one more body which is particularly interested in disseminating down to these things as being the crux of the issue, I think it is going to be dealt with better, as in other areas of science, if we can foster a diversity of things from the bottom up.

77. The crunch point of our recommendation 266 was that the Commission would not just be a regulatory body but would be an advisory body in relation to the role of the public.

(*Professor Sir Robert May*) I am just saying in respect of educating the public in this area there are already a large number of bodies possessed of this goal and seeing it as important. This would be one more important player if it exists.

**Dr Bray**

78. May I return to the earlier points made by Sir Kenneth when he was saying the concept of a Commission that he was getting from today's evidence is somewhat different. There are different models. The Health and Safety Commission has broadly a public understanding and co-operation role as well as a regulatory role. The Medicines Commission is perhaps more narrowly regulated. If you read the Medicines Act there is nothing in the Act which says that it has to be. I wonder, can I draw Sir Kenneth's attention to what he said himself in his evidence to the Committee on 19 April when asked about the Committee having to come to some conclusions and observations on the adequacy of the present monitoring systems and the present legislation. He replied: "We need a mechanism... There are a lot of people involved and there needs to be a mechanism for somehow co-ordinating that but at the same time not being inflexible and stifling initiative in a variety of different organisations. I think it would be most sensible to have a single mechanism rather than a number of mechanisms. The point I was making is that there are a number of players who are interested in developing genetic issues. I think there should be a single mechanism and that mechanism has perhaps to be sure that it is not just too narrow, to consider only genetic issues, because the genetic issues go beyond just a very small area. They may actually involve other issues. Some of the ethical issues go beyond simply genetics...." Sir Kenneth, your evidence then was very influential in shaping the views of the Committee. Have you changed your mind?

(*Professor Sir Kenneth Calman*) I very rarely change my mind, as you know.

**Chairman**

79. A true Scot!

(*Professor Sir Kenneth Calman*) I think that is still appropriate. The issue for me is whether the Commission which you have suggested is the appropriate one and that, in terms of the Government response, it meets the needs. What I would say, of course, is that part of the function that



14 February 1996]

PROFESSOR SIR KENNETH CALMAN  
AND PROFESSOR SIR ROBERT MAY

[Continued]

**[Chairman Cont]**

Sir Robert and I are here today to do is to listen to the discussion as we did to the discussion before and I think we have both found that very helpful.

**Dr Bray**

80. Can I just, for the sake of sweetness and light and general agreement, ask you are you aware that the Committee of course realises the advantages of moving informally through a non-statutory committee because that does not require primary legislation with the Commission later coming along with some experience of how the thing operates and so on. Also there are many different models of even how advisory committees can function. You could ask one of the present committees' chairmen to convene as chairman of the other committee.

(*Professor Sir Kenneth Calman*) I find that an extremely helpful comment in relation to how things are likely to develop forward. I say it once again, the discussion has I think been very helpful.

**Mrs Campbell**

81. I just want to come back to screening and something specific in the Government's reply, if I can just quote it to you. It says: "The Government expects that where the evaluation of a proposed screening programme suggests that it is clearly desirable ... then consideration will be given to providing it." Sir Kenneth, what powers do you have to ensure that desirable screening programmes are provided by purchasers, rather than merely being "considered"?

(*Professor Sir Kenneth Calman*) I think this is a very, very important issue. If I take you back to the paper we produced in 1994, which I think set that out, what that paper said was that from a wide variety of scientific and research issues things will pop up and say "Maybe we should screen for this", whether it is ovarian cancer or aortic aneurysms or whatever. When that comes up from the research community it needs to be looked at in the broad: is this a useful thing to do; do we have the technology to do it; how can it be done on a population base? The screening committee, which I described at the beginning, would be that and therefore we do have that mechanism.

**Chairman**

82. Is that a national influence?

(*Professor Sir Kenneth Calman*) Yes. The whole purpose of the 1994 screening document was to work towards that. We now have that and I think that provides the mechanism. The Health Technology Assessment Group, which will say "Here is something we might screen for", can be looked at in the round and if the programme is appropriate it is taken forward with proper quality assurance, proper staffing, proper ways of continuing to evaluate. That is the way we would like screening programmes to continue and indeed to develop further. Our current breast cancer screening programme is a very good model of that. The evidence said we should be screening for this, the Forrest Committee looked at it, developed it and then pushed it through. If

something comes up at the genetics end from Professor Bobrow or Sir David that is the mechanism with which it will be placed. That is why this thing has been tested on individuals, the screening programme, because the issues of screening, ethical issues for example, confidentiality, are very similar across a whole range of screening programmes.

**Dr Williams**

83. In our inquiry we have got the impression that the screening service as now provided is highly variable across the regions. We were quite impressed by professor Harper in Cardiff and the cover that he gave to the whole of Wales from the centre in Cardiff. Is there not every reason to move strongly in that direction? Downs Syndrome and phenylketonuria deficiency, those are the only programmes that have got national coverage. Should that not be the way ahead, organised maybe centrally as well as regionally?

(*Professor Sir Kenneth Calman*) I agree. First of all we have got strong regional services and they have all developed in slightly different ways. The Welsh one is a particularly good one but there are other exceptionally good ones around the country. We want to ensure that they continue to develop and that they provide that service on a national basis, if we agree that that service should be provided on a national basis. That is quite an important caveat.

**Mr Thompson**

84. Throughout this evening's session you have been saying that we have produced a very interesting report but perhaps you do not fully understand what we are getting at. Let me reverse that and put that to you in the context of the response we have received. You have said that no screening programmes should be introduced "without national guidance". Does that mean that screening programmes such as those for Downs or thalassaemia could no longer be introduced without central scrutiny?

(*Professor Sir Kenneth Calman*) No. I think you have got to make a distinction between national screening programmes in which there is nationally agreed guidelines with quality control, evaluation, etc., and some conditions which may not require a national programme—thalassaemia would be one for example—in which you might be looking at particular populations in particular parts of the country.

85. How does that relate to paragraph 43 where it says: "The Department of Health has set up mechanisms to ensure that any proposal for screening is subject to careful evaluation before introduction"?

(*Professor Sir Kenneth Calman*) I think it is quite important we do not stifle the development of screening. Therefore, there will always be in some areas some screening programmes which are evaluating whether this is worthwhile or not. We need to do that. The next issue is whether that is a feasible proposition which actually could be taken into a national screening programme. I see no difference between the two. There are some in which



14 February 1996]

PROFESSOR SIR KENNETH CALMAN  
AND PROFESSOR SIR ROBERT MAY

[Continued]

**[Mr Thompson Cont]**

I think it is local, it is for one part of the country to develop, pilot and understand it. If that works then you can begin to think about it on a national basis.

Chairman: Thank you very much, Sir Robert, Sir Kenneth, for coming here and hanging around. It was fairly late in the evening before you kindly came

and answered our questions. We are most grateful to you both. Thank you for the vigour with which you have given your answers. Thank you so much.



28 February 1996]

[Continued

WEDNESDAY 28 FEBRUARY 1996

## Members present:

Sir Giles Shaw, in the Chair

Mr Spencer Batiste  
Mr Ian Bruce  
Mrs Anne Campbell  
Dr Lynne Jones

Mr Andrew Miller  
Mr Patrick Thompson  
Mr Alan W Williams

## Examination of Witness

THE RT HON STEPHEN DORRELL MP, Secretary of State for Health, examined.

## Chairman

86. Secretary of State, a renewed welcome to you and a particular welcome because in seeking a further round of discussions with the chief interested parties in respect of the Committee's report on human genetics and science and its consequences we felt that before we could arrive at a conclusion of our own from the Government's response it was desirable to obtain some clarification on some of the reasons which led the Government to the response which it has made. Perhaps I may preface our questioning by two points of observation. The first is that the report that this Committee produced has created, I think it is reasonable to say, a very significant impression certainly within the medical and scientific public and those who take a professional or otherwise interest in genetics. We therefore think we owe it to that substantial body of public opinion to do the best we can in refining our response to ensure that we do understand it fully and it should reflect properly the enormous importance which is now attached to the report we produced. Secondly, within that report and, indeed, within the Government's response it is very clear to us that your own Department is crucially important, not just because of its provision for medical services throughout the country but also because in the application of the science your own Department has a very great role to play. It was of no surprise to us that the majority of responses in the Government's response came from your own Department and we feel that gives us the justification for asking you to come here today and we obviously greatly welcome that opportunity. I will ask the first question. The issue of genetic science obviously has wide implications to a number of Departments in Government and is of great prevailing importance. Do you consider that as Secretary of State for Health you have a peculiar or particular responsibility to take the lead in considering the implications of genetic science?

(Mr Dorrell) I think I would be cautious about saying that I had a lead responsibility. I clearly have an important responsibility because a lot of the implications of the developing science will obviously work their way through into the National Health Service, particularly if it develops in the way that the Committee's report suggests that it might. The implications, for example, for the insurance industry

or for employment considerations and, indeed, the implications in terms of the cross-referencing between genetic science and other aspects of scientific research, all fall either partially or completely outside my strict departmental brief, so I would be cautious about saying that I have a lead responsibility for those reasons. If I may, I would like to append to my answer to your first question a comment that I would like to make to the Committee at the beginning of the session because I think it might take the discussion on. Your question asked me whether I felt that this is something where the Department of Health has a key role and my answer perhaps illustrated part of the concern that led the Committee originally to recommend the establishment of a Human Genetics Commission that would bring together some of these cross-departmental interests. The Committee will know that in the Government's response we did not feel that it was right to proceed with a Commission on precisely the basis that the Committee had recommended and I think it is fair to say the Committee attached to that recommendation three particular characteristics in its proposal which made the Government pause. The first was the proposition that we should define in statute for the long-term what the Commission should look like. The second is that we should accord to it a regulatory function and the third is that we should accord to it a function of monitoring the provision of NHS services in different localities. Those three elements the Government is not persuaded on and continues not to be persuaded on. I have been following the second round of evidence sessions of the Committee quite closely and have had discussion internally within the Department following those sessions and, indeed, with yourself, sir, in conjunction with Ian Taylor from the DTI. I think as a consequence of those further discussions with the Committee there is another element of the Commission proposal with which I certainly do have more sympathy and which I would like to suggest that more work is done on and that is the oversight cross-departmental role over the ownership of the science and the implications of the science in its broader sense, particularly looking at the moral and commercial implications of the development of that science on a broad basis. I do think that there is a question which the Committee has asked where we have not yet fully delivered an answer in terms of how the Government is going to



28 February 1996]

THE RT HON STEPHEN DORRELL MP

[Continued]

**[Chairman Cont]**

deliver a cross-departmental view of those considerations. I intend to set in motion a review within the Government of that aspect of the Commission proposal and I would like to keep in touch with you, as Chairman of the Committee, about that idea.

Chairman: I am sure the Committee would agree that that is a very welcome suggestion. It does, in fact, underline the second question I was going to ask because if your Department, for example, does not take the lead then how can we achieve what we really see as a trans-departmental problem, particularly when in respect of the Commission we are looking at other aspects than that, ie health therapy, education, public confidence, awareness and so on.

**Mr Batiste**

87. That is extremely helpful as an introduction to our discussion and I think it meets what was the fundamental concern of most of us, which was that there were a range of initiatives going on across the board independent of each other and without any coherence. One of the real problems of government is always what is happening as new sciences break the traditional boundaries of departmental responsibility. Can I ask whether in the context of the sort of commission that you might be thinking about it would matter where it was located in government? You would not, for example, have a preemptive strike that it has got to be located in the Department of Health or anywhere else? This is a matter that could be open for discussion, is it?

(Mr Dorrell) I would resist the description of a "commission" because I do not think that is a word that accurately describes the sort of body that the Committee had in mind. What I am describing is something which I regard as a more evolutionary approach but addressing a specific element of the Committee's concerns, namely the cross-departmental issues and the moral and commercial issues raised by a developing science. As regards to who would be responsible for that, I think that is an issue we would need to examine further and we would need to see what emerged from the kind of further deliberation I had in mind.

88. What sort of time-frame might we look for?

(Mr Dorrell) One of my predecessors used to say to officials in the Department that he wanted something done but he wanted it done in less than a geological timescale, so I think that is probably the best description I can offer the Committee this afternoon.

**Chairman**

89. We felt, and it became clear from the evidence we obtained both in the United States and here, that there was a need to at least address the issue of how far the public will have increased confidence as opposed to increased anxiety in the development and application of genetic tests in science. I think it does require a timescale of some importance, does it not?

(Mr Dorrell) I cannot commit myself to a timescale this afternoon, but I accept that public understanding of where we are, where we are likely to

get to and how fast, and what are the implications of that movement is one of the issues that a cross-departmental view should be expected to provide.

**Mrs Campbell**

90. Secretary of State, I welcome your initial statement too, although I must say I am a little bit more concerned after hearing what you have just said. Can I first of all say that a geological timescale cannot compare with a biological timescale in the sense that this is an area where science is progressing very fast and we are going to need answers soon. As you know, last week we examined Professor May, the Chief Scientific Adviser, and he told us that the decision not to set up a Commission was based on, first of all, "trading costs and benefits" and, secondly, "to minimise bureaucracy while maximising the protection of public interest". I think what you have just described to us is another perhaps over-arching body bringing together the eight committees which you mentioned in your response. Is that really going to minimise bureaucracy or is it going to magnify it somewhat?

(Mr Dorrell) It is important not to imagine that there is one relatively small group of people who can bring together all the expertise that is necessary to achieve the kind of both over-arching view and specialist knowledge at application level that the original proposal would have involved. That is why I prefer to maintain, for example, a specific advisory committee looking at testing and a specific advisory committee looking at therapy where there are very specialist applications of scientific knowledge and ethics that need to be considered. The extra value that would come from an over-arching view is one that I concede is worthy of further examination. I am not committing the Government to establishing one, I am committing us to examine that element of the Commission proposal which the Committee put forward. I very strongly prefer an evolutionary approach to this rather than seeking to set it all on a statutory basis or to imagine that the right way is to take all the existing structure and sweep it away and replace it with something else. We do not know how quickly the science is developing. It may be developing very fast or it may be developing more slowly than some of the enthusiasts believe. I think it is important that the structures within the Government—I agree with Mrs Campbell—need to change quickly enough to deal with a changing world, but they need to be responsive to it as well and we need to think as we go along rather than imagining we can set it all out in concrete and that will do for ten years.

91. Are you now thinking of something that would be more hierarchical in nature in that you are looking at a reporting body to which the eight committees would report?

(Mr Dorrell) No, I am not looking at that. I have indicated that there are some aspects of the Commission proposal which I accept are not covered by the present committee structure. It is a fair question to ask how Government is covering those aspects that are not covered by the existing committee structure.



28 February 1996]

THE RT HON STEPHEN DORRELL MP

[Continued]

**[Mrs Campbell Cont]**

92. So this would be a ninth committee?

*(Mr Dorrell)* At least to start with, yes.**Mr Miller**

93. I will keep off the analogies with a geological timescale as the only person who has worked on geology in the Committee only to say that perhaps one day I may write a paper on the fossils of Westminster! Some of the points that you have made seem to me to be dodging the issue. You talked about an evolutionary approach. We in our paper (paragraph 286) draw a comparison with the evolution of the Human Fertilisation and Embryology Authority. We had in mind the need to have an evolutionary development. We clearly had in mind the need to have a cross-departmental body and we clearly had in mind a body which could deal with the moral, ethical, legal and health issues and so on. It came as no surprise to me to see in a response from the Alzheimer's Disease Society to the Government's response, a body which I am sure you hold in equally high regard as I do, that they praised the concept of the Commission and go on to say, "In contrast the Society feels that the Government's proposal for an Advisory Committee on Genetic Testing is unimaginative. We do not accept that adding to the existing system of bodies already in place will enable the Government to 'continue to provide an appropriate level of coverage and control' in the future. A Commission would enable policy-makers to make informed decisions on genetic issues aware of the broader picture of developments in the field." Is that not a much better approach than the kind of approach that you are adopting? It is much more clear-cut. Whilst I also welcome the approach you are taking, I think you are still dodging the issue. Would it not be better to follow that kind of approach?

*(Mr Dorrell)* The efficacy of that kind of approach depends upon being able to bring together, into a single body, a manageable number of people with the required expertise to deal with each of the specific applications of the science covered by the present range of committees. I am not denying that that may one day be possible, but what I am quite clear about is that given the uncertain and very new nature of the world that we are dealing with where there are committees that have established their value and have started to deliver work of importance in the field with which they have been charged, it is incumbent upon anyone who wants to replace them to demonstrate that the alternative structure would work better. I think the existing committee structure is targeted at specific aspects of the problem. I do not think anyone has argued that those committees themselves are not dealing adequately and professionally with the specific issues that have been put in their remit. What has been argued is that there has not been any one specifically charged with the overview and, as I have said, I think that that is a fair question to ask and that is the question I have undertaken to pursue.

94. But you would agree that it is possible for bodies of the nature that we have recommended to evolve? They do not have to have fixed structures forever and a day. They can start in a modest way

and develop their functions as a greater understanding develops of the need to bring in cross-departmental functions that are described in the Report, can they?

*(Mr Dorrell)* Absolutely. It is clearly in my approach to this that individual bodies can develop, but we do not want to cut off existing bodies until we have proved that we have got something that is better.

**Mr Batiste**

95. I do not think any of us in preparing our report were in any way trying to underplay the value of the work that the existing committees are doing, nor would any of us want to set a proposal for an alternative in concrete. An evolutionary approach is certainly one that would commend itself to me to try and draw on the best of what we have got. One is aware that so far attempts by government to draw together the new areas of activity across departmental boundaries in a big way has not necessarily been wholly successful and the mechanism by which one tries to achieve it in this fundamentally important science is therefore particularly important. Thinking in terms of what you have said to us this afternoon, I have to say that to have a ninth committee amongst eight without some element of insight into what the other committees are doing on a real-time basis is going to make it very difficult for them to exercise a real oversight role because the science does move very fast and the pace of change is driving everything else. To effectively exercise oversight over science you have to have people on the committee who are very well plugged in to where the fringes of the work are taking place in the other committees as well, which is why just having nine committees instead of eight does not necessarily address the problem.

*(Mr Dorrell)* Clearly the over-arching committee must be aware of the work going on in each of those eight fields, that is true. The reason why I resisted the proposition that this was a hierarchical structure was that I did not want to imply that the existing eight committees became sub-committees of a broader committee. If we proceed with the establishment of a ninth committee it would be an independent activity that would clearly have to plug in to what is going on in each of the fields where there are already specialist oversight committees established.

96. As far as the oversight is concerned, clearly the decision-making is going to be located in Government rather than delegated to an oversight committee. That I understand from your answer. But there would necessarily have to be within Government a mechanism between yourselves, the Department for Education, Office of Science and Technology and the DTI for actually managing the oversight committee and identifying which departments are going to take the lead should legislative change be necessary. Has your thinking gone sufficiently far yet as to know where such a mechanism might be located and what it would consist of?

*(Mr Dorrell)* No, I cannot offer the Committee any guidance on where we might conclude that the base of such an oversight committee would be established.



28 February 1996]

THE RT HON STEPHEN DORRELL MP

[Continued]

**[Mr Batiste Cont]**

As I emphasised, I have been following the evidence that has been given in the second round of the Committee's hearings and it seemed to me that since I was due to give evidence this afternoon and as I had already concluded that this was a specific question that needed further examination there was not much point in me coming here and baldly saying we were not going to do something that I had already decided we should do.

**Chairman**

97. We are very grateful for that. Behind Mr Batiste's point was the search for some view that other departmental interests, let us say those of insurance or whatever, might also come within an oversight concept if we believed it was relevant to the application and practice of genetic science or genetic screening.

(Mr Dorrell) The Committee has asked a question to which I do not believe the Committee has had a fully satisfactory answer to and that is why I am asking it internally. The question is how does Government maintain a cross-departmental view of all the different applications of this evolving science and that is what we are reviewing.

**Dr Jones**

98. If you have been following our last session, Secretary of State, you will be aware that Professor May in his response mentioned that there were adequate co-ordinating arrangements between the various bodies, but when he was asked what these were he could not actually say what they were. What do you know about the current co-ordinating arrangements and how are those going to be changed when the new Advisory Committee on Genetic Testing is up and running? How do you see those arrangements—to use your terminology—evolving and how would you like to see them evolve?

(Mr Dorrell) I suppose the answer to the second half of the question is that it depends on the results of the further review that I have told the Committee this afternoon we propose to undertake. How this cross-government view evolves depends on what emerges from that process. As to how that is done at the moment, the answer is that the Chief Scientific Officer and the Chief Medical Officer have a cross-government view and their supporting staffs are in a similar position being rooted in a department but with a cross-government perspective. Having said that, there is not much point in my having said that I am going to look at the cross-departmental handling of this issue and then sitting here and saying that everything is satisfactory. I said I think the Committee has asked a question to which the answer has not been wholly satisfactory and that is why I am taking it away.

99. But it is not just a question of the Chief Scientific Officer and the Chief Medical Officer, it is these various advisory committees which are to some extent at arm's length from Government. To some extent we would want to see these issues being dealt with by a body or bodies that are at arm's length from Government. How are they co-ordinating and feeding back?

(Mr Dorrell) The supporting secretariats to the different committees clearly have the capacity to talk to each other. They are dealing in a scientific world where although there is a lot going on, as with all related scientific communities, there is intense dialogue within the community. The different elements of the community are aware of how the science is developing. They also talk to themselves outside the context of these committees about the ethical, commercial and legal implications of the work that they are doing. I do not sense at this moment that there is a danger of major new developments going on in one part of the wood, as it were, that affect the work of a specialist committee and of which that committee is wholly unaware. Having said that, clearly as the world develops and as the issues multiply this will become more complex and that is why the committee has asked the question it has and why I have undertaken to take it away.

100. I do not think we doubt that there is good dialogue between the scientific community; it is the dialogue perhaps between the scientific community and the health bodies and commercial and ethical bodies which are of concern. Do you accept that there are inadequacies in the current arrangements because that is within the remit of the new Advisory Committee on Employment?

(Mr Dorrell) The Advisory Committee on Genetic Testing has been given a specific brief upon both the scientific and ethical questions raised by the use of genetically-based tests. That is one element of this broad picture, but, as the Committee quite rightly says, there are other elements and the evolving science raises questions related to testing, raises questions in the longer term possibly related to therapy and it raises questions on the use of information derived from genetic tests. There is a wide range of issues. I believe that most of the specific questions, where the science crystallises to a specific policy question, are actually covered by this range of committees that we have. The further question the committee has asked, which I have said today I am going to take away, is one that addresses the extent to which of the co-ordination is undertaken and that is clearly going to become a more complex issue as the science develops.

**Dr Williams**

101. Could I welcome the Secretary of State's comments so far this afternoon on the rethink of the Government's response. Indeed we had some indication of that from the Chief Medical Officer in our last session when he talked about the Government or himself certainly being in a listening mode and the Chief Scientific Advisor also making quite cautious remarks of having an open mind as to our recommendations. As I have understood the Secretary of State's review, the parts of pure science screening and regulation you are happy with within this present structure but it is only these employment, insurance, social issues that the review will look at. I take that as a substantial step forward but if I was cynical—which I am not—I could read into this that the Government is kicking into touch, if you like, the review, there is no commitment other than to look at the problem again and to look at just one part of a



28 February 1996]

THE RT HON STEPHEN DORRELL MP

[Continued]

**[Dr Williams Cont]**

large fraction of our recommendation. When you mentioned the geological side I did become a bit concerned. On that political timescale, could I urge progress. Could I urge as a starting point obviously you use our report and our formulation and there are great advantages in considering these social, employment, insurance issues alongside screening and regulation and the science because they interact with each other and that in the review the starting point should not be the fraction of the Commission that you described to us but the starting point should be our proposal of that Commission.

(Mr Dorrell) I am beginning to regret having used the phrase "geological timescale". It was intended to be a relatively light hearted commitment to get on with it. Perhaps I can substitute the proposition: the Committee has asked a question, I have recognised in this specific element and I do not think the question has been fully answered, we are undertaking a further review and certainly I am not inclined to allow that to spin out. I cannot give the Committee a timescale but I will keep in touch with you, Mr Chairman.

Chairman: Understood.

**Mr Thompson**

102. Secretary of State, as a new Member of the Committee I have a fairly steep learning curve on this whole subject and I want to stay with the question of the Human Genetics Commission, which is what we have been talking about all the way through this afternoon so far. Right at the very beginning you made what I thought was a very interesting remark which I do not necessarily take issue with at all. You said "You do not feel that the Secretary of State or indeed the Department of Health should take a lead...", you qualified that a bit but you recall saying that "...with regard to the moral, ethical, commercial considerations involved" and I do understand that. To me that in a sense strengthens the idea of a Commission. In evidence to this Committee, the Chief Medical Officer and the Chief Scientific Adviser both hinted that an overarching body for the regulation of genetics—and to my mind that means a Commission—had not been ruled out completely. Do you see the possibility of a Commission, as envisaged by the Committee, as hinted at by those two witnesses, being established at some point in the future? I am not going to attempt to refer to my geology degree or to geological time or to biological time but possibly historical time.

(Mr Dorrell) Do I see a further Committee that may emerge from a review—

103. The Commission being established.

(Mr Dorrell)—do I see that growing into a Commission on the model described by the Committee? Certainly I cannot say that is impossible, although I must say very clearly to the Committee—and perhaps this relates to the part of Dr Williams' question that I did not answer directly—that I am not persuaded that a brief to a Commission which is set out in paragraph 144 of the Committee's report is one that I envisage any Government frankly finding attractive in the foreseeable future. I think that a Commission which has delegated to it for example the power to regulate companies offering genetic services and has delegated to it the power to monitor

the availability of genetic diagnosis and screening and make recommendations to the local purchasers in the health service and a number of other specific powers both to regulate and to oversee what is going on in the National Health Service, both of those I find unattractive for two reasons in dealing with the two cases separately. I think in a world where nobody can know how this science is going to develop over the next five or ten years, I think, it would be a very bold Parliament, frankly, that gave to an unelected body a regulatory function in this sort of world. I think it is one thing to ask for an Advisory Committee where the recommendations be brought to Government and ultimately to Parliament, I think it is quite another to delegate the regulatory function to an unelected body. As far as the NHS is concerned, we have a system of purchasing accountability which is much better focused than it has ever been before in terms of identifying the range of services we want and comparing them as between one district and another. I am not in favour of introducing a specific statutory function in addition to that purchaser line, through a Human Genetic Commission. So both, for those elements, certainly I do not find the case made. What I have sought to do with the Committee this afternoon is to pick up the specific suggestion that there is in the current committee structure an inadequate overview of the evolving science, whether it is in the health service or in the employment context, from an advisory point of view and it is that question which I am going to take away.

104. Just to follow that up very briefly, the point about regulation I understand and appreciate but the wording I used a moment ago in the question was the question of—picking up your remark earlier—taking a lead whether it be ethical, moral or whatever. I feel the regulation point, in a sense, is not what I was driving at at all, it is a question of taking a lead in society which is not necessarily usurping governmental functions at all, certainly not in my mind. The question I want to put is in what circumstances would a Commission of that sort be appropriate at all?

(Mr Dorrell) I think I have just set out the reason why, for the Commission of the kind sketched out by the Committee, I do not think the case has been made.

105. Any Commission?

(Mr Dorrell) In terms of the specific question Mr Thompson asked, do I think a Committee of the kind I described might have a function in leading public opinion in understanding what is happening and what are the implications of what is happening in genetic science, I agree with Mr Thompson about that. I do think that one of the functions of having an overarching Advisory Committee would be to catalyse thought on the implications of this science in the form of advice to Government. I am quite sure in the context of this kind of fast changing scene both Government and Parliament would want to keep to themselves their respective roles in reacting to the kind of advice that a Committee might offer.



28 February 1996]

THE RT HON STEPHEN DORRELL MP

[Continued]

**Chairman**

106. I think this brings us, Secretary of State, on to another aspect of our own report and indeed which you have just picked up and that is the role in fostering a public understanding of what is afoot, a well informed public which must be of benefit to the health service for which you are responsible. This educative role, public awareness role and projection and above all achieving a better trust between public and let us say genetic science or genetic medicine seemed to us one of the crucial lessons to be learned in advance of proceeding with some rapidity in the development of genetic therapy etc.. It is therefore, from what you have said, part of your increased remit towards the overarching concept that public education of these issues should be addressed through that, is that right?

(Mr Dorrell) Yes, it is, Mr Chairman. One of the first questions, of course, such a Committee if it were to be established would ask itself is how quickly this science is developing and how far away are we from the kind of genetic therapy that some theorists are predicting currently? I think it is true to say there is almost no active genetic therapy currently being provided but there are clearly people working on seeking to develop active genetic therapy. One of the things the Committee would want to look at is how quickly that is going to evolve into clinically effective treatments and what are the implications when that work is successful.

**Mr Bruce**

107. If I could on that question come in with a comment and a query which is relevant particularly to you, Secretary of State. In my constituency I have a gentleman who has known for years that he is dying of Andersen Fabry's disease, his name is Graham Hill. He and his family and friends have all been raising money for research into this particular disease and effectively are looking for the cure. When one talks about geology and geological timescales—and I have to declare my interest of having no level of geology—it does demonstrate that people are really interested in this. I think when people are caught expressing their concerns about just theoretical research, when you have an individual who is looking for this therapy, it is very important we highlight that. I just wonder what the feedback from your Department is Secretary of State to the scientists saying: "Look, we have got people we cannot treat" and trying to get the boot on the other foot of saying necessity is the mother of invention, what can we do to accelerate what is happening. Of course, when somebody has one of these diseases, knows they have a limited lifespan, all this theory we might go into becomes rather a matter of academia as far as they are concerned, they are worried about their life and they are looking to find the fastest possible treatment and are willing to be experimented on themselves if that is going to help others in the future.

(Mr Dorrell) I fully understand that, Mr Chairman, and we are all looking, all the time, for new treatments which are going to be fully effective cures for conditions which are currently incurable. One of the results of being Health Minister (and I am now in my second term in the Department) is that

you visit a lot of hospitals and you meet a lot of people and gradually you become more admiring of those treatments that are successful and more aware of how many conditions there are for which there are no known cures. The will or necessity is not in medical science always the mother of invention. I am strongly in favour of providing money for research where there is a reasonable chance of that research producing effective cures but I am afraid it is not true to say that in medical science necessity is necessarily and inevitably the mother of invention.

**Dr Jones**

108. I find your remarks about regulation somewhat surprising. After all, the Government has seen fit to set up regulators for the privatised utilities and also for financial services, is this not analogous? I do not see why you should balk at the proposal.

(Mr Dorrell) The reason I think it is not analogous is that we are dealing with a speculative world because we do not know either the pace or the nature of the scientific advance that is going to come in the genetic world. If you set up a regulator for a water industry you know what the brief of the regulator is and you define it quite closely in the brief to the regulator. We cannot possibly know what the brief to a regulator of this kind of world is because we do not know the questions that the regulator is going to have to answer.

109. The fact we do not know the questions is all the more reason for setting up some kind of arrangement. You must be aware surely there is widespread public suspicion and hostility to developments in genetic science. Only a week or so ago I think all MPs received a letter from the Genetics Forum which encompasses a whole range of worthy bodies including the RSPCA and genetics interest groups. They are highly suspicious of genetic science. There is a lot of opposition, for example, to the patenting of genes, that exists in Parliament as well, I think there is a lot of opposition amongst MPs. There was an Early Day Motion on the subject. There is opposition in Europe and people feel there is a scope for—as the Genetics Forum says—systematic abuse of genetic information which will get out of hand before the controls are introduced. They feel that the Government has abandoned this necessary cautious approach. Now when we look at, for example, the work on in-vitro fertilisation and other forms of fertilisation treatment, do you not feel the setting up of the Human Fertilisation and Embryology Authority has helped to create a kind of public confidence that has allowed developments in that area? Surely the public does need to be reassured that there is appropriate co-ordination and regulation of this? It is a fast developing science, the progress has been enormous.

(Mr Dorrell) The science will develop at the pace that is driven by the scientific development, that is what will determine that. The question for policy makers is how the ethical, industrial, resource implications are worked through in a very wide range of different fields. I agree that the HFEA has been a successful development in a narrowly defined field. What I think is different between that world and the one we are talking about this afternoon is that the



28 February 1996]

THE RT HON STEPHEN DORRELL MP

[Continued]

**[Dr Jones Cont]**

kind of questions which are likely to emerge in human fertilisation and embryology are now reasonably well known. I do not think—with respect—that we do know the kind of questions that are likely to emerge or with any certainty that are likely to emerge and that is why—because the science is at an earlier stage of development—I prefer following what is the same course which led to the HFEA, Mr Miller reminded us, namely that we have an evolutionary approach of the Committee structure out of which some authority may ultimately grow. I do not think we have reached that stage yet. I think, if I may say so, the letter from which you quote is not a bad illustration of why that is because people have concerns about the development of the science. I do not believe that Members of Parliament would find it a satisfactory response to write back to those people and say: "Well we are doing this because the authority has the power to do it and the authority has done it". What they would expect Parliament to do is to deal with the issue that has been raised.

**Dr Williams**

110. The Government has agreed to set up an Advisory Committee on Genetic Testing and within its terms of reference it said the following: "to advise on testing individuals for genetic disorders, taking account of ethical, social and scientific aspects". Does that Committee then have the brief to look at problems of employment and insurance? You do mention "taking account of ethical, social and scientific aspects".

(Mr Dorrell) The answer to that is yes.

111. Generally, in our response to our section on insurance and employment, the Government did not seem to recognise there was much of a problem.

(Mr Dorrell) The Advisory Committee on Genetic Testing will offer advice to ministers, Government and ultimately to Parliament on the terms on which genetic tests should be made available, bearing in mind the factors that are listed in its terms of reference, namely the science, the ethics and the social considerations. In other words, are the tests effective, on what terms should they be made available, what counselling—most importantly—should be provided to the people who undergo the tests and to whom should the information be made available and on what terms.

**Mrs Campbell**

112. Secretary of State, when we made our recommendations about the Human Genetic Commission, we felt it rather important that only a minority of members should have a professional or financial interest in genetic science. We know for your new Advisory Committee Dr John Polkinghorne is to be the chair, he is a physicist and a churchman. Is it your intention a significant proportion of the Committee members are non geneticists?

(Mr Dorrell) Yes.

113. What sort of proportion?

(Mr Dorrell) I cannot give you precise numbers because we have not decided the final make up of the Committee yet but the answer is certainly that it must have a substantial representation of lay non specialist interests. If it is to offer ethical and social advice as well as scientific advice, it needs them.

114. Have you decided yet what range of interests you want to represent?

(Mr Dorrell) No, we have not established the full membership of the Committee but a broad range of interests I think is essential if the advice of the Committee is to do what it is there to do, that is to say to lead public opinion, as I think Mr Thompson suggested it needs to do, and to offer Government advice which there would be a pre-disposition on the part of the public to believe is advice the Government might have.

115. What sort of staff resources will it have?

(Mr Dorrell) Enough!

**Mr Bruce**

116. Secretary of State, will the new Advisory Committee on Genetic Testing have any responsibility for screening programmes?

(Mr Dorrell) It will have responsibility for advising on the terms on which tests might develop into screening programmes. We have some tests already that are used in what you might term targeted screening programmes, screening populations of high risk people, and that would be part of the advice that the Advisory Committee would offer, yes.

117. What interaction will they have with the National Screening Committee which was referred to I understand by Sir Kenneth Calman?

(Mr Dorrell) The National Screening Committee looks way outside the field of genetic tests and it is responsible for looking at any proposals that come for screening programmes. It offers us advice on the kind of tests that we should use to examine specific screening programmes. Quite a large number of proposals come forward for screening for particular types of conditions and we have some principles which will be established by that Committee and monitored by that Committee by which we will assess screening proposals. The genetic screening proposals will be tested against those principles like all other screening proposals but the genetic proposals raise other issues as well which would be the specific preserve of the Advisory Committee.

**Dr Jones**

118. I have a very quick question: will the Advisory Committee have access to DTI ministers?

(Mr Dorrell) I think the answer is that if an Advisory Committee asks for advice it will get it, yes.

Mr Miller: On the question of statutory powers there seems to be a certain amount of confusion. In paragraph 287 of our report we indicate very simply that some of the functions of our proposed Commission will require statutory powers so that the body will require a statutory basis. The Government's reply seemed to suggest that the Committee may be given statutory powers.

Chairman: This is your Advisory Committee.



28 February 1996]

THE RT HON STEPHEN DORRELL MP

[Continued]

**Mr Miller**

119. Firstly, what are those statutory powers that you would envisage fitting in there? Secondly—and you will recall I have been pressing the Government on issues of transparency on a number of issues relating to drug crises—how do you respond to the British Society for Human Genetics who say to us that: “The fact the Government has chosen a non statutory advisory committee suggests that they wish to allow commercial influences to operate in a non transparent way. Since the decision to set up an Advisory Committee was apparently taken in June 1995, before the Select Committee report, we doubt whether the Government intends to take the report seriously”.

(Mr Dorrell) The report of what, this Committee?

120. Yes?

(Mr Dorrell) I hope I have indicated this afternoon that I am taking it seriously and I have indicated which bits of the questions the Committee has asked I do not think we have yet had an answer to which I find fully satisfactory. It may be that I shall write back to the Committee ultimately and say: “Well I have looked at this further and I think we have adequate machinery, this is it”. We have not yet had an answer that I find fully persuasive. In terms of what are the statutory powers that are envisaged for the new Advisory Committee on Genetic Testing, I think, if I may, I will write to the Committee about that. I have a feeling that is simply leaving an option open rather than having any specific power in mind but I will write about that. In terms of whether the approach is the result of being craven in the face of the commercial interest, I find that very difficult to square with any of the things I have said this afternoon. I regard it as important and also I regard it as almost impossible to square with the kind of people that sit on these Advisory Committees who are quite clearly people of independence and of substance and who are no more the creature of the drug industry I am sure than Mr Miller.

121. You do understand that here we have a very eminent group of people in the field who are expressing that concern? It is not the invention of this Committee, it is the concern of professionals in the field who have made that point?

(Mr Dorrell) Yes, I understand that but I have given my answer also.

**Mr Batiste**

122. Sir Kenneth Calman told us that Professor Bobrow has been asked to continue to chair the Genetics Research Advisory Group. I would like to ask you about terms of reference for the Committee: will they change? How will it interact both with the new overarching committee and also with the Advisory Committee on Genetic Testing? How do you see the interaction?

(Mr Dorrell) I see their briefs as being rather different. The Genetic Testing one is clearly designed to deal with proposals for the evolution or to monitor the use of genetic tests. What used to be called the Research Group and is now going to be called the Advisory Group on Scientific Advances in Genetics is described in my notes as an expert committee to

advise the Director of Research and Development of the NHS and the Chief Medical Officer on the implications of advances for the NHS and for public health. That is the brief of the new committee, I have not in front of me the brief of the old committee but it is obviously quite closely related. It is intended to maintain an overview of the development of genetic science and what are its implications for the health service and public health.

123. It will be specifically focused on the health service?

(Mr Dorrell) Yes.

**Mr Thompson**

124. In the Government's reply to the Select Committee Report, the Government said: “Further advice on ethical matters is provided by the Nuffield Council on Bioethics”. Yet in the week that the reply was published the Government set up its own Advisory Group on Xenotransplantation—which I learnt today is the transplantation of organs from animals to human beings—rather than waiting for the Nuffield Council Report which is to be published next month. If the Department of Health needs an advisory group on the ethics of xenotransplantation, why does it not need a Commission on genetic issues as a whole so we do not have such a plethora of groups and councils like the Nuffield Council which the Government does not control and so on? We seem to finish up with an awful lot of committees and groups.

(Mr Dorrell) The Nuffield organisation sets up its own committees and I am not responsible for that. Their committee is producing ideas specifically on ethics related to xenotransplantation. The Xenotransplantation Group that I established in common with these other committees we have been talking about is intended to be a combination both of ethical and scientific and practical considerations in order to produce a recommendation that reflects all of those different interests. As regards the question of the plethora of committees, I understand how somebody coming at it first on, as indeed I did, sees it as another list of committees with a long list of initials but when I examine it, I think I have given already the answer that I have to the Committee, namely that these are committees that have developed an expertise in their field and I am very reluctant to depart from that approach until we have another one that is demonstrably better and I do not think we have yet.

**Mrs Campbell**

125. Secretary of State, the Nuffield Council is an independent body and I think you are expecting the Nuffield Council to give further advice on ethical matters. I assume because it is an independent body you cannot request it to consider particular matters, do you think that is a disadvantage?

(Mr Dorrell) I imagine if I contacted the Nuffield Council and offered them a question, particularly if there was a resource attached to it, then they would not necessarily rule out immediately doing some work on it. Clearly they are independent people. I do not know whether they do work for other people



28 February 1996]

THE RT HON STEPHEN DORRELL MP

[Continued]

**[Mrs Campbell Cont]**

specifically or whether they are purely self-generative but I am not responsible for them. As I said to Mr Thompson I shall read their work on bioethics and xenotransplantation with interest.

**Chairman**

126. Could I turn now to screening programmes. In the Government reply to our report: "Mechanisms to ensure that any proposal for screening is subject to careful evaluation before introduction ... under the aegis of the NHS R&D programme, the Health Technology Standing Group and its Population Screening Panel" these were mentioned as being part of the response. These were announced in 1994, where were they operational if they are operational and what have they considered so far?

(Mr Dorrell) The Committee on Screening Programmes, I am fairly sure is operational because I have seen advice of the kind of principles that we apply to screening programmes but I think, if I may, I will write directly to the Committee on the specific question.

127. Understood. At the moment only one genetic condition, phenylketonuria—PKU is a much better description—is screened for nationally. There are conditions such as thalassaemia for which a national screening programme is inappropriate but local screening programmes in areas where there are large numbers of likely carriers would be appropriate. We have had evidence that such local programmes are not always available. Is there a mechanism to ensure that appropriate screening programmes are established locally?

(Mr Dorrell) The short answer to that is yes it is the health authority. In an answer to an earlier question I referred to targeted testing, targeted screening programmes because there is the example you quote, Mr Chairman, of sickle cell anaemia, the same is true of thalassaemia and Tay Sachs Disease. Those are three specific conditions where there is a particular population where there is that high risk. It is part of the brief clearly of the health authority where there is a particular concentration of that population to look at the possibility of providing a targeted screening programme for that population. That is part of the process of managing the health service resource through local health authorities.

128. That raises the problem that some may find it not possible to do because of resource limitations.

(Mr Dorrell) Some indeed will not need to because they do not have the group of the relevant population in their area.

129. The health authority has to produce the funds.

(Mr Dorrell) Indeed, it is part of the normal function of any health authority. This is the whole purpose of having purchaser health authorities in the way that we have them to look at the health needs of the specific population, not the population in general but the specific population of the area for which they are responsible, and to use the health budget, the NHS budget, in a way that targets health needs in that particular district.

**Dr Jones**

130. Would these needs be taken into account in distribution of resources?

(Mr Dorrell) I cannot say that specific condition is measured in the formula but what is measured certainly is the general morbidity as well as the social conditions of an area.

**Mr Miller**

131. Is this not another area where the overarching committee responsibilities come into play because it is not simply a case of looking at, let us say, health authorities and adjoining health authorities that may want to engage in particular studies, it may be that the focus of a particular study impacts heavily on a particular local health authority but adjacent social service departments may be interested, for example, in work related to mental illness, schizophrenia is a good example. Is this not again an area where consideration needs to be given to the cross departmental activity that significantly transcends the traditional boundaries of the NHS?

(Mr Dorrell) I am not sure I follow that I am afraid. It seems to me this is as clear an example almost as it is possible to give of how a local purchaser health authority is responsible first for analysing health need in its district. For example, if there is a Caribbean population that is particularly at risk of sickle cell anaemia then the question that the health authority ought to ask is whether some form of targeted screening is necessary for that population for that condition. If you do not have a Caribbean population in your area then that is a question that health authority does not need to ask. I would have thought it is as good an illustration as it is possible to conceive of of that principle in action.

**Dr Williams**

132. The final area is the provision of genetic services generally. As I understand they grow out of medical schools or regional health centres and are provided from that headquarters into hospitals and so on. Our concern is that as we move towards a higher proportion of GP fundholders they get more and more purchasing power and more and more effective power within the health service of premature devolution to them. We have had some conflicting evidence where Sir Kenneth Calman has reassured us that all decision taking should be at the highest level within the Department of Health in regional centres but can you give us a similar reassurance that in this relatively new area of medicine the purchasing power at this stage stays with the regional health centres and that it is not devolved at this stage to the GP fundholders?

(Mr Dorrell) I cannot give that assurance because the purchaser authority is already at district level. The position here is this there are eight or nine regional centres that deliver the great bulk of genetic testing services within the NHS. They each have purchase contracts with roughly 100 health authorities that are the purchasers of that service on behalf of their local population. That is the position now. As of 1 April the purchasing of genetic testing and counselling services is part of the redefined fund



28 February 1996]

THE RT HON STEPHEN DORRELL MP

[Continued]

**[Dr Williams Cont]**

for which fundholders are responsible. So in an area where there is a large number of fundholders the responsibility has until now been with the health authority and it will pass, at least formally, to the fundholders on 1 April in respect of their own population. It will then be open to fundholders to continue to purchase that service from any one of the regional centres as their health authority already can, that is a freedom the health authority has already. Some fundholders may well use that, others will be free if they wish to do so to block—in the jargon—it back, that is to say ask the health authority, and take the advice of the health authority on how to exercise the power that they have.

133. If we trace things back just two or three years, as I understood genetic services could be top sliced from the central budget and that power was not passed on to health authorities. Is that not more appropriate when it comes to advances in medicine such as in this field?

(Mr Dorrell) I cannot answer for what happened three years ago. Certainly it is the position now that the authority to buy genetic services as part of an integrated health service rests with the health authority. Perhaps the example we were just talking of, of the tendency for a particular population to suffer from particular conditions, is quite a good illustration of why this is an important freedom for a health authority to have. It is not much good having an access for a certain number of cases to a regional centre if you have a large population that needs a particular type of testing facility. In the existing structure, as of today, the health authorities are the purchasers of this service from fourteen regional centres. As the science develops it would not surprise me to see more centres of this expertise emerging but at this moment there are fourteen. The flexibility that the system gives to health authorities is one that I would want to preserve. It seems to me if it is right for the health authorities to have it, it is also right for fundholders to have it as long as it is understood that fundholders do not work—in the great majority of cases—in isolation with this type of service. By far the norm is for the fundholders to deal with the health authority either on the basis that they block it back to the health authority or more often that they work closely with the health authority and one of them acts as the lead on the purchasing of this service.

**Chairman**

134. I think there was some evidence given to the Committee that there were cases where health authorities were not willing to provide such screening services for ethnic groups within their care. If that was to be the case how would that be corrected?

(Mr Dorrell) It is something which is part of the normal range of discretion that would be open to a health authority. If it was felt to be an improper use of the discretion then it is something that could be raised through the normal health service accountability ultimately to me and therefore to Parliament.

**Dr Williams**

135. Could I come back with one final comment. With general practitioners, on average they would have qualified ten or 15 or 20 years before and I accept that they will be innovative individuals but their training will be ten or 15 years behind the time, as it were. It will be very difficult if they get total purchasing power for them to make the right decisions and that threatens to undermine our regional centres.

(Mr Dorrell) I think that would be true if the fundholder, the GP typically, not only was not abreast with all the latest developments in genetic science—there would be plenty in that position—but was wilfully ignorant about it and refused to recognise there was a role for it. The overwhelming majority of GPs if they are not themselves specialist in this field, recognising for a practice population that does not have a large number of Caribbean patients, for example, they would take the view simply I think that this is something where they should allow somebody else to lead that element of their purchasing. That reflects practice in quite a lot of the specialist purchasing within a fund.

**Mr Batiste**

136. One of the pieces of evidence that was given to us as a result of the nine centres for the genetic testing, one of its advantages was that because of the relatively small number of them whilst maintaining the confidentiality of individuals they have been able to pick out trends and that might not be as easily noticeable if that service was fragmented. Accepting what you have said so far about the devolution to fundholders, nevertheless its ability to pick up trends is a useful facility to have. How do you think we can avoid throwing this particular baby out with the bath water?

(Mr Dorrell) I agree it is an important element of the quality of the service. Not only do I agree with it I think that it is almost certain that fundholders would agree with it as well. Giving the fundholders or health authorities—because the same principle applies whether it is the health authority buying or the fundholder buying—the responsibility of purchasing the service is not the same thing as saying the service is going to be fragmented. Indeed, in this type of service, what will happen is what has already happened when health authorities have been purchasing the service, namely they will buy the service from centres that have established themselves with a track record that is respected not just in this country but around the rest of the world as well. I do not see a risk of fragmentation as a result of these decisions. What I think will emerge is a system that is more flexible and more responsive to precise population need in different parts of the country but still built, I anticipate, around a limited number of centres of excellence, although if that grew I imagine that would be something that would be as welcome to the Committee as it would be to me.



28 February 1996]

THE RT HON STEPHEN DORRELL MP

[Continued]

**Mr Miller**

137. We would agree that the current regional centres are centres of excellence providing ethnic services. Are you confident, Secretary of State, that the devolution towards GP fundholders will not undermine those services? If there was any evidence that came forward in the future, what would you do about it?

(*Mr Dorrell*) It seems to me very unlikely it would lead to the undermining of it. Obviously I see or have available to me—I would not pretend to see every one of them—the monitoring of the effectiveness of the value that we get for these services. I think it is inconceivable either the GPs or the health authorities as purchasers of the service or the regional centres as providers of the services would allow a fundamental change to take place which led to a diminution of the value of the service without the issue coming to public attention. In those circumstances, of course, we would have to look at what was happening and

take appropriate action. The experience so far of increased accountability to local purchasers, both health authorities and fundholders, has not been a fragmentation and diminution of value, I would argue it has been exactly the opposite, not just in genetics but across the broad field of health provision.

Chairman: Secretary of State, thank you very much for answering our questions. Thank you in the first place for being here and so skilfully dealing with these issues and thank you particularly for the initiative you have shown in having another look perhaps at the overarching possibilities for your Advisory Committee in accordance with certainly many of the suggestions which the Committee has made in its report. We look forward to seeing you in due course, perhaps when we debate our own response to the Government's report which we do now with some encouragement, I think. Thank you very much indeed.

**Letter to the Chairman of the Committee from Rt. Hon. Stephen Dorrell, Secretary of State for Health**  
(11.3.96)

I undertook to write to you on a number of points arising from the discussions with your Committee on 28 February. I hope that the Committee finds the enclosed memorandum and the following additional observations helpful.

The Committee asked in what circumstances the Advisory Committee on Genetic Testing (ACGT) might be given statutory powers. Because the ACGT will be dealing with novel and complex developments, we shall be taking a cautious and evolutionary approach to the question of legislation. It is worth reflecting on the way in which regulation of embryo research and assisted reproduction developed. The predecessor of the Human Fertilisation and Embryology Authority was a non-statutory body which issued licences on a voluntary basis. That body provided valuable experience when we came to formulate the legislation which eventually became the Human Fertilisation and Embryology Act. The Gene Therapy Advisory Committee (GTAC) provides a reassuring model of voluntary regulation. Although non-statutory, it is clearly working well in regulating experimental therapy. I cannot say whether, eventually, this body or the ACGT will become statutory but I can say that we shall be well placed from the experience of these bodies to proceed to legislation if that seems right. There is, of course, a statutory element relating to the work of GTAC where the products used need Medicines Act clearance. A further point is that the EU is working on a proposal for a Directive on in-vitro diagnostic devices which would include genetic test kits. If the Directive is ultimately adopted we may need a statutory mechanism of control so we are keeping this possibility in mind.

On 28 February we also discussed the terms of reference of the Advisory Committee on Genetic Testing. The Select Committee may find it helpful if I expand a little on the extent to which I would expect the Advisory Committee to be involved in employment and insurance aspects of genetic testing. In my opening remarks I said that insurance and employment considerations fell "either partially or completely outside my departmental brief". However, it would be unrealistic and indeed unhelpful to expect the Advisory Committee to ignore all the non-clinical uses to which test results might be put. For example, a genetic test that identified a predisposition to disease due to exposure to an industrial chemical could well be of great value to both potential employees and employers in industries where such exposure cannot be avoided totally. In such circumstances the Department of Health would not have the leading role, but there would of course be interest in the Department of Trade and Industry, the Department for Education and Employment and the Health and Safety Executive.

It was recognised when my predecessor consulted on the terms of reference of ACGT that some overlap of interest would occur. In practice my expectation is that the ACGT will draw Health Ministers' attention to any issues which it believes another Government department might wish to address. In addition I envisage Departments with a major interest having observers present at ACGT meetings, if they wish.

I am sending copies of this letter and memorandum to colleagues in the Department of Trade and Industry and the Department for Education and Employment.



28 February 1996]

[Continued]

### Supplementary Memorandum from the Department of Health

#### INTRODUCTION

1. Subjects covered in this memorandum are:

- evaluation of screening programmes (Q126)
- GP fundholding—purchasing of genetic services (Q132–136)
- NHS accountability arrangements as they apply to screening provision (Q134).

These arose as matters calling for additional comment when the Secretary of State for Health gave oral evidence to the Select Committee on 28 February.

#### EVALUATION OF SCREENING PROGRAMMES

##### *Background*

2. The purpose of screening in health care is to detect those who, seemingly healthy, face substantial risks of having or developing a significant disorder, that might be alleviated through subsequent intervention or appropriate preventative measures or of bearing affected children. The intervention might be a diagnostic procedure or preventive action; it might be the provision of information, supported by counselling, to guide important choices and decisions.

3. Before a screening test is introduced there should be sound knowledge of the natural history of the disease concerned, and the probability that it will occur, and the damage and burden that it can inflict. The interventions available to those who are identified by a positive test should have been assessed and as much information as possible obtained about their effectiveness and cost-effectiveness. In addition the test to be used in screening must give few false positive or false negative results, and be reliable. Screening can cause inadvertent harm. For example, findings that are falsely positive can cause needless anxiety, and those that are falsely negative can generate unwarranted reassurance. Lastly, the possible benefits and disbenefits to the individuals involved of knowing the result must also be known.

##### *Government Position*

4. The Government is firmly of the view that any genetic testing should be subject to the following ethical principles—

the decision whether or not to undergo testing is for the individual to make;

that decision must be informed by knowledge of the possible significance of the results for that individual;

confidentiality must be preserved.

Such testing should not be offered or undertaken unless the significant and possible consequences of the investigation are known, there is the prospect of measurable benefit, and the individuals concerned are able to make a decision that is informed by the knowledge, and act upon it.

5. The Government further believes that, whenever possible, screening programmes should only be introduced when efficacy, acceptability and cost/benefit have been demonstrated beforehand in rigorous evaluative studies. As with any other health care intervention there is a need to evaluate the potential cost-benefit of population screening. The health benefits of screening should represent good value in relation to its other sequelae.

6. The Government believes that the principles and requirements set out above apply to screening programmes in the context of pregnancy and parenthood, neonatal life and childhood, and that screening for detection of the carrier state in genetic disorders should be subject to these principles.



28 February 1996]

[Continued]

7. The Department of Health has set up mechanisms to ensure that proposal for a screening programme can be subject to careful evaluation before introduction. Under the aegis of the NHS R&D Programme, the Health Technology Standing Group and its Population Screening Panel now provide a mechanism to evaluate screening before widespread introduction. Detailed research studies have been commissioned in respect of:

- Evaluation of methods of screening of Down's syndrome
- Screening of cystic fibrosis (systematic review)
- Screening of haemoglobinopathies (systematic review)
- Screening for fragile X (systematic review)
- Neonatal screening for inborn errors of metabolism (systematic review)
- Evaluation of genetic counselling in general practice
- Evaluation of genetic analysis of haematological disorders
- Evaluation of cytogenetics laboratory technology
- Efficacy and cost-effectiveness of rhDNase in cystic fibrosis
- Cost-effectiveness of screening for hypercholesterolaemia versus cases finding for familial hypercholesterolaemia (systematic review)
- Aneuploidy detection in uncultured amniotic fluid cells for 48-hour diagnosis of Down's syndrome

#### *National Screening Committee*

8. Potential programmes will be examined by the new National Screening Committee which is being set up currently. Furthermore, there will need to be effective co-ordinating arrangements for the management of any programme which is to be introduced, like those that we have put in place for the breast and cervical cancer screening programmes.

9. The National Screening Committee will:

Establish evaluative reviews of the clinical and cost effectiveness of existing national screening programmes. In the light of these evaluations, the case for modifying or terminating existing programmes will be made.

Consider a broad range of evidence from research, clinical and cost effectiveness, health economics, public health, and those who manage, deliver and use the NHS, to determine where there is a justifiable case for initiating new screening programmes.

Identify to the appropriate research programmes (Department of Health Policy, NHS, and those of Research Council) where further research based on evidence is required and award the priority that should be attached to its acquisition.

In its advice to the NHS Executive Board and Ministers seek—wherever it is feasible or appropriate—to make best use of existing mechanisms and resources.

#### **GP FUNDHOLDING AND THE PURCHASING OF GENETIC SERVICES**

10. Health Service Guidelines on GP Fundholding (HSG(95)64), gave particular consideration to genetic services (para 11, and Annex D). The Guidelines also referred to the guide "Population Needs and Genetic Services—an Outline Guide" which was sent to all general practices in June 1993. The Select Committee has copies of these circulars.

11. These documents set out the objectives and functions of a genetic service. Some of those functions (genetic screening—ie testing of individuals usually within families—and counselling) now lie within the range of purchasing responsibilities of GP fundholders. A genetic service incorporates functions which lie beyond the compass of service elements that fundholders might purchase.

These include, for example, promoting the identification and surveillance of kindred who are at risk, yet who may be widely dispersed nationally. This calls for confidential records of genetic data and the means of linking data through confidential family registers. Regional centres have established such mechanisms to ensure continuing and anticipatory care for those who are at risk. National professional networks, linked through regional centres, enable this function to be carried out to best effect.

12. An inherent strength of genetic services, within the context of rapidly developing science, is close collaboration between research and clinical service. A regional service provides a source of expert advice for purchasers of services and also gives guidance and which make a significant contribution in this field.

13. Some fundholders may wish to purchase genetic testing and counselling; but the majority, who have not developed specialist knowledge in this field, will take the advice of the health authority on how best to exercise the powers they have. Among the factors which will influence these decisions will be the need to



28 February 1996]

[Continued]

maintain the quality of these services as a whole, and the effective integration and collaboration of the elements described above, on which the quality of the service depends. Such considerations would encourage fundholders, if they wish to do so, to take the advice of the health authority on how to exercise the power they have. Many, perhaps most, will decide that the lead for purchasing should lie elsewhere.

14. Similarly, Sir Kenneth Calman's reply to QQ44, 48, 49 and 50, sought to reiterate the integrated collaborative nature of a comprehensive genetic service in the context of fundholding decisions on how the specified elements of it might be purchased in the most responsible way.

#### NHS ACCOUNTABILITY ARRANGEMENTS AS THEY APPLY TO GENETIC SCREENING PROVISION

15. The Select Committee asked how the NHS accountability arrangements would identify and correct the situation where screening services were inadequate. In the following paragraphs, the Department has set out how the current arrangements operate.

16. The NHS operates within a tightly defined system of Parliamentary and Public Accountability. The Chief Executive of the NHS Executive is responsible for and directly accountable to the Secretary of State for the management and overall performance of the NHS in England. The NHS Executive comprises a headquarters and eight Regional Offices. Health Authorities account to the NHS Executive through a well-developed business planning and performance management system. Health Authorities are required to publish annual purchasing plans and an annual report and authorities are held to account through corporate contracts with the regional offices who are responsible for monitoring and reviewing progress. The aim is to minimise direct intervention by the NHS Executive, but this is sometimes necessary where there is serious management or financial failure, a requirement for structural change, difficult operational pressures or persistent poor performance.

17. In addition recognising the fundamental importance of public and parliamentary accountability in the NHS, the Chief Executive had designated all Executives of Health Authorities and Trusts as accountable officers ensuring they are answerable to Parliament through him for efficient effective and proper use of all resources in their charge.



6 March 1996]

[Continued

## WEDNESDAY 6 MARCH 1996

## Members present:

Dr Jeremy Bray, in the Chair

Mr Spencer Batiste  
Mr Ian Bruce  
Mrs Anne Campbell

Dr Lynne Jones  
Mr Andrew Miller  
Mr Patrick Thompson

## Letter to the Clerk of the Committee from the Office of Science and Technology (5.3.96)

## HUMAN GENETICS

Thank you for your letter of 22 February to Philip Dale asking for DTI comments on the recent proposal for a directive on legal protection of biotechnological inventions.

I enclose a short Memorandum produced by the Patent Office which we trust addresses the issues you raise.

## Paragraph 218 (of HC(1994-95)41-I)

"There manifestly is no consensus on a Directive to harmonise patent law and we consider that imposition of a Directive could be more harmful than the differences in the criteria for patentability in different countries under the current system."

Although last March it was felt that there was little need for a directive, the present proposal contains provisions which, on balance, could improve the present climate of legal uncertainty. In particular, French law excluding products or elements of the human body from patentability, and the current European Patent Office (EPO) practise of not granting patents on any plants or animals, have altered the situation (although the EPO position could be reversed if appeals are successful). Debate of the issues is therefore timely.

## Examination of Witness

MR IAN TAYLOR, MBE, MP, Minister for Science, examined.

## Chairman

138. Mr Taylor, may I welcome you to the Committee? Thank you for coming back in this reprise of the session that we had on the last report. We are impressed by the fact that you are appearing alone and that you are fully capable of speaking for the office in all aspects of this policy and we thank you for that. May I ask, first of all, whether there are any general principles regarding the responsibilities of the Office of Science and Technology which would guide us in the consideration of this particular topic? Genetic science is one particular area of science which has applications over a range of Government policy and this must arise in relation to other fields of science. Is there any general principle which can guide us and which guides you in looking for just how that responsibility should be carried in Government?

(Mr Taylor) Thank you, Dr Bray, as Chairman, in welcoming me all by myself; I am delighted to be before the Committee and I was most impressed with the work that had obviously gone into the report; and I am glad of an opportunity to continue the discussion. The OST does regard itself as the transdepartmental department in terms of science. You have taken evidence from the Chief Scientific Adviser and he and I would both regard our role as looking for the implications for science programmes across departments. Obviously the Research

Councils themselves for which we are directly responsible nevertheless clearly interface with other Government departments, whether it be Environment or Health or whatever. So we do think that when it comes to something as complicated and as multidisciplinary as genetics, then there is a role for the OST to play. Indeed, we acted as the co-ordinator for the Government's response to your report. Obviously very considerable emphasis in that case was on the Department of Health and we worked very closely with them. The general principle is that we see ourselves as a co-ordinating department, working on a case by case basis in relationship with other departments, depending on how much of a lead they take on any one subject.

139. The position is broadly that as questions come up in a particular area of science there is an initial presumption that if it is not dealt with already within the machinery of Government, because it arises from some new body of science, that OST should at least take the initiative in raising it?

(Mr Taylor) Yes, you phrased it the right way. We would not make the assumption that we were going to end up with the responsibility, but we would make the assumption that it had to be raised and then discussed in Government as to where it was best likely that the matter could be dealt with.



6 March 1996]

MR IAN TAYLOR, MBE, MP

[Continued]

**[Chairman Cont]**

140. Is it not likely, such is the nature of politics generally, that any issue that will win brownie points for the department will be sought by that department and any embarrassing issue people will avoid?

(Mr Taylor) Your experience in Government has left you somewhat cynical; I would not be that cynical. But there are clearly degrees of enthusiasm as to whether one would wish to pursue a particular issue. This report, for example, needed to be co-ordinated across ten Government departments, if you include the regional departments. That is quite an exercise and obviously there are aspects of it which are more positive in terms of what action might be possible and others which are less positive. My job is to see that at least all the bits are in place and then to make an assessment on how we go forward and how we can tackle them. Of course, the various existing committees that look at some of the aspects of genetics also have sponsoring departments.

Chairman: Thank you. Coming on to the application of those principles to the consideration and the actual drafting of this report, Mrs Campbell has some questions.

**Mrs Campbell**

141. Minister, when the Chief Medical Officer came to give evidence to us last week, he seemed to be saying to us that it would be sensible to have a single mechanism, rather than a number of mechanisms—that is a direct quote from what he said—when giving advice about genetic issues and I wonder whether the Chief Scientific Adviser and the Chief Medical Officer consulted about the Government's reply?

(Mr Taylor) Most emphatically they were consulted, yes, and I hope that came across in the evidence that they gave jointly to you.

142. It seemed to me that some of their evidence was actually conflicting with the reply which we have had from Government and yet leads me on to supposing that the scientific advice that they gave to you was not actually listened to? Is that correct?

(Mr Taylor) No, that would be unfair, but it is true to say that it is not only Government that is thinking through the issues that are involved here. Therefore, as I think the Secretary of State for Health indicated last week, we are keeping an open mind—certainly the Chief Scientific Adviser is keeping an open mind—to see how various events can affect our thinking. The Chief Scientific Adviser is very keen on a bottom up approach to some of these matters, rather than a top down approach and that may also influence the way that we place emphases on how we are going to deal with what is a hugely exciting but nevertheless very complicated subject.

**Mr Miller**

143. You said that ten Government departments were involved and your department was responsible for co-ordination; a lot of expertise in all of those departments. The reality is that the Government response to a study which you acknowledged resulted in a lot of hard work has been extremely disappointing from our point of view. The Alzheimers Disease Society described the response as

unimaginative, the British Society for Human Genetics as disappointing, and one can find adjectives like that in many of the papers that have been sent to us since the study. It would be helpful if we could perhaps get a better grip on how you undertook that mechanism so that we can analyse whether we feel it is the mechanism that has produced a result which is out of kilter with the profession or whether we are dealing with a disagreement with your department? How did the OST exercise its transdepartmental role in drafting the Government reply?

(Mr Taylor) I am not sure I can entirely accept your view that the Government's response was so disappointing, bearing in mind that we actually agreed with most of the thrust of what you, as a Committee, were saying. If you go through the recommendations there were those which related to Government and there was quite considerable agreement between ourselves and yourselves. There are clearly different emphases which I am sure we are going to come on to in terms of whether there should be some form of Commission or whether there are particular measures on insurance, but overall not only did we welcome the work you were doing, but we accepted the conclusions. In terms of the mechanism for co-ordinating, I think there are layers in which that happens. Formal consultation can involve exchanging copies of the report with the request for specific reactions. One has to go much wider than just the ten Government departments; obviously the MRC were involved in the consultation exercise and the purpose is to try to get, on the detailed points that were raised by the report, an agreed line to take. An agreed line to take on something that is as new and evolving as this is not necessarily going to be easy and I do not disguise that fact. There are different attitudes in different departments and different paces of reaction. Our purpose is to come forward with an agreed line and that is what happened on the publication of this at the beginning of the year. I do not think I would criticise anyone involved in that process simply because the conclusions of the Government in this response were not entirely identical to every one of the conclusions of the Committee.

**Chairman**

144. Would it be reasonable to say that the process carried out was that the report as published by the Committee was circulated by the OST official to the affected departments, they commented on paper and the replies were consolidated into a draft Government reply and then that was commented on by senior OST officials and outside organisations?

(Mr Taylor) Yes, but even accepting that, that probably misses out on quite a lot of detailed discussion and argument between various interested parties and this is exactly what was happening. I do stress that where we are in this is in reasonably new territory in terms of some of the implications, so there had to be much more detailed discussion than the framework that you have just given, which is the normal way of consulting in my department.



6 March 1996]

Mr IAN TAYLOR, MBE, MP

[Continued]

**[Chairman Cont]**

145. If one could characterise the general attitude of the Committee it was that it was putting forward a very mainstream view of the science and its applications in directives, but that, to command public confidence, needed an apparatus of reassurance and of continuing oversight and to do that we felt that further development and machinery were appropriate. But what the Government seems to have done is to accept our endorsement of the mainstream importance and value of this work and then to ignore most of the support systems which are needed to win public acceptance?

(Mr Taylor) You have touched on more than one aspect. If we are talking about public understanding we agree with the Committee. The question is how do you achieve that? It is fair to say that there are many amongst those we consulted who felt that they were already doing a considerable amount to encourage public understanding. Various committees that were already sitting, for example, would think that the areas that they were working on were a contribution to public understanding. Maybe more public awareness of their activities should be gained, but they do not necessarily think that the work that they are doing is in any sense other than a contribution to greater public confidence. Individual activities of, let us say, research councils where they have a statutory duty as well as a funding duty to increase public understanding. There is a lot of effort to do that and the idea that it should be pulled together is one that I am not unsympathetic to. I think the Secretary of State for Health said as much last week. With respect, what you came forward with in your proposal was to do something very different—to set up a statutory body raising a whole series of separate questions over and above the question as to whether we needed to pull together something on better understanding by the public.

**Mr Batiste**

146. If I can pursue that a little, because we are going to come in a moment to some questions about this new committee which is being proposed for oversight, but I would like to focus on this as a particular example by which we can judge how the transdepartmental discussions took place? Having heard the Secretary of State for Health last week, it is quite clear that the primary reason why our commission, with the list of responsibilities that we defined, was not acceptable. It was because he saw it as an intrusion into the operation of the National Health Service and fair enough, we understand that. But the core of what we were about was to find an oversight mechanism and the appearance to us in the Committee was that it was only because we took the relatively unusual step of re-opening an inquiry, albeit for this rather limited purpose, that we actually got the transdepartmental mind to focus on what was actually behind our proposal rather than the formal aspects of that proposal and hence to come forward with an idea for a committee which actually meets the principle if not the form of what we were about. Now does that mean that henceforth, in trying to deal with strategic issues, we are now always going to have to come back for a second bite to help you in your discussions?

(Mr Taylor) I want to get on to some of the detail when you have asked me these questions. I would have to say that in opening up the debate, and having published your report, I rather think that has enabled you to clarify some of your intentions. Therefore in this particular and perhaps unique circumstance perhaps the Government and the Committee are both learning from the process.

**Chairman**

147. Before coming on to the detail about dealing with the drafting of the legislation, may I just draw your attention to the statement in paragraph 104 of the Government reply? The very categorical statement is made with respect to the scope of medical insurance that: "The Government has yet to be persuaded by any evidence that such problems may occur in the foreseeable future." In view of the fact that there are certain States in the United States which already, by law, prohibit the use of genetic information in insurance underwriting, it does seem to be an extremely dogmatic statement for the Government to have made?

(Mr Taylor) Well it has the virtue of being succinct! There are dangers—and I know the Committee did not do this—just reading across from what is going on in the United States to this country. There is a huge sensitivity in the United States largely because of the way that insurance is a substitute for a health service and we know the difficulties that accompany most insurances for those who have already fallen ill. There is a huge sensitivity there which is not quite the same, certainly not the same as would exist in the United Kingdom. Secondly, the insurance industry here has indicated that it is not undertaking genetic tests in the foreseeable future. You might wish to be pedantic about the word 'foreseeable' but it is certainly some way into the future and therefore at the moment we consider it slightly premature to anticipate something that is not happening. I saw the ABI this morning, at my request, to update myself on where they were. I was a little concerned that it had gone rather quiet and I share the Committee's concerns. The fact that we did not adopt the recommendation of the Committee did not mean that we were not concerned about it. My instinct, I freely admit, is to try and do anything other than legislating in an area which I regard as complicated, likely to move and therefore likely to render legislation out of context before it has almost gone through the House. I openly confess that instinct to the Committee. What I am anxious to do with the industry is to find out whether they have a clear understanding of what they want to do and I do believe that when the ABI told me this morning that they had taken some time to consult amongst themselves about a common position and they are now ready to go back and look at the situation in conjunction with experts, academics and industry, then I think that is probably a reasonable explanation of why it had appeared to have gone quiet. Where the industry is right, is in warning us all, including the Government, not just this Committee, that this area of insurance is fraught with difficulty. As they openly said this morning, there is no obligation on insurers to cover an individual, but the



6 March 1996]

Mr IAN TAYLOR, MBE, MP

[Continued]

**[Chairman Cont]**

reality in the commercial market is that insurance companies are looking always at ways to cover individuals so they are trying to expand the market rather than cut off sections of the community from insurance. So we have got an opportunity to work with the grain, with the industry to get some common positions which could reassure the public that there will not be discrimination.

148. I think the Committee would like to return to the insurance question later when we have the framework within which that interacts and deal with issues like screening?

(Mr Taylor) Fine.

Chairman: May we pursue the question generally of the scope of the proposed machinery for handling cross-departmental issues? Mr Batiste.

**Mr Batiste**

149. Obviously we were delighted last week when the Secretary of State for Health said that following his discussions with you that you were now minded to examine the possibilities of a cross-departmental committee. What we would like to do next is really to examine your thinking on this subject and where it has got so far. First of all I suppose the issue is you now have these ten departments to get back on board and start the discussion; how far has the process gone?

(Mr Taylor) Well as personally I was in Japan for most of the period during the last week, it has not gone as far as it otherwise might have done. However, I fully support the Secretary of State's comments to this Committee that we need to review exactly how this might be organised in-house and how it might be structured.

150. As far as the time scale for this process is concerned, the Secretary of State for Health said he did not anticipate that it would take a geological age for it to be worked through. We have been striving to find a little more precision in timing than that. How quickly do you think the process can be brought forward with a specific proposal?

(Mr Taylor) I would hope a matter of weeks. It appears from the questioning that the Committee made and also the way the responses were received, that we may be working on reasonably common understandings and therefore I would hope that this would not be protracted, certainly because I, like you, would wish there to be public confidence in the process.

151. Do you think or have you given any thought in the discussion so far whether this sort of committee, with its oversight role, should be internal within the civil service or an independent body?

(Mr Taylor) I do not want to put words in Stephen Dorrell's mouth, but I think what he was saying was that he was going to take away and review the need for the committee. But he accepted the arguments that were being put forward about certain aspects of it in relation to the implications of the science, the moral and commercial implications of development, public understanding and the rate of development of the science and its applications. Those were the points that he indicated might need to be looked at. So on the basis that there were to be such a body, I

do not think I can be categorical as to where it would be based. Clearly from the Office of Science and Technology's point of view we regard this as one of the most exciting of all the areas of potential activity of science and technology in this country. It has huge implications for the wellbeing of our citizens. It has huge implications for the industrial base, because we are second to the United States and we want to make sure that we maintain that, perhaps even catch up. In all of those circumstances, the OST/DTI can take a co-ordinated view. However, the Department of Health has a very important role to play and if the Committee will forgive me I cannot give a clear answer to the question simply because there are further talks that will be necessary.

152. It is clear from our discussions last week that what you are considering is the existing structure of the eight committees, with the possibility of the ninth committee as part of the mechanism and some of the committees will be located, as they are now, in various places, some of them outside Government, some of them in different departments. I understand that we are going to come back to some questions about that in a moment, but I wonder if I could kick off on these detailed points about looking at the scope that you feel this oversight committee might undertake. You will recall that we had a number of specific suggestions as to the areas of activity that our commission should undertake. Bearing in mind that we are talking now not about a formalistic approach to it in terms of a statutory commission, but in terms of genuinely having identified areas we felt needed oversight, how would you anticipate your response might be to the listed areas that we included in our report?

(Mr Taylor) We think that some of the listed areas that you have included in your report are already well covered by specialist committees. My judgment—and this came quite a lot to the fore in the consultation part of the Government's response—was that there is a great deal of expertise required and we would not wish to try to pull that out and put it into an over-arching Commission which would either be so enormous as to contain all the experts or would actually not have all the expertise within it. I have drawn up a list which I am delighted to pass to the Committee of where we see the proposed functions of the Commission as proposed by yourself against the current arrangements for handling these issues. In my judgment I would not want *prime facie* to disturb those arrangements. For example, defining and monitoring genetic disorders relevant to employment, the HSC Occupational Health Advisory Committee is working on that and that is right; regulating genetic medicines, the Medicines Control Agency is looking at it. Where we did agree was that there was justification for a new committee, the Advisory Committee on Genetic Testing, and I think as Stephen Dorrell said last week, even if a new committee were to be set up the ACGT would still have a very important role to play and therefore it would stay. So I think it is quite difficult to look at any new committee as if it were to replace any of the existing committees. Therefore it would be very much geared to trying to provoke a greater sense of public confidence, that the very potentially emotional aspects of human genetics were in safe



6 March 1996]

MR IAN TAYLOR, MBE, MP

[Continued]

**[Mr Batiste Cont]**

hands and that there was some committee that was looking at all aspects of it without actually trying to do the work itself.

**Chairman**

153. Have you looked at the Medicines Act to see the frame of reference and the terms of reference of the Medicines Commission?

(Mr Taylor) The Medicines Control Agency does include genetic medicines. If you are asking if I have actually read it, no. I think that is a matter where the Department of Health would certainly take the lead.

154. Yes, indeed, but if you look at the Act and regulations made under the Act in relation to future committees and compare it with the terms of reference of the Committee on Genetic Testing announced by the Department of Health along with the publication of the Government response and also with the outline of responsibilities we outlined in our report, of them all much the simplest definition of scope is in the Medicines Act and when you actually come down to legislating you are much more general than you are in terms of setting up a Government committee with tightly defined terms of reference?

(Mr Taylor) Well, I would have to have a word with the Secretary of State for Health on this specific matter, but the Advisory Committee on Genetic Testing as has been proposed by the Government to be set up, provides a very necessary function. Whether the terms of reference will be tightened or broadened over a period of time is not a matter at this moment that I can make a judgment on. However, I will certainly ask my officials to look at the specific points you have made because I am unsighted on it.

155. The general background is that in an area like medicines where there has been a long history of government regulation and interest when statutory regulation is called for, it could hugely simplify the problem and leave the Committee on Safety in Medicines, for example, to deal with new evidence on safety of birth control drugs very precisely, very directly so that merely the publication of a report from the Committee on Safety in Medicines is sufficient to secure observance of its recommendations?

(Mr Taylor) Well I repeat that that is an interesting point, but I would rather not comment on detail because Ministers tread warily on other Ministers' toes.

Chairman: I understand that.

**Dr Jones**

156. In relation to any new committee that might be set up, have you any thoughts on its composition, range of expertise that might be needed?

(Mr Taylor) If it is a committee to reassure the public in the broadest possible sense of that term, then I think it would need experts and people who the public regarded as having good judgment. Do not ask me to name names because that is extremely invidious, but if my principle is right that the experts carry on as they are doing—with maybe some modifications over time—then I think the committee itself should not just have people who themselves are

experts in any aspect of the genetic field, but I cannot judge the balance or the number to make it effective at this stage. That is something we must look at further.

**Mrs Campbell**

157. I asked the Secretary of State for Health last week if the new committee would be an over-arching committee, if it would be one that was hierarchical in that it sat above the others and he told me it would not. Well, I am still interested in that relationship to existing committees and I wonder if, for example, you think it should contain members of those other committees?

(Mr Taylor) I think it might, but I do not like the word over-arching because it is a friendly word that has less friendly connotations. What does over-arching mean? If it is just a comfortable arrangement to overview what is going on, then there is some merit to it. If it is actually saying: "No, we are going to state our position and have the power to intrude", which is a quasi-regulatory power, then I am not so comfortable until I know what the extent of those powers are. So although I cannot put myself in the mind set of Stephen Dorrell in replying to your question, I have a hesitancy as to that particular word. However, I see no reason why there should not be people who are already involved in this process being on this committee, but then I would not see it as taking someone from each of the committees. We also have to work with the grain as well. The Nuffield Committee is itself doing extremely valuable work; I think it published a report today, which I have not had time to read yet. We would want to work with Nuffield because it also has outside support from the Wellcome Trust and others. So in consulting on who the committee might have on it if it were formed, we have to look as widely as possible.

158. You do not have any pre-set views about the structure?

(Mr Taylor) Not that I can share with you this afternoon, which is not me trying to be evasive. Your Committee has made a move, as I sense it, to a less statutory acceptance and we have made a move to a recognition that your Committee has made an extremely good point about public confidence. Let me just say, if I might, about how I see it as a DTI/OST Minister as opposed to the Department of Health. I would be profoundly concerned if the biotechnology industry, with its links with the science base, were to be over-regulated. This would be effectively inviting the Americans to do the whole thing, to put it bluntly. There have been signs in Germany, where regulation has been forecast, that Bayer and Hoechst in Germany have actually moved outside the European Union to the United States, rather than take the risk of coming here, which at the moment is more friendly to exploration but might be covered by the wrong sort of regulation in the European Union. We have to be very careful for the interests of the science base and the emerging industry that we do not assume that regulation is going to help. However, it is equally important to me that the public is taken along as we go because a sudden negative reaction by the public could be as counter-effective as over-regulation. It is a very



6 March 1996]

MR IAN TAYLOR, MBE, MP

[Continued]

**[Mrs Campbell Cont]**

delicate balance and your Committee has been quite right in provoking us into thinking this issue through.

**Mr Batiste**

159. In the spirit of compromise which pervaded that last answer, could I just express what I think our concern would be in retaining eight committees with a ninth in addition and that is that each of the eight committees in place is looking at a relatively well defined field in which they are acquiring considerable expertise of a science which, as you have described, is moving so fast it is sometimes difficult for people who are not involved in those very specific areas to know how fast they are going and where the fringe is. An overview committee of any kind, if it is to be effective, has actually got to be able to have access to where the fringes are in the other eight committees that are doing the detailed work and I hope that in the structure you would come up with you would actually see the need for the inter-communication between the committee network as a very essential part of the over-view process?

(Mr Taylor) I have noted your comments carefully.

**Mr Thompson**

160. There is a great deal of international activity in genetics at present. Is there not a case for a body which could ensure that international proposals could be considered in the round by those with broad expertise in the area?

(Mr Taylor) The international aspects are quite complicated, but clearly there are two main dimensions of that; the European and then wider afield. We want to take as active a part in those as possible and it would be implausible to think that any committee that was set up as a result of these discussions did not have somebody who was aware of what was going on in other areas. It is important for all sorts of reasons, in terms of industrial opportunity, in terms of the development of clinical trials in universities, and in the context of regulation that there is a European Union dimension which provides some degree of safety in each of those points for people who are practitioners. The wider international dimension is also important for us to watch and observe very closely.

161. Do you believe that could be done just as effectively by the committee structure proposed by the Government as by the commission that was talked about in the Select Committee report?

(Mr Taylor) Yes, I do, because any action at the European level would have to be handled by more traditional Government departments. They are interested in the Council of Europe, they are interested in the European Commission, they are interested in UNESCO, there are implications in the World Trade Organization too; all sorts of levels of inter-action. But if a problem was identified, it would then be up to a Minister or a Government department to take action.

**Chairman**

162. Could we pursue one aspect of the international issues as an example here? The European Directive concentrates on patenting and in that it copes with patenting the genes of animals, of plants and of humans. Now this Committee took a different cut; it looked at human genetics as a whole of which patenting is one example and I think on the whole we did come up with a more balanced set of recommendations that were apparent in a previous draft of the European Directive. Is there a case for keeping a step ahead of the argument in our own national arrangements so that they can be observed by other countries and perhaps copied and perhaps implemented into an issue?

(Mr Taylor) It is perfectly true that for reasons I said earlier about a desire to avoid the wrong regulatory environment, that we would be wise to anticipate any potential development and for Ministers as individuals with responsibilities to take part in fora where we can influence the shape of thinking. For example, I was at the trilateral discussion on biotechnology in early January in Brussels with the Parliament, the Commission and Members of the Council. I was actually only one of two Ministers who attended; otherwise Ministers were represented by officials, but I regarded it as important to go and make some clear statements. We do try to anticipate some of these debates. One of the committees I have not yet mentioned, which goes under the most appallingly long title is the Interdepartmental Group on Genetic Modification Technology or IGGMOT. There are 17 departments and agencies represented on the group, chaired by the Office of Science and Technology and it does discuss on its agenda quite regularly potential EU Directives or measures that might need to be taken or influenced or concerns that might be raised, for example, by the European Parliament. So I would not want to give the impression that we were passive at all and I would endorse your idea that in many cases we ought to be pro-active.

**Mr Bruce**

163. Minister, I firstly apologise because I am a late arrival on all of these and the temptation for me as a deregulator when people are suggesting another ninth committee on top of the eight that we have is to say: "Is this really what the Committee wanted?", but I have bitten my tongue so far and I shall continue to do that. One area of what the report is saying which I think is extremely important is what the public are thinking about genetics generally and the worry I think we all have that the scientists can go off and do wonderful work and all of a sudden we find public opinion says: "You cannot go any further". Now the Committee suggested that the commission should have a role in fostering public understanding of genetics and indeed in some of your answers you have touched on the fact that this commission, if it was to come about, would be something that would have a wide range of people and people who hopefully the public would trust. Sir Robert May spoke of the roles of the Research Councils in fostering an understanding of science and I think we are a little concerned that there might be a danger the



6 March 1996]

MR IAN TAYLOR, MBE, MP

[Continued]

**[Mr Bruce Cont]**

public may consider the efforts of the Research Councils as being vested interests. I wondered what your comment would be on this, how we can ensure that the public are not brought along, so to speak, but are fully informed of what is happening and they understand both the benefits and the possible problems of genetic science?

(*Mr Taylor*) I do not think that the Research Councils would be regarded as partial in this, or I rather hope not. There are many aspects of the Research Councils' work where it is quite important that the public do understand and that is why we put a burden upon them. Interestingly enough, in his report, Sir Arnold Wolfendale went further and said that anyone in receipt of Government funds for science should spend at least part of his time in the year taking on the burden of informing the public as to why he or she is doing that research, whatever it is. The other aspect, where the Research Councils can do a good job—and it is an important thing for us all to bear in mind—is that inevitably when we have this type of discussion we are looking at some of the dangers, the negatives, the worries. But actually of course there is the other side of that and the whole process of mapping the human genome is immensely exciting and could do terrific new things for the wellbeing of mankind. The Research Councils can provide that broader perspective, which could be supplemented by the biotechnology companies themselves and by anyone else who wants to get involved in the debate. I would make one other point which is that when you put six academics together, you probably will get seven opinions, whether they are economists or geneticists, so it is unlikely that there would be such a biased view that the public would think they were being given an unfair account.

164. I wonder, Minister, if you feel that the public are really understanding it? If I can give a constituency example, which is always an advantage that one can do, I have a constituent, a Mr Graham Hill, who suffers from Anderson Fabry disease. Virtually single handed my constituents are raising money for research workers dealing with this particular disease and they in their own minds think that genetics is at such a point that if they raise enough money they will give him an injection and he will be cured overnight, when what we actually know is that we are trying to get the research to a stage where he may well become a guinea pig and obviously we are all hoping and praying that that will actually solve the problem, but I do find it often very difficult to explain to the public exactly where we are on the research and I think that we really do need to get that message over to people so that they understand both the benefits that could come from it and of course this, to a certain extent, will counteract the downside where people are saying: "I do not want genetics. Genetics is modified tomatoes or whatever it may be and something that is not necessary".

(*Mr Taylor*) I share your concern about the real state of public understanding, so much so that perhaps you ought to look at what you just said—which is that by genetic testing he might actually become a guinea pig—because there are some connotations there which in the public mind, wrongly expressed, could be appalling. But on the serious side of it, we are a long way from doing what

could be done some time into the next century. We do not yet know how to correct some of the problems that we can now identify in any particular gene. One of the matters that we have to get across to the public is that genetic sequencing and identification of genes might well lead to more traditional medicine or medical treatment rather than genetic treatment. This is a very important point that we need to communicate, that the first stage of better understanding of our genetic sequence for any given gene is that you may get early warning that there is a problem of cancer or a problem of Alzheimer's which could then give the ability to treat in more traditional ways. It is a long way into the future before you begin to understand the interaction of several genes and we must not assume that just because there is a predisposition someone is going to automatically suffer. There could be other factors which could be more life threatening, such as the wrong diet in certain cases to that person's life expectancy. However, in the future it may well be possible to genetically engineer recombinant genes and other aspects. We just have to prepare for that, but not let the public think that we are so far ahead that this can be done immediately.

**Mrs Campbell**

165. May I ask the Minister just to expand on that because I did not really quite understand? When you were talking about conventional medicine being available for early treatment, do you mean that if somebody has a genetic predisposition to, let us say, Alzheimer's, you might try to start treating Alzheimer's early rather than waiting until it is fully developed?

(*Mr Taylor*) Let me confess I am not a medic. What I am saying is that the evidence that I have read is that we must understand where genetic science can take us, but that before it can get us to the ultimate we are going to go through a period where we are learning better about ourselves and the treatment we can take rather than that there will immediately always be a genetic solution to a genetically identified problem. There may be opportunity for a better lifestyle if one is identified as being susceptible to an hereditary problem, for example, and it may be that one tries to protect oneself by better living or available medicinal drugs.

166. And that is what you meant by conventional medicines?

(*Mr Taylor*) Yes, sorry. In terms of 'conventional' I am probably using a word that has ambiguous connotations. I apologise in that sense; I did not hear myself say that but if I did, then I understand your question.

**Dr Jones**

167. Turning back to insurance, a little while ago you said that you thought the insurance companies were trying to expand their market rather than trying to cut off individuals and of course the general thrust of Government policy is to encourage insurance companies to take a greater role in our general welfare. Whilst I acknowledge what you are saying that they are probably not wanting to cut off



6 March 1996]

MR IAN TAYLOR, MBE, MP

[Continued]

**[Dr Jones Cont]**

individuals, there is a possibility that individuals might have their premiums hiked or not have discounts available to them. Are you actually prepared to sit by and allow the emergence of an insurance system for which rates for health or life insurance could differ markedly according to the genetic status of the person insured and all the implications that that might have for the willingness of people to undertake genetic testing which, in the long term, will be of benefit to us all?

(Mr Taylor) I raised the latter point with the ABI this morning and they certainly do not want to get into a situation whereby any knowledge that is available would put people off from finding that knowledge in the first place, that is, by being happy to have a genetic test. So we must not assume that the insurance industry as a whole is hell bent on a particular measure or series of measures on availability of information which would discourage people from learning more about themselves. I do not think we are anywhere near a situation where the insurance industry is going to try and demand information or skew their insurance rates against a particular individual largely because I repeat there is no certainty between identification of a genetic predisposition and the emergence of that genetic trait.

168. Well there are in some circumstances?

(Mr Taylor) They are very specific. I think Huntington's Disease is one.

169. But the insurance companies are saying that they think they should have the right to any genetic testing and that if an individual does have a genetic test that they should tell their insurance company about it. We know all that happens over the HIV testing. Could you give us a categorical assurance that the Government is not prepared to sit by and allow that sort of two-tier system to develop?

(Mr Taylor) We would not want to see the insurance industry so frighten potential insurers away from testing that there were not the developments in the scientific knowledge that testing would be associated with. So I can give you that statement, but I do not know that that was entirely what you wanted. What I am not prepared to do is tell the insurance business how it should regulate its assessment of risk because otherwise effectively the Government would be underwriting the insurance industry. What I want to see is the ABI come up with a code of practice which reassures me that they are approaching this in a very responsible way. Genetics at the moment is not life threatening. If you take the population as a whole it is not about to suddenly reduce the life expectancy of all of us just because we happen to know our genetic sequence—I think HIV is different in that context—but reassuring the public about it and about the confidentiality of information is perfectly understandable. One point that is vital though is that it is very difficult for anyone to say that an insurer who is writing a risk should not have access to information. The Government would be ill advised to start telling insurance companies: "No, you cannot have information". I go back therefore to trying to find a proper and responsible code of practice with the insurance industry as to how it would behave.

170. In coming to an assessment as to whether the insurance industry had come up with the goods, how would you make that assessment? Would the new Advisory Committee on Genetic Testing take responsibility for advising Ministers?

(Mr Taylor) They would advise us if they felt that there was evidence coming to hand that there were abusive practices or worrying practices in the insurance industry, yes.

171. Obviously they come under the umbrella of the Department of Health, which does not have direct responsibility for matters such as employment and insurance, so how would they feed into Ministers in the DTI? Would they have access?

(Mr Taylor) With any committee like that that the DTI/OST and the Department of Health would be working closely together in any event. I repeat it is in no interest of anyone in Government to see a problem in relation to insurance. I want to work out with the insurance industry a reasonable code of conduct which could be adjusted as time went by, as the human genome project goes further ahead, and as we become more aware of not only monogenetic problems but genetic problems from several genes interacting, the whole issue of multi-factorial problems. We would want to work with the industry to see how that code of conduct was adjusted as time went by.

172. We are grateful that you have actually met with them and hope that that will get the thing moving?

(Mr Taylor) The agreement this morning was that we would have a further meeting when they had had talks with experts in the genetic industry and when they had begun to be clearer about the sort of arrangement that they were going to issue publicly.

173. The cynics amongst us would say that you had had that meeting because you were appearing before this Committee today and after this has all gone away in a few weeks' time it will be back to the hands-off approach and let them get on with it?

(Mr Taylor) Ah, but I am not as cynical as that!

#### Mr Miller

174. Some of the professionals in the genetics industry are expressing very serious concerns. Professor Harper from the University of Wales wrote to the Committee on 29 January saying: "Sadly since August 1995 the insurance representatives have declined to meet further, even though in my view at last good progress was being made". So I think you are being, if I may say, rather complacent in terms of the insurance issue. The British Society for Human Genetics accuses the Government of abdicating responsibility for issues of employment and insurance. Now the simple fact that you are brushing aside the Chairman's comments in relation to the American evidence, which does exist, is wrongly placed in insurance terms. The Government have, for example, introduced a requirement for home owners to take up employment policies, but such policies would be extremely difficult for people who have a genetic trait if the industry is allowed to go uncontrolled. It is already using genetic information, albeit derived from anecdotal information rather



6 March 1996]

Mr IAN TAYLOR, MBE, MP

[Continued]

**[Mr Miller Cont]**

than testing, as a means of determining risk. For example, they ask, do they not, about the health of your parents? "Did your mother and father suffer from any heart condition?" Now these things are developing, they are with us now. You say you are encouraging that dialogue. You say you have made some progress this morning. How are you really going to push them, because I think they really are going to have to be pushed very hard if we are not going to see some of the unacceptable possible developments emerging? What will you do if the insurers and geneticists are unable to reach agreement, let us say, within a year from now?

(Mr Taylor) I reject the charge of being complacent because I am confident in my own mind that that is not at all what I have been. I have already said that I would wish the ABI to be more rapid in its progress. It has now consulted with members and it has assured me this morning that it is ready to talk to other geneticists and to the Nuffield Committee, and I think that Professor Harper is one of those that it will be regaining contact with. An issue for the ABI is that it is a trade association representing its members; unless it has talked to its members and got a common agreement it cannot take action. If it took action it would not necessarily have the power to pull all its members to adhere to that policy. The second reason I do not think I am complacent is that I would not be satisfied if the next thing I heard about was in a year's time. This is a continuing process of discussion so the year point is not the key benchmark for me; it is that I now expect them to come back to me having made significant progress over the next few weeks and certainly a public announcement before the summer. Now that was what I discussed with them this morning so, with respect, it is not a question of complacency, but a recognition that this is a very complicated area. Of course you are right; of course the insurance industry, in its own interest and the interest of all the other premium payers, assesses risk. Of course it does. The question is whether it is doing it reasonably and that is why I am so interested in the code of conduct which they are to produce. Let me just make one point finally clear here; it is not in the interests of people taking out insurance that the insurance companies are not getting information, because that is not likely to lead to insurance premiums declining. So there is a wider interest here in making information available, but it is crucial to understand that genetic science is not life threatening as such and taking the community and the actuarial calculations as a whole, genetics therefore should not be regarded only as a negative in terms of the insurance industry.

175. So you are now actually agreeing, contrary to your paragraph 103 in your response where you are rejecting our concept of a review in 12 months' time; it will actually be in 12 months' time by which time you are expecting to see something on this? You are back on board with us?

(Mr Taylor) I am not rejecting previous views. I am just taking into account the passage of time.

**Chairman**

176. ABI is, as you say, a trade association. Whilst the pattern has been, in the discussions the Committee has had with the ABI, is that it has dealt with a small group of officers and members of the Association who are well briefed on the technical problems and they in turn have been interestingly the actuaries and the actuaries have approached the Royal Society and a joint meeting with geneticists is set up. Now the effect of the Committee's report was to say: "Look, this is not just conversation. We are expecting a practical outcome in terms of a workable coincidence in fact" and the impact of the Government's reply from informal meetings with the industry was very clearly for them to feel: "Well, the pressure is off" and in particular the chief executives and the general management of the insurance industry ceased to be concerned about it as a problem. Now was your meeting today with the staff and the experts or was it with the Council of the ABI representing the chief executives and the general management?

(Mr Taylor) My meeting this morning was with Mr Smee and Mr Bowley. Mr Smee is the Head of Life Insurance at ABI and Roger Bowley of Equitable Life and Chairman of the ABI Medical Affairs Committee.

177. They are very knowledgeable in this area and were indeed among the people this Committee—

(Mr Taylor) They gave evidence to this Committee, yes.

178. That is not where the problem with the insurance industry lies. It is with the general management and with the chief executives feeling: "What are the pressures upon the industry? Where are the opportunities for the industry?"

(Mr Taylor) It is also fair to say that I happened to be with two chief executives of insurance companies last night at the Innovation Lecture and they were quite knowledgeable in general terms about the issues because I happened to mention that I was appearing before the Committee today. That was in private conversation so I will not identify who they were, but I can assure you that this is a matter which concerns the insurance industry very broadly. I am not naive, but I do think it is a matter on which we have to work with the insurance industry. It is going to be very difficult just to impose regulations on an unwilling industry. We have to work with them and that is a much better basis for public confidence than any other means that we are likely to find.

**Mrs Campbell**

179. Minister, may I outline to you just three of the areas that we were rather worried about. One was that people might be discouraged from taking tests if they thought they would be disadvantaged by their insurance companies, that a whole class of people would be excluded from any possibility of insurance which might have serious implications in view of some of the Government's recent policy decisions about mortgage insurance which Andrew Miller mentioned a moment ago. Also the possibility that we have a rogue insurance company that comes along and says: "If you take a test and you are given



6 March 1996]

MR IAN TAYLOR, MBE, MP

[Continued]

**[Mrs Campbell Cont]**

a clean bill of health, we will give you very cheap insurance for either life or health or whatever" and that would force other companies to follow similar practices. I think those are the sorts of issues that we are worried about. What we would like to know is how the Government intends that the discussions that are taking place between insurers and geneticists are monitored? Is that going to be specifically the job of the Advisory Committee for Genetic Testing and should it also be the task of that Committee to ensure that the industry is using genetic information properly?

(Mr Taylor) The latter certainly. I think the former may well be but it is also a matter for me as the Science Minister to take an interest in it and I have done so. For the reason which I repeat I am as concerned as the Committee to make sure that proper arrangements are worked out with the insurance industry because I do not want there to be a public backlash or an obstacle to the continuance of the development of the benefits I can see genetics bringing to the community as a whole. But I do not want to do it in a regulatory fashion, I want to do it in a co-operative fashion and that is what we are trying to do. Of course there may be problems from time to time and we will have to take action when that happens, but I do not think we should give the impression that there are problems of any significance at the moment because they certainly have not been drawn in detail to my attention. Obviously if there is an issue then I look forward to receiving details.

180. Do you think that you personally over the next 12 months are going to have time to monitor closely what the insurance industry is doing?

(Mr Taylor) It is remarkable how the interest of a Minister translates into the activities of his officials!

**Mr Thompson**

181. Just coming in on that question if I may, what is there to prevent at the moment—and I am also a new member of the Committee and therefore I was not in on this from the start—but what is there to prevent an insurance company right now offering cheap insurance for someone who happens to have a clean set of genes?

(Mr Taylor) Because we would not know whether the genes were clean or not yet.

182. But we might do in the very near future. I am asking a question which a member of the public could well ask?

(Mr Taylor) That is why the question is an extremely serious one, but my answer to it is that we are nowhere near that yet so however valid the question is, I do not think we should try to anticipate the response. If we found that there was abusive practice in the market which was leading to the public being put either at risk or that the marketing of that company was suspect, then action could be taken under existing powers.

183. I must pursue this one, particularly in the light of the reaction, and that is that we are near enough to it to be discussing issues related to it, so because we are near enough to be discussing it, we cannot just push it on one side and say: "Well, it is not coming

yet". There is a possibility some time in the future—and I am not an expert in this subject and therefore I would not speculate on when the time is—but some insurance company may jump the gun; that is what I am saying and it could happen while we are all looking the other way?

(Mr Taylor) It could happen, but it is unlikely to happen at the moment and let me try to put it in a—

**Chairman**

184. It will not happen all at once. It will happen in pieces. For example, you can tell now that you will not be liable to certain types of diabetes?

(Mr Taylor) But can I please try to turn that round so that the public who will avidly be reading every moment of this exchange do not get concerned even by the questions that are being asked? The reality is that genetic testing is not life threatening. Indeed, from an insurance point of view a genetic test that shows a problem can actually be helpful because if you have heart disease or your genetic profile indicates that you may have heart disease, you may be so concerned to find that that trait is in you that you take some preventative action. If you did not know that you had that predisposition, you might go away and eat loads of butter or whatever else is supposed to be bad for heart disease. It is the same with blood pressure. In other words, the whole process of insurance is complicated. The very identification of a genetic problem does not necessarily mean that you are uninsurable in any sense of the term. If you give up smoking, if you take this, or that precaution you may well actually bring your premium down. So I do not want the public to suddenly think that we have a whole series of negatives simply because of the process of genetic sequencing in relation to insurance.

**Dr Jones**

185. A little while ago you were, quite rightly, pointing to concern that we did not want over-regulation of biotechnological developments and I think that this Committee certainly shares that view. On the other hand you did allude to the fact that if there was a lot of public confidence that could have just as bad an effect as over-regulation. I think that is why this Committee came to the view that we wanted a mechanism which could provide a broad framework of regulation. I think that is what we are still anxious to achieve. One issue which I think people get quite exercised about is the patenting of genes and we made what I thought was quite a clear recommendation in relation to that that genes could be patented we thought, but only in conjunction with a known utility and that any different utilities would not be caught up by the initial patenting. Now this has caused some concern. It has been raised by SmithKline Beecham who did not like it at all. On the other hand most of the scientific community I think welcomed an attempt to pinpoint this issue. For example, when we saw Professor Bobrow recently he expressed concern that we were having an absolute epidemic of defensive patenting, with people patenting things which lacked novelty, which actually could be detrimental to the development of



6 March 1996]

MR IAN TAYLOR, MBE, MP

[Continued]

**[Dr Jones Cont]**

these technologies. Could I ask for you to comment on the Committee's view? Do you think the holder of a patent on a gene has a right to control all the uses of that gene that might be discovered in the future?

(Mr Taylor) It is a complicated area, but the current patenting in this country is only in respect of novelty, inventive step and industrial applicability. In other words, there has to be some specific characteristic and it would be unlikely the patents would be granted for gene sequences of unknown function. So the Committee and the existing practice, in this country at least, are in harmony and I do not think there is a disagreement between us; and certainly if there was any thought that that might not have been the case I am happy to confirm that that is the basis on which the Patent Office works at the moment.

186. No, but the question is that the gene is part of the patent, but really with sequencing now being so routine, the patent really does not relate so much to the gene as to the use to which it is going to be put. That is where the novelty lies. So why should the patent holder of one particular use have some say in the development or some rights in respect of the development of a completely different use, which does happen to use that particular gene sequence?

(Mr Taylor) There is a very important exemption in United Kingdom law which follows actually the wording of the Community Patent Convention to which we are obviously a signatory and that means that the use of an invention for research purposes is not an infringement of the patent unless the research is for commercial ends. Now that over-rides the existence of a patent for commercial development so if I have understood your question correctly the existence of a patent in relation to a novel step involving a gene does not preclude use or clinical trials in a research context in areas covered by that patent. What it does cover is a commercial exploitation in the field that the patent covers. Clearly if some interesting development has taken place then there may well be an argument for cross-licensing but that is a matter between the parties concerned.

187. That is not quite the point. We did express the need for some clarification on what constituted research, but that is really not the point. Why is it that if a commercial company carries out some research which happens to just utilise that fragment of DNA but is a completely different use for that DNA which really owes nothing to the other patents, the initial patent holder should be able to require a licence from that other company?

(Mr Taylor) Unless I completely misunderstood the question—and if I have misunderstood the question I am probably going to ask for further particulars and write to you—I do not think it is possible to patent anything as general as a part of a gene or a gene unless there has been a novel sequence and therefore you are attaching it to a particular process or an application; I repeat novelty, inventive step and industrial applicability. So it is something in connection with the gene which has been discovered rather than the gene itself.

**Chairman**

188. That novel application does not cover all possible future—

(Mr Taylor) Precisely, so I—

Chairman: I wonder if I could take up your offer to write to us on this because first of all the representations of SKB do need careful examination themselves and secondly your own reply, I am sure, we shall be interested in?

**Mr Batiste**

189. I wonder if I could just clarify that problem because it would be very helpful if you would write on this? To put it into a particular context, if a particular gene sequence is known to have a particular utility which is novel—it may be a diagnostic of some kind—then it is logical that there should be a patent and that anything that is downstream of that diagnostic should be covered by that patent, because subsequent research would follow from that initial discovery. But if the same gene sequence subsequently in the connection of a multi-gene function has a totally different purpose and there is something quite different discovered from it that owes nothing to the original utility at all, our concern is that some of the claims that are being now drawn on patents are expressed in such wide terms that the catchment will have no relevance to the nature of what was filed, but merely seeking the proprietary right in the gene, irrespective of what people discovered from it afterwards?

(Mr Taylor) There have been some debates in the United States that may be more applicable, and I believe that in the United Kingdom your concerns would not be well grounded, but because we are dealing with such a hugely important and technical matter then I would prefer to write to you. I think you will find that my views expressed to you will be upheld but the detail will be greater.

**Chairman**

190. We will write to you enclosing the evidence that we have had and look forward to your reply?

(Mr Taylor) Thank you.

**Mr Batiste**

191. Still continuing just for the moment with patents, but not going into the technicality of the patents in the same way, though I think we are all indebted to the Parliamentary Office of Science and Technology for the very interesting paper that it has just produced on patenting which covers quite a lot of the detail for people trying to follow these debates. If we can just come for the moment to the European dimension on this and the Convention, you will appreciate that in our report we took a view that once the European Parliament had killed off the last effort towards a Directive the best thing they could do now was to keep out of the process altogether because the existing European Convention to which you have referred as the Community Convention—trying to put it in a nutshell in a very non-technical way—is basically a simple method of registering a patent



6 March 1996]

MR IAN TAYLOR, MBE, MP

[Continued]

**[Mr Batiste Cont]**

which still could be challenged in any of the signatory countries' courts in terms of their own domestic legislation for patents and therefore we have a considerable degree of flexibility domestically, even within the existing Convention. Now our concern is that there were, even in relation to the last efforts at a Directive, some quite difficult elements within it which were probably just about justified on the basis of trying to achieve a common position. That having failed, we did not feel now that given the elements of diversity that there appeared to be across Europe on this subject which has led largely to the German pharmaceutical industry outsourcing all its genetic research largely in the United States, that to try and reach a European consensus was going to be a very worthwhile and profitable operation from our point of view and yet we have just heard that a new Directive has been produced. What is the Government's view on that?

(Mr Taylor) Bluntly, we have changed our view or our view has certainly mutated. The Directive that has been in draft form and on which I have just signed a Standing Order to present to Parliament, is we think probably going to help as long as there are no further changes to it in the European Parliament. The reason for that is that there is evidence of different tendencies and interpretations in different countries and we think the industry as a whole would find it welcome to have a re-clarification of view as to what the attitude to patenting was across the Community. It also happens that the draft is in line with our practice and therefore we are comfortable that if that draft were to be adopted then we would certainly not be in any way out of line with what would become the practice throughout the rest of Europe.

192. So the representations then from the British pharmaceutical industries were extremely concerned at the very close relationship between the location of genetic research and the patent environment in the country in which it takes place and as we have seen from Germany is very easy to drive this hugely important area of research out of your country totally? So you are satisfied that the representations from the British pharmaceutical industry would be that they find this Directive, on balance, satisfactory?

(Mr Taylor) They would certainly not want it to be extended or altered in any way and we hope that the European Parliament this time would be responsible in its discussion of the document rather than trying to use it as a Christmas Tree.

**Mr Thompson**

193. Who would have access to reports from the Health and Safety Commission's Working Group on Genetic Screening? A straightforward question.

(Mr Taylor) Free?

194. In any respect?

(Mr Taylor) I am not sure of the answer to that because I do not know the basis on which they would provide their information, so I think I would have to duck that question and ask my officials to brief me better on how the Health and Safety Commission

actually issues its reports. At the moment it is not envisaged that formal reports will issue, though this is not ruled out. That is the current situation.

195. Do we have any information on the frequency of reports or is that not known or perhaps you could incorporate it in the answer?

(Mr Taylor) No, the answer is it will meet regularly but I do not know that it is actually timed. The Health and Safety Commission's Occupational Health Advisory Committee did set up a working group on genetic screening which has a watching brief and its brief is to look at the implications for health and safety in the workplace. It has met twice and I would imagine that it would meet as regularly as the members think it is necessary to do so and it reports back, of course, to the Health and Safety Commission.

**Chairman**

196. Thank you for that background.

(Mr Taylor) Again if, as so often, Chairman, there are little bits of detail which I do not keep in my mind and if my officials on reflection feel that there is elucidation to be given then I am only too happy to give that elucidation.

197. It is entirely understandable and does illustrate the difficulty of having so many different committees on different subjects?

(Mr Taylor) Yes, but you will be glad to know that I will not have to sit on all of them!

**Mr Miller**

198. May I take you on to the comparison with existing legislation? In the Disability Discrimination Bill there is regulation that impacts upon the behaviour of insurers and employers towards people who have a known disability. Now you seem to be reluctant to regulate towards people who are perfectly healthy today, but may have the risk of suffering from a disability in the future as a result of newly identified genetic information derived from tests. Is that the case?

(Mr Taylor) The existence of a genetic predisposition which in this case might lead to disability is not itself a disability. It does not predict the timing of the emergence of symptoms of disability and therefore is different from the scope of the Disability Discrimination Act. So although there may well be a progressive disorder diagnosed, it could well be pre-symptomatic and in those circumstances I do not think it is covered by that particular piece of legislation, nor would the individual concerned necessarily wish it to be because there may be many years of perfectly normal life before the disability became evident. Once it became evident, there would be of course a different set of circumstances.

199. In the area of employment, for example—and one can think of logical examples where a particular condition would prohibit someone from carrying out a function; the notion of someone who was susceptible to, say, epileptic fits becoming an airline pilot is an obvious one—the sharing of that sort of information between an employer and employee is



6 March 1996]

Mr IAN TAYLOR, MBE, MP

[Continued

**[Mr Miller Cont]**

obviously quite critical in terms of the broader safety of the public as well as the safety of the individual, but just because somebody may be developing—let us say there was a test that could identify Alzheimer's, and God forbid in many respects because I am not sure that I would want to know that I was going to be struck down with that, but if there was one readily available, would it not be reasonable to say to an employer: "No, you cannot require your employee to take that kind of test if they do not want it"?

(Mr Taylor) I do not think that employers could have the right to insist that employees had tests. I would be uncomfortable personally about that. It is something that could be negotiated between employers and employees.

**Dr Jones**

200. Job applicants?

(Mr Taylor) Yes, but it is a very complicated area. It would depend to some extent, of course, on the nature of the job. If there was a health risk to others as well as to the individual if they had a particular disorder then it would be worth the applicant knowing as well as the employer knowing, but as a generality we are certainly not about to emerge into a period where there would be automatic disclosure of all genetic characteristics when applying for a job. However, over a period of time it may well be that individuals will want to know about their genetic character and so will employers. If there then were to be discrimination on genetic grounds then that would be a matter of some concern. If the person were already an employee then it would be the industrial tribunal that could look at that, for example. I am trying to translate what is a worrying general statement into practically how you might then handle it.

Dr Jones: What about job applicants? Sorry.

**Mr Miller**

201. You will acknowledge though that the problem is not as cut and dried as saying there ought not to be regulation. Are you saying that you can envisage circumstances, as the technology advances, where it may be necessary to bring about regulation to protect particularly the employees from potential discrimination?

(Mr Taylor) We go back to this word 'regulation'. I would want greater evidence of a need for a regulatory framework which was outside those protections to employees which currently exist. In other words, I am not yet convinced that one should regard genetics as such as something requiring its own regulatory framework. I am concerned that individuals are not discriminated against and therefore I would want to see whether the existing circumstances left them vulnerable, but I do not presuppose a new set of regulatory environments simply because of the genetic situation.

**Mr Thompson**

202. If I could just follow on for a moment? This is the trouble with being new to the Committee; you suddenly find things that already—but this is linked in a way to the question we discussed a bit earlier about insurance. Is there not a danger that all the various issues that have been discussed and just been related now could catch up with us rather more quickly than we suppose and therefore we really have to be thinking well in advance of the issues, rather than waiting for things to happen? That is not a very well focused question, but I think it is what the public are going to say. What I am trying to express is: "What are the public going to say?" and I think, Minister, we have to try and get ahead of the game on this rather than wait by linking the various questions that have come up during the course of the afternoon?

(Mr Taylor) These are matters which the public should be aware of, but again my judgment is that genetic testing is something that individuals may well wish to entertain because better knowledge of what is likely to happen to them can also lead to a better ability to reduce its likelihood of incidence. So the individual may well gain confidence from genetic testing. An employer in a dangerous occupation or where, as I said earlier, there could be danger either to the individual or other employees, does have an interest in getting common ground with all employees and employees' representatives to find a way of protecting the wellbeing of all the people in the company. Now how that is done I would rather leave to an arrangement to be decided at company level rather than a series of regulations, but I am certainly not going to say never to something which at the moment is a hypothetical question.

**Mrs Campbell**

203. I think the problem is, Minister, we are talking about hypothetical questions because the science has not yet sufficiently developed, but I think one of the things that does worry the Committee is that with the development of fairly cheap genetic tests we will soon be able to identify a class of people who may not have developed a genetic disease but who nevertheless may have been identified as being vulnerable to particular diseases. You have rejected our proposals on employment and insurance, so is there not a possibility that we will get a genetic under-class who can get neither employment nor insurance and you, as a Government Minister, are you not worried about the effect that is going to have on public expenditure? Will it not create costs to the State?

(Mr Taylor) I simply do not see that as a plausible scenario in the current circumstances. I am much more concerned about the genuine existence of an under-class which has nothing to do with genetics.

204. Me too?

(Mr Taylor) In other words, I believe we have problems. I was the responsible Minister in the North-East for a while—I do not want to get into detail, Chairman; you would rule me out of order—but genetics did not come into it. There were clearly problems in certain localities about persistent unemployment passing from generation to



6 March 1996]

MR IAN TAYLOR, MBE, MP

[Continued]

**[Mrs Campbell Cont]**

generation where there were still job opportunities in the surrounding environment. Those are matters in which I genuinely consider Government should take an interest, with local people, in trying to solve and which are of much more immediacy than the scenario you have painted. But I am not complacent. We will obviously keep our eyes and ears open as matters progress.

**Mr Batiste**

205. Minister, may I give you one further illustration of how complex the issue is because there may indeed be situations—we are still talking hypothetically because the testing is not there yet—where the Health and Safety at Work Act commitments on an employer to provide a safe working environment may positively put a legal duty on an employer where, for example, a particular job has a hazard to people who have a genetic susceptibility to a particular type of disease to actually undertake some type of genetic screening and that has to be compared and separated to things that are relevant to the job and things that are not relevant to the job. So I think the flexibility you have described is actually terribly important.

(Mr Taylor) The flexibility I described is important. I also suggest that the work of one existing committee and the one new committee would both be relevant to looking at circumstances that you are describing, the Health and Safety Executive's committee and the new Advisory Committee on Genetic Testing.

**Chairman**

206. We are grateful to you for having carried the discussion further. May I just, in concluding, draw your attention to what were the respects in which the Secretary of State for Health felt difficulty about the Committee's proposal for a commission and so that is against a background which you are very familiar with. Parliament can sometimes be bounced into legislating on issues as a result of pressure from the media, public concern blowing up about some issue in sensitive views like humane biology or rights for dogs or something like this. Against that kind of background, it is for the convenience or in the cause of good government to have available well set out procedures for how to deal with an issue and procedures which are established as carrying public confidence because they are already in operation and have worked successfully in a number of cases. It is against that kind of background that we put forward proposals for the commission. The particular respects in which the Secretary of State took exception to these was that the statute would commit government for a long time, that it would include regulatory functions and that it would monitor the NHS. Well, I do not think that the terms of reference of the Testing Committee really go very much further, or less far in those directions, than the Committee would wish to go in the proposals that it made. So can we, in conclusion, ask you to say what your hope is for the balance of outcome from the

Government's further considerations of the issues in question as to readiness to respond to a very rapidly developing field on the one hand, and on the other hand having a tried and tested machinery for dealing with the issues already in place and working?

(Mr Taylor) The Government should, as you rightly say, have a system for reacting to problems rather than having to invent systems at the moment that they happen. Nevertheless it is true to say that until we get a bit of shape to what is happening it is very difficult to say that we would now know exactly how we would want to structure something for the future. I am not trying to tie the hands of any health or any science or technology minister five years down the track because I simply do not know the speed at which all this is going to happen. In certain areas it may be much slower than the experts think it is and in some areas much faster; it is very unpredictable. Therefore we do need to be flexible. We need not to give the impression to industry that we are trying to regulate something which is only just emerging. We want risk capital to come in, so the signals we give to industry at the moment are as important as the signals we give to the public. Industry will very closely relate to the basic science and strategic science that is being carried on in our universities where there are terrific centres of excellence which I have certainly visited and I am sure the Committee has. Any new committee that comes in must bear those factors in mind and not try to anticipate something that has not yet developed. Your Committee, in its discussions since we published our report, has moved some way in our direction. We have moved some way towards the Committee, by understanding that there does need to be, in embryo, an arrangement which could give overall public confidence that the very exciting areas of biotechnology are monitored to make sure some of the possible worries are not allowed to get out of control or to become falsely exaggerated. We are looking at that aspect of it and that is precisely what Stephen Dorrell himself said when he came before the Committee last week. I want the other committees not only to continue their work, but to make sure that they are confident that they have the powers and the scope to do the work that they are charged to do, including the new committee under Dr Polkinghorne. That committee is going to find its own job definition growing as items which we have been discussing in detail today, like insurance and employment, develop because it will want to look at genetic testing in the context of those matters. So again I do not want to be over-prescriptive about the way that that particular committee should define its terms of reference. It will have access to Ministers and it will be able to call evidence and to investigate matters. In due course this Committee may return to the subject when we are a little clearer as to how the whole genetic process is developing.

Chairman: We thank you, Mr Taylor, for coming along and demonstrating your command of the issues and express the confidence that that will be manifest in the final decisions of the Government following our reactions. Thank you.



6 March 1996]

[Continued

**Letter, enclosing a memorandum, from Mr Ian Taylor, MBE, MP, following oral evidence given on 6 March 1996 (26.3.96)**

I undertook to write on a number of points arising from discussions with your Committee on 6 March, when Jeremy Bray was in the Chair.

The Committee asked for clarification of the circumstances in which gene sequences can be patented (or can form part of a patent), and the extent to which those patents preclude uses of the sequence information unrelated to those in the original patent. These questions raise complex issues which do not lend themselves to a simple, non-technical response. I have, therefore, had my officials set out the workings of the current system in the attached short memorandum. I hope that this proves useful to the Committee.

I also spoke on 6 March about the working group on genetic screening set up under the auspices of the Health and Safety Commission's Occupational Health Advisory Group (OHAC). The Committee said that they would be interested to know who would have access to reports of the group and when it was established. I understand that the group was set up by the OHAC in July 1995 and that it has met twice since. Its terms of reference state that it should report back to OHAC and it would be for them to decide whether the working group's report should be submitted to the Health and Safety Commission (HSC). HSC would decide whether wider dissemination were appropriate. I am informed that the working group is expected to report in the first instance later this year.

Finally, I enclose a table<sup>1</sup> which summarises how Government currently deals with the various functions the Committee considered might fall to the proposed Human Genetics Commission. When I gave evidence, I offered to show this to the Committee and I understand that you would indeed be interested in seeing it.

**Memorandum submitted by the Office of Science and Technology**

1. This memorandum addresses certain aspects of the law concerning the granting of patents for the protection of biotechnological inventions which the Minister for Science and Technology undertook to clarify when he gave oral evidence to the Select Committee on 6 March.

2. The Committee asked for clarification of the circumstances in which gene sequences can be patented (or can form part of a patent) and the extent to which those patents preclude uses of the sequence information unrelated to those in the original patent.

**PATENTING OF GENE SEQUENCES**

3. The position according to existing patent law is that in order for a patent to be granted, an invention must fulfil the three requirements of novelty, inventive step and industrial applicability.

4. This means that the product or process set out in the claims as interpreted in the light of the description must be new and not obvious with respect to what has gone before, and it must also be capable of being used in any kind of industry.

5. Certain exclusions from patentability are set out in the 1977 Patents Act (and the European Patent Convention—EPC) so that, for example, methods of treatment of the human or animal body by surgery or therapy, or methods of diagnosis practised on the human or animal body, are not capable of industrial application. However, products (compositions or substances) invented for use in such methods are patentable.

**SCOPE FOR PATENTS**

6. This is best understood by considering hypothetical examples, though it must be stressed that every case has to be decided on its merits.

7. Case 1 claims a human gene sequence *X*, and according to the description *X* has function *a* and can therefore be used to treat medical condition *A*. This sequence has not been published before it is not obvious in the light of the prior art, and it is clearly capable of industrial application so a patent is granted with a claim to *X per se*. Following normal patent considerations the claim does not need to refer to the function of *X*.

8. Case 2 is a later patent claiming the use of *X* in thickening egg whites; in the description reference is made to Case 1 but it is pointed out that there is no reason to think that a treatment for medical condition *A* would also have the effect of thickening egg whites and this use has not been disclosed anywhere before. This argument appears to be acceptable given the then current picture of knowledge, and a patent is granted for the use of *X* in thickening egg whites. However, because a claim to *X per se* was granted in Case 1, the proprietor in Case 2 must obtain a licence from the proprietor of Case 1 if he wishes to exploit his invention.

<sup>1</sup> See Annex



6 March 1996]

[Continued]

9. Case 3 was also filed after Case 1 and claims a pharmaceutical comprising X for treating disease B. This claim falls foul of Section 2(6) of the 1977 Patents Act (and the corresponding article in the EPC) since a medical use has already been indicated in Case 1. However the claim in Case 3 may be amended to read "Use of X in the preparation of a medicament for the treatment of disease B", which can be allowed and is known as a "Swiss-type claim" for historical reasons. As for Case 2, however in order to exploit the invention of Case 3, a licence must be obtained from the proprietor of Case 1.

10. A set of examples against a different background also can be considered. Case 10 claims human gene sequence Y, which according to the description has function C and can be used to treat ailment C. However, Y itself was published in a research paper before the earliest date of the patent application. A claim to Y on its own must therefore be rejected because it is already known. The function was not disclosed in the research paper or elsewhere, and so a claim can be granted to "A pharmaceutical composition comprising Y for the treatment of ailment C".

11. In later Case 11, Y has been found useful as a nutritional supplement for pigs. This is novel and inventive and a claim can therefore be granted for "A nutritional supplement for pigs comprising Y". There is no need for the proprietor of Case 11 to obtain a licence from the proprietor of Case 10 in order to make or sell the pig food supplement.

12. Case 12 is filed after Case 10 and is for the treatment of disease D using Y. It is similar to Case 3 above in that the claims must be in the form "Use of Y in the preparation of a medicament for the treatment of D", but no licence is required from the proprietor of Case 10 (or Case 11) as the inventions claimed do not overlap.

13. It can be seen from the examples that patents for gene sequences must include utility (or some other distinguishing feature) in the claims only if the gene sequence itself is already known. If it is not already known, then claims can be granted to the sequence *per se* provided it involves an inventive step and is capable of industrial application. In respect of the latter it would be expected that a utility that was not common to gene sequences in general would be disclosed in the description of the invention.

14. The three criteria for patentability of novelty, inventive step and industrial applicability apply to inventions in all fields of technology as set out in Article 27 of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement; that article goes on to say that patents shall be available without discrimination as to the field of technology. It would therefore, be difficult to argue that introducing differential requirements for the patentability of gene sequences was compatible with our requirement under TRIPS.

## Annex

*Table summarising proposed functions of Human Genetics Commission and the current arrangements for handling these in Government (based on tasks identified in para 280 of the Select Committee's Report)*

<i>Proposed Functions of the Commission</i>	<i>Current arrangements for handling these issues</i>
Regulation of genetic medicines	<i>Medicines Control Agency</i> regulates all medicines, including genetic medicines.
Regulation of standards of laboratories offering screening	<i>NHS Executive</i> has piloted quality assurance schemes for cytogenetics and molecular genetics which are now run by the UK External Quality Assurance Programme.
Approval and monitoring of screening programmes	<i>National Screening Committee</i> will advise on all national screening programmes, including genetic screening, starting later in 1996.
Consideration of pre-natal testing for particular disorders	<i>Health Authorities</i> are responsible for local screening programmes, eg Haemoglobinopathies and Tay Sachs disease.
Definition and monitoring genetic disorders relevant to employment	<i>HSC Occupational Health Advisory Committee (OHAC)</i> has established a working group on genetic screening and monitoring which will report back to OHAC in first instance.
Review of law and practice of patenting	<i>Standing Advisory Committee on Industrial Property</i> advises on all issues of intellectual property.
Monitoring effect of genetic medicine on insurance market	<i>DTI</i> will maintain watching brief. <i>Advisory Committee on Genetic Testing (ACGT)</i> will draw Health Ministers' attention to any issue that it believes another Government Department should address (eg in respect to insurance).



6 March 1996]

[Continued

*Proposed Functions of the Commission*

Research into ethical, legal and social issues raised by genetics

Encouraging public education and debate on genetics

*Current arrangements for handling these issues*

ACGT will consider ethical, legal and social aspects *inter alia*. Research Councils (MRC/ESRC) coordinate research in this area.

OST's Public Understanding Campaign and efforts of Research Councils' amount to considerable bottom-up effort. National Curriculum and extra-curricular programmes on genetics.



## APPENDICES TO THE MINUTES OF EVIDENCE

### **Memorandum submitted by Professor Peter Harper and the Royal College of Physicians Clinical Genetics Committee (25.1.96)**

In general, the government response is very disappointing by comparison with the high quality and decisive recommendations of the committee's report itself. To be more specific:

1. The formation of a new advisory committee on genetic testing is welcome and should help to meet concerns in this specific area. Much will depend on how widely the committee wishes and is permitted to draw its remit and the resources provided for it. The remit will certainly need to be wide and comprehensive if problems are to be identified and avoided in the area of genetic testing. This is probably a more relevant consideration at present than whether the proposed committee is advisory or statutory.
2. Many of the important issues in genetics lie outside of the field of the Department of Health and range considerably beyond questions of genetic testing. Issues such as those relating to employment, insurance and more general fields of social concerns were among the main recommendations of the committee where its proposed human genetics commission would have given oversight. It is most unfortunate that these have not been acted on.
3. The fact that the proposed genetic testing committee is to be based in the Department of Health means that no general approach to the area of genetics and its developments is likely to be taken, but rather a piece meal one; given the rapidity with which new research is translated into important applications, some in the health field, others in other directions this is likely to mean that any regulation or other measures will be reactive rather than proactive. Given the farsighted nature of the report itself, this response is particularly disappointing.
4. Major measures are currently being undertaken in this field in other European countries and by the European Commission. It is extremely disappointing that following a report which has received wide consensus not only politically, but among scientists and those in industry, the government response is not only very limited, but likely to be overtaken by actions in other European countries and in the European Community.

Given the general dissatisfaction with the government response that has been voiced in a number of quarters including societies representing families with genetic diseases, the committee's plan to take further evidence before making a formal reply to the government seems entirely justified. It is to be hoped that further consideration will allow the measures raised in this letter and by others to be acted on.

### **Letter to the Clerk of the Committee from Professor Peter Harper (29.1.96)**

#### **GENETIC TESTING AND INSURANCE**

When the House of Commons Science and Technology Committee was taking evidence, it asked for my views on this topic, as well as those of the insurance industry. The Committee's report called for urgent discussions between the industry and those in medical genetics and shortly afterwards, at the industry's request, two preliminary meetings were held under the auspices of the Nuffield Foundation.

Sadly, since August 1995, the insurance representatives have declined to meet further, even though, in my view at last, good progress was being made. I can give you no reasons for this, but since you are again taking evidence, you might find it helpful to ask the industry itself.

I gather that there is to be a meeting next Autumn between the Royal Society and the Institute of Actuaries, but have no information on the nature of this meeting. To the best of my knowledge there have been no discussions with any of my colleagues or with the societies involved with genetic disorders, something which seems unfortunate in view of the importance of the issue.

### **Memorandum submitted by the Association of British Insurers (12.1.96)**

The Association of British Insurers would like to offer the Committee its reaction to the Government's response to their recent report on human genetics, in particular that section of the report dealing with insurance matters.

The Association has noted the Government's indication that it does not want to impose a year's deadline for the development of arrangements concerning the handling of genetic information by insurers and that it does not believe that legislation would be appropriate now or in the foreseeable future; but that it will expect to see substantial progress made within that timescale.



As far as the insurance industry is concerned, there will be no slackening in our efforts to devise suitable arrangements. Certainly we do not regard the Government's response as giving the industry any cause to treat the subject with less urgency, although we believe that a specific deadline was probably inappropriate as arrangements may well emerge in several instalments, rather than as a single announcement.

After initial contact with other interested parties, the Association has, over the last few months, mounted an industry-wide consultation exercise which has helped identify the practical issues which need to be addressed. With a much broader understanding of the position of member companies, we will shortly be entering into further discussion with the other parties involved, in particular geneticists but also others.

We expect to report the position reached in the summer and we hope that this will allow both Government and the Select Committee to conclude that we have made the progress which both evidently seek.

#### **Memorandum submitted by SmithKline Beecham (12.2.96)**

We welcome Government recognition of the importance of genetics research, its potential considerable impact in delivering innovative products and services of great value to healthcare, and the central role of pharmaceutical companies.

#### **PATENTS**

SmithKline Beecham welcomes the overall conclusions of Government that the existing framework of patent law is adequate to accommodate the demands of modern genetic research, providing the necessary protection for gene-based inventions to encourage the development of new healthcare products and at the same time protecting third parties and society at large from abuses of monopoly.

SmithKline Beecham has concerns that no direct criticism was made of the serious ambiguity in the Committee's conclusion that "only a combination of a gene and a known utility . . . should be patentable in the context of that utility". This point has been widely interpreted to suggest gene patent claims should be limited to the disclosed utility, a development which would conflict with existing legal principles and contravene GATT-TRIPS by discrimination on the grounds of technology. It is noted that the Government took the alternative interpretation of the Committee's point, namely that a disclosure of a utility sufficient to satisfy normal patentability requirements is required, rightly concluding that there is no need for provisions specific to the patentability of genes. Nevertheless, coupled with the public interpretation, the Government's position could lead to further confusion about the scope of gene claims. Accordingly, an express rejection by the Government of any suggestion that the scope of a gene patent should be use-limited would add clarity to the Committee's useful report.

SmithKline Beecham strongly endorses the Government position on the EC draft Directive on the Legal Protection of Biotechnological Inventions. A Directive enhancing the legal framework should proceed. If, however, it appears that it will be more harmful to have the Directive than not, SmithKline Beecham urges the Government to press for withdrawal of the draft.

#### **ETHICAL, LEGAL AND SOCIAL ISSUES**

We welcome Government agreement with the Report that these implications of genetics are an important area for further research. SmithKline Beecham recognises and accepts the responsibility to contribute to this research and to the discussion of the issues.

SmithKline Beecham supports informed public debate on ethical, legal and social issues related to genetic research. We are therefore concerned that, at the European level, there are not appropriate mechanisms and fora to discuss these issues. We would encourage the investigation of possible mechanisms and fora to promote discussion of ethical, legal and social issues.

#### **RIGHTS OF SUBJECTS**

We welcome the Government statement on principles in genetic testing that are similar to our principles, described in evidence to the Committee (Consent; Confidentiality; Counselling; Communication; Care and Treatment).

We ask that there should be further clarification of those Department of Health mechanisms described as ensuring that new screening programmes are carefully evaluated before introduction (paragraph 43). While we appreciate the potential value of the recent initiatives (NHS R&D Programme/Health Technology Standing Group/Population Screening Panel) we believe strongly that the mechanisms must be considered in conjunction with the operation of the new Advisory Committee on Genetic Testing in order to ensure that private screening activity is appropriately conducted.



## REGULATION OF TESTING

Earlier this year we welcomed the announcement, by the Secretary of State for Health, of the Government intention to establish a UK Advisory Committee on Genetic Testing to help ensure that genetic tests were supplied safely and used ethically. We now confirm our view that this is a valuable initiative and we stand ready to work with this Committee. We would welcome the opportunity to be involved in Committee activities on an ongoing basis. We recognised the strength of feeling expressed in the Science & Technology Committee Report that there are alternative possibilities in devising a framework to ensure that the scientific promise in prevention, detection and treatment of disease is delivered for the benefit of patients. Therefore, we also welcome the commitment by Government to monitor the activity of the Advisory Committee to ensure that it is constituted for optimal effectiveness.

## GENETIC SCIENCE AND INDUSTRY

We do not share Government optimism about the continuing ability of UK pharmaceutical companies to attract well-trained staff. We are experiencing general problems in consequence of the declining academic infrastructure and we find that our recruits require a period of "remedial education" to acquaint them with modern instrumentation and techniques. We ask Government to accord this issue the greatest importance.

We agree that there is a poor level of business awareness among bioscience (and other) graduates. While we welcome specific initiatives such as the competition led by the University of Nottingham, the problem can only be resolved by integrated efforts to facilitate a culture of industry-academic partnership.

## PUBLIC UNDERSTANDING OF SCIENCE

We welcome Government restatement of its appreciation of the importance of public understanding and we applaud the constructive lead taken by OST. However, because of the critical importance of the issues associated with human genetics—well described in the Report—we believe that there is great merit in thinking further about initiatives to improve science education and public awareness. We recognise the dangers of a misinformed public, which can lead to undue restrictions on scientific research, thereby decreasing opportunities to develop disease treatments and cures. In the interest of protecting society's interest in improved healthcare, we strongly encourage the development and implementation of education initiatives to correct and avoid misunderstandings that may eventually lead to public lobbying against the use of genetic research.

## Memorandum submitted by Nuffield Council on Bioethics (13.2.96)

1. The Nuffield Council on Bioethics has considered the Government Response. It has the following observations to make, taking into account the simultaneous announcement by the Department of Health (DH) of the new Advisory Committee on Genetic Testing (ACGT) and its terms of reference.

2. The Council's concerns were set out in its report *Genetic Screening: Ethical Issues* (1993, reprinted 1995). Immediately at issue are the arguments and recommendations on the following topics:

Employment

Insurance

Introduction and implementation of genetic screening programmes

The Council's views on these matters were set out in Chapters 6, 7 and 10 respectively of its report.

3. The Council has noted the Government's references to its work (Response . . . paragraphs 9, 97 and Annex A). But the Council questions whether the Government Response has attached sufficient weight to the arguments and recommendations made by the Council on these three topics. Much will depend both on the interpretation of the terms of reference of the new DH Advisory Committee on Genetic Testing, and also on whether that Committee is adequately staffed for the proactive extensive rôle that, in the Council's view, should be undertaken by the ACGT.

## EMPLOYMENT

4. The Council recommended as follows:

"6.27 At present, the use of genetic screening by employers in the UK does not appear to be a cause for concern. We have found evidence of only one existing screening programme: that programme can be justified quite readily on the grounds of safety, not only of those being screened but also of third parties. Nevertheless we recognise that the matter needs to be kept under review. We recommend that the Department of Employment keeps under review the potential use of genetic screening by employers.



6.28 Subject to prior consultation with workplace representatives, and with, as necessary, the Health and Safety Commission, we recommend that genetic screening of employees for increased occupational risks ought only to be contemplated where:—

- (i) there is strong evidence of a clear connection between the working environment and the development of the condition for which genetic screening can be conducted;
- (ii) the condition in question is one which seriously endangers the health of the employee or is one in which an affected employee is likely to present a serious danger to third parties;
- (iii) the condition is one for which the dangers cannot be eliminated or significantly reduced by reasonable measures taken by the employer to modify or respond to the environmental risks.

Although it may be appropriate to introduce a genetic screening programme on these limited grounds, it should only be done if accompanied by safeguards for the employee, and after consultation with the co-ordinating body recommended in paragraph 9.7."

5. The Council notes that the Government will "keep the situation under review", but is concerned that paragraphs 97–99 of the Government Response fail to recognise the need to establish, at least during the years immediately ahead in which genetic testing is becoming more widely available, strict criteria to govern any screening requirements which employers may wish to introduce.

#### INSURANCE

6. The Council recommended as follows:

"7.36 Our recommendations about the use of genetic screening and genetic tests by insurance companies follow from the following considerations:—

- (i) the difficulty of assessing what may be slender evidence on the genetic susceptibility of individuals to develop polygenic and multifactorial diseases (for example, some cancers and some heart disease);
- (ii) an awareness that ordinary commercial practice will lead companies to be over-cautious in their assessment of the risks derived from medical data; and
- (iii) the possibility of abuses.

7.37 We recommend that British insurance companies should adhere to their current policy of not requiring any genetic tests as a prerequisite of obtaining insurance.

7.38 In the light of the arguments summarised in paragraph 7.36, we recommend that there should be early discussions between the Government and the British insurance industry about the future use of genetic data, and that pending the outcome, the companies should accept a temporary moratorium on requiring the disclosure of genetic data. There should, however, be two exceptions:

- (i) first, in the case of those individuals where there is a known family history of genetic disease that can be established by the conventional questions about proposers' families, then individuals may be asked to disclose the results of any relevant genetic tests (see paragraph 7.28); and
- (ii) the moratorium should apply only to policies of moderate size. The limit would be a matter to be settled between the Government and the industry in the context of arranging the moratorium.

The importance of the discussions that are recommended is highlighted by the considerations set out in paragraphs 7.7 and 7.8."

7. The Council recognised that the sensitivities of both proposers and the insurance companies did not easily lend themselves to regulation, whether statutory or not. Hence the Council's emphasis—supported by the recommendation of a moratorium—on the need for time to work out an equitable code of practice for the use of the emerging genetic information for insurance purposes.

8 The Council therefore welcomes the support in the Government's Response (paragraph 101) for such an approach. It assumes that the ACGT will monitor the discussion taking place with a view to ensuring that "substantial progress" is effectively achieved by the end of this year.

#### INTRODUCTION AND IMPLEMENTATION OF GENETIC SCREENING PROGRAMMES

9. It is not clear to the Council from the Government Response whether the Advisory Committee on Genetic Testing will exercise its rôle relating to genetic screening, on the basis set out in paragraphs 31–43 of the Response, in the thorough way which the council judged necessary. Adequate staffing will be essential for the purpose.

10. The Council recommended as follows;



"10.20 We recommend that the Department of Health in consultation with the appropriate professional bodies formulate detailed criteria for introducing genetic screening programmes, and establish a central coordinating body to review genetic screening programmes and monitor their implementation and outcome. (Paragraph 9.7 summarising paragraphs 9.1–9.4).

10.21 As a contribution to the discussion of criteria for screening programmes, we suggest they should include the following:

- (i) the aims and purposes of the entire programme;
- (ii) the predictive power and level of accuracy of the particular screening test;
- (iii) the value to those being screened of the knowledge gained. For each programme this should have been researched as an integral part of the follow-up to the pilot programme;
- (iv) the availability of therapy for the particular condition, accepting that lack of treatment does not necessarily mean that screening is not worthwhile;
- (v) the potential social implications; and
- (vi) the resource costs."

11. The Council further amplified these recommendations in a passage in the memorandum that it submitted to the House of Commons Select Committee, as follows:

"6. This proposed coordinating body should undertake the following tasks:

- (1) Review of major pilot projects. This would be an overview since we assume that research and pilot projects would continue to be referred automatically to Local Research Ethics Committees (LRECs).
- (2) Provision of guidelines, if found necessary, to LRECs on criteria to be adopted in reviewing research and pilot proposals.
- (3) Monitoring, on a continuing basis, major pilot programmes and the implementation of population genetic screening programmes. The aim would be to fund experience, and to review sensitive aspects of such programmes, such as:
  - (a) good practice in giving information;
  - (b) best practice in securing that consent is both real and voluntary;
  - (c) maintenance of technical standards in quality control;
  - (d) minimising undue anxiety among those being screened and among other members of their families;
  - (e) best practice in the communication of test results; and, in particular,
  - (f) reviewing the necessary practice of proper counselling and monitoring its results—covering, for example, how well the distinction is understood between carrying and actually being affected by a given genetic disorder.
- (4) Funding the experience of the impact of genetic screening programmes as a guide to their future development as part of the health care services.
- (5) Review of the ethical, social and legal aspects of the implementation of genetic screening programmes insofar as such considerations affect the health of the nation, for example:
  - (a) the implications for health of possible misinterpretation, or even abuse, of the results of genetic screening programmes;
  - (b) reluctance to secure the health benefits of genetic screening because of implications either for employment or insurance."

12. In discharging its terms of reference the Council also assumes that the Advisory Committee on Genetic Testing:

- 12.1 will take full responsibility for advising Ministers, as part of the remit to "take account of ethical, social and scientific aspects" on the implications for both employment and insurance matters;
- 12.2 will have access to Ministers in the Department of Trade & Industry as may be necessary on issues relating to employment and insurance policies.



### Letter to the Chairman of the Committee from the Alzheimer's Disease Society (12.2.96)

The Alzheimer's Disease Society's written submission to the Committee's inquiry into human genetics in December 1994 raised a number of concerns about the possible misuse of genetic information, issues around consent and confidentiality, and the need for more effective regulation of genetic testing.

Our observations were made in the context of the then recent scientific discoveries identifying a genetic risk factor—Apo E—in late-onset Alzheimer's disease. At that time predictive and diagnostic testing based on these discoveries was theoretically possible but had yet to be developed. This year the first commercial diagnostic test using Apo E has been launched in the United States (*Financial Times*: "The gene of distress" 23/1/96).

In view of these developments in the field of genetics and Alzheimer's disease the Society welcomed the Science and Technology Committee's proposal for a Human Genetics Commission. The broad remit of the commission would, in our view, have meant a coherent and flexible regulatory response to the range of ethical, health and social issues raised by genetic research and in particular genetic testing and screening.

In contrast the Society feels that the Government's proposal for an Advisory Committee on Genetic Testing is unimaginative. We do not accept that adding to the existing system of bodies already in place will enable the Government to "continue to provide an appropriate level of coverage and control" in the future. A commission would enable policy-makers to make informed decisions on genetic issues aware of the broader picture of developments in the field.

Our understanding is that the advisory committee will not be able to examine the knock-on affects of genetic testing on rights to information, employment and insurance even though this is likely to be one of the key areas of concern to individuals in the future. Its establishment on a non-statutory basis will also mean that the committee will lack the necessary authority and powers to influence policy and practice.

The Society is further disappointed by the Government's comments on insurance and specifically its rejection of the Committee's recommendation that a deadline be imposed on the insurance industry to develop a solution to the regulation of genetic information by insurers.

We believe that in adopting a hands-off approach to this issue the Government is storing up problems for the future. Ministers have made clear their desire to see more people plan and provide for their future long-term care costs through insurance. As yet, however, there are insufficient safeguards to prevent those people shown to be most likely to need such care through genetic testing from having their applications refused or being discriminated against through higher premiums.

In conclusion the Society will continue to support the Science and Technology Committee's recommendations in this area and would be happy to provide further information or evidence as necessary.

### Memorandum submitted by Genetic Interest Group (19.2.96)

GIG, scientists working in the field, the Science and Technology Committee and Government have welcomed the advance of genetic science and its applications—it promises to improve treatments and increase the choices available to individuals. However, many involved in the field have raised a number of concerns; in particular in relation to the way in which genetic testing is carried out and in relation to the use of genetic information in non-medical contexts. GIG has already expressed its disappointment with the Government's response to the Science and Technology Committee report on human genetics as it touches on these issues. In this document we expand on the concerns we have raised.

The chief defect in the Government's response is that it proposes neither a mechanism to examine and control the use of genetic information in non-medical contexts, nor a mechanism to take a cross-departmental look at issues thrown up by genetic science and its applications: the Advisory Committee on Genetic Testing, linked to the Department of Health, will deal only with issues relating to genetic testing. By restricting the remit of the committee in this way, the committee will not be able to address other issues, and Government will lack a mechanism for getting information that will enable it to act promptly, and in advance of problems emerging.

The Science and Technology Committee argued that employers and insurers should be denied access to genetic information. This proposal has been rejected. The Government's point is that employers and insurers should draw up voluntary codes of practice, which for employers should reflect "their own circumstances, needs and priorities". This can only be taken to mean that employers and insurers can do as they like. However, Government has not presented an argument as to why, say, employers should have access to genetic information. Nor has it outlined what, if any, safeguards will be needed to protect individuals against the misuse of genetic information.

Underlying the Government's response is the view that a body of case law needs to be built up before regulation is devised and imposed. But why wait for examples of bad practice before establishing good practice? By passing the Disability Discrimination Act the Government recognised that regulation of employers and insurers was needed as regards their dealings with people with a disability. Why not establish



a framework to deal with similar issues in relation to people who are currently healthy but who know they will or may develop a disability or illness in the future? Those who experience unfair discrimination in the process of establishing the reality of the problem will feel justifiably aggrieved that they had to suffer when the danger had been clearly anticipated and solutions proposed.

The combination of the Disability Discrimination Act and lack of regulation of the non-medical uses of genetic information might actually encourage discrimination. During the passage of the Disability Discrimination Bill as it was then, GIG pointed out that an unfortunate consequence of the Bill might be that it would encourage the unscrupulous to "get their retaliation in first". For example, under the terms of the Disability Discrimination Act, employers are under an obligation to make allowance for the special needs of disabled employees. Given that this is the case, an unscrupulous employer might seek to ensure that such obligations did not fall on them by refusing employment to pre-symptomatic individuals; that is, those who will or might develop a genetic condition at some point in the future.

The spirit of the Disability Discrimination Act would seem to imply that employers should be denied access to genetic information except in clearly defined circumstances where public safety is an issue. But the Government seems determined to refuse to extend protection to the pre-symptomatic. GIG is particularly disappointed by the Government's lack of action on this connected set of issues because it did indicate, during the passage of the Disability Discrimination Bill, that GIG's concerns would be addressed by the Science and Technology Committee inquiry and by Government in its response. The Science and Technology Committee has proposed a solution; but this has been rejected.

What all this illustrates is a failure to take an overview of the issues. This failure is evident in other ways. Take the example of the use of genetic information by insurance companies. GIG is aware of the fact that the industry feels it must have access to genetic information if insurance is to work. In explicitly rejecting legislation, Government clearly intends to rely on voluntary codes of practice. Let us assume then that insurers will increasingly ask for genetic information as a pre-condition of access to a range of products. This will have serious consequences—for individuals and for Government departments other than the DTI. Specifically, given that the direction of social policy is to require individuals to make provision for themselves in a number of areas of their lives—such as mortgage protection, income protection and long-term medical care—what will happen if a genetic pre-disposition makes it difficult for someone to gain insurance at an affordable rate, a problem which will affect them across the board as they would find higher rates being asked for each policy? Such an individual will want to turn to the state for assistance.

The interaction between trends in social policy with an issue such as insurance company access to genetic information brings us back to the issue of regulation. This is a matter for Government, because Government itself is encouraging the development of a market for insurance through legislation and policy proposals which encourage people to obtain an increasing range of social goods through insurance.

Taken together, the issues outlined above illustrate the need for a coherent and coordinated strategy spanning the range of Government activities—both to ensure fair treatment for those at risk, and to facilitate cross-departmental investigation of the issues. A Human Genetics Commission, an idea rejected by Government, would have been well placed to take an overview and to highlight the need for action as and when it arises.

These and other related issues to do with the non-medical uses of genetic information should not be ignored. Whether or not all the specific proposals made by the Science and Technology Committee are feasible, their report raised the right issues and suggested responses which deserved a more positive reception from Government. Unless Government is prepared to act strategically now, and give clear messages that it will effectively regulate and control the uses to which genetic information can be put, it will create a problem that will be expensive and time-consuming to resolve and which will only be resolvable after many people have experienced unfair discrimination and been significantly disadvantaged as a result.

#### **Letter to the Chairman of the Committee from The Genetics Forum (16.2.96)**

We understand that you would welcome comments on the Committee report and the government response. Although we did not present evidence due to other commitments, we have followed the issues closely and were highly disappointed that the government rejected most of the key recommendations.

We support the concept of a Human Genetics Commission with a wide-ranging remit and responsibility for monitoring new developments and making recommendations. We would go further and call for a Public Biotechnology Commission, consisting of lay and professional members, with a mandate to overview all genetic engineering issues and with sufficient resources to initiate research into the "value-laden" issues.

There is, as the Committee found, a clear need for new legislation to protect genetic privacy, setting down the principles and creating the climate within which discrimination by employers, insurers and others will not be permitted. The idea that we should wait for systematic abuse of genetic information before introducing controls, which seems to be the government position, is an abdication of responsibility and a tacit abandonment of the precautionary approach to modern genetics.



In our view, we need now to create the ethical and legal framework within which human gene technology can operate. If these issues are to be ignored unless, or until, disaster or scandal strikes, our legislators will have failed us.

Whilst there are parts of your report that we do not agree with, notably the statement supporting a narrow interpretation of the morality exclusion in patenting life-forms (and I enclose a copy of a Declaration of Principles on this subject setting out the views of many leading NGOs and academics), we welcome the call for more research and debate into the ethical, legal and social implications of genetics. We believe that the creation of a public policy forum is the right way to achieve this. We also believe that the rights of individuals to genetic privacy should go hand in hand with a transparent and democratically accountable system of policy making.

#### DECLARATION OF PRINCIPLES—NO PATENTS ON LIFE

The undersigned organisations and individuals oppose the granting of patents on genetic material originating or derived from humans, animals and plants.

We believe that the extension of patent law to the basic genetic structure of living matter means treating life itself as a mere commodity, with adverse moral and practical consequences for humankind, the animal kingdom and the natural environment.

There is presently no unequivocal bar to patenting life-forms. We believe that the following should be declared to be unpatentable as being contrary to public morality:

1. Humans, human parts, human tissue and all genetic matter originating or derived from human sources.
2. Processes and techniques for genetic modification of such human matter and methods, treatments and therapies for applying such processes and techniques.
3. Animals, animal parts, animal tissue and processes for the genetic modification of animals.
4. Plants, seeds, plant tissue and other propagating material.

Signed by:—

The Genetics Forum

Royal Society for the Prevention of Cruelty to Animals (RSPCA)

National Federation of Women's Institutes

The Farm and Food Society

Greenpeace UK

National Association of Housewives

Compassion in World Farming

Catholic Institute for International Relations

British Union for the Abolition of Vivisection (BUAV)

World Society for Protection of Animals

Friends of the Earth UK

The Ecologist

Edward Goldsmith, Ecoropa UK

The Food Commission

Sustainable Agriculture, Food & Environment Alliance

Bakers Food & Allied Workers Union

National Federation of City Farmers

Whole Earth Foods Ltd

Consumer Watch

Elm Farm Research Institute

Animal Aid

Third World Quarterly

Baby Milk Action Group

Permaculture Association

Feminist International Network of Resistance to Reproductive & Genetic Engineering UK

Ecological Foundation

The Soil Association

Scientists for Global Responsibility



Camphill Devon Community  
 Biodynamic Agricultural Association  
 Reforest the Earth  
 GreenLine Magazine  
 New Farmer & Grower  
 The Vegan Society  
 World Development Movement  
 Manchester University Students Union  
 Reverend Professor Andrew Linzey, Mansfield College, Oxford  
 Professor Steven Rose, Biology Faculty, Open University  
 Professor Brian Goodwin, Biology Faculty, Open University  
 Dr Mary Bell, Open University  
 Professor Tim Lang, Thames Valley University Centre for Food Policy  
 Dr Erik Millstone, Science Policy Research Unit, University of Sussex  
 Dr Eric Brunner, University College London  
 Dr Mae-Wan Ho, Director, Bio-electrodynamics Laboratory, Open University  
 Jeanie Simmons, Open University  
 V Benigalim, Open University  
 Dr Abby Munson, University of Cambridge  
 Joy Greenall, Ecology Consultant  
 17 Friends, Quaker Group of Kingsbridge, Devon  
 Frances Tindall, Mrs Hudson and Mrs G M Ewer, members of Christian Ecology Link  
 R Brighton, Worcester College of Agriculture  
 Eric Barrus, Open University  
 Professor Hilary Rose, University of Bradford  
 Dominic Hogg, Cambridge University  
 James Robertson  
 Anton Pullard  
 58 Members of the Congregations of Christ Church, St. Matthews and St. Peters Churches, Southborough, Tunbridge Wells, Kent  
 The Baptist Union of Great Britain (on human tissue paras 1 and 2 only)  
 Professor Mark Williamson, University of York (excluding processes and techniques)  
 Christian Medical Fellowship (on human tissues, paras 1 and 2 only)  
 The Goldsmith Foundation (excluding treatments and therapies from para 2)  
 and many other individual supporters.

*Notes:—*

A patent is a form of intellectual property giving exclusive rights of commercial exploitation for up to 20 years. In March 1995, the European Parliament rejected a directive which would have extended the scope of patentability of genetically engineered matter, largely on ethical and moral grounds. The Inter-Parliamentary Union, with 1,500 delegates from 114 countries meeting in Madrid in April 1995 adopted a resolution calling for a ban on all human gene patents, reaffirming the inviolability of the human body.

This is what some other leading voices have to say on the subject:—

"The granting of patents no longer depends on purely technical considerations: from now on, applications will have to bear scrutiny in respect of the wider social implications". European Patent Office Annual Report 1991, p9.

"Scientists and industrialists alike have grown to realise that technological innovations invariably have to be assessed in the context of the human environment". "... in every area of technological innovation there will always be cases in which the patent system comes up against barriers which then have to be reassessed within the existing legal framework". EPO Annual Report pp 11-16

"... human tissue as such should not be bought or sold or otherwise treated as an object of commerce". Nuffield Council on Bioethics, Report on Human Tissue-Ethical and Legal Issues April 1995, para 13.29.



European Member States should adopt a Protocol to the European Patent Convention "... which would set out in some detail the criteria to be used by national courts when applying the immorality exclusion to patents in the area of human and animal tissue". Nuffield, para 13.43.

"This House... urges the European Commission to reassess its policy on biotechnology and genetic engineering to ensure proper respect for human life, animal life and integrity of the natural environment;" Early Day Motion 904, March 1995, UK Parliament, carrying the endorsement of 97 MPs from all the main parties, congratulating the Euro-Parliament on voting to reject the patent directive.

"... inventions, the exploitation of which is likely to ... seriously prejudice the environment are to be excluded from patentability as being contrary to 'ordre public' ". EPO ruling on Plant Genetic Systems patent application for herbicide-resistant plants. February 1995.

"Members may exclude from patentability inventions, the prevention... of which is necessary to protect human, animal or plant life or health or to avoid serious prejudice to the environment. ... Members may also exclude from patentability... plants and animals. ...." TRIPS section of GATT agreement, Art 27, 1994.

"We do not believe that living organisms should be patented. ...." "... we believe that the identity of the human genome is the collective property of the whole human race. ...." "The results of human genome work should be freely available and should not be treated as a marketable commodity" British Medical Association-*Our Genetic Future*.

#### Memorandum from the British Society for Human Genetics (27.2.96)

I attach some comments from the British Society for Human Genetics.

I should explain that the BSHG did not make any submission to the Committee in its original enquiry (although several members did) because the Society came into existence only on 1 January 1996. However, the BSHG amalgamates the entire memberships of the four professional societies concerned with genetics services viz, the Clinical Genetics Society, Clinical Molecular Genetics Society, Association of Clinical Cytogeneticists and Association of Genetic Nurses and Counsellors. In addition, we are moving to include researchers in human genetics who do not work in diagnostic centres. This the BSHG is now the largest and broadest based professional society in this field in the UK, and we hope to develop our role of speaking for the human genetics community.

#### COMMENTS ON SELECT COMMITTEE ON SCIENCE AND TECHNOLOGY REPORT ON HUMAN GENETICS, AND ON THE GOVERNMENT RESPONSE

We were impressed by the report of the Select Committee. The committee had identified some key social and ethical issues in the application of advances in human genetics and made sensible proposals.

The response of the Government was disappointing, principally because it adopted a laissez-faire attitude to precisely those aspects of genetics where legislation is most likely to be valuable.

The Government appears completely to abdicate responsibility for issues of employment and insurance (para. 98, 100). The Advisory Committee reports to Health ministers, and will be unable to address these issues adequately. This is particularly deplorable because it is likely that legislation against genetic discrimination in insurance would be relatively non-contentious. It would not adversely affect insurers as a group. Their problem is if different companies pool risk to different degrees. If all companies use the same rules, no company is disadvantaged relative to its competitors, but probably only legislation could achieve this. Despite the statement in para. 101, we are not aware of any significant continuing discussions between insurers and clinical geneticists about these issues.

We recognise that gene patenting is a difficult and complex issue, and that the Government's hands are not entirely free. However, we believe a more restrictive and less laissez-faire approach to gene patenting would be in the public interest, helping ensure that publically funded research was conducted efficiently and used for public benefit.

How effective an Advisory Committee on Genetic Testing will be is hard to predict. Much will depend on the vigour, authority and breadth of the Advisory Committee, and on how much attention the Government is prepared to pay to its recommendations. The fact that the Government has chosen a non-statutory advisory committee suggests that they wish to allow commercial influences to operate in a non-transparent way. Since the decision to set up an Advisory Committee had apparently been taken by June 1995, before publication of the Select Committee report, we doubt whether the Government intended to take the report seriously.



Speaking on behalf of the professions, we doubt that the Government response will help clinical geneticists feel secure, either in believing that the public understand what they are doing and have ways of reaching agreements on the rules for clinical practice, or that the professions will not be exploited by outside intervention. In short, we very much regret the wholly inadequate Government response to an excellent report, and hope it is still not too late to secure a change of attitude.

**Memorandum submitted by The Royal Society (7.3.96)**

*This submission was prepared by a group under the Chairmanship of Professor P J Lachmann SecRS. The other members were: Reverend Professor G R Dunstan CBE, Professor J H Edwards FRS, Professor P A Jacobs FRS, Mr D Shapiro and Professor Sir David Westherall FRS. It has been endorsed by the Council of the Royal Society.*

We have considered the Government's response to the House of Commons Science and Technology Committee's report "Human Genetics: the Science and its Consequences" and offer the following comments.

The striking advances in the understanding of human genetics that have come about in the last 40 years have already contributed substantially to understanding the influence of genetic factors on disease and to diagnosing genetic disorders. There is every reason to believe that rapid advance will continue. Thus, inevitably, there will be an increase in the availability and demand for genetic testing. Potentially, there is much to be gained—to the benefit of individuals and the general population. There is every hope of therapy for the prevention and treatment of many serious disorders of later life, both of body and mind, provided the genetic predispositions are defined well ahead of the time when manifestation would be expected.

Our main concerns are that testing should be carried out properly and in agreement with the individual, or their parents, or with anonymity: we accept the need for population screening to assist research and policy development. Results or samples related to genetic tests should be made available to third parties *only* with the consent of the individual and only made available for research purposes with consent or with the assurance of anonymity. The issue of confidentiality here is not fundamentally different from that of the use of other medical data, and a similar level of vigilance is required to avoid abuses.

Apprehension has been expressed that people with "abnormal" genetic profiles might be victimised by employers. Although there are already many tests for genetic disorders the incidence of infringements of the employment rights of individuals appears to be slight. That does not, however, argue against the need for a regulatory framework. We comment on insurance issues below.

Generally we believe that progress in genetic screening should be welcomed. Diagnosis of a particular genetic profile, coupled with informed advice, might give individuals the opportunity to obtain treatment, or to change their life-style or employment to the benefit of their health. We quoted the example of Goodpasture's disease and the dangers of exposures to organic solvents in our earlier evidence to the Inquiry.

We are aware that there has been much concern over the possibilities for abuse. As a result some would advocate strong, overarching regulation. We support the principle of regulation but note the difficulty of regulating for a future which must be fluid and is, at the moment, speculative.

Establishment, by the Government, of the Advisory Committee on Genetic Testing (ACGT) is a positive step. We would suggest that the remit of the ACGT should be interpreted broadly, particularly with regard to advising on the ethical, social and scientific aspects of genetic testing. There is included in current regulatory arrangements the Gene Therapy Advisory Committee (GTAC) which is required to approve all protocols in that area. We would suggest that the ACGT should be similarly empowered in the areas of genetic testing and screening. The new combination of the ACGT plus existing arrangements should be monitored closely. If after a limited period of time it is not working well we would urge the Government to reconsider the proposal for a Human Genetics Commission.

The issues related to insurance are complex and there is great potential for misunderstanding between the interested parties. We believe that of prime importance is a continuing dialogue between insurers, physicians and scientists that addresses the development of genetic testing and the quality control of results. Information should be exchanged regularly and special care taken to ensure consistent interpretation.

We would therefore urge the Government not to relax its resolve to encourage the dialogue in order that its wish "to see substantial progress within twelve months" is realised. The Royal Society, for its part, is promoting the dialogue by co-hosting a conference with the actuarial profession: "Human Genetics—Uncertainties and the Financial Implications Ahead" to take place on 25-26 September 1996 at the Society.

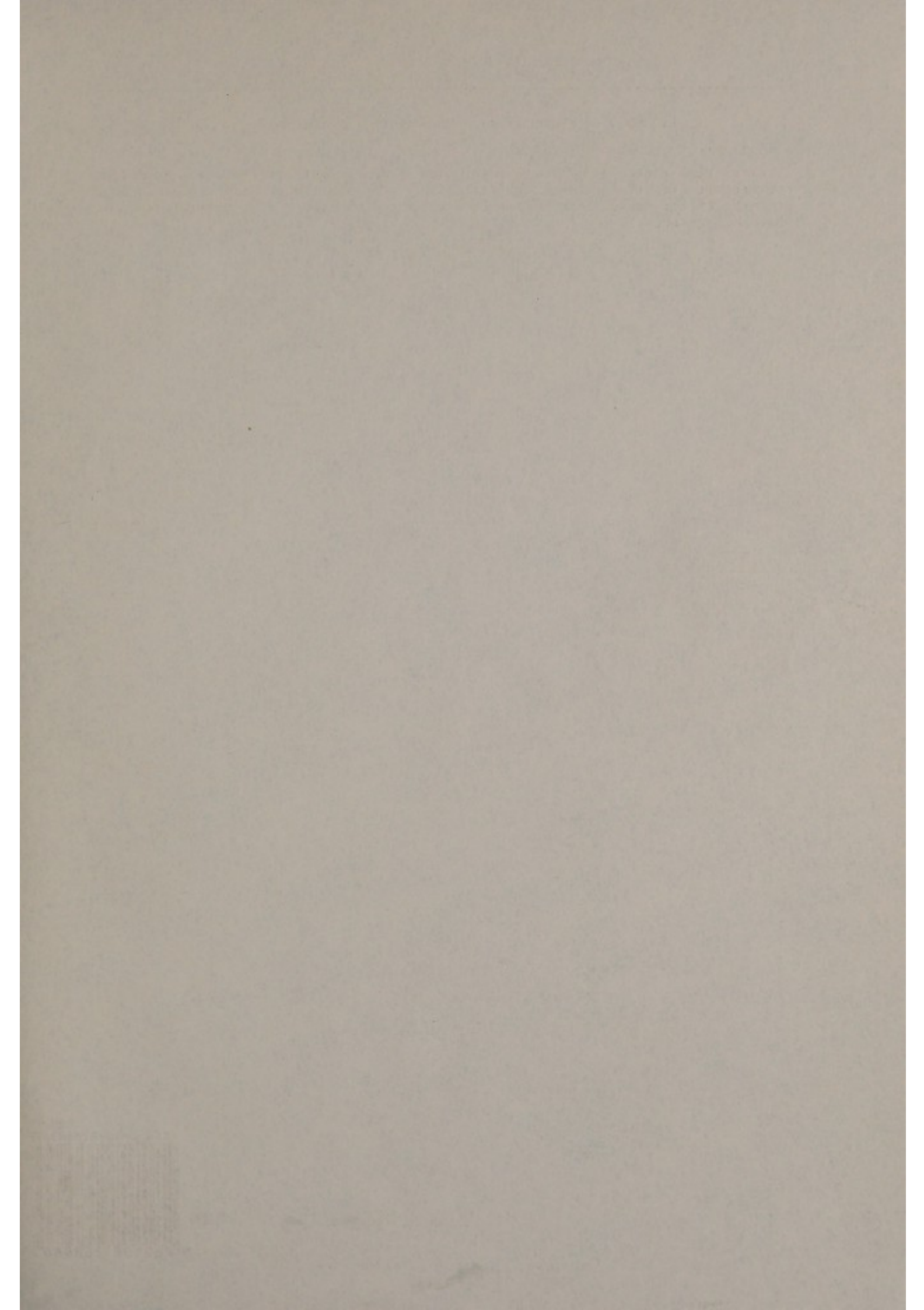


**Letter to the Clerk of the Committee from Association of British Insurers (6.3.96)**

Thank you for your fax of 1 March.

I am writing to confirm that our discussions with parties outside the industry were put into suspense whilst we conducted a consultation exercise within the industry. Now that the consultation exercise has been completed and the views of the industry are better understood, we feel in a better position to return to discussions with others.







Letter to the Clerk of the Supreme Court, dated November 10, 1960

Dear Mr. Chief Justice:

I am writing to you today to express my deep appreciation for the work that you and the other Justices have done in the past few years. It has been a privilege to know you and to watch you work. I hope that the Commission's findings will be helpful to you in your work. I am sure that the Commission's findings will be helpful to you in your work. I am sure that the Commission's findings will be helpful to you in your work.

ISBN 0-10-226896-7



9 780102 268966







Published by HMSO and available from:

**HMSO Publications Centre**

(Mail, fax and telephone orders only)

PO Box 276, London SW8 5DT

Telephone orders 0171 873 9090

General enquiries 0171 873 0011

(queuing system in operation for both numbers)

Fax orders 0171 873 8200

**HMSO Bookshops**

49 High Holborn, London WC1V 6HB

(counter service only)

0171 873 0011 Fax 0171 831 1326

68-69 Bull Street, Birmingham B4 6AD

0121 236 9696 Fax 0121 236 9699

33 Wine Street, Bristol BS1 2BQ

0117 9264306 Fax 0117 9294515

9-21 Princess Street, Manchester M60 8AS

0161 834 7201 Fax 0161 833 0634

16 Arthur Street, Belfast BT1 4GD

01232 238451 Fax 01232 235401

71 Lothian Road, Edinburgh EH3 9AZ

0131 228 4181 Fax 0131 229 2734

The HMSO Oriel Bookshop

The Friary, Cardiff CF1 4AA

01222 395548 Fax 01222 384347

**The Parliamentary Bookshop**

12 Bridge Street, Parliament Square,

London SW1A 2JX

Telephone orders 0171 219 3890

General enquiries 0171 219 3890

Fax orders 0171 219 3866

**HMSO's Accredited Agents**

(see Yellow Pages)

*and through good booksellers*

©Parliamentary copyright House of Commons 1996  
Applications for reproduction should be made to HMSO

ISBN 0 10 226896 7