

## THE BSE INQUIRY

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### DAY 67

Friday 16 October 1998

Sir Joseph Smith	Director, PHLS, 1985-92. Senior Lecturer, Department of Bacteriology and Immunology, London School of Hygiene and Tropical Medicine, 1960-65; Consultant Clinical Bacteriologist, Radcliffe Infirmary, Oxford, 1965-69; GP, Islington, 1970-71; Consultant Epidemiologist, Deputy Director, Epidemiological Research Laboratory, PHLS, 1971-76; Director, National Institute for Biological Standards and Control, 1976-85. Member, Committee on Safety of Medicines, 1978-86 (Chair, Biology Sub-Committee, 1981-86); member, Joint Committee on Vaccination and Immunisation, 1976-93; MRC member, 1989-92; Council member, Royal College of Pathology, 1988-90; Chair, Committee on Vaccination and Immunisation Procedures, MRC, 1976-93; Chair, Simian Virus Committee, MRC, 1982-93
Dr Diana Walford	Senior Principal Medical Officer, DoH, Oct 87 - Sept 89; Deputy CMO and Director of Health Care, NHS Management Executive, Oct 89 - Nov 92; Director of PHLS since Jan 1993

### REFERENCES TO HEARINGS BUNDLES AND WITNESS'S COMMENTS AND CORRIGENDA

#### Witness comments and Corrigenda

1. Please see further comments of Dr. Walford in Witness Statement 182B which can be found in hearing bundle series "WS" at dividers headed "Walford, (Dr D) 3".
2. Please see further comments of Sir Smith in Witness Statement 181A, which can be found in hearing bundle series "WS" at dividers headed "Smith, Sir Day (2)".

#### References to Hearings Bundles

No additional references.

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**In The Matter Of:**

*BSE Inquiry*

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*Day 67*  
*October 16, 1998*

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Hercules House  
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16TH October 1998

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**THE BSE INQUIRY**  
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**The Committee**

THE CHAIRMAN  
(SIR NICHOLAS PHILLIPS)

PROFESSOR MALCOLM FERGUSON-SMITH

MRS JUNE BRIDGEMAN  
- - - - -

**Representation**

MR STUART CATCHPOLE - Counsel for the Ministry of  
Agriculture, Fisheries and Food  
MS SARAH MOORE - Counsel for the Department of Health  
MR DAVID BODY - Solicitor for the nvCJD families  
MR STUART ISAACS QC - Counsel for the National Farmers  
Union  
MR PAUL WALKER, MR KEITH FREEMAN, HARRY MATOVU and  
ANDREW THOMAS - Counsel for The BSE Inquiry

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(Transcription of Smith Bernal International  
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[1] Friday, 16th October 1998  
 [2] (9.30 am)  
 [3] SIR JOSEPH SMITH and DR DIANA WALFORD:  
 [4] MR WALKER: Chairman, Professor Ferguson-Smith,  
 [5] Mrs Bridgeman, good morning. There is a matter which  
 [6] I must mention briefly. On 5th October, Day 62 of our  
 [7] Hearing, I asked a question of one of our witnesses as  
 [8] to whether he had any reason as to why a particular  
 [9] person had resigned. The reply given to me described a  
 [10] particular rumour, and added very fairly that the  
 [11] witness was not prepared to discuss what was given as  
 [12] rumour. The rumour concerned a matter which I consider  
 [13] has no relevance to the Inquiry. I do not think it is  
 [14] right that mere rumour as to a serious matter irrelevant  
 [15] to the Inquiry should remain on the transcript.  
 [16] Accordingly I have proposed that the relevant lines in  
 [17] the transcript, which are at lines 7 to 16 of page 52,  
 [18] should be replaced by a brief statement that those lines  
 [19] have been omitted. The matter is made all the more  
 [20] serious because of an unfortunate error in transcription  
 [21] which led to a quite incorrect name being set out as the  
 [22] name of the person referred to in my question. It is a  
 [23] most unusual course to ask for the transcript to be  
 [24] altered, but I hope in these exceptional circumstances  
 [25] the Committee will give its approval.

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[1] will move on to Phase 2. Phase 2 is concerned with  
 [2] clarification, conflict of evidence and potential  
 [3] criticism. It is at that stage that the Committee will  
 [4] seek to identify any potential criticisms which it wants  
 [5] witnesses to answer. If it does identify potential  
 [6] criticisms they will be set out in a letter.  
 [7] Today we are not concerned with that at all. We  
 [8] are part of Phase 1 and that means I am going to ask you  
 [9] questions about what you did at the time, what you said  
 [10] at the time and your reasons at the time. I might also  
 [11] ask you whether you think something could have been done  
 [12] differently and if it had been done differently, what  
 [13] the result would have been. Neither I nor members of  
 [14] the Committee today will be making any criticisms of you  
 [15] whether explicit or implicit in our questions. That is  
 [16] not what we are seeking to do. If when I ask a question  
 [17] or a member of the Committee asks a question you think  
 [18] there is a criticism express or implied, any suggestion  
 [19] that you should have done something rather than could  
 [20] have done something, I would like you to say so at  
 [21] once. Then we will stop and make sure we stick to the  
 [22] purpose of today which is to establish and review the  
 [23] facts. Is that acceptable to you Sir Joseph?  
 [24] SIR JOSEPH SMITH: Yes.  
 [25] MR FREEMAN: Dr Walford?

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[1] SIR NICHOLAS PHILLIPS: Mr Walker, it is a very unusual  
 [2] course. The circumstances are very unusual as well. We  
 [3] consider it quite appropriate that you should take that  
 [4] step.  
 [5] MR WALKER: Thank you.  
 [6] MR FREEMAN: Yes. Good morning. Each of you have supplied  
 [7] a statement to the Secretariat, that is right, is it  
 [8] not?  
 [9] THE WITNESSES: Yes.  
 [10] MR FREEMAN: I wonder if you could kindly check the  
 [11] published version of your statement at some suitable  
 [12] point - I do not mean now - and let us know if there  
 [13] are any errors in transcription. Is there anything you  
 [14] wish to add to the statement you have provided to us  
 [15] immediately?  
 [16] DR WALFORD: I do not, thank you.  
 [17] MR FREEMAN: Sir Joseph?  
 [18] SIR JOSEPH SMITH: I do not think so.  
 [19] MR FREEMAN: Before we start our discussion, I must remind  
 [20] you of something that all witnesses are reminded about.  
 [21] That concerns the Phase 1 and Phase 2 approach which the  
 [22] Committee has adopted at this Inquiry. The purpose of  
 [23] today is simply to establish and review the course of  
 [24] events. Eventually, towards the end of this year many  
 [25] others will have been interviewed, then the Committee

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[1] DR WALFORD: Certainly.  
 [2] MR FREEMAN: I am most grateful. The other important point  
 [3] I must mention concerns hindsight. When I am asking you  
 [4] questions about what you said or did at the time in  
 [5] general I shall want you not to use hindsight. It is  
 [6] difficult but it is important that the Committee should  
 [7] have an understanding of what was in your mind at the  
 [8] time. Just occasionally I will say: "Let us look back  
 [9] with the benefit of hindsight". Unless I do that could  
 [10] you work on the basis that I am asking you to recall  
 [11] what was in your mind at the time in question, Sir  
 [12] Joseph?  
 [13] SIR JOSEPH SMITH: Yes.  
 [14] MR FREEMAN: Dr Walford?  
 [15] DR WALFORD: Yes.  
 [16] MR FREEMAN: Are there any general remarks either of you  
 [17] would like to make at the outset; Sir Joseph?  
 [18] THE WITNESSES: No.  
 [19] MR FREEMAN: Dr Walford, it may be useful to make sure you  
 [20] have your witness statement to hand. You have produced  
 [21] very kindly two witness statements. Sir Joseph,  
 [22] I wonder if you could do the same with your single  
 [23] witness statement. Now you have produced a witness  
 [24] statement that dealt with your period when you worked  
 [25] for the Department of Health until December 1992?

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[1] **DR WALFORD:** Yes.

[2] **MR FREEMAN:** Then you very kindly produced the statement in

[3] relation to your period as Director of the PHLS?

[4] **DR WALFORD:** Yes.

[5] **MR FREEMAN:** Sir Joseph, in your witness statement you also

[6] deal with periods where you were working in other jobs

[7] outside the PHLS. And initially what I want to canvass

[8] with you Dr Walford is something of those early days.

[9] **DR WALFORD:** Very well.

[10] **MR FREEMAN:** I wonder if we could just turn to paragraph 7

[11] of your witness statement, the first witness statement,

[12] Walford 1. If you could indicate to me when you have

[13] found that paragraph 7?

[14] **DR WALFORD:** Yes, I have.

[15] **MR FREEMAN:** It may be useful - I do not know whether Sir

[16] Joseph has been given a copy of your witness statement?

[17] **SIR JOSEPH SMITH:** I have, thank you.

[18] **MR FREEMAN:** It may be useful to follow where I am taking

[19] Dr Walford to. And when I take Sir Joseph it may be

[20] useful if you go to that too because I may ask you to

[21] comment on certain matters as they arise. You say in

[22] paragraph 7:

[23] "In early 1988, when BSE was first brought to the

[24] Department of Health's attention, IMCD was made up of

[25] five branches".

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[1] **DR WALFORD:** No, I do not. I think those minutes were

[2] circulated quite some substantial time after the

[3] meeting.

[4] **MR FREEMAN:** I am most grateful. Just putting yourself back

[5] then at that time with some degree of benefit of

[6] hindsight, what do you think you would have made of that

[7] sentence at the time if you had read it?

[8] **DR WALFORD:** Taking it on its face, it seems to be

[9] reassuring, insofar as it appears to imply that

[10] Dr Watson felt this was an animal disease without

[11] implications for human health.

[12] **MR FREEMAN:** Of course we know that this is related to the

[13] work of zoonoses. Did you have a view on that, at that

[14] time?

[15] **DR WALFORD:** I do not remember the meeting at all,

[16] unfortunately. I could not say whether I had a view or

[17] not.

[18] **MR FREEMAN:** No. We are going to return to this area in

[19] relation to something said much later on. I would like

[20] to move on.

[21] **SIR NICHOLAS PHILLIPS:** Before you do, presumably this

[22] would not have been tabled as an item for discussion at

[23] the meeting had it not been considered to be a potential

[24] zoonosis?

[25] **DR WALFORD:** I do not know why MAFF chose to do this. This

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[1] Could I ask you if you had any direct experience

[2] of CJD prior to that time?

[3] **DR WALFORD:** No, I did not have any direct experience.

[4] **MR FREEMAN:** Let us move on to paragraph 8 of your

[5] statement, please. There you say:

[6] "... I first heard of the existence of BSE at a

[7] meeting of the Central Zoonoses Group ..."; is that

[8] correct?

[9] **DR WALFORD:** That is correct.

[10] **MR FREEMAN:** You say that meeting took place on 17th

[11] February 1988. At the end of that paragraph, paragraph

[12] 8, over the page, you chaired a meeting and the summary

[13] of the minutes of that meeting concluded, I do not

[14] believe we need to turn it up, it is this sentence:

[15] "There is no evidence to suggest that there may be

[16] a risk to human health".

[17] May I ask you first of all: did you draft that

[18] sentence? Was that one you were responsible for

[19] drafting?

[20] **DR WALFORD:** No, that summary was either produced by

[21] Dr Watson or by the MAFF Veterinary Officer who

[22] accompanied him and provided the secretariat function to

[23] the meeting.

[24] **MR FREEMAN:** Do you remember reading that sentence at the

[25] time?

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[1] would have been put on the agenda by MAFF. It was, as I

[2] have seen the papers now it appeared all we had was an

[3] agenda with the series of items. And the minutes which

[4] were circulated, including the summary, actually

[5] appeared, as they tended to do in those meetings, quite

[6] some time after the event.

[7] **MR FREEMAN:** Could you please look at paragraph 10 now and

[8] I will read if I may the second sentence of that

[9] paragraph:

[10] "... the Department had been advised by Mr Rees,

[11] the Chief Veterinary Officer, that the Permanent

[12] Secretary of MAFF had written to him [that is the Chief

[13] Medical Officer] seeking the Department's views on the

[14] possible human health implications of BSE".

[15] Then in paragraph 11:

[16] "In response to that minute, the Chief Medical

[17] Officer wrote to me on 7 March 1988 to the effect that

[18] if this is a new disease of cattle, if it behaved like

[19] scrapie and kuru, there should not be a problem in man,

[20] but we should nevertheless take urgent advice from the

[21] experts."

[22] What did you think at the time, if anything, of

[23] the timing of this request?

[24] **DR WALFORD:** Of the request to see the Chief Medical

[25] Officer? I have no recollection of what I thought at

Page 8

[1] the time.

[2] **MR FREEMAN:** No. What I am asking you, really, is: did you

[3] think that this was an appropriate moment to approach

[4] the Chief Medical Officer?

[5] **DR WALFORD:** I cannot help you. Unfortunately I cannot

[6] remember that period at all.

[7] **MR FREEMAN:** After all there was a huge germ pool in cows, a

[8] growing epidemic at that time?

[9] **DR WALFORD:** There was a growing problem in animals, yes.

[10] **MR FREEMAN:** And zoonoses were known to you?

[11] **DR WALFORD:** Indeed.

[12] **MR FREEMAN:** You cannot recall at all whether you formed any

[13] view on whether this request had come at the right time

[14] or whether it should have come earlier or later, or

[15] anything of that kind?

[16] **DR WALFORD:** I cannot remember that period and I cannot

[17] help you as to what view I might have formed, I am

[18] afraid.

[19] **MR FREEMAN:** I am not going to press you on it any further.

[20] Are you able to say what the CMO's reaction was to his

[21] advice being sought on this new SE in cows?

[22] **DR WALFORD:** I do not recollect that I had a meeting

[23] directly with the CMO on this. As far as I can judge,

[24] certainly looking at the papers because I have nothing

[25] else to go on, the first interaction I would have had

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[1] that sort of period, April 1988] the CMO decided that

[2] BSE would be dealt with by Dr Hilary Pickles... Since

[3] BSE was a new animal disease and not a known zoonotic

[4] disease, there was no particular reason for it to be

[5] dealt with in my Division," I see that.

[6] Did you accept the assumption at that time that

[7] BSE was a new animal disease and not potentially a

[8] zoonotic disease?

[9] **DR WALFORD:** Again I do not remember what I did or did not

[10] accept at the time. I presume it was open to some

[11] doubt. Certainly after the CMO had come to see me it

[12] must have been open to some doubt and that is why all

[13] the arrangements were being set up to deal with it.

[14] **MR FREEMAN:** When you refer to the CMO coming to see you, is

[15] that the visit you refer to in your statement or some

[16] other visit that you mention?

[17] **DR WALFORD:** The 3rd March meeting.

[18] **MR FREEMAN:** In paragraph 16 you are then concerned with the

[19] Richmond Committee. As I understand the Richmond

[20] Committee, that grew out of matters like salmonella?

[21] **DR WALFORD:** Yes.

[22] **MR FREEMAN:** Another important matter with the Department of

[23] Health that had arisen. Did you know any reasons at the

[24] time why BSE should not be considered by the Richmond

[25] Committee?

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[1] with the CMO on this was the response on 7th March to

[2] Ann Dawson's minute of 3rd March.

[3] **MR FREEMAN:** That was as I have already said to the effect

[4] that if this new disease of cattle behaved like scrapie

[5] and kuru, there should not be a problem in man.

[6] Did you have a view on the scrapie analogy at that

[7] time?

[8] **DR WALFORD:** I do not remember my views on these things.

[9] I do not think I was in any position to have a view on

[10] it because this was an entirely new area for me.

[11] **MR FREEMAN:** Can you help us with the phrase: "If this new

[12] disease of cattle behaved like scrapie ..." just

[13] concentrating on the kuru part, "... there should not be

[14] a problem in man"; can you help us at all with that?

[15] **DR WALFORD:** Only to say looking at that minute now and not

[16] recalling it of course from when I first saw it, I was a

[17] bit surprised about the kuru bit because obviously kuru

[18] is a disease which affects man.

[19] **MR FREEMAN:** I suppose it might have meant that it was only

[20] transmissible by cannibalism, something of that sort?

[21] **DR WALFORD:** Or possibly inoculation.

[22] **MR FREEMAN:** Could we turn to paragraph 15 now of your

[23] statement? Just for the benefit of the public I will

[24] just read a bit of this if I may:

[25] "Around this time [we are dealing with late March,

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[1] **DR WALFORD:** No, I simply obviously, having seen the

[2] papers, have seen the memo and letters or rather the

[3] minute from Sir Donald, which obviously indicated that

[4] he did not want the Richmond Committee to examine the

[5] issue. But personally I would have thought that the

[6] Richmond Committee was a reasonable forum in which a

[7] putative zoonotic disease might be discussed.

[8] **MR FREEMAN:** Would you care to expand on the reasons why the

[9] Richmond Committee would have been an appropriate forum

[10] for that?

[11] **DR WALFORD:** The Richmond Committee was concerned with the

[12] microbiological safety of food and all aspects of safety

[13] of the food chain. Here was at least an issue which

[14] might be considered of interest to them, even if they

[15] did not necessarily have the expertise to deal with it

[16] directly, it being a novel type of disorder.

[17] **MR FREEMAN:** Now, the sentence you then put in paragraph 16

[18] is:

[19] "He wished [meaning the CMO] personally to clear

[20] any question which was felt to be sufficiently important

[21] to justify reopening the issue at that stage".

[22] Did you ask him why he did not want it considered

[23] by -

[24] **DR WALFORD:** I do not remember anything about the period

[25] unfortunately, so I do not know. I doubt very much if

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[1] I would have questioned Sir Donald's view on this  
[2] matter.  
[3] **MR FREEMAN:** And why was that?  
[4] **DR WALFORD:** Because he had been dealing with the Southwood  
[5] Committee. This was an area in which he was personally  
[6] intensely involved; and I would have taken the view that  
[7] if Sir Donald did not feel it was appropriate for the  
[8] Richmond Committee to examine the issue, then it was not  
[9] appropriate.  
[10] **MR FREEMAN:** You would have deferred to him on the matter?  
[11] **DR WALFORD:** Indeed so.  
[12] **SIR NICHOLAS PHILLIPS:** Can you remember whether you  
[13] yourself had done any reading up at the time? This was  
[14] an unusual corner of science, to learn more about it?  
[15] **DR WALFORD:** I think, and this is where I do not have to  
[16] use hindsight, I recall how intensely busy we were at  
[17] the time on salmonella in eggs, listeria in pate and  
[18] cheeses. We had a spate of extremely nasty public  
[19] health incidents that my division was dealing with. We  
[20] had very few staff and I was occupied above and beyond  
[21] what sometimes seemed reasonable on dealing with those  
[22] matters. And I do not recall having taken a particular  
[23] interest in this, because I had other very major  
[24] interests to take care of.  
[25] **MR FREEMAN:** Yes, thank you. Thank you very much. I am

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[1] I would like to just ask you this: did you know if an  
[2] audit was ever done in the Department of Health of  
[3] bovine products?  
[4] **SIR JOSEPH SMITH:** I have no knowledge of any such audit.  
[5] **MR FREEMAN:** Would one have expected one in your view  
[6] including things like mechanically recovered meat, which  
[7] products and exactly what proportions, that kind of  
[8] thing?  
[9] **SIR JOSEPH SMITH:** This is in 1988?  
[10] **MR FREEMAN:** 1988/89.  
[11] **SIR JOSEPH SMITH:** I think the question of the possibility  
[12] of transmission in foods was being addressed and was a  
[13] matter before that the Southwood Committee gave  
[14] attention to. They would certainly, I would have  
[15] thought, have signalled the possibility that the means  
[16] by which bovine material get into the human food chain  
[17] would be important. Now, whether that would be for the  
[18] Department of Health or MAFF to have addressed that in  
[19] detail, I could not be sure.  
[20] **MR FREEMAN:** Whoever's responsibility it was, presumably one  
[21] would have expected an audit to be done of bovine  
[22] products including for example mechanically recovered  
[23] meat?  
[24] **SIR JOSEPH SMITH:** I would have thought it was a proper  
[25] thing to have considered.

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[1] going to turn to Southwood largely with Sir Joseph, but  
[2] I am going to return to that. Did you consider the  
[3] Tyrrell Committee report on research at any time?  
[4] **DR WALFORD:** I may well have read it. I did not do more  
[5] than read it, I do not think.  
[6] **MR FREEMAN:** You realise, of course, there was only what is  
[7] described as one three star project for the Department  
[8] of Health, no?  
[9] **DR WALFORD:** I am sorry. I cannot help you on that.  
[10] **MR FREEMAN:** If you cannot, you cannot. Do not worry, there  
[11] is no large disappointment on the matter. But if I tell  
[12] you then that there was one three star project and that  
[13] became translated largely into the CJD Surveillance  
[14] Unit, that does not come as a surprise to you?  
[15] **DR WALFORD:** Right. Right.  
[16] **MR FREEMAN:** I am going to come back to the surveillance  
[17] unit later on, but do you know, in your time at the  
[18] Department of Health or indeed at any other time,  
[19] whether - I am choosing my words carefully, but I may  
[20] be choosing the wrong word here - if you know an audit  
[21] was ever done within the Department of Health of bovine  
[22] products?  
[23] **DR WALFORD:** I do not know that and I would not have been  
[24] involved in it had it taken place.  
[25] **MR FREEMAN:** Sir Joseph, you have been very patient.

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[1] **MR FREEMAN:** Presumably that audit should have also covered  
[2] things like vaccination products?  
[3] **SIR JOSEPH SMITH:** Oh yes.  
[4] **MR FREEMAN:** We can come on to that in a moment, the reasons  
[5] for that. Medicines in general.  
[6] **SIR JOSEPH SMITH:** Especially injectable medicines.  
[7] **MR FREEMAN:** I follow that. Presumably also including  
[8] tallow and gelatin in medicines?  
[9] **SIR JOSEPH SMITH:** I think it needed to be thought of.  
[10] That was probably a less obvious consideration at the  
[11] time than things that might be injected.  
[12] **MR FREEMAN:** I am going to explore that in a moment because  
[13] the distinction you draw is between parenteral and  
[14] topical and oral transmission?  
[15] **SIR JOSEPH SMITH:** Yes.  
[16] **MR FREEMAN:** Cosmetics. Do you think they should have been  
[17] explored?  
[18] **SIR JOSEPH SMITH:** I would not have thought so, at that  
[19] time certainly.  
[20] **MR FREEMAN:** Is that because they are purely topical?  
[21] **SIR JOSEPH SMITH:** Yes.  
[22] **MR FREEMAN:** Dr Will has told the Inquiry that no such audit  
[23] was ever done. Is that something that surprises you?  
[24] **SIR JOSEPH SMITH:** Of foods?  
[25] **MR FREEMAN:** Well, of bovine products.

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[1] **SIR JOSEPH SMITH:** I suppose – yes.  
 [2] **MR FREEMAN:** Now you served on the Committee on the Safety  
 [3] of Medicines. I know that was an earlier period ending  
 [4] in 1986?  
 [5] **SIR JOSEPH SMITH:** Yes.  
 [6] **MR FREEMAN:** Could you give a very brief idea, it is  
 [7] something we are going to explore later on, but can you  
 [8] give a brief idea of the work of the Safety Committee on  
 [9] Medicines, what it involves?  
 [10] **SIR JOSEPH SMITH:** It addressed in the main applications  
 [11] for product licences for new products submitted by the  
 [12] pharmaceutical industry. These went in the first place  
 [13] to the secretariat of the CSM for assessment and the  
 [14] application consisted of a lot of documents, that sort  
 [15] of size (Indicates). Then they would be presented  
 [16] usually to a sub-committee. There was a main  
 [17] sub-committee dealing with most of the pharmaceutical  
 [18] products and a second one dealing with biological  
 [19] products, which is an uncertain definition but embraced  
 [20] things like vaccines and products which could not be  
 [21] chemically assayed, physically and chemically assayed,  
 [22] because they required biological standards to measure  
 [23] their potency against.  
 [24] **MR FREEMAN:** Indeed. The solicitors acting for you have  
 [25] informed us that during 1988 you made inquiries in

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[1] Institute of Biological Standard and Control. What I  
 [2] can particular remember is being told that the drug  
 [3] firms have this well in hand and that Wellcom in  
 [4] particular, and I think they have ensured that they have  
 [5] most of the supplies of foetal calf serum available in  
 [6] New Zealand tied up and they had taken action on it very  
 [7] early, and also that the matter was very much on the  
 [8] table at the – I am not sure if it was – the licencing  
 [9] authority, whether it was then the Medicines Control  
 [10] Agency, I cannot remember.  
 [11] **MR FREEMAN:** If I am looking down it is not because I am not  
 [12] interested in what you are saying, I am checking whether  
 [13] you have covered the material I am about to ask you. It  
 [14] is not intended to be impolite.  
 [15] You went to some degree to understand exactly  
 [16] which ones might be a likely route of transition?  
 [17] **SIR JOSEPH SMITH:** I wanted to make sure it was being  
 [18] considered in detail, if it was considered first at all,  
 [19] and then make sure it was being addressed.  
 [20] **MR FREEMAN:** I am most grateful for that answer. Could you  
 [21] please tell me as far as you can which ones exactly you  
 [22] thought were as it were the ones that ought to be  
 [23] examined?  
 [24] **SIR JOSEPH SMITH:** I think –  
 [25] **MR FREEMAN:** I am not looking for an exhaustive list because

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[1] relation to human medicines?  
 [2] **SIR JOSEPH SMITH:** Yes.  
 [3] **MR FREEMAN:** Can you explain, particularly of course those  
 [4] which might contain bovine products, can you say what  
 [5] prompted you to do that?  
 [6] **SIR JOSEPH SMITH:** Well, it seemed to me that – I am not  
 [7] sure exactly when it was, that is my problem – that if  
 [8] there was to be any risk of transmission from bovines,  
 [9] the most important route would have been by inoculation.  
 [10] **MR FREEMAN:** Yes.  
 [11] **SIR JOSEPH SMITH:** A number of injected products contained  
 [12] bovine materials.  
 [13] **MR FREEMAN:** We will come on to what those might have been.  
 [14] Can I ask you in what role you were doing that  
 [15] particular inquiry?  
 [16] **SIR JOSEPH SMITH:** I think really I was doing it as just me  
 [17] because I was worried about it.  
 [18] **MR FREEMAN:** No just about it, if I may say so. You were  
 [19] doing it in your private capacity, but as somebody who  
 [20] knew quite a lot about it?  
 [21] **SIR JOSEPH SMITH:** Yes.  
 [22] **MR FREEMAN:** How did you make those inquiries?  
 [23] **SIR JOSEPH SMITH:** Well, I know I made – I think the  
 [24] likely thing is, but I am not sure, is I would have rung  
 [25] Geoffrey Field who is the Director of the National

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[1] I promise you we are going to go into this in another  
 [2] part of the Inquiry.  
 [3] **SIR JOSEPH SMITH:** The one that was forefront in my mind  
 [4] would have been vaccines because a number of viral  
 [5] vaccines are prepared in tissue cultures in which the  
 [6] cells are grown in the presence of foetal calf serum.  
 [7] These, of course, are injected into healthy children.  
 [8] **MR FREEMAN:** It is as part of the children's vaccination  
 [9] programme that these are used?  
 [10] **SIR JOSEPH SMITH:** Yes.  
 [11] **MR FREEMAN:** Would it apply to holiday vaccines as well, or  
 [12] not?  
 [13] **SIR JOSEPH SMITH:** I would have to give that a little more  
 [14] thought.  
 [15] **MR FREEMAN:** Do. Do not think you have to answer it now.  
 [16] Perhaps I will remember to ask you it again. When we  
 [17] get to your coffee break –  
 [18] **SIR JOSEPH SMITH:** Off the cuff I think probably not.  
 [19] **MR FREEMAN:** Would you like to think about that when we get  
 [20] an opportunity over the break? I will try to remember  
 [21] to ask you after the break about it.  
 [22] So you thought inoculation was the most likely  
 [23] route of transmission if there was one?  
 [24] **SIR JOSEPH SMITH:** Yes.  
 [25] **MR FREEMAN:** Did you form a view on how likely that was?

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[1] **SIR JOSEPH SMITH:** I thought it was extremely unlikely;  
 [2] but, you know, the consequences of there being a danger  
 [3] from something like that injected into healthy people  
 [4] was, I thought, serious.  
 [5] **MR FREEMAN:** How seriously at that stage did you take any  
 [6] other route, namely topically or orally?  
 [7] **SIR JOSEPH SMITH:** I thought that it was much less likely  
 [8] to be a problem although they could not be excluded.  
 [9] You could not say there was absolutely no risk.  
 [10] **MR FREEMAN:** Were you deriving your views from your own  
 [11] knowledge or from what was said in the Southwood Report  
 [12] or both?  
 [13] **SIR JOSEPH SMITH:** I think I made these inquiries before  
 [14] Southwood reported but I am not sure. It would have  
 [15] been from my own understanding of the issues.  
 [16] **MR FREEMAN:** Now, did you ask anything about whether  
 [17] products had been removed from shelves, that kind of  
 [18] thing?  
 [19] **SIR JOSEPH SMITH:** No. No.  
 [20] **MR FREEMAN:** Did you ask about which countries it was  
 [21] proposed to source bovine materials from?  
 [22] **SIR JOSEPH SMITH:** Well, insofar as I specifically asked  
 [23] about foetal calf serum used in human vaccines, they  
 [24] were being sourced from countries which as I understand  
 [25] had not known scrapie and were therefore regarded as

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[1] **MR FREEMAN:** What route, if any, is there for applying a  
 [2] less stringent form of control? For instance, if you  
 [3] wanted to try to ensure that a particular ingredient was  
 [4] only sourced from outside the UK, was there any legal  
 [5] way of doing that? Would you make it a condition of the  
 [6] licence?  
 [7] **SIR JOSEPH SMITH:** Sir, my knowledge of the legalities is  
 [8] pretty limited. I think the answer is yes. The  
 [9] licencing authority can review the product licence and  
 [10] decide to modify it or vary it to take account of new  
 [11] knowledge.  
 [12] **SIR NICHOLAS PHILLIPS:** We also know there was a practice  
 [13] of issuing guidelines. In practice, would the approach  
 [14] be to issue guidelines and only if those were not  
 [15] complied to think of more stringent measures?  
 [16] **SIR JOSEPH SMITH:** My recollection is that it would tend to  
 [17] be a bit more vigorous than just issuing of guidelines,  
 [18] because you are dealing with the safety of medicines.  
 [19] **MRS BRIDGEMAN:** Is that because guidelines were a rather  
 [20] loose sort of way of controlling things, people did not  
 [21] have to follow them?  
 [22] **SIR JOSEPH SMITH:** I think a drug firm would be very unwise  
 [23] not to follow the guidelines because they would be in  
 [24] serious risk of having their licence withdrawn. A lot  
 [25] of pressure could be put on the drug firms directly to

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[1] very, very unlikely to be presenting a risk.  
 [2] **MR FREEMAN:** Presumably countries like New Zealand?  
 [3] **SIR JOSEPH SMITH:** New Zealand was the one I particularly  
 [4] remember being told about.  
 [5] **MR FREEMAN:** Did you ask anything further about products on  
 [6] the shelves?  
 [7] **SIR JOSEPH SMITH:** No, but I did ask: is the Medicines  
 [8] Control Agency or the Medicines Division of the  
 [9] Department looking at the problem? I was told they were  
 [10] looking at it seriously.  
 [11] **MR FREEMAN:** Did you know about the relevant shelf life of  
 [12] that these products had?  
 [13] **SIR JOSEPH SMITH:** I would have had a general idea yes.  
 [14] **MR FREEMAN:** Could you give that general idea now?  
 [15] **SIR JOSEPH SMITH:** With vaccines it could be a year,  
 [16] possibly two years; that sort of time.  
 [17] **SIR NICHOLAS PHILLIPS:** Could you just give us a little  
 [18] general help on this area? We know that medicines are  
 [19] regulated by the grant of a licence, and presumably a  
 [20] licence can be recalled?  
 [21] **SIR JOSEPH SMITH:** Yes.  
 [22] **SIR NICHOLAS PHILLIPS:** That is a very Draconian step to  
 [23] take. Presumably it means that particular product  
 [24] cannot be used?  
 [25] **SIR JOSEPH SMITH:** Yes, it has been done.

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[1] get a move on with various things to make sure they were  
 [2] moving quickly and fast. There was a lot of  
 [3] interchange, I can particularly remember it over the  
 [4] replacement of human growth hormone by the genetically  
 [5] made product. And the sub-committee was discussing  
 [6] repeatedly with the licencing authority the progress  
 [7] being made on that. Then the licencing authority in  
 [8] turn was putting pressure on the drug firms to make sure  
 [9] they were responding quickly, as indeed of course they  
 [10] wanted to.  
 [11] **MR FREEMAN:** May I follow on from the questions that have  
 [12] been asked by the Committee members and ask you this:  
 [13] were you aware of whether anybody did have their licence  
 [14] revoked or varied in that way?  
 [15] **SIR JOSEPH SMITH:** Yes. I cannot remember but it was not  
 [16] all that infrequent an event.  
 [17] **MR FREEMAN:** Do you know what happens then? There is an  
 [18] appeal process, is there not?  
 [19] **SIR JOSEPH SMITH:** Yes.  
 [20] **MR FREEMAN:** Presumably one can obtain documentation  
 [21] relating to that appeal process. Is that in the public  
 [22] domain, do you know?  
 [23] **SIR JOSEPH SMITH:** It was - the whole business was  
 [24] surrounded by commercial confidentiality which meant  
 [25] I suspect it could not, but I do not know.

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[1] **MR FREEMAN:** Can you help us a little bit more? Do you know  
 [2] whether in that period people who had their – I mean  
 [3] here commercial organisations and the like, if they had  
 [4] revoked or varied, you told us they took them to  
 [5] appeal. Who did they appeal to?  
 [6] **SIR JOSEPH SMITH:** They appeal to the licencing authority.  
 [7] The appeal, whether always – but I think probably  
 [8] perhaps always was heard by the Committee of Safety of  
 [9] Medicines.  
 [10] **SIR NICHOLAS PHILLIPS:** Could I just be clear, are we  
 [11] talking generally or are we talking in the context of  
 [12] BSE?  
 [13] **SIR JOSEPH SMITH:** I am talking generally, sir.  
 [14] **MR FREEMAN:** May I ask in relation now, this is tying you  
 [15] down a bit, are you aware of whether that happened in  
 [16] relation to any materials which were bovine materials,  
 [17] which may have come from cows with BSE? Do you know  
 [18] whether anybody's licence was revoked in relation to  
 [19] that, or varied?  
 [20] **SIR JOSEPH SMITH:** Certainly not up to the time I had left  
 [21] the CSM.  
 [22] **MR FREEMAN:** You left in 1986?  
 [23] **SIR JOSEPH SMITH:** Yes.  
 [24] **MR FREEMAN:** Were you aware after that period whether  
 [25] anybody had had that happen?

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[1] **MR FREEMAN:** You say as much in your statement. You say in  
 [2] fact in your statement at paragraph 17, Sir Joseph,  
 [3] this, if we may just turn it up, paragraph 17. If you  
 [4] can tell me when you have got to it please?  
 [5] **SIR JOSEPH SMITH:** I have it.  
 [6] **MR FREEMAN:** I am grateful. You say in the third sentence  
 [7] of paragraph 17:  
 [8] "Whilst still concerned, I was reassured by the  
 [9] conclusions and recommendations of the Southwood Report  
 [10] in 1989".  
 [11] The concerns, are they the same concerns you have  
 [12] been speaking about, or those and some other ones or  
 [13] some completely other concerns?  
 [14] **SIR JOSEPH SMITH:** It would have been embracing the whole  
 [15] area. But I suppose particularly in my mind when  
 [16] I drafted this were the food question, and the  
 [17] possibility of transmission by food.  
 [18] **MR FREEMAN:** Did you consider the risk remote yourself?  
 [19] **SIR JOSEPH SMITH:** Yes.  
 [20] **MR FREEMAN:** You said as much?  
 [21] **SIR JOSEPH SMITH:** Yes, I thought it was remote; and it was  
 [22] Southwood, clearly people with expertise I did not  
 [23] possess, was reassuring on that.  
 [24] **MR FREEMAN:** You pause there. Was it the word "remote" you  
 [25] did not like or...?

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[1] **SIR JOSEPH SMITH:** No I was not.  
 [2] **MR FREEMAN:** I am going to leave that area now. I do not  
 [3] know if the Committee have any further questions on it.  
 [4] Now, Sir Joseph, you have been in an abattoir,  
 [5] have you?  
 [6] **SIR JOSEPH SMITH:** I do not think I have.  
 [7] **MR FREEMAN:** You had concerns about slaughterhouses and the  
 [8] personnel working there in particular, I think, did you  
 [9] not?  
 [10] **SIR JOSEPH SMITH:** Well, to the extent that – I thought  
 [11] that inoculation was a route and the one to be most  
 [12] worried about was from medicines. Inoculation in things  
 [13] like slaughterhouses and laboratories I thought was an  
 [14] appreciably more remote risk, based on the fact that  
 [15] scrapie had long been around and there was despite,  
 [16] I think I understand, good studies of it, no evidence  
 [17] had been found that that had been transmitted in that  
 [18] way. And by analogy it seemed a remote risk. But it  
 [19] was something that needed to be thought about.  
 [20] **MR FREEMAN:** I am most grateful. Dr Walford, did you read  
 [21] the Southwood Report at the time or shortly after it was  
 [22] published?  
 [23] **DR WALFORD:** Almost certainly I will have done.  
 [24] **MR FREEMAN:** Presumably Sir Joseph you read it?  
 [25] **SIR JOSEPH SMITH:** Yes.

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[1] **SIR JOSEPH SMITH:** No, I thought the word was "remote".  
 [2] I do not think the pause – I am unaware of any  
 [3] significance, I am sorry.  
 [4] **MR FREEMAN:** Not at all. I am so sorry. I wanted to give  
 [5] you an opportunity because you did pause in case there  
 [6] was something else you wanted to add to, you see? What  
 [7] did you understand by "remote" at the time?  
 [8] **SIR JOSEPH SMITH:** Could not be ruled out. That it was  
 [9] extremely unlikely but one was wise to take  
 [10] precautions. It was – back into the question of  
 [11] defining risk, which is jolly difficult.  
 [12] **MR FREEMAN:** You may be pleased to hear that I am not going  
 [13] to canvass "risk" at length with you. I am sure the  
 [14] Committee will be delighted by that proposition.  
 [15] Pursuing it just for one more question. It has been  
 [16] suggested that what "remote" means is theoretically  
 [17] possible, it has also been suggested negligible. Would  
 [18] you care to comment on that, negligible risk,  
 [19] theoretically possible?  
 [20] **SIR JOSEPH SMITH:** It is dealing with the meaning of words,  
 [21] they often convey different things to different people.  
 [22] "Negligible" to me carries a slight feeling that oh  
 [23] well, it is there but it is so rare that it is not  
 [24] important. "Remote" is a word I would be more  
 [25] comfortable with, that there was a possible risk but it

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[1] was very, very small that it would turn out to be one.  
 [2] **SIR NICHOLAS PHILLIPS:** "Negligible", so remote that one  
 [3] can neglect it; whereas "remote" does not carry that  
 [4] connotation.  
 [5] **SIR JOSEPH SMITH:** Yes, thank you sir.  
 [6] **MR FREEMAN:** Could we go to year book 94/1.27/6.1? It is in  
 [7] the PHLS supplementary hearing bundle. Another small  
 [8] thanks to our bundles team who has been doing sterling  
 [9] work at the Inquiry finding these documents.  
 [10] Could you please now just look at this  
 [11] memorandum? I am concentrating here now with  
 [12] Dr Walford. This is concerned with a recent address to  
 [13] a medical society in Norwich where you were asked  
 [14] questions by two members of the audience about PHLS's  
 [15] role in relation to BSE. I am going to read paragraph 2  
 [16] out:  
 [17] "I responded along the lines that BSE was not  
 [18] thought to be a human pathogen, hence PHLS was not  
 [19] currently engaged in work on BSE ..."  
 [20] That is a matter to which I am going to return  
 [21] Dr Walford. It is the second half I want to ask you  
 [22] about now:  
 [23] "...but that we were keeping an open mind on the  
 [24] issue. I thought, as indeed I have always felt, that  
 [25] this was an intellectually difficult line to sustain".

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[1] throughout the period were, at least in private you  
 [2] would have been looking for, at least in private, you  
 [3] would have been looking for statements of the kind that  
 [4] it is unknown whether it is a human pathogen. That is  
 [5] what you would have been looking for?  
 [6] **DR WALFORD:** I think that would have been a more  
 [7] appropriate statement to make than it is not a human  
 [8] pathogen. After all, the CJD Surveillance Unit had been  
 [9] set up for that purpose, to see whether or not there was  
 [10] some association with CJD.  
 [11] **MR FREEMAN:** It was not a just in case thing for you, it was  
 [12] a necessary thing because it was unknown?  
 [13] **DR WALFORD:** Absolutely.  
 [14] **SIR NICHOLAS PHILLIPS:** Could you just help us? You said  
 [15] the official line was PHLS is not concerned with this  
 [16] because this is not a human pathogen. What was the  
 [17] source of your understanding that that was the  
 [18] justification for excluding PHLS from consideration of  
 [19] BSE?  
 [20] **DR WALFORD:** I think I had been told by several people  
 [21] after I joined PHLS about the general line, if you will,  
 [22] relating to the PHLS. Certainly my first knowledge of  
 [23] this issue probably came about in relation to a problem  
 [24] we were having with the scientist who was engaged on  
 [25] working on BSE/CJD. And that was a current concern at

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[1] I want to ask you, first of all just thinking  
 [2] about Southwood, you have told us that you read  
 [3] Southwood. Did you accept at the time that the risk was  
 [4] remote?  
 [5] **DR WALFORD:** I do not honestly remember what I thought at  
 [6] the time, but I assume that with an expert committee set  
 [7] up specifically to look at these matters I would have  
 [8] been reassured.  
 [9] **MR FREEMAN:** Yes. Let us just examine the sentence if we  
 [10] may:  
 [11] "I thought, as indeed I have always felt, that was  
 [12] an intellectually difficult line to sustain".  
 [13] Presumably the line you found difficult to sustain  
 [14] was that BSE was not thought to be a human pathogen?  
 [15] **DR WALFORD:** No, I think the line I found difficult to  
 [16] sustain was that we did not know and the PHLS was not  
 [17] involved in looking to see whether or not it was. It  
 [18] seemed to me that was why the CJD Surveillance Unit had  
 [19] been set up, in order to establish whether or not there  
 [20] was any link between BSE and human cases of CJD. I did  
 [21] not know how I could sustain the argument that it was  
 [22] not a human pathogen when we did not know; and it was  
 [23] the sort of work in which the PHLS should have been  
 [24] engaged to try to ascertain whether or not it was.  
 [25] **MR FREEMAN:** So what you would have been looking for

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[1] the time that I joined the PHLS. I suspect that what  
 [2] I knew about BSE/CJD at that time related to what I was  
 [3] told in relation to this particular scientist.  
 [4] **SIR NICHOLAS PHILLIPS:** Yes.  
 [5] **MR FREEMAN:** I am most grateful. Now, in paragraph 18 you  
 [6] say:  
 [7] "I thought the PHLS should be involved" - I am so  
 [8] sorry, I should make sure you have the statement in  
 [9] front of you. Go to paragraph 18 of your statement.  
 [10] This document, I believe, can be closed now, the PHLS  
 [11] supplementary bundle. You might want to keep it handy  
 [12] for later.  
 [13] I hope you have found your paragraph 18 in your  
 [14] statement?  
 [15] **DR WALFORD:** Yes.  
 [16] **MR FREEMAN:** You say:  
 [17] "I thought the PHLS should be involved in its  
 [18] study, particularly on the epidemiological side?"  
 [19] **DR WALFORD:** I seem to have the wrong paragraph here unless  
 [20] I am looking at the wrong thing.  
 [21] **MR FREEMAN:** It may be me, forgive me. I am so sorry, it is  
 [22] in paragraph 19:  
 [23] "From I believe early in 1990, however, it was  
 [24] made increasingly clear to me that the Department of  
 [25] Health and Ministers did not wish the PHLS to work on

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[1] BSE/CJD ...", that is the point we just covered.  
 [2] Paragraph 19 of your first statement. Shall I read it  
 [3] again?  
 [4] **DR WALFORD:** It is still not the same paragraph. It is 20  
 [5] then, I think, in my statement.  
 [6] **MR FREEMAN:** I am just going to take a moment. Yes, I am  
 [7] now back on track. I am most grateful. Thank you very  
 [8] much. No need to try to track this through your  
 [9] statement. This is the question I want to ask Sir  
 [10] Joseph, really. It is a question for Sir Joseph really,  
 [11] that is where the muddle was coming up.  
 [12] Could you look at paragraph 19 in your statement?  
 [13] I am so sorry, it is Sir Joseph's statement that we  
 [14] should be looking at. Paragraph 19 in your statement,  
 [15] Sir Joseph. I am going to read the first sentence:  
 [16] "From I believe early in 1990, however, it was  
 [17] made increasingly clear to me that the Department of  
 [18] Health and Ministers did not wish the PHLS to work on  
 [19] BSE/CJD, nor to be seen to work or comment upon the  
 [20] subject, and especially that CDSC should not be  
 [21] involved. This caused me much concern".  
 [22] I assume the next sentence expresses your concern:  
 [23] "I thought that the PHLS should be involved in the  
 [24] critically necessary human epidemiological studies of  
 [25] BSE/CJD and that PHLS could make a valuable contribution

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[1] previous topic which was your understanding of the  
 [2] reason why the PHLS was not to be involved, Dr Walford  
 [3] said her understanding was because this was an animal  
 [4] disease and not a zoonosis, but from what you have been  
 [5] saying I do not understand that that was what you were  
 [6] led to believe as the reason for not involving the  
 [7] PHLS.  
 [8] **SIR JOSEPH SMITH:** I could not really understand the  
 [9] reason. I thought that there were points made in  
 [10] particularly Dr Pickles' letter to me of 1st February  
 [11] 1990, I think, where she said it might cause concern or  
 [12] belief that the disease was transmissible to people.  
 [13] Whether that was the basis, I do not know. But it did  
 [14] not seem to me necessarily the case. I mean, you could  
 [15] argue that were the PHLS to be involved that would  
 [16] reassure the public that it had a body like us at least  
 [17] looking at it. I did not know the reason. It did not  
 [18] seem to me, I share Dr Walford's view, that saying it  
 [19] was unlikely to be transmitted, nevertheless studies  
 [20] were needed to establish that.  
 [21] **MR FREEMAN:** Let us look at the letter Dr Pickles did send  
 [22] you, which you kindly provided for us. We have it in  
 [23] the year book. 90/2.1/5.1 to 5.3. That is year book  
 [24] 90/2.01/5.1 to 5.3. Now, this letter is a letter from  
 [25] Dr Hilary Pickles to you Sir Joseph. It is dated 1st

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[1] to their planning and operation".  
 [2] **SIR JOSEPH SMITH:** I do not think it entirely expresses my  
 [3] concerns.  
 [4] **MR FREEMAN:** Do go on to express them, please?  
 [5] **SIR JOSEPH SMITH:** What made me, I think, particularly  
 [6] unhappy as well was that it was - had become clear to  
 [7] me that we should not be involved, to be seen to be  
 [8] involved or to comment. That made me pretty  
 [9] uncomfortable. That is certainly how I felt at the  
 [10] time.  
 [11] **MR FREEMAN:** Yes. Can you give some expression as to why  
 [12] that matters, please, Sir Joseph?  
 [13] **SIR JOSEPH SMITH:** Well, firstly by commenting or  
 [14] contributing, I think we could have brought help and  
 [15] support to the surveillance programme. I must say  
 [16] I thought as it had been evidently decided that the PHLS  
 [17] were not to, that Dr Will was a very good choice to be  
 [18] the lead person doing it, as a neurologist with a  
 [19] special interest in CJD. But we could have helped him  
 [20] with our resources and the expertise that particularly  
 [21] PHLS epidemiologists had.  
 [22] **MR FREEMAN:** I wonder if you could try to give a brief  
 [23] summary of the sort of things that the PHLS might have  
 [24] brought to it.  
 [25] **SIR NICHOLAS PHILLIPS:** Before we get there, on the

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[1] February 1990 and it is headed "PHLS interest in CJD and  
 [2] BSE".  
 [3] Now, before we go into the letter, you will see in  
 [4] the first sentence the formal responsibilities of the  
 [5] PHLS are very wide within microbiology. Would you  
 [6] please give a description, a brief one if you can, of  
 [7] the work of the PHLS?  
 [8] **SIR JOSEPH SMITH:** Well, as a body it was engaged in the  
 [9] human infections it concerned, which would include  
 [10] zoonosis. It was engaged in diagnosis, surveillance of  
 [11] them, providing expertise to clinicians and  
 [12] microbiologists elsewhere in typing and sub-typing  
 [13] organisms and identification of different ones,  
 [14] providing expertise in clinical diseases. But also a  
 [15] specialist function that was epidemiological that it was  
 [16] operating as an entity which could bring epidemiological  
 [17] expertise and support and expert laboratory help to the  
 [18] investigation of disease, outbreaks, chronic diseases,  
 [19] things of that sort.  
 [20] **MR FREEMAN:** I mean the PHLS had been involved in a huge and  
 [21] wide ranging activity in relation to combating  
 [22] infection, had it not?  
 [23] **SIR JOSEPH SMITH:** We were heavily involved, salmonella was  
 [24] obviously a very big problem during my time, salmonella  
 [25] in chickens and eggs of course. We had to deal with

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[1] things like HIV, Aids which required an intense effort  
 [2] on our part. E.coli outbreaks, paediatric disease,  
 [3] listeriosis and so on; a whole range of things which  
 [4] were very pressing.  
 [5] **MR FREEMAN:** Dr Walford, I would like to ask you as well  
 [6] because I know you also have an interest in zoonosis,  
 [7] the sort of work the PHLS were involved in would be  
 [8] everything from influenza in chickens to all sorts of  
 [9] parasites, that kind of thing. Would you care to expand  
 [10] on that area?  
 [11] **DR WALFORD:** Well, the PHLS is concerned with infections of  
 [12] all kinds. We do not discriminate between the organism  
 [13] which causes the infection. We are clearly interested  
 [14] in all aspects of infection, and in generating  
 [15] information which allows the authorities, enforcement  
 [16] authorities or the policy makers to take action to  
 [17] combat infection.  
 [18] **MR FREEMAN:** Now, just dealing with this question of  
 [19] enforcement, would you have a real interest, an active  
 [20] interest in the process of enforcement? Would you want  
 [21] to know about its practicalities?  
 [22] **DR WALFORD:** The PHLS are not an enforcement agency and do  
 [23] not become involved in enforcement. On the other hand  
 [24] we do become involved in assisting Environmental Health  
 [25] Departments in their work in enforcing regulations and

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[1] **MR FREEMAN:** I know I am going off slightly tangentially.  
 [2] Although those are strictly speaking not communicable  
 [3] diseases and there is no diagnostic test in relation to  
 [4] those cancers, is there, you would still be interested?  
 [5] **SIR JOSEPH SMITH:** I think we would be interested if there  
 [6] was a causal relationship with an infection.  
 [7] **MR FREEMAN:** That is a fair answer. Dr Walford do you wish  
 [8] to comment?  
 [9] **DR WALFORD:** If I might intervene. In fact, several of  
 [10] those diseases are communicable; human pathoma(?)  
 [11] virus is a sexually transmissible disease; hepatitis B,  
 [12] which causes cancer of the liver, is a communicable  
 [13] disease. Those particular viral disorders associated  
 [14] with cancers are very much disorders with which we would  
 [15] have a considerable interest and we do.  
 [16] **MR FREEMAN:** I have heard that described as your interest in  
 [17] diseases via a vector. Would I be describing it  
 [18] effectively or is that something different again?  
 [19] **DR WALFORD:** No, that is a mosquito type or something like  
 [20] that.  
 [21] **MR FREEMAN:** Thank you. I promise you one learns a lot as  
 [22] one goes through this Inquiry. I do not pretend to  
 [23] understand everything of course, that is why you are  
 [24] here.  
 [25] Could you help me please with this: going now to

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[1] ensuring that, say, contaminated foodstuffs is removed  
 [2] from the shelves.  
 [3] **MR FREEMAN:** Let us relate this a little, if we may. Sir  
 [4] Joseph would you care to comment on that? What was the  
 [5] relationship between the PHLS and the Environmental  
 [6] Health Officers on the ground, so to speak?  
 [7] **SIR JOSEPH SMITH:** If I can just follow what Dr Walford  
 [8] said. I think we were very interested in control,  
 [9] making sure that the controls needed were identified and  
 [10] acted upon. And that required great interface with  
 [11] departments of public health in the country, with the  
 [12] communicable disease public health doctors and with the  
 [13] Environmental Health Departments in the country. We  
 [14] would liaise with them very considerably.  
 [15] **MR FREEMAN:** Do you mind if I cut across you for a moment?  
 [16] Save your next point, please. Is this right, around the  
 [17] country there is a whole network of consultants in  
 [18] public health? They have experience in a wide range of  
 [19] infections and diseases, including for example  
 [20] experience in cancer and the like, even if you may not  
 [21] be directly involved in that?  
 [22] **SIR JOSEPH SMITH:** We would not. I think the only expertise  
 [23] we might be able to offer in relation to cancers would  
 [24] be the association of certain cancers with virus  
 [25] infections.

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[1] the letter of 1st February 1990, just going back to that  
 [2] now, we see the first sentence of it says:  
 [3] "The formal responsibilities of the PHLS are very  
 [4] wide within microbiology but I do not think they can be  
 [5] read to include animal disorders".  
 [6] Dr Walford, would you care to comment on that  
 [7] sentence?  
 [8] **DR WALFORD:** The PHLS has no locus in specifically animal  
 [9] diseases. If the disease is confined to animals then we  
 [10] would not actually have a locus, nor would we have  
 [11] expertise in that area. Obviously if the disease is a  
 [12] zoonotic disease we have intense interest in that area.  
 [13] **MR FREEMAN:** It is a question of establishing whether it is  
 [14] one or not, I suppose. That provides a whole spectrum  
 [15] of difficulty, does it not? It is a logical difficulty  
 [16] apart from anything else: when does one decide it is a  
 [17] zoonosis if one does not actually do the work to  
 [18] discover whether it is one?  
 [19] **DR WALFORD:** In general these instances are discovered  
 [20] because of human disease which we then track back to the  
 [21] animals, rather than looking at the animals and seeing  
 [22] whether they give rise to disease.  
 [23] **MR FREEMAN:** Do you think that is the only way in which it  
 [24] can be done?  
 [25] **DR WALFORD:** Discovering an association between them?

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[1] **MR FREEMAN:** Yes. You went from A to B so to speak. Why  
 [2] can one not go from B to A?  
 [3] **DR WALFORD:** I think one of the things that those experts  
 [4] who were involved tried to do was to see if the agent  
 [5] which was causing it was an agent causing BSE which was  
 [6] transmissible to other species. Obviously they could  
 [7] not try it on man but they could try it on other  
 [8] species.  
 [9] **MR FREEMAN:** I am most grateful, thank you. We have heard a  
 [10] lot of evidence about the experiments that had been done  
 [11] in relation to that. Did you ever form a view, however  
 [12] firm, on whether this would cross the species barrier,  
 [13] BSE?  
 [14] **DR WALFORD:** I do not think that I had anything like enough  
 [15] information to be able to form a view, nor indeed might  
 [16] I personally have had the expertise. I would certainly  
 [17] need to have called upon colleagues in the PHLS with far  
 [18] more expertise in these areas than I have.  
 [19] **MR FREEMAN:** We will come on to that area later on. I am  
 [20] not going to pursue it now with any vigour.  
 [21] **MRS BRIDGEMAN:** Could I ask because I am interested, at the  
 [22] end of this paragraph, with the notion that there was  
 [23] zoonosis and shadow zoonosis. Had you had any  
 [24] experience where something was declared zoonosis under  
 [25] legislation but it was not a zoonosis really so we are

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[1] **MR FREEMAN:** Could we go now to the second page of the  
 [2] letter, and what in effect we were discussing, quite  
 [3] apart from whether it was a zoonosis, was whether it  
 [4] fell fairly and squarely within the PHLS's remit. That  
 [5] is in effect what we were discussing. There is a  
 [6] paragraph here, the third paragraph down:  
 [7] "Everyone agrees CJD is not communicable in the  
 [8] normal sense though it can be transmissible  
 [9] iatrogenically as well as experimentally to animals.  
 [10] There seems no need for the CDSC to get involved in the  
 [11] monitoring process. Indeed, if they were to be  
 [12] involved, this might give the message that somehow CJD  
 [13] can be spread person to person".  
 [14] It sounds like being stuck between a rock and a  
 [15] hard place, if I may say so. Given the press interest  
 [16] involved, do you think the PHLS would have amounted to  
 [17] an impression that this was a new communicable disease  
 [18] that had arrived in humans? Do you think it would have  
 [19] given that message out?  
 [20] **SIR JOSEPH SMITH:** I do not think so, no.  
 [21] **MR FREEMAN:** It is quite a - it is something that is being  
 [22] suggested?  
 [23] **SIR JOSEPH SMITH:** Yes, I mean I can understand some people  
 [24] may think that. But as you say, I mean it was quite  
 [25] clear from the recommendations of the Southwood Report

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[1] not going to treat it like one?  
 [2] **SIR JOSEPH SMITH:** No, I had not.  
 [3] **MRS BRIDGEMAN:** This was unique in your experience, that  
 [4] having been declared a zoonosis, the PHLS was not going  
 [5] to be involved?  
 [6] **SIR JOSEPH SMITH:** I do not remember one before.  
 [7] **MRS BRIDGEMAN:** We heard from Sir Kenneth Calman that the  
 [8] PHLS would not have been the right body because it only  
 [9] covered England and Wales. Have you any comment on  
 [10] that?  
 [11] **DR WALFORD:** I read it in the transcript of Sir Kenneth's  
 [12] evidence. It was certainly the first time the evidence  
 [13] had been deployed, as far as I recall. I have to say  
 [14] that I do not think it has any force. Although we are  
 [15] an England and Wales body and the statute only covers  
 [16] operation in England and Wales we do and can, by  
 [17] consent, coordinate surveillance across the UK; and  
 [18] indeed we coordinate surveillance for certain conditions  
 [19] across Europe. Just recently, for example, as a  
 [20] particular example of why it is possible provided  
 [21] everybody is happy that we should do it, we have just  
 [22] signed a contract with Northern Ireland to provide the  
 [23] Regional Epidemiological Service to Northern Ireland and  
 [24] that was done at the request of the CMO of Northern  
 [25] Ireland.

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[1] and the Tyrrell Committee, which were in the public  
 [2] domain, that the epidemiological studies to establish,  
 [3] hopefully to establish that it was not transmissible  
 [4] were very important. The fact that this was being done  
 [5] by the PHLS would only have said hopefully you have an  
 [6] organisation capable of doing that engaged in the work.  
 [7] **MR FREEMAN:** Are you in effect saying then - I see you  
 [8] nodding Dr Walford, do you agree with that? Is there  
 [9] anything further you would like to comment on on it?  
 [10] **DR WALFORD:** I think it is interesting to speculate, indeed  
 [11] to reflect on the thought that the general public  
 [12] understood at the time and understands perhaps as much  
 [13] about the work of the PHLS as is implied in this  
 [14] document to have made the inference that it must mean  
 [15] that it was communicable from person to person. I agree  
 [16] absolutely with Sir Joseph that if there was such an  
 [17] understanding of what the PHLS did, and we have noticed  
 [18] unfortunately the public is not as aware as it might be  
 [19] of the resource that there is in the PHLS, they would  
 [20] have been reassured by our involvement.  
 [21] **MR FREEMAN:** I suppose what you are saying is this would  
 [22] have shown to everyone and the world that BSE as a  
 [23] possibility of being transmitted to humans was being  
 [24] taken seriously?  
 [25] **DR WALFORD:** Thoroughly investigated.

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[1] **MR FREEMAN:** Really the early involvement of the PHLS might  
 [2] have given out a positive message?  
 [3] **DR WALFORD:** Indeed.  
 [4] **MR FREEMAN:** I want to move on to something else, so I do  
 [5] not know whether there are any questions that the  
 [6] Committee want to take up in relation to this matter?  
 [7] **SIR NICHOLAS PHILLIPS:** Yes, there certainly are.  
 [8] **PROFESSOR FERGUSON-SMITH:** I am looking at the laboratory  
 [9] studies of CJD. It has been suggested to us that  
 [10] because there was not a laboratory test for this  
 [11] condition and something that would not be available to  
 [12] the network of Public Health Laboratory, in fact the  
 [13] whole service, then there really was not much point in  
 [14] the PHLS being involved. I would be interested to hear  
 [15] your comments about that.  
 [16] **SIR JOSEPH SMITH:** Well, I was not too uncomfortable with  
 [17] that because I had, as I think I mentioned in the  
 [18] evidence, been involved with an MRC meeting on it. It  
 [19] was very clear that what was needed was basic research  
 [20] work in areas many of which, most of which in fact we  
 [21] had no body of expertise: protein chemistry for example,  
 [22] neurobiology. In that sense I think I was comfortable  
 [23] with the fact that we were, after the board meeting,  
 [24] allowed to do it but with research grants only. I was  
 [25] comfortable with that. It was the epidemiological

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[1] which may be spread over the country. In those events  
 [2] often you have to get individuals to go to visit the  
 [3] patients with the agreement of their doctors to do  
 [4] questions. In that I think we could have been extremely  
 [5] helpful.  
 [6] **PROFESSOR FERGUSON-SMITH:** So that is over and above  
 [7] leaving it to the responsibility of, for example,  
 [8] neurologists around the country to inform about possible  
 [9] epidemic?  
 [10] **SIR JOSEPH SMITH:** I think. Neurologists are clearly  
 [11] critically important in this; but there is also the  
 [12] epidemiological aspect. I mean the interviewing of  
 [13] somebody exposed to a disease has to be done very  
 [14] carefully; and I think modern epidemiologists and those  
 [15] in the PHLS are experienced in devising the sort of  
 [16] analytical questionnaires that have to be given to make  
 [17] sure you get an as unbiased and as complete a set of  
 [18] answers as possible to enable you to explore the  
 [19] possible hypotheses linking the infection or disease in  
 [20] question with possible aetiological factors. That is an  
 [21] expertise which we, I think, were experienced in.  
 [22] **PROFESSOR FERGUSON-SMITH:** Were these resources and this  
 [23] expertise offered to those involved in the study of BSE  
 [24] and new variant CJD, possible new variant CJD?  
 [25] **SIR JOSEPH SMITH:** I did not ring up anybody and say we

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[1] element I was very uncomfortable with.  
 [2] **PROFESSOR FERGUSON-SMITH:** That of course would not mean  
 [3] that you did not have resources that might help to  
 [4] develop diagnostic tests. The ELISA test for example  
 [5] and DNA tests were coming along at that time?  
 [6] **SIR JOSEPH SMITH:** I think there was no handle at that time  
 [7] on which to pin those ELISA tests to detect infection.  
 [8] I think as soon as such a test was on the horizon, then  
 [9] we could have been a valuable source for that kind of  
 [10] work.  
 [11] **PROFESSOR FERGUSON-SMITH:** Might you have contributed to  
 [12] the more rapid development of such tests?  
 [13] **SIR JOSEPH SMITH:** I think the more rapid exploitation of  
 [14] it, yes.  
 [15] **PROFESSOR FERGUSON-SMITH:** The other point I wondered  
 [16] about, you had not only a network of laboratories around  
 [17] the country but also a network of communicable diseases  
 [18] on the ground. Would they have had a helpful role in  
 [19] the surveillance for this disease?  
 [20] **SIR JOSEPH SMITH:** Yes, I believe they would. I mean, what  
 [21] you would have had to do essentially is to case finding  
 [22] studies of a rare condition. We were experienced in  
 [23] that in relation to rare conditions, in particular of  
 [24] childhood, but we were experienced in that sort of  
 [25] study, but also looking for rare cases in an outbreak

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[1] have these, I have to say that. On the other hand,  
 [2] I think those involved in considering the way the work  
 [3] should go were deeply aware of the expertise we could  
 [4] bring to it.  
 [5] **SIR NICHOLAS PHILLIPS:** Sir Joseph, have you read  
 [6] Sir Kenneth Calman's evidence?  
 [7] **SIR JOSEPH SMITH:** I skimmed it, that is all.  
 [8] **SIR NICHOLAS PHILLIPS:** Can I remind you of what he said on  
 [9] this topic? The first thing he said was he did think  
 [10] that the PHLS might have had a useful role to play in  
 [11] communication with your communication network.  
 [12] **SIR JOSEPH SMITH:** Yes.  
 [13] **SIR NICHOLAS PHILLIPS:** Then he added they was not sure  
 [14] they would have added anything in terms of the  
 [15] epidemiology of the disease. He went on to say this:  
 [16] "The key issue was to be the identification of  
 [17] people, young or old, because we did not know at the  
 [18] time who had a neurological disease. That was one to  
 [19] look out for. That was not necessarily what PHLS had  
 [20] the expertise in. That was our neurological colleagues,  
 [21] indeed the CJD Unit at the time."  
 [22] He was then asked:  
 [23] "Did you see any advantage in the PHLS developing  
 [24] such an interest or activity?  
 [25] "Answer: If they had to do that, (a) it would

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[1] have been two sources and (b) they would have had to  
[2] have brought on a whole lot of neurologists because the  
[3] whole purpose of the CJD Unit is when there is a  
[4] possible individual who might be affected with the  
[5] disease, they go interact, check on the examinations,  
[6] and that is an expertise which is not available within  
[7] the PHLS. It would seem unreasonable to duplicate that  
[8] when we already had it in Edinburgh."

[9] **SIR JOSEPH SMITH:** I mean, I think there is - I do not  
[10] think it is a complete - I do not think that is a  
[11] complete picture. I think we could - what I do not  
[12] know is the expertise that was available to the CJD  
[13] Surveillance Unit. It may have had, and indeed at the  
[14] time I was - understood that it had access to all the  
[15] necessary expertise. But I am not sure that it did; and  
[16] I think we may well have been able to bring the sort of  
[17] experience I have been talking about to this. But I do  
[18] not actually know that is the case, but I believe we  
[19] could have.

[20] **SIR NICHOLAS PHILLIPS:** The surveillance unit had the  
[21] assistance of Dr G Smith?

[22] **SIR JOSEPH SMITH:** I think that is Peter Smith.

[23] **SIR NICHOLAS PHILLIPS:** Would he have had available to him  
[24]

[25] **SIR JOSEPH SMITH:** He is a very distinguished and able

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[1] know a lot of this. But when I read Sir Kenneth's  
[2] evidence I was surprised at the notion that any such  
[3] neurological unit might have to be set up within the  
[4] PHLS. It is absolutely clear a right decision was taken  
[5] to have a neurological pathology unit, that was  
[6] essential because there was no method of case  
[7] ascertainment - of case verification rather of these  
[8] rare conditions. But the PHLS would have been able, and  
[9] indeed in my view should have worked in close  
[10] partnership with such unit to provide the field  
[11] epidemiology in particular.

[12] One of the interesting things that I subsequently  
[13] learnt about the epidemiological input to the unit, and  
[14] I endorse everything Sir Joseph said about the expertise  
[15] of Professor Peter Smith, was he told me personally that  
[16] he had not been involved in the design of the case  
[17] control study but merely in the statistical analysis of  
[18] the data. Furthermore, the unit did not have available  
[19] to it field epidemiologists to go out with the  
[20] neurologist to administer these very complex food  
[21] questionnaires. There is a colossal possibility of bias  
[22] when you administer food questionnaires, food recall  
[23] questionnaires in these circumstances. And the design  
[24] of these questionnaires and their administration is a  
[25] very skilled job which our field epidemiologists have.

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[1] epidemiologist at the School of Hygiene and Tropical  
[2] Medicine. I am not sure he himself would have had the  
[3] sort of field experience of the sort of study we are  
[4] talking about, but he would have known where to get that  
[5] expertise.

[6] **SIR NICHOLAS PHILLIPS:** The other question I asked  
[7] Sir Kenneth Calman was whether, taken that the decision  
[8] was reached: we must set up a specialist unit to look at  
[9] this field, could it have been set up within the PHLS?

[10] **SIR JOSEPH SMITH:** I think undoubtedly, yes.

[11] **MR FREEMAN:** Yes, thank you very much.

[12] **PROFESSOR FERGUSON-SMITH:** Can I just add: how important  
[13] was it to have the number of fieldworkers and the number  
[14] of people in the network on the ground around the  
[15] country that the PHLS had? How important would that  
[16] have been in the surveillance, if that had been used?

[17] **SIR JOSEPH SMITH:** Possibly not in the early stages when  
[18] there were very few cases. It is possible the centrally  
[19] located group coped with it. But as the Inquiry perhaps  
[20] broadens and you have to go into very considerable  
[21] detail on the cases, the involvement of people locally  
[22] could have helped.

[23] **DR WALFORD:** If I might comment please, because obviously  
[24] this happened at a time and I was not aware of this  
[25] letter in fact until very, very recently, so I did not

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[1] And however skilled the research neurology registrars  
[2] available to the unit may have been, they did not have  
[3] training appropriate or sufficient training in this area  
[4] and a partnership with the PHLS would have allowed a  
[5] field epidemiologist to go out with the neurologist to  
[6] interview cases, or rather to interview their relatives.

[7] **SIR NICHOLAS PHILLIPS:** Have you considered the  
[8] questionnaires used by the surveillance unit?

[9] **DR WALFORD:** No, I have not seen them.

[10] **MR FREEMAN:** Thank you. I want to now show you a document  
[11] which in fact your solicitors provided for us I think  
[12] either yesterday or just the afternoon of yesterday.

[13] And I believe it is in a loose bundle which has been  
[14] provided to the Committee. They do not have it readily  
[15] to hand, we can provide another copy. That is meeting 3  
[16] of the PHLS Strategic Review Group of 24th March 1994.

[17] I am sorry it has not found its way into the year book  
[18] yet.

[19] You have seen this document before, Sir Joseph,  
[20] have you?

[21] **SIR JOSEPH SMITH:** Yes.

[22] **MR FREEMAN:** And you have seen this document before,  
[23] Dr Walford?

[24] **DR WALFORD:** Absolutely.

[25] **MR FREEMAN:** I want to go first, although there may be a

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[1] number of things I am going to take you to in this  
 [2] document, I want to go first to page 5 of the document,  
 [3] please. Do you have it? Then this is said, at the top  
 [4] of page 5:  
 [5] "Sir Donald Acheson first addressed issues about  
 [6] the distinctive strengths of the PHLS and his assessment  
 [7] of its international standing. The key points were as  
 [8] follows:  
 [9] "The PHLS is recognised as a system which is  
 [10] admired nationally and internationally...  
 [11] "Other countries lack this accountable network of  
 [12] laboratories and regard it as an ideal system," that  
 [13] being described earlier on.  
 [14] Taking those points and following on from my  
 [15] question about do you remember that it might have shown  
 [16] that the Government and Department of Health took the SE  
 [17] seriously as a human health issue, did the PHLS have a  
 [18] role internationally in terms of - how did you relate,  
 [19] for example, to our European partners? Did you have  
 [20] contacts with France and Germany and so forth?  
 [21] **DR WALFORD:** Very much so indeed. In fact the Director of  
 [22] the Communicable Disease Surveillance Centre chaired a  
 [23] group of bodies involved in European surveillance called  
 [24] the Charter Group. I am not sure whether the Charter  
 [25] Group was in place at the time of this minute of

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[1] Dr Walford, but one of your concerns - we may come back  
 [2] to it and describe how this really came about - but one  
 [3] of your concerns was that the PHLS should at least  
 [4] develop a capability in prion disease. Would you care  
 [5] to expand on that?  
 [6] **DR WALFORD:** Yes, this came out of discussions in the  
 [7] Strategic Review Group, reviewing the Public Health  
 [8] Laboratory Service and some of those discussions are in  
 [9] the minutes of the Review Group, but clearly they are  
 [10] condensed. What was the concern for us was that  
 [11] although we were not to be permitted to engage in the  
 [12] surveillance of CJD at that time, there would come a  
 [13] time when, particularly if there became some feeling  
 [14] that there was a human health hazard, that the  
 [15] Government would turn to us very rapidly. Our concern  
 [16] was that we were in no way prepared to handle that, as  
 [17] we should have been and as we would have been had we  
 [18] been fully involved. In particular the science of  
 [19] prions was something that our scientists, our doctors  
 [20] had not been involved in.  
 [21] What is meant by the small capability there is  
 [22] that we should have perhaps seconded a couple of our key  
 [23] scientists to laboratories working on prion disease so  
 [24] that we had a better understanding of the molecular  
 [25] issues, not necessarily that we would do any basic

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[1] Sir Donald's evidence, but he was very active, as were  
 [2] other colleagues in CDSC, in Europe at the time. There  
 [3] is a surveillance network in Europe which we are in many  
 [4] respects leading players in. We do, as I have said  
 [5] before, coordinate several networks of surveillance in  
 [6] Europe.  
 [7] **MR FREEMAN:** We do know that MAFF personnel and scientists  
 [8] being called on by MAFF went to Europe to meet other  
 [9] people in Europe who were concerned about BSE. And do  
 [10] you think the involvement of the PHLS might have made  
 [11] some contribution in terms of international confidence  
 [12] in relation to the crisis as it emerged?  
 [13] **DR WALFORD:** If the PHLS had been involved in surveillance,  
 [14] yes, rather than just accompanying people on visits to  
 [15] Europe where that might not have necessarily conveyed  
 [16] any particular message. But I would have felt from our  
 [17] colleagues overseas, particularly for example in the  
 [18] centres for disease control in Atlanta, with which we  
 [19] have the very closest of relationships, that they would  
 [20] have felt it appropriate, proper, and in many respects,  
 [21] as I say, reassuring for the PHLS to have been involved.  
 [22] **MR FREEMAN:** Would you just pause for a moment, please?  
 [23] I want to see if there is anything else that - yes,  
 [24] could you please go to page 3? Now, one of your  
 [25] concerns was, this is quite a bit later on in the story

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[1] research there because it was quite clear we did not  
 [2] have the expertise for basic research in this area,  
 [3] which was unknown to us. Should a putative diagnostic  
 [4] test become available or if we could see opportunities  
 [5] for developing a diagnostic test, we would be reasonably  
 [6] up to speed with the science of prions to enable us to  
 [7] do that.  
 [8] **MR FREEMAN:** Yes, thank you for that answer. Would it have  
 [9] helped you to lead to the identification of new variant  
 [10] CJD, do you think?  
 [11] **DR WALFORD:** It is clear if there existed an ante-mortem  
 [12] test for infection with prions then surveillance takes  
 [13] on a whole new dimension. We would have been able to  
 [14] undertake surveillance in the way in which we normally  
 [15] do, which is based on laboratory tests.  
 [16] **MR FREEMAN:** I want to turn now to this development of a  
 [17] diagnostic test and discuss it with you. Before I do,  
 [18] Sir Joseph, do you want to comment on this matter? Do  
 [19] you think it would have been a good idea for the PHLS to  
 [20] have developed a modest capability in the area of prion  
 [21] disease?  
 [22] **SIR JOSEPH SMITH:** I think the idea of seconding one or two  
 [23] people to work in a reputable centre to gain hands-on  
 [24] experience of it would have been useful to put us in a  
 [25] position to exploit any development that might lead to a

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[1] diagnostic test as early as possible. I thought that  
[2] was a good proposal.  
[3] **MR FREEMAN:** You mention in paragraph 22 of your statement,  
[4] you make mention of Dr Narang?  
[5] **SIR JOSEPH SMITH:** Yes.  
[6] **MR FREEMAN:** Do you think Dr Narang was right to seek a  
[7] diagnostic test?  
[8] **SIR JOSEPH SMITH:** Well, yes. In principle, yes.  
[9] **MR FREEMAN:** Is this something the PHLS in general was  
[10] equipped to do?  
[11] **SIR JOSEPH SMITH:** Well, in respect of electron microscopy,  
[12] I would have thought very much so. It is in the areas  
[13] of protein detection and protein chemistry and the  
[14] questions of genetic susceptibility to prion disease  
[15] I think would have been then outwith our expertise.  
[16] **MR FREEMAN:** Do you have a view on whether Dr Narang's work  
[17] has got us any closer to a diagnostic test?  
[18] **SIR JOSEPH SMITH:** Up to the time I had left I think the  
[19] main development he had worked on was the use of a more  
[20] rapid electron microscopic diagnostic method for  
[21] post-mortem brains. And we were - it would seem to be  
[22] certainly in his hands to work satisfactorily but which  
[23] needed, we thought, to be evaluated independently to see  
[24] how robust and reliable it might be in practice. What  
[25] the practical value of the test was I was more uncertain

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[1] **DR WALFORD:** Pre March 1996 we were not permitted to work  
[2] on CJD, BSE/CJD.  
[3] **MR FREEMAN:** Yes. Thank you. I want to return a little to  
[4] epidemiology and surveillance in the light of the  
[5] answers that you have given. If I may make an  
[6] observation that very clear and helpful answers they  
[7] have been. What was the justification for not carrying  
[8] out surveillance in children from say 1990. I do not  
[9] know whether, Sir Joseph, you would like to answer that  
[10] first. Was there a justification for not carrying out  
[11] surveillance in children?  
[12] **SIR JOSEPH SMITH:** I am not aware of a justification for  
[13] not doing it. It would seem to me important to do it.  
[14] **MR FREEMAN:** The target given was 16 to 75. What was being  
[15] looked at were changes in sporadic CJD, what was  
[16] regarded as classic or sporadic CJD?  
[17] **SIR JOSEPH SMITH:** I am not sure of the rationale for  
[18] that. I assume it must have been to do with the  
[19] evidence of susceptibility to prion disease of certain  
[20] ages and the incubation period being long. It would  
[21] have been wise, I think, to have embraced paediatric  
[22] surveillance in the surveillance of CJD.  
[23] **MR FREEMAN:** Could you explain what the British Paediatric  
[24] Surveillance Unit is, please?  
[25] **SIR JOSEPH SMITH:** Well, we set up in 1985, I think, a

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[1] about, but it could have been certainly of practical  
[2] value but only in the post-mortem sense then.  
[3] **MR FREEMAN:** Dealing with ante-mortem tests, concentrating  
[4] on that, this may be a highly speculative question or at  
[5] least the answer may be. Only answer it if you think  
[6] you can of course. If the PHLS had been directed to  
[7] work on this subject, that of an ante-mortem test, do  
[8] you think it might have produced one?  
[9] **SIR JOSEPH SMITH:** I do not know. We might have. But I do  
[10] not know sir.  
[11] **MR FREEMAN:** Dr Walford, do you want to say something about  
[12] that?  
[13] **DR WALFORD:** Only to say although we have not been directed  
[14] to work on that test, the Leeds Public Laboratory in  
[15] partnership with Dr Stephen Dealler has won a  
[16] substantial research grant from the Department of Health  
[17] to develop an ante-mortem test.  
[18] **MR FREEMAN:** We are speaking the same language because you  
[19] say this in your paragraph 23, subsection 4, that since  
[20] March 1996 there is at the Department of Health a funded  
[21] research project, as you say, to develop a diagnostic  
[22] test.  
[23] I do not think this is a very difficult question  
[24] but if it is you will say so. Is there any special  
[25] reason why this had to wait until post March 1996?

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[1] linkage with the British Paediatric Association to keep  
[2] under surveillance rare paediatric diseases to establish  
[3] basic information about them, incidence, relationships  
[4] to causative factors. The scheme involved active case  
[5] searching, which is very important, in which essentially  
[6] you have to get the cooperation of paediatricians to  
[7] report monthly on whether they have seen these chosen  
[8] diseases or not. If you do not get answers, you have to  
[9] go back to them to make sure you get every possible  
[10] case. This had been very successful, particularly two  
[11] examples I would particularly associate it with was of  
[12] Reye's syndrome, which is a rare complication of the use  
[13] of Aspirin in febrile, fever diseases, such as  
[14] influenza, and established that that linkage did exist  
[15] in this country, and that led to modifications about the  
[16] national advice on the use of Aspirin in children. Also  
[17] sub acute sclerosing pan encephalitis, which is a rare  
[18] encephalitis which is a complication of measles. We  
[19] were particularly keen to establish whether or not this  
[20] could occur after measles vaccine. The surveillance  
[21] showed that, in fact, the vaccine protected against it.  
[22] That was a group of children with neurological disease  
[23] which may well have included possible cases of CJD.  
[24] **MR FREEMAN:** I can see that Dr Walford is anxious to speak  
[25] about this. That is because we have both read the same

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[1] material. Dr Walford, I am not going to prevent you  
[2] from doing so. You say something about this in  
[3] paragraph 23, do you not, of your statement? It is your  
[4] second statement.  
[5] **DR WALFORD:** Yes. Just to say that this - the BPSU  
[6] arrangements, I believe, are a good model for what we  
[7] might have done in relation to the surveillance of CJD  
[8] as a whole. Firstly, of course, it is active  
[9] surveillance; it is polling the neurologists or  
[10] particular groups of clinicians actively and expecting  
[11] null returns from them also. That is a very powerful  
[12] means of detecting rare conditions. Secondly, that  
[13] operates on, effectively, a UK wide basis. We work  
[14] closely there with the British Paediatric Association  
[15] together with ourselves. So that essentially we could  
[16] have covered the UK in relation to such a survey; and  
[17] the same thing could have applied had we been asked to  
[18] take on collaborative work in relation to the  
[19] surveillance of CJD in all age groups. We would have  
[20] worked then with partners - partners - neurologists  
[21] just as we do. There is a comparable network called the  
[22] British Neurological Surveillance Unit.  
[23] **SIR NICHOLAS PHILLIPS:** If one asks the question, in that  
[24] area, in what respects, if any, would you have been  
[25] better placed to carry out such surveillance than a new

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[1] CJD Surveillance Unit being set up, what would your  
[2] answer be?  
[3] **DR WALFORD:** In the paediatric area?  
[4] **SIR NICHOLAS PHILLIPS:** Yes.  
[5] **DR WALFORD:** We had significant experience of running this  
[6] scheme. We provided the consultant epidemiologist, who  
[7] was actually the adviser to this scheme. It had worked  
[8] particularly well as a partnership, that was the British  
[9] Paediatric Surveillance Unit. We also had partners in  
[10] the British Neurological Association and the Institute  
[11] of Neurology. Equally, we could have operated such a  
[12] scheme together with those parties. On the other hand,  
[13] we could equally well have operated it in partnership  
[14] with Dr Will's unit.  
[15] **SIR NICHOLAS PHILLIPS:** What you are really saying, as  
[16] I understand it, is you already had in place the  
[17] communication links with the world of neurology that you  
[18] could have tapped?  
[19] **DR WALFORD:** Absolutely.  
[20] **MR FREEMAN:** Just to reinforce this point, could you look at  
[21] paragraph 16 of your statement? What you say there is  
[22] that you invited Dr Will, 14th December 1995, to the  
[23] PHLS at Colindale in order to give him access to the  
[24] PHLS database in cases of could you pronounce it?  
[25] **DR WALFORD:** Sub acute sclerosing encephalitis. SSPE.

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[1] **MR FREEMAN:** I would like to learn a bit as we go along.  
[2] Can you explain what that is, please?  
[3] **DR WALFORD:** Sir Joseph previously described it. It is a  
[4] slowly developing dementing disorder which usually  
[5] occurs some 7 years or so after measles - when I say  
[6] "usually occurs", of course it is extremely rare, but  
[7] it occurs some quite long period after.  
[8] **MR FREEMAN:** Are these similar clinical signs, in diagnostic  
[9] terms, to new variant CJD?  
[10] **DR WALFORD:** Sir Joseph may know more about this than I do;  
[11] I am sure he does. Clearly Dr Will felt that miss  
[12] classification could occur. He thought there might be  
[13] such a case, and was keen to examine our database  
[14] there. That database is part of the register we are  
[15] able to hold of rare diseases.  
[16] **MR FREEMAN:** Is there any reason why that database could not  
[17] have been examined well - when was it set up exactly?  
[18] **SIR JOSEPH SMITH:** 1985.  
[19] **MR FREEMAN:** So at any period after 1988 is there any reason  
[20] why it could not have been looked at?  
[21] **DR WALFORD:** None at all.  
[22] **MR FREEMAN:** I want to ask you again, I believe you have  
[23] answered these questions adequately. This is before we  
[24] perhaps break for coffee. Nobody thought apparently  
[25] that CJD would occur in children. I want to ask you

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[1] whether at the time, was that a valid proposition?  
[2] **SIR JOSEPH SMITH:** I mean, I do not have great expertise in  
[3] the field, but I think it was an understandable; but it  
[4] would have been, I think, wise to address the  
[5] possibility that it could have occurred in children. If  
[6] the disease were to be transmissible to humans one did  
[7] not know the incubation period; and there was evidence  
[8] from the study of prion disease generally that the  
[9] incubation period of prion disease could often change  
[10] when a disease was experienced in a fresh animal  
[11] species. So you could not forecast what the incubation  
[12] period would be in humans although it was likely to be  
[13] long, but you did not know it.  
[14] **MR FREEMAN:** Yes. Perhaps asking the question in a  
[15] different way, maybe it is just exactly the same answer:  
[16] but what was the scientific justification in your view  
[17] for excluding the group from study?  
[18] **SIR JOSEPH SMITH:** I have no idea what that would have  
[19] been. I doubt if there was a strongly - I doubt if  
[20] there was an overwhelming reason. There may have been  
[21] contributory factors such as the long incubation period.  
[22] **MR FREEMAN:** Do you want to comment, Dr Walford?  
[23] **DR WALFORD:** I can only speculate. CJD had not really been  
[24] known in this age group, this younger age group. It is  
[25] possible that the case definition therefore dictated in

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[1] some way which group of the population was going to be  
 [2] looked at.  
 [3] **MR FREEMAN:** I want to ask one question in addition to the  
 [4] one I have already asked you to contemplate over the  
 [5] break. I hope it will not spoil your coffee break. It  
 [6] is really this: perhaps you would like to put your mind  
 [7] to the question whether all these benefits that the  
 [8] PHLS, all these benefits you are saying the PHLS would  
 [9] have brought to the arena, whether it would have  
 [10] actually have made a difference to identifying a case of  
 [11] new variant CJD?  
 [12] **DR WALFORD:** To identifying a case?  
 [13] **MR FREEMAN:** To identifying a case.  
 [14] **SIR NICHOLAS PHILLIPS:** We will have about a quarter of an  
 [15] hour.  
 [16] **PROFESSOR FERGUSON-SMITH:** Before we do so, it is not clear  
 [17] to me what the result of this offer of the access to the  
 [18] PHLS database on SSPE, what the conclusion was of this  
 [19] offer. What happened, could you tell us that?  
 [20] **DR WALFORD:** Certainly. Dr Will was very keen to examine  
 [21] the database and he came down very rapidly after my  
 [22] telephone call and went through all the cases and felt  
 [23] that there were a small number of cases that really  
 [24] deserved further scrutiny. He I believe took away  
 [25] copies of the particular case information for the

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[1] bacterial vaccines may be the bacteria grown in culture,  
 [2] which certainly in days of old were made in broths  
 [3] prepared by cooking up animal things like ox heart and  
 [4] so on; and the veterinary – the viral vaccines were  
 [5] generally made – are generally made in tissue culture  
 [6] which probably increasingly are now chemically defined  
 [7] cultures but certainly may still include fresh serum in  
 [8] some of them, foetal calf serum in particular. I would  
 [9] not know that without going to the product licences  
 [10] which I would not have access to. The short answer is  
 [11] I do not know, I apologise.  
 [12] **MR FREEMAN:** Absolutely no need to apologise. Thank you for  
 [13] trying. I also asked both of you if you could identify  
 [14] whether the PHLS's involvement, given all the benefits  
 [15] you have described, would have made any difference to  
 [16] the identification of new variant CJD. Would you care  
 [17] to comment on that?  
 [18] **DR WALFORD:** I wonder if I might comment on behalf of both  
 [19] of us since you gave us the opportunity to confer over  
 [20] coffee. Obviously we cannot know whether that might  
 [21] have been so. But I do think that there was a good  
 [22] chance that we might have been able to ascertain cases  
 [23] that could not necessarily, would not necessarily have  
 [24] come to the attention of a surveillance which was done  
 [25] predominantly through the neurological network. We have

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[1] purpose of looking into it in more depth.  
 [2] **PROFESSOR FERGUSON-SMITH:** And was there any follow-up?  
 [3] **DR WALFORD:** I have not heard if he found any particular  
 [4] case misclassified as a result of that look. But it was  
 [5] clear that that was a search that needed to have been  
 [6] done.  
 [7] **PROFESSOR FERGUSON-SMITH:** Thank you.  
 [8] **SIR NICHOLAS PHILLIPS:** Thank you.  
 [9] (11.10 am)  
 [10] (Short Break)  
 [11] (11.26 am)  
 [12] **MR FREEMAN:** I hope you had a pleasant coffee break. Sir  
 [13] Joseph, do you recall I asked you to consider holiday  
 [14] vaccines and whether that might have been a concern?  
 [15] **SIR JOSEPH SMITH:** Yes. I thought hard about it and the  
 [16] answer is I do not know. The reason is I think to  
 [17] actually find out the ingredients in the vaccines you  
 [18] would have to go through the product licence of each,  
 [19] because that would be probably not generally in the  
 [20] public domain, although in principle I think that all of  
 [21] the vaccines which might be used for holidays which  
 [22] would include, of course, the children's vaccines,  
 [23] because children would need to ensure if possible their  
 [24] ordinary immunisation schedule was up-to-date, would  
 [25] have to be looked at and thought about because the

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[1] huge experience in multiple source case ascertainment,  
 [2] which means that any possible source of cases can be  
 [3] looked at by us. We have already described the SSPE  
 [4] register which was not obviously known to the CJD  
 [5] Surveillance Unit.  
 [6] We are aware of all the various registers. We are  
 [7] well used to using hospital discharge statistics,  
 [8] obviously death certificates also, but I believe that  
 [9] the unit did look at death certificates. We had the  
 [10] opportunity to go into the British survey of paediatric  
 [11] cases, had we been involved at an earlier date.  
 [12] I believe we potentially had the opportunity to  
 [13] ascertain cases, perhaps those which presented  
 [14] atypically perhaps presenting to psychogeriatricians or  
 [15] to paediatric psychiatrists, because psychiatric  
 [16] symptoms are a significant problem in new variant CJD,  
 [17] it appears, that we might have been able to ascertain  
 [18] the cases, more cases than they had done.  
 [19] That said, I wonder if I might just say that  
 [20] I think we potentially might have done that even more  
 [21] effectively because the whole surveillance would have  
 [22] been totally plugged in to the public health  
 [23] fraternity. Where SEAC was hampered I believe, and  
 [24] where maybe the CJD Surveillance Unit equally, was that  
 [25] it was not plugged into the normal public health

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[1] fraternity and had we been able to discuss in the way we  
[2] normally do with all public infectious diseases with all  
[3] our public health colleagues throughout the country,  
[4] then they may have brought to our attention quite  
[5] possibly putative cases that we could have asked the  
[6] Neurological Surveillance Unit to look at. Clearly we  
[7] would have been in a position to take their collective  
[8] wisdom on an issue in a way I do not believe the  
[9] Government was able to do.

[10] **MR FREEMAN:** I would like to follow that up a little by some  
[11] specific cases. We know that in 1994 there was a case  
[12] of a young person who I am just going to check the age  
[13] - Vicky Rimmer, who was aged 16 at the time. She went  
[14] into a coma. Now, it was one of the diagnoses on her -  
[15] obviously people were trying to do a differential  
[16] diagnosis - one of the diagnoses that was suggested was  
[17] CJD, and nobody knew then that it was a new variant  
[18] case.

[19] Later on, on 1st April 1995, another young person,  
[20] 19 years old; then on 22nd August 1995 a third. Now,  
[21] I say a third because of course the first may or may not  
[22] have been one. Do you think that if the PHLS had been  
[23] involved - what do you think your reaction would have  
[24] been to the emergence of those three cases in August  
[25] 1995? Would you care to answer that, Dr Walford?

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[1] Surveillance Unit study up and running as fast as  
[2] possible. It did only take off in 1997, whereas we had  
[3] obviously within the service and within the British  
[4] Paediatric Surveillance Unit been thinking of  
[5] establishing such a survey, such a surveillance very  
[6] much earlier; and it should, I think, have been set up  
[7] as soon as this anxiety was raised and taken forward in  
[8] a very active surveillance mode, were cases of CJD in  
[9] teenagers being missed because they were presenting  
[10] atypically, and indeed one might have done a respective  
[11] trawl of the various neurological presentations which  
[12] had come to that unit and to see whether or not any case  
[13] could be pulled out which might conceivably have  
[14] represented a misdiagnosed case of CJD.

[15] **MR FREEMAN:** I want to focus on one category of people here  
[16] apart from the paediatric cases. One possible category  
[17] that may have been missed, I put it no higher than that,  
[18] I know not. The Inquiry has no conclusion on this, but  
[19] one category that may have been missed is people who  
[20] might be regarded as in the care of psychiatric - as  
[21] they called to be psychiatric geriatricians, perhaps now  
[22] the right term is psychiatric care of the elderly. In  
[23] those days they were called psychiatric geriatricians.  
[24] People were placed in their care. They could be  
[25] people in an intermediate age group. What I mean by

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[1] **DR WALFORD:** I think that this would have constituted a  
[2] highly unusual event, if I have understood the  
[3] epidemiology of sporadic CJD correctly, insofar as it  
[4] was extremely unusual to have cases in such young  
[5] people. Therefore, I suspect we would have treated this  
[6] as, as it were, an outbreak, a cluster, an outbreak  
[7] which needed investigation in the way that we would  
[8] normally go into an investigation of an outbreak, with a  
[9] very intensive case control study and looking at risk  
[10] factors and really obviously subject of course to the  
[11] diagnosis having been confirmed by the CJD Surveillance  
[12] Unit, which would have been their job.

[13] **MR FREEMAN:** Well, now, the latter two cases were confirmed  
[14] and were confirmed by 22nd August 1995. And what was  
[15] decided upon them was that there should be - this did  
[16] cause some concern, but the words used were: "This was  
[17] not a unique event". Something of the statistics of six  
[18] to nine people in 3,000 cases of CJD cases worldwide in  
[19] 75 years are I believe the real statistics. Words like  
[20] "not unprecedented" were used or "not unique". A  
[21] decision was made at that stage, it seems, to continue  
[22] with the CJD Unit doing its surveillance; that is how it  
[23] was described. Would you care to comment on that?

[24] **DR WALFORD:** I think what we would have almost certainly  
[25] wanted to do would be to get the British Paediatric

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[1] that is perhaps something over 60 years of age, but not  
[2] strictly speaking regarded as elderly. They were  
[3] showing the sort of signs which would be confused with  
[4] dementia, that kind of thing. Would you have looked at  
[5] those sort of cases, do you think?

[6] **DR WALFORD:** Yes, I think I mentioned earlier that  
[7] psychogeriatricians, as I perhaps wrongly alluded to  
[8] them, would have been a group which I would have  
[9] thought, given the psychiatric presentation as  
[10] I understand of new variant CJD, should have been looked  
[11] at very carefully.

[12] **MR FREEMAN:** Now, we do not know for sure what contact there  
[13] was made with them by the CJD Surveillance Unit, but you  
[14] would presumably have had a network of contacts that  
[15] would have involved them, would you?

[16] **DR WALFORD:** Not specifically psychogeriatricians. We are  
[17] able to make contact with clinicians in a general way.  
[18] It is accepted that the PHLS, when it is inquiring in  
[19] relation to an infection, is able to make contact and it  
[20] is understood the reason for making such contact is well  
[21] understood and we get significant cooperation. We would  
[22] have, should we have wanted to do that, have been able  
[23] to get a database of who these individuals were and  
[24] actually to have polled them in the way I have  
[25] described.

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[1] **MR FREEMAN:** You have described very more than adequately in  
 [2] my view, you have described how you would have acquired  
 [3] information, you would have regarded that as something  
 [4] more than just raw data from which you could have drawn  
 [5] some conclusions and so on. What I want to talk to you  
 [6] about is perhaps the other half of this aspect, is  
 [7] having got your information and drawn some albeit  
 [8] tentative conclusions, how one might get that  
 [9] information back into the public health professional  
 [10] world.

[11] I am going to start with Sir Joseph here because  
 [12] it is a way in, I think. If you turn to paragraph 16 of  
 [13] your statement, Sir Joseph. Do you have it?

[14] **SIR JOSEPH SMITH:** Yes.

[15] **MR FREEMAN:** You describe there, in other circumstances than  
 [16] perhaps the one we are describing, a fast-track  
 [17] professional letter. Can you describe what you mean by  
 [18] a fast-track professional letter?

[19] **SIR JOSEPH SMITH:** It was a term used by the Department of  
 [20] Health for a letter on an urgent topic that needed to be  
 [21] - to convey information of importance to the medical  
 [22] profession, is how I understand it.

[23] **MR FREEMAN:** Is it your impression that those letters are  
 [24] read?

[25] **SIR JOSEPH SMITH:** I would have thought this one was because

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[1] adequately, described it that this was a real concern,  
 [2] you had got one case of potential CJD in a young person  
 [3] and two confirmed cases; would that, do you think, have  
 [4] resulted in something in a Communicable Disease Report?

[5] **SIR JOSEPH SMITH:** Well, I think that would have been  
 [6] certainly a very practical means of conveying the  
 [7] information. It may have needed a bit of  
 [8] supplementation, but I think it would be a very good  
 [9] vehicle.

[10] **MR FREEMAN:** Perhaps Dr Walford could help with this. Have  
 [11] things changed over the years? Is that the main means  
 [12] by which the PHLS disseminates information?

[13] **DR WALFORD:** The Communicable Disease Report is a very  
 [14] important weekly means of disseminating information to  
 [15] the field, as Sir Joseph has said. There are  
 [16] developments of course, as you well understand, since  
 [17] that time. It is the case that even I think, Joe, in  
 [18] your time there was an electronic means of communication  
 [19] called Epinet, which meant that we could communicate  
 [20] with all public health professionals, departments of  
 [21] public health, district directors of public health, to  
 [22] alert them to something. Subsequently, of course, we  
 [23] have had even further electronic developments insofar as  
 [24] we have our PHLS website home page, the Internet and we  
 [25] also publish on behalf of the European Community an

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[1] it was addressed, as I recall, to ophthalmic surgeons  
 [2] and neurosurgeons, who would I think have already been  
 [3] alert to the potential for a risk there. You might have  
 [4] expected that one to have been read but there is clearly  
 [5] always a problem of communication.

[6] **MR FREEMAN:** What means does the PHLS have to disseminate  
 [7] information? I am going to ask both of you this.  
 [8] Perhaps Sir Joseph could start in his time?

[9] **SIR JOSEPH SMITH:** The principal vehicle we had was the  
 [10] Communicable Disease Report which is a weekly  
 [11] publication prepared to give current infection  
 [12] statistics and a comment on current infection issues of  
 [13] importance. This goes to all public health doctors,  
 [14] microbiologists, Environmental Health Departments in the  
 [15] country, including Scotland. And that enables the  
 [16] people in a locality to be aware of current issues, and  
 [17] for example the consultant in communicable disease  
 [18] control of each district would have it and would, I am  
 [19] positive, read it to see what current issues were.

[20] If there was for example something like this, he  
 [21] would think it his responsibility, I would expect, to  
 [22] ensure that the information was conveyed within his  
 [23] district to those who needed to know.

[24] **MR FREEMAN:** Let us say if you had been involved, you had  
 [25] formed a view as Dr Walford very, again more than

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[1] electronic surveillance bulletin and we can actually  
 [2] flash up on that bulletin within 24 hours' notice across  
 [3] Europe any developments which are key.

[4] Now, it is not clear to me, of course, and I would  
 [5] not wish to use any hindsight here, whether or not we  
 [6] would have employed that mechanism. But our CDR appears  
 [7] on the website.

[8] **MR FREEMAN:** What is CDR?

[9] **DR WALFORD:** Communicable Disease Report. There would have  
 [10] been more instant access than the paper document. The  
 [11] front page of the paper document, which is the "stop  
 [12] press", here is something really quite important, is  
 [13] read very widely by those with a need to know.

[14] **MR FREEMAN:** Was it "Epinet"?

[15] **DR WALFORD:** E-P-I-N-E-T.

[16] **MR FREEMAN:** Could you say to whom that is sent?

[17] **DR WALFORD:** It goes to all directors of public health,  
 [18] consultants in communicable disease control, Public  
 [19] Health Laboratories. I think that is the main  
 [20] distribution.

[21] **SIR JOSEPH SMITH:** National Health laboratories certainly in  
 [22] Wales when it started.

[23] **MR FREEMAN:** How would this information for example have  
 [24] found its way to, say, a psychiatrist first and a GP  
 [25] second?

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[1] **DR WALFORD:** I would be delighted but surprised if  
 [2] psychiatrists or general practitioners read the  
 [3] Communicable Disease Report. However, if the public  
 [4] health fraternity was seized of an issue of concern,  
 [5] then that obviously gets disseminated through their  
 [6] local mechanisms. That is probably the way in which  
 [7] general practitioners might have become -  
 [8] **MR FREEMAN:** People speak to each other. There are local  
 [9] meetings where public health professionals speak to GPs  
 [10] and the like, do they not? There are Medical Society  
 [11] meetings?  
 [12] **DR WALFORD:** Absolutely.  
 [13] **MR FREEMAN:** There are a number of means by which the  
 [14] material would descend as it were. This is perhaps a  
 [15] speculative question, but can you say, in dealing with  
 [16] reducing health scares, if that is what they are, do you  
 [17] think there is advantage in, as it were, letting  
 [18] everyone know in the health professional side about  
 [19] something that is emerging?  
 [20] **DR WALFORD:** I do not know that that would deal with health  
 [21] scares because the health scares are not generated by  
 [22] the health professionals, they are generated in general  
 [23] by a good story in the media. It does not seem to me  
 [24] there is any good way of getting information out for  
 [25] further discussion without it generating a scare. That

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[1] see that?  
 [2] **DR WALFORD:** If we are talking about paediatric cases at  
 [3] the time I do not know if they would have contemplated  
 [4] CJD even at the lowest end of the differential  
 [5] diagnosis. I do think health professionals are very  
 [6] interested in what they are reading in the media.  
 [7] Sometimes, if the system is not working adequately in  
 [8] getting high quality advice out, they will have to rely  
 [9] on the media for the information it can get.  
 [10] **MR FREEMAN:** Given that you do have a means for getting  
 [11] proper information out, do you think this might have  
 [12] found its way to GPs, psychiatrists, those type of  
 [13] people where it seems people were initially sent when  
 [14] they had a case of new variant CJD?  
 [15] **DR WALFORD:** If we felt that was something that needed  
 [16] doing, then the front page of the Communicable Disease  
 [17] Report would have requested public health professionals  
 [18] to ensure that their local GPs knew about it.  
 [19] **MR FREEMAN:** And psychiatrists presumably?  
 [20] **DR WALFORD:** And psychiatrists, whichever route you chose.  
 [21] **MR FREEMAN:** If you had learned that the first clinical  
 [22] signs of CJD could be confused, and therefore people  
 [23] were being sent towards psychiatrists, one, of course,  
 [24] hopes psychiatrists will do some neurological test to  
 [25] see whether they in fact are a psychiatric patient or

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[1] in my view is not a good enough reason for withholding  
 [2] the information. And I am very impressed by the  
 [3] American way of doing things, which is to put everything  
 [4] in the public domain. True, they have a Freedom of  
 [5] Information Act, but in essence they say what they are  
 [6] doing, what they are going to do, what they have done in  
 [7] relation to a particular condition to the point  
 [8] sometimes of tedium, so that people become very familiar  
 [9] with the fact that something is going on. But again the  
 [10] American media perhaps do not take up the issues in  
 [11] quite the way that the UK media tend to do.  
 [12] **MR FREEMAN:** To provide a little focus for this line of  
 [13] questioning, I am trying to imagine a family or a person  
 [14] who comes to their GP unsure of what is wrong with their  
 [15] child or their relative or themselves, and they present  
 [16] with psychiatric problems. And CJD of course is to the  
 [17] low end of a differential diagnosis that you might make  
 [18] in relation to those psychiatric problems. You are not  
 [19] going to put it to the top of your agenda, are you?  
 [20] Health professionals are not listening to the health  
 [21] scare stories, what they are listening to is their  
 [22] professional training. That is what they are  
 [23] concentrating on, is it not? Their training would tell  
 [24] them CJD is at the lower end of the differential  
 [25] diagnosis when presenting with these problems; do you

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[1] not?  
 [2] **DR WALFORD:** Indeed, I wonder if I could make the point,  
 [3] in general if we are not approaching microbiologists or  
 [4] public health professionals, one would expect the  
 [5] Department of Health to contact the relevant  
 [6] professional associations. It is not, in general, the  
 [7] PHLS's role and it would probably be transgressing on  
 [8] other people's role, particularly the Department of  
 [9] Health, to contact the relevant professional  
 [10] associations, Royal College and so on, in order to get  
 [11] that particular information into that particular domain.  
 [12] **MR FREEMAN:** Sir Joseph, do you think if the PHLS had been  
 [13] involved in this way in disseminating this information,  
 [14] health care professionals might have rated CJD and new  
 [15] variant CJD more highly?  
 [16] **SIR JOSEPH SMITH:** I am not sure what you meant by rated it  
 [17] more highly.  
 [18] **MR FREEMAN:** Would have pushed it up the scale of  
 [19] differential diagnosis?  
 [20] **SIR JOSEPH SMITH:** I agree with what Dr Walford was saying  
 [21] about the benefits of giving the information out so that  
 [22] people have all the information available and do not  
 [23] believe that anything is being hidden. In that sense  
 [24] I favour that very much. And the CDR is a vehicle and  
 [25] subsequently the electronic means which are now

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[1] available I think are extremely valuable in this way.  
 [2] I would just comment on the last point that  
 [3] Dr Walford made about encroaching possibly on the  
 [4] patches of other organisations. I think if you are  
 [5] dealing with something like the question you were asking  
 [6] about alerting psychiatrists in the country, the  
 [7] approach that would go through the local communicable  
 [8] disease control consultant to his or her local  
 [9] colleagues could be very productive. And that is  
 [10] something which would happen quite outwith any  
 [11] possibility of treading on other people's fields.  
 [12] **MR FREEMAN:** I want to turn to another area.  
 [13] **SIR NICHOLAS PHILLIPS:** Just before you do, it is easy to  
 [14] understand the importance of specialists being fully  
 [15] informed as to the range of possibilities when they are  
 [16] examining a patient. But as far as the general  
 [17] practitioner is concerned, my reaction listening to  
 [18] these questions it is really unrealistic to expect,  
 [19] if a GP is told there is a remote possibility of this  
 [20] very nasty disease, that to affect the action of the  
 [21] GP. Because the GP will do nothing unless he or she  
 [22] reaches a conclusion that this calls for specialist  
 [23] advice. That conclusion is not going to change.  
 [24] **DR WALFORD:** I think that is absolutely right. A GP would  
 [25] actually refer a patient with an unexplained psychiatric

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[1] **SIR JOSEPH SMITH:** Well, when I came into the post in 1995,  
 [2] the conclusions of the review that had been - of the  
 [3] PHLS which had been conducted by Government in  
 [4] 1994/1995, they had recommended that the peripheral  
 [5] network be disbanded and transferred to the management  
 [6] of the local health districts. That decision had not  
 [7] yet been overturned. It was not overturned until some  
 [8] months after I had been in post, not I think because of  
 [9] me, but the decision was being reached that that was  
 [10] inappropriate. But that was a great pressure then to  
 [11] ensure that we were managing in the rapidly changing  
 [12] media of Government requirements for management,  
 [13] corporate plans, forward looks, stringent financial  
 [14] controls; and coupled with this there were heavy  
 [15] financial pressures of funding below the level of  
 [16] inflation, which in a period of inflation caused great  
 [17] pressures, and there was a lot of morale problem within  
 [18] the service as a result of these pressures and a lot of  
 [19] very heavy workloads upon senior managers throughout the  
 [20] service.  
 [21] Also, another huge development which was causing  
 [22] great pressure on us was the pressures of the changes  
 [23] made in the National Health Service, whereby instead of  
 [24] the laboratories - each laboratory doing the work for  
 [25] its local public health departments and hospitals from

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[1] disorder to the appropriate specialist, whichever  
 [2] specialist, be it a psychiatrist or neurologist, they  
 [3] felt was appropriate, rather than to try to make, in  
 [4] general - I generalise here of course - a diagnosis  
 [5] themselves.  
 [6] **SIR JOSEPH SMITH:** I was more or less going to agree in  
 [7] respect of CJD, yes. But in other diseases it can be  
 [8] very valuable. I was thinking of botulism for example,  
 [9] where an alertness to the possibility that somebody  
 [10] seeing double might have botulism is a valuable piece of  
 [11] information which one would wish GPs to be aware of so  
 [12] they could spot cases early, because that then may be  
 [13] treatable.  
 [14] **MR FREEMAN:** I just wanted to explore it, that is all, in  
 [15] that way. Now, the new area that I want to turn to that  
 [16] I hope we can deal with fairly swiftly is that, and let  
 [17] us take it over time if we can Sir Joseph, in your time  
 [18] when you were heading PHLS, were you aware of a change  
 [19] of any pressure that was brought to bear in terms of  
 [20] costs? I am thinking here about management structures  
 [21] and that kind of thing. We know that some staff were  
 [22] lost in your time. Can you comment on that?  
 [23] **SIR JOSEPH SMITH:** Well, the pressure felt very heavy.  
 [24] **MR FREEMAN:** Can you describe it over time, can you think  
 [25] back to this?

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[1] central funding, they had built contracts, we had to  
 [2] build up an edifice which enabled us to contract in such  
 [3] a way that each one of our laboratories had something  
 [4] like 25 or 30 contracts annually to negotiate, which was  
 [5] a completely new load on us.  
 [6] **MR FREEMAN:** Could you say what you mean by an edifice?  
 [7] **SIR JOSEPH SMITH:** Expertise in finance because the main  
 [8] negotiating area was the cost element. We had to have  
 [9] central expertise in finance to support the local  
 [10] laboratory directors in negotiating contracts with their  
 [11] health districts.  
 [12] **MR FREEMAN:** Were you aware of where that pressure was  
 [13] coming from?  
 [14] **SIR JOSEPH SMITH:** Government.  
 [15] **MR FREEMAN:** Were you aware specifically where it was coming  
 [16] from in Government?  
 [17] **SIR JOSEPH SMITH:** I thought the Prime Minister.  
 [18] **MR FREEMAN:** You were never told that it was the Health  
 [19] Minister in your time who was applying this pressure or  
 [20] anything like that?  
 [21] **SIR JOSEPH SMITH:** I think they were very interested in it,  
 [22] particularly when Mr Dorrell came into post. He was  
 [23] I think specifically interested in the financial  
 [24] controls, which was after all his area of expertise. He  
 [25] was far more interested in that than the infection side

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[1] of our work, if I can say so.  
 [2] **MR FREEMAN:** Would you care to comment on that Dr Walford?  
 [3] How did it appear to you when you arrived in your post?  
 [4] You had some experience of it when you were in the  
 [5] Department of Health itself, I suppose?  
 [6] **DR WALFORD:** Yes indeed. Sir Joseph wrote to me when I was  
 [7] in the Department of Health, because by then I was the  
 [8] Director of Health Care on the NHS Executive, to seek my  
 [9] help and support in trying to resolve some of these  
 [10] issues. I hope I did what I could to improve matters  
 [11] for the PHLS, because my big concern, and it was Sir  
 [12] Joseph's as well, was that the PHLS would lose  
 [13] surveillance data as a result of this. However, when  
 [14] I arrived at the PHLS in 1993, a sort of arrival present  
 [15] appeared about five, six months after I joined the  
 [16] service in the person of an undersecretary at, or Grade  
 [17] 3 at the Department of Health who visited me at  
 [18] Colindale to announce that the Department had decided to  
 [19] cut our central financial – our centrally funded budget  
 [20] by £7 million over three years.  
 [21] That was of course a tremendous blow and after a  
 [22] lot of negotiations including, involving Ministers, that  
 [23] was reduced to £5.3 million over the three year period  
 [24] from 1994/1995 onwards. Since 1994/1995 we have  
 [25] actually suffered real term cuts of £9.5 million in our

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[1] budget, which is 15 per cent of our central funding; and  
 [2] indeed we were also not given any growth money for  
 [3] developments, which is something that we had always had  
 [4] the benefit of in the past and we have had to generate  
 [5] another £2 million of internal savings which  
 [6] cumulatively, taking the two things together, amounts to  
 [7] £10.5 million on our central funding or something of the  
 [8] order of £50 million, i.e. about 19 per cent.  
 [9] That of course has had a significant impact on us  
 [10] and we have been told we will not get any inflation  
 [11] funding for the year 2000, 2001 and beyond. So it has  
 [12] been a significantly difficult resource environment.  
 [13] **MR FREEMAN:** Yes. Now Sir Joseph, I want to ask you again  
 [14] how this might have affected, for example, some of the  
 [15] smaller laboratories around the country. I want to  
 [16] focus on Newcastle here. Could you say anything about  
 [17] that? You had a laboratory in Newcastle?  
 [18] **SIR JOSEPH SMITH:** Yes.  
 [19] **MR FREEMAN:** How might it have affected the work of the  
 [20] Newcastle laboratory, taking that as an example?  
 [21] **SIR JOSEPH SMITH:** Do you mean the pressures or the lack of  
 [22] money or both?  
 [23] **MR FREEMAN:** No, I mean within that smaller unit you have a  
 [24] number of people in a relatively flat structure, as  
 [25] I understand it, pursuing free science within the

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[1] guidance that has been given. Am I wrong or ...?  
 [2] **SIR JOSEPH SMITH:** It would have encroached considerably on  
 [3] the management time of the director and his  
 [4] administrative support, in that he would have spent a  
 [5] tremendous amount of time negotiating contracts and  
 [6] maintaining contracts for provision of services.  
 [7] **MR FREEMAN:** Now, Dr Narang, where did he fit into that  
 [8] structure?  
 [9] **SIR JOSEPH SMITH:** Dr Narang was a scientist employed in the  
 [10] Newcastle Public Health Laboratory.  
 [11] **MR FREEMAN:** What level does that mean? Does that mean he  
 [12] supervises himself?  
 [13] **SIR JOSEPH SMITH:** To a considerable extent. It would  
 [14] depend upon the grade. He was employed as a scientist,  
 [15] and at his grading he would have had, in principle,  
 [16] responsibility for his work although it would be subject  
 [17] certainly to direction by the head of the laboratory,  
 [18] and by his immediate manager, which I think was Dr Cod.  
 [19] **MR FREEMAN:** Yes, did you know Dr Narang or did you come to  
 [20] know him?  
 [21] **SIR JOSEPH SMITH:** I came to know him well.  
 [22] **MR FREEMAN:** At what point did you come to know him?  
 [23] **SIR JOSEPH SMITH:** I think shortly after I arrived in the  
 [24] PHLS he asked for an appointment to see me and he asked  
 [25] if I could fund for him some computer equipment he

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[1] needed. I was unable to find the funds for him.  
 [2] **MR FREEMAN:** What was his reaction to that?  
 [3] **SIR JOSEPH SMITH:** Disappointment, understandably.  
 [4] **MR FREEMAN:** What was the next time you had any interest in  
 [5] Dr Narang?  
 [6] **SIR JOSEPH SMITH:** Well, I think – I am trying to  
 [7] remember. I think probably it was – I am trying to  
 [8] remember the sequence. I think there were concerns  
 [9] within the laboratory of the direction his work was  
 [10] going in.  
 [11] **MR FREEMAN:** Now, Dr Narang's evidence on this, really, is  
 [12] that he was free to do some work initially, really, of  
 [13] his own – the work that he was specifically interested  
 [14] in himself, provided it did not interfere with the broad  
 [15] work that he was being required to do. I believe he  
 [16] described he spent 25 per cent or something more of his  
 [17] time involved in it. Did you know what he was involved  
 [18] in? Did you know what he was doing?  
 [19] **SIR JOSEPH SMITH:** Well, in the diagnostic work, supporting  
 [20] the diagnostic work of the laboratory, primarily  
 [21] electron microscopy in relation to biological diseases.  
 [22] The remainder of his time was spent on research into the  
 [23] electron microscopic aspects of prion disease or slow  
 [24] virus diseases.  
 [25] **MR FREEMAN:** Do you remember when Dr Narang left the

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[1] service? I know this is the subject of civil dispute,  
 [2] I am not going to go into that aspect of it. Do you  
 [3] remember when he left the service?  
 [4] **SIR JOSEPH SMITH:** This was I think after I retired.  
 [5] **MR FREEMAN:** Do you remember, Dr Walford, when he left the  
 [6] service?  
 [7] **DR WALFORD:** I cannot remember the exact date. I know that  
 [8] around about August 1993 the process of – that was in  
 [9] place of a disciplinary hearing was determined in that  
 [10] it was decided that just in case Dr Narang's technique  
 [11] turned out to be a useful one, there should be an  
 [12] opportunity for him to validate, have that test  
 [13] validated by independent scientists; and we released him  
 [14] on secondment with full pay from the PHLS to take that  
 [15] secondment with Professor Oxford. That was supposedly  
 [16] going to last for about a year; but my recollection was  
 [17] that I do not think it lasted a full year and  
 [18] subsequently it was found that his post in Newcastle  
 [19] PHLS, which incidentally is one of our bigger  
 [20] laboratories out in the – not Colindale, was no longer  
 [21] necessary; and his post was declared redundant.  
 [22] **SIR NICHOLAS PHILLIPS:** Could I ask this: we do not want  
 [23] obviously to go into the area of the civil dispute, but  
 [24] as I understand what you said earlier, PHLS had been  
 [25] told not to do work on CJD; and Dr Narang was doing some

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[1] Whilst it was a bit difficult in that it was a small –  
 [2] although it is a large PHLS laboratory it is not a big  
 [3] research media. Towards the end of that time there were  
 [4] big health and safety points raised. Yes, I was happy  
 [5] to support the investigation of the validity of his  
 [6] technique.  
 [7] **MR FREEMAN:** Yes. I would like to ask you this as my second  
 [8] to last question: was the emergence of new variant CJD a  
 [9] surprise to you? May I ask Sir Joseph that first?  
 [10] **SIR JOSEPH SMITH:** Yes. Yes, it was, very much so.  
 [11] **MR FREEMAN:** And Dr Walford?  
 [12] **DR WALFORD:** I am trying to recall whether it was a  
 [13] surprise or not. It had always been biologically  
 [14] plausible. I suspect what might have been surprising  
 [15] was that it was a different species of CJD if I can put  
 [16] it that way, it was a different presentation. That  
 [17] might have been surprising. But it was always  
 [18] biologically plausible.  
 [19] **MR FREEMAN:** Always biologically plausible, but enough of  
 [20] the science just looking at scrapie and so on shows that  
 [21] there are many strains and that when SEs cross species  
 [22] barriers as they do, they tend to mutate. Why would one  
 [23] not think that a new variant would arrive in humans?  
 [24] **DR WALFORD:** I am not sure I fully understand the question.  
 [25] **MR FREEMAN:** Perhaps put very badly Dr Walford. Could you

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[1] work trying to find a diagnostic test, or various  
 [2] diagnostic tests for CJD. What was the basic attitude  
 [3] of PHLS to his carrying out that kind of research?  
 [4] **SIR JOSEPH SMITH:** Well, I think this was in my time.  
 [5] **SIR NICHOLAS PHILLIPS:** Yes.  
 [6] **SIR JOSEPH SMITH:** And it was a bit difficult to defend  
 [7] because of our funding pressures. On the other hand it  
 [8] was possible that he had a diagnostic test of value, the  
 [9] "grid technique" it is called. And if that were to  
 [10] have been of value, it was important that it was checked  
 [11] and tested to see if it worked in other people's hands.  
 [12] And to that extent I think it was necessary to try to  
 [13] see that that work was followed through. He was also  
 [14] getting research funds from I think a private source,  
 [15] which worried me slightly in the sense that it was not  
 [16] peer review research funding. But he was getting extra  
 [17] funding to support some of the work he was doing.  
 [18] **SIR NICHOLAS PHILLIPS:** But as I understand it in principle  
 [19] you had nothing against him carrying out, as it were, on  
 [20] the side or in his own time this line of research,  
 [21] albeit it could not readily be brought within the PHLS  
 [22] activities?  
 [23] **SIR JOSEPH SMITH:** I think he had spent many years of his  
 [24] professional life on this. He was, at that time,  
 [25] certainly helpful in general electron microscopy.

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[1] try to tease something out of the question to make some  
 [2] sense?  
 [3] **DR WALFORD:** I am no expert in this area. I can only say  
 [4] that one does know that when an organism crosses a  
 [5] species barrier, or sometimes is passaged, goes through  
 [6] several people – it may even be in the human, polio is  
 [7] a case in point, when it goes through people it can end  
 [8] up more virulent when it emerges – that it is possible  
 [9] for a particular organism to become more virulent or to  
 [10] change its characteristics and for a host to become  
 [11] susceptible to it, whereas they would not have been  
 [12] susceptible to the original organism. Not being a  
 [13] microbiologist, I hope Joe can tell me whether I have  
 [14] that right or not?  
 [15] **SIR JOSEPH SMITH:** Well, it is not easy. I mean, I have  
 [16] difficulty with it at first because it did not seem to  
 [17] be a point source. It was as if because it was  
 [18] appearing in cattle, in different parts of the country.  
 [19] This led me to think that it was probably revealing a  
 [20] capacity of the scrapie agent to infect cattle that  
 [21] probably had always had but had not been tested, because  
 [22] the sheep offal had not previously been used for cattle  
 [23] food. In that case the agent was likely to behave like  
 [24] scrapie, although if it changed in properties its  
 [25] adaptation to cattle may have occurred. Now, that would

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[1] not necessarily lead one to believe it would therefore  
 [2] be more virulent for humans or more infectious for  
 [3] humans. I did not see any reason to expect that; but in  
 [4] reality it has turned out that it is an important  
 [5] variant that can do that. I was surprised.  
 [6] **PROFESSOR FERGUSON-SMITH:** It is controversial, is it not,  
 [7] that it might be a point source of infection, because it  
 [8] is rather obscured by the length of time of incubation?  
 [9] **SIR JOSEPH SMITH:** Absolutely. It is interesting, yes.  
 [10] **MR FREEMAN:** I want to ask you one tiny supplementary, just  
 [11] in relation to something you have just mentioned there.  
 [12] You have touched on the ruminant feed. You presumably  
 [13] know what an ELISA test is, do you?  
 [14] **SIR JOSEPH SMITH:** Yes.  
 [15] **MR FREEMAN:** I am just thinking here of the role of  
 [16] Porton down; that came under the umbrella of the PHLS.  
 [17] Might that have had some contribution to make there?  
 [18] **SIR JOSEPH SMITH:** It could have. It had no expertise in  
 [19] prion disease; it never, so far as I know, studied it.  
 [20] But it did have considerable expertise and resources in  
 [21] human biochemistry in immunology; and I think it was a  
 [22] resource that perhaps could have contributed quite  
 [23] significantly.  
 [24] **MR FREEMAN:** They once let me through the gates there, Sir  
 [25] Joseph. I was just very pleased to come out of them

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[1] administrative colleagues who would wish to make sure it  
 [2] reflected their Ministers' wishes. I could not say more  
 [3] than that, I do not think.  
 [4] **MRS BRIDGEMAN:** You also referred, in your written  
 [5] evidence, to the annual meeting about the corporate plan  
 [6] with the junior Minister?  
 [7] **SIR JOSEPH SMITH:** Oh yes.  
 [8] **MRS BRIDGEMAN:** Did the Minister, before he actually wrote  
 [9] you the letter which said categorically "hands off",  
 [10] I think, "on BSE", indicate it is not what I want you to  
 [11] do? Did he, at that meeting, express these views? I do  
 [12] not see it in the written minutes. Was that a first  
 [13] direct expression of the Minister's view about it?  
 [14] **SIR JOSEPH SMITH:** In the 1989 accountability review, in my  
 [15] original witness statement I said at that meeting  
 [16] nothing was said about what I had written in the 89  
 [17] corporate plan. In fact it must have been said because  
 [18] I have said in answer to the four questions, I think,  
 [19] that you sent later, because I have seen since then,  
 [20] which I got from the Inquiry, I think Dr Pickles had  
 [21] mentioned it, two items, one was a departmental briefing  
 [22] note prior to that meeting for the ministerial team,  
 [23] departmental team, which invited the Chief Medical  
 [24] Officer to say that we should not be engaged in  
 [25] non-communicable disease, and he did not see spongiform

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[1] again, is all I would say, and no more than that about  
 [2] it.  
 [3] **SIR JOSEPH SMITH:** I hope that was not the PHLS site.  
 [4] **MR FREEMAN:** No, I can say that straight away. I only have  
 [5] one further question. I do not know whether the  
 [6] Committee have any other questions they have at the end.  
 [7] **MRS BRIDGEMAN:** I have a question that I wanted to ask,  
 [8] going back to the freedom of choice about what kind of  
 [9] work you could do at the PHLS. I was interested in your  
 [10] statement, Sir Joseph, about references to directions  
 [11] from Ministers and officials that actually meant you  
 [12] felt you could not step beyond what was required. I was  
 [13] not quite clear on that point, and it does link with the  
 [14] corporate planning process and what circumscription that  
 [15] gave as well. I was not clear to what extent, and at  
 [16] what point you felt it was a ministerial wish as  
 [17] distinct from what one might call the normal jousting  
 [18] between officials about budgets and value for money and  
 [19] all the rest of it. What led you to think, when  
 [20] Dr Pickles wrote, that really you were getting a formal  
 [21] direction from Ministers?  
 [22] **SIR JOSEPH SMITH:** I would have assumed that the letter,  
 [23] which was obviously carefully written, had been vetted  
 [24] by her colleagues. I would have assumed that, whether  
 [25] it was I do not know. It would have included senior

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[1] encephalopathies as a communicable disease. So that  
 [2] must have been said, although when I wrote my statement  
 [3] I did not remember that. There is also a letter at the  
 [4] end of November from Hilary Pickles to our Press and  
 [5] Publications Officer at the time, Miss Murphy, Christine  
 [6] Murphy also saying in that we essentially were not going  
 [7] to be involved in the work. So I think it was said in  
 [8] the presence of the Minister at the 89 accountability  
 [9] review, although I cannot remember it being said. At  
 [10] the accountability review the following year, 90, when  
 [11] I think Mr Dorrell was in the chair, in December 90, it  
 [12] was said and it was then included in his letter to us  
 [13] written in January.  
 [14] **MRS BRIDGEMAN:** Yes. Thank you. That is a helpful little  
 [15] piece of history for us. The related question is about  
 [16] the corporate planning process and I would be interested  
 [17] in Dr Walford's views as well, having sat in a quango  
 [18] and struggled with corporate planning process and held  
 [19] the officials back, I know what the process is like. To  
 [20] what extent, because you had this slightly unusual  
 [21] arrangement of the medical officer sitting on your board  
 [22] looking on and deciding on the corporate plan, to what  
 [23] extent were your choices about what you did  
 [24] circumscribed by that particular set of arrangements?  
 [25] **SIR JOSEPH SMITH:** I think I had the feeling over the period

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[1] of my 7 years there that the level of circumscription  
[2] was tightening throughout that period. Early on - 85,  
[3] 86 - we were pretty free, but increasingly what we  
[4] could do and what we might spend our resources on was -  
[5] perhaps "circumscribe" is perhaps not the right word,  
[6] except in the context of CJD in general, the Department  
[7] had to rely on what our knowledge and expertise of what  
[8] the priority areas would be. It would be I think  
[9] unusual for the Department to have disagreed with us  
[10] working in a particular area of infection. So the  
[11] circumscription probably related more to the level of  
[12] accountability than we had to accept, and we were after  
[13] all spending public money, rather than the  
[14] circumscription of the work we did except in the case of  
[15] CJD.

[16] **MRS BRIDGEMAN:** I would be interested because you also did  
[17] refer, Dr Walford, in 1993 to this very savage cut that  
[18] was imposed on you. So that was arbitrary presumably,  
[19] was it?

[20] **DR WALFORD:** That was my understanding, it was a figure  
[21] virtually plucked from the air.

[22] **PROFESSOR FERGUSON-SMITH:** Would this limit the work for  
[23] example that the PHLS might do outside the UK, abroad,  
[24] on following epidemics that might have an impact in the  
[25] UK?

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[1] else?

[2] **DR WALFORD:** At the time we did the strategic review of the  
[3] PHLS, we did put out a questionnaire as to the work that  
[4] the PHLS should be involved in. At that time BSE was  
[5] raised as an issue by a number of respondents. So, yes  
[6] it has always been, I think, an undercurrent within the  
[7] public health fraternity that the PHLS, to whom they  
[8] would normally look for this sort of advice, support and  
[9] to be involved with this area of work, concern to them  
[10] that we have not been.

[11] **PROFESSOR FERGUSON-SMITH:** I have one very brief question  
[12] relating back to the epidemiology. I wondered if  
[13] occupational involvement would be something that the  
[14] PHLS might wish to follow, both in CJD and in other  
[15] disorders, of course? I am thinking, of course, about  
[16] the incidence of the disease in farmers and one abattoir  
[17] worker. Is this something that you would have addressed  
[18] and used additional resources available to you that  
[19] would not be available to others?

[20] **DR WALFORD:** I would certainly think, and looking at the  
[21] evidence that Professor Stephen Palmer and Dr Roland  
[22] Salmon of the Welsh unit, with particular experience in  
[23] zoonotic disease, that occupational exposure was a key  
[24] risk factor to investigate; and it would have been one  
[25] that we would have wished to investigate very

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[1] **DR WALFORD:** Mercifully much of the work done abroad is  
[2] funding by the European Commission, so we were able to  
[3] continue with that. What we did have to do was withdraw  
[4] from six Public Health Laboratories because we could no  
[5] longer afford to maintain the full network.  
[6] I wondered if I might deal with your point about  
[7] corporate planning and priorities. Personally I think a  
[8] corporate planning process is a discipline which it is  
[9] appropriate for an organisation such as the PHLS to go  
[10] through in quite a rigorous fashion. We have developed  
[11] the prioritisation of your work now very significantly  
[12] I believe. But we do it in wide consultation with the  
[13] public health community and with the Department of  
[14] Health so that at the end of the day the priorities we  
[15] believe we should engage in have actually been  
[16] determined through this process of gathering information  
[17] and opinion from the public health fraternity.  
[18] Interestingly enough, in our latest exercise called the  
[19] Overview of Communicable Disease, which is our priority  
[20] setting document, CJD was clearly enunciated by the  
[21] public health fraternity as something that the PHLS  
[22] should be engaged in as a priority.

[23] **MRS BRIDGEMAN:** This had never been raised by them before  
[24] during those previous years of consultation, or was it  
[25] because it was seen as being dealt with by somebody

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[1] rigorously. I believe we would have had the capacity to  
[2] do that.

[3] **MR FREEMAN:** I am grateful. Is there anything else from the  
[4] Committee?

[5] **SIR NICHOLAS PHILLIPS:** No.

[6] **MR FREEMAN:** I have one last question for you then. Sir  
[7] Joseph, I would like to ask you this first. Have you  
[8] changed your diet at all over the period of BSE?

[9] **SIR JOSEPH SMITH:** I actually have not. No, I have not.

[10] **MR FREEMAN:** And Dr Walford?

[11] **DR WALFORD:** I have not.

[12] **MR FREEMAN:** I am grateful. Thank you very much.

[13] **SIR NICHOLAS PHILLIPS:** Could I thank you both very much  
[14] for the help you have given us. We have had a very  
[15] interesting and helpful morning.

[16] **MR FREEMAN:** Thank you.

[17] (12.20 pm)

[18] (Hearing adjourned until 9.30 am  
[19] on Monday 19th October 1998)

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