The BSE Inquiry / Statement No 181

Sir Joseph Smith

(scheduled to give evidence Friday 16th October 1998)

THE BSE INQUIRY

THE STATEMENT OF SIR JOSEPH SMITH

Response to a request from the Secretary to the BSE Inquiry to provide a written statement of evidence.

Sir Joseph Smith, MD, FRCP, FRCPath, FFPHM, Dip.Bact. Professional address: c/o Public Health Laboratory Service, PHLS Headquarters, 61 Colindale Avenue, London, NW9 5DF.

Posts Held, 1985-1996

1. Until August 1985 I was Director of the National Institute for Biological Standards and Control (then at Holly Hill, Hampstead, London). I was responsible to the National Biological Standards Board for the management and scientific work of the Institute. The Board is responsible, on behalf of UK Health Ministers, for the provision of biological standards and for scientific work concerned with the control of biological products used in human medicine.

2. In August 1985 I became Director of the Public Health Laboratory Service of England and Wales (PHLS), and remained in that post until I retired at the end of 1992. I was based at PHLS headquarters, 61 Colindale Avenue, London, NW9 5DF. I was responsible to the PHLS Board for the management and scientific work of the Service.

Links with Farming, Pharmaceuticals, Etc

3. In 1969 I worked for the Wellcome pharmaceutical company as head of bacteriology at the Wellcome Research Laboratories in Beckenham, Kent. I hold a small number of shares in Glaxo-Wellcome. The PHLS Board had a marketing agreement with Porton Products Limited, to which I refer in paragraph 6.4 below. I have had no other links with farming or commercial companies.

The Role of the PHLS, 1985-1992

4. The PHLS Board's responsibility, as described in The Public Health Laboratory Service Act 1960, is to "provide a bacteriological service for the control of infectious diseases", for which it is accountable to the Health Ministers of England and Wales. The National Health Service Act 1997 (Schedule 3) incorporated the PHLS Board. The PHLS was funded from the central funds of the Department of Health and Social Security/Department of Health.

5. The Public Health Laboratory Service Act 1979 gave the Secretary of State the power to include in the role of the PHLS additional activities which could be carried out

in conjunction with a microbiological service. The PHLS Board's responsibilities were extended under the Act to include management of the Centre for Applied Microbiology and Research (CAMR) at Porton Down. CAMR was formerly the Microbiological Research Establishment of the Ministry of Defence.

The PHLS Organisation and Work

6. In the time I served as its director, the PHLS organisation included the following:-

6.1 52 Area and Regional (peripheral) diagnostic PHLS laboratories spaced over England and Wales, each providing diagnostic services and support for outbreak investigation to local hospitals, public health authorities and environmental health departments. Each laboratory also provided surveillance data and microbiological samples to the central PHLS units at Colindale, and also took part in national investigations into infectious diseases.

6.2 The Central Public Health Laboratory (CPHL) at Colindale, London, which provided national reference laboratory services to both PHLS and NHS laboratories.

6.3 The Communicable Disease Surveillance Centre (CDSC), also at Colindale but with a Welsh Unit located in Cardiff. CDSC served as the epidemiological arm of the PHLS. It kept human infectious diseases under surveillance and, working with other PHLS units, provided expert epidemiological support for the study of infectious diseases including the investigation of outbreaks. Its surveillance function was based upon regular returns of diagnostic data from the peripheral and central PHLS laboratories, supported by other information, including when necessary reports from clinicians and others.

6.4 CAMR, Porton Down. As well as providing a few services supporting the PHLS' public health work, such as diagnostic tests for dangerous pathogen infections, CAMR was expected by the Secretary of State for Social Services to generate income from its research. To this end the Board in 1985 made an agreement with Porton Products Limited for marketing the products and processes resulting from CAMR research.

6.5 The Headquarters office, at Colindale, London.

7. In the period 1985-92, the PHLS was heavily involved with investigations into a range of human infections, including AIDS and HIV infection, Botulism, E-coli infections, Legionnaires' disease, Listeriosis, Meningitis and Salmonellosis.

8. As well as the activities referred to above, the PHLS also engaged in research, mostly applied research, with the aim of improving the diagnosis, prevention and control of infections and communicable diseases. Much of this work, such as studies on salmonella contamination in poultry and eggs, could be done economically and efficiently by the Service through the collaboration of its constituent parts, where necessary with relevant non-PHLS bodies.

9. During the period 1985-92 PHLS policy was increasingly subject to DoH and Welsh Office influence. The PHLS Board membership included a Deputy Chief Medical Officer from the DoH and (until July 1989) a DCMO from the Welsh Office, and other DoH staff attended as observers. An important development in this period was the

introduction of annual Accountability Reviews with Health Ministers, the first in 1986. In these Reviews the PHLS Board was required each year to present its Corporate Plan. Although prepared by the PHLS, the Corporate Plan was written in the context of regular dialogue between DoH and Welsh Office officials and the PHLS. At the Annual Accountability Review Ministers would consider the Corporate Plan, including the work which the PHLS proposed to undertake and its spending plans. The PHLS would be challenged on some points in the Corporate Plan, although in practice it reflected the discussions which had already taken place between the PHLS and the DoH. Starting in 1988 annual "Customer Liaison" meetings were held with DoH and Welsh Office officials at which they could be updated on our work and concerns and they could express their expectations and wishes. In addition, there was day-to-day contact with appropriate DoH scientific and medical staff, particularly in relation to current outbreaks of infectious disease.

Committee Membership 1985-1992

10. During this period I was a member of a number of committees of the Department of Health and the Medical Research Council. In none, so far as I can recall, was there any work or responsibility connected with BSE/CJD, except: (a) that of the Committee on Safety of Medicines in relation to the transmission of CJD by human growth hormone; (b) a meeting of the "Central Zoonosis Group" in 1988; and (c) on two occasions connected with my membership of the Medical Research Council (MRC).

Committee on Safety of Medicines (1985)

11. I was a member of the Committee on Safety of Medicines (CSM) from 1978 to 1986, and served as chairman of its Biological Subcommittee from 1981 to 1986. The possibility of CJD being transmitted by human growth hormone arose during this period and was considered by the sub-committee in May 1985. The subcommittee advised the CSM that growth hormone extracted from human pituitary glands should as soon as possible be withdrawn and replaced with hormone made by genetic manipulation technology. The CSM accepted this advice.

Central Zoonosis Group (1988)

12. This title was given to a regular meeting between scientists from the Ministry of Agriculture, Fisheries and Food (MAFF), the DHSS, and the PHLS. The purpose of the group was to discuss issues relevant to diseases transmissible from animals to humans. Although I do not recall it, I appear to have been present at a meeting of this group on 17 February 1988, when a MAFF presentation was made on a new disease of cattle, BSE, the cause of which was not known at that time.

Medical Research Council (1989/1990)

13. The MRC held two relevant meetings which I attended. The first of these meetings, on 28 September 1989, was an MRC review of scientific opportunities for slow virus research, and I acted as chairman. (This role did not reflect any expertise in the field on my part; presumably the MRC wished to have as chairman a Council member who also had some background in infections.) The meeting was attended by scientists from a number of UK groups engaged in this field of research and also several researchers from other countries. The meeting impressed upon me the difficulties and complexities of laboratory research into these diseases, much of which had moved into areas of biochemistry, molecular biology, neurobiology and genetics of which I had little knowledge, and in which the PHLS had limited expertise. At the same time, I could see

no reason why the PHLS should not be able to contribute to epidemiological studies, even though these would be difficult owing to the long incubation period of slow virus diseases, and the need to rely upon clinical judgment and post-mortem histopathology for diagnosis.

14. The second MRC meeting, in December 1990, was a seminar on molecular approaches to research in human spongiform encephalopathies. I attended as a member of the invited audience. It involved presentations by a number of leading British and international experts. The difficulties of basic research in this field were again apparent.

SEAC (1990)

15. I was also informally asked to serve on SEAC. Sir Donald Acheson telephoned me to ask if I would accept an invitation to join it. This was in the latter half of 1990, but I cannot recall exactly when. I said that I would be happy to serve. In the event, I received no letter of invitation but was twice telephoned by an official asking if I would be available on some specific dates for a meeting. In the event, I had unavoidable commitments on the dates offered and I received no further contacts on this subject.

Consultant Adviser on Microbiology

16. I was invited on two occasions in 1992, in my capacity as Consultant Adviser on Microbiology to the Chief Medical Officer, to comment upon a draft "fast-track Professional Letter" about measures to be taken by neurological and ophthalmic surgery teams when operating upon patients with or at risk from CJD. After seeking the advice of colleagues with expertise in the control of hospital infection, I provided comments on both occasions.

PHLS Work on BSE/CJD 1985-1992

17. I first became concerned about BSE when I learned (when or how I cannot now recall) about the disease and the likelihood that it was passed by feeding cattle with meal

19. From I believe early in 1990, however, it was made increasingly clear to me that DoH and Ministers did not wish the PHLS to work upon BSE/CJD, nor to be seen to work or comment upon the subject, and especially that CDSC should not be involved. This caused me much concern. I thought that the PHLS should be involved in the critically necessary human epidemiological studies of BSE/CJD, and that the PHLS could make a valuable contribution to their planning and operation. I raised my concerns, several times I believe, with DoH officials and finally Dr Pickles agreed to write to me to set out the DoH position, which I thought needed PHLS Board discussion. A copy of the DoH letter, from Dr Pickles, dated 1 February 1990, is attached (attachment 2) **(YB 90/02.01/5.1-5.3)** together with my covering paper to the Board and the consequent Board minute (attachment 3) **(YB 90/04.26/3.1-3.4)**.

20. The DoH letter from Dr Pickles was considered by the PHLS Board at its meeting on 26 April 1990, which was attended by four DoH officials. We were told that the necessary national epidemiological work was to be done by others. This work, funded by the DoH, was well planned and was either starting or in progress and it had access to the required specialist expertise. In these circumstances, it was difficult to resist the department's wish that the PHLS should not take part in epidemiological studies of these diseases. Also, the PHLS Board was accountable to Ministers and could not disregard their express wishes as set out in a formal DoH letter. The Board concluded that PHLS should not engage in epidemiological work upon BSE/CJD, but could do laboratory research provided it was supported by research grants.

21. The question of work on BSE/CJD was raised again by the DoH at the Accountability Review in December 1990. The PHLS was told that we should not become involved in this work and we confirmed that the Board accepted this. Mr Stephen Dorrell wrote on 25 January 1991 to the PHLS Chairman, Dr Malcolm Godfrey, about the Review (attachment 4) **(YB 91/01.25/4.1-4.2)** and addressed the question of spongiform encephalopathies in his second paragraph. The PHLS understood this to be confirmation of his direction that we should not be involved in this work.

22. In the event, therefore, as far as I was aware, no PHLS activities were concerned with BSE or CJD, with the exception of the following:-

22.1 Research work from 1985-1992 by one scientist, Dr Narang of the Newcastle PHLS laboratory, who had a long-standing interest in this group of diseases. This work was carried out by Dr Narang because of his personal interest in pursuing it and not as part of a general PHLS programme in this area. His work has been the subject of separate comment.

22.2 An epidemiological investigation of an apparent excess of cases of CJD in the North of England. This arose because of a report by Dr Narang that there had been an unusually high rate of CJD. I wrote to Dr Bartlett, Director of CDSC, on 22 November 1989 inviting him to look into this. It was investigated by a group which included a CDSC epidemiologist. I was informed that increased ascertainment rather than a significant rise in the disease was suggested by their investigation but that careful prospective monitoring was needed. I understand that the findings were passed to Dr Will of the CJD Surveillance Unit in Edinburgh with a recommendation that surveillance should be based on active case reporting by clinicians and pathologists.

22.3 The PHLS was invited in mid-1990 to submit a memorandum on BSE to the Agriculture Select Committee of Parliament. The letter I sent to the

Committee, dated 11 June 1990, is given at (attachment 5) **(YB 90/06.11/12.1-12.2)**.

23. The PHLS did continue to maintain a watching brief in relation to BSE/CJD. As noted in my letter to the Agriculture Select Committee, if appropriate areas of work in which we could usefully have been involved had been identified the position would have been reviewed.

24. I have been asked to comment on parts of a statement made to the Inquiry by Dr Will Patterson. I broadly agree with the statements and views at paragraphs 2, 3, 4, 5 and 6.2 of that statement, save that

24.1 the PHLS remit related to infectious diseases affecting humans and concerned England and Wales, rather than the whole of the UK;

24.2 in respect of paragraph 5.3, the phrase in line 2 "had the potential" does not wholly reflect expert views at the time. The Southwood stated that it was "most unlikely that BSE will have any implications for human health".

24.3 with reference to paragraph 6.2, the PHLS was asked not to work on BSE/nvCJD, rather than not asked to work in this area.

25. Paragraph 9.1 of Dr Patterson's statement appears directly to criticise the PHLS for its failure to take a more active role in research and discussion concerning BSE/CJD. He states that this seriously undermined the effectiveness of the United Kingdom public health framework to protect the population from infection. I am unable to say whether the absence of a substantial contribution from the PHLS had this effect. At the time, however, the PHLS had been assured by the DoH that the measures required to ensure a proper response to this apparently new disease were being taken and that it was not necessary for the PHLS to take an active role. Indeed, as appears from the documents referred to above, we were advised that involvement on our part could be counter-productive.

Issued on behalf of the witness by:

The BSE Inquiry Press Office

6th Floor Hercules House

Hercules Road

London SE1 7DU

Tel: 0171 261 8377 / 8383

Fax: 0171 803 0893

Website: http://www.bse.org.uk

email: inquiry@bse.org.uk