## Mad Cow Disease inquiry reveals how British government protected pharmaceutical companies at expense of public health

Paul Mitchell 9 December 1999

Most attention during the crisis surrounding Bovine Spongiform Encephalopathy (BSE), commonly known as Mad Cow Disease, has focused on the risk of eating beef. However evidence to the ongoing British government BSE Inquiry shows how the potentially greater risk from the use of cow by-products in vaccines and other medicines was covered up.

The Blair government set up the BSE Inquiry in March 1998 and it is due to report in March 2000. Its aim is to "establish and review the emergence and identification of BSE and its human equivalent, and of the action taken in response to it up to 20 March 1996". This was the date that the then Conservative Health Minister, Stephen Dorrell, admitted that there was a link between BSE and a new form of the disease in humans called new variant Creutzfeld-Jakob Disease (CJD). Forty-eight people have died of the disease so far and the final number could be much greater due to a suspected long incubation period. CJD may have affected its latest, and youngest, sufferer—a 13-year-old girl.

BSE and nvCJD are related diseases that attack the nervous system and make the brain spongy, resulting in dementia and death. It is almost impossible to eradicate. Most knowledge of the disease comes from research into a variant of it found in sheep, Scrapie. This disease has been known for more than 200 years but does not appear to harm shepherds or those who eat lamb or mutton. From the beginning of the epidemic it was assumed that BSE would behave like Scrapie and not infect humans, despite the fact that feed contaminated with Scrapie was thought to have caused BSE in cattle. Because of the potential danger from Scrapie, pharmaceutical companies did not use sheep as ingredients in medicines or in their production.

The Inquiry was told that the first hint that BSE was a health problem arose in July 1987. John Sloggem, a government Pharmaceutical Officer, was investigating a new medicine. He found that the Committee for the Safety of Medicine (CSM) had refused it in 1984, because it wanted

proof that "slow virus contamination was not a problem" in the cow brain used to make the medicine. He investigated further and was told about a "scrapie-like disease that is occurring in cattle" and had the impression that "the cattle slow virus issue was a matter that was not widely known and should not be publicised".

It was not until December 1987 that the agricultural and farming ministry, MAFF, produced an internal report entitled "BSE—implications for biological products". It recommended a ban on the use of suspected or confirmed cases of BSE and the most infective materials—nerves and lymph—in all cattle.

In February 1988 MAFF officials warned Sir Donald Acheson, the Chief Medical Officer at the Ministry of Health, about BSE. They said "it was necessary to assess the risk in humans in order to justify the cost of any control measures taken by MAFF". They agreed to set up an expert working party to be chaired by Sir Richard Southwood, Professor of Zoology at Oxford University. Meanwhile "the agreed approach was to await the findings and report from the Southwood Working Party before finalising our advice on BSE and medicines".

The Inquiry was told how the veterinary industry trade association, the National Office of Animal Health (NOAH), met with MAFF and "felt that the publication of Guidelines was required to protect the UK image and demonstrate to the (European) Commission that we had a clear action policy".

By November 1988, the CSM had proposed draft guidelines. They said no immediate action should be taken against medicines taken orally in view of the widespread consumption of beef. The pharmaceutical companies should use low risk by-products from certified healthy herds and show that they could eliminate the Scrapie-like agent.

MAFF replied that many of the guidelines were unworkable. They concluded, "Extravagant action now to deal with a contingent risk could (in the future) seem to be wholly disproportionate."

By now, according to the Inquiry, the CSM also "realised that virtually none of the current essential human or animal vaccines could comply with (their own) Guidelines and there may be several years of some vaccines in stock to make matters more difficult. Public confidence in the vaccination programme must not be put in jeopardy and yet supplies of some vaccines are very limited." This was a genuine worry. A vaccination scare during the period 1980-88 had led to 123 deaths from measles and 50 from whooping cough in England. There had been a number of other health and food "scares" leading up to the BSE crisis, in which the public had started to lose confidence in science and government. This was the end result of a process involving commercial competition, pressure from business interests, intensive farming techniques, deregulation and cutbacks.

When the pharmaceutical companies received the guidelines, they were told they were just "best practice" for the future and a "purely precautionary measure" against "a remote risk".

The final version of the Southwood Report was published on February 27, 1989. It said that cattle would prove to be "dead-end" hosts for the BSE agent and it was unlikely that there would be any implications for human health.

At the next meeting of NOAH and MAFF, the minutes record "Sir Richard Southwood's Report had thus far turned out to be a damp squib. However, it was stressed that care must be taken to ensure that certain elements of the press do not get hold of the wrong impression about the safety of vaccines—both human and veterinary—and cause major problems."

On July 5, 1989, Southwood wrote to Dr. David Tyrrell who was investigating what research was needed into BSE. He stated: "I just hope that the Ministry and others will, notwithstanding the ridiculous attitude towards public expenditure, find the necessary funds to undertake the high priority research.... You are absolutely right to point out gently how we were forced to argue from analogy with scrapie and one waits with some anxiety for the experimental confirmation of that assumption. Personally I would have thought the possibility of human infection was moderately high if some medicinal products were made from tissues of infected animals and injected into humans."

Kenneth Clarke, Secretary of State for Health at the time, was shown the Tyrell letter at the Inquiry. He said he had not seen it before and would have ordered the withdrawal of all suspect vaccines. He admitted that a significant number of patients could have become infected.

Whilst the Inquiry revealed some of the secret workings of government, pharmaceutical companies have been protected by confidentiality clauses in the 1968 Medicines Act. The Inquiry was warned not to mention their names—instead the

word "redacted" appears in the transcripts.

The Inquiry heard how investigations found there were 111 medicines administered by injection using the most risky by-products—brain and lymph. Most were made from imported material, but a range of homeopathic medicines and surgical sutures were not. The sutures used for sewing up tissues after operations were manufactured by the main British supplier referred to as "Z". They were made from cleaned cow intestines that the company processed at the rate of 2,500 a day. Against the advice of their own guidelines, officials renewed the licence on condition the company used intestines from clean beef cattle 18 months to two years old.

A minority recommended the use of intestines from BSE-free countries. The Inquiry was shown minutes where officials pointed out that "the agreement with the Company is 'confidential' so that there will be no direct comparisons" between the conditions they had set and the recent ban on offals, including intestines, for human consumption. Four years later, government officials announced that a study had detected BSE infectivity at the end of the small intestine from calves as young as six months old.

By July 1992 the BSE Inquiry was told all vaccines available in Britain fully complied with the guidelines and did not use British cattle by-products. By the end of the same year 40,000 cattle had shown symptoms of BSE. The number incubating BSE was much larger.

But what of the stocks of vaccines? According to the *Daily Telegraph*, the BSE Inquiry has failed to establish what happened to them and "pharmaceutical companies have so far declined to volunteer the information". One Inquiry spokesperson said, "It is possible that we will never know whether all these vaccines were destroyed or whether they were used." All the Labour Health Minister, Tessa Jowell would say is they were "not disposed of or discontinued".



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