URGENT DECISION

SofS

Sir, this note is 'for the record' can you take a look & see if you are content? Thanks

GRO-C: Stephen

13/10

CONFIDENTIAL – POLICY
DRAFT

455/18/2
13/10/2000

BSE INQUIRY REPORT: BRIEFING MEETING

Note of meeting held at 6.00 pm 11 October 2000, Room 406 Richmond House

Present: SofS, Simon Stevens (Sp/Adv), Darren Murphy (Sp/Adv), Chris Kelly, Rob Beasley, Peter Martin, Gina Wakeman, Alan Harvey, Lincoln Tsang, Maggie Jackman, Pat Troop, Justin Fenwick (Counsel), Leigh Ann-Mulcahey (Counsel), Greer Kerrigan, Anita James, Brian Bradley, Stephen Waring (note)

Care for people with vCJD

1. Dr Troop (PT) reported that discussions taking place with OGDs (MAFF, HMT, CO, No 10, devolved admins.) had covered prompt provision of enhanced packages of care. There was interest in the establishment of a centralised fund to complement local health and social care provision. Initial costings had suggested figure of c.£45k has been suggested, to include elements of hardship following loss of employment etc., and is considered to be on the high side. It would be possible to create a "virtual" national network which could be developed further should numbers increase. This would have the support of the devolved admins.

2. SofS indicated that he had not envisaged subsidising local packages of care or local funding, but developing a mechanism to enable rapid expertise, support and equipment to be brought in very rapidly and to be able to "knock heads together" at a local level to ensure prompt action. He agreed that expert support to the existing national co-ordinator (including nursing and other appropriate expertise) was the right way to go. Though central funds provided a disincentive to using local expenditure, there remained a case for this, since prompt support was essential.

3. A paper should be produced for costed packages of care based on average cases. Costs of enhancing national co-ordination should also be included.

ACTION: PT

Financial support/compensation issues

4. A meeting on compensation issues, chaired by the Lord Chancellor (in view of the setting of legal precedents and the possible need for mediation) has been proposed for next week.

5. Counsel (JF) suggested that if compensation were offered for this kind of problem it would be very difficult to avoid compensation for future "disasters. There would also then always be louder calls for an Inquiry on each occasion, if this was seen to improve the compensation outcome. With haemophiliacs infected with HIV the approach had been to invite them to name a sensible figure, so that there was no criticism that the Government were being mean. Another advantage of mediation was that the claimants were more likely to keep the issues confidential. The difference between the current case and the haemophiliacs was that the litigation risk with the current plaintiffs was low. In addition the haemophiliacs were a small, defined number (c. 1850) and compensation was justified on the grounds

of their "double jeopardy" in that they were already significantly disadvantaged by their condition.

6. SofS asked whether providing compensation in this case would impact on the current hepatitis C (HCV) litigation. JF indicated that there were still arguments about "duty of care" to be resolved, and the NBA might not lose the case. The critical difference was that negligence or causation were still to be determined in the HCV case.

7. Perm Sec (CK) noted that this presented as a particularly horrendous case caused by feeding people infective material. Secondly, people feel they were misled by a Government who did not make all the facts available. While this could be setting a precedent, it might be a precedent which ought to be set.

8. JF outlined three possible approaches:

   - a standard payment (like the vaccine damage payment scheme – though this crude approach does not cater for exceptional needs);
   - a Trust Fund (with a proviso that the extent to which the fund would be replenished would depend on the satisfactory development of care packages and the number of future cases);
   - a discounted compensation scheme (though this may mean payments forever hereafter).

9. The fund for haemophiliacs was administered by the Macfarlane Trust, a pre-existing charity with independent trustees, whose terms were extended. The sum provided was negotiated with their counsel, based on the number of claimants and discounted full liability. In the vCJD case it would be attractive to the Government as the trustees make the decisions, and the sum would be less than a compensation package. An agreement could be negotiated to set up a charity whose trustees are not appointed by either Government or the families' representatives.

10. SofS felt that we needed a paper to make the argument for some form of compensation, making clear the pros and cons, and making explicit the read-across to HCV, and any issues of precedent, not only for this department. The realistic options seem to be a flat rate *ex gratia* payment or a trust fund. This would then indicate the need for a narrower package of care, without hardship elements. He felt that the trust fund should be promoted as the best solution.

ACTION: PT/JF

11. JF indicated that it would be essential to go into informal mediation with the families' counsel to determine whether such an approach would be acceptable. Negotiation over amounts of money could then take place quickly once an announcement was made. On the day of publication SofS could state that packages of care for primary victims would definitely be funded. As it would not be possible to have a deal in place by 26 October, SofS could say that we have already taken steps to ensure that we can have full and open discussions with the families – indicating that "we want to see what we can do".

12. SofS stressed that there was a strong moral imperative here; that he wished to be seen to be taking the initiative; and that he needed a form of words for the date of publication which went as far as possible, without prejudicing the financial outcome. A paper was needed on this.

ACTION: PT/CK/JF

Medicines

13. Maggie Jackman (MJ) explained that the Report raised the issue of vaccines and in particular delays in implementing guidelines for the use of bovine materials and the accuracy of related records. Childhood vaccines are not implicated in the aetoiology. One significant statement in the Report is that BSE might have emerged as early as 1970, when all experts have only ever considered 1980 as the starting point. PT felt that this was not necessarily based on good evidence

14. Many "seedlots", which are used to start the vaccine production process, were created in the 1960s and are still in use today. Although bovine material is used in seedlots, it is material of "no detectable infectivity" (principally foetal calf serum). In response to questions, Lincoln Tsang indicated that to start the process of vaccine production again from scratch, which included relicencing etc. would take at least 10 years. Most manufacturers are based overseas (principally in the US) and therefore purchasing from overseas effectively takes place now.

15. SofS felt that the lesson from the Inquiry was that if we can't give concrete assurances on safety then we must tell the public, but with full information on the potential risks (i.e. of vaccination programmes suffering). People voting with their feet on vaccine uptake would be a serious outcome. He asked for an urgent analysis of precisely which vaccines are implicated, and whether there is any possibility of "safe" alternatives.

ACTION: PT/MJ/LT

16. CK noted that the Department was not in a bad position, since a study had been commissioned which had confirmed that our actions were appropriate. Phillips had agreed that the balance had been right in not withdrawing vaccines. LT noted that the US FDA had carried out independent analysis and had reached the same conclusion as the CSM, but both were probably based on the assumed start date of 1980.

17. SofS made clear that we must have a policy of maximum openness on this issue.

Stephen Waring
PS/SofS
13 October 2000