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- 1 year
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"huh"

RESTRICTED POLICY

Dr Rejman, HC(M)1

From: ROGER SCOFIELD, CA-OPU
Date: 12 April 1995

Copies: Mr C Blake
Mr A James
Mr Kelly
Mr Burrage

HEPATITIS C

1. We spoke about Anita James' minute of 31 March and your reply of 6 April.

2. I am grateful to you for sending me a second copy of your minute of 22 December, addressed to me, with a note on the chronology of introducing testing for Hep C. This was sent while I was on my pre-Christmas leave and it is possible that this explains why I had not been able to recall the document. It is a helpful summary of the key developments during the '89-91 window period.

3. We agreed that it would be helpful if SolB4, CA-OPU and yourself agreed the "rules" for "discovering" relevant papers.

4. It seems to me that, as in many other areas, the law of diminishing returns applies; it is more important to spend a few days pulling out the most important papers, than to embark upon a task which may last many weeks and only add limited additional material. There is clearly a real urgency for us to come up with some advice on the strength of our overall position. Secretary of State has read my submission over the weekend and commented that we must be sure to keep No 10 and the PM involved as this matter develops. No doubt she is feeling particularly sensitive at the moment after the reaction to the London closures and wants to make sure that anything she does, or the Department does, has the PM's and Cabinet's backing. This may make the agreement of the right way forward even more difficult than before.

5. The immediate pressure upon us is coming from the Haemophilia Society whose starting position is that they accept that there has not been negligence, but they are claiming equality of treatment with those of their number who were infected with HIV through blood products and who were subsequently awarded payments under the HIV settlement. If we were to go ahead with a settlement for Hepatitis C, in respect of Haemophiliacs, then the issue of negligence would not emerge.

6. If we refuse the claims of the Haemophiliacs in respect of Hepatitis, then it is possible that some of them will go ahead with claims based upon negligence. There is no question of our having failed to use the new tests on these products in good time, since the introduction of heat treatment effectively killed

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of the viruses from 1986 onwards and the tests only became available in 1986. However, there were presumably a whole series of arguments about whether the patients were fully informed of the risks that they ran and whether the blood products were obtained from the best source of blood, ie were they from UK donors who had been screened by the elimination of any who might be in a high risk group or did they come from products imported from the US, because of failures on our part to be self-sufficient in factor 8 etc. You know these arguments much better than I do and no doubt they are all set out in the papers which were looked at in relation to the HIV litigation.

7. However, if we do come to a settlement with the Haemophiliacs in respect of HCV, then in my view, we will have to extend this to include those infected through blood transfusion. The key issue here would be whether we could persuade all those who are seeking to prove negligence in this respect, particularly with regard to the window period, to drop their claims. They are a less organised group and Graham Ross would be very keen to encourage them to have a go on the back of legal aid. Thus even if the Government were so minded, we may not find it easy to come to a satisfactory settlement.

8. For this reason, it would seem to me that the most likely scenario under which we might have to argue our case will be in respect of negligence in the handling of blood transfusion patients during the window period. If there is a likelihood that we might lose in respect of negligence in this period, we might want to settle out of court, at which point, we would be likely to have to include in the settlement, anyone who had received treatment after, say, the beginning of 1989. There would be enormous pressure upon us to extend this to cover all those infected through transfusion and in practice we would find it almost impossible not to include the Haemophilia patients as well.

9. It would of course be possible to be found negligent in say the last few months of that period, if, for example, it could be shown that satisfactory tests were available and we had been unduly slow in getting our act together. There are of course complications like our desire to go forward on a UK-wide basis and the impact of the Gulf War etc. If we were found negligent in a very small area, it might just be possible to ring fence this and for us to avoid the knock-on effect I have described above.

10. As I understand it, our worry is as much about what might come out in the course of a court action as the actual verdict and I suggest therefore that any examination of documents should be addressed as much to their presentational significance as to the case for negligence itself. There is no doubt in my mind that there are a number of documents which would show that the process of deciding whether or not to test took account of cost and the impact on the blood supply and stocks etc. There are also the ethical problems over what you tell those who are found to be positive. But looking at all of this from the point of view of the recipient who is now in end stage liver failure, or perhaps the father of a child who was infected in this way, one

can see that these explanations and defenses would seem pretty irrelevant, compared to the fact that tests could have been carried out and were not.

11. Another whole area of vulnerability is the action by other countries in introducing Hep C tests. Whilst it would be understandable that one or two countries might jump the gun and go ahead before the tests were really of any great value, we are actually asked to believe that pretty well every major blood transfusion service in the world, apart from the UK, decided to go ahead with such useless tests a year or more earlier than we did. On the face of it, this sounds as if either they were all a bunch of clowns or we must have had particularly good reasons for hanging back.

12. Again, we know how long it takes to carry these things through Committees and to undertake additional tests and to ensure that every RTC is at the same stage as the others, so that the procedure can be introduced on a UK-wide basis - but when we put all these things together, the story sounds as if there was an inordinate administrative or bureaucratic delay.

13. I am drawing out these uncomfortable areas because, if any one of them can be used to establish a case to be answered, then we may be dragged all the way to the court.

14. In looking at our papers therefore, it would seem to me that the first priority should be looking at the papers for, and records of the meetings of the ACVSB, including any special sub-committees etc and including any official groups within the blood service. We should be looking for papers which either relate to possible claims for negligence (judged from the perspective of the recipient and not from our own) and also for papers which, if exposed in public, might be used to ridicule the way in which the service is managed or decisions on safety are taken.

15. We also discussed the need to review the workings of the ACVSB and MSBT and in particular to review decisions made in the past which may need to be looked at again in the light of further developments and in particular the experience of the Hep C Look Back exercise. I suggested a number of examples in a recent paper. It would seem to me that whilst going through the ACVSB and MSBT papers, it would be worth cataloguing all the issues which have been raised and the actions taken to ensure that no stone has been left unturned.

16. These are my thoughts on this exercise and I would be glad to discuss them further with Charles Blake and Anita James, but you and Dave Burrage know the papers much better than I do and will have your own ideas as to how this exercise should be carried out. But we must not allow the impossibility of mounting a perfect three month's perfect exercise to keep us from the necessity of undertaking the sort of two-day investigation which might suffice for the present.

17. Happy to discuss.

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