

Ms Bateman

AIDS SCREENING TEST: ABBOTT LABORATORIES

1. Mrs Fosh's minute of 31 July set out the results of the first stage of the agreed two stage evaluation. The test from Abbott Laboratories was not recommended because:

- a. it took twice as long to perform thus it would be expensive in staff time and operationally inconvenient;
- b. it had a higher rate of false positive i.e., identifying AIDS antibodies when none were present.

Abbott like other manufacturers had endorsed the research protocol for the evaluation.

2. Abbott have since argued vigorously that their product should be included in the next stage of the evaluation i.e., trials in the BTS. Now that Abbott have seen the result of the PHLS evaluation they claim that they have many more results from field experience with the test than the sample which the PHLS used. Their data shows a much lower false positive rate but this is still higher than that of the recorded tests. They are prepared to supply kits for the BTS trial free of charge.

3. Abbott fear that their exclusion from the UK BTS will have repercussions for them elsewhere. They will therefore lobby on the basis that:

- a. their test has been accepted elsewhere and UK is the one out of step;
- b. the PHLSB evaluation was not adequate; and probably
- c. the UK could have had their test in place months ago and we have dallied to allow the preferred UK manufacturer to catch up.

The premature leaks in the press that Wellcome were favourites has not helped in refuting (c).

4. On the grounds of the time required to perform their test and the false positive rate we have sufficient technical reasons for excluding Abbott from further consideration. However to be scrupulously fair we will put additional data from Abbott to our Expert Advisory Group for their advice. Because of the importance of the UK market and the effect of their failure here on other markets they can be expected to lobby hard. If we let Abbott in then in fairness the other failures should be treated similarly. This would effectively invalidate the PHLS part of the evaluation.

5. Advice sought

Is MS(H) happy that we should hold to the agreed strategy and resist Abbott's approaches.

GRO-C

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2 August 1985

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Dr E Harris
Mr Cashman
Dr Smithies
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