

Mr Hart

From: Dr J S Metters  
9 October 1989

Copies to:

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Mr Dobson  
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Mr Canavan

GRO-C

13/10

#### ANTI-HCV TESTING OF BLOOD DONATIONS

Thank you for copying me Dr Gunson's letter of 2 October. As he mentions the Chiron test will be discussed at the Advisory Committee on the Virological Safety of Blood (ACVSB) on 6 November.

2. At their July meeting ACVSB discussed this test and concluded there was insufficient data available on its performance. Meanwhile Ortho have been pushing the test very hard and offering a number of free tests. They also arranged for some transfusion centre directors and other experts to attend a meeting in Rome on 14 September where the experience of 100,000 tests at different European centres were reported. At least eight UK participants were at the meeting including three members of ACVSB (Drs Gunson, Mitchell and Mortimer).

3. The main points that concerned ACVSB at their last meeting were that the Chiron test cannot be independently validated, and as a result we have no idea of the false positive or negative rate. Some recent reports suggest that patients with chronic hepatitis test negative to Chiron, despite the fact they may be transmitting the virus, and that they were previously Chiron positive. Hardly a reassuring finding if confirmed. From Dr Gunson's letter the specificity still seems to be a problem, and if so it could well deter the Committee from recommending the general introduction of Chiron.

4. Another factor that will influence the Committee is that no country has as yet put it into routine use and the test does not have FDA licence, and is unlikely to get one until next Spring at the earliest.

5. We have not seen the data from the Rome meeting, but if it is comprehensive it could sway the balance.

6. The tone of Harold Gunson's letter suggests that he is convinced that Chiron will eventually be introduced. However, my impression from the last meeting was that other members were much more sceptical, particularly on

validation. Dr Gunson is, however, absolutely right to draw attention to the financial implications for BTCs.

7. The Committee are well aware of the cost implications and the need for a uniform policy for all UK BTCs. However I do not think it is a foregone conclusion that ACVSB will recommend its introduction at their November meeting. They may well opt "to wait FDA's consideration".

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