



SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE

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JDC/MM

04 August 1989

Dr A McIntyre
Scottish Home and Health Department
St Andrew's House
EDINBURGH



Dear Archie

NANB (Chiron) Testing

I have now had a Mr Peter Savage (Ortho) in to see me and can report (as promised) the following (not in any order of importance or necessarily important at all):

1. I advised Mr Savage that the decision to introduce this testing would be made on a UK basis and that a key group in the decision making process would be the group originally chaired by Dr E Harris (DOH). I therefore declined to discuss start dates, ordering policies etc.
2. Mr Savage advised me that the next meeting of the Dr Harris group was scheduled for 17th October 1989. In advance of this Ortho have arranged an informal meeting with Dr Gunson, Dr Barbara and Dr Contreras to look at the preliminary UK (BTS) data. The meeting would take place at 1 pm in the Strand Palace Hotel, London on 23rd August. Ortho would wish to have SNBTS representation. (Note this has since been confirmed by HG and it is hoped Dr Mitchell and Dr Follett will attend).
3. I pursued Mr Savage on confirmation testing which I believe is a crucial issue, both with regard to its absolute scientific/medical value but also a means whereby we can regain some initiative over Ortho.

In brief they have a confirmation test (RIA) but it uses the same antigen as the screening test (scientifically weak but at present better than nothing). The main problem is that Ortho currently do not wish/plan to market it. Mr Savage indicated that Ortho (UK) would make arrangements to send screen repeat positives to Ortho (USA) to be confirmation tested (probably at least 1500/annum from SNBTS alone).

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National Medical Director: Professor John D. Cash

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National Administrator: Miss Morag Corrie

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1 indicated to Mr Savage, that in my view this proposal was wholly unacceptable. We would wish/insist that the confirmation testing, which has a profound influence on the lives of many donors, was in our hands. (1 would strongly advise the Harris Group to take up this issue. The technology could be transferred: the block is almost certainly a marketing ploy. Aside from significant ethical and logistic problems 1 would suggest this issue will permit the UK BTS to gain some of the highground over Ortho).

4. Ortho wish to negotiate on a UK BTS price for the test (looks like £1,50 per test is the area). But they would also like to negotiate separate (local) add-on features which relate to further price reduction if rapid payment of bills take place) (Seems OK but not sure how practical).
5. Mr Savage indicated that "Denmark will start full testing on 1st October". Detailed questioning revealed that this statement was exceedingly speculative and, at most, at the present time, it applied to one major hospital blood bank in Copenhagen.
6. Mr Savage believed that full testing in the USA would commence "towards the end of the first quarter of 1990". (1 would think this judgement is correct).
7. Mr Savage suggested that after the UK decision "to go" has been made there should be formed a UK BTS/Ortho Working Committee in order to facilitate the introduction of the programme (good idea but we will need to watch this doesn't become a long-term market strategy to the exclusion of other companies).

Footnote:

I would advise that the UK proceeds as follows:

- (a) Let it be known to Ortho that a decision whether to introduce Chiron testing throughout UK BTS will be made at the special meeting to be held on 17th October 1989.
- (b) That after the meeting on 17th October, and presuming the inevitable that it will be agreed testing will be introduced - but in a co-ordinated fashion, Ortho be advised that

3.

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- (i) A date for commencement will be considered when Ortho agree to make arrangements for confirmation testing technology to be transferred to UK (NHS) laboratories,
- (ii) that commencement will also be subject to the kit system getting an FDA licence.
- (c) Subject to conditions (b) above being acceptable and delivered then I would suggest that the UK BTS plans to commence full testing on 1st June 1989 but significant funding is made available from 1st April 1990 for a two month run-up period (using stored sera) both at RTCs and confirmation laboratories.

Hope these comments are helpful.

Kindest regards.

Yours sincerely

John D Cash

SC Dr Genson

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