ABBOTT

M Kenny

I should be grateful if you would answer this letter on behalf of MSCHJ.

R. A. Schoellhorn
Chairman of the Board
and Chief Executive Officer

Abbott Laboratories
Abbott Park
North Chicago Illinois 60064

GRO-C

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December 11, 1985

20/12/85

The Rt. Hon. Bernard J. Hayhoe, M.P.
Minister for Health
Department of Health and Social Security
Alexander Fleming House
Elephant and Castle
London, SE1 6BY

Dear Minister:

Many thanks for your letter of November 1 on the subject of HTLV-III tests. I am most grateful for this thoughtful reply and the explanation which you give of your Department's approach, although you will not be surprised to learn that we do not agree with conclusions drawn. Data from the DHSS evaluation (Table III, The Lancet, October 19, 1985, pp. 873-877) indicate that the two kits selected for use in the U.K. are, in fact, among the least sensitive tests studied. Of equal concern is that a false-negative result was obtained with two of the kits evaluated, one of which was selected for use in the U.K. (Table I).

However that may be, you will, I am sure, be interested to know that Abbott Laboratories is developing a rapid and easy to use confirmation technique which will be available early in 1986. This will mean that the medical and logistical problems associated with false positive samples will be avoided. This in turn will allow a greater emphasis on the sensitivity of test systems. In addition, Abbott Laboratories will be adding a second protocol to our test procedure and this will reduce the total testing time to two

hours without reducing the sensitivity of the test. This new procedure will also allow the initial dilution stage to be achieved more rapidly with less effort and by less highly trained personnel. The result should be to facilitate use of the kits in a manner compatible with the stated needs of the National Blood Transfusion Services in the U.K.

I would be grateful if you could let us know how your Department will in the future evaluate, approve and communicate significant improvements such as the ones which I have mentioned. Clarification on these points are very important to us since I understand that the various blood transfusion centers in the U.K. will find it difficult to use new tests or procedures unless your Department recommends the tests concerned.

Our scientific management will, as you suggest in your letter, provide some additional documentation and insights to Mr. David Kennedy of the Scientific and Technical Branch, including the basis for approval by the U.S. Food and Drug Administration. In that material we will discuss specifically the issue of sensitivity, including recent published reports indicating a higher level of sensitivity for the Abbott test when compared to some other tests.

We sincerely hope that this further evaluation, along with the new information that is emerging, will result in an expeditious decision by the Department to include the test provided by Abbott Laboratories on your list of tests that can be recommended for use by Regional Transfusion Centers.

Let me conclude by saying how much I appreciated our talk on the issues of interest to the Pharmaceutical Manufacturers Association. It was certainly of great help so far as I was concerned in understanding better the position adopted by the British government. It was very good of you to spare your time for this purpose and I hope we shall have the opportunity to see each other again soon.

Sincerely,

GRO-C

RAS:mrb