3, WESTMINSTER GARDENS,
MARSHAM STREET,
LONDON, SW1P 4JA
TEL. 01-828 2448

17th September, 1985.

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

Dear Minister

I was very sorry to learn that you will be unable to attend the dinner arranged for September 24th to enable your predecessor to meet the Chairman of Abbott Laboratories in his capacity as President of the Pharmaceutical Manufacturers Association of the U.S.A. and I greatly hope that you will be able to suggest another date in the near future. The American Pharmaceutical Companies are, as you will learn, much exercised about H.M.G.'s policy regarding prescription drugs and are inclined to suspect discrimination against them. I am therefore convinced that an early discussion between you and Mr. Schoellhorn is important in order to try to clear the air.

Another matter of concern, not of course relevant to the Pharmaceutical Manufacturers Association, is the selection of approved tests to detect the HTLV III anti-bodies. As I understand the position, the Department, after a delay of some six months from the time at which the Abbott and other tests approved

The Rt. Hon.
Bernard J. Hayhoe, M.P. 17th September, 1985

in the U.S. were available, has selected two tests: One is the Wellcombe test (never used so far as I know except on an experimental basis) and the other is the Organon test, which has recently been introduced in Europe but has not yet been approved in the U.S. The Abbott test, which is far the most widely used in the rest of the world, has been excluded. This seems to me an eccentric decision to put it mildly and apparently justified on the grounds that the Abbott test produces somewhat more "false positives". This is marginally true but false positives can of course be eliminated subsequently. "False negatives" are clearly far more dangerous and indeed fatal. Sensitivity or the ability to detect anti-body to the virus is the most important criterion for tests intended to screen donated blood because this minimises the likelihood of false negative results allowing contaminated donations into the blood supply.

The Abbott test is I believe accepted even by the DHSS as the most sensitive. If the DHSS recommends U.K. blood banks not to use the Abbott test the result seems likely to be that a higher number of contaminated blood donations will enter the blood supply of the U.K.

I enclose a briefing memorandum which Mr. Schoellhorn has prepared. Of course Abbott would be happy to make any further useful clarification.

Abbott's primary immediate objective is to be allowed to make a scientific presentation in a meeting with representatives of the DHSS who have a direct role in formulating policy.

Yours

GRO-C

D R A F T

(2)

Ms Bateman

MS(H)'S LUNCH ON 1 OCTOBER 1985 WITH MR R A SCHOELLHORN, CHAIRMAN OF ABBOTT LABORATORIES INC

As requested I attach briefing for MS(H) on the issue of the selection of HTLVIII antibody test kits for use in blood donation screening.

As stated in Mr Schoellhorn's letter of 18 September 1985, Abbott are holding a symposium ("Scientific Advisory Committee" in their terms) in London today; it is expected that Abbott will use that opportunity to promote their test kit. The Department's Scientific and Technical Branch judged it inappropriate to attend, but if any further developments emerge as a result of that meeting, supplementary briefing will be prepared.

ALUN J WILLIAMS
HS1A
1208 HAN H
X GRO-C

27 September 1985

copies to: Mr Langsdon
Mr Higson
Mr Long
Mr M A Harris
Dr A Smithies
Mr P Lister
Mr D Kennedy

(3)

BRIEFING FOR MS(H) LUNCH WITH MR SCHOELLHORN, CHAIRMAN OF ABBOTT LABORATORIES INC ON 1 OCTOBER 1985

SELECTION OF HTLV III ANTIBODY TEST KIT FOR USE IN NATIONAL BLOOD TRANSFUSION SERVICE

SUMMARY

Abbott Laboratories Inc wish to put to MS(H) their view that this country is mistaken in not choosing Abbott's own HTLV III antibody test kit for use in routine screening of blood donations. This brief gives MS(H) the background to our approach, summarises Abbott's objections and suggests the line for MS(H) to take with Mr Schoellhorn. MS(H) will wish to avoid being drawn into a discussion of technical matters at the lunch on 1 October 1985, but may wish to offer a written response on the points raised; a draft reply is attached (flag).

BACKGROUND

Abbott's concerns are expressed in the letter of 17 September 1985 from Sir Philip de Zulueta (flag), and the memorandum of 18 September 1985 from Mr Schoellhorn (flag). In essence they point out:

1. this country is out of step with the rest of the world in

   a. its delay in implementing blood donation screening, and

   b. its rejection of Abbott's own test

2. our main/sole criterion in evaluating tests was to achieve a low rate of "false positives" (ie antibodies detected when none present), whereas Abbott see a low false negative rate (antibodies present but not detected) as most important.

3. our evaluation conclusions do not agree with Abbott's wide experience of their own test elsewhere. Abbott maintain that their test offers the lowest rate of false negatives.

These comments reveal a misunderstanding of this country's approach and a difference of opinion between UK experts and Abbott on the technical merits of Abbott's test. There has already been correspondence with Sir Philip de Zulueta on some of these aspects (flag), before the results of our evaluation emerged.

LINE TO TAKE ON ABBOTT'S CRITICISMS

(1)(a): UK approach to introducing screening tests

With advice from its Expert Advisory Group on AIDS, the Department decided that the public health would be best protected by evaluating the test kits available, to ensure that satisfactory tests were chosen for diagnostic and blood donation screening purposes. The delay in starting routine screening was accepted as inevitable but necessary. Progress in other European countries to introduce routine screening has been patchy. Even in the USA, although the first tests were formally approved for use by the Food and Drugs Administration (FDA) in March this year, their obligatory use for blood screening has been introduced by various federal states only in the last few months. The UK is thus not as far behind as Abbott imply.

(1)(b): Status of the UK evaluation of test kits

This country does not operate a formal approval system such as that of FDA in the USA. The UK comparative evaluation of the tests was intended to identify the test or tests most suitable for use in this country for both diagnostic and blood donation screening. The fact that Abbott's test did not emerge from the first stage

of evaluation amongst the two leading candidates for evaluation in the Blood Transfusion Services does not imply failure or disapproval by DHSS, but only that other kits (Wellcome + Organon) were considered to have additional advantages.

(2): UK criteria in selecting tests

Abbott mis-state the criteria for selecting tests during the evaluation process. Adequate sensitivity (a low false negative rate) was one of the most important criteria used in the first evaluation stage at the Public Health Laboratory Service (PHLS). Given that as a pre-condition, other factors are then legitimately added in selecting the tests, viz specificity (low false positive rate) and ease of operation (speed, simplicity of method etc). It was on these additional criteria that Abbott's test did not find favour - compared to other tests, it took much longer, had extra steps (where errors might increase) and gave more false positives.

(3) Results of UK evaluation work

Like the other manufacturers, Abbott were given the opportunity, before work started, to comment on the proposed methodology (the protocol) that was to be used in the first PHLS stage of evaluation. Abbott made no comments questioning the validity of the Department's approach before agreeing to take part in the evaluation. When the results were produced, favouring other kits, Abbott objected. They were invited to submit other rebutting data; that which has been provided has been considered by our evaluation experts, but has not changed their conclusions. Further requests for information (particularly on the basis on which FDA approval was given, and the risks of Abbott's reagents transmitting AIDS virus) have not been met.

(6)

FUTURE COOPERATION

Abbott are clearly disappointed by their failure so far to penetrate the UK blood screening market; they themselves however acknowledge that they are attempting to improve their test kit. MS(H) may wish to point out that the UK is aware of how rapidly advances are being made in the test methods available. When routine screening starts shortly in the Blood Transfusion Service, any contracts to buy test kits are likely to be very short-term (2-3 months) so that the position can be kept under review. The UK will be very interested in "second generation" antibody test kits from all manufacturers, including Abbott.

D R A F T

(7)

Dear Mr Schoellhorn

HTLV III ANTIBODY TESTING

When we met for lunch recently, I promised to let you have a reply to your memorandum of 18 September 1985 which accompanied Sir Philip de Zulueta's letter of 17 September 1985. I hope I may be able to clear up certain misunderstandings about my Department's approach to the question of introducing routine screening of blood donations for HTLVIII antibody, and our evaluation of the various commercial tests available.

No doubt you are already aware of the previous correspondence on this matter between Sir Philip and my predecessor, Kenneth Clarke. Our objective remains the protection of the safety of blood transfusions, and the comparative evaluation of the available tests was necessary to ensure that any test or tests chosen was satisfactory.

Contrary to your impression, one of the most important criteria adopted by the UK in its evaluation, was that of sensitivity (ie a low false negative rate). I am advised that the first stage of evaluation by the PHLS concluded that the tests available were all sufficiently sensitive, but that those selected for consideration in the Blood Transfusion Service had additional advantages in terms of specificity (low false positive rate) and operational facility especially the time required to carry them out.

The additional data your company provided was carefully considered by our evaluation experts, and I know that you have had meetings with senior officials in my Department's Scientific and Technical Branch at which your views were fully explored. Nevertheless, if you wish to send me any further evidence or data, I would be pleased to arrange

for it to be examined carefully. This might well include some of the documentation which officials have already suggested might be helpful, for example, the basis on which FDA approval was obtained, and action to demonstrate that your test kit and reagents could not transmit live AIDS virus.

As I explained to you during our lunch, the Department is well aware of the speed with which changes are taking place in the development of these test kits. When routine screening is introduced shortly, contracts for the purchase of particular test kits are likely to be short-term, to allow the National Blood Transfusion Service to take advantage of any significant improvements which may occur in test kits available from all manufacturers.

I hope you will be reassured by my explanation of this country's approach to this problem.

B HAYHOE