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Briefing Memorandum for Mr B Hayhoe

Please let me take this opportunity to give you a personal briefing on a matter of growing concern. I refer to actions that have been taken and decisions that are being contemplated with regard to the screening of donated blood for evidence of the presence of the virus believed to cause Aids. My objective in providing you with the following technical information and scientific analysis is to assist the UK government in implementing blood screening in a way that reduces the potential for contaminated blood to enter the blood supply.

As you may know, the DHSS has conducted comparative analyses of blood screening tests from several sources in order to identify the test or tests most appropriate for use in the UK. We were perplexed when we first learned that the test developed by Abbott Laboratories was not considered appropriate for use in the UK blood banks. Our Scientific Project Manager visited the UK in an attempt to determine why conclusions were reached there that were inconsistent with the results obtained in hundreds of settings screening millions of units of blood throughout the world.

It appears that the criteria in the UK call for blood screening tests with the lowest possible incidence of false positive results. This can be achieved in any of the available tests by establishing parameters that decrease sensitivity of the test, including the test we developed. However, we are not willing to do this because the nature of the technology being used in all of the tests is such that decreasing the sensitivity of the tests lowers its detectability, thereby producing a higher rate of false negative results. Therefore, to reduce the incidence of false positives one must be willing to allow more blood units to be transfused that are positive for the antibody to the virus, some of which contain live virus and will infect recipients and lead to the onset of Aids.

The design goal established by blood collecting agencies and health agencies throughout the world has been to reduce false negative results to the lowest level possible in order to protect the blood supply. In my opinion, the most effective means of doing this while avoiding unnecessarily discarding blood donations, and avoiding the inappropriate

notification of blood donors with false positive results is to (a) use a test with the highest practical level of sensitivity, (b) discarding blood donations only if subsequent results using the same tests are positive, (c) notifying donors of positive results only if the donated blood is positive when a confirmatory test such as western blot is positive, using established guidelines for the counselling of donors, including a referral to the donor's physician, or not notifying donors at all until more precise tests for viral infection are available, tests currently under development by Abbott.

We have observed a consistency in the following conclusions:

1. The primary public health objective in implementing blood screening is to protect the blood supply from contaminated donations, with a resulting objective of avoiding false negative results, requiring a criterion for maximum detectability.

2. In order to protect a blood supply, one accepts a slight reduction in specificity, resulting in a very small but relatively higher level of false positive results, ameliorated by policies concerning the notification of donors, donor counselling and/or subsequent testing for confirmation. Confirmatory testing of positive results virtually eliminates the reporting of false positive results.

3. The incidence of Aids transmitted through blood transfusions is an endemic and growing problem in every society. The long delay between infection and the onset of symptons is such that the disease spreads at an exponentially greater rate than would otherwise be the case as a result of the symptomless nature of early infection and unrecognised infection of others over many years.

4. Aids is a serious and growing threat to populations other than those in which Aids was initially identified and represents a growing threat to society at large.

Another issue raised by the DHSS study was the question of ease of use of the test. Extensive industrial engineering studies conducted at Abbott Laboratories showed the Abbott test to require slightly less labour than the microtiter method, but the Abbott test had longer incubation times. This resulted in five hours needed to run the Abbott test as compared to two and a half hours for the microtiter method. Abbott certainly views the incubation as clearly less important than the sensitivity of the test. However, the company is planning to reduce the incubation time by one and a half hours in a few months as further extensive clinical trials confirm that there is no consequent reduction in sensitivity.

Blood banks in Great Britain have been informed that screening must occur in October of this year and that the test available from Abbott Laboratories is not recommended. The next opportunity for us to present our views formally appears to be limited to a meeting of a Scientific Advisory Committee on September 27 of this year, after screening may have been initiated with tests using specificity as their principal criterion.

I respectfully recommend this matter to you with some urgency in view of the fact that comparative analyses continue to be performed that indicate that some of the tests that are available, and that are recommended for use in the UK have a sensitivity level that results in a failure to identify blood samples that are known to be contaminated with the Aids virus. Data will be presented at a scientific meeting in October that may indicate a significant false negative error rate when tests of this nature are adjusted for maximum specificity at the expense of sensitivity.

We have a strong desire to work with you and to share the results of our experience in helping many nations to assure a safe blood supply quickly and effectively. I respectfully request that an opportunity be made available to further explore these matters prior to the execution of policies now being formulated. Representatives of our scientific staff are available to meet with the appropriate policymakers to provide the DHSS with a thorough briefing on the technology and science that we believe can assist you in meeting the objective of a safe blood supply.

Respectfully,

R A Schoellhorn
Chairman
Abbott Laboratories Inc