Alpha THERAPEUTIC CORPORATION

INTEROFFICE CORRESPONDENCE

FROM: REGULATORY AFFAIRS
M. Carr

DATE: March 1, 1985

TO:

RE: Meeting with FDA on Prison Source Plasma, February 26, 1985

I had requested a meeting with Dr. Petricciani after the Fractionation Industry meeting to include only the four commercial manufacturers. Present were: Bob Reilly, Mike Rodell, Steve Holst, and myself. Steve Ojalla had to catch a plane.

We had all agreed that we would introduce the subject by asking the status of the study we had heard FDA was performing on prison plasma and Bob Reilly did so. Dr. Petricciani went briefly into the background of why they decided to institute such testing. He became aware that they were receiving more applications for Source Plasma establishments in prisons. They had had problems in the past with the shipment of HBsAg reactive units from prison sources and falsification of records. With the concern over AIDS and concern over the conduct of any kind of studies or activities associated with prisoners, they felt that if there were more and more prison sources of plasma that they were in a very uncomfortable position over how FDA could justify these with no scientific data, particularly in the socio/political atmosphere. If challenged, he believes they must have a scientific basis for allowing this to continue, otherwise this could be a political bombshell.

Therefore, they arranged with one license applicant who is now licensed and collecting to monitor certain parameters to get a better idea of the situation. A field investigator visits the center on a random basis and randomly selects plasma units to be tested.

The parameters that they are studying are particle associated reverse transcriptase, which would pick up both HTLV-III virus and non-A, non-B hepatitis but can't differentiate between the two; virus recovery studies for HTLV-III, a test for syphilis which simply reconfirms the laboratory test results of the facility, and the same for HBsAg. Although it wasn't available at that time, they would like to add HTLV-III antibody testing.

If prison plasma can't be differentiated from non-prison plasma, they would then consider relaxing the guidelines.

When I asked him for a time period or a potential target date, he stated that they have received further funds for AIDS study so results will be speeded up because they will contract out the testing. It is expensive and involves several hundred donors. He also indicated that the timing was affected by their priorities. He felt that it would be more rapid once the HTLV-III tests were licensed and they could get some of these concerns behind them.

When asked as to what their reaction would be if a manufacturer wanted to do such a study, he stated that they would consider it good complementary information.

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I informed him that since we had made these agreements two years ago, much more had been learned, and with a shortage of plasma now and more expected with the advent of HTLV-III testing industry management was questioning why the differentiation from other donor sources. I stated this for his information simply to prepare the way for any further inquiries we wish to make on our own.

Ncte that Armour apparently has absolutely no interest in this subject but was willing to be present. Steve Holst obviously believes Hyland does have an interest but was really nonpartcipatory since he is so new to his job. Although Bob Reilly was willing to participate in discussions on this, he obviously considers this as stated, a potential bombshell and does not want to press further since it does not represent the majority of his constituency. If we wish to press further it would be my recommendation that we try to do so with Hyland and Cutter.

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Do We Want To Pursue?

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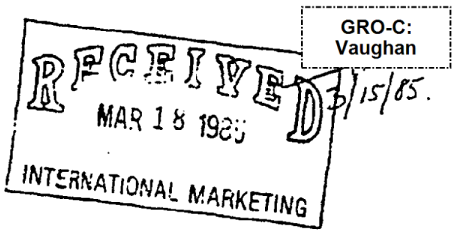
To: Pete De Hart

Pete,

How much material do we get currently (gross plasma)? Could this represent an opportunity to source substantial incremental amounts? If yes, we probably do want to pursue.



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