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All Plasma Center Managers Robert Barden

FROM SUBJECT

Questions and Answers About AIDS

2/8/83

COMES TO Plasma Center Owners

Regional Plasma Center Managers

There is a packet of information enclosed with these questions and answers. Before you begin the screening of your donors, it is imperative that you have a formal training session with your employees on all the changes which are occuring. The following questions were developed to anticipate those your employees and donors might ask.

- 1. Q. Is the FDA asking Cutter to implement these changes in procedure?
 - A. Not exactly. We have taken these precautions voluntarily but the FDA is wanting to know what we are doing and pushing us in the direction we are taking.
- 2. Q. Will there be regulatory changes concerning AIDS?
 - A. We are not sure what form the FDA will choose, but we do expect to see at least some guidelines published in the very near future.
- 3. Q. What are the other Fractionators doing about AIDS?
 - A. We are not exactly certain of all the details, but essentially the same as we are.
- 4. Q. What product is affected by AIDS?
 - A. Right now, it is believed that Factor VIII and Factor IX, Koate^R and Konyne^R, can pass AIDS on to the recipient. We know that 8 or more hemophiliacs have contracted AIDS. It is assumed that the coagulation products they used were the source of the disease.

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EXHIBIT I

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- What should you do if you determine one of your donors has AIDS 5. Q.
 - A. Stop all donations, isolate any plasma on hand and call Bill Tarleton for directions. (415) 420-5151.
- 6.
- Q. What should you do if you feel someone is a male homosexual but A. We must rely on our donor's integrity, therefore we would accept
 - the donor unless there was proof to the contrary. Q. Can transexuals donate?
 - A. Not if they are sexually active because most were male by birth and would be considered homosexual if they are having sex with a male
- Q. If someone admits to having been "gay" in the past, is that grounds
- A. It depends on how long ago they stopped being a homosexual. If they stopped prior to 1978, then they should be considered safe, however this is a gray area and if there were any hint that they might have
- been active more recently, they should be suspended. Q. Why is 1978 a cut-off period?

A. AIDS first showed up in 1979 and since it has a long incubation time. the initial exposure could have been in 1978.

Q. Why is the doctor checking the donor's lymph nodes and skin surface? A. The Lympth nodes become svollen in ALDS cases and skin lesions are also common in AIDS cases.

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- 11. Q. If a donor has swollen lymph glands or skin lesions, does that mean the donor has AIDS?
 - A. Definitely not! There are many other illnesses that have these symptoms and it could be any one of them. The donor should be referred to his doctor or a clinic for a checkup.
- 12. Q. Is there a test for AIDS on the horizon?
 - A. No. A lot of effort is going into research on AIDS, but they still do not know what causes AIDS so a test that is specific for AIDS will take quite some time.
- 13. Q. Regarding AIDS symptoms, what is meant by persistant diarrhea, and night sweats?
 - A. Persistent diarrhea means that symptoms last for seven days or longer. Night sweats occur while a person is sleeping.

14. Q. Can we legally refuse to process male homosexuals?

A. Yes. We can refuse any donor based on reasons of health. Since we have no test for AIDS, and since it is possible that a male homosexual has been exposed to AIDS, we can reject them due to an uncertain health status.

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