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[Meeting Among FDA [Food and Drug Administration] and HCFA [Health Care Financing Administration] Staff] [loose]

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February 14, 1994

Meeting Among FDA and HCFA Staff to Review Lookback Rulemaking Project and Discuss A Joint Plan For Implementation.

Overall Objectives

- To ensure that each agency has a clear understanding of the other's companion rule as well as how it will be monitored and interpreted.
- To define the actions which will enable us to carry out an effective joint agency task.
- To construct a blueprint or outline of the actions which can be used to guide the agencys' efforts as well as educate others as to how the task will be carried out. E.g., A presentation to the staff and members of the House Subcommittee on Oversight and Investigations.

Immediate Objectives of Today's Meeting

- Revist the proposed rules and where they are heading.
- Identify mechanisms/methods that can be used to implement.
- Identify means of documentation for the task.
- Establish points of contact (POC)
- Agree on some follow up steps so the system can be ready once the rules are.
- Identify loose ends.

Mechanisms/Methods to keep in mind

- Memorandum of Understanding
- Instructions to Investigators/ Surveyors
- Training of Investigators/Surveyors
- Functional location of POCs

Is there a track record to build on? YES

- Exchange of Information on blood transfusion fatality reports
- Registration status of firms

Subcommittee's Points of Reference

- What agreements, protocols, and policies have been established between FDA and HCFA regarding: Steps in reviewing patient records; process for notification of consignees, physicians, and receipients; process for testing receipients for HIV; steps to be taken to ensure compliance with notification.

PMD/2-13-94/Lookback/

Office of the National AIDS Policy Coordinator

Executive Office of the President
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Washington, D.C. 20500

Phone: (202)632-1090
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Deliver To: Steve Lee

Sent From:

____ Kristine Gebbie, RN, MN, National AIDS Policy Coordinator

✓ Sam Shekar (690-6248)

____

Number of Pages: 8 + Cover Fax Number: _____ Date: 2/9/94

Message:

* HIV Lookback Meeting — Background Brief*
(Monday 9AM–9:30AM) — Original Agenda* & Invite Letter
for KG
— Kessler's Testimony

* New agenda will incorporate Kristine's opening speech

I have both FDA's & HCFA's regulations (lengthy) — will send by Fax if you need it / otherwise by courier tomorrow

February 9, 1994

NOTE TO: Kristine Gebbie
Arthur Lawrence

FROM: Sam Shekar SS

SUBJECT: February 14 FDA-HCFA HIV "lookback" meeting

On Monday, February 14, from 9 AM - 12 noon in Conference Room N of the Parklawn building in Rockville, FDA will host a meeting to discuss the joint FDA-HCFA final regulations on HIV "lookback" testing and counseling (Attachment). Recommendations from the 1988 Presidential Commission on AIDS included a charge to DHHS to ensure notification, testing and counseling of individuals who had or would receive blood/blood products that were subsequently found to be derived from HIV-infected sources. Within the Department, both FDA (responsible for blood-banking regulatory approval) and HCFA (responsible for hospital compliance with the Medicare/Medicaid programs, with strong impact for JCAHO) adopted these and other recommendations in 1988, and jointly began a rules writing process for their "companion" regulations.

After much delay, the companion proposed regulations were published in the Federal Register on June 30, 1993 by the agencies (Attachment). The proposed rules allowed for a 60-day public comment period; the agencies have assessed those comments and are now developing final regulations on the "lookback" issue. They have been prompted recently in this activity by our office's encouragement of a final resolution, as well as by inquiries from the E&C/Subcommittee on Oversight and Investigations, at which Dr. Kessler testified this summer (Attachment).

Primary reasons for the five year delay in completion of this process included: significant agency disagreements over scope and definitions of blood products/components to be regulated; strong resistance by hospitals and their associations of a federal mandate with no additional funding authorization; lack of prioritization due to changes in leadership within the AIDS Commission, the Administration and the agencies themselves; and lack of focused pressure by community groups (unsure of its impact on confidentiality and medical insurance classification).

Underlying all of these was a sense that the real crisis in HIV-transmission through blood was "over", due to more stringent screening of blood donors, and testing of blood, by the late 1980's. However, blood donations given by individuals in the "window" period of HIV infection (before antibody development) still make the "lookback" process necessary.

PROPOSED AGENDA

I. Introduction - Mike Dubinsky

II. Explanation of the Proposed FDA Lookback Rule and Status of Comments Received - S. Falter

III. Explanation of the Proposed HCFA Lookback Rule and Status of Comments Received - HCFA

IV. HCV Lookback - FDA, Office of Blood Research and Review

V. How FDA would assess Compliance with Lookback Rule - FDA, Office of Regional Affairs & CBER

VI. How HCFA would assess Compliance with Lookback Rule

VII. How FDA will Instruct/Train Investigators - FDA, Office Regional Affair & CBER

VIII. How HCFA would Assess Compliance with Lookback Rule

IX. Sanctions for Non-Compliance - FDA

X. Sanctions for Non-Compliance - HCFA

XI. Wrap Up - Next Steps - Mike Dubinsky

JAN 25 1994

Dr. Sam Shekar
National AIDS Policy Office
RM 738G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. Shekar:

I am writing on behalf of the Food and Drug Administration (FDA) to request your assistance in coordinating a meeting with appropriate staff in the Health Care Financing Administration (HCFA). The purpose of the meeting would be to prepare a presentation on lookback for staff members from the Subcommittee on Oversight and Investigations. The following discussion traces the events underpinning the need to make the presentation.

On July 28, 1993, Dr. Kessler, Commissioner of FDA, as well as staff from the Center for Biologics Evaluation and Research and other FDA components, testified before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, concerning Regulation of the Blood Industry. Rulemaking on lookback for recipients of blood from donors who subsequently test positive for the presence of antibody to HIV, was among the topics covered. As you are aware, the lookback rulemaking process involves companion rules prepared by FDA and HCFA.

The Subcommittee expressed particular concern about the manner in which FDA and HCFA will carry out, and coordinate, our respective functions regarding implementation of the rules. Dr. Kessler during the course of his testimony at the July hearing provided overall assurances that FDA and HCFA would effectively carry out the assigned responsibilities. Prior to the hearing, he had spoken with Dr. Bruce Vladek, Administrator of HCFA. Copies of pertinent sections from the draft hearing transcript are enclosed for your ready reference.

Since the hearing, additional information about the lookback rules, e.g. the submission of public comment, has become available. Consistent with the recommendations of our Blood Product Advisory Committee, FDA is exploring the need for a lookback type process when donors subsequently test positive for antibody to hepatitis C virus. The interest of the Subcommittee in the topic of lookback and how we will jointly carry out our roles is therefore timely.

I am proposing that the meeting be arranged among appropriate programs and rulemaking staff from HCFA and FDA, and take place during the week of February 14, 1994. Arrangements as to the day, time, and place can be formulated after you review this letter and the proposed agenda, which is also enclosed. The phone number for my office is 301-594-2066 (voice), 301-594-1944 (facsimile).

Thank you for your attention to this request.

Sincerely,

P. Michael Dubinsky
Acting Director
Office of Compliance
Center for Biologics Evaluation
and Research
Food and Drug Administration

Enclosures

Mr. MOORHEAD. Yes, doctor?

Dr. KESSLER. All questioning is done confidentially. We would be happy to supply for the record, exactly how the military assures the safety of the blood on those carriers. I am not aware of any processing that is done on those. I think they--let me supply that for the record, unless Dr. Epstein knows. Let me do that, if I can.

Mr. MOORHEAD. We are to about the last four minutes of vote, so I have to yield back the balance of my time.

Mr. BROWN. The gentleman's time has expired. I have a couple of questions, Dr. Kessler. You had mentioned in my previous question about the five step process under your new rules. You did not mention, however, hepatitis testing. You talked only of HIV. Is that including those or will that be included, in the new proposal?

Dr. KESSLER. The lookback regulations apply for HIV disease. We have just within the public health service, the CDC, the NIH and FDA, we constantly reassess whether there should be lookback for other diseases beyond HIV. I think it's fair to say that the agreement from CDC, NIH and FDA, is that it makes sense to revisit the question of other diseases including Hepatitis at the December Blood Products Advisory Committee.

When you look at lookback as a public health protective measure, lookback is not--I mean, if you want to make sure

that anyone who has had a transfusion is then tested for hepatitis six months down the road if that's a risk and you want to be able to get someone treated or avoid secondary infection, it's not clear to me that lookback is necessarily the most efficient process.

What lookback really depends on--there's a fortuitous aspect to lookback. It's only if the donor happens to come back to donate a second time. With regard to HIV it's in place. With regard to hepatitis, I think the public health service agencies that it's an issue that needs to be raised again, and we will raise it at the December Blood Products Advisory Committee.

Mr. BROWN. Dr. Zoon, do you have any comments on that?

Dr. ZOON. I just wanted to make a statement regarding that. There are several factors that have initiated our re-look at the hepatitis question, and one is the advent of a recently life confirmatory test for hepatitis C. The other is a now available treatment for those infected individuals which is interferon.

With those two parameters plus with looking at the comments on the lookback proposal and looking at the appropriateness of lookback for some of the hepatitis viruses, that is under consideration. I think other PHS components in their discussions, feel that this is an appropriate thing to revisit. We will be looking into it

over the next several months and completing our activities after an advisory committee.

Mr. BROWN. Dr. Kessler, in the proposed regulations why is the Health Care Financing Administration been brought into this the way that you are proposing?

Dr. KESSLER. If you go back to the 1960's Congressman, HCFA has responsibilities for inspecting hospitals. They do that on a routine basis. There is a memorandum of understanding that was established back in 1979, and it was signed again in 1983, the MOU.

HCFA, when they are in the hospitals, they inspect against both the HCFA standards as well as FDA standards.

Mr. BROWN. Does HCFA have the ability to ensure or verify that hospitals will in fact notify attending physicians?

Dr. KESSLER. I have spoken with Dr. Vladek on this question. There is a proposed regulation that we issued on whether this system is the best system, of both HCFA and FDA doing it together. We are open to suggestions on that broader issue.

I think that with regard to the specific question, HCFA's proposed rule will require either the physician to notify the recipient or if the physician refuses or is not available, the hospital transfusion service must notify the recipient.

Mr. BROWN. This Committee has heard from time to time and

fairly regularly, when often times there are two Federal agencies overseeing the same issue or dealing with the same issue, this typically has--I have not been on this Subcommittee all that long but in past Subcommittee meetings and in the history of the Subcommittee--frown on that, when so often if two people are in charge nobody is in charge.

Assure the Subcommittee if you would, Dr. Kessler or Dr. Zoon or both, why that won't happen with the sort of joint jurisdiction of HCFA and the FDA on this issue.

Dr. KESSLER. I have spoken to Dr. VladeK who is head of the Health Care Financing Administration, and we both pledge to you to make sure that we will oversee to make sure that this job gets done.

Mr. BROWN. My time has expired. The gentleman from Oregon, Mr. Wyden.

Mr. WYDEN. Thank you. Dr. Kessler, what is your sense of how much this beefed up program in the blood area is going to cost the agency? Have you all made any efforts to try to calculate what this will take in the area of resources?

Dr. KESSLER. If you would be a little more specific, Congressman. We are a small agency.

Mr. WYDEN. I just want to give you the opportunity to give us a sense of what this may cost before we get to the usual scenario which is Congress talks about more activist role for the agency and very often neglects the resources.

"Lookback Proposed Rule"

List of Comment Letters

1. The New York Hospital-Cornell Medical Center
2. Blood Bank of Delaware
3. Sinai Hospital of Baltimore
4. San Diego Blood Bank Foundation
5. Florida Association of Blood Banks
6. Sarasota Community Blood Bank, Inc.
7. Greenville Regional Hospital
8. Greenville Regional Hospital-duplicate
9. Sacremento Medical Foundation
10. American Society of Clinical Pathologists
11. California Association of Hospitals and Health Systems
12. American Association of Blood Banks
13. Council of Community Blood Centers
14. Parkland Memorial Hospital
15. Serologicals
16. American Blood Resources Association
17. American Red Cross
18. Write on Queue
19. Department of Defense-Armed Services Blood Program Office
20. Highland Park Hospital
21. Case Western Reserve University
22. College of American Pathologists
23. St. Luke's Episcopal Hospital
24. Council of Community Blood Centers-duplicate
25. Institute of Pathology

"Lookback Proposed Rule"

Comment Letters

BLOOD BANKS

1 - New York Hospital-Cornell Medical Center
Director, Blood Bank & Transfusion Service

2 - Blood Bank of Delaware, Inc.
Responsible Head

4 - San Diego Blood Bank Foundation
Compliance Officer

6 - Sarasota Community Blood Bank
Responsible Head

8 - Greenville Regional Hospital
EVP/COO

9 - Sacramento Medical Foundation
Sacramento Blood Center
Medical Director/CEO

15 - Serologicals
Responsible Head

23 - St. Luke's Episcopal Hospital
Texas Medical Center
Houston, TX
Medical Director
Blood Bank & Transfusion Service

PATHOLOGY GROUPS

3 - Sinai Hospital Blood Bank (Baltimore)
Dept. of Pathology

7 - Greenville Regional Hospital
Dept. of Pathology and Laboratory Medicine
Medical Director/Laboratory Services

10 - American Society of Clinical Pathologists
President

14 - Parkland Memorial Hospital
Pathology Dept., Dept. Director

20 - Gloria B. Coker, M.D.
Pathologist
Highland Park Hospital

Covington, LA

21 - Brooks Jackson, M.D.
Associate Professor
Director of Clinical Pathology
Case Western Reserve University

25 - Institute of Pathology (DUPLICATE OF #21)
Case Western Reserve University
Division of Clinical Pathology
Director of Clinical Pathology

22 - College of American Pathologists
President

ASSOCIATIONS & BIG SUPPLIERS

5 - Florida Association of Blood Banks
President

11 - California Association of Hospitals and Health Systems
General Counsel

12 - American Association of Blood Banks (aaBB)
Executive Director

13 - Council of Community Blood Centers (CCBC)
Executive Director

24 - Council of Community Blood Centers (DUPLICATE OF #13)
Executive Director

16 - American Blood Resources Association (ABRA)
Director, Government Affairs

17 - American Red Cross
Responsible Head, Blood Services

19 - U.S. Dept of Defense
Armed Services Blood Program Office
Director

INDIVIDUALS

18 - Write on Queue
Maxine Bender Segal (parent of children with hemophilia)

"Lookback Proposed Rule"

Summary of Comments

Comments on General Information

-Suggests the SSA Blood Donor Locator Service be expanded and adapted to include transfusion recipients to facilitate necessary testing and counseling to limit spread of disease. C-1

-Current burden experienced:
*Increased workload due to more complicated patient illnesses.
*Costs rising faster than hospital revenues.
*Vacant positions cannot be filled.
*Greater need for efficiency increases need for skilled Medical Technologists which cannot be met due to declining numbers.
*Escalating demands and diminishing resources.
Current practice for HIV notification:
*tedious retrieval and examination of patient records
*four attempts to notify patients M.D.
*if unable to contact M.D. or if M.D. denies relationship with patient of refuses to notify patient case is referred to Maryland Public Health Dept.
The proposed rule will place an even greater burden on the health care system. C-3

-Agrees and supports concept of lookback. C-6

-Supports quarantine and notification procedure as proposed. C-9

-Additional circumstances when a blood establishment can reliably and consistently receive information that should result in the initiation of a lookback should include notification by the U.S. Military, Health Department and physician of a former donor found now to be HIV-infected or carry a diagnosis of AIDS. C-9

-Believes AABB recommendations for lookback, already in place, to be more appropriate and useful. C-9

-Supports proposed rule and does not feel it places undo hardship on the blood banking industry. C-9

-Suggests the use of "transfusion service" instead of "consignee" and "transfused patient" instead of "recipient" because it is more clear. C-13,24

-Supports the proposed rule to strengthen lookback requirements. C-14

-Comments are not specific to this proposed rule. C-18

-Suggests that reform is necessary so that providers of blood products are not liable if certain steps have been taken to assure optimal safety of blood products. C-20

-Believes that the Blood Donor Locator Service is inactive in a number of states and would be a helpful service, if available. C-23

Comments on 21 CFR 606.100

-Suggests SOP's for notification list titles of authorized persons to provide and receive notification, instead of names which will change with time. C-9

Comments on 21 CFR 610.46(a)

-Notification when confirmatory testing is indeterminate is almost always unwarranted. Notification and quarantine needed only with positive confirmatory test. C-9

-Disagrees on the notification of recipients based on only ELISA results with unavailable "confirmatory " test results due to unnecessarily worrying the recipient in a majority of cases since more than 90% of repeatedly reactive ELISA results for anti-HIV 1/2 on voluntary blood donors are not confirmed on Western blot assays and are thus false positives. C-12

-Clarify what is meant by consignees be notified "of the results of the tests." It would be unnecessary and confusing to provide negative or indeterminate test results, especially if the blood products were returned to the blood donor center. C-13

-The proposed regulations are silent on the subject of Western blot indeterminate results. C-13,24

-Recommends, consistent with CDC data that shows the unlikely occurrence of a Western blot indeterminate donation being infectious, that regulations state clearly that quarantined donations from donors who test indeterminate be discarded, however, no lookback/recipient notification need occur. C-13,24

-Concerns focus on actions taken as a result of repeatedly reactive tests prior to confirmatory testing. Believes that screening test are not intended to be diagnostic without further confirmatory testing. Believes it is inappropriate to take any lookback action based on screening tests alone, since all units are quarantined until testing is completed, and the quarantine period extends until confirmatory testing is conducted on all units initially testing repeatedly reactive. C-15

-Suggests that Sec.610.46(a) and 610.46(b) will result in the

"temporary" quarantine and subsequent release of most units previously drawn from donors that are now testing repeatedly reactive by screening tests, that are followed by a negative confirmatory test. Suggests this complicated exercise creates significant opportunity for human error and should be limited to situations in which it is reasonable to expect that failure to quarantine could cause harm. C-15

-Suggests notification of consignees should be limited to previous units that now are confirmed positive or indeterminate for anti-HIV. Believes this limited notification will avoid the paper exercise of quarantining units pending receipt of confirmatory test results, thus allowing blood establishments and consignees to focus their efforts on the most important measures aimed at ensuring the safety of the blood supply. C-15

-Sec. 610.46(a) is unclear when it states that all blood and blood components for the last five years from a donor who tests repeat reactive must be quarantine. In the supplementary information , Section III. E. states that if a licensed non-reactive result from a previous donations is on record, only blood and blood components collected less than 12 months prior to the reactive result must be quarantined. Further, Section III. G. states that units collected more than 12 months prior to the non-reactive test "need not be quarantined". All of this information should be specified in Sec. 610.46(a). C-17

-Suggests that since FDA has determined that 12 months prior to the previous non-reactive test result represents a 99% confidence level for the "window", it is unclear why Sec. 610.46 (a) requires the quarantine and notification of consignees of all blood and blood components intended for transfusion collected in the previous five years from a repeat reactive donor with no mention of previous non-reactive test results. C-17

-Supports a proposal that Sec. 610.46(a) require the quarantine and destruction of all blood and blood components collected from a repeat reactive donor less than 12 months prior to a previous non-reactive test result, never to exceed 5 years from the date of the repeat reactive test result, of 6 months prior to repeat reactive test result for components intended for further manufacture. C-17

-Proposes that Temporal Requirements (Sec. III G of PR) should specify that "lookback" for transfused components continue for the 12 month period prior to the donor's last non-reactive EIA test only, but not to exceed five years from the date of the repeat reactive test result. The would be consistent with requirements form quarantine of blood components. C-17

-Disagrees with the requirement to notify consignees of blood components that test repeatedly reactive before confirmatory testing is completed. Estimates that this measure prevents the

transfusion of only 2-3 infectious units collected during the "window" period at a cost of approximately 2 million dollars per unit. Additional example: If 18,000,000 blood components are transfused yearly, with approximately 1/225,000 components are HIV infectious despite testing, then 80 infectious units are transfused yearly, despite testing. Red cells and platelets represent 80% of all transfused products and are transfused within 8 weeks of donation before the donor can be tested in a repeat donation. Of the remaining 20 infectious fresh frozen plasma and cryoprecipitate components, 75% will be transfused within two months of donation leaving 5 potentially infectious unit. Approximately one-half of these donors will not return for donation and will not be retested so that only 2-3 infectious units will be destroyed before transfusion. It should also be noted that half of the recipients of these components will die within one year due to other causes. C-21,25

-Suggests the proposed rule should exempt small pools of plasma intended for further manufacture into non-injectable products to remain consistent with the requirements for large pools of plasma and because these small pools, sometimes created at the collection facility, may include plasma considered to be in short supply or may have no alternative supply. C-16

-Suggests that small pools of plasma intended for further manufacture into non-injectable products are sufficiently safe due to their intended use as <u>non</u>-injectable products and for that reason should be releasable from quarantine. Suggests Sec. 610.46(a)(1)(i) be amended to allow quarantine of all units, as appropriate, except small pools intended for further manufacture into non-injectable products. C-16

-Requests clarification of the term "consignee". Plasma collection establishments and manufacturing facilities often share the same establishment license number. Under strict interpretation, this could result in the destruction of both large and small pools of plasma found under the same license number. Although the clear intent of the rule is to protect these large pools of plasma created at a manufacturing facility. The current language would have the opposite effect in certain circumstances. C-16

-Suggests that to avoid defining a manufacturing facility as a consignee, the definition should hinge on the shipment of plasma <u>to a manufacturing facility</u> rather than on shipment to a consignee. This would clarify the situation in which the same establishment license includes both the collection establishment and manufacturing facility. C-16

<u>Comments on 21 CFR 610.46(b)</u>

-Suggests 3 week time period to notify consignee of confirmation testing to ensure 100% compliance due to limitations of reference

laboratory testing schedule. Also, negative and indeterminate tests require more time to complete than do positive tests due to the additional testing required.
Two week timetable is mute point since recall of all products from previous donations for a donor with repeatedly reactive results would guarantee safety. C-2,5

-Suggests 4 week limit as attainable, without compromising patient safety. Two week limit to perform more specific testing not practical and reasonable due to limitations of offsite laboratory testing. C-4

-Suggests 3 week turn around for follow up test results.
C-5,6

-Two weeks is not adequate for notification of consignees.
C-2,4,5,6,9

-Eight weeks for notification is more feasible. C-8

-Suggest eight weeks for recipient notification. C-9

-Disagrees with the two week requirement for performance of more specific testing and notification of consignees due to use of outside laboratories for this testing. C-12

-Disagrees with the two week period for testing and notification of consignees. C-13,24

-Proposes the regulation should read " if possible, within two weeks but not more than 30 days..." and require documentation for those instances when more than two weeks is needed, which would offer greater flexibility for the occasional, unavoidable delays in completing the testing . C-13,24

-Disagrees with the two week period for recipient notification as unrealistic. C-13,24

-Proposes a 30 day period for recipient notification to be as likely to prevent a secondary infection as the 2 week period because more than 90% of all repeatedly reactive samples are false positive. Further, the likelihood that a confirmed positive donor was in a serological "window" upon a previous donation is minuscule. (CDC now estimates that fewer than 10 such window transmissions occur annually.) The odds are even lower that one of these will occur in a repeat donor. C-13,24

-Disagrees with the two week time limit to complete Western blot testing as not realistic. C-14

-Recommends the time limit for completion of Western blot testing be changed to six weeks. Delays are often encountered due to

waiting for release of new lots of manufacturer's kits or due to time needed to send the sample to a reference laboratory. C-14

-Suggests FDA should refrain from specifying the time limit necessary to perform additional testing. C-16

-Suggests that the two week time limit for testing and notification may not be possible due to circumstances outside of the collection facilities' control. C-16

-Suggests that if a time limit for testing and notification must be defined, four weeks is more reasonable. C-16

-Disagrees with the two week time limit for confirmatory testing. Believes this limit is too restrictive and will greatly increase the costs associated with testing. C-17

-Proposes a 15 working day limit on confirmatory testing would allow adequate time for batching work and for unforeseen circumstances. C-17

-Disagrees with the two week time limit for notification of consignees as impossible within the US Armed Forces due to transfers of personnel throughout the world. C-19

-Recommends that the two week limit for notification of consignees be changed to "as soon as possible". C-19

-Disagrees with the two week limit for notification of consignees due to technical problems encountered with Western blot testing. C-21,25

-Proposes a 4 to 6 week time limit for notification of consignees. C-21,25

-Disagrees with the two week limit for notification of consignees because it creates a significant burden for the collecting facility. Further, at the estimated rate of 0.1 to .03 percent of donors testing repeatedly reactive and with 10 percent of these likely to be confirmed positive this proposed rule will demand a great deal of effort and cost with very little effect on the safety of the blood supply. C-22

<u>Comments on 21 CFR 610.46(c)</u>

-Recommends lookback and notification not be required for products donated 12 months or more prior to a donor's last licensed negative test, if there is a record of such a test. C-1

-Re: 21 CFR 610.46(c): Could documented negative HIV test results from other laboratories allow us to invoke the 12 month lookback past the most recent negative result? Such evidence of negative

serology could be provided by independent clinical laboratories, health departments, military labs, other blood banks, etc. C-5,6

-Clarify: Licensed more specific tests are available for HIV-1 antibody but none exists for HIV-2 antibodies. How is testing and notification handled in this case? C-5,6

-Sections III E of the PR is unclear in discussing quarantine of blood components for which confirmatory testing results is not made available within the two week requirement. It is not specified whether subsequent availability of a negative confirmatory result will allow release from quarantine. C-17

-Sec. 610.46(c) is unclear because it does not specify the disposition of quarantined blood components collected within the 12 month period prior to a previous non-reactive test result. For a donor who tests repeatedly reactive, but has a negative confirmatory test, it is unclear whether all components which are quarantined may be released , or only those collected more than 12 months prior to a previous non-reactive test result. If the intent is to release only components collected more than 12 month prior to the non-reactive test, then based upon the revision of 610.46(a) proposed in comment number 87, this subparagraph is unnecessary. C-17

-Sec. 610.46(c) might be interpreted that blood components collected more than 12 months prior to the last non-reactive test may be released from quarantine if the confirmatory test result from a repeat reactive EIA test is simply not available, or indeterminate, of positive. It is unclear whether the phrase "in addition" extends the requirements of the first sentence , to the second or distinguishes them as separate. C-17

Comments on 21 CFR 610.47(a)

-Need additional instruction regarding indeterminate HIV antibody results and disposition of quarantined products when the licensed, more specific test is positive. C-5,6

-Re: 21 CFR 610.47(a): Needs Clarification: In situations where transfusion services are provided to hospitals by community blood centers, which entity is responsible for notifying the patient's M.D.? Is it the transfusion service which performs the compatibility testing as required by Sec. 610.47(a)? Or, is it the hospital that infuses the blood product as required by 42 CFR 482.27? Clarify "service", "transfusion service" and " agreement" as mentioned in these regulations. C-5,6

-Clarification needed: Do these regulations apply to all regulated blood establishments, including small hospital based transfusion services that also draw blood donors? C-10

-Proposes that Sec. 610.47 require transfusion services to notify physicians "promptly" upon receipt of confirmatory results, rather than within the two week time limit which disregards availability of confirmatory test results. If confirmatory test results are not forwarded to the transfusion service within four weeks of notification of potentially infectious blood it must be incumbent upon the transfusion service to request this result from the blood manufacturing establishment. C-17

Comments on 21 CFR 610.47(b)

-Temporal limitations on need to trace recipients should be clarified and emphasized to reduce unnecessary work. C-1

-Responsibility for determining whether a recipient should be notified in a particular case should remain with the physician (if known). In certain cases, the harmful effects of notification may exceed the benefits of notification. Hospital should accept responsibility for notification only when unable to locate M.D. or unable to obtain M.D.'s acceptance of this responsibility. C-1

-If hospital is required to know and document outcome of M.D's counseling and test of patients, there must be a mechanism for such information to be provided. Currently, such information is retained by M.D. and not shared. Additionally, not all M.D.s performing counseling will be members of the staff of the hospital responsible for notification. C-1

-Suggests it is more reasonable to require due diligence be demonstrated and documented in the hospital's efforts to trace the recipients. Experience suggests investigation to locate recipient and to identify recipient's current M.D. requires greater than eight weeks.

-Suggests hospital send series of notification letters increasing in explicit information until recipient responds, if unable to obtain cooperation from M.D. in this process. C-1

-Termination of unsuccessful tracing should be authorized by hospital sponsored "lookback advisory committee". C-1

-If M.D. is resistant to notification, explicit mandate for hospital to violate and supersede doctor/patient relationship is necessary. C-1

-Proposes hospitals be permitted to formally contract with blood centers to supervise notification, counseling and testing procedures if the recipient's physician is unavailable or declines to cooperate. C-7,8

-Agrees hospital transfusion service should have procedure for notification of recipients through physician of record. C-9

-Suggests a hospital based physician carry out notification if physician of record is not available. C-9

-Supports as appropriate for hospital to receive information regarding HIV lookback situations, the notification of any recipient of such a product through the recipient's physician or through another M.D. if necessary. C-11

-Concerned that the regulation requires more of the hospital while imposing no obligations upon the physician. C-11

-Proposes that physicians be required to participate in the l-ookback efforts. C-11

-Physicians are more likely to have current patient information regarding address etc, and health and lifestyle than the hospital. C-1

-California state places the responsibility on the physician to both provide information to patients regarding blood products in advance of non-emergency transfusion and to get informed consent for an HIV test if ordered. C-11

-Hospital involvement should be limited to situations where the recipient's M.D. is unavailable. C-11

-Clarify how a hospital is to know that a physician has "declined" to notify a recipient. C-11

-The regulation is worded as to imply that the hospital is required to document the attempt to notify both the "attending physician and the recipient" which is inconsistent with other language elsewhere in the document. C-11

-What is the hospital's obligation if the physician notifies his patient but fails to provide information or referral for counseling and how would the hospital know exactly what the M.D. has done? C-11

-Disagrees with the requirement that transfusion services notify patients in lookbacks when the physician declines, as it may unnecessarily interfere in the practice of good patient care. For example, there may be no justification for notifying a terminally ill patient who is celibate. C-13,24

-Recommends that the physician be able to document to the transfusion service his reason for declining to notify a patient. If the physician declines notification and documentation thereof, only then should the transfusion service be required to directly inform the recipient of possible transmission. C-13,24

-Supports placing the burden of notification of recipients of

potentially infectious blood with physician of record and the transfusion service. Believes it is desirable to minimize the contact between the blood manufacturing establishment and the recipient of potentially infectious blood. C-17

-Proposes that it should be the responsibility of the blood manufacturing establishment, rather than the transfusion service, to determine the responsibilities and procedures for notification of potentially infectious blood consigned to the transfusion service. This will allow the manufacturing establishment to continue to operate in an efficient and consistent manner within required time limits for such notifications. C-17

-Suggests that it is the primary physician's responsibility to notify the recipient because he ordered the blood. C-20

-Suggests more consistent requirements between FDA and HCFA. The HCFA proposal makes the hospital responsible for the notification of the recipient's physician rather than the transfusion service, as is the case in the FDA proposal. C-22

-Proposes that it is preferable for the attending physician to notify the recipient due to the patient physician relationship. C-22

-Recommends, similar to the HCFA proposed rule, that the hospital be responsible for notification if the attending is unavailable. C-22

-Recommends that hospitals be required to make lookback files available to the transfusion service to assure that follow-up with the collecting facility and FDA inspectors would be accomplished. C-22

-Recommends that hospitals must contact the attending physician and it must be left up to the discretion of the attending physician to notify the patient. Any variance from this interferes with the physician-patient relationship. C-23

<u>Comments on 42 CFR 482.27</u>

-Suggests "agreement" allow the two entities to designate the party responsible for physician notification. C-5,6

-It is not possible to have a written agreement with each blood supplier. Suppliers may ship outside their service area due to resource sharing, and hospitals may receive blood form all over the country and Europe on occasion. C-9

-Disagrees with requirement for hospital to form agreement with any outside blood bank supplying them. C-11 482.27(c)(1)

-No requirement for agreement necessary with suppliers necessary because FDA would require blood centers to notify hospitals if potentially HIV infected units had been made available to the hospital. Any agreement should be a matter for these two parties to decide. C-11 610.46

-Disagrees with the need or purpose for requiring the agreement to touch on "the procurement, transfer and availability of blood and blood products" since these matters are not touched upon in the proposed regulation. C-11

-Proposes that establishing requirements by regulation is more flexible and efficient than having to make them by regulation and contract. Also, this would avoid potential conflicts in the event regulations are modified. C-11

-If hospitals are required by regulation to have agreements with blood centers, it puts blood centers in a position to impose additional terms through the agreements that the hospital would not otherwise wish to accept (e.g., indemnification arrangements). C-11

-Hospitals can need to obtain blood from sources, other than their usual supplier, with whom they have no agreement. Would this mean the hospital has obtained the blood illegally? C-11

-If a hospital obtains blood from a source without an agreement, could an injured patient argue that the hospital was negligent to do so? C-11

-Disagrees with the excessive requirement for an agreement with each blood supplier. C-12

-Recommends that two week time limit for notification of consignees be changed to "as soon as possible". C-19

-Requests an exemption for the Dept. of Defense from the requirement for a written agreement with each blood supplier due to the use of numerous blood donor and transfusion services of the sister military branches and includes frequent use of the centralized storage and distribution depot on McGuire AFB, N.J. C-19

-Disagrees with the estimate of 2.5 million dollars annually for this proposed rule. Estimates it will necessitate spending more like 5 million dollars annually to prevent 2.5 transmissions per year. Believes this is not a cost effective way to control the AIDS epidemic and will further raise the cost of health care. C-21,25

Comments on FDA/HCFA

-Pleased that FDA and HCFA are working together to establish these regulations. Believes that regulation of blood bank obligations of this type are better achieved through direct regulation by the FDA. C-11

-Doubts that FDA has resources needed to enforce the requirements so it would be best managed by HCFA in collaboration with other accrediting organizations such JCAHO, CAP AND AABB. C-23

-Recommends consistent terms and the avoidance of the term "blood bank", which can refer to either a transfusion service or a freestanding community blood center. The proposed FDA regulation refers to "consignees" and "transfusion services" while the HCFA regulation refers to "hospitals and "blood banks". C-13,24

Comments on Costs Imposed by PR

-Disagrees with the figure of $2,469,000 for the expected total annualized cost of this proposed rule. Expects cost to be much higher due to increased number of EIA repeatedly reactive results caused by a variety of factors including changes in the manufacturer's cutoff to meet CBER criteria for lot release. C-9

-Rate of EIA repeatedly reactive for anti HIV is over 3 times that of last year with none confirmed by Western blot, although many are indeterminate. Suggests proposed rule would result in much more than 3 times the effort envisaged to carry out the lookback and quarantine efforts which is currently done for confirmed positive Western blot results. C-9

-Believes goals of proposed rule are laudable but also believes more HIV is spread through the more usual modes of transmission and therefor, our limited health dollars should be spent in ways other than proposed here. C-9

-Believes AABB recommendations for lookback, already in place, to be more appropriate and useful. C-9

-Supports proposed rule and does not feel it places undo hardship on the blood banking industry. C-9

-Clarification needed: Do these regulations apply to all regulated blood establishments, including small hospital based transfusion services that also draw blood donors? C-10

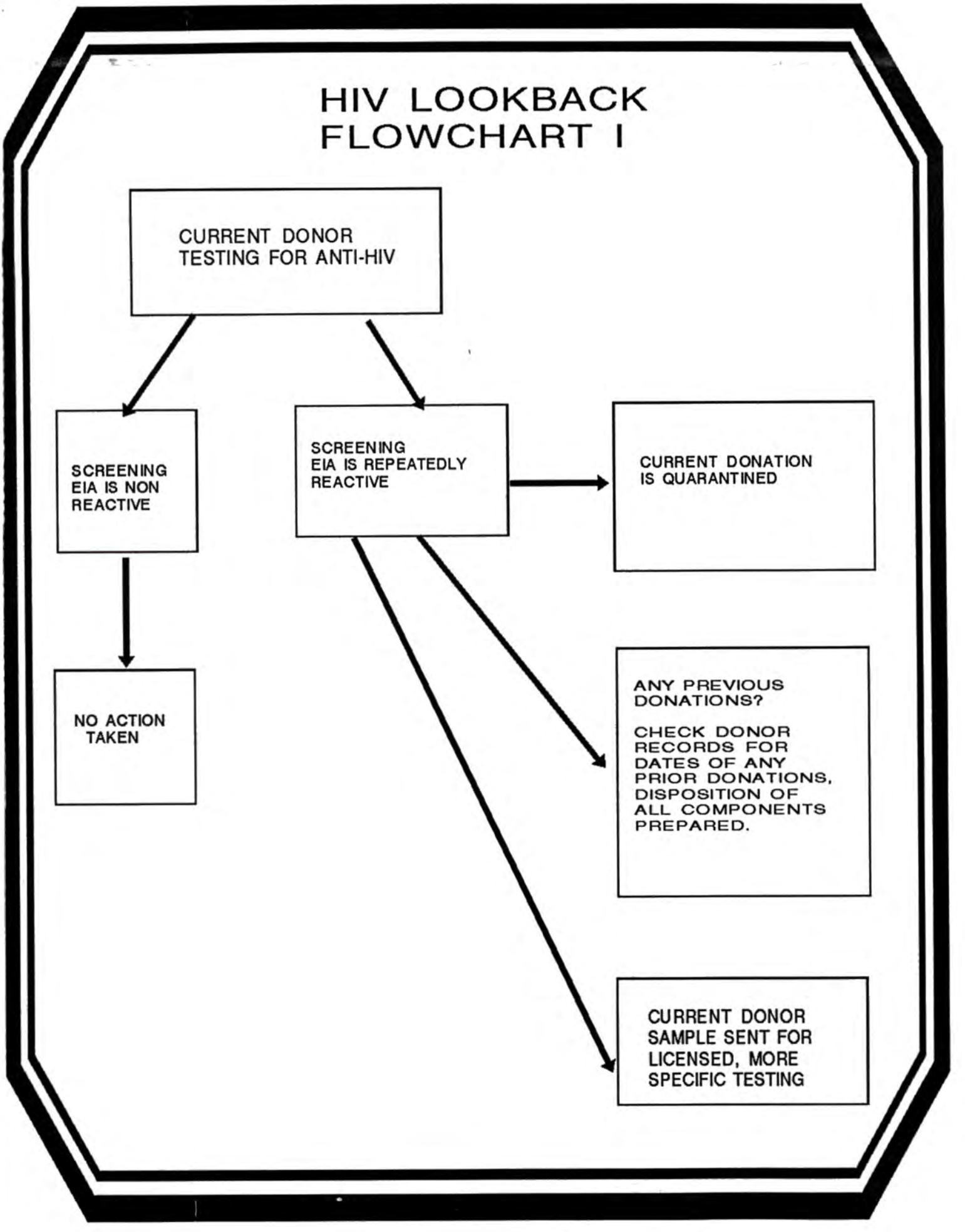
-Concerned that hospital-based donor centers, due to economic factors associated with increased regulation, may be forced to close, compromising their ability to meet patient needs. C-10

-Disagrees with the annualized cost. Believes that for an annual

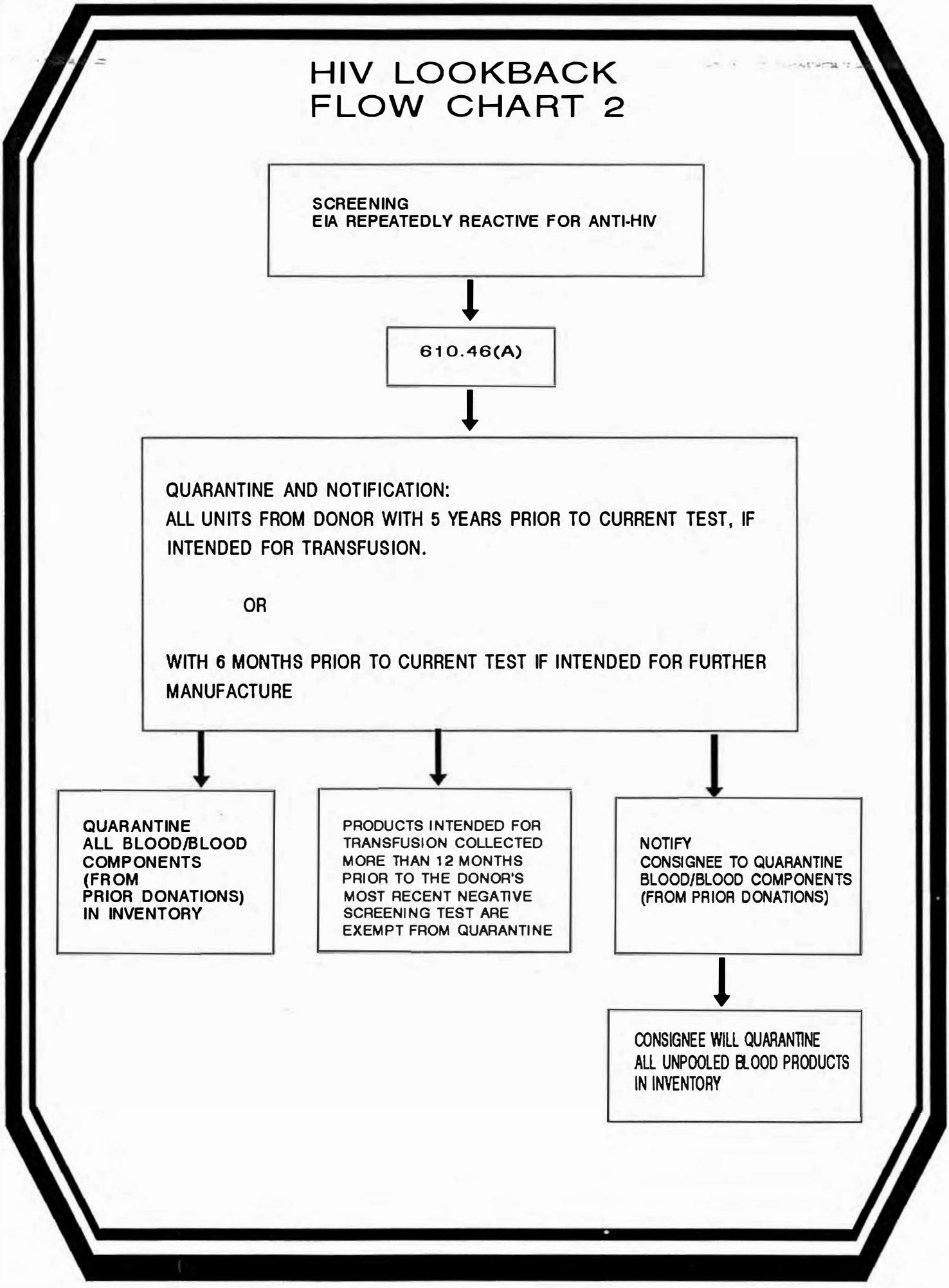
collection of 12,000,000 blood donations, a repeat reactive rate of 0.1% will require the quarantine of from one to four components from 12,000 donations. Based upon FDA's estimate of 2.5 million dollars, the resulting cost is approximately $208 per donation to quarantine and notify consignees of up to four components. Believes the cost to be more realistically in the range of $500 per occurrence, which would more than double the FDA's estimate. The cost will be even higher if the two week limit is not extended to allow for the economies of batching.
C-17

C=Comment letter

HIV LOOKBACK FLOWCHART I



HIV LOOKBACK
FLOW CHART 2



HIV LOOKBACK
FLOW CHART 3