

Committee of Ten Thousand

Advocacy for Persons with HIV/AIDS
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December 22, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sirs;

The Committee of Ten Thousand is pleased to submit the attached comments on three proposed rules:

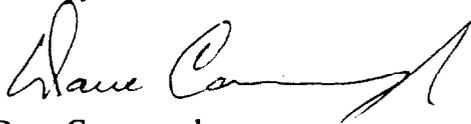
Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents: Proposed Rule - Docket No. 98N-0581,

General Requirements for Blood, Blood Components, and Blood Derivatives; Notification of Deferred Donors: Proposed Rule - Docket No. 98N - 0607, and

Plasma Derivatives and other Blood-Derived Products; Requirements for Tracking and Notification: Advance Notice of Proposed Rulemaking - Docket No. 98N - 0815.

Please do not hesitate to contact us if you have any questions concerning these comments.

Thank you.



Dave Cavanaugh
Government Relations

98N-0607

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Committee of Ten Thousand

Comments on Proposed FDA Blood Initiative Rules

Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents: Proposed Rule - Docket No. 98N-0581

A. Required Testing

COTT supports the expanded testing requirements proposed, and those for confirmatory testing and deferral. We are concerned, however, about the data behind the contention that HBsAg reactive plasma need not be further tested for HB core antibodies.

B. Affected Products

COTT supports testing of autologous donations. The high error rate in use of autologous blood makes the current risk to the general blood recipient population of untested autologous blood unacceptable. COTT supports improvements in marking, handling and storage of such units as well.

COTT also supports application of testing requirements to blood & blood products intended solely for use in manufacture or in medical devices, as required for the last ten years and now expanded through the use of the re-definable term 'communicable agents.'

C. Exceptions

COTT opposes only monthly testing of even dedicated apheresis donors. The recipients of such plasma are entitled to no less safety precautions than any other blood or blood products recipient. Despite the cost savings from such infrequent testing, given the possibility and likelihood of up to 15 donations per month per donor, risk factors in the apheresis donor population necessitate far greater vigilance than this.

D. Further Testing

COTT supports specifying that supplementary re-testing of repeatedly reactive blood and blood products be required by industry, not merely recommended.

E. Testing Responsibility

COTT supports requiring labs used in industry blood testing be FDA-registered and CLIA-certified.

F. Release or Shipment Prior to Testing

COTT opposes emergency release of untested or incompletely tested blood and blood products for emergency use. While it could be held that any viral contamination so contracted would be less life-threatening than a given emergency, proof thereof may not be obtainable, and the patient's right to be informed of the risks from such contaminated blood are not provided for under this language.

G. Restrictions on Shipment or Use

COTT supports the proposed restrictions on shipment or use, for the reasons given in the draft rule, but opposes exclusion of autologous blood from this rule. COTT supports the use of re-entry algorithms when FDA-approved only.

H. Compliance with Lookback Requirements

COTT of course supports the earliest possible expansion of HIV lookback requirements to embrace the programs begun in the last two years for HCV lookback. We only lament once again that HIV lookback itself was never done, even years after the tragic massive exposure of our community.

I. Donor Deferral

COTT is strongly opposed to the FDA proposal to permit donors testing repeatedly reactive for HTLV, types I and II or anti-HBc to serve as donors of Source Plasma. In addition to the stated associations to exposure to other possible risks, we feel that the relationships between HTLV and HIV, and between HBc and other issues affecting the liver, are not well enough understood at this time.

Committee of Ten Thousand

Comments on Proposed FDA Blood Initiative Rules

General Requirements for Blood, Blood Components, and Blood Derivatives; Notification of Deferred Donors: Proposed Rule - Docket No. 98N - 0607

New Sec. 630

COTT supports the proposal to require blood and plasma establishments to defer donors positive for HIV-1, HIV-2, HBV, HCV, HTLV-I, and HTLV-II, and notify such donors of the deferral, the reasons therefor, and additional counseling and care resources. COTT would urge FDA to go further and require notification of those who these establishments defer voluntarily for medical reasons, so as to improve consumers' information about their own health status and provide them the widest possible range of medical options by informing them as soon as a problem is detected.

While COTT concurs that blood and plasma establishments should obtain confirmatory supplemental test results before contacting the donor, and understanding that this may take some time, over and above that required for basic screening tests, we feel that allowing eight weeks from date of donation for this is excessive given the need for earliest possible information for informed decision-making by such infected donors. Four weeks should be sufficient for basic and supplemental testing and first attempted contact; if a second or third attempt is required, an additional two weeks could be allowed.

Changes to Sec. 610

As noted in our comments on the current proposed rule on donor testing, COTT feels that the proven high risks of allogeneic use of blood collected for autologous use necessitate application of comparable protections thereto.

In addition, they should be required to be notified as for other donors found infected under procedures of this section.

COTT supports FDA requirements for collection of donor permanent address information to aid in post-donation recontact. Industry objections at the November open forum notwithstanding, the rule would not preclude telephone contact as they prefer in most cases, and it would, as indicated by example, eliminate potentially high-risk transients.

Committee of Ten Thousand

Comments on Proposed FDA Blood Initiative Rules

Plasma Derivatives and other Blood-Derived Products; Requirements for Tracking and Notification: Advance Notice of Proposed Rulemaking - Docket No. 98N - 0815

A. Types of Products

COTT opposes waivers for industry from these notification requirements solely due to a low proportion of the product going into patient custody, such as IVIG. If no streamlining solution can be found, the higher cost of tracking all of the product in order to be sure to cover such end uses should be factored into the overall cost-benefit on the regulation, not assessed by product.

B. Reasons for Notification

It is unfortunate that this rule as drafted covers only patient notification for disease risk, given the large number of health-threatening recalls which our community endures annually due to manufacturing errors.

COTT strongly supports FDA's decision to develop a rule for tracking of blood and blood products through the distribution chain, all the way to the patient, and specifically one including responsibilities for consignees to notify patients. Too often in practice notification has not extended to the patient -- the only one in the distribution chain with a vital personal investment in receiving recall or other risk information.

C. Responsibility for Notification and Tracking

While the voluntary system developed by industry and plasma users groups is laudable, as FDA notes it depends on continued voluntary industry support and consumer group recruitment efforts. These in 18 months have not produced enrollments even up to one-third of the number of patients at risk. From our long experience suffering ill effects without having received recall notices, we concur with FDA's assertion that "continued success of patient notification cannot be assured without regulatory standards for the performance of such notification programs and without a clear mechanism of enforcement..." We question your reference to continued success, however, as do you in three paragraphs later: "FDA believes that patients having custody of plasma derivatives are not consistently notified of lot-specific product recalls or withdrawals associated with a potential increased risk ..."

D. Tracking Consignments

In requesting data on administrative burden of tracking, COTT encourages FDA to use great caution, if not a numerical deflator, in accepting such estimates. While there will clearly be a burden, this level of true product accountability is decades overdue. While there has been little

true cost estimation of the LACK of this accountability, in terms of harm to patients, suffice it to establish the scale thereof by repeating here the calculations used in the Ricky Ray Fund effort: \$60,000 per year additional care cost per individual with hemophilia due to HIV infection, times 13 years since processes were successfully changed, multiplied by 7,500 such individuals identified in the legal settlement of 1997 and again in the Ricky Ray program office in HRSA in 1998, equals a cost of this manufacturing failure of \$9.7 BILLION to date, borne by individuals and families, only \$1.5 Billion of which has been or can hope to be relieved by compensation or "compassionate" payments.

E. Initiation of Notification

Whether initiated at FDA or at the manufacturer, COTT suggests that the first scientifically valid finding that there is a risk in the product be sufficient to put notification steps in action. Expert discussion notwithstanding, it was only a little over a decade ago that scientific evidence, presented with the weight of a federal agency behind it, was insufficient to trigger emergency manufacturing changes, much less patient notification, for another five YEARS.

F. Timing for Notification

To repeat our comments on the current proposed rule on notification, COTT supports the earliest possible notification once a problem is found, whether it be of donors from lab tests, or consumers from product contamination. We support FDA's proposal for first contact in the latter case within two days and completed contact within one week. Rather than weaken this version under pressure from industry that it is unfeasible at present, since there is no system in place now for this complete-chain-through-to-the-patient notification, the proposed two-day requirement should be held as the requirement, and industry given a (brief) phase-in period to attain it (2-4 months).

G. Who Should Be Notified

COTT supports a system for notification of all users of a product, with lot identifier information, so that a) consumers can establish privately whether their supply is affected, and b) administrative burden to manufacturers is not so high that the system is never fully implemented. Whichever system is put in place should be evaluated at yearly intervals, including obtaining consumer reaction, and a conscious discussion of the advisability of switching to the other system entertained after a tryout period of one-two years.

H. Information Included in a Notification of Patients

COTT supports provision of lot, risk and action steps information, amplifying the risk section to address susceptibilities due to co-infection with hepatitis, since that has become so prevalent in the plasma users community and affects health status in such fundamental ways.

I. Adequacy of the Notification Process - Quality Assurance

COTT supports a requirement for industry evaluation, for QA purposes, including consumer feedback, but it only would be of value if made part of an overall FDA-sponsored objective evaluation of both individual manufacturer efforts and the notification system as implemented in

general. Elements of both should include average, range and variance statistics for first attempt and final contacts, variations therein by geography and other factors such as type of consignee, and consumer satisfaction/recommendations. The FDA meta-evaluation should be independently contracted out, and make use of selected primary data collection as well as use of the industry reports.

J. Notification and Product Recalls / Withdrawals

See our comments under "B. Reason for Notification." We support FDA's proposal to extend these notification procedures to recalls and withdrawals, of which there are many and in which patient notification from industry has been poor to nonexistent. We are concerned that FDA's questions seem to imply that some procedures for recall/withdrawal notification could be relaxed if this disease notification procedure were put in place and extended in kind to recalls; we want no relaxation of the recall/withdrawal notification system, just the opposite.

We give no specific recommendations on integration, of the two systems, for this reason. We think it vital that there be a rapid, emergency recall notification system, as proposed elsewhere in these rules, and the disease notification process, while also needing to be rigorous, should in no way detract from the procedure for recalls due to manufacturer error and other non-disease factors -- again, of which there have been many.

K. Informing Patients of the Notification Process

We concur that patients should be informed before any need arises that a notification system has been developed, and feel that this information should accompany the product, not be called for at the time of receipt of prescription due to difficulties in reliably getting the documents into physician's hands and to the patient at the time indicated. We feel the document should be product-specific, to aid the patient in understanding what actions to take if such a notification is received, and should be in the form of a separate, high-color flyer, not a part of labelling. FDA should set common design specifications for these, but they could be produced and distributed by manufacturers along with shipments of product.

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