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June 16, 2003

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

Re: Docket No. 00N-1484: Proposed Rule: *"Safety Reporting Requirements for Human Drug and Biological Products"*

To Whom It May Concern:

Delta Blood Bank appreciates the opportunity to comment on the Food and Drug Administration's proposed rule relating to safety reporting requirements for Human Drug and Biological Products.

It appears the FDA is considering adding blood and blood components to the current safety reporting requirements that now apply to drugs and biological products. We disagree with this consideration. Although blood and blood components are considered drugs, they are very different from other marketed drugs. These are not dispensed to patients for use at home, such as medications. While post marketing surveillance and reporting of adverse experiences may be helpful for medication, the same rules do not easily apply to blood and blood components. A problem with one lot number of a blood component (alloimmunization or TRALI, for example) does not necessarily point to an adverse trend for all blood products produced that day or from that donor. Additionally, blood donor centers and transfusion services already have reporting systems in place to report blood product deviations and transfusion services send sentinel events to JACHO. This proposed rule will lead to duplicate reporting by both donor centers and transfusion services.

On page 12414 of the Federal Register, the FDA states that these new reporting requirement would not impose significant new burdens on blood establishments, as blood collection and transfusion services are currently required to conduct investigations and prepare and maintain reports. They say that the blood establishments would simply submit reports already maintained by the establishment, instead of having these reports be reviewed by FDA at the time of inspection. We disagree with this assessment. With a blood donor center our size collecting approximately 55,000 donations per year, it appears that more than 55 additional reports would be required based on the definitions listed in this proposed rule. You have estimated 16 hours of work per report. This translates to over 880 hours a year of additional reporting to the FDA by one blood center. Additionally, these reports may be of experiences not "unexpected", as donor reactions do occur and patients do become alloimmunized.

The proposed rule goes on to say that voluntary reports have alerted FDA to defects in manufacturing of products, i.e. 1997 adverse reactions caused by a leukoreduction filter, and if mandatory reporting had been in place the time of resolution may have been shortened. We believe because this was a voluntary report, and therefore an unusual occurrence, it was noticed by FDA immediately and prompt action was taken. If this report had been part of an FDA required reporting system, action may very well have been delayed, by the thousands of reports submitted by blood centers and transfusion services to the FDA . The current voluntary system of reporting is working. Blood Centers and Transfusion Services recognize unusual events and do report to FDA, an example is White Particulate Matter.

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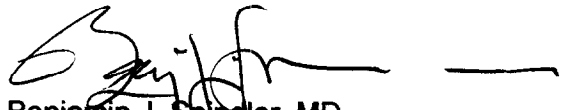
If reporting is determined to be required, we request the reports be confined to significant, expected events. For example, reports of TRALI and alloimmunization, although serious events, are not unexpected and are investigated at the time of occurrence. Reporting to the FDA would not change the outcome of these types of reactions.

Page 12436 outlines the proposal that all serious "suspected adverse reaction" (SAR) be reported. It goes on to say that FDA understands blood establishments and transfusion services already report deviations from the manufacturing process, and now propose all serious events also be reported to FDA. This requirement is followed with a list of the type of reaction that is expected to be reported. We believe this list is difficult to interpret, as follows:

- In one case, the rule requires all SAR requiring medical intervention to be reported. Medical intervention is not defined. In reality, every time a donor is attended by donor center staff for a reaction, it could be considered medical intervention. Every time a patient has chills and/or fever, there is medical attention given and an investigation of the reaction.
- In another example, citrate reactions requiring "significant' medical intervention be reported but not those that require only "medial intervention". You do not distinguish the difference between medical intervention and significant medical intervention. We recommend a significant medical intervention be defined as only those donors requiring hospitalization or emergency room care
- For blood transfusion reactions, you would require reports of induced alloimmunization that prevents effective transfusion therapy. Is giving incompatible blood per procedure after the patient has become alloimmunized "prevention of effective transfusion therapy?" What about the patient who becomes alloimmunized and compatible blood can not be found?
- You would require any complication from improper blood administration including failure to use a standard blood filter (e.g. air embolus). We are concerned that these types of complications are not readily known by the transfusion service, so getting the information to report may be difficult if not impossible.

The FDA requires the reporting be accomplished using Form FDA 3500a (the current form used to report medical device problems). We disagree with the use of this form. This form is cumbersome to report the requested information and to find the needed information to complete the form. This form does not capture the type of information that appears to be important when investigating a donor reaction or a transfusion reaction incident. We suggest, if additional reporting, beyond current reporting utilizing the blood product deviation reporting system is required, a form specific to blood center and blood transfusion adverse events be designed to facilitate accurate, important information that can be easily analyzed by your staff.

Respectfully,



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