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STATEMENT

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Irradiated Blood Components

Statement before the Food and Drug Administration's Blood Products Advisory Committee

G. Michael Fitzpatrick, Ph.D., Chief Policy Officer

July 23, 2004 – America's Blood Centers (ABC) is a national network of locally-controlled, non-profit community blood centers that provide nearly half of the U.S. blood supply from volunteer donors. Collectively, ABC total blood collections exceeded 7 million donations in 2001. ABC members provide blood services in 45 states and in Québec, Canada, and serve more than half of the 6,000 hospitals in the U.S.

The ABC members appreciated the position taken by FDA and CBER in March of 2003 when this subject was first addressed. The rationale presented by FDA in continuing to allow the irradiation of blood components, primarily red blood cells, regardless of the licensed anti-coagulant or additive solution they were collected in indicated FDA's awareness of the clinical need for these special products in support of patient care. Most of the in-vivo survival studies that were conducted during the early 1990's indicate normal survival of irradiated cells up to 28 days post-irradiation even at day 42. As Dr. Moroff's data presented today demonstrated, the long term survival for control and irradiated cells was comparable.

The latest study cited by FDA this morning concludes that average 24 hour in vivo recoveries for irradiated TRIMA RBC are > than 75 percent, but FDA contests that conclusion in their statement. While FDA rightfully points out that the donors' at one site had a mean survival of < 75 percent in the test units and another site had mean survival in the control units of < 75 percent the conclusion that one site's results cannot be included in the analysis and the other site's results can be used to change the dating period completely ignores the third site that had > 75 percent survival in both the test units and the controls. We do not understand the parsing of the data in this manner. It would appear that parsing out the three sites data results in a tie with the tie breaker's data tainted by poor control data. The FDA analysis makes no comments about the fact that the mean survival in the WB (control) irradiated units is

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less than the mean survival of the units collected by an automated instrument and in “novel” anticoagulant at all sites.

A review of this limited data would indicate that more analysis is required before drawing any conclusion. What was the impact of the use of 3000 cGy at the one test site, why are the irradiated red cells from the control units exhibiting lower survival rates than the test cells, was there a single individual with an extremely low survival rate in the study conducted at site 3 that skewed the results? We believe FDA should have answered these and other questions before bringing such an important matter to the BPAC.

Blood products are irradiated for the needs of specific patients and are usually transfused within hours of being irradiated. There appears to be no assessment by FDA of the current practices of hospitals and blood banks regarding the dating and transfusion practices of irradiated units.

Several members responded to an urgent ABC request asking about the impact of the suggested change by FDA and I received seven responses immediately. All seven responses indicated that the major impact would be a possible increase in errors from having to use a manual system for dating irradiated products until the software used to track and implement expiration date can be changed. All were concerned about implementing such a change manually and inserting a process that could create more clerical errors when most of the irradiated units they transfuse are transfused shortly after irradiation no matter what the age of the unit is at the time of irradiation. In addition, two centers expressed concerns about hospitals that may irradiate and store products for inventory.

Our members are also concerned that this change is being promulgated in the absence of reports of any potential patient harm being prevented. We would like to see an analysis of Blood Product Deviation Reports and adverse event reporting prior to making a change of this magnitude.

In closing, I would like to say that ABC, as always, supports the use of good clinical and laboratory data in the formulation of regulation, policy or guidance. We feel that the data presented today is important to review, but does not begin to establish the evidence needed to change the current guidance and information published by FDA regarding the dating of irradiated products. We ask that the questions presented in this statement be asked and answered – first, to establish the need to change current requirements and second, to base the changes on a body of evidence – not one study of 24 donors that does not meet the N required by FDA to provide statistically significant data. Thank you for the opportunity to address the committee regarding this subject.

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