Transfusion Related Acute Lung Injury (TRALI)

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FDA reports:

- TRALI implicated in 10 - 14% of fatalities of the last three years

- Reactions :3, FY97, 12,FY 98, 17,99

- 75% cases, donor products tested HLA /granulocyte antibody positive
Options for reducing morbidity & mortality

1. Deferral of donors implicated in a single unit or in more than one multiple unit TRALI case.

2. Identify donors with risk factors followed by:
   - screen for HLA/granulocyte antibodies
   - deferral
   - diversion of plasma to non-injectables

3. Establishment of improved physician education about TRALI and improved surveillance mechanisms for donors implicated in non-fatal as well as fatal TRALI cases
TRALI

Presentations:

- Dr. Mark Popovsky, President, Cell Processing Division & Corporate Medical Director, Haemonetics Corp. Associate Professor of Pathology, Harvard Medical School

- Dr. Patricia Kopko, Associate Director, Sacramento Medical Foundation Blood Centers, Assistant Clinical Professor, Medical Pathology, University of California, Davis

- Dr. Lynn K. Boshkov, Associate Professor and Director of Transfusion Medicine, Oregon Health Sciences University

- Dr. John Finlayson, Associate Director for Science, OBRR
Questions for the Committee:

1. Should FDA consider interventions at this time to identify donors and/or donations with an increased risk for producing TRALI in a recipient?

1a. If not, what data are needed to define appropriate measures
2. If yes (in 1.), would it be appropriate to identify blood donors with a history of:

- i. multiparity (3 or more pregnancies)
- ii. allogeneic transfusion
- iii. implication in a single unit case, or more one multiple unit TRALI case.
2b If yes (in 1.), for donors with risk factors (as in 2), would it be appropriate to:

- i. limit collections for transfusion to plasma reduced products (e.g. washed RBCs; apheresis platelets)
- ii. divert the plasma collections to the manufacture of non-injectable products
iii. screen for anti-HLA/granulocyte antibodies and permit negative donors to continue donating routinely
iv. defer such donors