



# Unrelated Products Received From Outside the NDMP Structure

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**FDA Liaison Meeting**  
**January 4, 2007**

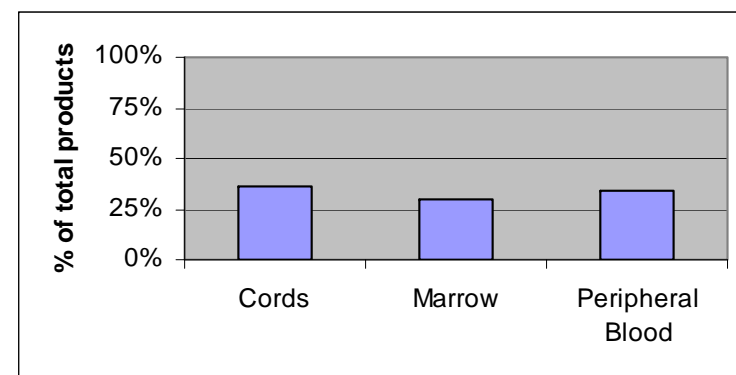
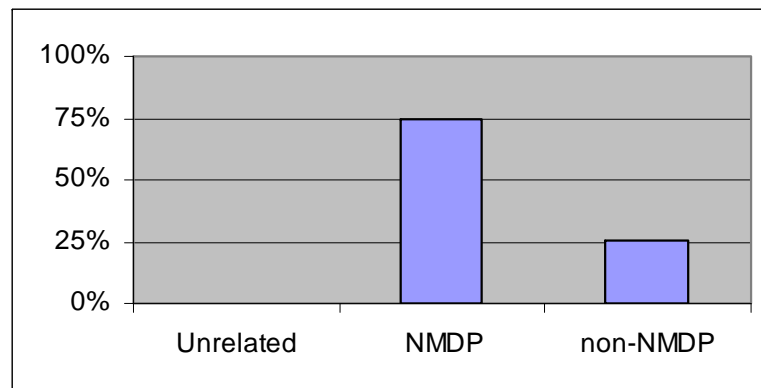
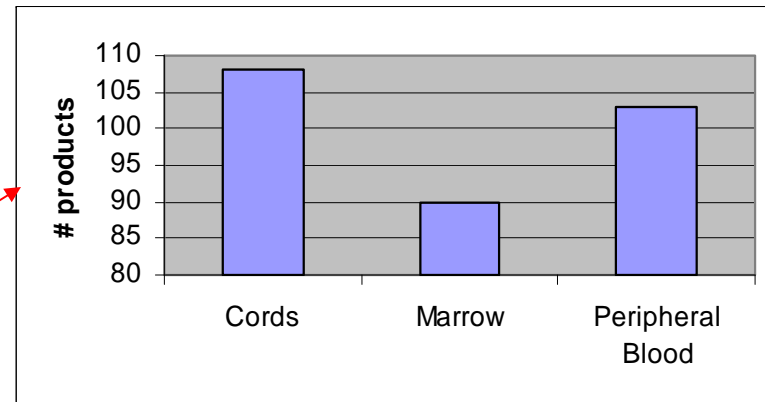
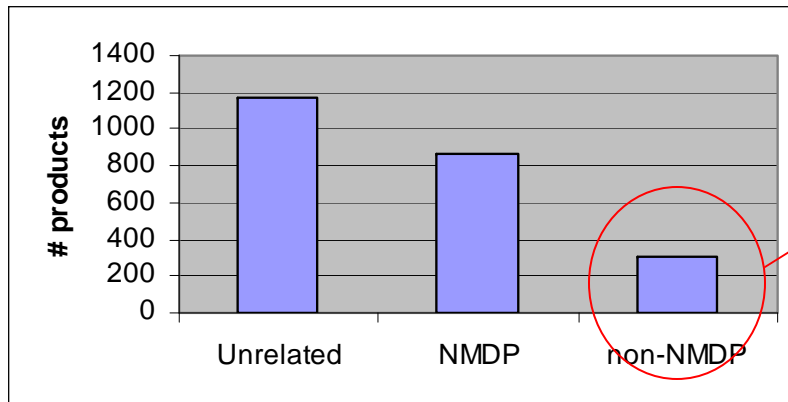


# Goals

- Snapshot of the current situation with unrelated transplants
  - Talked to Directors from 9 centers
    - Included the Top 5 Centers based on NMDP numbers
  - Breakdown of numbers of products
  - Rough numbers
    - Point out trends
- Subset analysis of three of the centers

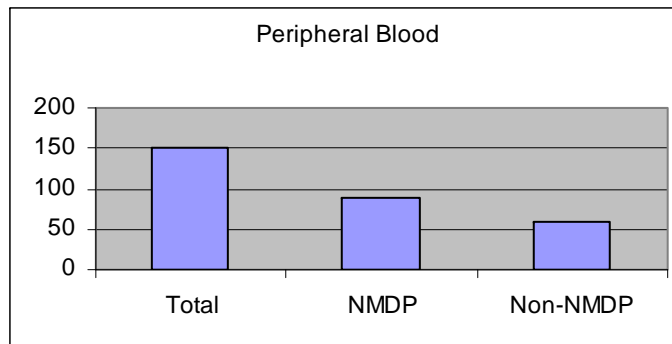
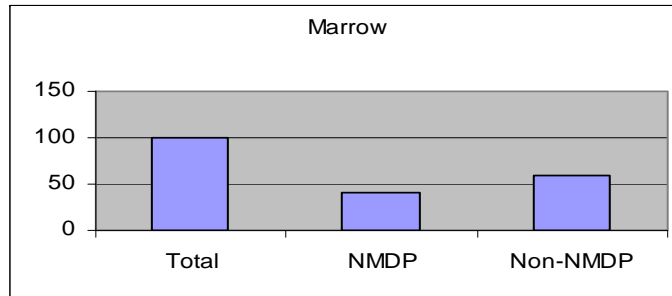
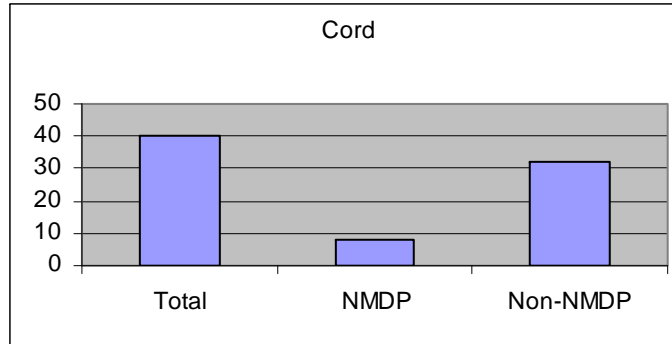
# Transplant Centers

n= 9



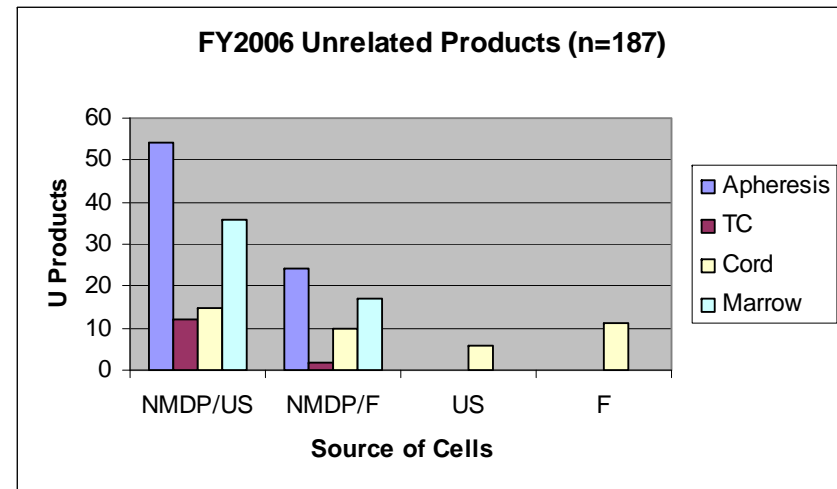
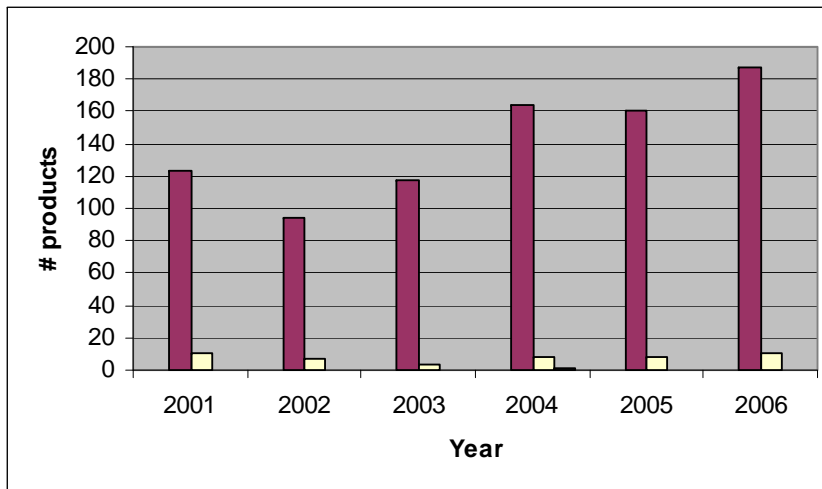
# Large Unrelated Transplant Center

n=290 Unrelated Products



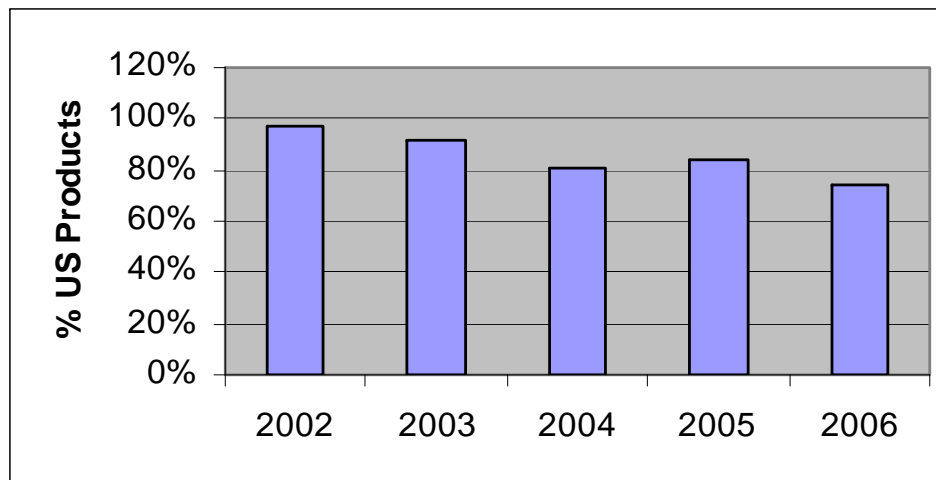
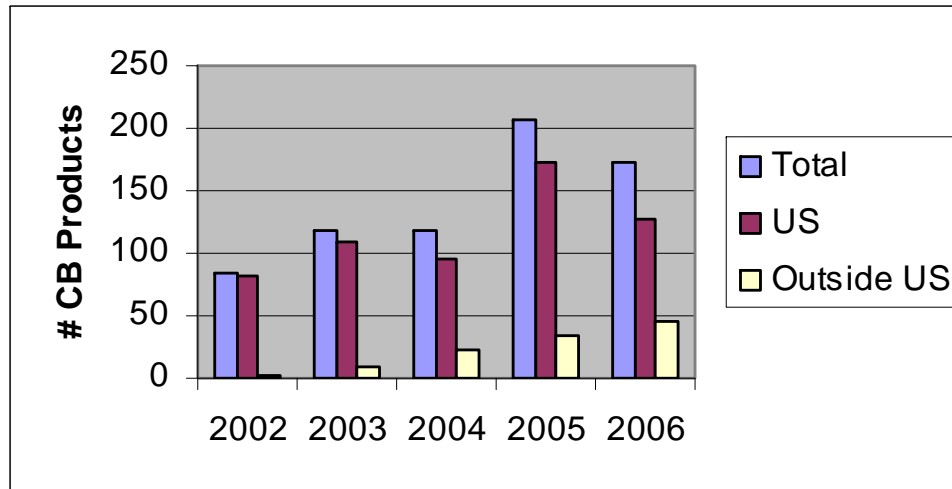
# Unrelated Transplant Center #2

n=187 Unrelated Products



# CB Transplant Center

2006, n = 172





How do transplant centers  
qualify collection centers?



# Qualification of Vendor

- Wide variation from center to center
  - Variation between types of products
- None of these are licensed products



# Audit Form

## RECEIPT OF HPCs/LYMPHOCYTES FROM NON-NMDP SUPPLIERS

Patient Name \_\_\_\_\_ History # \_\_\_\_\_  
Requesting Physician \_\_\_\_\_ Expected Date of Infusion \_\_\_\_\_  
Shipping Facility \_\_\_\_\_  
Shipping Facilities Address \_\_\_\_\_  
Phone # and Fax # \_\_\_\_\_  
Contact Name and Phone # \_\_\_\_\_

### Additional information required from shipping facility:

Collection and processing facilities' FDA registration number \_\_\_\_\_  
Collection and processing facilities' accreditation information (FACT, AABB, other) \_\_\_\_\_  
\_\_\_\_\_

### Copies needed:

- Summary of the product collection
- Summary of donor eligibility determination (allogeneic donors only)
- Infectious disease marker results (within appropriate time frame from collection date)
- Name of laboratory performing infectious disease tests and that they are FDA registered.  
\_\_\_\_\_
- Copy or summary of processing information to include:
  - Type of processing
  - Sterility
  - Flow Analysis
  - Any additional quality control of product

The collection and processing facility is approved as a supplier.

Quality Assurance: \_\_\_\_\_ Date: \_\_\_\_\_



# Qualification of Vendor

## ■ Qualification

- Audit forms
- Check for FDA registration
- Check for AABB/FACT accreditation
- Instructions of expectations
- Require paperwork beforehand to get English translation
- Infectious disease testing kits
  
- Note- they would use the product even if these things were not accomplished



# Qualification of Vendor

- No Qualification

- NMDP is first choice but if not available
- Medical Decision
- HLA is top priority and/or cell numbers for CB
- Monitor engraftment
- Urgent Medical need



# Points to consider

- Do we need a better data set?
  - CIBMTR data and then follow up survey
- Should there be minimum requirements for qualification of collection centers?
  - White paper?
  - Guidance document from FDA?
  - Everything must come through NMDP?
- Sliding scale based on clinical indication or basic minimum requirements
- FDA approved ID testing kits?
  - HPC-A – everyone is following guidelines
  - HPC-C – accepting what collection/storage facility has