Bergen Community Regional Blood Center, Inc.

Community Blood Services

The HLA Registry

Elie Katz Umbilical Cord Blood Program

The NJ Cord Blood Bank

Irving and Doris Gamow Stem Cell Research Institute

Dennis Todd, Ph.D. ACBSCT presentation September 15, 2014

Who Is Bergen?

- A non-profit 501(c)(3) corporation:
 - Bergen Community Regional Blood Center (Bergen) collects, tests, processes and distributes blood, platelet concentrates and plasma from its technical center in Bergen County, New Jersey.
 - 2013 revenues \$34,679,000
 - NJ Cord Blood Bank, \$1,882,449
- Bergen also operates:
 - The New Jersey Cord Blood Bank
 - The Elie Katz Umbilical Cord Blood Program
 - The HLA Registry
 - An NMDP affiliated Apheresis Center

The NJ Cord Blood Bank

- 1996, Bergen's board authorized the establishment of a cord blood stem cell bank
 - Autologous bank
 - Allogeneic bank
 - Units listed with BMDW
- 2006, Bergen's program merged with Coriell Institute for Medical Research's, NJ Cord Blood Bank
 - Combined program became a division of Bergen
 - Autologous banking and contract processing operated under the Elie Katz Umbilical Cord Blood Program
 - Allogeneic banking operates under the NJ Cord Blood Bank

Funding The NJ Cord Blood Bank

- Support from Bergen's blood center operations
- Sale of cord blood units
 - **\$35,000/unit**
 - Bergen has donates units for uncompensated care patients
 - Bergen does not charge NJ researchers for units used in qualified laboratory studies
- NMDP program support
- NCBI contract
 - Completing year 5
 - Renewed for an additional 5 years
- Private contributions
- State of NJ

Blood Center Support

- The practice of Transfusion Medicine is changing dramatically
 - Reduced utilization of blood
 - 30% decrease in transfusions over last 5 years (NYT, 8/22/2014)
 - Increased regulation
 - FDA
 - NYDOH
 - NJDOH
 - Increased pressure on product pricing
 - Hospital systems
 - Competition among blood providers
 - Increased merger activity among blood suppliers
- As blood center margins decrease, support for the cord blood program will be severely reduced

Bergen Cord Blood Facts

- Through August 2014
 - 6,075 units in inventory
 - 1,823 NCBI qualified units banked
 - 30.6% B/AA
 - 31.9% White (non-Hispanic)
 - 21.5% White (Hispanic)
 - 275 units shipped for transplant
 - Non-qualified units are sold to commercial bio-banking entities biotech start-ups
 - 1,700 low TNC units sold to the Polish Cord Blood Bank
 - Not qualified for NMDP program
 - Pharmaceutical company research

Bergen Cord Blood Facts

- Less than 10% of Bergen's collected units qualify for banking
 - TNC count greater than or equal to 900 million cells
 - 25% of inventory has a TNC count <900 million cells</p>
- Bergen operates 5 collection sites
 - Staffed with Bergen employees assisted by medical center personnel
 - St. Joseph's Regional MC, Paterson, NJ
 - Holy Name MC, Teaneck, NJ
 - Newark Beth Israel MC, Newark, NJ
 - Temple University MC, Philadelphia, PA
 - Lankenau MC, Wynnewood, PA
 - Bergen closed 4 collection sites

FDA Licensing Activities

- Consultants
 - Senior retired pharmaceutical company regulatory officer
 - Transfusion Medicine boarded physician
 - Adult transplant physician
- Clean Room
- Revalidation of procedures
- Developed on-line training program for collectors
- Anticipated BLA filing
 - 4th quarter 2014, 1st quarter 2015

Conclusions

- Without the support of our stem cell contracting program, the NJ Cord Blood Bank will not become self sufficient
- Without the support of HRSA and the NCBI contract I would be forced to close Bergen's public banking program
- Bergen's Board of Trustees continue to be supportive.... but very concerned!