

Year-End 2018 Report of CBA Accomplishments

– Advocacy, Education and Market Expansion



Joanne Kurtzberg, MD

In a year-end report to the CBA Board of Directors, President Joanne Kurtzberg provided an update on the association's recent accomplishments. Among the highlights were the launch of an annual international congress, completion of the first year of the association's official scientific journal, an expanded global presence, major steps toward international harmonization of cord blood banking regulations, and participation in medical meetings targeting health professionals in related cell therapy fields. Presented below are highlights of her summary of CBA accomplishments.

CORD BLOOD CONNECT – the launch of an international congress for cord blood and perinatal research and education

Undoubtedly the most ambitious accomplishment of the year was the inaugural *Cord Blood Connect* international congress that was held in September in Miami Beach. Thirteen organizations in or closely allied with cord blood and perinatal tissue banking and therapies collaborated with CBA in the development of this break-through event.

Attendees from 33 countries participated in scientific and technical sessions, workshops, poster session, exhibits, networking and social events. A celebration of the 30th anniversary of the first cord blood transplant and gathering of the pioneers of cord blood banking and transplantation were highlights of the meeting. Dr. Eliane Gluckman was awarded the first CBA Lifetime Achievement Award. The congress was fully financed by sponsors, exhibitors and registration fees.

ADVOCACY – an effective voice for the cord blood community in public policy, legislation, regulation and delivery systems

- The association's Government and Global Affairs Committee, with representatives from 14 countries, completed guidelines for harmonizing government regulation of cord blood banking around the world. Draft "model criteria" for regulations will be presented to the CBA Board of Directors for approval in January 2019.
- The association provided testimony to the FDA on its draft guidances on the evaluation of devices used in advanced therapies for regenerative medicine, and on expedited programs for regenerative medicine therapies for serious conditions.
- CBA and industry leaders met several times with the FDA about improving the process of cord blood bank licensure and optimizing cord blood bank regulations.
- The association supported an initiative for pilot reporting of regenerative and cell therapy outcomes to the Center for International Blood and Marrow Transplant Research. This could potentially lead to the CIBMTR serving as the registry for collecting and reporting treatment outcome data for regenerative medicine and cellular therapies. The CBA also supported the FDA's proposal for blanket INDs for multi-center clinical trials to collect clinical data.
- CBA, together with the National Marrow Donor Program, led a coalition that is preparing for reauthorization of the Stem Cell Act in the United States, providing funding for another five years for the C.W. Bill Young Program and the National Cord Blood Inventory.

MARKET EXPANSION – broadened consumer access to banking services and cellular therapies

- The association continued to co-produce or collaborate with major conferences for health care professionals, presenting research advances in banking and cellular therapies. This included full-day sessions at the International Society for Cellular Therapy annual meeting and the Phacilitate Gene & Cell Therapy World Forum.
- Webinars addressing future therapeutic indications for cord blood were co-produced with FACT. The webinars are archived and can be accessed on the CBA website. The registration fee was waived for CBA members.
- Planning began for the third leadership summit with commercial industry partners to explore collaborations that expand uses of and

demand for cord blood and related birthing tissues.

QUALITY – accreditation for banks and standards for products and services

- The CBA Board of Directors adopted and published as official policy "Top 10 Essential Requirements for Cord Blood Banking," which identified procedures and specifications that always should be met when banking cord blood.
- The CBA Quality Standards Committee completed and issued a study that compared the current systems of standard-setting and accreditation for cord blood banks.
- Association leaders collaborated with other cell therapy and health care organizations through active participation in the Bipartisan Policy Center to seek expedited regulatory approval of novel therapies without sacrificing quality.
- CBA provided input for the 7th edition of NetCord-FACT Cord Blood Standards. The association has representatives on the standards and accreditation committees for both AABB and FACT.

EDUCATION – aware, informed and empowered parents, donors, health care providers and general public

- Authoritative and balanced information for expecting parents continued to be published on the CBA website, making it an important resource about public and family banking options.
- Position statements were issued on screening for Zika virus and on delayed cord blood clamping.
- CBA members were invited to submit myths that they encounter about cord blood therapies and banking. The association's Website Task Force then wrote a factual response for each myth which was published on the CBA website and promoted to expecting parents.
- A campaign to provide information about cord blood banking to parents representing racial and ethnic minority ancestry through social media was launched by the association's Public Education Committee.
- Recordings of sessions and presentations at the *Cord Blood Connect* international congress were posted online, where they can be accessed and streamed free of charge.

RESEARCH AND DEVELOPMENT – advancement and rapid adoption of novel technologies and therapies

- The association completed the first year of publishing cord blood research in its official journal, *STEM CELLS Translational Medicine*.
- The association's subsidiary foundation received more than \$240,000 USD to support clinical research that expands access to autologous and related cord blood therapy for children with cerebral palsy and autism.

THE YEAR AHEAD

In the year ahead, CBA looks forward to the second annual *Cord Blood Connect* international congress, Sept. 13-15, in Miami Beach, to reauthorizing the Stem Cell Act of 2005 for continued funding of the National Cord Blood Inventory, to furthering efforts to harmonize international regulations with the goal of providing access to hematopoietic cell transplantation and cellular and regenerative therapies to all patients in need.