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**When Caveat Emptor Isn’t Enough:**
Direct-to-Consumer Stem Cell Clinics Pose Novel Medical, Ethical and Regulatory Challenges

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**Human Platelet Lysate:**
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New Uses – and Misuses – of Cellular Therapies

As AABB staff members are preparing for the 16th International Cord Blood Symposium, I find myself reflecting on how far the cellular therapies field has progressed in the past year alone. In 2017, within the span of just three months, the Food and Drug Administration approved the first two CAR T-cell therapies prescribed to treat two types of cancer, B-cell acute lymphoblastic leukemia and some types of diffuse large B-cell lymphoma. These treatments represent not just new medications or procedures, but a whole new paradigm in treating cancers that have resisted other forms of treatment. CAR T cells are also being investigated as treatments for autoimmune diseases, other hematological cancers, solid tumors and congenital disorders, including sickle cell disease and beta thalassemia.

This month, AABB News explores topics related to cellular therapies. The first feature article, beginning on page 10, discusses unproven stem cell therapies and direct-to-consumer marketing of these unregulated treatments.

AABB formed a joint working group with the International Society of Cellular Therapy in December 2015, and the group’s first project has been to start exploring pooled human platelet lysate (HPL) as a non-animal derived source of cell culture growth supplement to support the development of cellular therapy products. The second feature, which begins on page 18, focuses on HPL and the opportunities it presents for expanding mesenchymal stromal cells.

Other articles in the May issue cover the San Diego Blood Bank, the Indian Immunohematology Institute’s recent basic serology training for lab techs in south Asia and the generosity of the National Blood Foundation's 2017 donors.

I would like to use this opportunity to encourage AABB members to attend the 16th International Cord Blood Symposium, to be held June 14-16 in San Diego. This event is a fantastic opportunity for professionals in cord blood and perinatal cell and tissue banking, processing and research to network and learn while earning continuing education credits. The advance registration deadline is in just a few days. I’d also like to remind readers that the AABB 2018 Annual Meeting will be held October 13-16 in Boston. It is not too soon to start planning.

Mary Beth Bassett, BS, MT(ASCP)
AABB President
AABB/ISCT Cooperative Agreement Yields First Project

By Donna Regan, MT(ASCP)SBB
Guest Contributor

When AABB and the International Society for Cellular Therapy (ISCT) partnered to form the Joint Working Group in 2014, their goal was to define and oversee projects of mutual interest that would help to support traditional — and advance novel — cellular therapies. Neither group knew exactly where the partnership would lead, but leaders from both organizations recognized a shared focus in the cellular therapies field and wanted to make use of the overlap in their membership and their joint resources to further cultivate the field. During my tenure as president of the AABB Board of Directors, I was appointed a co-chair of the Joint Working Group. The inaugural group was made up of three members from AABB and three from the ISCT. The other members from AABB were Naynesh Kamani, MD, former vice president of AABB’s Center for Cellular Therapies and Research; and Michele Sugrue, MS, MT(ASCP) SBB, of the University of Florida Health’s Shands Cancer Hospital. The members from the ISCT are my fellow Working Group co-chair, Lynn O’Donnell, PhD, secretary of the ISCT Global Executive Committee; Janice Davis-Sproul, MAS, MT(ASCP)SBB, of Johns Hopkins Medicine; and Queenie Jang, BSc (Pharmacy), MBA, ISCT’s CEO.

The Joint Working Group began meeting regularly and straightaway proposed our first interorganizational initiative: The Preparation of Pooled Human Platelet Lysate project (HPL), which is featured in this issue of AABB News. The goal of the project is to address the increasing need for a non-animal derived source of cell culture growth supplement to support cellular therapy product development, specifically mesenchymal stromal cells. We obtained executive approval from both AABB and ISCT for the project in 2015 and began recruiting experts from a number of related areas and from around the globe, including blood suppliers, HPL manufacturers, MSC researchers, laboratory professionals and quality and regulatory specialists. So far, the project team has identified several topics for further exploration: comparing the effects of HPL versus fetal bovine serum on cell expansion, evaluating the downstream effect of pathogen reduction, standardizing HPL production and developing measures to evaluate the safety and efficacy of HPL products.

The Joint Working Group has evolved and expanded to include an additional member from each organization: David Stroncek, MD, a member of the AABB Board of Directors and chair of the AABB Cellular Therapies Section, and for ISCT, Diane Kadidlo, MT(ASCP)SBB of the University of Minnesota. Lizette Cabellero, BS, MT(ASCP), ISCT Global Secretary has replaced Lynn O’Donnell, and Christina Celluzzi, PhD, MS, senior manager of the AABB Center for Cellular Therapies, has replaced Naynesh Kamani. A second project proposal is underway and will be recruiting soon.

Stay tuned — there’s no telling where these investigations will lead!
Although the San Diego Blood Bank has expanded significantly since its founding in 1950, it remains dedicated to its original mission of “saving lives with quality blood services in partnership with the community.”

Originally started by the local medical society to provide blood products to hospitals in San Diego County, the San Diego Blood Bank boasts an impressive history, including an affiliation with legendary medical researcher Jonas Salk, MD. In addition, the facility has continually expanded its operations, outgrowing several of its previous homes, and today is considered one of the most innovative blood collection institutions in the United States.

The San Diego Blood Bank remains a leader in blood banking, now processing an average of about 10,000 units of blood each month for hospitals throughout four counties in Southern California. But it has grown far beyond its blood banking origins and today also operates in the fields of cellular therapies, cord blood banking, breast milk banking, precision medicine research and more.

David Wellis, PhD, chief executive officer of the San Diego Blood Bank, spoke with AABB News recently about the facility, its projects and the role he sees for blood banks in the future of health care.

Greater Impact

Wellis said he is pleased with the progress of the San Diego Blood Bank and is now promoting additional advancements. “We call our vision ‘SDBB Version 2.0,’ which involves leveraging and extending our current infrastructure, capabilities and partnerships to have an even greater impact on our community’s health,” he told AABB News.

Wellis is an advocate for diversifying business – he spoke about this topic at the recent AABB National Blood Foundation Leadership Forum in Scottsdale, Ariz. – and believes that for blood banking facilities to continue to grow in the current environment, it is essential to broaden their services and offerings. He noted that the San Diego Blood Bank has partnered with more than 100 other companies, startups, research institutions and universities involved in the life sciences. The results of these partnerships include providing support for researchers conducting clinical trials, health coaching for patients at risk for diabetes, testing to determine autism risk in pediatric patients and various other projects.

Wellis stressed that blood banks are in a unique position to build partnerships that can further advance health care. “Blood banks operate in the center of health care, and also hold a unique position in the community,” he said. “In many cases, blood banks have been an important part of the community for many years, have built strong relationships over time and are trusted by donors and the community.”

In addition, many blood banks have a plethora of data about their donors that could be instrumental in gaining a better understanding of health over time. “Many blood banks have loyal donors who have been giving blood at the same location for years,” Wellis said. “Each time a donor donates, they are given a mini-physical. Because of this, blood banks
have a vast amount of longitudinal data about our community’s health.”

This idea, and Wellis’s promotion of it, has been beneficial for the San Diego Blood Bank and has been instrumental in its advancement. In fact, this concept has led to the San Diego Blood Bank taking on an integral role in one of the most important current ongoing research studies in the United States.

All of Us Research Program
During his 2015 State of the Union Address, President Barack Obama announced the creation of the Precision Medicine Initiative, designed to learn more about disease risk and promote research aimed at offering individualized care to patients. Part of this initiative is the All of Us Research Program, led by the National Institutes of Health (NIH), with a goal to study the lifestyle, clinical data and genomics of one million American volunteers.

When the program was announced, it was not yet determined where volunteers would enroll to participate in the study or which facilities would help to collect the data. Various organizations were invited to submit proposals for data collection plans. The San Diego Blood Bank was among those submitting proposals.

Wellis was invited to the White House to present his ideas and speak about how blood banks would be an ideal venue for the collection of this data. He argued that blood banks are already established, have a strong relationship with the community, are highly trusted and, in many ways, are already conducting smaller-scale versions of the data collection that would be required. “I also highlighted that the San Diego Blood Bank was in an ideal locale to begin to collect data, considering it has a very diverse population,” Wellis said. “The All of Us Research Program is emphasizing diversity to ensure data collection on the widest swath of the population as possible so that the future of medicine serves everyone. Our facility is already working with a very diverse population.”

Wellis said he was confident about his proposal but understood the competition included not only a variety of leading health care facilities but also some of the most well-known names in the fields of technology, business and education. However, when the selections were made, the San Diego Blood Bank, in partnership with the Scripps Translational Science Institute and University of California San Diego, received two NIH grants and will be responsible for supporting both outreach and data collection locally and in partnership with other blood banks across the country.

Data Collection
The San Diego Blood Bank recently opened a dedicated room at its facility for the All of Us Research Program and data collection is now underway. So far, more than 600 participants have been enrolled at the facility and outreach to recruit more volunteers is ongoing. Data collection is scheduled to continue for 10 years.

The San Diego Blood Bank sends collected samples to the Mayo Clinic and data is transferred to Vanderbilt University for analysis. Additional programs and partners are expected to join soon.

There is significant enthusiasm at the San Diego Blood Bank about this program and excitement about the potential implications for precision medicine research. “The data being collected through the All of Us Research Program and others represent boundless possibilities. It is expected to help researchers develop better individualized treatments for various diseases and improve testing for those at risk,” Wellis said. “The San Diego Blood Bank’s involvement in these programs is another way we can help save lives today and improve life tomorrow.”

The San Diego Blood Bank has already enrolled more than 600 volunteers in the All of Us Research Program.