

CORD BLOOD ASSOCIATION ADVISORY COMMITTEE RESPONSES TO PUBLIC COMMENTS

On Sept. 17 the members of the Cord Blood Association Advisory Committee reviewed public comments about *A Plan for a Cord Blood Association*.

The plan was published online in mid-August [<http://tinyurl.com/association-plan>] and comments were invited from any and all who are in or served by the cord blood community. A request for comments was sent by e-mail to more than 1,000 people known to be employed within or otherwise connected to the cord blood industry. An announcement of the comment period was also sent to subscribers to the Advisory Committee's LinkedIn discussion group, and was posted with the LinkedIn discussion groups and included in the e-newsletters of several other organizations that serve the cord blood community.

The Advisory Committee wishes to thank everyone who had an interest and took the time to submit comments, information, questions and recommendations – many of which were complimentary, and all of which were considered when final adjustments were made to the plan. Legal counsel has now been directed to proceed with the drafting of bylaws based on the plan.

To be as responsive as possible, the Advisory Committee members agreed to reply to the public comments. The purpose is to explain the thinking of the committee for recommendations that were not accepted. The replies, below, are listed in no particular order other than the sequence in which comments were received.

Regarding the term “cord blood community,” I think that the word “blood” is too limiting for those who work with other cord tissues. I suggest perhaps “umbilical cord banking community.”

The Advisory Committee's intent is for the association to be inclusive, with a scope that encompasses all umbilical cord and placenta tissues. Although the recommendation may be technically accurate, it was the decision of the Advisory Committee to accept and conform to common usage of the terms “cord blood” and “cord blood banking” in reference to the collection, storage and clinical use of these tissues.

The Mission Statement says that the association's purpose is to save lives and change medicine. We will not directly save lives. Maybe we can say “contribute in the changing of lives and support medicine in its future treatment.” If some patients die, it is not the fault of the association.

Pharmaceuticals save lives. Medical devices save lives. Workplace regulations save lives. The Advisory Committee believes that it is no less accurate to say that cord blood saves lives.

The Values Statement lists “compassionate support and education for patients and donors.” We should also be involved in education of our members.

The Advisory Committee fully agrees about the importance of member education. However the committee felt that this is more of a program priority than a value. The plan states that education is one of the association’s five priorities, with a goal of aware, informed and empowered health care providers.

The list of who is eligible for membership mentions public and private banks. You forgot cord blood research banks.

The inclusion of banks engaged in research is implied. Many public and private cord blood banks are involved in research.

Quality products and services is one of the five initial priorities of the association. We should not duplicate the good work of AABB, FACT, NMDP, etc.

The Advisory Committee fully agrees. The plan states that the association will promote standards and accreditation as a means to assure quality products and services. It would be senseless to create new standards and accreditation when satisfactory programs already exist.

People representing laboratory and clinical research should be added to the Board of Directors.

Any of the 13 members of the Board of Directors may be directly or indirectly involved in laboratory and clinical research. This includes the four representatives of public banks, the four representatives of private banks, and the five at-large members.

The Advisory Committee chose not to assign seats on the Board of Directors to specific occupations or functions because there are so many complex and overlapping categories – i.e., laboratory investigator, clinical investigator, patient, donor, transplant clinician, obstetrician, pediatrician, nurse, midwife, vendor, health policy expert and regulatory official – all of which are important but could bloat the size and efficiency of the Board if every interest has its own designated seat. All of these categories can be appropriately represented on committees of the association.

By requiring a minimum number of stored cord blood units, the association may be denying membership to small banks or to clinical and laboratory research programs.

The Bylaws will not specify a minimum number of units that a bank must have in storage. That number will be determined by the Board of Directors as it adopts policy on membership requirements. The unique situations of various categories of banks, including those with research programs, can be considered at that time.

The Bylaws will have only three basic requirements for banks: that they (1) be actively engaged in collection, processing, testing, storage, selection and/or release of umbilical cord blood or related tissues, (2) be accredited, and (3) have a minimum number of banked cord blood units.

What is the difference between an association, a society and an alliance? Each alternative has its own financial, legal, political and other meanings that should be considered before deciding on the best fit.

The Advisory Committee considered a host of words for the organization, including academy, alliance, association, center, coalition, congress, consortium, council, federation, foundation, group, guild, initiative, institute, organization, network and society. The committee was not aware of legal or financial implications regarding the choice. In the end, it was decided that “association” was acceptable for its common use by trade or professional organizations.

Is the establishment of a cord blood association considered a “new beginning” for the next 25 years, or a continuation of the past 25 years?

In the sense that the organization represents the entire cord blood community, it is a new chapter for an industry that has been fragmented over the past 25 years. A goal is to put compartmentalized growth into the rear view mirror and seek industry-wide opportunities through unity.

What is meant by “evidence-based research”? Science-based and evidence-based are not the same.

The writer is referring to the Values Statement that summarizes the association’s highly regarded beliefs and convictions. One of those is “innovative, evidence-based research that advances medical technologies and therapies.”

Scholars continue to argue the difference between the terms “evidence-based” and “science-based.” For our purpose, the statement denotes that the association and its members intend to apply the best available research results or evidence when making decisions about health care. Evidence-based practice can include clinical judgment, expertise and patient preferences.

Why are integrity, high ethical standards and mitigation of suffering included in the Vision Statement? These should be self-evident for an organization whose purpose is to provide high-quality stem cell products to treat patients.

The Vision Statement imagines the association’s future and how the association will be perceived. It states that the association and its members will be recognized as “having integrity and high ethical standards” and for “mitigating suffering through improvement of the practice of medicine.”

That perception of the association will not come automatically. It will have to be earned.

The Vision Statement says that the association will be recognized as “the voice of the cord blood community.” Is it being assumed that the 150 or so participants at the Cord Blood Summit held in June in San Francisco represented the voice of the cord blood community?

The Summit was open to all who wished to attend and hear or participate in the discussion. The 150 people in attendance were a reasonable cross-section of the cord blood industry, but hardly a scientifically chosen representative sample. Whether the association becomes the voice of the cord blood community will depend on how effectively it represents the interests of and is supported by that community.

Standards and accreditation are among the association’s priorities. Is it a priority to promote higher standards or just to get more cord blood banks accredited?

The priority is quality products and services. Standards and accreditation are means to that end.

In the best of all worlds, every cord blood bank would adhere to accepted standards and achieve accreditation. Although that ideal may never be fully achieved, it is expected that the association will always strive to move the industry in that direction.

A priority for the association will be “rapid adoption of novel technology and therapies.” Does this mean “best practices,” or “minimum guidelines” defined by NetCord-FACT Standards, or “initial minimum criteria” established by regulatory agencies?

Rapid adoption of novel technologies and therapies presupposes that those technologies and therapies have survived rigorous laboratory and clinical research and testing. Adoption of technologies and therapies should not run ahead of scientific study and evaluation.

Best practices, guidelines, standards and regulations all have a role in determining which technologies and therapies are worthy of adoption.

How does the governance and structure of the association enable it to be “efficient and nimble”?

Several provisions in the Bylaws will help the association to be productive and agile. The Board of Directors will be relatively modest in size: 13 voting members. This can help avoid cumbersome, unwieldy decision-making that often impedes large policy and governance committees. The tripartite structure of the Board will encourage its members to work together for the benefit of the whole community and eliminate jockeying for numeric superiority.

Efficiency and agility, however, can only be facilitated, not guaranteed, by the structure of the organization. Ultimately, the determining factors will be the

leadership skills and commitment of the Board members, coupled with the management skills and commitment of the staff.

What are the factors for and against nonprofit?

The Advisory Committee did not consider a for-profit organization. It was assumed from the beginning that no part of the association's income or any surplus or assets would inure to the benefit of its directors, officers or any private shareholder, member or individual.

It would appear that the Advisory Committee has already made decisions without the need of the "voice of the cord blood community" and therefore has already contradicted its own plan.

The members of the Advisory Committee are from a variety of places throughout the cord blood community. Their first action was to consider the polling and discussion at the Cord Blood Summit held in June in San Francisco. The committee then created and promoted a LinkedIn discussion board to receive comments from the cord blood community. The draft plan was published in mid-August, and a request for comments was widely distributed. All comments have been carefully reviewed. The Advisory Committee has opened communications pathways and vigorously encouraged input throughout the development of the plan.

If the Board of Directors is not elected by the members, there can be neither "balance" between one segment and another, nor can it be a "voice of the cord blood community."

Balance on the Board of Directors is not a likely outcome of election by the members. Elections assure an annual contest among cord blood community segments vying for numeric advantage on the governing body.

Furthermore, there are practical electoral issues: Is the vote of an individual member equal to that of a bank member? If not, how are the votes to be weighted? Are the votes of non-banking members (such as donors and obstetricians) equal to those of cord blood bank personnel? If not, how are the votes to be weighted? Is a private banker entitled to choose representatives for public bankers, and vice versa? How are those in hybrid banks to be classified? The complications are mind numbing.

The Advisory Committee's solution to assure balance is a tripartite board with four public banking members, four private banking members and five at-large members. The Bylaws will require that the nominating committee solicit and encourage candidate recommendations from the entire membership.

With the tripartite structure, energy that otherwise might be spent on internal jousting for political advantage can be directed to the challenges and opportunities of the entire industry.

People with a business acumen should head up the organization. It should have the equivalent of a COO and CFO and other professionals to handle oversight, legal, financial and other responsibilities.

Among the powers given to the Board of Directors, as stated in the plan, is to select a chief executive officer, support and evaluate the chief executive, ensure effective planning, monitor and provide financial oversight, ensure financial resources and protect the organization's assets. It is assumed that a professional staff, led by a salaried Executive Director, will be employed to implement the policies and programs of the association.

The tax-exempt status needs to be examined in much greater detail. What are the association's "business, political and socio-economic needs"?

The Advisory Committee carefully considered the available choices for federal tax exemption for the new association. The benefits and liabilities of the alternatives are described briefly in the plan.

With the advice of legal counsel, it was decided that the association should seek to incorporate as a nonprofit trade association, enabling it to address the business, political and socio-economic needs of the cord blood industry. It also will organize a subsidiary nonprofit foundation to address scientific and educational needs.

With respect to business, political and socio-economic needs, the plan states five initial priorities. But these needs can be expected to evolve over time.

For a nonprofit association such as this, what are the regulations concerning gifts and grants from individuals, companies and foundations? What will this money, particularly gifts from individuals or companies, be used for?

The use of gifts, grants and other income by tax-exempt organizations is governed by federal laws and regulations. All income must be used exclusively for the purposes of the organization, as stated in its articles of incorporation. The specific allocation of funds to programs and activities will be determined by the Board of Directors.

If a cord blood bank does not meet the minimum number of stored units, could a minimum number of years in existence (for example five years) be an alternative for accommodating banks in small countries or markets?

The Bylaws will state that a member bank must have a minimum number of cord blood units. It will be up to the Board of Directors to determine that minimum, which may vary from time to time and among categories of banks. For example, public banks and private banks, which typically differ in inventory size and financial resources, may have different requirements for minimum number of units.

My personal preference is for the association to be cord blood bank-centric to help them distribute more products from their inventories.

Early on, the Advisory Committee carefully evaluated whether the members of the cord blood association should be banks or individuals, or a combination. A subcommittee was appointed to study the question and its ramifications. Ultimately the Advisory Committee's decision was the same as the recommendation of the Cord Blood Summit in June in San Francisco: that the association should seek to represent and serve both banks and individuals within the cord blood community.

Is it really important that both public and private banks work together to develop our field to overcome common challenges?

The Advisory Committee strongly believes that it is essential for the future of the industry that public and private banks work together. The plan for the association has been structured accordingly.

I'm curious about whether the intent of the association is to be U.S.-only or international.

Although incorporated in the United States, the association is intended to represent and address the needs of the cord blood community worldwide, without limitations imposed by political or national boundaries.

The cord blood association should be open to all constituencies and organizations, both domestic and international, that have a stake in cord blood banking (vendors, regulatory and policy makers, and health care programs).

The Advisory Committee fully agrees. As stated in the plan, "The cord blood association will embrace all cellular therapy organizations that have compatible values. It will be vitally important for the association to work in concert with other organizations to effectively achieve its goals."

Collaboration makes sense, first, to avoid unnecessary duplication. Even more important, organizations can have greater combined resources and accomplish more when they work together toward common objectives.

The Cord Blood Advisory Committee, itself, was self-selected and the initial Board of Directors will be chosen by the Advisory Committee members. A better method would be an open nomination process for the initial slate for the Board of Directors.

Today – as back in June – there are no association members to submit nominations. Neither is there a nominating process, or criteria for eligibility to submit a nomination, or a system for receiving, reviewing and approving nominations. This will be remedied in the future by the association's policies and Bylaws requiring that nominations be sought and encouraged from the members.

Some concerns have been raised within the community that the process thus far has been less than transparent.

The Advisory Committee has vigorously fostered communications with the cord blood community, both to explain its activity and to encourage input.

- The process began with the Cord Blood Summit in June at the International Cord Blood Symposium at which anyone who had an interest could participate. Electronic polling at that event gathered participant opinion that was displayed in real time, and the polling results were published after the gathering. Everyone who wished to offer a question, information or recommendations was heard during the discussion.
- The Advisory Committee used the polling results and the Summit discussion as a starting place for its deliberations.
- A LinkedIn discussion board was created and publicized so that anyone in or served by the cord blood community could publicly post comments, questions and recommendations. An e-mail address was promoted so that communications could also be sent privately to the Advisory Committee.
- A draft plan for the cord blood association was published on line, and public comments were requested through an aggressive e-mail campaign, postings on LinkedIn discussion boards, and announcements in the e-newsletters of several organizations that serve the cord blood community.
- The submitted comments were all evaluated by the Advisory Committee. The responses, here, are part of that review.

At the beginning of the process, the Advisory Committee members agreed to (1) place the interests of the cord blood community ahead of personal interests and allegiances, (2) devote the time and attention necessary to accomplish this important work, and (3) commit to openness and transparency. The committee has strived to fulfill that commitment.