

**COMMITTEE ON ESTABLISHING A NATIONAL
CORD BLOOD STEM CELL BANK PROGRAM**

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This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations nor did they see the final draft of the report before its release. The review of this report was overseen by **Nancy Ascher**, Professor and Chair of the Department of Surgery, University of California, San Francisco and **Enriqueta Bond**, President, Burroughs Wellcome Fund, Research Triangle Park, North Carolina. Appointed by the National Research Council and Institute of Medicine, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

Preface

An effective National Cord Blood Stem Cell Bank Program should take into account current and future science; the needs of patients, physicians and donors; quality assurance; and outcomes assessment. Balancing of all these perspectives presents a substantial challenge, and tensions among current organizations active in the field led, in part, to the request for this report from the Institute of Medicine and formed a background for all of the committee's information gathering and deliberations.

The small number of extremely knowledgeable specialists in this field—many of whom have very close ties to at least one of the major participants in the organizational debate—meant that in order to ensure inclusion of all important perspectives on equity, access, and outcomes, membership on the committee changed several times. Although the changes ensured an extremely rich range of viewpoints, it may have confused some observers.

The following truths regarding cord blood collection and transplantation became apparent at the first meeting and informed the committee's discussions and recommendations throughout the study:

- The goal of ensuring the best care for patients requires that transplant physicians be provided with timely, complete, and accurate information on available hematopoietic stem cells from both adult donors and umbilical cord blood at the time of decision making about a transplant. Information about bone marrow donor programs and experiences had to be considered.
- Quality assurance for the collection, storage, and use of cord blood is essential, as is a coordinated approach to the collection of complete information on the outcomes of all hematopoietic stem cell transplants.

The committee appreciates the generosity of the many bankers, transplant physicians, transplant recipients, and scientists who shared their experiences and data during open meetings and site visits and in correspondence with the committee. Invaluable knowledge was gained, none of which could have been fully assimilated without the assistance of the very able staff supporting this report.

Finally, a fully coordinated quality national system to support hematopoietic stem cell transplantation cannot be accomplished by any one action or reorganization. This report includes both a discussion of what such a system should look like when it is complete and focuses on the key steps that respond to immediate concerns and move toward the long-term goal. The interested community is urged to keep the goal of comprehensive support for hematopoietic stem cell trans

plantation in mind while struggling with the inevitably messy process of arriving at that point. The committee's overall goal of a seamless program of access to hematopoietic stem cells points directly to a single national program encompassing the existing marrow donor program and this cord blood program. Providing meaningful recommendations on how to accomplish such a program, however, would have required study of the existing NMDP and other adult HPC programs and the ways to merge them with the specifics of a cord blood program well in excess of the time and resources available to the committee. For that reason, the report highlights the need for coordination at many points, expects analysis of outcomes from all sources of cells, leaves the door open to contractual arrangements with core components of the existing program when consistent with policy direction, and anticipates that the question of full integration will be dealt with in the future.

Kristine M. Gebbie
Chair

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