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Associate Commissioner for Policy and Planning

The function of the Committee, as stated in its Charter, is to advise the Commissioner of the Food and Drug Administration in discharging responsibilities as they relate to assuring safe and effective biological products for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility.

Dr. Laughlin advised the FDA that she has a financial interest related to the above stated topic that could potentially be affected by her participation in the matter at issue. Dr. Laughlin reported that she consults with an affected firm, [REDACTED], as a member of the Medical Advisory Board. The consulting is related to the topic. She receives [REDACTED] per year from December 2006 to present.

Under Section 208, Dr. Laughlin is prohibited from participating in any matter affecting these interests, unless she receives a waiver. However, as noted above, you have the authority under 18 U.S.C. 208(b)(3) to grant a waiver.

For the following reasons, I believe that it would be appropriate for you to grant a waiver to Dr. Laughlin that would allow her to participate in the discussions before the Committee:

Dr. Laughlin is Director of the Allogeneic Bone Marrow Transplant Program at Case Western Ireland Cancer Center. She is recognized as an expert in unrelated umbilical cord blood allogeneic transplantation for the treatment of leukemia and lymphoma in adults. The Committee will address safety issues related to cord blood transplantation in children and adults and she will provide critical expertise for the committee's discussion of clinical trials of umbilical cord blood transplantation in adults for the treatment of hematologic malignancies. Three other adult cord blood transplant experts were invited but were unavailable.

Dr. Laughlin's consulting as a member of the Medical Advisory Board for [REDACTED] is very broad in nature. Medical Advisory Boards offer advice on many topics including long-range strategy and proposals for new research programs. The chance is remote that the committee discussion of the topic will have a direct and predictable effect on Dr. Laughlin's financial interest.

For these reasons, I believe that Dr. Laughlin's participation in the deliberations of the advisory committee will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

