The RAC continues to explore the issues raised by the potential of in utero gene transfer research. However, at present, the members unanimously agree that it is premature to undertake any human in utero gene transfer experiment.

**Rationale:**
Significant additional preclinical and clinical studies addressing vector transduction efficacy, biodistribution, and toxicity are required before a human in utero gene transfer protocol should proceed. In addition, a more thorough understanding of the ontogeny of human organ systems, such as the immune and nervous systems, is needed to better define the potential efficacy and risks of human in utero gene transfer. Prerequisites for considering any specific human in utero gene transfer procedure include an understanding of the pathophysiology of the candidate disease and a demonstrable advantage to the in utero approach. Once the above criteria are met, the committee would be willing to consider well rationalized in utero gene transfer protocols.