

**EXTRAORDINARY PETITION PROCESS  
ADDITIONAL ANALYSIS – OPTION B**

**Background**

At the July 20, 2010 Science Subcommittee meeting, members of the Subcommittee discussed a proposal to permit the Board to request that an application could be referred for additional analysis under limited circumstances. The Subcommittee did not reach a conclusion regarding the proposal but agreed to consider further public input and to reconsider the proposal at its next meeting. The proposal is intended to create a procedure whereby the Board can request a limited analysis, under a narrow set of circumstances, in response to an extraordinary petition.

**Proposal**

When a material dispute of fact exists and the Board is unable to resolve the issue at the meeting at which the application is considered, the Board may conditionally deny funding for the application, subject to a limited analysis of the application. The option for additional analysis for an application should be reserved only for those circumstances in which the Board is unable to reach a decision at meeting at which the application is presented. Programmatic issues, such as whether the agency's portfolio is well-balanced among diseases, should not be a justification for additional analysis, nor should clear errors in the review of an application that have been identified by staff and presented to the Board. The procedure for the limited additional analysis of an application should consist of the following:

- The limited additional analysis of an application will be conducted by subgroup of the Grants Working Group led by the Administrative Chair of the Grants Working Group. The Board shall designate three other scientific members of the Grants Working Group to serve with the Administrative Chair on this subgroup of the Grants Working Group. The Administrative Chair may seek outside specialists to assist in analyzing the scientific issues referred to it by the Board. Both of the Vice Chairs of the Grants Working Group, the Board Chair, and another Patient Advocate from the GWG, with the priority for the Patient Advocate who represents the disease type that is the target of the proposal (if applicable) will be invited to listen and ask questions as well as participate in the recommendation to the Board. That recommendation, which will be to reconsider or not reconsider, will be made by through a motion and a vote of the scientists and advocates from the GWG. Substitutes can be designated by the Administrative Chair in consultation with the co-chairs in the event of conflicts of interest or unavailability.
- If the recommendation of this special panel is to not reconsider, the Board's original determination not to fund the application shall remain in effect.

- If the recommendation of this special panel is to reconsider, the recommendation shall be reported to the Governing Board and shall be included on the agenda for its next scheduled meeting, which shall consider whether or not to modify its decision on funding the application.
  
- If 35% of this special panel is in favor of recommending reconsideration, a minority report of this recommendation will be reported to the Board and reconsideration of the application shall be included on the agenda for its next scheduled meeting.