



Technology
Evaluation
Center

August 21, 2006

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD20852
Filed electronically

**Re: Guidance for the Use of Bayesian Statistics in Medical Device
Clinical Trials- Draft Guidance for Industry and FDA Staff. Docket
#2006D-0191**

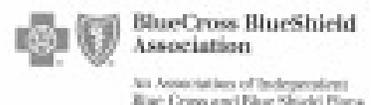
Dear Sirs:

The Blue Cross and Blue Shield Association (BCBSA) Technology Evaluation Center (TEC) appreciates the opportunity to provide comments on the Draft Decision Guidance referenced above on the use of Bayesian statistics in medical device clinical trials. These comments are offered on behalf of the 38 independent Blue Cross and Blue Shield Plans that are members of the Blue Cross and Blue Shield Association and that provide health benefits to 96 million members- one in three Americans.

A Bayesian approach to device development has attractive and coherent aspects. At the same time, we are concerned that reporting will lack sufficient transparency to enable external appraisal of the validity of conclusions. For example, the Summary of Safety and Effectiveness of the BAK/Cervical Interbody Fusion System is one example of a Bayesian approach. Yet with respect to describing the prior distribution employed, the document (<http://www.fda.gov/cdrh/pdf/P980048b.pdf>) states only that "The Bayesian analysis methods employed to assess safety and effectiveness combine data with a diffuse prior distribution to determine the posterior distribution of the parameters of interest." Because a number of different priors can be diffuse, it is important to specify the prior in detail

We believe results derived from applying Bayesian approaches require transparency with particular attention to the following:

Blue Cross and Blue Shield Association
Technology Evaluation Center
225 North Michigan Avenue
Chicago, Illinois 60601-7680
312.287.8345



1) There should be a clear description of how priors were developed. Priors should be specified in detail. Informative priors should be clearly developed in an unbiased manner.

2) Models used, including hierarchical ones, should be provided in detail for inspection and also described in language understandable to individuals having modest familiarity with Bayesian methods.

3) Sensitivity analyses should be required to justify robustness of models and prior specification.

Thank you for your attention to our concerns.

Sincerely,



Naomi Aronson, Ph.D.
Executive Director