Director, Division of Data Policy  
Room 440D Humphrey Bldg.  
Dept. of Health & Human Services  
200 Independence Avenue  
Washington DC 20201

Re: Information Quality Comments  
Draft Guidelines, 67 F.R. 21685

Dear Director:

The Section of Administrative Law and Regulatory Practice of the American Bar Association is pleased to submit comments on the proposed guidance for Data Quality that your agency has proposed under Section 515 of Public Law 106-554. The views expressed herein are presented on behalf of the Section of Administrative Law and Regulatory Practice. They have not been approved by the House of Delegates or the Board of Governors of the American Bar Association and, accordingly, should not be construed as representing the position of the Association.

These comments are focused on the mechanisms proposed for implementation of section 515’s “correction of information that does not comply with (OMB guidance)”. In commenting on the mechanisms we hope to improve them; these comments do not suggest that any of the substantive missions of the agency discussed in your published proposal would or would have our Section’s support. Because many of the nation’s experts in the administrative process and information policy are members of our Section, we hope to speak to the process and procedural aspects of the proposed guidelines.

1. We endorse the creation of a user-friendly website that will describe means by which to submit requests for correction. (HHS Guidelines, Page 18 of 20, Part I, section E, para. 2) Facilitating the corrections process is fully consistent with the OMB guidelines and the purposes of Section 515.
2. The Department should adopt a position defining “influential” at a level that is more aligned with Section 515’s desire for quality in the data used by federal agencies for their “important” decisions (See OMB Guidance, 67 F.R. 8455 col. 2). NIH makes a reasonable determination (VII, Page 32 of 36) of the types of disseminated information that “have the potential of being considered influential”. The NIH acknowledges that how information will be used “cannot always be anticipated” so the term “influential” is broadened to include research and recommendations.

3. By contrast, we do not support the FDA choice to limit “influential” information to only those rulemakings or actions that are expected to “have an annual effect on the economy of $100 million or more”. This seems quite narrow – making it rare that a study would be subjected to the transparency measures accorded to influential information. (FDA Draft Guidelines, Page 25 of 33, Item VII A para. 2) “Important” FDA policy decisions and rules may have an effect under a level of $100,000,000 effects but still be important to major constituencies.

This choice of an extremely high threshold by FDA and perhaps other HHS entities will frustrate the purpose of section 515, because there will be so few times that an analysis of supporting data’s reproducibility will be exposed for public view. For example, FDA adopted a rule on hypoallergenic cosmetics that depended on a survey commissioned by another federal agency; the methodological flaws of that survey led the sponsor of that survey to disclaim its validity; the survey was central support for the FDA rule; when FDA’s rule was challenged the rule was vacated (not remanded) by the D.C. Circuit in 1977 and that rulemaking has never been attempted again. (Almay v Califano, 569 F.2d 674 (D.C. Cir., 1977)) For those who are concerned with allergens in cosmetics, the study was “important” but may have had under $100,000,000 effects.

4. Adaptation of the Safe Drinking Water Act principles to risk decisions that are not classic “risk assessments” has been attempted by several HHS agencies. We note that the FDA at page 29 of 33, item VIII-C, commits itself to disseminate risk information in “comprehensive, informative and understandable” ways. We suggest FDA move this closer to the SDWA norms by adding to this a statement of uncertainties or a brief data that fail to support the
conclusion drawn by the agency study (OMB, 67 F.R. 8458 col. 1 items (iv, v))

5. We commend that provision in NIH Guidelines at part VI(4) that if a complaint is determined not to be legitimate, the data owner “must provide a clear explanation of the rationale for that determination to the complainant.” The response is also directed to explain the basis for the support and substantiation given to the data as it was prepared. This directive is a prudent method of response; agency communication about why a decision was made can be very helpful in fostering positive outcomes and in deterring further appeals of the challenged statement.

Thank you for considering these comments. If you wish clarification, please contact Professor James O’Reilly, Chair of our Committee on Government Information & Privacy, at (513) 556-0062.

Sincerely,

C. Boyden Gray
Section Chair