AMERICAN BAR ASSOCIATION

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Office of Management and Budget
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Submitted via email: OMB_RAbulletin.omb.eop.gov

Dear Dr. Beck:

On behalf of the American Bar Association (ABA) and its more than 400,000 members, I write to submit the ABA's comments on OMB's proposed draft "Risk Assessment Bulletin." As the Chair of the ABA Section of Administrative Law and Regulatory Practice, I have been authorized to express the association's views on this important subject.

In August 1999, the ABA House of Delegate adopted a recommendation sponsored by this section proposing principles for the conduct of formal risk assessments in advance of regulatory action concerning health and safety issues.² OMB's draft risk assessment standards are generally consistent with the ABA recommendation, and we support the Bulletin insofar as it advances the recommendation. The following comments seek to indicate the significant and numerous points of agreement between OMB's draft standards and the ABA recommendation and those areas where the ABA recommendation would suggest a revision in OMB's approach.

Justification

The ABA recognizes that many of the requirements in the Bulletin are consistent with good practice recommendations for risk assessment issued by the National Academy of Sciences and other professional organizations. As stated, there is also substantial congruence with the ABA recommendation. Nevertheless, the ABA believes that it is important that OMB articulate a justification for the Bulletin. The legitimacy of the large administrative state is based in significant part on two factors: (i) the high level of expertise possessed by agencies, and (ii) their respect for the limits on their power imposed by statutory and executive directives. In view of the first factor, the ABA believes it would behoove OMB to explain what problems it believes are occurring within the agencies that warrant the creation of new federal risk assessment guidelines and to identify the ways in which the Bulletin addresses them. In so doing, OMB should explain why it and OSTP --

¹ Office of Management & Budget, Proposed Risk Assessment Bulletin, 71 Fed. Reg. 2600 (2006).

² American Bar Association, Recommendation 103(b) (August, 1999). A copy of the Recommendation is attached.

rather than the agencies -- are best suited to resolve those problems. In view of the second factor, OMB should clarify that it does not intend to impose any requirements on an agency that go beyond what the President can impose in an executive order. In particular, OMB should clarify that, to the extent its Bulletin conflicts with an agency's statutory mandate, the latter must govern.

Risk Information

The ABA recommended that agencies provide complete contextual information about risk evidence³ and that risk assessors clearly explain the judgments that they make.⁴ We therefore support the clear exposition of these categories of information in risk assessments. As a general matter, we believe transparency and explanation requirements are important and will improve the process of risk assessment in the federal government. We would note that OMB based these requirements on the considerable literature that supports the exposition of such information, as did the ABA in its recommendation.

The ABA recommendation also indicated that "[r]isk assessment should provide scientific estimates and characterizations of the nature and magnitude of the risks posed to human health, human safety and the integrity and quality of the environment" As the ABA intended, OMB has sought to require agencies to provide scientific estimates and characterizations of the nature and magnitude of risks posed to human health, human safety and the environment.

The ABA recommended that "an agency should document in the administrative record both its own evaluation of a risk assessment, and whether and how it was used in its decision process." OMB does not require this last step, presumably because its Guidelines are focused on risk assessment and not risk management. We would ask, however, that OMB consider mandating this procedure. It is not uncommon for agencies to blur the risk assessment and risk management components of regulation, particularly when it is politically convenient for an agency to insist that it must take some action on the basis of the scientific evidence before it, when in fact the agency's decision is based on regulatory policy and is therefore a matter of risk management.

Flexibility

The ABA recommended that "[r]isk assessment requirements must allow for flexibility in assessing the variety of relevant risks and should acknowledge that risk assessors may exercise professional judgment on these matters." OMB recognizes the necessity of flexibility when it requires

³ The ABA recommended that risk assessments must explicitly acknowledge and explain the limitations of the process in terms of methodology, data, assumptions, uncertainty and variability. In particular, agencies should fully disclose qualitative aspects of risk, the reasonable range of uncertainties, and the experience of variability in the populations exposed to the risk. ABA Recommendation, supra note 2, $\P1$.

⁴ *Id.* ¶4 ("[r]isk assessors should identify and explain their judgments.").

⁵ *Id*. ¶1.

⁶ Proposed Bulletin, *supra* note 1, §§V-VI.

⁷ ABA Recommendation 103(b), *supra* note 2, ¶3.

⁸ See Wendy E. Wagner, The Science Charade in Toxic Risk Regulation, 95 COLUM. L. REV. 1613 (1995).

⁹ ABA Recommendation 103(b), *supra* note 2, \P 2.

compliance with the standards in the Bulletin "to the extent appropriate." ¹⁰

The ABA also recommended that the "amount of effort that goes into a risk assessment should be reasonable in relation to the significance and complexity of the decision, the value of additional information, and the need for expedition." OMB's proposal satisfies this suggestion, although it creates an ambiguity that deserves clarification. OMB acknowledges the level of effort should be commensurate with the importance of the risk assessment, and the "scope and content of the risk assessment shall be determined on the basis of the objectives of the assessment and the best professional judgment, considering the benefits and costs of acquiring additional information before undertaking the assessment." But OMB then adds that agencies shall consider whether the information is sufficient "considering the benefits and costs of acquiring additional information before undertaking the assessment." OMB should acknowledge that an agency may interpret its mandate to authorize it to take action based only on current available information in order to ensure the public is adequately protected.

While OMB recognizes the importance of flexibility in the proposed standards, the preamble could be clearer regarding the need for flexibility. This is important because OMB defines "risk assessment" very broadly to be "a scientific and/or technical document that assembles and synthesizes scientific information to determine whether a particular hazard exists and/or the extent of possible risk to human health, safety or the environment." This definition includes not only the assessment of health risks, such as cancer, but also the assessment of safety risks, such as the risk of injury or death in an automobile accident. OMB's broad definition is appropriate. The ABA recommendation noted, "Risk assessments can be useful across a broad range of agency programs and decisions." Nevertheless, many of the techniques discussed by OMB are best used to evaluate health risks and can be unnecessary or even inappropriate to assess other types of risks, such as safety risks posed by motor vehicles or airplanes. OMB could assist agencies if it identified in its preamble which techniques it considers as generally appropriate for what types of risk assessment.

Weight of the Evidence

The ABA also recommended that risk assessments "should be based on careful analysis of the weight of all available evidence." The reference to "all available evidence" indicates that agencies should ultimately characterize risks based on both quantitative and qualitative evidence. ¹⁸ For

¹⁰ Proposed Bulletin, supra note 1, §II.1.

¹¹ ABA Recommendation 103(b), *supra* note 2, ¶8.

¹² Proposed Bulletin, supra note 1, §III.2.

¹³ Id. §III.2.

¹⁴ Id. §III.2.

¹⁵ Id. §I.3.

¹⁶ ABA Recommendation, *supra* note 2, ¶8.

¹⁷ Id.

¹⁸ The report accompanying the recommendation explained that "scientific' should not be read to limit risk assessment to quantitative (numerical) techniques or results." Report to ABA House of Delegates regarding ABA Recommendation 103(b), (August, 1999), at 8. Although only the "Recommendation," and not the accompanying "Report" is adopted by the ABA House of Delegates as official ABA policy, the Report contains useful background information that helps explain the Recommendation and place it in context.

general risk assessment, OMB articulates a similar expectation. It requires agencies to provide "a characterization of risk, qualitatively, and, wherever possible, quantitatively." Moreover, it requires that risk assessments "giv[e] weight to both positive and negative studies in light of each study's technical quality." The ABA supports these provisions.

We do have a question, however, concerning a "weight of the evidence" approach in the context of influential risk assessments. For influential risk assessments, where human health effects are a concern, OMB instructs agencies to determine which effects are adverse by using "the best available scientific information generally accepted in the relevant clinical and toxicological communities." We assume that OMB intended that the word "scientific" should not be limited in this context to quantitative (numerical) information, but OMB has not defined the term. Because of the potential for confusion, the ABA recommends that OMB clarify that an influential assessment of when human health effects are adverse should be based on the weight of both the qualitative and quantitative scientific evidence.

Objectivity

OMB's proposed standards require risk assessments to be "scientifically objective ... as a matter of substance, neither minimizing nor exaggerating the nature of the magnitude of the risks." While the ABA agrees with and support this goal, we believe the Guidelines would be improved if OMB more directly addressed the issue of science policy judgments in risk assessment.

The ABA recommended that the risk assessment process "should be constructed to avoid bias and political pressure" and that, "[w]here relevant, additional economic, social, and political factors that were not incorporated into the risk assessment should also be considered when risk managers make regulatory decisions."²³ This language reflected an aspiration that the risk assessment process be "objective" as well as a realization that risk assessments involve judgments which make it misleading to characterize risk assessments as purely "objective."²⁴ The goal is that risk assessments should be based on "recognized risk assessment methods" and not be "merely political or rhetorical."²⁵

The aspiration to have an "objective" risk assessment process was captured in the Red Book's distinction between "risk assessment" and "risk management." Nevertheless, it is simply not possible for risk assessment to be shorn of any policy element and to do so would be counterproductive. As a NRC committee has explained:

[T]he Red Book made it clear that judgment (also referred to as risk-assessment policy or science policy) would be required even during the phase of risk assessment. The present

¹⁹ Proposed Bulletin, supra note 1, §IV.3.

²⁰ Id. §IV.4.b.

²¹ Id. §V.7.

²² Id. §IV.4.a.

²³ ABA Recommendation 103(b), *supra* note 2, ¶1.

²⁴ Section Report, *supra* note 18, at 7.

²⁵ Id. at 8.

²⁶ NATIONAL RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT (1983).

committee concludes further that the science-policy judgments that EPA makes in the course of a risk assessment would be improved if they were more clearly informed by the agency's priorities and goals in risk management.²⁷

As the NRC excerpt quoted above indicates, the conduct of risk assessments, particularly those examining health effects, requires the use of policy judgments. For example, risk assessors must make a policy judgment in extrapolating the results of animal data to construct a dose-response curve for humans. In such settings, no scientific data exists that answers the precise question that the agency is seeking to answer.²⁸ The ABA therefore believes that OMB should clarify that its use of "objective" means risk assessment should not be skewed by political and rhetorical elements, but still allows for the use of risk assessment assumptions based on general scientific knowledge of the phenomena in question or inferences considered by risk assessment professionals as an appropriate way to bridge uncertainties. While it is not possible to eliminate the use of science policy in making risk assessments, this practice should be entirely transparent, ²⁹ as discussed earlier.³⁰

The ABA also has a concern about OMB's intentions regarding the use of conservative risk assessment policies in the context of influential risk assessments. For such assessments, OMB requires the evaluation of whether a health effect is adverse to be based on "the best available scientific information generally accepted in the relevant clinical and toxicological fields." In its preamble, OMB states that "it may be necessary for risk assessment reports to distinguish which effects are adverse from those which are non-adverse." OMB should clarify that, by its use of the word "may," it is leaving open the possibility that an agency's mandate might require it to focus on changes caused by toxic exposure or other disruptive activities even where those changes are "non-adverse."

A similar confusion arises concerning OMB's description of the relationship between risk assessment and risk management. In the preamble, OMB recognizes that regulatory statutes contain a wide variety of standards that guide risk management decisions. OMB also notes, however, that in light of these statutes, risk management is based on "acceptable risk" considerations. ³³ We request OMB to confirm that it is using this phrase generically, and that it is not attempting to override or preempt particular statutory standards; e.g., the Clean Air Act ("adequate margin of safety") or the Resource Conservation and Recovery Act ("to protect human health and the environment").

²⁷ NATIONAL RESEARCH COUNCIL, SCIENCE AND JUDGMENT IN RISK ASSESSMENT 259-60 (1994). 28 See Environmental Protection Agency, Proposed Guidelines for Carcinogenic Risk Assessment, 61 Fed. Reg. 17,960, 17, 964 (1996):

[[]D]efault assumptions are necessarily made in risk assessments in which data gaps exist in general knowledge or in available data for a particular agent. The default assumptions are inferences based on general scientific knowledge of the phenomena in question and are also matters of policy concerning the appropriate way to bridge uncertainties that concern potential risk to human health (or, more generally, to environmental systems) from the agent under assessment.

²⁹ ABA Report, *supra* note 18, at 6 ("To the extent that the use of particular assumptions or the remaining uncertain are problematic, all agree that the best cure is *transparency*, that is, full disclosure in the process, explanation of choices, and the appropriate participation by affected parties.")

³⁰ See notes 3-4 & accompanying text.

³¹ Proposed Bulletin, supra note 1, §V.7.

³² Id. at 20.

³³ Id. at 4.

Ranges and Central Estimates

Policy judgments are employed in risk assessment for another reason. Agencies commonly employ conservative risk assessment policies when they operate under statutory mandates that require them to minimize dangers to the public.³⁴ Again, we assume that OMB does not intend to prohibit this practice since it offers agency decision-makers useful information when they turn to risk management. As the NRC indicated, a risk assessment is more useful when it is "clearly informed by the agency's priorities and goals in risk management."³⁵ At the same time, we recognize that "the use of multiple conservatism reflects a highly contested policy choice in a given risk assessment."³⁶ The ABA therefore agrees with OMB that risk estimates ought to include "whenever possible, a range of plausible estimates, including central or expected estimates, when a quantitative characterization of risk is made available."³⁷

For highly influential risk assessments, OMB requires that a risk assessment shall "[h]ighlight central estimates as well as high-end and low-end estimates or risks when such risks are uncertain." Unlike the prior requirement, this requirement does not contain a "whenever possible" quantification, which may be an oversight since other provisions concerning highly influential risk assessments contain such a qualification. If not, an absolute requirement is problematic since "the lack of information may be so profound that choosing a 'best' value is little more than a guess or hunch. Likewise, "choosing an average is little better; where variability is great, a single figure can be highly misleading. OMB could, however, ask agencies that fail to provide a central estimate to explain why such an estimate could not be made.

Alternative Mitigation Measures and Countervailing Risks

OMB requires that risk assessments that will be used for regulatory analysis include "a comparison of the baseline risk against the risk associated with the alternative mitigation measures being considered, and assess, to the extent feasible, countervailing risks caused by alternative mitigation measures." While this requirement appears to be consistent with the ABA recommendation, ⁴³ we believe OMB could clarify the requirement. We assume that OMB means that the agency should identify for the risk assessors what regulatory options it is considering so that risk assessors can

³⁴ *See*, *e.g.*, EPA Office of the Science Advisor, "Staff Paper: An Examination of EPA Risk Assessment Principles and Practices" (March 2004), at 16 ("By taking an overall public health protective stance..., EPA's approach to risk assessment takes into account the variety of language found in the various statutes...."), *available at* http://www.epa.gov/osa/pdfs/ratf-final.pdf.

³⁵ Note 26 & accompanying text.

³⁶ ABA Report, supra note 18, at 5.

³⁷ Proposed Bulletin, supra note 1, §IV.7.e.

³⁸ Id. §V.3.

³⁹ *See id.* §V6. ("Characterize, to extent feasible, variability"), §V.8 (Provide discussion, to the extent possible, ..."). 40 ABA Report, *supra* note 18, at 5.

⁴¹ *Id*.

⁴² Proposed Bulletin, supra note 1, §III.7.b.

⁴³ ABA Recommendation 103(b) noted that "[r]isk comparisons can be helpful for placing risks in context." *See* note 2, *supra*, ¶6.

provide risk information concerning such alternatives, and that OMB does not expect risk assessors to assess as a policy matter which regulatory alternatives should be adopted. Otherwise, the Guidelines would mandate risk management procedures in the course of assessing risk. Moreover, OMB should clarify that the decision of when and whether to conduct these alternative assessments will be guided by the applicable statutory mandate.

Public Participation

The ABA recommended that "[p]ublic procedures associated with risk assessments should be conducted through a transparency process that allows input from and understanding of the results by persons and groups interested." OMB meets this expectation when it states that agencies "shall follow appropriate procedures for peer review and public participation in the process of preparing the risk assessment."

OMB also requires agencies to prepare a "response-to-comment" document which identifies significant comments on the risk assessment, and provides responses to those comments, including a "rationale for why the agency has not adopted the position suggested by commentators and why the agency position is preferable." We support this provision as a default expectation, but we recommend that OMB also permit agencies, in cases where they intend to proceed by notice-and-comment rulemaking, to defer responding to comments filed on a proposed risk assessment until the completion of the comment period in rulemaking. Based on the ABA recommendation referenced above, we believe that design of risk assessment procedures must take into account the impact of such procedures on an agency's capacity to promulgate regulations. From this perspective, we are concerned that the preparation of a separate response-to-comment document prior to rulemaking may have the potential in some circumstances to ossify an already burdened rulemaking process. We do not believe that this exception would relieve agencies from the obligation of responding to comments on a risk assessment. If an agency ignores comments that point out significant flaws in the risk assessment, it runs the risk of a judicial remand. Moreover, OMB can ask agencies to justify invoking the exception.

As noted, OMB requires agencies to respond to "significant" comments in its "response to comment" document. In its preamble, OMB instructs agencies that "[s]cientific comments are presumed to be significant." We suggest that OMB delete this instruction. It is unnecessary since OMB has required the agency to respond to all significant comments. Moreover, agencies are likely out of an abundance of caution not to bother to overcome the presumption, which means they will end up answering non-significant objections. Finally, it suggests to the public that it does not have a valid role in the risk assessment process or at least not as valid a role as that of industry

⁴⁴ ABA Recommendation 103(b), *supra* note 2, ¶7.

⁴⁵ Proposed Bulletin, *supra* note 1, §III.5.

⁴⁶ Id. §V.9.

⁴⁷ In an analogous context, the ABA in 1992 recommended that the "President and Congress ... exercise restraint in the overall number of rulemaking impact analysis" and "assess the usefulness of existing and planned impact analysis." American Bar Association, Recommendation 113 (February, 1992). The recommendation reflected concern that multiple analysis requirements can have the "effect of stymieing appropriate and necessary rulemaking." Report to ABA House of Delegates regarding ABA Recommendation 113(November, 1991), at 2. A copy of the Recommendation is attached.

⁴⁸ Proposed Bulletin, *supra* note 1, at 20.

groups, which are generally in a better position to hire scientists to write their comments. By comparison, the ABA's risk assessment recommendation suggests that agencies should reach out to the public to seek its participation in commenting on risk assessments. OMB's position is inconsistent with the spirit, if not the letter, of this suggestion.

Exceptions

OMB exempts risk assessments performed "with respect to individual agency adjudications and permit proceedings (including a registration, approval or licensing) unless the agency determines that compliance with this Bulletin is practical and appropriate and the risk assessment is scientifically or technically novel or likely to have precedent-setting influence on future adjudications and/or permit proceedings." We recognize that this language is nearly identical to that in OMB's Peer Review Bulletin. We objected to this language because of its inclusion of some subset of adjudications in the proposed Peer Review Bulletin. We questioned OMB's authority to apply that Bulletin to adjudications at all, inasmuch as they are not subject to Executive Order 12866, the Paperwork Reduction Act, or OMB's Guidelines promulgated under the Information Quality Act. In addition, we objected because we believed there were significant practical problems with integrating peer review into adjudications, and we provided an example of an agency adjudication before an Administrative Law Judge. We repeat our objections to the inclusion of some adjudications in the proposed Bulletin for the same reasons.

Some adjudications may involve decisions for which peer review and/or risk assessment might be appropriate, but specific procedural limitations apply to various types of adjudications that may raise practical and legal problems with applying the peer review and/or risk assessment guidelines to such adjudications. For example, Section 554 of the Administrative Procedure Act prohibits an ALJ from "consult[ing] a person or party on a fact in issue, unless on notice and opportunity for all parties to participate." Such a restriction would make it very hard for an ALJ to conduct either peer review or a risk assessment. This restriction is just one example of the possible legal problems that might be caused by imposing peer review or risk assessment requirements on adjudications. However, just as Section 554 does not apply to all adjudications and this particular language does not apply to applications for initial licenses, there may be ways to accommodate peer review and risk assessment in certain types of adjudications. Unfortunately, neither the Peer Review Bulletin nor the proposed Risk Assessment Bulletin attempts to distinguish among adjudications based upon the procedural limitations applicable to them. The ABA suggests that OMB identify these different categories of adjudications and specify for each category whether and how peer review and risk assessment may be conducted consistent with the procedural limitations imposed on adjudications by regulation, statute, and the Constitution.

⁴⁹ ABA Recommendation 103(b), *supra* note 2, ¶8 ("Particular efforts, proportional to the overall effort involved, should be made to reach persons and groups who do not have the technical expertise to use [risk assessment] materials easily.") 50 Proposed Bulletin, *supra* note 1, §II.2.b

⁵¹ See 70 Fed. Reg. 2677 (Jan. 14, 2005).

⁵² See §3(e) (defining regulatory action the promulgation of a rule or regulation).

⁵³ See 44 U.S.C. §3518(c)(1)(B)(ii).

⁵⁴ *See* OMB Information Quality Guidelines, §IV.2. (defining "dissemination" not to include information disseminated in the course of adjudicative processes).

Finally, we note that none of the legal problems mentioned above apply to imposing peer review and/or risk assessment requirements on an agency as a prerequisite to submitting information as a party to a proceeding to the agency decisionmaker for consideration. There may, however, be practical problems. For example, unlike in the rulemaking context, the agency historically may not have produced a risk assessment document to submit as evidence in a licensing or adjudicatory proceeding. Before OMB mandates compliance with the Bulletin by an agency concerning its participation as a party, it should consider whether and how the Bulletin should apply to different types of submissions by an agency in adjudicatory proceedings.

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Thank you for considering our comments. If you would like more information regarding the ABA's position on these issues, please contact me at (317) 274-4091.

Sincerely yours,

Eleanor D. Kinney

Elon D. Kuwe

Chair

ABA Section of Administrative Law and Regulatory Practice

RECOMMENDATION 103(B)

ADOPTED BY THE

AMERICAN BAR ASSOCIATION HOUSE OF DELEGATES

AUGUST 1999

RESOLVED, That the American Bar Association recommends that:

Any formal requirement, promulgated by the Congress (in legislation), the President (in executive orders), or an agency head (in directives or rules), that agencies of the Federal Government undertake formal risk assessments in advance of regulatory action concerning health and safety issues should be consistent with the following principles:

- 1. Risk assessment should provide scientific estimates and characterizations of the nature and magnitude of risks posed to human health, human safety and the integrity and quality of the environment, and should be based on careful analysis of the weight of all available evidence. The process should be constructed to avoid bias and political pressure. Where relevant, additional economic, social, and political factors that were not incorporated into the risk assessment should also be considered when risk managers make regulatory decisions.
- 2. Risk assessment requirements must allow for flexibility in assessing the variety of relevant risks and should acknowledge that risk assessors may exercise professional judgment on these matters.
- 3. Risk assessors should identify and explain their judgments, and an agency should document in the administrative record both its own evaluation of a risk assessment, and whether and how it was used in its decision process.
- 4. Peer review though adding time and expense can improve risk assessments. The nature, significance, and complexity of the risk assessment should dictate when peer review is used and the scope and nature of any peer review.
- 5. Risk assessments should explicitly acknowledge and explain the limitations of the process in terms of methodology, data, assumptions, uncertainty, and variability. In particular, agencies should fully disclose qualitative aspects of risk, the reasonable range of uncertainties, and the existence of variability in the populations exposed to the risk.
- 6. Risk comparisons can be helpful for placing risks in context, but risk assessments should be approached with care, particularly among dissimilar risks, and critical features of the compared risks should be fully disclosed.

- 7. Public procedures associated with risk assessment should be conducted through a transparent process that allows input from and understanding of the results by persons and groups interested. Particular efforts, proportional to the overall effort involved, should be made to reach persons and groups who do not have the technical expertise to use such materials easily.
- 8. Risk assessments can be useful across a broad range of agency programs and decisions. Risk assessments should be statutorily required, however, only for regulatory decisions of sufficient significance to warrant the effort. The amount of effort that goes into a risk assessment should be reasonable in relation to the significance and complexity of the decision, the value of additional information, and the need for expedition.
- 9. Any judicial review of a risk assessment should occur only as part of the review of a final agency action for which the assessment was made.

RECOMMENDATION 113

ADOPTED BY THE

AMERICAN BAR ASSOCIATION HOUSE OF DELEGATES

FEBRUARY 1992

BE IT RESOLVED, That the American Bar Association urges the President and Congress to exercise restraint in the overall number of required rulemaking impact analyses, assess the usefulness of existing and planned impact analyses, ensure that agency administrators and employees receive adequate training concerning the implementation of analyses, and ensure that agencies adhere to recommendations of the American Bar Association and the Administrative Conference of the United States (ACUS) pertaining to such impact analysis requirements.