COMMENTS

on

Office of Management and Budget

PROPOSED BULLETIN FOR GOOD GUIDANCE PRACTICES

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by

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Introduction

We appreciate the opportunity to provide comments on the Office of Management and Budget (OMB)'s Proposed Bulletin for Good Guidance Practices (the "Bulletin"). The Bulletin is an important step towards standardizing agency guidance development. Our recommendations are intended to help strengthen the Bulletin by suggesting ways that the Office of Information and Regulatory Affairs (OIRA) might clarify definitions, expand public participation in guidance development, and strengthen the administrative process to allow regulated entities to participate in the development of, and if necessary challenge, positions the agencies take in guidance documents.

We endorse OIRA's effort to develop uniform practices for federal agencies to follow in developing and using guidance documents. Agency guidance has long been a valuable means of informing the public and the regulated community of agency interpretations of regulatory obligations and agency policy. Yet, as OIRA has correctly stated, some guidance issued by agencies today lacks transparency and procedural safeguards. Further, as has long been the case, agency guidance may be developed by personnel who do not have a full technical appreciation of the real-world difficulties that may be encountered in implementing guidance.

Most importantly, once agencies commit to a position in a guidance document, they may become inflexible in applying it, and may apply it in such a way as to create binding regulatory obligations. The OIRA has cited several cases in which courts have found that agency guidance had become, in effect, a binding agency rule with significant consequences to regulatees or other affected stakeholders, and working unreasonable hardships on affected parties. Most examples of such hardships never reach the courts. Finally, even where good guidance practices are in place, as they are at the Food and Drug Administration (FDA), agencies may treat policies stated

in guidance documents as legal requirements. For example, in a recent case the FDA applied two guidance documents in such a way as to establish binding legal requirements under its Quality System Regulation, which imposes quality assurance requirements on medical device manufacturers (21 C.F.R. pt. 820). The court rejected the FDA's attempt to rely on these guidance documents to establish legal requirements, holding that the guidance contained "suggestions" that "may be of some value as evidence of some standards suitable for some manufacturers, but in no sense are specifically embraced by the regulations, nor have changes been made in the regulations to incorporate them." *United States v. Utah Medical Products, Inc.*, 2005 WL 2716299 (D. Utah Oct. 21, 2005). The Bulletin will help correct these problems and will promote quality, fairness, and accountability in the development of guidance.

We believe that OIRA's Good Guidance Practices will aid the judicial process and be of assistance to judges by resulting in clearer, less prescriptive guidance documents, therefore producing fewer instances where judicial intervention is necessary. The draft Bulletin directs agencies away from preparing the type of guidance that on its face tends to create binding obligations that should be covered by notice-and-comment rule making. The Bulletin also cautions agencies away from enforcement action or "jawboning" that applies guidance as if it were a binding requirement.

We also believe that there is nothing in the draft Bulletin that would tend to promote more rather than less judicial review. To the contrary, the Bulletin provides for the type of "administrative due process" that will reassure courts that agency guidance has been prepared, both with due regard for the interests of regulated parties and with a proper appreciation of the limits of the agencies' guidance-writing authority. The transparency and opportunity for back-and-forth with the agency afforded significant guidance will not be mistaken by the courts as an

agency confession that rule making would have been warranted (see also I, below). Nor are the courts likely to accept the limited notice and comment available under the OMB Bulletin as the substantial equivalent of the rigorous notice-and-comment required under the Administrative Procedure Act and other statutes. If cases arise where an agency should have been engaged in notice-and-comment rule making the courts can and will require it, as the court did recently in the *Utah Medical* case.

Summary of Specific Recommendations

Specifically, we recommend:

- OIRA should require agencies to provide notice and comment on all significant guidance documents.
- To facilitate early collaboration with the regulated community, OIRA should require agencies to publish annually and provide for public comment a list of guidance documents under development, proposed for development, or proposed for revision.
- OIRA should require agencies to maintain a list on their websites of all current guidance documents.
- OIRA should broaden the definition of significant guidance documents to capture highly controversial issues that may arise and for which guidance may be developed, not just issues that relate to interagency concerns or important Administration priorities.
- For guidance documents that set forth specific technical methods or procedures for meeting regulatory obligations, OIRA should create a safe harbor against enforcement for regulated entities that adhere to the guidance.
- OIRA require federal agencies to develop an administrative process that would allow regulated entities to challenge agency interpretations of regulatory obligations set forth in guidance documents.

I. OIRA should require agencies to provide notice and comment on all significant guidance documents.

The heart of the OIRA's effort to promote transparency in guidance development lies in the Bulletin's provision that requires notice and comment for economically significant guidance documents. Bulletin, Section IV. Under this provision, an agency must publish in the Federal Register a notice that a draft guidance document is available, post the draft on the internet and make it publicly available in hard copy, invite public comment on the draft, and respond to public comments. The OIRA does not provide a rationale for limiting this important provision only to those guidance documents that are economically significant. While not always economically quantifiable, significant guidance documents that raise controversial issues, set forth initial interpretations of statutory or regulatory requirements, or concern novel or complex issues can and, more often than not, will significantly impact the regulated community and awaken concerns with affected stakeholders and the public. They are as deserving of public notice, comment, and agency response as economically significant guidance documents. If a guidance document is important enough to be deemed "significant" under the Bulletin, the public should have the opportunity to comment on the draft document, and the agencies should respond to those comments.

For example, EPA's Integrated Risk Information System (IRIS) establishes oral reference doses and inhalation reference concentrations (RfDs and RfCs, respectively) for chronic noncarcinogenic health effects and hazard identification, oral slope factors, and oral and inhalation unit risks for carcinogenic effects. These numerical, technically derived thresholds are used by the EPA and other agencies to inform regulatory standard-setting. Some IRIS entries may be economically significant, but others may not be and thus would not be subject to the

Bulletin's requirements. While EPA typically allows public comment on draft IRIS entries, there is no requirement that it do so.

We understand that EPA has raised a concern that the Bulletin may delay the Agency's development of IRIS entries. Given that the Agency has a specialized notice-and-comment process in place for IRIS entries, the Bulletin would not create additional obligations that would unduly burden the Agency. Rather, the Bulletin would standardize agency practice for all significant guidance documents, including IRIS entries. Standardizing IRIS comment processes does not necessarily entail delaying the preparation of ongoing IRIS entries and updates.

There is no bright line separating a document that is a "guidance" from a document that is a binding "rule." But in traveling the spectrum from "guidance" to binding "rule," as one approaches the gray area at the midpoint, clearly the interests of the affected parties become more important. While those interests may involve controversy, novelty, complexity, and emergent agency legal interpretation without passing the midpoint and requiring rule making, the nature of the blurred midpoint suggests that notice, availability, public comment, and agency response will help ensure that affected parties still are nevertheless informed, involved, and fairly treated.

Providing for public comment for all significant guidance documents furthers OIRA's goal of transparency and ensures consistent and ample opportunities for the public to participate in guidance development. We therefore recommend that OIRA expand section IV of the Bulletin to require notice and comment for all significant guidance documents.

II. To facilitate early collaboration with the regulated community, OIRA should require agencies to publish annually and provide for public comment a list of guidance documents under development, proposed for development, or proposed for revision.

Guidance documents are intended to clarify regulatory obligations and provide the regulated community with a better understanding of agency positions on specific issues. It follows that agencies and the regulated community should work collaboratively in developing meaningful, useful guidance documents. Agency guidance may be written by agency staff who have limited or no experience in or with the industry for which the guidance is being developed. Consequently, guidance may be written without either a full appreciation of the information the industry needs from the agency to understand its regulatory obligations or appreciation of the practical difficulties that may be encountered by industry when implementing agency guidance.

As proposed, the Bulletin does not contain adequate provisions for fostering meaningful collaboration. Section III.2.b provides only for public comment on significant guidance documents and a means to request that significant guidance documents be created, reconsidered, or modified. Indeed, section III.2.b forecloses dialogue between agencies and regulated entities by providing that public comments are for the benefit of the agency, and no formal response is necessary.

The OIRA modeled the Bulletin's provisions on the FDA's Good Guidance Practices, which the agency developed and Congress codified in the Food and Drug Administration Modernization Act of 1997. The FDA's Good Guidance Practices require that FDA publish annually, both in the Federal Register and on the Internet, a list of possible topics for future guidance document development or revision. The public is invited to comment on the list. The OIRA provided a similar "early notice" provision in its Peer Review Bulletin that requires agencies to post on the Internet a description of "highly influential scientific assessments" and

"influential scientific information" that the agency proposes to develop, together with details of plans for peer review. The peer review agenda process under the OMB Peer Review Bulletin is now fully functional and has provided an important means of informing stakeholders of the early development of agency science policy and of enabling stakeholders to participate in shaping the peer review of agency science.

Similarly, if a list of guidances proposed for development is made available for public comment, stakeholders will then be able to provide agencies with information and perspective that would foster the development of better guidance. This could include identifying the actual importance of particular guidance to industry, the issues that need to be addressed in forthcoming guidance, the difficulties which stakeholders have in complying with regulatory mandates, and concepts that would be employed in drafting more effective guidance.

We recommend that the Bulletin contain a provision stating that: "Once a year, each agency shall publish, both in the Federal Register and on the Internet, a list of guidance under development or proposed for future development or revision. Agencies should provide a mechanism for allowing the public to comment on the guidance topics."

III. OIRA should require agencies to maintain a list of all guidance documents in use on their websites.

Section III.1.b requires each agency to annually post on its Web site a comprehensive list of its significant guidance documents that identifies documents that have been added, revised, or withdrawn from the list. This provision facilitates easy access to significant agency guidance, but still places the burden on the regulated community to locate "nonsignificant" agency guidance. While "nonsignificant" guidance may be publicly available, finding it may require lengthy Internet searches or multiple telephone calls to obtain copies. In the Internet age and with the e-Government initiative, providing a centralized list of all guidance documents should

not be unduly burdensome to agencies. What burden there is would be justified by gains in transparency and accessibility. The FDA provides such a list annually, organized by the FDA centers. *See* http://www.fda.gov/opacom/morechoices/industry/guidedc.htm. FDA also publishes a comprehensive annual list in the Federal Register of all guidance currently in use at the agency. We recommend that OIRA adopt a similar requirement for all agencies.

IV. OIRA should broaden the definition of significant guidance documents to capture highly controversial issues that may arise and for which guidance may be developed, not just issues that relate to interagency concerns or important Administration priorities.

Section I.3 of the Bulletin defines a "significant guidance document" as a document that may: "(i) reasonably be anticipated to lead to an annual effect of $100 million or more or adversely affect in a material way the economy or a sector of the economy; (ii) raise highly controversial issues related to interagency concerns or important Administration priorities; (iii) set forth initial interpretations of statutory or regulatory requirements, or changes in interpretation; or (iv) concern novel or complex scientific or technical issues." The definition qualifies "highly controversial issues" as only those that relate to "interagency concerns or important Administration priorities." Perhaps OIRA means to impose an *additional* requirement, *i.e.*, that if an issue is highly controversial, it must additionally have inter-agency or White House implications, but it appears that controversy here is limited to inter-agency or Administration interests. Yet highly controversial issues regarding regulatory requirements do not often raise interagency concerns. As the definition appears to be written, regulatory issues that are highly controversial and confined to one agency may escape the reach of the Bulletin. We recommend that OIRA broaden the definition to capture other highly controversial issues that may arise and for which guidance needs to be developed. This can be accomplished by deleting the terms "interagency concerns or important Administration priorities" and having section I.3(ii) state

simply: "Raise highly controversial issues." In considering whether generalized or manufactured "controversy" may make controversial guidance too large a category to which to extend the extra requirements applicable to significant guidance, one must keep in mind that the existence and degree of controversy are left for the agency to determine.

V. For guidance documents that discuss specific technical methods or procedures for meeting regulatory obligations, OMB should create a safe harbor against enforcement for regulated entities that adhere to the guidance.

Some guidance documents set forth very detailed methods or procedures for meeting regulatory obligations. These often relate to complex technical and scientific issues, such as risk assessment procedures or analytic compliance methods. When regulated entities adhere to agency guidance in these situations, it may be appropriate for agencies to create a "safe harbor," *i.e.*, an explicit recognition that any party complying with a requirement in the manner set out by the agency shall be deemed to be in full compliance. This could be accomplished by OIRA's directing agencies to identify guidance documents that, if followed, create a rebuttable presumption that the regulated entity complied with the regulatory requirements. If the agency nevertheless enforces against the entity, the agency would have the burden of showing that even though the guidance was followed, the regulated entity failed to satisfy regulatory requirements.

VI. OIRA should require federal agencies to develop an administrative process that would allow regulated entities to challenge agency interpretations of regulatory obligations set forth in guidance documents.

The Bulletin is intended to facilitate public involvement in guidance development and to dissuade agencies from attempting to apply guidance documents to create binding regulatory obligations. The notice-and-comment provisions of the Bulletin, as well as OMB's direction that guidance documents cannot include mandatory language such as "shall, must, required, or requirement," help achieve these objectives. Nevertheless, situations will continue to arise

where agencies misuse guidance documents to create binding regulatory obligations. The *Utah Medical* case cited above demonstrates that even if an agency adopts good guidance practices, this is no guarantee that the agency will not attempt to enforce a guidance as if it were a rule.

Situations will also arise where the regulated community disagrees with an agency's interpretation of the law. Although, section III.2 of the Bulletin requires agencies develop a means for the public to submit comments electronically on significant guidance documents, and to request that significant guidance documents be created, reconsidered, or modified, it does not require an agency to respond to the comments. Thus, the Bulletin allows the regulated community to challenge the legality or wisdom of guidance, but it does not provide any means to resolve the dispute on the pragmatic level. Only after an agency enforces against an affected entity is an administrative or judicial forum available to resolve the dispute.

An administrative process allowing the regulated community to challenge an agency's interpretation of the law in guidance documents, and the agency's use of guidance documents, could be accomplished if OIRA were to direct agencies to develop formal dispute resolution processes. Congress directed the FDA to create such a process, and the agency has done so by directing affected entities to contact supervisory personnel in the responsible office so that issues can be resolved at the FDA staff level. If a dispute cannot be resolved at the staff level, affected entities may move up the chain of command and ask the agency's chief mediator and ombudsman to become involved. A similar dispute resolution mechanism across agencies would help avoid entrenched positions that may otherwise be resolved in the courts.