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January 5, 2006

John D. Graham, PhD
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
725 Seventeenth Street, NW
New Executive Office Building, Room 9013
Washington, DC 20503

Re: Draft Bulletin for Good Guidance Practices

Dear Administrator Graham:

Amgen is writing to comment on the draft bulletin issued by the Office of Management and Budget (OMB) regarding policies and procedures for agencies to develop, issue, and use guidance documents (Draft Bulletin).¹ As a science-based, patient-driven company committed to using science and innovation to dramatically improve people's lives, Amgen is vitally interested in improving access to innovative drugs and biologicals. Both access and innovation require a clear and consistent regulatory framework from the agencies involved in approving new products, setting coverage and reimbursement policies, and issuing reports on the appropriate uses of these products. Though Amgen is regulated by and interacts with numerous federal agencies, we deal most extensively with the following three agencies within the Department of Health and Human Services (HHS):

- the Food and Drug Administration (FDA),
- the Centers for Medicare and Medicaid Services (CMS), and
- the Agency for Healthcare Research and Quality (AHRQ).

Therefore, we have prepared specific comments on the Draft Bulletin in the context of the regulatory guidance practices of these agencies.

¹ The Draft Bulletin is accessible at <http://www.whitehouse.gov/omb/inforeg>.

We share OMB's concern that agency "guidance documents may not receive the benefit of careful consideration accorded under the procedures for regulatory development and review."² In particular, we agree that "[t]he absence of procedural review mechanisms can undermine the lawfulness, quality, fairness and accountability of agency policymaking," and "can impose significant costs on or limit the freedom of the public without affording notice and an opportunity to participate."³ Accordingly, we strongly support OMB's goal to ensure that "agency guidance practices [are] more transparent, consistent and accountable," and to provide a meaningful opportunity to comment on significant agency guidance. Our comments below—which are largely clarifications of the proposed procedures—are all intended to further that goal.⁴

Most importantly, we recommend clarifying that the exception in section 1.2 for documents issued pursuant to 5 U.S.C. § 553 is limited to documents that are subject to the full notice and comment rulemaking procedures in that section.

Our concern is the provision in section 553 that notice and comment rulemaking may not be required for certain "interpretive rules and statements of policy."⁵ To avoid any risk that this exception would swallow the proposed new rules, we believe the Draft Bulletin should be clarified so that no agency could claim it was acting pursuant to section 553(d)(2) (so as to be within the exception to the Draft Bulletin), but that notice and comment was not required under section 553—thereby creating the very problem the Draft Bulletin was intended to remedy. This seems clearly to be the intent as the Draft Bulletin is meant to apply to guidance documents that "[s]et forth initial interpretations of statutory or regulatory requirements, or changes in interpretation or policy," and also provides that "[a]gencies may not circumvent the significant guidance document

² See *Draft Bulletin* at 2.

³ *Id.* The Draft Bulletin, other OMB reports, and the case law, all point out these problems. Our experience with some of the guidance document practices at the CMS and AHRQ has confirmed the problems that can be caused by lack of public comment and lack of consideration at senior leadership levels within the agencies.

⁴ Our experience with the FDA, CMS and AHRQ confirms the importance of clear rules for guidance documents that ensure careful consideration and the opportunity for comment by the regulated community. Although all three of these agencies are within HHS, they have widely separate regulatory guidance practices. In particular, our experience with the now well-established GGP practices at the FDA has been particularly useful in assuring that our and industry's concerns with draft guidance documents are dealt with in a forthright and open fashion. There are many examples of FDA draft guidance documents that have been greatly strengthened on the basis of public comments. We agree with the Draft Bulletin that the FDA experiences—while not perfect—are clearly a useful model for developing GGPs across HHS agencies. In contrast, however, some of the guidance document practices of CMS and AHRQ involve little to no public stakeholder involvement, much less formal comment consideration.

⁵ See 5 U.S.C. § 553(d)(2); see, e.g., *Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87 (1994).

requirements by using alternate means of communication to disseminate new or different regulatory expectations to a broad public audience for the first time.”⁶ To avoid any confusion or circumvention of these rules, however, we suggest the proposal be clarified by replacing “pursuant to 5 U.S.C. § 553 or § 554,” with “pursuant to the notice and comment rulemaking provisions of 5 U.S.C. § 553 or the adjudication provisions of 5 U.S.C. § 554” in the second line of I.2.

Three additional clarifications would be appropriate in the definition of “significant guidance document” in section I.3.

These clarifications include the following:

- (1) make absolutely clear that the four factors in the definition are in the disjunctive, by adding “or” at the end of I.3(i) and I.3(ii) (it is already at the end of I.3(iii));
- (2) clarify that the exception for “contractor instructions” is meant to be a narrow one limited to specific instructions for a particular contract, and does not include more general statements of interpretation or regulatory guidance (and is strictly limited to the requirement that agencies not circumvent these requirements by using alternate means to disseminate new or different regulatory expectations);⁷ and
- (3) include a general provision that if there is any doubt as to whether a document qualifies as a “significant guidance document” it should be treated as such under these provisions (for example, a new paragraph 6 to the definition section stating that: “To further the beneficial purpose of this Bulletin, doubts about whether a document qualifies as a “significant guidance document” shall be resolved in favor of considering the document to be a “significant guidance document.”).

We also believe that it is important that there be some enforcement mechanism for this significant new policy.

This would include both monitoring agency compliance generally and also ensuring that the exceptions are not misused and that agencies do not seek to circumvent these procedures by disseminating guidance in other forms. We believe that OMB should fulfill this important role (it already is assigned that role for developing exemptions where the procedures are not feasible and appropriate, see section IV.2), and that agencies should be required to regularly

⁶ See *Draft Bulletin* at 9.

⁷ For example, there have been cases where we believe CMS has included more general policy directives in letters to individual contractors. See also 70 Fed. Reg. 51321, 51322 (Aug. 15, 2005) (noting that CMS will implement a statutory requirement for a prior determination process through detailed “instructions to our contractors”).

report to OMB on their implementation of these procedures so that it can exercise that oversight function. We also believe that, contrary to section V, judicial review should be available to ensure that the important benefits of these new procedures are achieved.

Finally, in implementing the Public Access provisions in section III, we recommend that agencies be required to provide a link on their home pages to a page devoted to guidance documents.⁸

As more information becomes available on agency websites, it often becomes more difficult to find specific topics. Guidance documents are important enough that we believe each agency should facilitate easy access to them through such a link on the homepage. For example, as GGP becomes common throughout HHS, it would also be useful to have a consolidated webpage on the HHS website with all guidance documents, sorted by agency.

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Improved transparency, consistency and accountability among the various agencies that impact the development of innovative, life-saving biological therapies would greatly enhance the value of guidance documents. For this reason, Amgen appreciates the opportunity to comment on the important issues raised in the Draft Bulletin, and we look forward to working with OMB to ensure that meaningful policies and procedures are implemented to improve the quality and transparency of documents issued by various government agencies.

Please contact Chris Mancill by phone at (202) 585-9618 or by email at cmancill@amgen.com to arrange a meeting or if you have any questions regarding our comments. Thank you for your attention to these important matters.

Respectfully submitted,



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⁸ The FDA serves as a good example of this approach. See <http://www.fda.gov/cder/guidance/index.htm>.