Hugh M. O'NEILL
Vice President

January 9, 2006

VIA Electronic Mail to: OMB_GGP@omb.eop.gov

Dr. John D. Graham, PhD.
Administrator
Office of Management and Budget
The Executive Office of the President
725 17th Street, NW
New Executive Office Building
Room 9013
Washington, DC 20503

Re: Proposed Bulletin for Good Guidance Practices

Dear Dr. Graham:

Sanofi-aventis U.S. appreciates this opportunity to comment on the Proposed Bulletin for Good Guidance Practices (the "Proposed Bulletin"), released by the Office of Management and Budget (OMB) on November 23, 2005.

Sanofi-aventis is committed to fighting diseases throughout the world. In the new millennium, we have taken up the major challenges of discovering new compounds that are essential to the progress of medical science and launching pharmaceutical products that constitute real therapeutic progress for patients. Our mission is to discover, develop, and make available to physicians and their patients innovative, effective, well-tolerated, high quality treatments that fulfill vital health care needs.

Sanofi-aventis is pleased that the Proposed Bulletin "is intended to increase the quality and transparency of agency guidance practices and the guidance documents produced through them." As a company involved with the development and commercialization of drugs and biologicals,

our experiences have been principally with guidance documents issued by the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS). The policies announced and implemented through guidance documents issued by these agencies can have significant impact on our business as well as on the lives of our ultimate customers-patients. Therefore, it is vital that these documents be created through transparent and predictable procedures, with public access and feedback on all guidance documents and notice and opportunity for stakeholder input on all significant guidance documents. We share OMB's concern with ensuring that agency guidance documents be "developed with appropriate review and public participation, accessible and transparent to the public, of high quality, and not improperly treated as binding requirements."

Accordingly, we would like to share with you an example where CMS used a sub regulatory process to substantively change a provision of an OMB-cleared final rule that had been developed through the regular Administrative Procedure Act (APA) process of collecting and evaluating public comment. Specifically, we are referring to the CMS action that reversed a coding decision, which had originally placed four competing sodium hyaluraonate/hyaluronan products into a single Healthcare Procedure Coding System (HCPCS) code (J7318) for purposes of payment under Medicare Part B in 2006 and which was published in two OMB-cleared Final Rules issued by CMS[1]. CMS Transmittal 749, issued approximately one week after the publication of the Final Rules, negated the coding decision and instructed contractors to treat these products as they had in 2005, a direct contradiction to the coding decision published in the two Final Rules. The policy change was made without any public notice or opportunity to comment by interested parties, and was included in a program transmittal -- a document normally used only to provide technical instructions to contractors and not to establish or change program policy. In this case, the use of the transmittal process to bring about a change in program policy clearly subverted public review, comment, and transparent decision-making by governmental agencies.

We recommend that OMB include a program transmittal, which has the effect of substantively altering the outcome of a Final Rule, within the scope of documents OMB is targeting for implementation of the Proposed Bulletin. Further, we recommend that OMB require agencies to certify, when issuing a document, that they have followed Good Guidance Practices in developing the document or have determined that the requirements do not apply to the document. Such a requirement would encourage agencies to take care in deciding whether each document is subject to the Proposed Bulletin's requirements. Additionally, it would inform the public of the agency's treatment of the document and would help to familiarize the public with OMB's Good Guidance Practice requirements.

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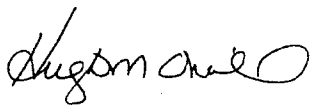
[1] "Medicare Program; Change to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" [CMS-1501-FC} RIN 0938-AN46 (Nov. 2, 2005) and "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar year 2006 and Certain Provisions related to the Competitive Acquisition Program for Outpatient Drugs and Biologics Under Part B" [CMS-1502-FC and CMS-1325-F] RINs 0938-AN84, 0938-AN58 (Nov. 2, 2005)

We also recommend that the OMB require each agency that issues a significant number of guidance documents to conduct a retrospective review and categorization of the types of documents issued by such agency over an appropriately recent time period consisting of at least the last 12 months, and provide such analysis to OMB. Such an analysis would assist OMB in ensuring that its proposed good guidance practices would be applicable to the appropriate types of documents generally issued by such agencies. The analysis also would help each agency ensure that the OMB good guidance practices are in fact applied in the future to the appropriate types of documents issued by such agency. As part of this process, we recommend that OMB issue a notice inviting other interested parties to conduct similar reviews and that OMB establish a process for formal review and comment by the public of specific identified examples, as appropriate. We believe these retrospective reviews will uncover some fundamental problems with current processes and highlight circumstances in which agencies currently are promulgating policy decisions in contractor instructions and other informal processes. These are precisely the situations for which an opportunity for public comment is imperative.

In closing, we thank you for your attention to these matters. If you have any questions, please feel free to contact me.

Respectfully Submitted,



Hugh O'Neill
Vice President, Integrated Healthcare Markets