KELLER AND HECKMAN LLP
Serving Business through Law and Science®

1001 G STREET, N.W.
SUITE 500 WEST
WASHINGTON, D.C. 20001
TELEPHONE 202.434.4100
FACSIMILE 202.434.4646
WWW.KHLAW.COM

January 10, 2006 (Corrected)

BY ELECTRONIC MAIL

The Honorable John D. Graham
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
New Executive Office Building, Rm. 10235
725 17th Street, N.W.
Washington, D.C. 20503

Re: Comments on the Office of Management and Budget's "Proposed Bulletin for Good Guidance Practices," 70 Fed. Reg. 71,866 (Nov. 30, 2005) **CORRECTED**

Dear Dr. Graham:

Keller and Heckman LLP is pleased to submit the following comments in response to the notice and request for comments published by the Office of Management and Budget (OMB) on its "Proposed Bulletin for Good Guidance Practices" (GGP Bulletin). We also appreciate the flexibility shown by OMB in extending the comment deadline to January 9, 2006.

Keller and Heckman LLP has an extensive general and regulatory practice and represents numerous trade associations and individual clients that are substantially affected by the broad spectrum of rules that are issued, interpreted and enforced by the federal regulatory agencies, and often used to establish a standard of care or performance in common law tort and contract litigation. While the views expressed in this letter are solely those of Keller and Heckman LLP, we believe they are shared by much of the business community that is subject to the mandates of federal regulatory agencies.

We have participated in all phases of numerous federal agency rulemakings – including the review of draft proposed rules, Small Business and Regulatory Enforcement and Fairness Act (SBREFA) reviews, rulemakings under the procedures established by the Administrative Procedures Act (APA), pre-enforcement legal challenges (settled and litigated), and subsequent proceedings before OMB for extension of its approval under the Paperwork Reduction Act. We have also participated in the development of numerous federal agency guidance documents – many unrelated to and many in the context of enforcement proceedings.

IDENTIFYING THE PROBLEM TO BE ADDRESSED

As a threshold matter, we believe it is critical to identify the problem, distinguish between its various forms, determine which forms are appropriately within the scope of the proposed GGP Bulletin, determine how they should be addressed in the GGP Bulletin and proceed accordingly. The introductory paragraph to Executive Order 12866, issued September 30, 1993, states:

> The American people deserve a regulatory system that works for them, not against them: a regulatory system that protects and improves their health, safety, environment, and well-being and improves the performance of the economy without imposing unacceptable or unreasonable costs on society; regulatory policies that recognize that the private sector and private markets are the best engine for economic growth; regulatory approaches that respect the role of the State, local, and tribal governments; and regulations that are effective, consistent, sensible, and understandable. We do not have such a regulatory system today.

E.O. 12866 subsequently sets forth the twelve Principles of Regulation. The twelfth principle reads as follows:

> (12) Each agency shall draft its regulations to be simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty.

Simply stated, we believe the twelfth principle calls for the regulatory requirements to be stated in a way that can reasonably be understood, something one would have thought was simply a restatement of the application of the Constitutional principles of Due Process.[1] Unfortunately,

[1] It is fundamental that a law which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application, violates the first essential of due process of law. Connally v. General Construction Company, 269 U.S. 385, 39 (1926). Thus, an occupational safety and health standard must give an employer fair warning of the conduct it prohibits or requires, and it must provide a reasonably clear standard of culpability to circumscribe the discretion of the enforcing authority and its agents. Dravo Corp. v. OSHRC, 613 F.2d 1227, 1232 (3d Cir. 1980).

See also the statement of Justice Thurgood Marshall in Grayned v. City of Rockford, 408 U.S. 104, 108-109, (1972):

> Vague laws offend several import values. First, because we assume that man is free to steer between lawful and unlawful conduct, we insist that laws give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly. Second, if arbitrary and discriminatory enforcement is to be prevented, laws must provide explicit standards for those who apply them. A vague

(continued …)

as the scope and complexity of regulatory programs have grown, it appears that the courts have adopted a relatively loose test of what constitutes fair warning to the regulated community.

In reality, if a rule is not written so that it establishes a reasonably clear standard, it would appear impossible to comply with at least six of the other Principles of Regulation set forth in E.O. 12866. For example, if there is no reasonably clear standard, per principle 12, it is unclear how the agency, OMB or anyone else would know whether the agency tailored its regulations to impose the least burden on society, per principle 11 of E.O. 12866.

Certainly, in large part due to your contributions, our regulatory system has seen major improvements since 1993.[2] However, as indicated by the quotation from the D.C. Circuit's 2000 opinion in Appalachian Power[3], which appears in the Preamble to the proposed GGP Bulletin, there is much more to be done. That quote describes what appears to be the larger aspect of the problem that the proposed GGP Bulletin is designed to address – the consequences of broad and ambiguous regulations following both their adoption and any pre-enforcement judicial review.[4]

The description of the situation, as provided by Appalachian Power, is substantially as follows:

1) "Congress passes a broadly worded statute."

2) "The agency follows with regulations containing broad language, open-ended phrases, ambiguous standards and the like."

3) "As years pass, the agency issues circulars or guidance or memoranda, explaining, interpreting, defining and often expanding the commands in regulations. One guidance document may yield another and then another and so on. Several words in a regulation may spawn hundreds of pages of text as the agency offers more and more detail regarding what its regulations demand of regulated entities. Law is made, without notice and comment, without

---

(…continued)

> law impermissibly delegates basic policy matters to policemen, judges, and juries for resolution on an ad hoc and subjective basis, with the attendant dangers of arbitrary and discriminatory application.

And see identical statements under the OSH Act in Diebold, Inc. v. Marshall, 585 F.2d 1327, 1335, 6 BNA OSHC 2002 (6th Cir. 1978) and Lloyd C. Lockrem, Inc. v. United States, 609 F.2d 940, 943, 7 BNA OSHC 1999 (9th Cir. 1979).

[2] Prior to your tenure at OMB, it was not even possible to find a copy of E.O. 12866 on the White House web site, much less whether a particular rule was under OMB review.

[3] Appalachian Power Company v. EPA, 208 F.3d 1015 (D.C. Cir. 2000)

[4] The situation is complicated by the fact that some agencies, such as OSHA, are required to issue Small Business Guidance Documents along with the final rule.

> public participation, and without publication in the Federal Register or the Code of Federal Regulations."

There appear to be two interrelated explanations for this state of affairs:

1) It is procedurally easier (and therefore takes far less time and resources) to issue guidance documents than go through the increasingly more demanding APA notice and comment rulemaking process; and

2) The United States Supreme Court has, in effect, provided regulatory agencies with an incentive to issue broad and ambiguous regulations by holding:

> [I]n situations in which the meaning of regulatory language is not free from doubt, the reviewing court should give effect to [defer to] the agency's interpretation so long as it is reasonable, that is, so long as the interpretation sensibly conforms to the purpose and wording of the regulations. Because applying an agency's regulation to complex or changing circumstances calls upon the agency's unique expertise and policymaking prerogatives, we presume that the power authoritatively to interpret its own regulations is a component of the agency's delegated lawmaking powers.[5]

While it is outside the scope of this proceeding, we respectfully suggest that Congress needs to allocate substantial additional resources to OMB so that OMB has the ability to fully perform its oversight function, which includes identifying and returning to the propounding agency for clarification: 1) overbroad and ambiguous rules submitted to it for approval by Executive Branch agencies; and 2) overbroad and ambiguous rules submitted to it for approval under the Paperwork Reduction Act (PRA) by independent agencies (as well as Executive Branch agencies).

We strongly support OMB's effort to develop a transparent, consistent process that must be followed by Federal agencies when they issue guidance documents in an effort to fill in the voids and uncertainty created by the broad and ambiguous regulatory language that has found its way into the Code of Federal Regulations. In a sense, the proposed GGP Bulletin seems to take the pragmatic approach that, where the courts have not found the rule so unclear as to strike it down, there is a need for an OMB oversight function so that the "informal continuation of the rulemaking process" is conducted in an open and transparent manner that provides for meaningful participation by the affected stakeholders.

[5] *Martin v. OSHRC (CF&I Steel Corp.)*, 499 U.S. 144, 111 S.Ct. 1171, 1175-6, 113 L.Ed.2d 117 (1991).

COVERAGE OF INDEPENDENT FEDERAL AGENCIES AND THE PRA

This leads to an important scope issue raised by the proposed GGP Bulletin. The proposal would exclude independent regulatory agencies from its coverage. While OMB has much more limited authority over the actions of independent regulatory agencies, we do believe it is appropriate to make it clear to all agencies subject to the PRA, that the PRA packages submitted to OMB represent the agencies' interpretations of those rules (and not simply a paperwork exercise). We believe OMB's approval under the PRA should be made expressly contingent on the agency enforcing the rules subject to the PRA as stated in the PRA package submitted to OMB. Should the agency adopt a materially different interpretation of a rule from that which was represented (explicitly or implicitly) to and approved by OMB, an adversely affected regulated entity should be positioned to assert that the rule is not enforceable in that manner.

INITIAL GUIDANCE VERSUS CHANGED GUIDANCE

It is important to note that the court's opinion in Appalachian Power does not mention or refer to an action where an agency has given its rule a definitive interpretation, and later attempts to significantly revise that interpretation without notice and comment rulemaking under the APA. We do not mean to suggest that activity does not happen and should not be addressed by the GGP Bulletin. However, it is a well-established principle of administrative law that agency interpretations, even when reasonable constructions of its rules, trigger notice and comment requirements under the APA when the later interpretation represents a significant change from a previous, definitive interpretation. *Alaska Professional Hunters Association, Inc. v. FAA*, 177 F.3d 1030, 1034 (D.C. Cir. 1999).[6]

---

[6] In *Alaska Professional Hunters Association*, the D.C. Court of Appeals held that a Federal Aviation Administration (FAA) notice that subjected guide pilots to FAA regulations without notice and opportunity for comment was invalid under the APA because the FAA Alaskan region had told fishing and hunting guide pilots that they were not required to abide by FAA regulations applicable to commercial air regulations. In that case, the Court stated:

> Our analysis of these arguments draws on *Paralyzed Veterans of America v. D.C. Arena*, 117 F.3d 579, 586 (D.C.Cir.1997), in which we said: "Once an agency gives its regulation an interpretation, it can only change that interpretation as it would formally modify the regulation itself: through the process of notice and comment rulemaking." We there explained why an agency has less leeway in its choice of the method of changing its interpretation of its regulations than in altering its construction of a statute. "Rule making," as defined in the APA, includes not only the agency's process of formulating a rule, but also the agency's process of modifying a rule. 5 U.S.C. § 551(5). *See Paralyzed Veterans*, 117 F.3d at 586. When an agency has given its regulation a definitive interpretation, and later significantly revises that interpretation, the agency has in effect amended its rule, something it may not accomplish without notice and comment. *Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 94-95 (D.C.Cir.1997), is to the same effect: a modification of an

(continued …)

We are therefore concerned by the approach to this issue apparently taken by the proposed GGP Bulletin. The Preamble to the proposed GGP Bulletin states:

> Guidance documents represent the agency's current position. Accordingly, §II(1)(a) states that agency employees may depart from significant guidance documents only with appropriate justification and supervisory concurrence.

Consistent with that Preamble passage, Section II.1.a of the draft GGP Bulletin reads as follows:[7]

> Agency employees may depart from significant guidance documents only with appropriate justification and supervisory concurrence.

In light of *Alaska Professional Hunters*, we respectfully submit that the limited procedural protections set forth in proposed Section II.1.a of the draft GGP Bulletin would suggest a reduction in the existing protections already imposed by the APA. An agency should be permitted to waive a requirement for good cause, extend a compliance deadline for good cause, or permit a substantially equivalent alternative means of compliance without APA notice and comment rulemaking. On the other hand, we do not believe the GGP Bulletin should include

---

(…continued)

> interpretive rule construing an agency's substantive regulation will, we said, "likely require a notice and comment procedure." 177 F.3d at 1033, 1034.

While the *Paralyzed Veterans* court did not require that the Department of Justice initiate a new rulemaking (its interpretation was not a significant departure from previous interpretation because the DOJ "never authoritatively adopted a position contrary to its [interpretation]"), it did elaborate on the necessity to do so when the Agency is making a significant departure from prior interpretations:

> Appellants' most powerful argument remains: that the Department of Justice's present interpretation of the regulation constitutes a fundamental modification of its previous interpretation and, even if it legitimately could have reached the present interpretation originally, it cannot switch its position merely by revising the technical manual. Once an agency gives its regulation an interpretation, it can only change that interpretation as it would formally modify the regulation itself: through the process of notice and comment rulemaking… Under the APA, agencies are obliged to engage in notice and comment before formulating regulations, which applies as well to "*repeals*" or "*amendments.*" *See* 5 U.S.C. § 551(5). To allow an agency to make a fundamental change in its interpretation of a substantive regulation without notice and comment obviously would undermine those APA requirements. That is surely why the Supreme Court has noted (in dicta) that APA rulemaking is required where an interpretation "adopt[s] a new position inconsistent with ... existing regulations." *Shalala v. Guernsey Memorial Hosp.*, 514 U.S. 87, 115 S.Ct. 1232, 1239, 131 L.Ed.2d 106 (1995); *see also National Family Planning & Reproductive Health Ass'n v. Sullivan*, 979 F.2d 227, 240-41 (D.C.Cir.1992). 117 F.3d at 586.

[7] This concern is also reflected in the definition of a "significant guidance document", which includes a document that sets forth "changes in interpretation or policy".

language indicating that an agency may make a material change that would impose additional requirements on the regulated community without APA notice and comment rulemaking.

DEFINING SIGNIFICANT GUIDANCE DOCUMENTS

To the greatest extent practical, we believe the proposed GGP Bulletin should require public notice and an opportunity for public comment, and an appeal to OMB, before any significant guidance is issued. Accordingly, with one change, we strongly support the use of each of the criteria in Section I.3 as an independent basis for classifying something as a "significant guidance document." Paragraph I.3(i) would include all guidance documents that "may 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."

We suggest amending this provision to read as follows: "may reasonably be anticipated to lead to an annual negative effect of $50 million or more (e.g., additional compliance costs, lost revenue) or adversely affect in a material way the economy or a sector of the economy. Ideally, we would like to lower that threshold amount in the hope that it would encourage the agencies to implement a more effective rulemaking process on the front end. As a practical matter, we are concerned that any lower amount would discourage the agencies from issuing helpful guidance and allow the uncertainty of what is required by a rule to continue until it was eventually clarified through the enforcement process. At the same time, given the relative ease with which the agencies can issue guidance documents, we are concerned about two aspects of this approach:

a) As with the assessment of major rules, it would appear to allow agencies to annualize economic impacts rather than reflecting the true costs as they are incurred; and

b) In any given year, the agencies would appear capable of issuing many more guidance documents, with a $49 million impact (a $99 million impact using the OMB-proposed threshold), than final rules developed under an APA rulemaking.

Accordingly, we suggest that OMB consider the possibility of including an additional category under the definition of "significant guidance document" that would be triggered if the aggregate annual impact of all guidance documents issued by any agency in a given year exceeded some figure – possibly $200 million.

OMB SHOULD MANDATE WEB ACCESS TO ALL GUIDANCE DOCUMENTS

While a guidance document issued by a Federal regulatory agency may not have an adverse annual effect on the regulated community of $100 million, it could easily have a major impact – potentially resulting in enforcement actions alleging willful violations with six-figure

fines – on the regulated entity that is not aware of it. Unlike the substantial resources that may be required to conduct a non-binding notice and comment proceeding, we are not aware of any basis for not requiring each federal agency to place a well-indexed and easily readable version of every guidance document it issues on the agency's web site, and to update those materials as guidance changes.

First, it seems highly inappropriate to require a regulated entity to undertake a search for those materials, which are in the control of the Federal agency. Second, it appears that some of those documents, including some we know to be of significance to a broad spectrum of regulated entities, would not be made available on a voluntary basis, even in response to a request under the Freedom of Information Act (FOIA).

On November 18, 2004, this office filed an FOIA request (see attachment) with the Occupational Safety and Health Administration (OSHA) asking for a copy of all Standard Interpretations issued by OSHA for the one-year period from January 1, 2000 to December 31, 2000 that were not then posted on OSHA's web site. In a letter dated April 1, 2005, OSHA responded (see attachment) as follows:

> This agency does not maintain any records that are responsive to your request. Due to the volume of interpretation letters that the Directorate of Enforcement Programs (DEP) generates and maintains, it is not possible to put every letter of interpretation on OSHA's website. Furthermore, DEP does not compile and/or maintain a list of interpretation letters that are not posted on the website.

We hasten to add that we believe OSHA has one of the better websites of any Federal agency, but nevertheless do not believe the current situation is acceptable. For the foregoing reasons, we urge OMB to delete the word "significant" from each use of the phrase "significant guidance document" in Section III.1, Internet Access, of the proposed GGP Bulletin.

* * * *

The stated purpose of the proposed GGP Bulletin is to ensure that agency guidance documents are: developed with appropriate review and public participation; accessible and transparent to the public; of high quality; and not improperly treated as binding requirements. We believe our suggested changes would further advance those objectives and the ultimate goals of this highly promising initiative. Thank you for your consideration of these comments.

Respectfully submitted,

Lawrence P. Halprin

Attachments(2) Lawrence P. Halprin

KELLER AND HECKMAN LLP
Serving Business through Law and Science®

1001 G STREET, N.W.
SUITE 500 WEST
WASHINGTON, D.C. 20001
TELEPHONE 202.434.4100
FACSIMILE 202.434.4646
WWW.KHLAW.COM

November 18, 2004

Jeremy W. Brewer
(202) 434-4164
brewer@khlaw.com

Via Facsimile

Ms. Carla Marcellus
FOIA Representative
U.S. Dept. of Labor
Occupational Safety and Health Administration
200 Constitution Avenue, N.W.
Room 3119, Directorate of Enforcement
Washington, D.C. 20210
telephone number: (202) 693-2100
fax number: (202) 693-1681

Re: Freedom of Information Act Request: Standard Interpretations issued by OSHA from January 1, 2000 and December 31, 2000 and from January 1, 2004 to present.

Dear Ms. Marcellus:

Pursuant to the Freedom of Information Act (FOIA)(5 U.S.C. §552), and OSHA's freedom of information regulations, please provide us with a copy of Standard Interpretations issued by OSHA from January 1, 2000 to December 31, 2000, and from January 1, 2004 to present. We are asking for all Standard Interpretations issued in those time periods that are not currently posted on OSHA's web site, along with the letters requesting the interpretations.

We are willing to pay all reasonable copying fees for this request. If you have any questions regarding this request, please do not hesitate to contact me at the number listed above. Thank you in advance for your assistance with this matter.

Respectfully,

Jeremy W. Brewer

U.S. Department of Labor

Occupational Safety and Health Administration
Washington, D.C. 20210

Reply to the attention of:

APR - 1 2005

Mr. Jeremy W. Brewer
1001 G Street, NW, Suite 500 West
Washington, DC 20001

Dear Mr. Brewer:

Thank you for your November 18, 2004, Freedom of Information Act (FOIA) request for Occupational Safety and Health (OSHA) records. You specifically requested copies of all standard interpretations issued by OSHA from January 1, 2000, to December 31, 2000, and from January 1, 2004, to the present that are not currently posted on OSHA's website.

This agency does not maintain any records that are responsive to your request. Due to the volume of interpretation letters that the Directorate of Enforcement Programs (DEP) generates and maintains, it is not possible to put every letter of interpretation on OSHA's website. Furthermore, DEP does not compile and/or maintain a list of interpretation letters that are not posted on the website.

I do not consider this a denial under the FOIA; however, if you do not agree, you have the right to appeal this response. If you wish to appeal, you may do so through the Solicitor of Labor under 29 CFR 70.22. The appeal must be filed within 90 days from the date the response was received. The letter should state in writing the grounds for appeal, including any supporting statements and arguments. To facilitate processing, the appeal should include copies of the initial request and the response of the disclosure officer. Address the appeal to Solicitor of Labor, U.S. Department of Labor, 200 Constitution Avenue, NW, Washington, D.C. 20210. The appeal and the envelope must be marked "FOIA APPEAL."

If you have any further questions, please feel free to contact DEP at 202-693-2100.

Sincerely,

Thomas Galassi

for Richard E. Fairfax, Director
Directorate of Enforcement Programs