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Before

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Subcommittee on Regulatory Affairs and Federal Management
"Examining the Use of Agency Regulatory Guidance, Part II"
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Chairman Lankford, Ranking Member Heitkamp, and Members of the Subcommittee, my name is Paul Noe, and I am the Vice President for Public Policy for the American Forest & Paper Association and the American Wood Council. Thank you for the honor to testify before you on agency use of guidance documents. This is an important and timely issue, and we applaud the Subcommittee for doing the hard work of addressing the challenges this issue presents.

I have been involved in regulatory policy in Washington for over 30 years, including the privilege of having served as counsel to this Committee under Chairmen Fred Thompson, Ted Stevens and Bill Roth, and as a drafter of agency good guidance practices when I served as Counselor to Administrator John Graham at the Office of Information and Regulatory Affairs (OIRA) in the White House Office of Management and Budget (OMB). My experience working for the heavily regulated forest products industry for the last seven years further reinforces my appreciation of the importance of guidance and the benefit of due process and good management practices. We strongly believe that effective good guidance practices are an important step towards a more transparent, fair and effective regulatory system.

The American Forest & Paper Association (AF&PA) serves to advance a sustainable U.S. pulp, paper, packaging, tissue and wood products manufacturing industry through fact-based public policy and marketplace advocacy. AF&PA member companies make products essential for everyday life from renewable and recyclable resources and are committed to continuous improvement through the industry's sustainability initiative - *Better Practices, Better Planet 2020*. The forest products industry accounts for approximately 4 percent of the total U.S. manufacturing GDP, manufactures over $200 billion in products annually, and employs approximately 900,000 men and women. The

industry meets a payroll of approximately $50 billion annually and is among the top 10 manufacturing sector employers in 47 states.

The American Wood Council (AWC) is the voice of North American wood products manufacturing, representing over 75 percent of an industry that provides approximately 400,000 men and women in the United States with family-wage jobs. AWC members make products that are essential to everyday life from a renewable resource that absorbs and sequesters carbon. Staff experts develop state-of-the-art engineering data, technology, and standards for wood products to assure their safe and efficient design, as well as provide information on wood design, green building, and environmental regulations. AWC also advocates for balanced government policies that affect wood products.

AF&PA and AWC work together to advance policies of issues of mutual concern, including regulatory reform. The forest products industry has seen both sides of the coin on agency guidance. In some instances, questions of implementation can be appropriately and effectively resolved through guidance. In others, the use of agency guidance may lack appropriate transparency and due process, even to the point of inappropriately substituting for regulation. Accordingly, AF&PA and AWC support legislative and administrative efforts that ensure transparency, due process and effective management for significant agency guidance.

I. Background

A. The Need for Good Guidance Practices

President Reagan's Executive Order 12291, which firmly established OMB review of rules, was quite broad in scope and applied to virtually all "rules" – including both regulations (legally binding legislative rules) and agency guidance (non-binding interpretive rules and policy statements). When President Clinton replaced the Reagan Order in 1993 with Executive Order 12866, it honed in on "significant" regulatory actions. Given the vastness of federal regulatory activity, and the limited resources of OIRA, it was eminently sensible to try to sort the significant agency activity from the insignificant. The problem is that while the Clinton Order applied to significant regulations, it neglected guidance documents – covering only rules that "the agency intends to have the force and effect of law." But there is no doubt that guidance documents can be quite significant. In fact, agencies issue over 3400 regulations annually, but the volume of guidance documents is orders of magnitude larger,[1] and nobody actually knows how many there are.

[1] *See, e.g.,* Peter L. Strauss, *The Rulemaking Continuum*, 41 Duke L.J. 1463, 1469 (1992) (noting that the formally adopted rules of the Federal Aviation Administration are two inches thick, but the corresponding guidance materials, over forty feet; Part 50 of the Nuclear Regulatory Commission's regulations on nuclear plant safety, in loose-leaf edition, is 3/16 of an inch, but the supplemental technical guidance is 9 3/4 inches; and the formally adopted regulations of the IRS occupy one foot of shelf space, but Revenue rulings and similar publications, about twenty feet); *see also* H. Comm. on Gov't. Reform, "Non-Binding Legal Effect of Agency Guidance Documents," H.R.

Starting in 2002, as part of its obligation to provide recommendations for reform under the "Regulatory Right-to-Know Act," OIRA requested public comment on problematic agency guidance and regulations, and received public nominations of 49 problematic guidance documents in need of reform.[2] OIRA received further public comments on problematic guidance in response to its request for public comment on its draft *Report to Congress on the Costs and Benefits of Federal Regulation* in 2004 and 2005[3] and on the proposed Bulletin.[4] The public response was striking – hundreds of comments from a wide array of groups raised concerns – small businesses, farmers, state and local governments, homebuilders, colleges and universities, large businesses, hospitals, trade associations, funeral directors, public interest groups, think tanks, bird watchers, and others. A cursory review of the Preamble to the OMB Bulletin, the comments that OMB received and posted on its website, and the scholarly literature[5] provide many examples.

Although guidance documents may not properly carry the force of law, they are a key component of regulatory programs. As the scope and complexity of regulatory programs has grown, agencies increasingly have relied on guidance documents to provide direction to their staff and to the public. That generally is to the good, and I want to clearly acknowledge that agency guidance often is both very important and very helpful to the regulated community and others. As OMB put it:

> "Agencies may properly provide guidance to interpret existing law through an interpretative rule, or to clarify how they will treat or enforce a governing legal norm through a policy statement. . . . Guidance documents, properly used, can channel the discretion of agency employees, increase efficiency by simplifying and expediting agency enforcement efforts, and enhance fairness by providing the public clear

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Rep. No. 106-1009 (2000) (noting that between March 1996 through 1999, NHTSA had issued 1225 guidance documents, EPA 2653, and OSHA 1641).

[2] OMB, Key to Public Comments, https://www.whitehouse.gov/omb/inforeg_key_comments (last visited June 24, 2016); *see also*, OMB, *Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local and Tribal Entities*, at pp. 75-85 https://www.whitehouse.gov/sites/default/files/omb/assets/omb/inforeg/2002_report_to_congress.pdf (last visited June 24, 2016).

[3] OMB, *Peer Review and Public Comments on the 2005 Draft Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities*, http://www.whitehouse.gov/omb/inforeg/2005_cb/toc.html (last visited June 24, 2016); OMB, *Public Comments on 2004 Draft Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities*, https://www.whitehouse.gov/omb/inforeg_2004_cb_list_2004cb/ (last visited June 24, 2016).

[4] OMB, *Comments on Proposed Bulletin on Good Guidance Practices*, https://www.whitehouse.gov/omb/regpol_good_guid_c-index/ (last visited June 24, 2016).

[5] *See, e.g.*, Robert A. Anthony, *"Interpretive Rules, Policy Statements, Guidances, Manuals and the Like –Should Federal Agencies Use Them to Bind the Public?"* 41 Duke L.J. 1311 (1992); Robert A. Anthony, *"Interpretive" Rules, "Legislative" Rules and "Spurious" Rules: Lifting the Smog*, 8 Admin. L.J. (Spring 1994).

> notice of the line between permissible and impermissible conduct while ensuring equal treatment of similarly situated parties."[6]

Unfortunately, many concerns have been raised that agency guidance practices should be better managed and be more consistent, transparent and accountable. These concerns are reinforced by the GAO report that Congress requested on implementation of the OMB Bulletin by four cabinet departments.[7] Moreover, there is growing concern that, in some cases, guidance documents essentially are being used in lieu of regulations -- without observing the procedural safeguards for regulations. As the D.C. Circuit put it:

> The phenomenon we see in this case is familiar. Congress passes a broadly worded statute. The agency follows with regulations containing broad language, open-ended phrases, ambiguous standards and the like. Then 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 public participation, and without publication in the Federal Register or the Code of Federal Regulations.[8]

The concern about the need for better management, transparency and due process for the development and use of guidance documents inspired OIRA to develop the OMB Bulletin for Agency Good Guidance provisions, supplemented by a provision in Executive Order 13422 for OMB review of agency guidance. In pertinent part, E.O. 13422 provided:

> "Significant Guidance Documents
> Each agency shall provide OIRA, at such times and in the manner specified by the Administrator of OIRA, with advance notice of any significant guidance documents. . . . Upon the request of the Administrator, for each matter identified as, or determined by the Administrator to be, a significant guidance document, the issuing agency shall provide to OIRA the content of the draft guidance document, together with a brief explanation of the need for the guidance document and how it will meet that need. The OIRA Administrator shall notify the agency when

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[6] OMB, *Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities*, at p. 72 https://www.whitehouse.gov/sites/default/files/omb/assets/omb/inforeg/2002_report_to_congress.pdf

[7] U.S. Government Accountability Office, *Regulatory Guidance Processes: Selected Departments Could Strengthen Internal Control and Dissemination Practices*, GAO-15-368 (April 2015) (reviewing implementation of OMB Bulletin for Agency Good Guidance Practices by the departments of Health and Human Services, Labor, Education and Agriculture and finding significant deficiencies).

[8] *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1019 (D.C. Cir. 2000) (striking down emissions monitoring guidance as requiring notice and comment through legislative rulemaking procedures).

additional consultation will be required before the issuance of the significant guidance document."

Together, Executive Order 13422 and the OMB Bulletin established the first government-wide "rules of the road" to manage the development and use of guidance documents. The E.O. 13422 gave clear authority to OMB to review significant agency guidance documents, a streamlined version of how OMB reviews significant agency regulations. The agencies, in turn, were required to give OMB advance notice of their upcoming significant guidance documents. OMB would be responsible for ensuring that other interested agencies in the federal family received notice, and occasionally, an opportunity to provide input into the most important guidance documents.

The OMB Bulletin on Good Guidance Practices fit hand in glove with E.O. 13422. First, agencies must implement written procedures for the approval of significant guidance documents by appropriate senior officials. Agency employees should not depart from significant guidance documents without appropriate justification and supervisory concurrence. Second, significant guidance documents must have standard elements, such as information identifying the document as guidance, the issuing office, the activity and persons to whom it applies, the date of issuance, title and docket number.

Most notably, agencies are directed to avoid inappropriate mandatory language. This provision was intended to help curb the problem of "regulation by guidance document" criticized in the *Appalachian Power* decision and others. It also will obviate wasteful litigation and increase fairness and accountability in the exercise of regulatory power.

The Bulletin also establishes public access and feedback procedures. For example, agencies are required to maintain on their Web sites a current list of their significant guidance documents, and to provide a means for the public to electronically submit comments on significant guidance documents, or to request that they be created, reconsidered or modified. Finally, the Bulletin establishes pre-adoption notice and comment requirements for guidance documents that rise to the level of being "economically" significant.

When President Obama took office, he retained the OMB Bulletin, but he rescinded E.O. 13422. To substitute for the good guidance provisions of E.O. 13422, the OMB Director issued a memo to restore the regulatory review process to what it had been under Executive Order 12866 between 1993 and 2007. The memo stated: "During this period, OIRA reviewed all significant proposed or final agency actions, including significant policy and guidance documents. Such agency actions and documents remain subject to OIRA's review under Executive Order 12866."

My understanding is that, under that approach, OIRA reviewed little guidance, and when it did, the practice was ad hoc and disorganized. This comes as no surprise since there was no written authority for the practice -- and no procedures governing it. The problem is that:

- OIRA desk officers had to ***already know*** the guidance existed, and

- They had to get permission to call in a guidance.

That is not the best way to run a railroad. Simply put, you can't review what you don't know exists. The review process has broken down when the first time OIRA desk officers know about an important guidance document is when they read about it in the Washington Post. How many significant guidances do you think an OIRA desk officer might not know about before it was issued? Plenty, I can assure you. And would it be clearly unreasonable for agencies to feel that OMB had no business looking at their draft guidance without any explicit authorization? It was no accident that the provision for OIRA review of guidance was elevated into an Executive Order rather than simply being added to the Bulletin.

Indeed, ignoring guidance inadvertently can undermine OMB's authority to review regulations, similar to how it undermines court review, as the D.C. Circuit explained in *Appalachian Power*. The agency could issue broad, open-ended legislative rules that pass through interagency review (and court review, and for that matter, Congressional review). Then the agency could follow with guidance "expanding the commands in the regulations" to a degree that would have raised concerns if those details had appeared in the regulations from the start. In fact, one might wonder how OMB's abstention from managing and coordinating significant guidance documents may have contributed to the growth in "spurious rules" cases in the courts, which increasingly have criticized agencies for issuing binding rules without observing the public notice and comment procedures that Congress required in the Administrative Procedure Act.[9]

B. The Precedent for Good Guidance Practices

Even before the OMB public comment process, there was a strong foundation for the good guidance practices in E.O. 13422 and the OMB Bulletin that was rooted in the recommendations of leading authorities that stood for decades. This foundation includes the work of many authorities – including the Executive Branch,[10] Congress,[11] the courts,[12] the American Bar Association,[13] and legal scholars.[14]

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[9] The growth in so-called "spurious rule" court cases in the 1990s may not be a coincidence. *See, e.g., Gen. Elec. Co. v. EPA*, 290 F.3d 377 (D.C. Cir. 2002) (striking down PCB risk assessment guidance as a spurious rule requiring notice and comment); *Appalachian Power Co. v. EPA*, 208 F.3d 1015 (D.C. Cir. 2000) (striking down emissions monitoring guidance as spurious rule requiring notice and comment); *U.S. Chamber of Commerce v. Dep't of Labor*, 174 F.3d 206 (D.C. Cir. 1999) (striking down OSHA Directive as a spurious rule requiring notice and comment). *See also,* OMB, *Final Bulletin for Agency Good Guidance Practices*, 72 Fed. Reg. 3432, 3435 (Jan. 25, 2007); OMB, *Key to Public Comments*, https://www.whitehouse.gov/omb/regpol_good_guid_c-index/ (last visited June 24, 2016).

[10] Recommendations of the Administrative Conference of the United States, *Agency Policy Statements*, Rec. 92-2, 1 C.F.R. § 305.92-2 (1992), *available at* http://www.law.fsu.edu/library/admin/acus/305922.html (stating that agencies should not issue statements of general applicability intended to be binding without using legislative rulemaking procedures and that agencies should afford the public a fair opportunity to challenge the legality or wisdom of policy statements and to suggest alternative choices); Recommendations of the Administrative Conference of the United States, *Interpretive Rules of General Applicability and Statements of General Policy*, Rec. 76-5, 1 C.F.R. § 305.76 (1992), *available at* http://www.law.fsu.edu/library/admin/acus/305765.html (stating that agencies should utilize APA notice and comment procedures for interpretive rules of general applicability or statements of general policy likely to have a substantial impact on the public); *The Food and Drug Administration's*

First, the Administrative Conference of the United States (ACUS)[15] issued recommendations for the development and use of agency guidance documents.As far back as the mid-1970s, for example, ACUS recognized the importance of ensuring a notice and comment process for the most significant guidance documents. ACUS Recommendation 76-5 states:

> "Before an agency issues, amends or repeals an interpretive rule of general applicability or statement of general policy which is likely to have a substantial impact on the public, the agency normally should utilize the procedures set forth in the Administrative Procedure Act subsections 553(b) and (c) .... Where there has been no prepromulgation notice and opportunity for comment, the publication of an interpretive rule of general applicability or a statement of general policy... should include ... an invitation to interested persons to submit written comments."[16]

ACUS Recommendation 92-2 later added:

Development, Issuance, and Use of Guidance Documents, 62 Fed. Reg. 8961 (Feb 27, 1997) (notice) (establishing FDA's original good guidance practices); OMB, *Draft Report to Congress on the Costs and Benefits of Federal Regulations*, 67 Fed. Reg. 15,014, 15,034-35 (Mar. 28, 2002) (detailing concerns over soliciting public comments on problematic agency guidance practices and specific examples of guidance documents in need of reform). *See also, infra*, note 21.

[11] *See, e.g.*, U.S. Government Accountability Office, *Regulatory Guidance Processes: Selected Departments Could Strengthen Internal Control and Dissemination Practices*, GAO-15-368 (April 2015); Congressional Review Act of 1996, 5 U.S.C. §§ 801-808 (2000) (providing fast-track procedures for Congressional resolutions of disapproval of rules and incorporating the APA definition of "rule" to cover guidance documents); *Food and Drug Administration Modernization Act of 1997*, 21 U.S.C. § 371(h) (2000) (establishing FDA good guidance practices as law); Congressional Accountability for Regulatory Information Act, H.R. 3521, 106th Cong. § 4 (2000) (proposing to require agencies to notify the public of the non-binding effect of guidance documents), H. Comm. on Government Reform, Non-Binding Legal Effect of Agency Guidance Documents, H.R. Rep. No. 106-1009 (2000) (criticizing "backdoor" regulation); *Food and Drug Administration Modernization and Accountability Act of 1997*, S. Rep. No. 105-43, at 26 (1997) (raising concerns about the lack of transparency and consistency in the use of guidance documents).

[12] *See, e.g., supra* note 9.

[13] ABA, *Annual Report Including Proceedings of the Fifty-Eighth Annual Meeting* 57 (1993) (recommending notice and comment for guidance documents likely to have a significant impact on the public); ABA, *Recommendation on Federal Agency Web Pages* 1 (2001), http://www.abanet.org/adminlaw/federa02.pdf (recommending that agencies post on their Websites, *inter alia*, all important policies and interpretations).

[14] *See, e.g.,* Robert A. Anthony, "*Interpretive" Rules, "Legislative" Rules and "Spurious" Rules: Lifting the Smog*, 8 Admin. L.J. I (1994); Robert A. Anthony*, Interpretive Rules, Policy Statements, Guidances, Manuals and the Like-Should Federal Agencies Use Them to Bind the Public?* 41 Duke L.J. 1311 (1992); *see also*, OMB, *Final Bulletin for Agency Good Guidance Practices*, at pp. 2-3 & n. 2, 6.

[15] ACUS is a federal advisory agency charged with providing recommendations on administrative procedure issues. ACUS has made hundreds of recommendations on administrative procedure issues, and most were adopted by agencies or by Congress. *See* Florida State University College of Law, *ABA Administrative Procedure Database*, www.law.fsu.edu/library/admin/acus/acustoc.html (last visited June 24, 2016).

[16] Recommendations of the Administrative Conference of the United States, *Interpretive Rules of General Applicability and Statements of General Policy*, Rec. 76-5, 1 C.F.R. § 305.76-5 (1992), available at http://www.law.fsu.edu/library/admin/acus/305765.html.

> "Agencies should not issue statements of general applicability that are intended to impose binding substantive standards or obligations upon affected persons without using legislative rulemaking procedures.... Policy statements of general applicability should make clear that they are not binding.... Agencies that issue policy statements should examine, and where necessary, change their ... procedures ... to allow as an additional subject requests for modification or reconsideration of such statements."[17]

In 1993, the American Bar Association (ABA) reaffirmed the ACUS recommendations on the use of informal notice and comment procedure for significant guidance documents.[18] In 2001, the ABA further recommended that agencies "explore means to maximize the availability and searchability of existing law and policy on their websites" and include "their governing statutes, all agency rules and regulations, and all important policies, interpretations, and other like matters which members of the public are likely to request."[19]

Moreover, Congress produced what became a model for OMB's Good Guidance Practices.[20] In the Federal Food and Drug Administration Modernization Act of 1997, Congress directed the FDA to issue regulations establishing good guidance practices.[21] Congress was particularly concerned about public knowledge of, and access to, FDA guidance documents; the lack of a systematic process for adopting guidance documents and for allowing public input; and inconsistency in the use of guidance documents.[22] Those same concerns apply to other agencies as well.

II. The Need for Congressional Action

The case for Congressional action is clear. The OMB Bulletin has been in effect since early 2007 in both Republican and Democratic administrations. Over nine years is far more than enough time for the agencies to have fully complied with basic good guidance practices, and clearly they have not. The GAO Report reinforces what

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[17] ACUS, *Agency Policy Statements*, Rec. 92-2, 1 C.F.R. § 305.92-2 (1992), *available at* http://www.law.fsu.edu/library/admin/acus/305922.html

[18] ABA, *Annual Report Including Proceedings of the Fifty-Eighth Annual Meeting* 57 (1993) ("[T]he American Bar Association recommends that: Before an agency adopts a nonlegislative rule that is likely to have a significant impact on the public, the agency provide an opportunity for members of the public to comment on the proposed rule and to recommend alternative policies or interpretations, provided that it is practical to do so; when nonlegislative rules are adopted without prior public participation, immediately following adoption, the agency afford the public an opportunity for post-adoption comment and give notice of this opportunity.").

[19] ABA, *Recommendation on Federal Agency Web Pages* 1 (2001), http://www.abanet.org/adminlaw/federa02.pdf.

[20] As OMB stated in its Preamble (pp. 4-5), FDAMA and FDA's implementing regulations, as well as the recommendations of the former Administrative Conference, informed the development of the Bulletin.

[21] The *Food and Drug Administration Modernization Act of 1997 (FDAMA)*, 21 U.S.C. § 371(h) (establishing FDA good guidance practices as law). Based on FDAMA, the FDA made some changes to its existing procedures to clarify its good guidance practices. *See Administrative Practices and Procedures: Good Guidance Practices*, 21 C.F.R. § 10.115 (2007).

[22] *Food and Drug Administration Modernization and Accountability Act of 1997*, S. Rep. 10543, at 26 (1997).

scholarship, public comments and oversight, have shown. All rulemaking starts with Congress having delegated that authority to the agencies, so it is reasonable and commendable for Congress to improve the rulemaking process as needed.

From my discussions with staff, I understand that the Chairman is considering a legislative proposal to elevate the good guidance provisions of the OMB Bulletin and E.O. 13422 into legislation. We would enthusiastically support this proposal, because it would be a timely good government initiative that is based on the recommendations of leading authorities that have stood for decades. I also think it would be fully consistent with the tradition of bipartisan solutions for improving the regulatory process that has been the hallmark of this Committee for decades. Where a reform has such strong support from non-partisan organizations and experts, and a compelling public need, the desire to improve the transparency and quality of the rulemaking process is more relevant than party affiliation.

To supplement my testimony, I have attached a law review article I wrote on the good guidance practices in the OMB Bulletin and E.O. 13422 which is a foundation for my statement, key recommendations of ACUS, and letters from the ABA Section of Administrative Law and Regulatory Practice supporting those good guidance practices against a rider in 2007 and urging the inclusion of significant guidance in President Obama's Executive order on regulatory review in 2009.

In summary, the failure to implement clear and transparent good guidance practices undermines the quality, fairness, lawfulness and accountability of the regulatory system. Effective good guidance practices could provide much needed transparency, due process, and management for the rulemaking process. These practices are foundational to good government and are long overdue. I would be happy to address any questions you may have. Thank you again for the honor to testify before you.

Attachments