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OFFICE OF MANAGEMENT AND BUDGET
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Chairman Sanchez, Ranking Member Cannon, and distinguished Members of this Subcommittee, thank you for inviting me to this hearing and for giving me the opportunity to testify before you today on the recently issued Executive Order 13422 and the related OMB Bulletin on Agency Good Guidance Practices.

I am Steven D. Aitken, the Acting Administrator of the Office of Information and Regulatory Affairs (OIRA), an office within the Office of Management and Budget (OMB). I have worked at OMB for nearly 18 years. Except for the past eight months when I have served as OIRA's Acting Administrator, I have served in the Office of General Counsel at OMB, first as an Assistant General Counsel and then as Deputy General Counsel.

A few weeks ago, on January 18th, the President issued Executive Order 13422, which made several amendments to Executive Order 12866 on "Regulatory Planning and Review." The most important of these amendments relate, not to the regulations that Federal agencies develop, but rather to the guidance that Federal agencies develop and provide to the public. In addition, also on January 18th, the OMB Director issued the OMB Bulletin for Agency Good Guidance Practices. This is the final version of the bulletin that OMB issued in proposed form for public comment in November 2005.[1]

As I will go on to explain, the Bulletin and the recent Executive Order share a common goal: namely, the good-government objective of improving the way that the Federal government does business – by increasing the quality, public participation, and accountability of agency guidance documents and their development and use. Moreover, as I will further explain, the Bulletin and the new Executive Order will operate in a complementary fashion to improve agency guidance documents. For this reason, in order to explain the Executive Order's guidance provision, it is first necessary to explain the common background for both the Bulletin and the

[1] Executive Order 13422 and the Final Bulletin are published in the Federal Register at, respectively, 72 FR 2763 (January 23, 2007), and 72 FR 3432 (January 25, 2007). OMB requested public comment on the proposed bulletin at 70 FR 71866 (November 30, 2005), and extended the comment period at 70 FR 76333 (December 23, 2005). These documents, along with the public comments that OMB received on the proposal and the OMB Director's memorandum issuing the Bulletin (Memorandum M-07-07), are available on OMB's website. The original version of Executive Order 12866, issued in 1993, was published in the Federal Register at 58 FR 51735 (October 4, 1993). Executive Order 12866 was previously amended once, in 2002, by Executive Order 13258, which was published in the Federal Register at 67 FR 9385 (February 26, 2002).

Executive Order and then to explain how the Bulletin is designed to improve the way that agency guidance documents are developed, issued and used. I will then provide a description and explanation of the Executive Order's guidance provision.

Following that, I will discuss the recent Executive Order's other non-guidance provisions. The first four that I will discuss are (1) its requirement that the already-existing Regulatory Policy Officer in each agency be designated by the agency head from among the agency's Presidential appointees (most of the agencies' Regulatory Policy Officers were already Presidential appointees, and also subject to Senate confirmation), and its typographical-error reference to a Regulatory Policy "Office" rather than "Officer"; (2) its requirement that an agency's commencement of a rulemaking either be authorized by the agency head or be approved by the agency's Regulatory Policy Officer (which will mean in practice that, in most if not all cases, an agency's commencement of a rulemaking will be authorized or approved by an agency official who is subject to Senate confirmation); (3) requirement that each agency aggregate the costs and benefits of the individual rules in the agency's section of the annual Regulatory Plan (Executive Order 12866 already required the agencies to include in the Regulatory Plan the estimated costs and benefits for each rule, and thus the only new feature is that the agency – rather than the public – will do the summing-up of the already-reported costs and benefits); and (4) its encouragement of agencies to consider using the Administrative Procedure Act's formal (rather than informal) rulemaking procedures for the agency's resolution of complex determinations.

Finally, I will discuss the recent Executive Order's amendment regarding "market failure," and I will seek to correct the misunderstandings that have arisen regarding this amendment. In sum, as I will explain further, the recent Executive Order does *not* introduce the concept of a market failure into Executive Order 12866; that concept has been a prominent feature of Executive Order 12866 since it was originally issued by President Clinton in 1993. In addition, the recent Executive Order does *not* make the identification of a market failure the only basis on which a Federal agency can justify regulatory action. Rather, the recent Executive Order expressly states that an agency can justify a regulation by reference to an "other specific problem that [the agency] intends to address." Moreover, the recent Executive Order leaves untouched the provision in Executive Order 12866 that expressly directs Federal agencies to "promulgate . . . such regulations as are required by law, [or] are necessary to interpret the law." In many cases, when a Federal agency is issuing a regulation, the agency is doing so for just those law-based reasons, and this will continue to be the case; nothing in Executive Order 13422 changes this.

Having explained what the new "market failure" language does *not* do, I will then explain what it actually *does* do, which is two modest things.

First, Executive Order 13422 states that the agency "shall identify *in writing*" the problem -- whether it is a market failure "or other specific problem" – that the agency "intends to address" through regulatory action. Stating explicitly that Federal agencies shall identify "in writing" the problem that the agency is seeking to remedy through regulatory action does *not* impose a new requirement on rulemaking agencies. Even if an agency did not identify in writing the precise nature of the problem that the agency is seeking to remedy through regulatory action

(in order to assist the agency in *its own analysis* of whether regulatory action is warranted and, if so, which regulatory alternatives would best accomplish the agency's intended result*)*, the agency should be doing so in the preamble to the proposed rule (to assist the public in understanding the agency's proposal and in offering their comments on it) and in the preamble to the final rule (to persuade the public, Congress, and the courts that the agency has exercised its regulatory authority in a reasonable and well-considered manner).

Second, in order to increase the transparency of Executive Order 12866, the recent Executive Order incorporates into Executive Order 12866 a reference to three classic examples of what constitutes a "market failure" – namely, externalities (which justify, e.g., the regulation of pollution), market power (which justify, e.g., the regulation of natural monopolies), and lack of information (which justify, e.g., the nutritional labeling of packaged foods). These three examples are *not* new to the implementation of Executive Order 12866. These examples were found in the discussion of "market failure" that was contained in the 1996 "Economic Analysis of Federal Regulations under Executive Order No. 12866" document that former OIRA Administrator Sally Katzen (working with the former Chairman of the Council of Economic Advisers, Joseph Stiglitz) issued to Federal agencies three years after President Clinton issued Executive Order 12866. Moreover, these three examples were contained in the draft Circular on regulatory cost-benefit analysis that OMB issued for public comment in 2003 and are contained in the final Circular A-4 that OMB issued later that year (and which remains in effect).

Background on the Good Guidance Provisions of the Bulletin and Executive Order:

As OMB has previously stated, agency guidance documents can have "enormous value."[2] As OMB explained in 2002: "As the scope and complexity of regulation and the problems it addresses have grown, so too has the need for government agencies to inform the public and provide direction to their staffs. To meet these challenges, agencies have relied increasingly on issuing guidance documents."[3] Guidance documents are issued by agencies throughout the Federal Government, and they address the wide range of societal activities that are affected, in one way or the other, by the Federal Government and its programs. Thus, it is not surprising that, depending on the situation, agency guidance can be addressed to individuals, businesses (both small and large), organizations, State, local, and tribal governments, and others.

For instance, guidance can take the form of an agency explaining to members of the public how they can participate in a Federal program. An example of this kind of guidance is the *Medicare and You* handbook that the Centers for Medicare and Medicaid Services (CMS) distribute to Medicare beneficiaries annually.

Guidance can also take the form of an agency providing advice and assistance to members of the public about recommended actions to ensure that they are in compliance with Federal laws and regulations. One element of this guidance can be explaining to the regulated community how the agency interprets or intends to enforce certain laws and regulations. In

[2] Office of Management and Budget, *Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Federal Regulations* (2002), p. 72.

[3] Office of Management and Budget, Draft 2002 Report to Congress on the Costs and Benefits of Federal Regulations, 67 FR 15014, 15034 (March 28, 2002).

addition to providing advice and assistance to the regulated community on how to comply with the agency's regulations, such guidance also furthers consistency and fairness in an agency's enforcement of its regulations.[4] Depending on the context, the audience for this guidance can include individuals, small entities (such as small businesses and organizations, as well as local governments), large corporations, and/or State governments.

Examples of this type of guidance are the compliance-assistance guides that Federal agencies prepare and make available to small businesses. Congress has required Federal agencies to prepare and issue such guidance in the Small Business Regulatory Enforcement Fairness Act of 1996.[5] In addition, Congress in the Small Business Paperwork Relief Act of 2002[6] assigned to OMB the responsibility, which is carried out by OIRA, of publishing annually in the *Federal Register* a notice that refers to small business the internet site where they can locate the compliance assistance resources that Federal agencies have prepared for their use. OIRA published the 2006 notice last summer,[7] where OIRA explained that small businesses can go to one Internet address (www.business.gov/sbpra) and find the compliance-assistance resources that are available from the 15 Cabinet Departments and 25 other Federal agencies.

In sum, agency guidance documents are intended to -- and do -- have an impact on society. Depending on the situation, this impact can be relatively small or can be very substantial. As a result, while it is the case that guidance documents (unlike regulations) are not legally binding on the public, agency guidance documents nevertheless can potentially have an impact on society that is of comparable magnitude to the impact that regulations have on society.

In recognition of the impact that its guidance has on society, the Food and Drug Administration (FDA) in February 1997 issued a "Good Guidance Practices" document to govern how the FDA develops, issues, and uses its own guidance documents.[8] Later that year, and building on this FDA policy, Congress in the Food and Drug Administration Modernization Act of 1997[9] directed the FDA to follow several procedures in its development, issuance, and use of its guidance documents.

One of the principal congressional requirements in the 1997 Act is that FDA "develop guidance documents with public participation and ensure that information identifying the existence of such documents and the documents themselves are made available to the public both in written form and, as feasible, through electronic means."[10] To this end, Congress directed

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[4] "Guidance documents, used properly, can channel the discretion of agency employees, increase efficiency by simplifying and expediting agency enforcement efforts, and enhance fairness by providing the public clear notice of the line between permissible and impermissible conduct while ensuring equal treatment of similarly situated parties." Office of Management and Budget, Draft 2002 Report to Congress on the Costs and Benefits of Federal Regulations, id., 67 FR at 15034.

[5] P.L. 104-121, Title II, Subtitle A; 5 U.S.C. § 601 note.

[6] P.L. 107-198, Section 2(a); 44 U.S.C. § 3504(c)(6).

[7] 71 FR 39691 (July 13, 2006).

[8] 62 FR 8961 (February 27, 1997).

[9] P.L. 105-115, § 405; 21 U.S.C. § 371(h).

[10] 21 U.S.C. § 371(h)(1)(A). This direction was consistent with prior recommendations by the Administrative Conference of the United States and the American Bar Association that agencies provide the public with an opportunity to comment on guidance documents. See Administrative Conference of the United States, Rec. 92-2, 1 C.F.R. 305.92-2 (1992) (agencies should afford the public a fair opportunity to challenge the legality or wisdom of

FDA to provide the public with an opportunity to comment on its guidance, either *before* or *after* its issuance, depending on the level of significance of the particular guidance document.[11] "For guidance documents that set forth initial interpretations of a statute or regulation, changes in interpretation or policy that are of more than a minor nature, complex scientific issues, or highly controversial issues, [FDA] shall ensure public participation prior to implementation of guidance documents, unless [FDA] determines that such prior public participation is not feasible or appropriate. In such cases, [FDA] shall provide for public comment upon implementation and take such comment into account."[12] By contrast, "[f]or guidance documents that set forth existing practices or minor changes in policy, [FDA] shall provide for public comment upon implementation."[13]

Congress also directed FDA to follow several additional requirements. For example, FDA "shall ensure . . . uniform internal procedures for approval of [guidance] documents"[14] and "shall ensure that employees of [FDA] do not deviate from [FDA's] guidance without appropriate justification and supervisory concurrence."[15] In addition, FDA "shall maintain electronically and update and publish periodically in the Federal Register a list of guidance documents," and "[a]ll such documents shall be made available to the public."[16]

Finally, Congress directed FDA, following the agency's review of the effectiveness of its previously-issued Good Guidance Practices document, to promulgate a regulation in 2000 "consistent with [the statute] specifying the policies and procedures of the [FDA] for the development, issuance, and use of guidance documents."[17] Following this directive, FDA in early 2000 issued for public comment a proposed rule on Good Guidance Practices.[18] After it reviewed and considered the public comments, FDA finalized the rule later that year.[19]

The FDA's Good Guidance Practices regulation is found at 21 C.F.R. § 10.115. Following the congressional direction in the 1997 Act, the FDA regulation provides that FDA, among other things –

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policy statements and to suggest alternative choices); American Bar Association, Annual Report Including Proceedings of the Fifty-Eighth Annual Meeting, August 10-11, 1993, Vol. 118, No. 2, at 57 ("the 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.").

[11] For the legislative history of this provision, see "Food and Drug Administration Modernization and Accountability Act of 1997," S. Rep. No. 105-43, at 26 (1997) (raising concerns about public knowledge of, and access to, FDA guidance documents, lack of a systematic process for adoption of guidance documents and for allowing public input, and inconsistency in the use of guidance documents).

[12] 21 U.S.C. § 371(h)(1)(C).

[13] Id. § 371(h)(1)(D).

[14] Id. § 371(h)(2).

[15] Id. § 371(h)(1)(B).

[16] Id. § 371(h)(3).

[17] Id. § 371(h)(5).

[18] 65 FR 7321 (February 14, 2000) (proposed rule).

[19] 65 FR 56468 (September 19, 2000) (final rule).

- shall seek public comment on its guidance documents, either before or after their issuance (depending on their level of significance) and consider the comments;[20]

- shall make its guidance documents easily available to the public by posting it on the Internet;[21]

- "must not include [in its guidance documents] mandatory language such as 'shall,' 'must,' 'required,' or 'requirement,' unless FDA is using these words to describe a statutory or regulatory requirement";[22]

- "must have written procedures" in each FDA center and office "for the approval of guidance documents," which procedures "must ensure that issuance of all documents is approved by appropriate senior FDA officials";[23] and

- must provide members of the public with an opportunity to submit and seek resolution of a complaint "that someone at FDA did not follow the requirements in [the regulation] or . . . treated a guidance document as a binding requirement."[24]

These FDA regulations went into effect in October 2000, and therefore have now been in operation for six years.

In sum, as I have just outlined, the Congress and the FDA both recognized that, because of the impact that FDA's guidance can have on society, it was important that FDA's guidance be subject to public comment (before or after its issuance); be readily available to the public; be developed through agency procedures that ensure the review and approval of appropriate agency officials before it is issued; be followed in practice by agency employees; and avoid the inclusion of language that would suggest to the public that the document is mandatory rather than what it actually is – namely, guidance.[25] It should also be noted that these requirements, in particular the requirements for internal-agency review and approval and for public comment, help to ensure that guidance documents are of high quality.

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[20] 21 C.F.R. § 10.115(g).

[21] Id. This direction is consistent with the 2001 recommendation by the American Bar Association. 3 American Bar Association, "Recommendation on Federal Agency Web Pages" (August 2001) (agencies should maximize the availability and searchability of existing law and policy on their websites and include their governing statutes, rules and regulations, and all important policies, interpretations, and other like matters on which members of the public are likely to request).

[22] Id. § 10.115(i)(2).

[23] Id. § 10.115(j).

[24] Id. § 10.115(o).

[25] Congressional interest in, and concern about, agency guidance documents is also reflected in House Committee on Government Reform, "Non-Binding Legal Effect of Agency Guidance Documents," H. Rep. No. 106-1009 (106th Cong., 2d Sess. 2000) (criticizing "back-door" regulation), and the 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).

The FDA Good Guidance Practices regulation also addresses concerns that courts have raised about the improper development and use of agency guidance documents. In its 2000 decision in the Appalachian Power case, the United States Court of Appeals for the District of Columbia Circuit discussed these concerns:

> "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."

Appalachian Power Co. v. EPA, 208 F.3d 1015, 1019 (D.C. Cir. 2000) (striking down emissions monitoring guidance as legislative rule requiring notice and comment). See also Gen. Elec. Co. v. EPA, 290 F.3d 377 (D.C. Cir. 2002) (striking down PCB risk assessment guidance as legislative rule requiring notice and comment); Chamber of Commerce v. Dep't of Labor, 174 F.3d 206 (D.C. Cir. 1999) (striking down OSHA Directive as legislative rule requiring notice and comment).

OMB's Issuance of the Proposed and Final Bulletin:

OMB believes that Federal agency guidance should be developed, issued and used through an agency's adherence to procedures that ensure quality, transparency, public participation, coordination, and accountability. For this reason, OMB developed (in consultation with Federal agencies) a draft OMB Bulletin that would establish as government-wide policy a set of "best practices" for achieving these goals.

As I earlier noted, OMB then sought public comment on this draft bulletin by issuing it in November 2005 as a proposal for public comment.[26] OMB received 31 public comments on the proposal, and these comments are available on OMB's website. As evidence of the diverse nature of Federal guidance documents, and of the groups in American society that are affected by them, below are examples of some of the associations that submitted comments (as noted below, these listed associations supported OMB's development of a bulletin on Good Guidance Practices, while also providing their suggestions for how OMB could improve the bulletin):

> **-- the Association of American Medical Colleges**, representing all 125 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and 94 academic and scientific societies ("The AAMC commends the OMB for its proposal to establish consistent and appropriate standards for developing good guidance practices within federal agencies.");

[26] 70 FR 71866 (November 30, 2005).

-- the National Association of Home Builders, representing more than 220,000 members involved in home building, remodeling. multifamily construction, property management, subcontracting, design, housing finance, building product manufacturing and other aspects of residential and light commercial construction ("The National Association of Home Builders (NAHB) would like to thank the Office of Management and Budget (OMB) for proposing a process to bring transparency and consistency to Executive Branch activities that affect the public directly, but do not qualify as rules under the Administrative Procedure Act **(**APA**)**.");

-- the American Society of Safety Engineers, representing 30,000 members ("ASSE commends OMB/OIRA for taking a proactive stance to ensure that agencies can readily provide interpretation and guidance of regulations, but still do so in a manner that affords due process to the regulated community and that is in accordance with the requisites of the Administrative Procedure Act, 5 USC 551 et seq.");

-- the National Funeral Directors Association, representing more than 11,000 funeral homes in all 50 states ("NFDA supports the Office of Management and Budget (OMB) proposal to establish standards to increase the quality and transparency of agency guidance practices and the guidance documents produced through them.");

-- the Association of Metropolitan Planning Organizations ("In general, AMPO strongly supports the Proposed Bulletin's intent and reliance on the guidance practices adopted by the Food & Drug Administration ('FDA**')** at 21 C.F.R. **5** 10.115.");

-- the Ornithological Council, which consists of eleven leading scientific ornithological societies - the American Ornithologists' Union, Association of Field Ornithologists, CIPAMEX, Cooper Ornithological Society, Neotropical Ornithological Society, Pacific Seabird Group, Raptor Research Foundation, Society of Canadian Ornithologists/La Société des Ornithologistes du Canada, Society for Caribbean Ornithology, Waterbird Society, and Wilson Ornithological Society - that together have a membership of nearly 6,500 ornithologists ("we would like to express our gratitude to OIRA for its efforts to improve agency guidance practices");

-- the Aircraft Owners and Pilots Association, representing over 407,000 members ("AOPA shares OMB's concern that agency guidance practices should be more transparent, consistent and accountable. We also agree with OMB that the absence of procedural review mechanisms undermines the lawfulness, quality, fairness and accountability of agency policymaking.");

-- the National Leased Housing Association, which represents the interests of housing agencies, developers, lenders, housing managers and others in providing federally assisted rental housing, and whose members are primarily involved in the Section 8 housing programs and are involved with the operation of rental housing for over three million families ("we commend OMB for its efforts");

-- the American Road and Transportation Association, whose membership includes public agencies and private firms and organizations that own, plan, design, supply and construct transportation projects throughout the country ("Once again, ARTBA is extremely supportive of the GGP and feels that it represents a significant step forward in the regulatory process. It will engender fairness and improved dialogue between agencies and those that have a vital stake in the guidance they issue. ARTBA and our members are eager to take advantage of the new opportunities for involvement in the guidance process offered by the GGP and help OMB make the GGP standard agency practice."); and

-- the Associated Equipment Distributors, representing 1,200 construction equipment distributors, manufacturers and industry-service firms (" Our association thanks the Office of Management and Budget (OMB) for recognizing the impact that guidance material issued by federal regulatory agencies has on the regulated community. We agree with the OMB that transparency in the guidance drafting process is critical, as guidance should not be used for rulemaking.").

As I have indicated, the comment letters from these associations can be found on OMB's website, along with the other comment letters on the proposed bulletin.[27]

On January 18th of this year, after considering the public comments and after further consultation with Federal agencies, the OMB Director issued the Final Bulletin on Agency Good Guidance Practices.[28] The final version of the Bulletin is very similar to the proposal in its overall framework, but – as OMB explained in the preamble to the final Bulletin -- OMB made a number of improvements to the Bulletin in response to comments that we received from the public and during the interagency review process.

The following are a few of the noteworthy provisions of the Bulletin, which reflect the requirements of the FDA's Good Guidance Practices regulation and are designed to improve the quality, transparency, public participation, and accountability of agency guidance documents:

- Each agency will ensure (as agencies should be doing anyway, as a matter of good internal management) that appropriate officials within the agency have reviewed and approved the agency's issuance of "significant" guidance documents;

- Agencies will maintain on their websites current lists of their "significant" guidance documents that are in effect, so that the public can know what guidance applies to them;

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[27] OMB also received comments, some supporting and others opposing the proposed bulletin, from the following (in alphabetical order): the Aeronautical Repair Station Association, the American Bar Association, the American Chemistry Council, the American Composites Manufacturers Association, the American Petroleum Institute, AMGEN, C. Blake McDowell (Professor of Law), Citizens for Sensible Safeguards (OMB Watch), Coalition for Effective Environmental Information, Consumer Specialty Products Association, General Electric Company, Keller and Heckman LLP, McKenna Long & Aldridge LLP, Mercatus Center, National Mining Association, Natural Resources Defense Council, PIMA County (AZ) Wastewater Management Department, Regulatory Checkbook, Sanofi-aventis, Stuart Shapiro Ph.D. (Edward J. Bloustein School of Planning and Public Policy, Rutgers University), U.S. Chamber of Commerce.

[28] OMB Memorandum M-07-07 (January 18, 2007), which is found on OMB's website. The final Bulletin is published in the Federal Register at 72 FR 3432 (January 25, 2007).

- Agencies will provide the public with access to and the opportunity to provide feedback on their "significant" guidance documents. Agencies will advertise on their websites a means for the public to submit comments electronically on these guidance documents; and

- For those guidance documents that are "economically significant" (e.g., , a guidance document that "may reasonably be anticipated to lead to an annual effect on the economy of $100 million or more"), agencies will publish drafts of the documents in the Federal Register, invite public comment on them, and prepare responses to the comments before finalizing the guidance.

In recognition of the potentially broad range of guidance documents that are issued by Federal agencies, the Bulletin also (1) includes certain express exclusions from the definition of "significant" and "economically significant" guidance document; (2) authorizes OMB to exempt "economically significant documents" (singly or by category) from the requirement for *prior* public comment before issuance; and (3) includes an express exception from the Bulletin's requirements for "emergency situations or when an agency is obligated by law to act more quickly than normal review procedures allow."

In light of concerns that have been raised about the final Bulletin and the Executive Order, this last point bears emphasis. The Bulletin does *not* stand in the way of a Federal agency responding appropriately to an emergency situation. In addition, the Bulletin does *not* override a Federal agency's obligation to comply with applicable laws.

Executive Order 13422

The Executive Order's Guidance Provision

In the furtherance of its goal to improve the guidance documents that Federal agencies develop and issue, the Bulletin is reinforced by the principal provision in Executive Order 13422, which the President issued, also on January 18th. Through an amendment to Executive Order 12866, which President Clinton issued in 1993, the recent executive order provides for a relatively informal process whereby *some* – but by *no* means all – of the "significant guidance documents" that are developed by Federal agencies will be submitted to OMB for interagency review.

It is important to underscore the point that this amendment provides for an *opportunity* for interagency review, and therefore that guidance documents are *not* treated the same as regulations. When he issued Executive Order 12866 in 1993, President Clinton directed agencies to submit the drafts of all of their "significant" regulations to OIRA for review (subject to certain limited exceptions). By contract, agencies are *not* required under the recent amendments to submit all of their "significant" guidance documents to OMB for review. Instead, the recent executive order requires agencies to *inform* OMB of upcoming significant guidance documents, which thereby provides an *opportunity* for interagency review to occur.

In this regard, just as the new Bulletin directs agencies to follow good guidance practices that, to a greater or lesser extent, are probably being followed by many agencies for many of their guidance documents (e.g., posting them on the agency's website), the recent Executive Order -- in recognizing the desirability of ensuring an *opportunity* for interagency review -- also reflects a practice that already happens in a number of situations.

In other words, interagency review of important guidance documents is *not* new. And, one reason why such review is desirable, and already happens, is because the programs and activities of one Federal agency often overlap or have implications for the programs and activities of one or more other Federal agencies. For example, in June of last year, the Department of Health and Human Services (HHS) issued a State Medicaid Director letter that provides guidance on the implementation of the provision in the Deficit Reduction Act of 2005 that requires individuals claiming U.S. citizenship to provide – when initially applying for Medicaid or upon the first redetermination – satisfactory documentary evidence of citizenship or nationality. Before HHS finalized and issued this guidance, OMB ensured that HHS consulted first with affected and interested agencies – the Departments of State and Homeland Security, and the Social Security Administration. This interagency consultation, which took place in a two-week period, ensured that HHS had the benefit of the expertise and experience of these other agencies and that the HHS guidance took into account the interests and programs of these agencies.

This *interagenc*y coordination, then, had the effect of improving the quality of the HHS guidance in the same way that the quality of guidance can be improved through *public participation* and *internal-agency review and approval*.[29] Thus, by ensuring that there is an *opportunity* for interagency review, this amendment made by Executive Order 13422 serves as a complement to the requirements in the OMB Bulletin for public participation and internal-agency review and approval.

In addition, as OMB explained in March 2002, interagency review of a guidance document is also justified because "interagency review can ensure that agency action is consistent with Administration policy and is beneficial from a broader, societal perspective."[30] This type of review during the development of agency *guidance documents* is entirely appropriate, for the same reason that the courts have held that it is appropriate to conduct this same type of review during the development of agency *regulations*. As the United States Court of Appeals for the District of Columbia Circuit explained in 1981 (in an opinion by Judge Wald):

> "The court recognizes the basic need of the President and his White House staff to monitor the consistency of executive agency regulations with Administration policy. He and his White House advisers surely must be briefed fully and frequently about rules in

[29] OMB made this same general point in March 2002 when OMB asked the public to identify examples of "problematic guidance documents" that would be potential candidates for reform. Office of Management and Budget, Draft 2002 Report to Congress on the Costs and Benefits of Federal Regulations, 67 FR 15014, 15035 (March 28, 2002) ("problematic guidance might be improved by interagency review").

[30] Office of Management and Budget, Draft 2002 Report to Congress on the Costs and Benefits of Federal Regulations, id., 67 FR at 15035.

the making, and their contributions to policymaking considered. The executive power under our Constitution, after all, is not shared -- it rests exclusively with the President.

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"The authority of the President to control and supervise executive policymaking is derived from the Constitution; the desirability of such control is demonstrable from the practical realities of administrative rulemaking. Regulations such as those involved here demand a careful weighing of cost, environmental, and energy considerations. They also have broad implications for national economic policy. Our form of government simply could not function effectively or rationally if key executive policymakers were isolated from each other and from the Chief Executive. Single mission agencies do not always have the answers to complex regulatory problems. An overworked administrator exposed on a 24-hour basis to a dedicated but zealous staff needs to know the arguments and ideas of policymakers in other agencies as well as in the White House."

Sierra Club v. Costle, 657 F.2d 298, 404, 405-06 (D.C. Cir. 1981). In that decision, the D.C. Circuit upheld the appropriateness of discussions between the White House and the Environmental Protection Agency, regarding a draft Clean Air Act rule. These discussions took place -- and EPA issued the rule -- in 1979, during the Administration of President Carter.

The Executive Order's Non-Guidance Provisions

In addition to providing an opportunity for interagency review of draft guidance documents, the recent Executive Order makes several (non-guidance related) process improvements. As is the case with the guidance amendments in the Executive Order and the new Bulletin, these process improvements are designed to encourage good-government practices. Because there has been some confusion in the press and elsewhere as to the meaning and impact of these changes, let me briefly go through them.

i. Regulatory Policy Officers

Concerns have been raised about the provisions in Executive Order 13422 regarding Regulatory Policy Officers. The initial point that should be made is that such officers are *not* new; when he issued Executive Order 12866 in 1993, President Clinton directed each agency head to designate a Regulatory Policy Officer within the agency. Nor is it new that, under the recent amendment, these Regulatory Policy Officers will be Presidential appointees. While the original EO 12866 did not require that agency heads choose a Presidential appointee to be the agency's Regulatory Policy Officer, the fact is that, in many departments and major agencies, the Regulatory Policy Officer has been a Presidential appointee.

And, I should note that the term "Presidential appointee" should not be confused with "political appointee." Presidential appointees are appointed by the President, whereas agency heads appoint "political appointees" who are in the non-career Senior Executive Service or are under Schedule C; these agency-head appointees are *not* Presidential appointees. Moreover, neither the President nor an agency head can create a Presidentially-appointed position in an

agency. Rather, only Congress can do so. And, when Congress does create a Presidentially-appointed position in an agency, Congress usually provides that this appointee shall be subject to Senate confirmation (a PAS official). Thus, by requiring that agency heads designate a Regulatory Policy Officer from among the agency's Presidential appointees, the President is actually ensuring that, in most cases, the Regulatory Policy Officer will be a PAS official.

In addition, concerns have been raised that Executive Order 13422 may require each agency to establish a new "Regulatory Policy Office" that would be headed by the agency's Regulatory Policy Officer. I would like to allay such concerns by explaining that this reference to a Regulatory Policy "Office" was a typographical error. The reference should have been to a Regulatory Policy "Officer" rather than "Office"; the Executive Order will be implemented accordingly.

ii. Commencement of a Rulemaking

Executive Order 13422 amends Executive Order 12866 to require that an agency's commencement of a rulemaking either be authorized by the agency head or be approved by the agency's Regulatory Policy Officer. As explained above, most if not all of the Regulatory Policy Officers will be -- as they generally have been over the years -- Presidential appointees who are subject to Senate confirmation. In practice, then, this will mean that, in most if not all cases, an agency's commencement of a rulemaking will be authorized or approved by an agency official who is appointed by the President and subject to Senate confirmation.

iii. Aggregation of annual costs and benefits in the Regulatory Plan

Section 4 of President Clinton's Executive Order 12866 established a "Planning Mechanism" that includes an annual *Regulatory Plan* that reports the most significant regulatory actions anticipated in the coming year and thereafter, along with the agency's estimate of each rule's anticipated benefits and costs. Executive Order 13422 amends this section to ask agencies, in addition, to aggregate the estimated costs and benefits of the individual regulations. While the interested public could always sum-up for themselves the cost and benefit estimates for each of the individual rules, this amendment enhances the transparency of the annual *Regulatory Plan* by requiring the agencies to do the aggregation.

iv. The Encouragement of Agencies to Consider Formal Rulemaking

Another of the amendments in Executive Order 13422 encourages rulemaking agencies to consider using the Administrative Procedure Act's formal – rather than informal – rulemaking procedures for the agency's resolution of complex determinations. Agencies already had the option of using the APAs' formal rulemaking procedures, and this amendment simply encourages them to consider the use of a tool that has been – and remains – available to them.

v. Market Failure

Executive Order 13422 amended Section 1(b)(1) of Executive Order 12866, which was – and remains – the first of that Order's "Principles of Regulation." As recently amended, Section

1(b)(1) now states that: "Each agency shall identify in writing the specific market failure (such as externalities, market power, lack of information) or other specific problem that it intends to address (including, where applicable, the failures of public institutions) that warrant new agency action, as well as assess the significance of that problem." Before explaining what this amendment *does* do, I would like to explain first what it does *not* do.

First, the concept of market failure is *not* new to this amendment, but instead has been an integral part of Executive Order 12866 since President Clinton issued it in 1993. Indeed, the overarching "Statement of Regulatory Philosophy," in Section 1(a) of the original Executive Order 12866 (*unchanged* by EO 13422), states that "Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as *material failures of private markets* to protect or improve the health and safety of the public, the environment, or the well-being of the American people" (italics added). Furthermore, the first "Principle of Regulation" that was articulated in Section 1(b) of the original Executive Order 12866 reiterated the requirement that each agency "identify the problem that it intends to address (*including, where applicable, the failures of private markets or public institutions that warrant new agency action*) as well as assess the significance of that problem" (italics added).

Second, the recent Executive Order does *not* make the identification of a market failure the only basis on which a Federal agency can justify regulatory action. The revised section also encourages agencies to identify any "other significant problem it intends to address." For example, recent regulations to provide disaster assistance to victims of Hurricane Katrina provide important social benefits, but do not address a market failure, per se. Moreover, the recent Executive Order leaves untouched the provision in Executive Order 12866 that expressly directs Federal agencies to "promulgate . . . such regulations as are required by law, [or] are necessary to interpret the law." In many cases, when a Federal agency is issuing a regulation, the agency is doing so for just those law-based reasons, and this will continue to be the case; nothing in Executive Order 13422 changes this.

Having explained what the revised "market failure" language does *not* do, I would like to now explain what it actually *does* do, which is two relatively modest things.

First, Executive Order 13422 states that the agency "shall identify *in writing*" the problem -- whether it is a market failure "or other specific problem" – that the agency "intends to address" through regulatory action. Stating explicitly that Federal agencies shall identify "in writing" the problem that the agency is seeking to remedy through regulatory action does *not* impose a new requirement on rulemaking agencies. As an initial matter, an agency should already have been identifying in writing the precise nature of the problem that the agency is seeking to remedy through regulatory action, *in order to assist the agency in its own analysis of whether regulatory action is warranted and, if so, which of the available regulatory alternatives would best accomplish the agency's intended result.*

Thus, in order to comply with the original version of Section 1(b)(1) of Executive Order 12866, agencies as a practical matter would have had to make (or at least should have made) this identification in writing. However, even if an agency did not do so, the agency should still have

identified the problem that it was seeking to remedy through regulatory action in the preamble to the proposed rule (to assist the public in understanding the agency's proposal and in offering their comments on it) as well in the preamble to the final rule (to persuade the public, Congress, and the courts that the agency has exercised its regulatory authority in a reasonable and well-considered manner). In sum, the requirement that agencies identify the need for the regulation in writing is a good-government measure. It encourages greater transparency in rulemaking, by helping the public and others understand the problem the regulation is intended to address, enabling more informed comment on whether the proposed rule will likely meet its objectives and whether there are other, better alternatives to address the identified problem.

Second, in order to increase the transparency of Executive Order 12866, Executive Order 13422 incorporates into Executive Order 12866 a reference to three classic textbook examples of what constitutes a "market failure" – namely, externalities (which justify, e.g., the regulation of pollution), market power (which justify, e.g., the regulation of the rates charged by natural monopolies, such as local gas and electricity distribution services), and lack of information (which justify, e.g., the nutritional labeling requirements for packaged foods). These three examples of market failure are *not* new to the Executive Branch's implementation of Executive Order 12866. To the contrary, three years after President Clinton issued Executive Order 12866 in 1993, these examples were included in the discussion of "market failure" that was contained in the 1996 "Economic Analysis of Federal Regulations under Executive Order No. 12866" document that former OIRA Administrator Sally Katzen (working with former CEA Chairman Joseph Stiglitz) issued to Federal agencies for their use in meeting the analytical requirements of Executive Order 12866 (as well as those of the Unfunded Mandates Reform Act and the Regulatory Flexibility Act).[31]

In its Part I on "Statement of Need for the Proposed Action," the 1996 "Economic Analysis" document had a Section A on "Market Failure," which provided separate descriptions of "Externality", "Natural Monopoly," "Market Power," and "Inadequate or Asymmetric Information." The 1996 "Economic Analysis document also included the following introductory discussion:

> "I. STATEMENT OF NEED FOR THE PROPOSED ACTION
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> "In order to establish the need for the proposed action, the analysis should discuss whether the problem constitutes a significant market failure. If the problem does not constitute a market failure, the analysis should provide an alternative demonstration of compelling public need, such as improving governmental processes or addressing distributional concerns. If the proposed action is a result of a statutory or judicial directive, that should be so stated.

[31] Memorandum for Members of the Regulatory Working Group from OIRA Administrator Katzen, "Economic Analysis of Federal Regulations under Executive Order 12866 (January 11, 1996), available on OMB's website at http://www.whitehouse.gov/omb/memoranda/rwgmemo.html. As Administrator Katzen stated in her transmittal memorandum, the "Economic Analysis" document "represents the results of an exhaustive two-year effort" by an interagency working group chaired by Joseph Stiglitz of the Council of Economic Advisers and Steve Kaplan, the-then General Counsel of the Department of Transportation.

"A. Market Failure

"The analysis should determine whether there exists a market failure that is likely to be significant. In particular, the analysis should distinguish actual market failures from potential market failures that can be resolved at relatively low cost by market participants. Examples of the latter include spillover effects that affected parties can effectively internalize by negotiation, and problems resulting from information asymmetries that can be effectively resolved by the affected parties through vertical integration. Once a significant market failure has been identified, the analysis should show how adequately the regulatory alternatives to be considered address the specified market failure."

Moreover, the three examples of market failure that are now referenced in the amended Executive Order 12866 (i.e., externality, market power, and lack of information) were contained in the draft Circular on regulatory cost-benefit analysis that OMB issued for public comment and peer review in 2003, and they are contained in the final Circular A-4 that OMB issued later that same year (and which remains in effect).[32]

And, thus, the use of these three market failure examples in the implementation of Executive Order 12866 is *not* new. Moreover, Executive Order 13422 did *not* substantively change the first "Principle of Regulation" in Executive Order 12866 or how this Principle is implemented by the Executive Branch. Instead, all that happened as a result of Executive Order 13422, with respect to these three examples of market failure, is that they are now mentioned in Executive Order 12866 itself (rather than only in the implementation documents). In other words, the recent amendment has simply increased the transparency of Executive Order 12866.

Some have expressed concern that this amendment to Executive Order 12866 could prevent agencies from issuing regulations to protect public health and safety, but this is not correct. Many of the most significant regulations that agencies issue are, in fact, driven by – and are in response to – market failures. As the 1996 OMB "Economic Analysis" document noted, "[e]nvironmental problems are a classic case of externality," and this Administration has issued a number of significant environmental regulations aimed at addressing environmental externalities, including EPA's Clean Air Interstate Rule (CAIR) and its Non-road Diesel Engines Rule. Similarly, regulations to protect homeland security, such as FDA's recent regulations under the Public Health Security and Bioterrorism Preparedness and Response Act, respond to inadequate private market incentives to respond to potential terror threats.

Another type of market failure that is mentioned in the amendment made by Executive Order 13422 stems from lack of information. An example of a regulation that is justified by the "lack of information" market failure was the Food and Drug Administration's recent regulation that requires the nutritional labels on packaged foods to display the amount of trans-fats in them. This labeling requirement is estimated to have considerable public health benefits, by providing consumers important information with which they can make purchasing decisions. Moreover,

[32] Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations, 68 FR 5492, 5514-15 (February 3, 2003); *Informing Regulatory Decisions: 2003 Report to Congress on the Costs and Benefits of Federal Regulation* (2003), at pages 121-122 (available on OMB's website).

this rule was the subject of a "prompt letter" that former OIRA Administrator John Graham sent to HHS in 2001 encouraging the agency to issue a rule to require the labeling of trans-fats.[33]

Finally, in both the CAIR and trans-fats rules, identification of a market failure, rather than a specific directive from statute, was the driving force behind the issuance of regulations that are expected to have significant public health and quality of life benefits.

Moreover, as noted above, nothing in this amendment to EO 12866 precludes agencies from justifying regulations on grounds other than the failure of private markets. Nor does it preclude agencies from justifying regulations on the ground that Congress has required the agency to promulgate regulations to address a particular situation, on the grounds that the regulations are necessary to interpret the law, or are made necessary by other compelling public need.

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Thank you again for this opportunity to testify. I would welcome any questions that the Subcommittee has.

[33] Letter from OIRA Administrator Graham to the Department of Health and Human Services regarding trans fatty acids (September 18, 2001) (available on OMB's website).