Comments on

OMB's Proposed Bulletin on "Good Guidance Practices"

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Citizens for Sensible Safeguards, a coalition of public interest groups which, together, represent millions of members nationwide, offers these comments in response to OMB's Nov. 30, 2005 notice in the *Federal Register*[1] inviting comments on OMB's Proposed Bulletin on "Good Guidance Practices."[2]

The public interest organizations working in partnership under the Citizens for Sensible Safeguards banner believe that the federal government has a vital role to play in protecting the public. "We, the people" create and use government institutions to accomplish shared goals. The unparalleled aggregation of resources that we have in our federal government entails a responsibility to use those resources to identify unmet needs and to act so that long-resolved problems do not erupt into new crises. FDR explained it best in one of the Fireside Chats: "It goes back to the basic idea of society and of the nation itself that people acting in a group can accomplish things which no individual acting alone could even hope to bring about."[3] The federal government is a powerful way for the people to act on a national basis to meet national needs.

Accordingly, the organizations in Citizens for Sensible Safeguards understand that sound policy — whether workplace health and safety, environmental protection, consumer safety, income security, adequate investment in social services, or other public protections — requires public institutions that balance efficiency and process, participation and expertise, flexibility and accountability. We take an interest in any proposed government-wide policy that would upset that delicate balance, unduly burden the agencies charged with protecting the public, and prevent the federal government from meeting the public's needs.

OMB's Proposed Bulletin is the latest in a series of government-wide process changes that upset that balance, distorting government priorities and hindering the ability of federal agencies to fulfill their congressionally mandated duty to protect the public. Under the guise of well-meaning good government principles, OMB has aggressively pushed radical policies over the last five years that have undermined the very role of government itself. In the name of accountability, OMB published guidance on cost-benefit analysis that forces agencies to place the interests of industry above public needs, putting the most vulnerable at even greater risk. In the name of sound science, OMB has opened fire on established scientific research with its approach to implementation of the Data Quality Act. Now, in the name of public participation, OMB proffers the Proposed Bulletin on Good Guidance Practices, a seemingly innocuous measure that will only further ossify government by making the issuance of guidance as burdensome and draining on agency resources as the rulemaking process has become.

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1. *See* Proposed Bulletin for Good Guidance Practices, 70 Fed. Reg. 71,866 (Nov. 30, 2005).

2. *See* OFFICE OF INFO. & REG. AFFS., OMB, PROPOSED BULLETIN FOR GOOD GUIDANCE PRACTICES (2005), *available at* <http://www.whitehouse.gov/omb/inforeg/regpol/good_guidance_preamble.pdf> (hereinafter "Proposed Bulletin").

3. *See* FDR, Fireside Chat, July 24, 1933.

We do agree that transparency and public participation are important goals. Accordingly, while we believe that there are better ways to achieve the goals of the public input and transparency requirements in § III of the Proposed Bulletin, we have no quarrel with the substance of that part of OMB's proposal. Our objections are instead focused on the unduly burdensome requirements in § IV of notice and comment for "economically significant" guidance documents, and we have some additional concerns about the potential for unnecessary politicization in the requirement of high-level review in § II.

Our comments have three major points to make:

1. The Proposed Bulletin is a solution in search of a problem. OMB claims that agencies are using general policy statements, handbooks, manuals, compliance guides, nonlegislative rules, and other informal matter as a vehicle for policy edicts that should go through the APA's notice-and-comment rulemaking process. Instead of taking the opportunity to improve the rulemaking process, OMB throws the baby out with the bathwater by adding new burdens to the production of information that the public needs.

2. The Proposed Bulletin is a roadmap for government that is less responsive to the public's needs. OMB would gain new power to intervene in day-to-day agency functions out of the public eye, while the public would also be left in the dark about agency policy. The Proposed Bulletin would force an unmanageably vast universe of distinct types of materials into a one-size-fits-all policy that, in the name of consistency, will threaten the consistency with which agency field offices implement government programs. The requirement that agencies subject guidance documents in high-profile issues to political review could result in the kind of inefficient bottleneck that is the hallmark of government mismanagement.

3. The Proposed Bulletin represents an unacceptable power grab by the White House. The principles and traditions of the American political order abhor the excessive centralization of authority that OMB would achieve with the Proposed Bulletin, which contravenes Congress's role in delegating responsibility and discretion to the agencies and assumes the right to amend the Administrative Procedure Act by executive fiat.

Finally, although we do not endorse the Proposed Bulletin and believe it is an inappropriate arrogation of power to the White House, we anticipate OMB's rejection of our arguments to set aside the Proposed Bulletin and offer, under protest, suggestions for reducing the risk of damage to public protections.

I. OMB'S PROPOSED BULLETIN IS A SOLUTION IN SEARCH OF A PROBLEM.

Agencies do not promulgate requirements for the sake of promulgating requirements. Government programs are purposive institutions created by democratically elected representatives and their agents to respond to the public's needs. When agencies use the authority granted to them by Congress to make decisions or create protective standards, they do so not for the abstract pleasure of exercising power but, rather, for the vital purpose of protecting the public.

The Proposed Bulletin is blind to the role of government in meeting the public's needs, and that blindness leaves OMB stumbling in the wrong policy directions. Starting with the questionable empirical claim that agencies are using guidance documents to announce requirements that should instead be legislative rules produced in accordance with the APA, OMB proceeds to an even more questionable response: clamping down on agencies' ability to develop guidance documents. Even if there is a problem with the impermissible use of guidance documents, the right solution should be to remove obstacles to the use of the regulatory process. Instead of making sure that government programs have the tools they need to serve the public, OMB has opted to make it increasingly difficult for agencies to do anything for the public.

Many of the organizations in Citizens for Sensible Safeguards have seen agency letters, preambles, handbooks, and other informal documents include assertions and policy changes that threaten public protections while avoiding the APA process.[4] Likewise, we have seen corporate special interests challenge such materials as part of a sequence of efforts to slow agencies down from promulgating and enforcing regulations that cost them money to comply with. We do not have sufficient information — and OMB certainly has not provided it — to know whether there really is a widespread pattern in need of an across-the-board solution of the sort OMB proposes. Moreover, we do know that there are ways to pursue solutions to any such problem, which include advocating better practice from agency staff, litigating impermissible policy making, or asking Congress to legislate a targeted answer.

Even if OMB's unproven empirical claim were true, a pattern of agency efforts to avoid notice-and-comment rulemaking in favor of subterfuge rulemaking via guidance suggests a need for altogether different solutions than those proffered in the Proposed Bulletin. Instead of preventing agencies from giving the public the information or protective standards it needs, OMB should carefully examine the length of time it takes for an agency to finish a rule and whether the many additional analytical requirements that have accreted to the regulatory process — what law professor Peter Strauss calls the "tertium quid" of the regulatory process[5] — constitute the real problem that needs to be addressed. Although a few analytical requirements call on agencies to ask themselves whether they are doing the

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4. For example, as recently as December 13, 2005, the U.S. EPA issued guidance contravening the Clean Air Act, at industry's behest, that does not require consideration during the permitting process of whether a new power plant should use clean coal technology (known as integrated gasification combined cycle), instead of conventional coal-burning techniques. Such guidance will have the effect of undermining our clean air and contravenes Congress's intent under the new energy law to incentivize the use of such technology.

5. Peter L. Strauss, *The Rulemaking Continuum*, 41 DUKE L.J. 1463 (1992).

best they can for the environment or the most vulnerable members of the public, most proceed from the assumption that agency action is probably unwarranted and must be justified. The following is just a partial list:

- **E.O. 12,866:** By far the most onerous executive order, E.O. 12,866 requires agencies to determine if the rule is a "significant regulatory action," meaning it has a significant impact on the economy or overall social cost of more than $100 million or is otherwise deemed significant by the agency or OMB. If so, the agency must prepare Regulatory Impact Analysis (RIA), detailing the costs and benefits of the regulation.

- **E.O. 13,045:** If the rule is economically significant, the agency must also prepare an evaluation of the environmental health or safety effects of the proposed rule on children and explain why the proposed rule is preferable to alternatives under E.O. 13,045.

- **Congressional Review Act:** The Congressional Review Act mandates that rules that have a significant impact on the economy or impose costs of over $100 million per year must be submitted to Congress with accompanying analysis before the rule can go into effect.

- **Unfunded Mandates Reform Act:** Agencies must also determine if the proposed rule will cause expenditures of more than $100 million by state, local or tribal governments, or the private sector. If so, the agency must analyze the costs and benefits of the rule and identify alternatives to the rule that would impose fewer burdens.

- **E.O. 13,132:** As if UMRA does not require enough, E.O. 13,132 requires agencies to determine the federalism implications of a proposed rule. If the rule has federalism implications and either imposes significant direct compliance costs on states or preempts state law, the agency must prepare a "federalism summary impact statement," including a summary of state and local officials' concerns about the proposed rule and the agency's position supporting the need for the regulation and a statement of the extent to which state and local concerns have been met.

- **Regulatory Flexibility Act:** Under the Regulatory Flexibility Act, agencies are required to determine if the rule will have a significant economic impact on a substantial number of small

entities. If so, the agency must prepare an initial Regulatory Flexibility Act analysis, detailing the impact of the rule on small entities, including an estimate of the number of small entities that will be affected, a description of information collection requirements on small entities, an explanation of measures taken to minimize burdens on small businesses, an explanation of why the rule was chosen and why alternatives were rejected. If the rulemaking does not impose a significant impact on a substantial number of small entities, the agency must certify and provide a factual basis for the conclusion.

- **Paperwork Reduction Act:** If the rule requires submissions of information by 10 or more persons, the agency must submit an information collection request including information necessary for OMB to determine if the information collection is necessary for the proper performance of the agency's function. If changes are made between the proposed and final rule, the agency may have to resubmit the information collection request before the final rule can take effect.

- **Trade Agreements Act of 1979:** Title IV of the Trade Agreements Act of 1979 requires agencies to determine if the rule sets a standard that creates an unnecessary obstacle to foreign commerce. If so, the agency may be required to use performance rather than design standards where appropriate. The agency must also consider and, where appropriate, use international standards.

- **E.O. 12,630:** If the proposed rule regulates private property for the protection of public health or safety, the agency must identify the public health and safety risk created by property use under E.O. 12,630. The agency must establish that the proposed rule substantially advances protecting the public from such risk and that the restrictions on property use are not disproportionate to the extent to which the property use contributes to the risk. The agency must also estimate the potential cost to the U.S. government if a court were to find the restriction a taking.

- **E.O. 13,211:** If rules have a significant energy impact, meaning the rule is a significant rule under E.O. 12,866 and is likely to have an adverse impact on the supply, use or distribution of energy or is otherwise considered to have a significant energy impact by OMB, then the agency is required to write an Energy Impact Statement, including an analysis of adverse

> effects and any feasible alternatives, and submit the statement to OMB.

Some statutes also build in yet more analytical requirements specific to a particular area of regulatory activity, such as effluent controls.[6]

The evidence available suggests that these requirements have induced paralysis by analysis. As has repeatedly been observed, the average time from 1974 to 1992 for FTC final rules to reach finality after their initial proposal was 63 months. [7] Likewise, the Occupational Safety and Health Administration has slowed significantly over the years as new burdens have been added:

> [OSHA] in 1972 spent about six months from inception to publication of the final rule on its first occupational health standard for asbestos. Two of its next three health standards, a generic rule for fourteen carcinogens and a standards for vinyl chloride, took about one year, and nine months, respectively. The next three standards, for cotton dust, acrylonitrile, and arsenic, each took over three-and-one-half years. These last three standards were promulgated during the relatively activist Carter Administration when OSHA was anxious to write new rules to protect workers. Today, OSHA health standards rarely take less than five years to promulgate.[8]

This pattern is so widespread that it has given rise to an apt characterization of the regulatory process as "ossified."

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6. *See, e.g.*, Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L.J. 1385 (1992):

> [W]hen EPA promulgates regulations establishing national effluent limitations for industrial point source categories based on the "best conventional control technology," it must demonstrate that it has analyzed the cost of taking a unit of pollution out of an industrial effluent stream using the prescribed technology in comparison with the cost of removing an equivalent unit of pollution from a municipal sewage treatment works. The agency must also compare the incremental cost of the prescribed technology with the incremental cost of installing somewhat less stringent "best practicable control technology." It must also analyze the age of equipment and facilities involved, the process employed, the engineering aspects of the application of various types of control techniques, process changes, and the non-water quality environmental impact (including energy requirements) . . . .

Id. at 1403-04.

7. *Id*. at 1389 n.22.

8. *Id*. at 1387-88.

We need government programs to be able to act on behalf of the public. The unparalleled aggregation of resources that we have in our federal government entails a responsibility to use those resources to identify our unmet needs and to act so that long-resolved problems do not erupt into new crises. OMB has already burdened the regulatory process so that agencies cannot quickly respond to the public's need for protective standards. If there is a problem with agencies failing to use the regulatory process, it is the fruit of OMB's own aggressive policies that undermine the role of government. OMB should offer solutions that make government agencies better equipped to address the public's needs, not less able to provide information to the public.

II. OMB'S PROPOSED BULLETIN WILL MAKE GOVERNMENT LESS EFFECTIVE AT SERVING THE PUBLIC'S NEEDS.

As usual, OMB masks the risks of its latest government-wide proposal with good government principles. OMB offers the Proposed Bulletin as a solution for its concern that "agency guidance practices should be more transparent, consistent, and accountable."[9] Such concerns, as well as the public's right to participate in important decisions, are important concerns that we all share. These concerns do not, however, exist without a context. The bottom line for questions of government management is not management itself but, rather, meeting the public's needs. However much we talk about good government, a government that is not responsive to the public's needs is not good enough.

The Proposed Bulletin is a roadmap for mismanagement of government. Despite touting transparency, consistency, and accountability, the Proposed Bulletin poorly serves the good government goals it claims to achieve. Instead, OMB's Proposed Bulletin will make government less transparent, impose the wrong kind of consistency at the expense of a consistency that the public needs, and burden the agencies' achievement of the very responsibilities for which they should be held accountable.

A. The Proposed Bulletin will apply a crude one-size-fits-all policy to an unmanageably immense universe of materials.

No one is opposed to "consistency" *qua* consistency. Nonetheless, consistency alone cannot justify a wide-ranging government process change unless it will create a needed consistency that improves the government's ability to protect the public. The problem with the Proposed Bulletin is that it does not justify the kind of consistency it intends to impose while robbing the public of a kind of consistency it has come to expect with guidance documents.

The Proposed Bulletin's definition of affected guidance documents notionally limits the scope of the Proposed Bulletin while actually applying new burdens to an immense universe of agency materials. OMB's Proposed Bulletin defines the materials subject to the new "good guidance practices" requirements as

9. Proposed Bulletin, *supra* note 2, at 2.

(1) a document produced by an agency other than an independent agency
(2) that is public or subject to the Freedom of Information Act
(3) and is neither a rulemaking or an adjudication,
(4) that describes an agency's
(5) *interpretation of* or *policy on*
(6) a *regulatory* or *technical* issue
(7) and *may*
  (a) raise "highly controversial issues,"
  (b) implicate "important" Bush administration priorities,
  (c) provide initial interpretations of statutory or regulatory requirements,
  (d) announce changes in previous interpretations or policies,
  (e) address "novel or complex *scientific* . . . issues,"
  (f) address "novel or complex . . . *technical* issues," or
  (g) be "economically significant" by being reasonably anticipated to
    (i) "lead to an annual effect of $100 million or more" or
    (ii) "adversely affect in a material way the economy or a sector of the economy."[10]

The term "guidance documents" would suggest a focus on materials like compliance guides, but this definition is incredibly capacious, sweeping in an immense universe of diverse materials, the sheer volume of which would overwhelm agencies forced to apply these new requirements. The definitions of "significant guidance documents" and "economically significant guidance documents" are so broad that they could result in any or all of the following scenarios:

- The Department of Labor is called upon frequently to offer guidance to workers and employers. Between 1996 and 1999, DOL "issued 3,374 guidelines, manuals, policy statements, handbooks and such that qualified as guidance." [11] Any subset of that output would still be substantial. For example, between 2001

10. *Id.* § I at 9 (emphasis added).

11. Cindy Skrzycki, *Finding a Way to Better Guidance*, WASH. POST, Dec. 20, 2005, at D1.

and 2005, OSHA issued 574 standard interpretations, 300 of which interpreted standards for the construction industry alone. Recent standard interpretations address, *inter alia*, employees' rights upon termination to access to a physician's written opinion and respirator fit test results, whether DOT's labeling requirements for shipments of biohazardous materials suffice in lieu of OSHA's requirements, the requirement that respirator breathing air cylinders must be maintained in a fully charged state, and engineering controls for removal of asbestos-containing construction mastic.

- The Department of Labor's Wage and Hour Division is often called upon to "respond to public inquiry about application of the wage and hour laws" — responses that, in the 1970s, averaged "roughly 750,000 letters each year," none of which are "in themselves binding on the public" but merely "indicate circumstances in which the Division might seek a judicial remedy."[12] An early federal court case determining the standard of review for such letters decided that only the approximately 10,000 of those letters then signed yearly by the administrator would constitute final agency action ripe for APA review, adding that "advisory opinions should, to the greatest extent possible, be available to the public as a matter of routine."[13] Because such letters are interpretations of statutory and regulatory requirements that could, for firms that decide to comply with the advice, generate costs in the $100 million range, they could be subject to exactly the kinds of burdensome requirements that the early court decision wisely declined to incentivize.

- EPA's Risk Screening Environmental Indicators model integrates hazard and exposure data to rank sources of toxic chemical releases.[14] The ranking of toxic chemical

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12. Strauss, *supra* note 5, at 1486.

13. *Id*. at 1486-87 (quoting National Automatic Laundry & Cleaning Council v. Schultz, 443 F.2d 689, 697 (D.C. Cir. 1971)).

14. *See* EPA, Risk Screening Environmental Indicators, *available at* <http://www.epa.gov/opptintr/env_ind/index.html>; *see also* Ken Weinstein, *Committee Co-Sponsors 9th Section Fall Meeting Panel: Rules Versus Guidance*, *available at*

release sources could constitute an interpretation of a technical issue that is "controversial," a "novel or complex scientific . . . issue[]," or a conclusion reasonably anticipated to "adversely affect in a material way" the companies responsible for the toxic releases. The Proposed Bulletin could require EPA to justify its rankings in response to comments filed by the worst polluters.

- The IRIS database, which contains risk information on the effect of toxic chemicals on human health, guides industries on the safe level of exposure to a variety of chemicals. Subjecting this controversial data to peer review and notice-and-comment could cripple the ability of EPA to release this important information on the adverse human health effects of a variety of chemicals. The state, local and federal governments often rely on IRIS data to set regulated exposure limits. Opening up IRIS data to notice and comment could, thus, hinder federal and state agencies from setting appropriate exposure limits.

- The Superfund program relies extensively on guidance documents to carry out the work of cleaning up contaminated sites. The guidance documents give instructions on how to assess and clean up the sites as well as provide important information to the public on the risks of the contaminated area. Relying on notice-and-comment for such a large universe of guidance documents would substantially hamper an already sluggish cleanup program.

- EPA recently introduced the "Arsenic Virtual Trade Show" website (http://www.arsenictradeshow.org/), which gives water utility companies compliance guidance on removing arsenic from drinking water. The website is able to give the regulated industry the latest information on the most cost-effective and efficient means for removing arsenic. If EPA were forced to go through a notice-and-comment period in order to tell industry about better means of compliance, both members of the regulated community and the general public would lose out.

<http://www.abanet.org/environ/committees/pesticides/newsletter/nov01/weinstein.html>.

- The FAA alone "generates approximately 215 feet of domestic and international notices yearly";[15] if even a fraction of that output were subject to the Proposed Bulletin's notice-and-comment process, the FAA would end up diverting substantial resources away from ensuring safety for air travel.

- The National Weather Service not only reports on weather and air conditions but also gives consumers guidance on the best course of action to take in severe weather conditions. NWS heat advisories, for instance, advise the public, especially the young and elderly, when to stay indoors because of severe heat. Instructing individuals to stay indoors potentially has a significant economic impact on businesses, but subjecting heat advisories to a notice-and-comment period would be an absurd and potentially dangerous burden on the NWS with potentially hazardous results for the public.

- U.S. Customs Service ruling letters setting tariff classifications for particular imports, such as determining whether Mead day planners should be classified as bound diaries subject to tariff or in a duty-free class of "[r]egisters, account books, notebooks, order books, receipt books, letter pads, memorandum pads, diaries and similar articles,"[16] would constitute an initial or changed interpretation of statutory and/or regulatory requirements that, in some cases, could result in a company bearing the cost of import tariffs which, combined with the downward pressure on profits and indirect economic effects, could in the hands of an enterprising economic analyst be found to reach $100 million or more. There are 49 different customs offices that, when the Supreme Court reviewed the *Mead* case, issued 10,000 to 15,000 such classifications. These ruling letters could conceivably be subject to full notice and comment.

- The USDA issues notifications to the general public on food preparation, such as advisories that meat and poultry products should be cooked until they reach

15. Strauss, *supra* note 5, at 1469 n.20.

16. United States v. Mead Corp., 533 U.S. 218, 224 (2001).

> specific internal temperatures. If USDA were to update its assessment of doneness temperatures, there could be economic consequences for restaurateurs, cookbook publishers, and manufacturers of meat thermometers. Conducting notice and comment on such changes could make the USDA docket website rival *Gourmet* magazine's web message boards.[17]

The distinct kinds of materials and heterogeneous subject matters that could come within the Proposed Bulletin's reach serve a wide range of public needs and are so diverse that a one-size-fits-all policy like the Proposed Bulletin poses a serious risk of causing more problems than it solves.

OMB has given us reason to believe these risks are significant. Although OMB purportedly based its proposal on existing Food and Drug Administration regulations on guidance practices, it is interesting to note that FDA's regulations expressly exclude changes "that are of more than a minor nature."[18] FDA also expressly rejected ACUS Recommendation 76-5 when it devised its good guidance policy, stating that it would invite litigation and require agencies to respond to matters of limited public interest.[19] It is quite likely that other agencies, which know their issues far better than OMB ever could and thus are far better positioned to evaluate the public's need for timely information, would respond similarly. OMB's one-size-fits-all edict does not give them that chance and ignores FDA's counsel that such a policy is overbroad.

Even assuming that OMB means for the Proposed Bulletin only to apply to compliance guides and other such explanatory materials traditionally referred to as "guidance documents," the Proposed Bulletin threatens to burden the production of valuable information. Agencies often explain how they intend to administer a statute or regulation through interpretive rules[20] and general policy statements that state an agency's tentative but not binding intentions for the future. [21] These explanations can provide structure to an agency's enforcement activities, [22] which in turn can create consistency in enforcement patterns across an agency's regional and program offices and offer the regulated public more clarity:

> The whole point of the exercise is to structure discretion, to provide warning and context for efficient interaction between the agency and

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17. *Available at* <http://www.epicurious.com/forums/>.

18. *See* 21 C.F.R § 10.115(c)(ii).

19. *See* 61 Fed. Reg. 9181, 9183 (Mar. 7, 1996).

20. *See, e.g.*, McCown v. Sec'y of Health & Hum. Servs., 796 F.2d 151, 157 (6th Cir. 1986); New Jersey v. Dep't of Health & Hum. Servs., 670 F.2d 1262, 1281-82 (3d Cir. 1981).

21. *See, e.g.*, American Hosp. Ass'n v. Bowen, 834 F.2d 1037, 1046 (D.C. Cir. 1987).

22. *See* Erringer v. Thompson, 371 F.3d 625, 633 n.15 (9th Cir. 2004).

> the affected public. This is the plain implication of the rationale for [the kinds of materials that the Proposed Bulletin would govern] — and, for that matter, the negative pregnant of section 552(a)(2), forbidding the citation of [them] "against a party other than an agency" unless they have been properly published and indexed.[23]

Even as priorities change from administration to administration, guidance documents can ensure that each incoming administration's approach to technical and policy issues is consistently applied on a fair basis nationwide, so that no member of the public is prejudiced by living in a jurisdiction covered by a field or regional office with either more stringent or less protective inclinations. This kind of consistency is particularly important for *federal* government programs, which are charged with providing national solutions for national needs.

By creating this new one-size-fits-all approach to "guidance documents" across the entirety of the federal government, OMB's Proposed Bulletin threatens to create disincentives to the production of the guidance materials that ensure this kind of valuable consistency. "Requiring internal procedures as the cost of giving advice or creating structure is a cost imposed in every case . . . . Careful attention needs to be paid to the costs of 'mak[ing] an agency reluctant to give [such notice of its views].'" [24] OMB does not appear to have thought through this trade-off.

B. The Proposed Bulletin will leave the public in the dark.

Another ill-conceived trade-off in the Proposed Bulletin is that its supposed transparency gains come at the cost of valuable information the public needs. One consequence of the "structured discretion" discussed above is that the public can have advance notice of an agency's approach to implementing its programs, long before an agency has to issue a warning letter to a Medicaid provider or impose a fine on a polluting company. The requirements of notice and comment and subjecting all guidance documents for approval by political appointees will delay the release of guidance and could create such heavy burdens that agencies will decline to produce the guidance at all.

Such has been the case in California, which has applied its Administrative Procedure Act and a variety of analytical requirements (including a parallel of OMB review) to nonlegislative rules and guidance documents.[25] Even though agencies are "often required to respond quickly to demands for guidance — for example, from a new court decision or a new statute or an emerging problem," agencies cannot provide guidance until the entire burdensome process has concluded. [26] Because of the significant costs and delays, California agencies emphasize case-by-case adjudication instead of

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23. Strauss, *supra* note 5, at 1486.

24. *Id.* at 1487 (quoting Schultz, 443 F.2d at 700 (emendations in original)).

25. *See generally* Michael Asimow, *California Underground Regulation*, 44 ADMIN. L. REV. 43 (1992).

26. *Id.* at 56.

simple prophylactic guidance to reveal their intentions.[27] They often avoid written materials to structure field staff decision making, relying instead on oral presentations at training sessions.[28] Just as likely is that the agencies produce no guidance at all, "thus shifting the burden of uncertainty onto the public."[29]

Meanwhile, OMB is setting itself up for a powerful new role in day-to-day agency affairs that will presumably take place entirely out of the public eye. The Proposed Bulletin requires agencies to consult with OMB before excluding any specific documents or classes of guidance documents from the notice-and-comment process expected of "economically significant" guidance documents. This consultation in case-by-case decisions of the Proposed Bulletin's applicability will give meaning to the Proposed Bulletin that the definitions of the Proposed Bulletin itself fail to provide, but the public will not have access to those backdoor decisions.

C. The Proposed Bulletin uses accountability as an excuse to undermine agency responsibility to protect the public.

Accountability means helping the people maintain control over their own government so that programs and services can continue to meet the public's long-term and emerging needs. Accountability should not, however, be the excuse for policies that so burden the public's agents that they cannot address the public's unmet needs. Given the risk that policies instituted in the name of accountability could come with costs that keep government from being responsive, it is important for any major accountability initiatives to build in reflexivity: checks that count the costs of accountability reforms, assess the performance of performance measurement rubrics, and make sure that reforms are not obstacles in the way of responsive government.

OMB has failed to create accountability controls for the Proposed Bulletin. As we explain above, the Proposed Bulletin will come with opportunity costs and measurable costs in staff time lost and public benefits unduly delayed. Given the high stakes involved, it is noteworthy that OMB has not applied to the Proposed Bulletin the same controls it insists are needed in routine government functioning. Although OMB has promoted the concept of mandatory "sunsets" or expiration dates

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27. *Id*. at 58. This very scenario is, in fact, part of the rationale for the APA's exemption of interpretations and other informal matter from notice and comment. *Accord see* American Mining Cong. v. Mine Safety & Health Admin., 995 F.2d 1106, 1111-12 (D.C. Cir. 1993) (cautioning that agencies' "ability to promulgate [interpretive] rules, without notice and comment, does not appear more hazardous to affected parties than the likely alternative. Where a statute or legislative rule has created a legal basis for enforcement, an agency can simply let its interpretation evolve ad hoc in the process of enforcement or other applications (e.g., grants). The protection that Congress sought to secure by requiring notice and comment for legislative rules is not advanced by reading the exemption for 'interpretive rule' so narrowly as to drive agencies into pure ad hocery—an ad hocery, moreover, that affords less notice, or less convenient notice, to affected parties.").

28. Asimow, *supra* note 25, at 58.

29. *Id*. at 59.

of all government programs,[30] OMB does not recommend any sunset of the Proposed Bulletin and its onerous requirements. OMB has zealously moved to assess the performance of government programs to measure their effectiveness[31] and ordered agencies to compare the costs and benefits of proposed regulations, while the Proposed Bulletin presumes its own effectiveness and builds in no safeguards to assess whether its purported benefits justify the costs. This inconsistency only resolves into coherence when we consider the shortcomings we identify above in section I of these comments: that OMB's Proposed Bulletin is another attack on the positive role of government.

Additionally, although it is not completely clear on the face of the Proposed Bulletin, we are concerned by the possibility that § II(1)(b) could create a political bottleneck in the agencies that could slow down or even politicize the issuance of guidance. The requirement that all "significant" guidance documents be submitted to "senior agency officials" for approval could distort an entire political economy of accountability of actors and significance of action that the informality of guidance documents helps to establish:

> [Notice-and-comment] rulemaking is both a less frequent and a more highly centralized form of rulemaking than is [the publication of informal guidance]. The relationship between these two forms of activity mirrors, within the agency, the relationship between legislation and rulemaking in the larger governmental context. One can imagine a framework of ever-increasing specificity, in which increasing detail is provided by procedures of diminishing rigorousness, adopted by actors of diminishing responsibility. At the apex lies the Constitution . . . . Legislation is more specific, adopted [by elected representatives]. Yet we accept that, in a complex society, [Congress may pass nothing more than] large frameworks for the resolution of issues, leaving their actual resolution in detail to agencies . . . whose political accountability is secured by appointment mechanisms and the possibility of presidential and/or congressional oversight. And the agencies in turn find that complex subjects, required procedures, and the twenty-four-hour day limit the capacities of those at the very top of the agency to deal with their responsibilities; ideally, those at the head take the most important of decisions, creating an internal framework or structure of essential judgments, and then leave the inevitable further details to be worked out by their more numerous and

30. *See* OMB Watch, *White House Demands Power to Restructure Government*, OMB WATCHER, July 11, 2005, *available at* <http://www.ombwatch.org/article/articleview/2916/1/330?TopicID=1>. For more, consult recent OMB Watch testimony on House bills that would implement the White House proposal, available at <http://www.ombwatch.org/regs/2005/testimonyresunsetresults.pdf>.

31. For background and analysis on the White House's performance measurement rubric, the Program Assessment Rating Tool, see Adam Hughes & J. Robert Shull, OMB Watch, *PART Backgrounder*, *available at* <http://www.ombwatch.org/regs/2005/performance/PARTbackgrounder.pdf>.

> expert staff—subject to techniques of control and oversight far more likely to be bureaucratic and procedural than directly political.[32]

The role of guidance documents in this scheme is to serve as "a means for supplying additional detail unreasonable to expect at the level of the agency head, and in a form sufficiently flexible to permit relatively fast and easy change."[33]

The nomenclature OMB has chosen to use in the Proposed Bulletin makes it difficult to predict in advance what really is at stake in § II(1)(b) of the Proposed Bulletin. A "guidance document" is almost any interpretation of a regulatory issue, interpretation of a technical issue, policy on a regulatory issue, or policy on a technical issue; "significant" ones are those that *may* meet elements (7)(a)-(g) that we summarized above,[34] none of which necessarily weeds out routine interpretations and the like for which there is little public value in requiring high-level review but great public value in the timely issuance of such information. Given the immense universe of materials covered by the Proposed Bulletin and the agencies' greater expertise in the issues at stake and the public's relative need for quick publication, it seems prudent for OMB to eliminate this section and allow the agencies to continue making their own decisions about materials that require high-level review, so that a one-size-fits-all policy does not create the risk of a bureaucratic bottleneck preventing the public from receiving the information it needs in a timely manner.

Moreover, agency guidance documents do not escape accountability when they stray from guidance to illegal rulemaking. As we explain below,[35] there are distinct outer boundaries to agencies' discretion in producing guidance, general policy statements, and non-legislative rules. Further, the agencies always remain accountable to Congress, which has the power to limit and expand the agencies' discretion as cases for such changes arise. Instead of creating for itself yet another powerful backdoor role in distorting policy and weakening protective standards for which it is not accountable to anyone, OMB should set aside the Proposed Bulletin on guidance and instead address the problem of paralysis by analysis that prevents agencies from meeting the public's needs.

III. OMB'S PROPOSED BULLETIN IS AN UNACCEPTABLE POWER GRAB.

Even the best of goals can be achieved in the worst of ways. Such is the case with OMB's Proposed Bulletin. Assuming *arguendo* that there is a problem with agencies using guidance documents to impose obligations on the public without being accountable to the public, it is wrong for OMB to legislate by executive fiat and to use the problem as an occasion to arrogate power that Congress has chosen to delegate directly to the agencies and not the White House.

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32. Strauss, *supra* note 5, at 1476-77.

33. *Id.* at 1478.

34. *See* text accompanying note 9 *supra*.

35. *See* text accompanying notes 38-42 *infra*.

OMB's Proposed Bulletin reverses important decisions about administrative law and government management that are now backed with 60 years of precedent. Congress already spoke to the balance of efficiency and process in the Administrative Procedure Act itself, which exempts "interpretative rules, general statements of policy, [and] rules of agency organization, procedure, or practice" from the notice and comment requirements applied to legislative rules.[36] The rationale is that agencies should have the flexibility to announce their intentions for the future, clarify how they will apply or enforce a statute or regulation, and create consistency across field offices in the day-to-day implementation of their work. In exchange for that flexibility, agencies essentially lose the power to bind the public to those decisions (although they can sometimes bind themselves), and reviewing courts will apply not *Chevron* deference but, instead, the lesser degree of respect called for in *Skidmore*.[37] When agencies do need to bind the public with a legislative rule, the stakes for the public are higher, and so they have to go through the APA process but are rewarded with court deference to their decisions.

Moreover, these guidance documents are not published in some completely lawless zone. Interpretive rules cannot be inconsistent with prior legislative rules, else they run the risk of not being applied.[38] They cannot create the substantive requirements that legislative rules can, else they can be rejected as having failed to comply with the APA. [39] Even when they stop short of being complete rules, informal materials that purport to create exceptions to otherwise permissible rules can be tossed aside.[40] In fact, even the flexibility inherent in such documents may have its limits, as courts could reject interpretive rules that are abrupt departures from longstanding practice.[41] Finally, the Freedom

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36. *See* 5 U.S.C. § 553(b)(A).

37. *See, e.g.*, National Railroad Passenger Corp. v. Morgan, 536 U.S. 101, 111 n.6 (2002) (declining to defer to Equal Employment Opportunity Commission's Compliance Manual interpretation of what constitutes continuing violations for purposes of determining timely filing); United States v. Mead, 533 U.S. at 231-34 (declining to accord *Chevron* deference to U.S. Customs Service ruling letters setting tariff classifications for particular imports); Christensen v. Harris County, 529 U.S. 576, 587 (2000) ("Here, . . . we confront an interpretation contained in an opinion letter, not one arrived after . . . notice-and-comment rulemaking. Interpretations such as those in opinion letters — like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law — do not warrant *Chevron*-style deference. Instead, [they] are entitled to respect under our decision in *Skidmore*[,] but only to the extent that [they] have the power to persuade.") (citations and quotation marks omitted); EEOC v. Arabian American Oil Co., 499 U.S. 244, 257 (1991) (declining to apply *Chevron* deference to EEOC interpretive guidelines); Martin v. Occupational Safety & Health Rev. Comm'n, 499 U.S. 144, 157 (1991) (holding that interpretative rules and enforcement guidelines are "not entitled to the same deference as norms that derive from the exercise of the Secretary's delegated lawmaking powers").

38. *See* Hemp Industries Ass'n v. DEA, 333 F.3d 1082, 1088 (9th Cir. 2003); Columbus Community Hosp. v. Califano, 614 F.2d 181, 187 (8th Cir. 1980).

39. *See, e.g.*, South Dakota v. Ubbelohde, 330 F.3d 1014, 1029-30 (8th Cir. 2003).

40. *See, e.g.*, Mt. Diablo Hosp. Dist. v. Bowen, 860 F.2d 951, 957-59 (9th Cir. 1988).

41. *See, e.g.*, Shell Offshore, Inc. v. Babbitt, 238 F.3d 622, 630 (5th Cir. 2001).

of Information Act already insists that the materials exempted from notice-and-comment rulemaking must be made public and limits their availability as precedent in enforcement actions.[42]

Congress has not empowered OMB to upset this delicate balance. Congress retains that power, and it has made targeted changes to this basic framework for specific cases over the years. For example, as OMB repeatedly observes, Congress waived this general exception for the Food and Drug Administration and essentially codified that agency's guidance practices.[43] In other cases, Congress has specifically empowered the agencies to make significant decisions, such as approving or rejecting state plans to implement cooperative federalism programs, without having to go through the APA process. Congress has had 60 years to consider across-the-board, one-size-fits-all policies of the type OMB is proposing, and it has opted to leave in place the current general scheme.

In the absence of any such direct intervention, Congress has left these matters up to the agencies to exercise their discretion. In fact, several agencies that implement public grants and benefits programs voluntarily waive the APA exemption for many of their important but otherwise exempt decisions. Some agencies already have guidance practices of their own for compliance guides, handbooks, and the like, and many have quality controls or other policies in place to govern the publication of many of the other kinds of informational materials that could conceivably be covered by the Proposed Bulletin. This mix of express and implicit delegations to the agencies means, among other things, that the agencies (which know their issues with more breadth and depth than any generalist in OMB) can develop policies appropriate for the specific kinds of information and public needs at stake in the many "guidance documents" the agencies produce.

Our concern in this regard is partly one of principle. Unless Congress legislates to the contrary, the president lacks the "authority to dictate decisions entrusted by statute to executive officers."[44] It is deeply problematic for OMB to interfere with Congress's decisions to delegate discretion to the agencies, particularly in the form of a proposal that seeks to advance good government. It is even more troubling that OMB is attempting to amend the APA by executive fiat. Any guidance documents — which would include interpretive rules, general policy statements, and more — that fall into the "economically significant" category would be subject to exactly the kind of notice-and-comment process hurdles from which Congress decided to exempt them. The sixtieth anniversary of the APA may be an occasion to consider how the law is working and even how it can be improved, but it is not time to rewrite the law unconstitutionally by executive pronouncement.

Although OMB does not arrogate to itself the power to review agency guidance documents before they can be published, OMB is nonetheless writing itself a significant and inappropriate role in day-to-day agency functioning. The Proposed Bulletin purports to offer agencies some flexibility in implementing the rigid notice and comment requirement for "economically significant" guidance

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42. *See* 5 U.S.C. § 552(a)(1)-(2).

43. *See, e.g.*, Food and Drug Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296, 2396 § 405 (codifying FDA guidance practices to regulate production of informal agency statements).

44. Robert V. Percival, *Presidential Management of the Administrative State: The Not-So-Unitary Executive*, 51 DUKE L.J. 963, 966 (2001).

documents, but that flexibility comes with a price: agencies can only exempt specific documents or classes of documents "in consultation with" OMB.[45] As we discuss below, the Proposed Bulletin will apply to a vast universe of materials and will almost immediately run into potential legal difficulties, so there will be need for much OMB "consultation." The day-to-day implementation of the Proposed Bulletin and its exemption clause will create many new opportunities for White House interventions in the agencies' work to protect the public.

More importantly, though, our concern is the effect on the public's ability to receive the information it needs. The Proposed Bulletin's interference in matters trusted by Congress to agency discretion concerns us because OMB knows far less than the agencies about what's at stake in the immense universe of materials governed by the Proposed Bulletin. As we have discussed above, we fear that the Proposed Bulletin, in particular § IV, will create unnecessary burdens on the publication and release of information that the public needs. We believe that the agencies are in a far better position than the generalists at OMB to exercise the discretion on issues of non-rulemaking materials with which Congress has entrusted them. The enormous risk of information delays and gaps that we have discussed above does not inspire confidence that the Proposed Bulletin will do a better job than the agencies currently do.

IV. OMB MUST, AT A MINIMUM, TAKE STEPS TO MINIMIZE THE DAMAGE FROM THE PROPOSED BULLETIN.

We reiterate our position that the Proposed Bulletin is largely a solution in search of a problem and an overreach of OMB's authority, but we realize that OMB is planning to forge ahead with this initiative. The best recommendation is for OMB to stop altogether, but we also offer, under protest, recommendations for narrowing the scope of damage that the Proposed Bulletin portends.

- The most troubling part of the Proposed Bulletin is the notice-and-comment requirement for "economically significant" guidance. Not only is the term "economically significant guidance" misleading and incomprehensible, but the added burden on agencies for guidance documents that fall under this domain would be onerous and draining on agency resources. Guidance documents are specifically exempt from APA notice-and-comment, and subjecting them to such procedures is an overreach of executive power. We propose that OMB eliminate APA-style notice-and-comment for "economically significant" or any other class of guidance documents.

- OMB should further clarify its vague and ambiguous definitions for various types of guidance documents.

45. Proposed Bulletin, *supra* note 2, § IV(2) at 11.

We suggest that OMB vastly limit the scope of guidance documents requiring formal notice and comment so as not to grind agency activity to a complete halt. Certainly, unnecessarily draining agency resources is not OMB's objective.

- The Proposed Bulletin gives OMB the authority to waive agency compliance with the bulletin for specific guidance documents. In the interest of transparency, we believe that any criteria OMB uses to approve or deny the waiver as well as any rationale provided by the agency for waiving the good guidance practice requirements should be made public on the OMB website. Ideally, OMB would maintain an online docket similar to the current docket that charts OMB's regulatory reviews under E.O. 12,866, but this docket should offer much more detail about OMB's instructions or "consultations."

- Though the Proposed Bulletin thankfully did not include analytical burdens on guidance documents, we would like to stress that these burdens, particularly cost-benefit analysis, should not be applied to guidance documents.

- The Proposed Bulletin was released immediately prior to Thanksgiving, and the comment period included major religious holidays. Given the short time the public has been given to review OMB's Proposed Bulletin, we request that OMB submit another draft for public comment and encourage OMB to confer with Congress in a broadly bipartisan manner. Considering the range of concerns that have been raised by us as well as those inside the agencies, we believe this issue requires further analysis and public discussion before OMB makes a final decision. Although OMB undoubtedly would like to finish its decision in time to observe outgoing OMB-OIRA administrator John Graham's exit from OMB on Feb. 1, we think that the issues raised by the Proposed Bulletin are too important to rush.

- Finally, we believe it is long past time for OMB or a nonpolitical office such as GAO to analyze the burden and opportunity costs attendant to the ossification of

the regulatory process, including time spent complying with the Proposed Bulletin.

Respectfully submitted,

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