Public Policy Network
March 27, 2009

The Honorable Peter Orszag
Director
Office of Management and Budget
Washington, DC 20503

Attn: Mabel Echols

Dear Director Orszag:

This responds to the President's memorandum of January 30, 2009, requesting the Office of Management and Budget (OMB), in consultation with regulatory agencies, to provide recommendations for a new Executive Order on Federal regulatory review.

I am a long-term participant in and observer of regulatory and regulatory analysis issues and performance. For two decades I headed the Division of Policy and Regulatory Review in the Office of the Secretary of the Department of Health and Human Services, and was responsible for assuring HHS compliance with Executive Order 12866 and its predecessors. I have prepared many Regulatory Impact Analyses (RIAs) and have reviewed and improved many dozens of RIAs and, more importantly, the policy decisions made in major regulations. I led the initial e-rulemaking Task Force and early implementation under the auspices of Sally Katzen of OMB and Kevin Thurm of HHS. I have also reviewed government-wide performance under the Regulatory Flexibility Act for the Office of Advocacy of SBA.

The existing regulatory review process is important and valuable. It contributes substantially towards improving rationality in rule-making decisions. It provides an important tool for Presidential oversight of Executive Branch program management. The general framework has been largely unchanged through the last three Executive Orders—EO 12044 (Carter), EO 12291 (Reagan and Bush), and EO 12866 (Clinton and Bush). Very importantly, each Executive Order has rested on the assumption that in-depth scrutiny would only be used selectively, for those regulations posing major policy issues warranting scrutiny by Executive Office staff and attendant delay. Equally importantly, each Executive Order has emphasized the objective use of cost-benefit analysis to analyze alternatives and determine whether the regulation is likely to maximize net social benefits (or, in some cases, minimize net social costs).

However in recent years, the regulatory review process has lost its focus and primary purpose. Through the first sixteen years under these Executive Orders it was clearly focused on the most important Federal regulations—those involving major costs, major policy issues, or major issues of interagency consistency. Only a relative handful of regulations were required to include Regulatory Impact Analyses, and selected for in-depth OMB scrutiny. It is true that OMB routinely applied a screening review to most Federal regulations, but only a fraction of these rules was selected for a more intensive review.

Over the past sixteen years, spanning the last two Administrations, there has been a gradual but major shift in practice. OMB now considers vast numbers of relatively routine regulations to be "significant" and to warrant an extended and extensive review. OMB does not limit its review to rules that present serious potential burden or policy issues, or to the most significant issues. Nor does OMB even limit its review to documents with regulatory purpose or effect. For example, OMB has for over a decade classified the annual *Federal Register* Notices announcing Medicare Part A and B premiums for the coming year as major rules. Each year OMB either "waives" preparation of an RIA, or a "pretend" RIA is included in these Notices. In fact, these notices do not meet any APA or EO definition of a "rule" (or, for that matter, the definition of "significant guidance" when guidance was reviewed). The Notices simply provide the public information on an actuarial computation already made and dictated by precise legal standards. There is no legal requirement to publish a *Federal Register* Notice. The matter could be handled equally as well by a Press Release. OMB could review these calculations without invoking EO 12866, without falsely asserting that these documents are Federal rules, without incorrectly classifying them as "economically significant," and without thereby subjecting these notices to the "major rule" clearance and reporting procedures of the Congressional Review Act. (The fifteen premium notices classified as economically significant rules and other examples I provide below are all readily visible on the Government Accountability Web site at http://www.gao.gov/legal/congress.html, where the GAO posts summaries of all allegedly major rules.)

As a second example, OMB routinely acquiesces in (or requires?) classifying the annual announcements of hunting season dates by the Fish and Wildlife Service of the Department of the Interior as economically significant rules (and "major" rules under the CRA). At the GAO Congressional Review Web site (searching all Department of the Interior rules using as criteria "major" and "hunting"), seventy-seven hunting season date rules issued in the last decade are listed as "major." While it is certainly the case that hunting as an activity is economically significant, the notion that the precise number of days selected for hunting seasons are reasonably so classified verges on the absurd. In fact, a document available on the DOI Web site (http://www.fws.gov/migratorybirds/reports/SpecialTopics/Mig%20bird%20Regs%20analysis%202008.pdf) both demonstrates and states that the differences in effects among potential alternative dates are economically insignificant. It might be argued that these rules are major because in theory the Fish and Wildlife Service does not have to issue a rule establishing hunting dates, and could thereby ban hunting, but that counterfactual is absurd.

These examples, and numerous others that could be provided, lead to an obvious recommendation: **Either in a revised EO or through changes in management process OMB should focus on the essential purpose of the EO—identifying and subjecting to policy review those documents that are actually rules and that involve major economic effects or major policy issues.** For this subset of regulatory documents, OMB should explicitly articulate a policy of focusing EO reviews and decisions only on major issues of genuine substance, as discussed below. While I am not wedded to any particular terminology, one visible and effective way to signal this redirection would be to bring back the word "major" as used in EO 12291, and either abolish the term "significant" or use it only to define a middle category of rules submitted to OMB for a quick review to assure that those rules are indeed not "major" and hence need no review. Regardless of how handled, no regulatory document should be labeled as "economically

significant" or "major" unless it is a rule, and genuinely creates economic effects of $100 million or more that would otherwise not exist.

A second major problem arises, and contributes to the first, because the threshold for "economically significant" (i.e., major) rules has remained at an annual economic effect of $100 million for three decades. In real terms, the threshold has decreased by two thirds. The original and important purpose of this threshold was to focus scarce analytic and review resources of both agencies and OMB on exceptionally important regulations. The effective reduction in the threshold means that ever more routine regulations are swept into the regulatory impact analysis and review process, which not only dilutes the ability of OMB to focus on and improve the most exceptionally costly regulations, but also subjects routine regulations with minimal burden to the very real costs of the review process. Since OIRA staff levels have remained roughly constant throughout this period, this also means that the time available for review of genuinely major rules has been drastically reduced.

Assuming that regulatory costs and regulatory improvement opportunities are both highly skewed (the vast majority of rules creating relatively low costs and low benefits), the net benefits of OMB review are necessarily far lower on the margin as the number of regulations subject to OMB review increases exponentially. My second recommendation is that: **The threshold for economically significant should be raised substantially, to annual economic effects of $250 million or more, in order to focus scarce analytic resources on the most important rules.** Intensive regulatory oversight creates many costs, including delay, and should be used sparingly and only where likely to achieve the most important gains. In this regard, the Congressional Review Act established in statute a threshold of $100 million, and the Unfunded Mandates Reform Act established a threshold adjusted for inflation that is currently about $130 million. It would be desirable to work with the Congress to establish a uniform threshold of $250 million under all three requirements, and to have that threshold adjusted annually for inflation.

These reforms, and additional changes described below, would mitigate both unnecessary delays and unproductive workload experienced by both agencies and OMB under the current practice. It is now a common practice for OMB to use the entire 90-day review window for routine but "significant" rules (OMB, to its credit, puts time-sensitive rules at the head of the review queue), and then to passback to agencies minor suggestions, often primarily editorial. Questions whose purpose seems to be to explain in detail to junior OMB staff the operations of agency programs rather than improve the rule often accompany the regulatory passback. Only rarely does OMB propose a major alternative of policy significance.

I make these points not to criticize OMB staff, who are exceptionally able and hard working, but to reform a review process in ways that reduce burdens on staffs while achieving the benefit of better timelines under both regulatory review and Paperwork Reduction Act review. The minor edits that OMB typically requires are a bureaucratic reflex after reviewing rules that should never have been reviewed and that pose no real issues—an almost irresistible impulse to demonstrate to oneself and one's colleagues that an otherwise useless review serves some purpose and has some outcome. Over time, the ever decreasing economic importance of the rules reviewed, necessarily reduce the potential "value added" by OMB review. The entire process is weakened by the focus on ever less important rules and ever less important passbacks. Hence, my third

recommendation is that: **Either by Executive Order revision or management directive, OMB should commit to performing a screening review of non-major rules with a turnaround time of never more than 10 days (the time frame set in EO 12291) or perhaps never more than two to three weeks.**

As noted above, OMB staff frequently suggests editorial and other minor revisions to rules. Over the years, agencies have doubtless found many and probably most of these useful either because they correct some infelicitous wording or because they identify a technical problem that would benefit from clarification. Agencies may even want and appreciate these comments. But there is no defensible reason for such comments being included in an official passback as if they were important substantive comments on policy or burden issues. Fourth, I therefore strongly recommend that: **OMB should discipline itself to distinguish between "important substantive" and "editorial and minor technical" comments, and include only the former as official passback. The latter could and should be appended, with the explicit understanding that the agency is entirely free to accept or reject them without any further discussion or delay. For major rules, OMB comments on the RIA should be included in the "important substantive" category.** Additionally, of course, some technical and scientific comments are not minor and should be treated as substantive. This policy should be promulgated in a written directive to OMB staff, issued as a standing instruction.

An even cleaner break with unproductive review would be for OMB to commit to make no comments, or at least no comments other than policy comments, on "significant" rules (using current terminology) that do not rise to the level of "major" or "economically significant."

EO 12291 contained an exceptionally important statement. It said that nothing in its review process "shall be construed as displacing the agencies' responsibilities delegated by law." This did not mean that issues could not be raised to the OMB Director or to the White House for resolution. It did mean that a decision of a cabinet Secretary, pursuant to his legal obligations, could not lightly be overruled by staff reviewers who wield the power of delay. I think restoration of such a provision is symbolically very important, and would reinforce the basic point that Departments and agencies are expected to carefully analyze alternatives and choose the option that maximizes net benefits to society, with OMB serving the President by performing a key review function, but not acting as final arbiter. Accordingly, as a fifth recommendation: **OMB should include language in a revised Executive Order or other issuance that states or restates clearly the policy that agency heads are responsible for regulatory decisions delegated to them, albeit subject to consultation with policy level officials in the Executive Office of the President.**

These recommendations, taken together, should not only reduce unnecessary regulatory delays by months for most regulations, but also provide significant workload relief for both OMB and agency staff and free up staff time to improve review of genuinely major rules. In sum, I cannot emphasize too strongly the need for OMB to do what it historically has done best: to focus on genuinely major rules that present potential alternatives that need careful scrutiny, and to ensure, by explicit policy guidance and daily practice, that minor rules are neither subject to review nor inappropriately classified as major.

I would also emphasize that while some critics argue that all OMB comments and passbacks should be public, and "on the record," such a "reform" would be destructive. The President is entitled to have the internal deliberations of his policy advisers and policy staff remain confidential. Candid back and forth exchanges between agencies and OMB staff are desirable, and would be all but impossible if likely to wind up on the front pages of newspapers or in advocacy press releases. What is important for the public is not the messy internal back and forth, but the resulting improvements in the published document.

It is not infrequently the case that a statute forces a regulatory policy that does not maximize social benefits. For example, certain safety and environmental statutes arguably do not allow minimizing costs even where health benefits are trivial or speculative. In those cases where the law actually creates a cost that the ensuing regulation cannot change, and there is no discretion as to whether the regulation is issued at all (a rare circumstance), then the RIA should make that distinction and identify the legislative change that would be needed to adopt the most cost-beneficial alternative. The RIA serves no policy oversight purpose if it simply totals all costs and all benefits without distinguishing between those amenable to discretionary policy decision and those that would require statutory change. It is in the interest of the branches of government and the public to understand what forces a bad regulatory outcome and who should be accountable for that outcome. I recommend, sixth: **OMB policy in a revised Executive Order or at the very least in a revised Circular No. A-4 should explicitly state that if a statute prohibits making a cost beneficial decision, that should in no way excuse an agency from creating an RIA that shows all important alternatives, whether or not those alternatives are allowed under current law, and from identifying what specific change in law would allow the agency to promulgate a rule that better improves social welfare than the one it is forced to promulgate.**

Amazingly, many allegedly major rules contain no Regulatory Impact Analysis. For example, the Medicare premium notices and the hunting season rules discussed above contain no RIA—no analysis of costs, no analysis of benefits, and no comparison of the costs and benefits of alternatives. This void is not infrequent even in genuinely major rules. For example, on July 25, 2008, the Department of Defense issued a proposed rule to reduce costs of the TRICARE Retail Pharmacy Program (73 FR 43394). The preamble claimed that the price controls imposed by the rule would reduce spending on prescription drugs in that program by approximately a billion dollars a year. The static cost savings were described, but there was no analysis of alternatives or of likely dynamic economic effects. Most saliently, the rule relies on manufacturers' wholesale prices to determine TRICARE reimbursement. Nowhere does the preamble mention that those prices are unlikely to remain unchanged with a billion dollars a year at stake, with resulting adverse effects on other public and private programs that use the same price indices in setting reimbursement levels, and also resulting in reduced savings to TRICARE. This particular rule implements a statutory provision, but that is irrelevant if the full range of benefits and costs is not accurately presented, and the likely failure to achieve the statutory target as a result of behavioral responses explained. On its face, this preamble violates EO 12866 and OMB Circular No. A-4.

The worst cases, however, are those in which the preamble refers readers to a physical document that allegedly exists and that allegedly can be obtained by writing to the agency. In practice, that document often does not exist, or if it exists fails spectacularly to meet the standards of EO

12866 or OMB Circular No. A-4. See **An Evaluation of Compliance with the Regulatory Flexibility Act by Federal Agencies**, at http://www.sba.gov/advo/research/rs215tot.pdf for the results of research on a similar lack of compliance with the Regulatory Flexibility Act, including the widespread preparation of "pseudo" analyses that purport to analyze regulatory effects but in fact utterly fail to do so. There is an amazingly simple remedy for such failures. Hence, seventh: **OMB should require, and enforce, that all economically significant rules' preambles contain a complete RIA that presents all important costs, all important benefits, appropriate alternatives, sensitivity analysis, and key assumptions—all technically competent and all presented in terms comprehensible to both expert and lay readers.** (Lengthy technical appendices could be left out, provided that they are available online at links included in the RIA.) Absent such a presentation, a fundamental purpose of the Executive Order is compromised because the public, who are by law entitled to an explanation of the proposed rule and the right to comment on the proposal and on alternatives, are denied the most important information to help them do so. This reform would be particularly important in an Administration committed to transparency.

Finally, the fundamental purposes of regulatory analysis and regulatory review cannot be achieved without significant improvements to the e-rulemaking Web site at www.regulations.gov. This Web site does not reliably identify all rules affecting particular subjects, has relatively primitive displays that suppress rather than reveal significant information about public comments (such as the name and affiliation of the commenter) until the comment is opened, displays useless comment code numbers and regulation code numbers that waste scarce screen space, has limited search capabilities that often fail to find significant comments (no "relevance" capability), and a tedious and time-consuming approach to moving from comment to comment that is functional, in practice, only for rules that receive well under a hundred comments. Any "user friendly" searchable Web site using Google or similar technology provides numerous examples of ways to improve its search and display capabilities (in fact, even the GPO Access Web site, which relies on the obsolete WAIS search engine to find relevant regulations, is far more user friendly than the regulations.gov Web site). Of particular importance, the e-rulemaking Web site does not provide any way to distinguish between thousands or tens of thousands of "campaign" comments on any controversial rule from the relative handful of thoughtful, in-depth comments from commenters who have actually read that proposed rule and who address its specific provisions. For routine rules that generate only a handful of comments these problems are not fatal. For major rules and economically significant rules (categories that the Web site fails to identify) or any other important rules that generate thousands of comments the Web site provides no useful tools for use either by potential public commenters (who should have instant access to comments of substance already posted) or to agency reviewers. With respect to agency reviewers, there will often be a dozen or more individuals in several agencies (including OMB itself) who review particular rules prior to final decisions and who would like to access easily and rapidly the most significant comments on those rules. Access is possible, but it is neither easy nor rapid. Important comments are drowned in the midst of hundreds or thousands of other comments. As a result, both the public review of rules and the policy review of rules are far more burdensome and far less effective than they could and should be. Eighth, **OMB and EPA should drastically improve the usability of the e-rulemaking Web site. Reforms should include a simple solution to campaign mail that was identified twelve years ago by the e-rulemaking Task Force—placing all comments on**

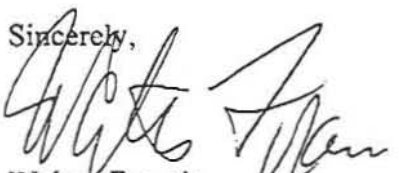
each rule into one of three categories: comments that suggest specific improvements to the proposed rule, comments that express general approval of the proposal, and comments that express general opposition to the proposal. As a recent example, the so-called "provider conscience" rule generated tens of thousands of campaign mail comments both pro and con. However, there were only a few hundred in-depth comments by persons who had actually read the proposed rule. All users should have been able to visit each group of comments separately, depending on their purposes and needs.

These eight recommendations, if adopted, will improve the general timeliness, effectiveness, and public participation in the rulemaking process for all rules, and radically improve the ability of both agencies and OMB to focus on and improve the rules with the greatest economic impact. Put another way, net social benefits of the regulatory review process will be substantially increased with adoption of these simple reforms.

Finally, the vexing question of improving regulatory decision-making and regulatory analysis in "independent" agencies remains. One potential option that avoids constitutional issues would be for OMB to offer to establish a voluntary review function for any independent agency. If the agency agreed, all of its major rules would be subject to OMB review just as if it were an Executive Branch agency (an agency would not be able to "cherry pick" which major rules went to OMB), with the agency retaining, of course, final decision-making authority. For any agency that did not agree to such an arrangement, OMB would adopt a practice used decades ago, of issuing publically, with accompanying Press Release, comments on proposed rules applying the same benefit-cost standards used for the Executive Branch. This practice was used effectively to identify fatal weaknesses in a number of proposed rules that quickly died. Today, an option allowing either approach might serve to assist the Consumer Product Safety Commission as it deals with non-existent health risks posed by minuscule amounts of lead in children's books in libraries throughout America, by lead in bicycle parts no child has ever ingested, and as it otherwise implements a flawed statute that unreasonably but not totally limits its discretion to make sensible regulatory decisions.

Thank you for the opportunity to contribute to your deliberations.

Sincerely,



Walton Francis
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cc Kevin Neyland, Acting Administrator, OIRA