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The Honorable John D. Graham
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, DC 20503

Dear Dr. Graham:

I am pleased to provide the following comments on OMB's latest draft report to Congress on the costs and benefits of federal regulation. As you know, I have provided extensive comments on each previous draft report and continue to share a vital interest in the success of OMB's efforts to effectively implement its responsibilities under regulatory accounting legislation.

Regulatory Checkbook is a nonpartisan, nonprofit, tax exempt public service organization whose mission is to monitor and report on federal agency compliance with important statutes and Executive orders related to regulatory process, analysis and decisionmaking. Since its founding less than one year ago, Regulatory Checkbook has taken an active role in both scholarly research on these issues and practical involvement in the development of solutions to many of the problems that have long vexed regulatory policy. In addition to conventional matters such as statutory and Executive order compliance and the improvement of regulatory analysis, substantial new work has begun on issues concerning data access, data quality and governmental peer review. Finally, Regulatory Checkbook is devoted to assisting in the development of innovative structures that could significantly enhance the effectiveness of centralized regulatory oversight.

This year's draft report is superior to its predecessors on one margin that is historically unappreciated: organization. I have discussed the draft report with many people interested in federal regulation, some of whom will no doubt be providing public comments of their own. A consistent observation that I have heard is that the draft report is organized in a thoughtful and intuitively appealing way. In addition, the text is unusually light on political rhetoric and the bureaucratic gobbledygook that permeated earlier editions. Where questions have arisen they seem to involve relatively subtle interpretative nuances reflecting the inher-

ent complexities of the subject matter. Earlier reports tended toward evasiveness and *argumentum non sequitur*, and it is refreshing to see much of this has been stripped away.

Because the draft report is so well organized and crafted, these comments largely follow the report's own structure.

## THE REGULATORY RESPONSE TO SEPTEMBER 11TH

This section of the draft report provides a fine summary of the major regulatory actions taken in response to September 11th. Many of the 41 regulations listed in Table 1 constitute very significant changes in federal policy. It is possible that OIRA performed a "full regulatory review and coordination function under Executive Order 12866," "ensured that all affected agencies were aware of what other agencies were proposing and facilitated their timely comments," and made sure that all September 11th related rules implemented "the Administration's best solutions to the circumstances caused by the terrorist attacks" (page 13).

It is more likely, however, that each of these agency actions was taken with very limited information under extreme duress. These facts likely conspired with a highly compressed schedule for OIRA review such that the Office is extremely unlikely to have performed as effective a review as it would have done under less trying conditions. Therefore, logic suggests that these regulations belong at the top of the list of actions that ought to be subject to credible and objective *ex post* review, including serious regulatory analysis that could not have been performed under emergency conditions immediately after September 11th. It is not in the public interest that resources be wasted on emergency initiatives that turn out to be ineffective, counterproductive, or grossly inefficient. *Ex post* review provides the mechanism for ensuring that the American people actually obtain the improvements in homeland security and public safety that were promised. To this day, a number of the air transport regulations on this list, such as passenger screening, checked baggage checking, and cockpit weapons remain exceedingly controversial. One reason is that rigorous analysis of the incremental costs and benefits of alternative regulatory approaches, unintended consequences, and risk-risk tradeoffs has not been completed and actively shared with the public.

## OPEN APPROACH TO CENTRALIZED REGULATORY OVERSIGHT

OIRA should be commended for the significant changes that it has made to enhance public disclosure of regulatory review consistent with the provisions of Executive order 12866 and legitimate needs for confidentiality within the government. In these comments I want to focus on OIRA's commitment to the Administration's E-government initiative. A realistic appraisal of OIRA's current information systems and information management

problems should be included in this report, for OIRA's needs are so great that substantial additional resources and effort will be necessary to overcome well over a decade of neglect.

OIRA relies on information systems to manage paperwork and regulatory reviews that are now 20 years old. By information technology standards, these systems are not merely long in the tooth – they are dinosaurs. It is quite possible that no federal agency currently relies on primary IT systems that are more antiquated. I understand that upgrading these systems may not be as urgent a national priority as repairing defects in air traffic control or the Social Security payments systems. Nevertheless, OIRA would have much more credibility in its oversight of agencies' IT policies and practices if its own house were not such a shambles. It is time for OIRA to acknowledge that OMB's persistent and hallowed culture of self-denial undermines the Office's credibility and effectiveness.

New information systems are only a start, for OIRA's records management desperately needs an infusion of resources. The OIRA docket was never "user friendly," but when it was compressed into half its previous space and staffing during the "OMB 2000" reorganization in 1994, conditions frankly became comical. OIRA's docket librarians have proved to be immensely resourceful but their task is Herculean. If more than two members of the public at one time took seriously OIRA's offer and visited its docket library, they would be best advised to first learn how to read and write while standing on one foot. The best training for using OIRA's docket library is riding Washington's Metro after 4th of July fireworks.

## GATEKEEPER FOR NEW REGULATIONS

*The Resurrection of the "Return Letter"*

OIRA correctly points out that a low number of "return letters" cannot be automatically assumed to be evidence of inadequate enforcement of Executive order 12866 principles, for it is theoretically possible that agencies have so effectively absorbed and inculcated these principles that few, if any, draft regulations fail to comply with them.

However theoretically plausible this argument might be, the likelihood that it is true is infinitesimally small. There is overwhelming evidence that public enforcement of Executive order principles essentially disappeared for several years. The threat of putting agency noncompliance on public display is OIRA's most credible enforcement tool. Innovations such as the "prompt letter" as "a modest device to bring a regulatory matter to the attention of agencies" underscores just how limited OIRA's tools actually are.

As OIRA implies, the optimal number of regulations "returned" is surely not zero. Apart from that, there is little that can be said *a priori* about what the optimal number is likely

to be. At the limit, OIRA would return all draft regulations that failed to comply with one or more of the procedural, analytic or decision-making requirements found in Executive order 12866. It is quite possible, however, that such a strict construction would require OIRA to return a huge percentage of draft regulations it reviews. Frankly, not all departures from Executive order principles are equally important and worthy of this response. Nevertheless, even much more modest criteria (such as an inviolable requirement for some credible benefits analysis) could lead to a substantial increase in the percentage of draft regulations returned.

OIRA reports that it returned 2.6 percent of all rules reviewed in 2001. This exceeds the return rate in all years since centralized review began, except 1984. The rate applies to a base of 700 draft rules reviewed, which is 18 percent higher than its average base of 591 rules during the period 1994-2000 in which only "significant" rules were reviewed. Thus, the actual return rate is higher than OIRA's statistics suggest. First, the larger base implies that a larger number of rules would have to be returned to maintain any specific rate. Second, and more importantly, all of these returns occurred during the second half of the calendar year. The expected annual number of draft rules returned based on these figures is approximately 36 per year, or 5 percent. Sustaining this rate would mean that OIRA had doubled the maximum level of public enforcement of Executive order principles achieved at any time over 21 years.

This figure – 5 percent – has interesting statistical properties. If it is assumed that draft rules submitted for review are distributed normally with respect to the degree to which they comply with Executive order principles and noncompliance with these principles is the basis for return, then OIRA would be returning only those rules whose quality is 1.6 standard deviations or more below average. If OIRA consistently returned rules this far into the tail of the quality distribution it would not be imposing a very high quality standard.

This is not to suggest that OIRA should establish a quota for draft rules returned, or that OIRA should focus exclusively on those actions whose quality lies below some statistical threshold. The consequences of noncompliance with Executive order principles vary, and they probably vary in ways that do not correlate well with the intrinsic quality of the agency's submission. In principle, OIRA should return any draft rule in which the adverse effects of noncompliance with Executive order principles (in terms of regulatory effectiveness, cost-effectiveness, or other relevant measures) exceed the adverse effects of delaying action while the agency makes repairs.

OIRA states that the reinvigoration of the return letter has had important internal management benefits. In particular:

> [A]gencies are beginning to invite OIRA staff into earlier phases of regulatory development in order to prevent returns late in the rulemaking process. It is at these early stages where OIRA's analytic approach can most improve on the quality of regulatory analysis and the substance of rules (page 22).

This is an especially welcome event. In comments on previous draft regulatory accounting reports, I have been critical of OIRA's apparent inability to improve the quality of the regulatory analyses on which agency decisions are ostensibly based. This has occurred because OIRA's professional staff participates too late in the regulatory development process to affect the analysis of alternative agency decisions. Further, OIRA has historically displayed a noticeable reticence toward returning draft rules just because they are accompanied by demonstrably substandard analysis. Past unwillingness to enforce even modest analytic standards created perverse incentives for agencies to be unconcerned about low analytic quality. OIRA's resurrection of the return letter, and its use in cases where analysis is lacking or substandard, surely changes these incentives for the better.

Agencies understand incentives. Indeed, they often blame allegedly cumbersome and confusing Paperwork Reduction Act procedures for their lack of useful data and the low quality of their analyses. With amazing frequency, agencies persist in estimating the regulatory costs borne by thousands of regulated parties based on data collected from less than 10 of them. They do this, of course, to evade the otherwise applicable PRA requirement that they obtain prior OIRA approval of an information collection request. It is impossible to argue that cost or benefit estimates derived this way could satisfy applicable information quality standards. OIRA should automatically return any draft regulation whose analysis is based on evading the PRA.

Basing analysis on approved information collection requests is necessary but not sufficient, however. Many information collection requests related to scientific, technical, statistical, financial or economic data are accompanied by supporting statements that set forth rigorous procedures for sampling, data collection, chain-of-custody, QA/QC, and analytic methods. When OIRA professional staff approve these information collections, they reasonably expect that agencies and their contractors will comply with their own protocols. But do they? OIRA does not ask and agencies do not tell. OIRA should demand that agencies document compliance with underlying protocols in every case where they rely on data from an OMB-approved information collection request. If an agency cannot document full compliance, or provide a credible explanation why it did not and persuasive evidence that noncompliance did no harm, then OIRA ought to return the draft regulation for deficient information quality.

In my comments on last year's draft report to Congress, I recommended that OIRA improve regulatory review by coordinating it with its statutory authorities under the Paperwork Reduction Act. Very often, data that are needed to perform scientifically and economically credible regulatory analysis must be obtained well in advance of regulatory development. OIRA approval is generally needed to collect these data, but OIRA rarely utilizes this opportunity to ensure that such data are collected. This occurs because OIRA is so transaction- and deadline-oriented that it cannot focus attention on regulatory issues looming on the horizon. Further, OIRA's professional staff inevitably have limits to their capacity to foresee future data needs.

Last year I called for a new procedure whereby the OMB professional staff could secure early agreement with agencies on "RIA Blueprints." This would be a transparent, public process consistent with the legal requirements of the PRA that would identify the data needed, find and plug data gaps, and end the sorry practice of relying on substandard data because better data that could have been obtained earlier aren't available now. This also would provide an opportunity for knowledgeable people and organizations to contribute at a stage in the regulatory development process where they can have maximum constructive effect. RIA Blueprints would describe in appropriate detail the data and methods to be used, the alternatives to be examined, and milestones for completion and public disclosure of each component of a regulatory analysis. Plenty of flexibility could be provided to amend these Blueprints by mutual consent if warranted by changed conditions. Procedures could be instituted that rewarded the private generation of higher quality data than an agency otherwise would use.

OIRA obviously would benefit, as would the public. But what's in it for regulatory agencies? OIRA would limit its analytic review of a draft regulation to the agency's compliance with the terms of the RIA Blueprint. Agencies would no longer have to confront last-minute requests for the analysis of new options using alternative models and different data. By completing and releasing individual RIA components early they could eliminate any dispute over whether they had fully complied with applicable Executive order analytic requirements. This would hasten OIRA review of the draft regulatory action, and Administration officials could focus on important policy issues and not be distracted or delayed by disputes over analysis.

This would be a win-win-win innovation – it would improve the practical utility to the agencies of information they collect, reduce the burden caused by collecting information that does not actually meet agency analytic needs, and eliminate most conflicts over analysis that routinely occur during regulatory review. Now that OIRA is focused so intently on improving information quality, an RIA Blueprint process could dramatically reduce the extent

to which agencies rely on substandard quality information because it is the only information that they have.

*OIRA's Memorandum to the President's Management Council*

From the agencies' perspective, the resurrection of the return letter may have been a difficult adjustment to the extent that they had grown comfortable with lax enforcement of Executive order principles. Fortunately, OIRA's September 20, 2001, memorandum to the President's Management Council provides an excellent roadmap for them to follow to ensure that they comply with these principles and reduce – perhaps to zero? – the number of draft rules OIRA is obliged to return for analytic deficiencies. In the remainder of this section I will comment briefly on certain criteria set forth in this memorandum.

- *Articulating consistency with Executive order principles and procedures, and the underlying statute*

A common observation over the years is that many agencies adopted certain boilerplate language in which they asserted compliance with Executive order principles but failed to provide either a supporting logical argument or empirical evidence. As this practice took hold, OIRA quietly accepted *pro forma* compliance as adequate and agencies became increasingly emboldened in the extent to which they used such boilerplate assertions. Over the last several years, boilerplate assertions of compliance became increasingly Orwellian, as agencies asserted that instances of total noncompliance with applicable requirements should actually be interpreted as compliance in full.

OIRA has revived the idea that agencies should actually provide credible, complete and transparent disclosure of information required by Executive order. This is refreshing. Because the practice of *pro forma* compliance has become ingrained it may take some time before significant improvement is observed. This could be expedited if OIRA returns a few draft rules in which *pro forma* compliance is egregiously misleading.

- *Formal regulatory impact analysis for economically significant regulations, performed in a timely manner in a way consistent with OMB's government-wide guidelines*

The language in the Memorandum clearly communicates that OIRA is serious that agencies must prepare regulatory impact analyses for their major rules, and that these documents must comport with reasonable and well-known quality standards. OIRA has proved that it is serious about this, having returned a number of draft rules because required regulatory impact analyses either did not exist or they failed to meet these quality standards.

An especially important feature is that OIRA has laid to rest any lingering doubt about whether regulatory impact analyses must be prepared in cases where an agency cannot legally rely upon it for decisionmaking:

> An RIA is necessary regardless of whether the underlying statute governing agency action requires, authorizes or prohibits cost-benefit analysis as an input to decisionmaking. The public and Congress have an interest in benefit and cost information, regardless of whether it plays a central role in decisionmaking under the agency's statute. Congress has mandated that OMB provide this information in this annual report to Congress on the costs and benefits of regulation (page 23).

Regulatory impact analysis is essential for informing Congress and the public about the likely consequences of regulatory actions taken to implement or achieve public purposes, even if by law it cannot affect today's decisions. Congress and the public are more inclined to support inflexible, inefficient and cost-ineffective public policies if they are kept ignorant of the consequences, and they often express grave reservations about the wisdom of these policies when they see consequences transparently revealed.

Agencies must perform credible and objective regulatory impact analyses if OIRA is to fulfill its statutory responsibility to report to Congress on the costs and benefits of federal regulation. Currently, independent agencies – which are exempt from centralized oversight under Executive order 12866 – display the worst record of performance in this regard. OIRA reports that it was only able to review reports submitted by these agencies to the General Accounting Office pursuant to their obligations under the Congressional Review Act. Because GAO performs an accounting rather than a review function, it is impossible for OIRA to rely on these reports for credible and objective information about the costs and benefits of major regulations issued by these agencies. Indeed, it is impossible for OIRA to fulfill its most elementary statutory obligation under the Congressional Review Act -- to determine which rules are "major" – without authority to require that these documents be prepared and to review them.

Merely having the authority to review regulatory analyses prepared by independent commissions would have little effect, however. Only eight of the 19 major rules issued by independent commissions during the latest reporting period included "some discussion" of benefits and costs, six had monetized cost information, and three had monetized information on benefits. OIRA is being extraordinarily charitable when it says that "it is difficult to discern whether the rigor and the extent of the analyses conducted by the independent agencies are similar to those agencies subject to the Executive Order" (pages 75-76).

OIRA will always be unable to motivate any progress among the independent commissions unless and until it gains the authority to require that they prepare regulatory impact analysis and to review them in a timely manner. This could be done through a targeted amendment to Executive order 12866 that removes the commissions' exemption from sections 1(b)(1)-(3), 1(b)(6), and 6(a)(3) for all actions determined by OIRA to be major under the Congressional Review Act. Such an amendment would not compromise in any way the commissions' independence from Executive branch policy supervision. Without such a change, OIRA cannot fulfill its statutory responsibility for regulatory accounting.

- *Adoption of the basic information quality and dissemination standards that Congress established in the Safe Drinking Water Act Amendments of 1996, and which were recently codified in OMB's government-wide guidelines for information quality*

Problems with the quality and objectivity of scientific information used for regulatory decisionmaking have been legion, and legendarily persistent. This language strikes at the heart of the problem by strongly encouraging agencies to adopt common-sense policies and practices regarding scientific information. It is hard for any agency to argue that, as a matter of policy, it should not use

> the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices

and

> data collected by accepted methods or best available methods.

For a start, agencies should no longer rely on information obtained by evading the Paperwork Reduction Act, whether from obtaining responses from under 10 persons or through an unapproved survey instrument, or by utilizing data collected in violation of an approved protocol. PRA compliance should be a minimum definition for "acceptable methods."

The additional SDWA language regarding "comprehensive, informative, and understandable" presentation of scientific information must be understood in context, for it follows that these criteria presume that the information being disseminated satisfies the quality standards that precede them.

- *Formal, independent external peer review conducted in an open and rigorous manner by qualified experts selected primarily on the basis of necessary technical exper-*

*tise, who fully disclose prior technical and policy positions taken on issues at hand along with sources of personal and institutional funding whether public or private*

OIRA has placed enormous weight on peer review, and while there is ample reason to support this approach there is also reason to be concerned. It is not at all clear that existing agency peer review practices comply with the criteria OIRA has set forth. For example, the degree to which governmental peer reviews are in fact "independent" is subject to dispute. The Environmental Protection Agency, which may have the most advanced and extensive peer review program of any Executive branch department or agency, expressly reserves the authority to select peer reviewers or to veto the selections made by its contractors. The power to veto is tantamount to the power to select, and the power to select destroys independence. Even if a contractor faces absolutely no interference whatsoever with its selection of peer reviewers in any specific case, its decisions inevitably affect the firm's ability to secure future agency business. OIRA does not define what it means by "independence," but common sense suggests that independence from the agency whose work is being reviewed is how the term should be understood. Current governmental peer review procedures fail this test.

The extent to which government peer reviews are conducted in an "open and rigorous manner" is also unclear. Peer reviews conducted fully in compliance with the Federal Advisory Committee Act may provide a minimum level of assurance that they are in fact "open." The mere applicability of FACA does not, of course, ensure actual compliance with FACA procedures. Peer review meetings conducted pursuant to FACA often provide only the façade of openness, with little opportunity for anyone to participate except the panel and the agency whose work is under review. Further, almost all of the real work of a FACA-compliant peer review goes on behind the scenes. FACA violations can be difficult to detect, harder to prove, and impossible to rectify. OIRA does not say whether FACA compliance meets its standard for openness. If it intends for this standard to apply, then it needs to explain why FACA provides adequate openness and provide specific criteria that could be used to independently and objectively determine whether the standard was not met.

More disturbingly, agencies are increasingly contracting out for peer review services in ways that are exempt from FACA by statute or case law. This includes peer reviews performed by academics and scholars hired by for-profit firms, non-profit entities, and the National Academy of Sciences. Exemption from FACA is an important factor that agencies consider advantageous when they decide what peer review model to choose. This means that current governmental peer review practices do not generally comply with OIRA's openness criterion. The trend is toward less openness even as the number of public meetings seems to rise without limit.

As to whether government peer reviews are adequately rigorous, one should look beyond the thickness of the final report before reaching conclusions. A typical governmental peer review requires panelists to examine a document that is hundreds of pages long and is supported by dozens upon dozens of references, many of which have never been externally peer reviewed. Hundreds more pages of public comments may have been submitted. Panelists have little time to read this informational deluge, much less assimilate it. To reduce the burden, panels are often structured so that each member is responsible for reviewing a small subset of the whole without much overlap from other members. Specialization renders few panelists knowledgeable about the full document and inclined to defer to other panelists on matters apart from their special focus. For this heroic undertaking, peer reviewers receive token compensation or none at all.

Another dubious trend is the practice of trying to make peer review panels represent stakeholder interests. This directly contradicts OIRA's expectation that primary emphasis be given to "necessary technical expertise." To the extent that stakeholder interests of any shape, form or design are accommodated, "necessary technical expertise" will be sacrificed. Even if technical expertise were unaffected, using stakeholder representation as a selection criterion irrevocably changes group dynamics. Reviewers acutely aware of the stakeholder interest that secured their selection cannot be expected to leave this knowledge at the conference room door.

The surest way to corrupt scientific peer review is to infuse it with stakeholder interest and gradually delegate it the task of resolving policy conflicts under the guise of science. As a tool, peer review developed in academic and scholarly settings to provide independent evaluations of scientific merit. The mere thought of subjugating the evaluation of scientific merit to stakeholder interest is both foreign and repugnant to academic freedom, unfettered scholarly inquiry and scientific method. The role of stakeholders ought to be limited to providing advice on policy matters, not evaluating the quality of science. Similarly, scientists should not be selected based on their scientific expertise and asked to opine on policy.

OIRA's approving reference to how well peer review worked in the case of the Environmental Protection Agency's arsenic standard reinforces these concerns. Multiple peer reviews were indeed performed. However, most of these reviews expressly dealt with policy matters, such as the identification of an appropriate Maximum Contaminant Level, that go well beyond the scope of an academic or scholarly peer review of underlying science, engineering and economics. Though the derivation of an MCL certainly contains scientific and economic content, the MCL is inherently a policy construct and not a technical scientific or economic one. Peer reviewers, presumably selected for their "necessary technical expertise," had no special competence in the policy issues which are irreducible elements of the inherently governmental function of deciding how "safe" drinking water should be. OIRA's deci-

sion to "give a measure of deference" to the arsenic peer reviews implicitly condones the delegation of critical public policy decisions to an unelected, unappointed and unaccountable panel of private individuals chosen because they have expertise in certain subordinate scientific or technical areas, and increasingly, politically attractive stakeholder affiliations.

*OIRA's Timely Review of Draft Rulemakings*

OIRA deserves commendation for substantially reducing, and apparently now eliminating, the number of draft regulations under review for more than the 90 days authorized by Executive order 12866. Complaints about delay have dogged OIRA since centralized regulatory review began in 1981. I have personal knowledge from my OIRA service during 1988-98 of draft regulations sitting unresolved during at least parts of three calendar years.

Contrary to claims often made by some, there is no evidence that these delays were ever caused by the negligence or political agendas of OIRA's professional staff. Delays arose because policy officials could not resolve policy disagreements and the default procedure was to take no action. OIRA's data show that this has changed; the new default procedure appears to be that a draft rule can be returned if the OIRA professional staff diligently make a timely case; the Administrator reserves the right to refrain from embracing all diligently and timely made cases; and in any case a decision whether or not to do so will be made quickly. That all draft rules that could be returned are not returned can be inferred from the number of rules returned; the estimated 5 percent annual rate is very high by historic standards, but it seems highly unlikely to exhaust the domain of draft rules in which significant disputes arise.

## PROACTIVE ROLE IN ESTABLISHING REGULATORY PRIORITIES

Four of the five "prompt letters" OIRA has sent are addressed to agency heads or program officials responsible for implementing statutory programs related to public health, safety or environmental protection. Each of these four letters encouraged the addressee to change its regulatory priorities either by expediting an action in progress or taking on an issue that heretofore the agency did not consider important. (The fifth letter is different; it is addressed to an agency chief information officer and best characterized as a data quality initiative.)

From OIRA's report it appears that some or all of the first four letters caused considerable heartburn among addressees, other EOP officials, or perhaps both. It seems quite plausible that an addressee might not agree that a prompt letter "simply constitutes an OIRA request that an agency elevate a matter in priority, recognizing that agencies have limited resources and many conflicting demands for priority attention," and might consider it instead unwelcome interference. Alternatively, an addressee could use a prompt letter to argue for additional budgetary resources and thereby undermine the objective of fiscal discipline. If

indeed these letters were "aimed at stimulating agency, public and congressional interest in a potential regulatory priority," then they would appear to have achieved their objective.

In a public forum held in December 2001, I raised the concern that an addressee could interpret a prompt letter as providing *carte blanche* to issue regulations in certain areas without benefit of rigorous analysis:

> It would be troubling if an agency responded by plowing forward with a regulation that was ineffective, inefficient, or otherwise distasteful. Worse, an agency could celebrate its good fortune by cutting short research and analysis. It might do this to avoid learning anything that could undermine the case for regulating. Scientific and analytic stasis would result if agencies conclude that ignorance is indeed bliss. For any regulation covered by prompt letter, OIRA needs to oversee its development very, very carefully to prevent its good intentions from going awry.[1]

Three of OIRA's five prompt letters -- to the Occupational Safety and Health Administration on automated electric defibrillators, the Food and Drug Administration on nutrition labeling for trans-fatty acids, and to the National Highway Traffic Safety Administration recommending a new high-speed, frontal offset crash test -- are all examples in which there is a risk that OIRA's encouragement could backfire. What will OIRA do if a draft regulatory action is submitted without adequate analytic support? Will OIRA acquiesce to analysis that makes the approach recommended in its prompt letter look artificially attractive? What is a credible analysis does not support the regulatory path that OIRA recommended? OIRA may need to establish an external, independent peer review panel to review any draft rule that was the subject of a prompt letter.

As mentioned above, the most recent prompt letter is different from the others insofar as it is based on OIRA's authorities under the Paperwork Reduction Act, including the recently enacted amendments on information quality. The program addressed by this letter – EPA's Toxic Release Inventory – has suffered longstanding problems in the timeliness of Agency reports, doubts about the accuracy of data contained in these reports, cumbersome and expensive requirements for data collection by covered entities, and grave doubts about the practical utility of these data for their intended purpose. (Toxic Release Inventory data are typically used as shorthand indicators of risk when in fact they measure mass. The ac-

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[1] See "Making Executive Review Work," Weidenbaum Center at Washington University in St. Louis (http://wc.wustl.edu/ExecutiveRegulatoryReviewTranscripts/Belzer.pdf [page 8]).

cepted formula for risk is hazard multiplied by exposure so that risk is zero if either term is zero. Mass is a poor and misleading proxy for either of these variables.)

Information quality issues offer fertile grounds for a host of new prompt letters. Not only are they clearly within OIRA's statutory purview, but they have the additional advantage of minimizing controversies over the setting of agencies' regulatory priorities. One can readily envision an energetic use of prompt letters to assist agencies in reducing burdensome paperwork and increasing the practical utility of information collection requests. By integrating these objectives with information quality, OIRA could dramatically improve the quality of data and analyses agencies use to set their own priorities. Higher quality data could reduce conflicts over priority-setting.

A program of prompt letters tied to PRA and data quality objectives would be fully consistent with my earlier proposal for an RIA Blueprint process. These initiatives have the same statutory foundation and provide reinforcing early intervention in the regulatory development process. They do not raise turf hackles by questioning agency regulatory or budget priorities, however justified such questions might be.

## OVERSEER OF ANALYSIS AND INFORMATION QUALITY

*Information Quality Guidelines*

OIRA's new efforts to improve information quality are welcome and may pose the greatest institutional challenge it has ever faced. The government-wide guidelines OIRA issued on September 28, 2001 (as interim final), and January 3, 2002 (as final), create substantial new agency obligations. That the achievement of high information quality standards is widely understood to be critically important but heretofore not achieved highlights both the magnitude of this challenge and the attractiveness of the opportunity.

As of this writing a couple dozen departments, agencies and commissions have published draft information quality guidelines as required by law and OMB's directive, with more on the way. Each agency has provided a very short opportunity for public comment (typically 30 days). Comments to two agencies are due by May 30th; 11 agencies by May 31st; and nine more agencies on or before June 7th. Members of the public (including Regulatory Checkbook) broadly interested in information quality face an impossible task in responding intelligently to more than a handful of agency requests for comment. This compressed process, which OIRA itself imposed on the agencies and the public, frustrates and may ultimately undermine the initiative.

Many agencies have proposed guidelines that are so vague or incomplete that public comment is largely a pointless exercise. In addition, most agencies have proposed language

that would exempt huge swaths of their activities from information quality standards. Given the opportunity to write targeted guidelines that reasonably take account of agency-specific needs, many have abused it by trying to fundamentally undermine both the law and OMB's government-wide directive. If any agency is permitted to issue final guidance that mimics its proposal, then for all intends and purposes the Data Quality Act will be a dead letter within that domain.

Agencies are expected to submit their draft final guidelines to OIRA by July 1st. One constructive thing that OIRA could do is to post on its website all draft final guidelines it receives and ask the public to comment directly to OIRA. This would be the first opportunity for the public to see what many agencies actually intend to do to implement the law consistent with OMB's directive. It could delay finalization of agency guidelines beyond the target date of October 1st. However, it seems foolish to hold fast to this date in the face of overwhelming evidence that much more needs to be done to ensure that agency guidelines are intelligently crafted and not riddled with loopholes, provisos, escape clauses, definitional advantages and other artful dodges. In its admirable zeal to ensure that the trains run on time, it is vitally important that OIRA also see that they travel to desirable destinations.

*Applying OMB's Information Quality Guidelines to this Report to Congress on the Costs and Benefits of Federal Regulation*

OIRA clearly states that it is serious about information quality. In particular, OIRA acknowledges that government agencies have greater responsibility to ensure the quality of information that they disseminate than underlying sources have to ensure that the quality of original data. OIRA summarizes this perspective clearly and succinctly:

> OMB's new information quality guidelines establish stricter standards for agency analyses of original data than for the data themselves. OMB believes that agencies are in a better position than OMB to establish specific quality standards for the generation of original and supporting data (page 35).

This poses a difficult problem for almost all of Chapter II of the draft report. Here, OIRA is "the agency" that is subject to OMB's information quality guidelines and which must meet "stricter standards" for "analyses of original data." OIRA has not demonstrated that the data it reports in Chapter II meet its own draft information quality standards,[2] which state in part:

[2] See www.whitehouse.gov/omb/inforeg/iqg_draft_guidelines.pdf.

> Much of the information OMB disseminates consists of or is based on information submitted to OMB by other Federal Government Agencies. OMB expects that agencies will subject information submitted to OMB to adequate quality control measures. In drafting the material to be disseminated, the Lead Division should review and verify the data submitted by the agencies, as necessary and appropriate (§ I.A.2).

Most of the data in Chapter II come from third-party sources (*i.e.,* academic researchers or regulatory agencies). OIRA is the "Lead Division" whose responsibility it is to "review and verify the data submitted by the agencies." OIRA may well "expect that agencies will subject information submitted to OMB to adequate quality control measures," but it is no more reasonable for OIRA to have such expectations of the agencies than it is for the agencies to have such expectations of its information sources. In many (if not most or all) cases, these data are presumptively biased because they were not derived independently of the policies and regulatory actions they describe. All are intended to be "influential" as OIRA has defined that term. None have been subjected to the kind of peer review that OIRA says it prefers and for which it offers agencies "a measure of deference." Data in Chapter II are clearly covered (as they should be) by OMB's proposed definition in § IV.4. They are not clearly presented as "opinions" rather than facts and OIRA is expressly relying upon them even though generated by non-OMB sources, and thus are not captured by the exemptions found in § IV.4.a and b.

On information quality matters, OIRA needs to set an example for the agencies it oversees. This means OIRA has two choices in its final report to Congress. First, it can perform a thorough pre-dissemination review of data quality according to the standards it expects agencies to follow in their own dissemination of third-party information. Second, it can incorporate into the text of Chapter II (and anywhere else that it disseminates this information) frequent and appropriate disclaimers so that readers understand that the data reported do not satisfy information quality standards. The first approach is attractive in principle but very difficult or perhaps impossible in practice. For example, OIRA lacks enough professional staff to conduct a thorough review. In contrast, the second approach is less appealing in principle but readily achievable in practice. The liberal use of disclaimers would ensure that users of the final report are fully aware of its data quality limitations. Whichever path OIRA chooses, having to confront this choice will help it understand the difficulties federal agencies face as they implement data quality standards throughout their programs.

With some effort, OIRA could satisfy a high level of information quality for some of the estimates in Chapter II, but only if it decided to substantially reduce their precision and if it clearly reported uncertainties. In Table 5, for example, OIRA purports to say that it can estimate the aggregate costs and benefits of major federal regulations issued from April 1,

1995, through September 30, 2001, with the precision of five significant figures and a margin of error of ± $500,000. Neither of these data quality claims can be supported, of course, and OIRA probably did not intend to make them. Yet, these data are guaranteed to be influential and OIRA knows that many users of these data (including some Members of Congress) will interpret them precisely as I have just done. At a minimum, OIRA should provide a strong interpretative caveat within Table 5 that explains precisely what these figures mean in data quality terms. Better yet, OIRA should report these data at a level of precision which it can demonstrate meets its data quality standards and not perform any arithmetic or mathematical operation whose results do not also meet these standards.

Table 7 summarizes agency estimates of costs and benefits for selected final rules for the most recent (18-month) reporting period. Ascribing these estimates to their originating agencies – a practice that, for better or worse, OIRA has followed since the inception of regulatory accounting – is an implicit denial of information quality claims. Nevertheless, OIRA has the responsibility to make this denial explicit and highly transparent. It would be a simple matter to include such a disclaimer in the footer of each page of the table. The language OIRA chooses to use sets the standard by which it could reasonably judge other agencies' compliance with data quality guidelines. (If OIRA includes no disclaimer at all in the final report, then it has the weakest of foundations for enforcing high expectations for other agencies' performance.)

Data quality concerns infect more than just Table 7, however. Throughout the accompanying text, OIRA characterizes these estimates as more precise, certain and "factual" than they really are. In no instance that I have found has OIRA disclosed any kind of data quality review. The reader is offered the opportunity to take these estimates or leave them, but is provided with scant information and analysis to inform this decision.

Before finalizing this draft report, OIRA needs to subject Chapter II to a careful pre-dissemination data quality review explicitly based on OMB's government-wide guidelines. It would be deeply worrisome if OIRA intended for agencies to meet very high standards for information quality but chose to exempt itself from the rigors involved.

## REFINING OIRA'S FORMAL ANALYTIC GUIDANCE DOCUMENTS

OIRA indicates in this report that it intends to revise its guidance for conducting regulatory impact analysis. I am very supportive of making sure that OIRA keep up to date with the latest developments in the field, and I yield to no one in my belief that obvious gaps ought to be plugged and my disapproval of provisions in the existing guidance documents that are incomplete, misleading or simply wrong. Nevertheless, OIRA has issued analytic guidance in 1990, 1996 and 2000. On most margins, the three guidance documents do not differ in any significant way and their advice remains valid. The fundamental problem is not

that these documents need to be updated but that they need to be enforced. To the extent that OIRA's guidance does not explicitly address certain issues or ought to be amended at the margin, OIRA economists have ample discretion to make these adjustments in appropriate cases. By reopening the matter yet again, OIRA may unwittingly send the incorrect signal that compliance can be further delayed until the next iteration of the guidelines is completed and OIRA confirms that – surprise! -- fundamental economic principles have not been repealed.

*Revisiting the Default 7 Percent Discount Rate*

The use of a default 7 percent real discount rate is might not be justified, though it should be noted that agencies vary in the extent to which they apply it. The pressure always seems to be to lower the rate based on one argument or another but with the common effect of increasing the present value of delayed benefits. This is true whether the benefits in question arise from a regulation intended to reduce health, safety and environmental risks or support the construction of a dam or dredging a river. The appropriate discount rate depends on the identity of the pocketbooks from whom the cost of compliance will be funded. In many cases, especially those in which costs will be borne by low-income communities or persons, the correct rate of discount may be quite a lot higher than 7 percent. (In EPA's recent arsenic drinking water standard, for example, a relatively low discount rate is probably appropriate only if federal taxpayers are going to cover the cost. If the true incidence of costs is on low-income communities and households, then the appropriate discount rate is their consumption rate of interest, which could easily exceed 20 percent.)

*Obtaining Risk Estimates Compatible with Benefit-Cost Analysis*

I am especially heartened to see that OIRA will focus on the problem of obtaining risk estimates that are compatible with benefit-cost analysis. This problem arose long ago in the context of virtually safe doses and then cancer risk assessment, both of which contain persistent, hidden and unquantified policy judgments because they are intended and designed to be precautionary. Making decisions in a precautionary manner is not inherently improper. Biasing risk assessments, however, is not. It is scientifically corrupt, fundamentally incompatible with accepted tools for benefit-cost analysis, and inconsistent with legitimate attempts to make precautionary decisions because it contravenes transparency. Just as one should not rely on financial statements that exaggerate revenue and undercount costs to inflate apparent profits, conventional risk assessment methods yield results that are unreliable for almost any analytic purpose.

*Dealing with Latency in both Risk Assessment and the Realization of Benefits*

Along these lines, OIRA's identification of latency as an important area for new analytic guidance is timely. The persistent practice of ignoring latency can exaggerate both the relevance of risk and the magnitude of benefits. Latency *per se* is an incomplete characterization of the problem, however. Leaving aside latency, the conventional approach has been to incorrectly assume that the benefits of risk reduction accrue immediately and in full even if the risk in question was caused by a lifetime of exposure to the hazard. In principle, benefits occur after exposure ceases only insofar as the risk phenomenon becomes absent (*e.g.,* motor vehicle accident risks yesterday do not carry over to today) or attenuated (*e.g.,* biological repair mechanisms revive after chemical exposure ceases). As a scientific matter, little may be known about the temporal pace of risk reduction, but we can be pretty sure that it is not generally immediate. A short-term remedy is to require agencies to use the same default assumption in temporally "ramping up" benefits that they used to quantify risk. Thus, if the applicable risk model is a linear function of exposure over a 70-year lifetime, then the default assumption for the ramp-up of benefits should also be linear over 70 years. Agencies should bear the same scientific burden on their efforts to expedite the realization of benefits that they impose on the use of alternative risk assessment models.

The impending harmonization of risk assessment methods for cancer and non-cancer endpoints intensifies this problem and makes the search for solutions more urgent. The expected outcome of harmonized methods is multiple new forms of virtually safe doses now amended with "margins of safety" or "margins of exposure." The use of these methods will encourage the public to retain a naïve, if not an extremely primitive, understanding of risk such that an event or activity is perceived as either "safe" or "risky." Further, economists have no tools to value these risk constructs, so the current direction harmonization is taking us poses a serious threat to the intelligent use of benefit-cost analysis.

*New Risk Assessment Models for Subpopulation Vulnerability: A Dubious Need*

On the other hand, OIRA's call for the development of new risk assessment methods "to account for the vulnerabilities of specific subpopulations" is deeply disconcerting. At a time when we continue to struggle to develop and implement valid and reliable central tendency estimates of risk, any diversion of resources toward secondary objectives sounds unwise. Even more than harmonization, this endeavor could undermine the use of benefit-cost analysis and reward the search for ever more arcane risk phenomena. In the limit, we could end up with every resident of the United States becoming a sensitive subpopulation on at least one (probably genomic) margin. It is hard to see how this would enhance rational risk management.

## TARGETING AGENCY REVIEWS OF EXISTING RULES

Last year, OIRA also requested recommendations from the public in lieu of offering its own list of "recommendations for reform" based on professional and institutional experience. Of the 71 recommendations received, OIRA determined that 23 of these deserved to be designated as "high priority." (Unfortunately, OIRA did not reveal the criteria it used to make these determinations. The only relevant statement provided is that the "distribution of nominated rules by agency reflects the concerns raised by public comments, not the interests of OIRA" [page 42].)

Appendix B of the draft report contains OIRA's description of how agencies have responded. In two cases, administrative reform was abruptly hasted by litigation. In all other cases, however, OIRA's discussion reveals little about what actions have been taken (in cases where any action has actually occurred) and even less in cases where little or nothing apparently has happened. For many items, the only text provided is an amusingly terse boilerplate reference that the agency is "considering several options" to address the issue.

OIRA offers no evidence that the solicitation of recommendations from the public is an adequate substitute for the statutory requirement that the Office provide "recommendations for reform." Nevertheless, OIRA is clearly persistent about it, having repeated its request yet again for the public to identify yet more candidates.

OIRA's discussion of the inherent problems associated with "look-back" provisions such as this is helpful and, for a change, refreshingly candid. For example, OIRA now acknowledges that the reform efforts of the National Performance Review were not effective (though it prefers to attribute this view to the General Accounting Office rather than its own experience). Further, it states a bit gingerly that "an across-the-board review of all existing rules could be a poor use of OMB and agency resources" (pages 90-91). This is, of course, a huge understatement.

What is missing from the draft report – and which was missing from all previous reports to Congress – is an informed reporting of the lessons learned from over 20 years of institutional experience reviewing federal regulation about the incremental costs and benefits of individual regulatory *programs*. The OIRA professional staff have substantial expertise and experience that does not shine through in this section of the draft report. Perhaps a political judgment has been made that it is wiser to continue laying low, but the public surely is not well served by hiding this bright light under a very large lead-lined bushel.

## REVIEW OF PROBLEMATIC AGENCY GUIDANCE

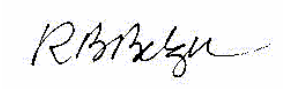
This new section is extremely welcome, for the problem posed by quasi-regulatory actions has been around a long time and shows few signs of abating. OIRA's discussion reveals that a serious effort may be underway to finally rein in these practices. Regulatory Checkbook tends to focus on how agencies comply with statutory and Executive requirements in rulemaking. Where agencies purposefully evade rulemaking procedures, it would be surprising to discover any compliance with Executive order requirements. Thus, Regulatory Checkbook is not now well-positioned to provide the kinds of detailed information that OIRA seeks on specific "problematic" guidance documents. Nonetheless, we commend OIRA for drawing attention to the problem and providing a necessary government-wide forum for beginning to address it.

More information about what OIRA intends to do with the information it obtains from public commenters would be useful. This is important for two reasons. First, public commenters may doubt that there is much reward for this effort given the fact that similar requests for comment on "recommendations for reform" have not had any perceptible impact. Second, members of the public who have vivid examples of agencies' abusive use of guidance have legitimate concerns that they could face retaliation if they make these examples known. Because OIRA has not offered a protective shield that could attenuate these concerns, it will be surprising if very many examples are forthcoming.

## CONCLUDING COMMENTS

I appreciate the opportunity to provide public comments on OIRA's latest draft report to Congress on the costs and benefits of federal regulation. I trust that these comments will be helpful and taken as constructive ideas for improving federal regulation, its oversight, and the manner in which regulatory information is reported to the American people. Should you or your staff have any questions about these comments, please do not hesitate to contact me.

Sincerely,



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