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From: Angela Logomasini
Sent: Thursday, June 15, 2006 5:30 PM
To: 'OMB_RAbulletin@omb.eop.gov'
Subject: Proposed Risk Management Bulletin Comment

June 15, 2006

Office of Information and Regulatory Affairs
Office of Management and Budget
727 17th Street, N.W.
New Executive Office Building, Room 10201
Washington, D.C. 20503

Re: Proposed Risk Assessment Bulletin

The OMB Proposed Risk Assessment Bulletin does a good job outlining basic standards that all agencies should follow when conducting risk assessments. Particularly useful are the standards that would apply to influential assessments. Requirements for transparency; peer review; best available science; reproducibility; and the use of central estimates, rather than worst case scenarios, are most welcome.

Yet the value of the bulletin may prove limited because it suffers from the same problems that have undermined many other regulatory reform initiatives: It gives agencies too much leeway to evade key requirements, and it may encourage them to waive the standards entirely.

OMB would be wise to revise this proposal in a way that would ensure stronger compliance, which is necessary to achieve improved regulatory accountability. After all, poorly designed regulations can have seriously adverse impacts on economic well-being and public health. In fact, a CEI report, *Reviving Regulatory Reform*(1) by Marlo Lewis Jr., points out how poorly crafted regulations can contribute to economic downturns. In addition, CEI's "death by regulation" project has documented many cases in which misguided regulations actually undermine public health and can lead to a net loss of human life.(2)

The risk management bulletin provides an opportunity for OMB to prevent such faulty regulation. This program will only work, however, if OMB finds ways to enforce its standards and/or provide incentives to agencies to comply. Too many similar efforts have largely failed because they lacked such provisions.

For example, Lewis's analysis of OMB Circular A-4—which was designed to advance "best practices in regulatory analysis"—documents disappointingly lowly compliance of that initiative. He concludes: "In summary, despite three decades of executive oversight and eight years of congressional mandated reports, regulatory accounting as practiced by federal agencies

remains an unreliable and misleading enterprise. Absent a basic change in the incentives agencies face, it is difficult to believe that Circular A-4 will succeed where previous presidential directives and OMB guidance documents have failed.”(3)

Other significant regulatory reform efforts have suffered similar fates because they also failed to hold regulators accountable. Consider the Data Access Law of 1999, which mandated that agencies release data used to justify rules. OMB issued a circular to implement its mandate, which as Lewis documents in his report, undercut the purpose of the law. It only granted public access to the data at the end of the regulatory process—leaving too little time for reanalysis of the data before issuance of the final rule.

After the Data Access Law was rendered largely ineffective, Congress passed the Data Quality Act in 2001. Thereafter, OMB developed relatively good, and potentially useful, government-wide data quality standards for the agencies. Rather than make those standards mandatory for all agencies, OMB basically requested agencies develop their own standards that could vary from the OMB standards. Unfortunately, many agencies issued data quality standards that were of considerably lower value than the OMB standards and that, in many cases, undermined the intent of the law. In addition, some agency guidelines held that the data quality standards are not subject to judicial review. Some courts have also held that the law is not subject to judicial review, further undermining enforcement.

The OMB Risk Bulletin, which is drafted under the authority of the Data Quality Act, may be headed down the same path as the many other weak regulatory reform efforts. While OMB cannot change how courts rule on private judicial enforcement, it could develop mechanisms for its own enforcement efforts that would create strong incentives for agency compliance.

Instead, the OMB bulletin provides few such incentives. It explicitly states in the discussion on “applicability” that the agencies shall follow the standards “to the extent appropriate.” Hence, if an agency deems it appropriate, it can dispense with such basic things as the use of best available, peer-reviewed science, transparency and reproducibility—even for influential policy decisions or major rules.

OMB does hint that it might reject rules based on studies that don’t meet the risk assessment standards, yet in the same paragraph it grants agencies the authority to defer or waive the guidelines. All agencies need to do is provide OMB with a brief description as to why they will waive or defer the rules. Perhaps OMB will halt egregious examples of noncompliance at this stage, but there is no assurance it will do so consistently if ever. OMB states that it expects such waivers/deferrals to be infrequent rather than stating that it will ensure they are infrequent.

If the risk bulletin is to have significant value, it should demand that all agencies follow these standards unless they gain explicit OMB approval for deviations. Emergency notices and the like would gain exceptions, but even most of these could benefit from a quick OMB review before granting of waivers.

OMB is responsible for holding regulatory agencies accountable to ensure public health and wellbeing does not suffer from misguided regulations. This bulletin offers OMB the opportunity

to begin holding agencies more accountable. But if OMB does not revise this bulletin to ensure proper enforcement of the standards, this effort might become little more than an empty promise.

Sincerely,

Angela Logomasini
Director of Risk and Environmental Policy
Competitive Enterprise Institute
1001 Connecticut Avenue, NW, #1250
Washington, D.C. 20036
(202) 331-1010 Fax: (202) 331-0640
Direct ph: (202) 331-2269
Notes:

(1) Marlo Lewis Jr., *Reviving Regulatory Reform: Options for the President and Congress* (Washington, D.C.: Competitive Enterprise Institute, 2005), <http://www.cei.org/pdf/4446.pdf>.

(2) For example, see Sam Kazman, "Death by Regulation," *Regulation* 14, no. 4, (Fall 1991).

(³) Lewis, *Reviving Regulatory Reform*, 30.