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Via email and fax

Lorraine Hunt
Office of Information and Regulatory Affairs
Office of Management and Budget
NEOB, Rm. 10202
Washington, DC 20503

Dear Ms. Hunt:

Re: Comments on OMB's draft *Report to Congress on the Costs and Benefits of Federal Regulations*; Ch. II, "Developing Better Regulation, Part B, "Approaches to Analysis and Management of Emerging Risks" (68 FR 5492 *et seq*., Feb. 3, 2003)

These comments address the OMB draft's request for public input on "Examples of approaches in human . . . risk assessment . . . methods addressed by U.S. regulatory agencies . . . which appear unbalanced." At 5499.

Fundamental goals of sound scientific assessment of potential human health risks are use of the best obtainable data and the reduction of uncertainty. At odds with these goals is the policy instituted by EPA via an "announcement" on December 14, 2002 that it would not use the results of "third-party" toxicity testing with human volunteers in any of its regulatory decisionmaking – at least not until it receives a report from the National Academy of Sciences and subsequently conducts, or considers whether to conduct, a notice-and-comment rulemaking, or unless it is legally required to use such data.

The EPA "policy" (actually a "rule") is remarkably "unbalanced" in numerous respects: (1) The policy established an irrational double standard for "third-party" human volunteer data as opposed to such data which is obtained from studies conducted or funded by federal agencies and used in regulatory decisionmaking or "guidance". Attached is a CRE paper which contains numerous examples of sponsorship and use of such studies by EPA and other federal agencies. (Attachment 1) And those examples only go back to 1990 and are not even the result of a comprehensive search. (2) EPA and other federal agencies have historically used third-party human volunteer research in regulatory decisionmaking and guidance, so the EPA policy is a radical departure from prior practice; yet EPA has never provided a cogent rationale (or any rationale) for the policy, as required by settled tenets of administrative law. (3)

U.S. federal agencies and international organizations have consistently recognized that human volunteer studies can (and often do) meet accepted international ethical standards and provide important, relevant, reliable data for human health risk assessment, and that such data must be considered. Attached is a second CRE paper which assembles statements on this subject by international health and risk assessment bodies such as the World Health Organization and the United Nations Environment Program. (Attachment 2) And such statements supplement that Nuremburg Code (1947) and the Declaration of Helsinki (1964, revised 2000) under which such studies have been conducted for decades. See the attached copy of comments delivered by CRE to the National Research Council committee convened to review this issue. (Attachment 3) (4) The policy is contrary to the Data Quality guidance issued by both OMB and EPA in ordering its personnel to ignore highly relevant scientific data which can contribute to reducing uncertainties in risk assessments.

In addition to the facts that the EPA policy is (a) contrary to accepted U.S. inter-agency and international ethical and scientific norms, and (b) contains no supporting rationale, it is remarkable that the EPA policy was promulgated without OMB/OIRA review, without notice and comment, and without consultation with other federal agencies, particularly the inter-agency Human Subjects Research Subcommittee of the Committee on Science of the National Science and Technology Council, which has been charged with oversight of such matters. Clearly, the OMB/OIRA guidance to agencies on regulatory review should be clarified in order to avoid such instances of unbalanced risk assessment approaches.

The OMB guidance we recommend should address the following points:

1. An agency statement of general policy is a "rule" under the Administrative Procedure Act. If such a "rule" is likely to have an impact on regulatory actions, or can be considered a regulatory action, it is subject to Executive Order 12866. An agency cannot escape the requirements of the APA and E.O. 12866 by calling a "rule" a "policy" and failing to publish it in the *Federal Register* and seek public comment.

2. Agencies should pay particular attention to the definition of a "significant" regulatory action (or "rule") in E.O. 12866, which applies to actions with would create a "serious inconsistency" with other federal agencies, or would raise "novel legal or policy issues arising out of . . . the principles set forth in this Executive order." The EPA human test data policy has created a serious inconsistency with other federal agencies, and it raised novel legal and policy issues arising out of the principle in the Executive order that each agency shall "base its decisions on the best reasonably obtainable scientific . . . information concerning the need for, and consequences of, the intended regulation." The EPA policy is also in conflict with the Data Quality standards in the OMB and EPA guidance, which require use of the best available data, particularly studies that address uncertainties. (See 68 FR at 5525 1st col.) The policy also interferes with production of the best possible cost-benefit analysis under the OMB guidance, since it results in additional uncertainty ("lack of knowledge") and is likely to result in a shift to unsupported assumptions in place of available data. (See 68 FR at 5518 1st col.)

3. In notifying OIRA of a planned regulatory action such as the human test data policy which could

be considered "significant" under the Executive order, agencies should inform OIRA of any issues the action might raise under the new OMB or agency-specific Data Quality guidance, as well as any other issues concerning compliance with other applicable law or the factors to be considered in designating a planned action as "significant" under the order. (See sec. 6(a)(3) of E.O. 12866.)

4. Planned agency rules which would change well-established agency practice or rules should be accompanied by a clear and cogent rationale explaining the previously established practice or rule and its rationale and the rationale for changing the practice or rule. Such changes should usually be regarded as raising novel policy issues, thereby making them "significant" within the terms of E.O. 12866.

5. Agencies cannot avoid OIRA review of a planned regulatory action simply by designating the rule as "interim". If the so-called "interim" rule is applicable to agency regulatory actions and its revision is tentative and the timeframe for reconsideration is indefinite, the rule must be considered final until it is actually rescinded or modified.

We believe it would be appropriate to address the above points in a guidance memorandum to agency heads.

Thank you for consideration of these comments.

Sincerely,

Jim J. Tozzi
Member, CRE Advisory Board

Attachments (3)