

Buyers Up ◆ Congress Watch ◆ Critical Mass ◆ Global Trade Watch ◆ Health Research Group ◆ Litigation Group

Joan Claybrook, President

July 1, 2002

Mrs. Theresa M. O'Malley Executive Officer Information Technology Center U.S. Department of Labor Room N-1301 200 Constitution Avenue, N.W. Washington, D.C. 20210

RE: Comments on the U.S. Department of Labor Draft Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by the Department of Labor

Dear Mrs. O'Malley:

Public Citizen is a non-profit consumer advocacy organization with approximately 150,000 members nationwide. For 31 years, we have had direct, practical involvement with a wide variety of federal health and safety protections. Public Citizen's Litigation Group has represented consumer groups, labor unions, worker groups, and public health organizations in standard-setting proceedings and in litigation involving OSHA and other health and safety agencies. Public Citizen's Health Research Group has also worked extensively to protect worker health and safety and is the nation's leading advocate for safe drugs and medical devices.

The Data Quality Act and OMB's enacting guidelines are ostensibly aimed at improving the accuracy of information disseminated by federal agencies. However, given OMB's expansive enacting guidelines, Public Citizen is concerned that the Act is susceptible to misuse by opponents of regulatory safeguards who may attempt to exploit the Act to dissuade agencies from disseminating information to the public or engaging in protective rulemaking.

Given these constraints, the Department of Labor (DOL) is to be commended for its overall approach to implementing the Act. The DOL has clearly made an effort to balance its many responsibilities to America's workers with the need to disseminate high-quality information without becoming mired in the unnecessary procedures called for by OMB's guidelines. Though Public Citizen believes that agencies should strive to disseminate accurate information, we have a number of observations and concerns stemming from the enactment of the Data Quality Act.

We urge the DOL to keep the mandates of the Data Quality Act in perspective. After all, the Act was not the subject of legislative hearings or debate. Rather, it was enacted as an obscure provision buried

in a massive appropriations bill. <sup>1</sup> It defies logic to suggest, as some have, that Congress intended this provision to work a substantial change in agency practices, especially since, although the Act was part of an appropriations bill, Congress did not provide agencies additional funds to implement the Act. All of these factors underscore that Congress clearly intended the Data Quality Act to have only a modest impact on existing agency practices.

First, we urge the Department to reject OMB's efforts to enlarge considerably an agency's responsibilities under the Act. Here, it is crucial to distinguish between the modest demands placed on any agency under the Act—to enhance the quality of information the agencies rely on in decision-making and to give affected members of the public an opportunity to seek correction of inaccurate agency records—with the formidable demands OMB's guidelines seek to place on agencies. Most disturbing is OMB's effort to persuade agencies to construct elaborate, process-laden, and unduly burdensome procedures for correcting allegedly inaccurate agency records.<sup>2</sup> Nothing in the Act suggests that Congress intended that agencies divert substantial resources to that end, and Congress' failure to appropriate funds to implement the Act suggests just the opposite. We urge the DOL to use as its guiding star the Act itself, and not OMB's unjustified construction of it.

In addition, the underlying problem with the Act and OMB's guidelines is that they implicitly accept the notions of a gold standard in research and the objective nature of scientific truth. Neither assumption is true, particularly with the challenging scientific questions customarily addressed by OSHA. OSHA typically regulates chemicals on the basis of animal experiments and retrospective human studies. From a design perspective, the animal studies are compelling because they are randomized and carefully controlled. Industry, however, has made a habit of attacking the relevance of animal studies for human safety (all the while happily inserting into the record claims of benefits based on animal data). The plain fact is that animal studies, particularly on carcinogenicity, are indispensable and the alternatives that have so far been offered by the industry have not been demonstrated to be adequate replacements.

Typically, OSHA has not regulated occupational carcinogens unless there are data from human studies that confirm a link between exposure and disease. Obviously, this addresses the inter-species

studies that comfrm a link between exposure and disease. Obviously, this addresses the

The Act was drafted, at least in part, by Jim Tozzi of the Center for Regulatory Effectiveness, a probusiness, anti-regulation advocacy group, and inserted at the last second as an appropriations rider by Representative Jo Ann Emerson.

OMB's effecting guidelines, appear to be animated by an underlying antagonism towards federal agencies and their essential role in safeguarding workers and the public. The perception that the guidelines are aimed at interests other than data quality arises in part from statements emanating from OMB, specifically, OIRA Administrator John Graham. For example, in OMB-OIRA's Draft Report to Congress on the Costs and Benefits of Federal Regulations, Administrator Graham focused on the corrective mechanisms of the Act, rather than its quality standards. Indeed, the first substantive provision of the quality guidelines mentioned in the Draft Report is the ability of "members of the public to challenge agencies when poor quality information is disseminated." (67 FR 15014. See also, 67 FR 15021, "The OMB guidelines provide affected parties concerned about poor quality information with the opportunity to seek administrative corrections to agency information, with assurances that their complaints will be addressed in a timely manner.") Administrator Graham repeated this sentiment just this month when he testified before the House Committee on Small Business. [See The Cost of Regulation to Small Business: Joint Hearing Before the Subcommittee on Regulatory Reform and Oversight and the Subcommittee on Workforce, Empowerment and Government of the House Committee on Small Business, 107th Congress June 6, 2002 (statement of OIRA Administrator John Graham, "[The data quality] guidelines will offer a new opportunity for affected members of the public to challenge agencies when poor quality information is disseminated. OMB has required each agency to develop an administrative mechanism to resolve these challenges, including an independent appeals mechanism."). Given his history for advocating anti-regulatory positions in his previous post at the industry-funded Harvard Center for Risk Analysis, Administrator Graham's enthusiasm for challenging federal agencies, and potentially slowing or halting the development of protective regulations, should not be a surprise to anyone.]

difference arguments put forth by industry. Randomized trials, however, are not feasible because they would, in most cases, be unethical and even then would not yield data for decades. Consequently, most regulation occurs on the basis of retrospective cohort studies, in which the investigator looks backward in time to see if some prior exposure is associated with disease in the recent past. Criticisms of such designs are inevitable, because of the lack of randomization and consequent potential confounding, but the unassailable truth is that this is the best we can do in the vast majority of circumstances. The response of regulated industry is generally to raise a series of often-marginally relevant scientific issues (which are then used to delay the process, tying up the agency in endless meetings), implicitly threaten lawsuits and, finally, actually file them. An army of industry-friendly consultants is always at the ready to lend these critiques an aura of respectability, often in the form of meetings with carefully selected presenters, followed by medical journal issues (often supported by industry) devoted to the conference with carefully selected authors. The medical literature is contaminated in the process. To this morass will be added the Data Quality Management guidelines.

As scientists and researchers are well aware, information quality is a moving target and study outcomes can be highly subject to manipulation. Obtaining "perfect" information is a quest for an unattainable Holy Grail. The task for federal agencies is to regulate based on the best available science at the time the agency is engaged in rulemaking, not to use the absence of perfect science as a convenient excuse to sit by idly as workers are exposed to hazardous chemicals. The United States Court of Appeals for the District of Columbia perhaps best expressed this concept, stating that "OSHA cannot let workers suffer while it awaits the Godot of scientific certainty." In this context, the data quality guidelines must be harmonized with, not prioritized above, existing authorizing statutes to ensure that agencies, particularly OSHA, properly carry out their responsibilities to workers and the public.

These comments first address several overarching issues regarding the data quality guidelines. Subsequently, the comments respond to specific provisions of the Department's guidelines, making recommendations and comments as appropriate.

### **General Comments**

In the preamble to the final guidelines to agencies, OMB states that

It is important that these guidelines do not impose unnecessary administrative burdens that would inhibit agencies from continuing . . . to disseminate information that can be of great benefit and value to the public. In this regard, OMB encourages agencies to incorporate the standards and procedures required by these guidelines into their existing information resources management and administrative practices rather than create new and potentially duplicative or contradictory processes.<sup>4</sup>

Additionally, OMB acknowledges in the preamble that pursuant to OMB Circular A-130, agencies "already have in place well-established information quality standards and administrative mechanisms that allow persons to seek and obtain correction of information that is maintained and disseminated by the agency." Given this language, the DOL properly chose to integrate its data quality guidelines with existing processes and procedures to the extent possible rather than creating new ones.

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<sup>3 &</sup>lt;u>U.S. Steelworkers of America v. Marshall</u>, 647 F.2d 1189, 1266 (1981) (interpreting 29 U.S.C. § 655(b)(5), OSHA's statutory requirement to act according to "the best available evidence.").

<sup>4 67</sup> FR 8453.

<sup>5</sup> *Id*.

The DOL should also clearly state at the outset of its final guidelines that when deciding whether to disseminate or use data, "quality" is only one factor among many that it will consider. First, the Department must answer to its core substantive mission, as directed by Congress, which according to the DOL's website, is to "guarantee workers' rights to safe and healthful working conditions; a minimum hourly wage and overtime pay; freedom from employment discrimination; unemployment insurance; and other income support." Second, the DOL should consider the benefits of timely information dissemination in carrying out its core mission and the general goal of democratic openness. The unwarranted withholding or delayed dissemination of agency information under the pretense of ensuring accuracy is an outcome the DOL must carefully guard against. Finally, the DOL must operate within budgetary constraints. As OIRA Administrator John Graham acknowledged, the Data Quality Act is an enormous unfunded mandate, the requirements of which will place off-budget burdens on the Department that could potentially cause a massive transfer of already scarce resources to addressing data quality complaints and procedural requirements at the expense of its primary missions. The DOL can avoid such a redistribution of resources by limiting the number of new policies and procedures initiated to enact the Data Quality Act and OMB's guidelines.

Furthermore, the DOL should include a section at the beginning of its final data quality guidelines emphasizing that public access to information is a central government responsibility that the DOL intends to uphold. Too few agencies have taken the opportunity to acknowledge and reaffirm their commitment to the important benefits derived from providing public access to government information. If there is any question about whether information should be disclosed and accessible to the public, the presumption must be in favor of the public's right-to-know as intended by the Federal Freedom of Information Act. The Environmental Protection Agency's draft data quality guidelines provide a good example of this type of statement.<sup>8</sup>

Finally, the Department should emphasize the language in its draft guidelines that acknowledges the importance of public access to agency information and the value of public input. As the DOL correctly notes, public access to information allows the public to suggest improvements in information practices and inform agencies when information might not meet quality standards. EPA's Toxics Release Inventory is a perfect example of data quality improving as a direct result of public access to the information. Of course, agencies should build in mechanisms for allowing incorrect information to be corrected. EPA's Integrated Error Correction Process (IECP) is an example for such a mechanism. This system has already resolved hundreds of corrections without ever removing public access to any data.

## Scope and Applicability of the Data Quality Guidelines

The Scope of the Data Quality Act Is Limited

As mentioned previously, the Data Quality Act is directed at ensuring the quality of information disseminated by federal agencies. In addition to addressing information quality, OMB, perhaps in response to pressure from regulated industry, emphasized and expanded on the corrective mechanism called for by Congress. Representatives of regulated industry have made it clear that they intend to attempt to use the corrective mechanism of agency data quality guidelines as a vehicle to delay or halt the development of federal regulations. William Kovacs, of the U.S. Chamber of Commerce, epitomized this attitude, stating that the data quality guidelines are "the biggest sleeper there is in the regulatory area and

<sup>6</sup> *See* http://www.dol.gov/opa/aboutdol/mission.htm.

<sup>7</sup> OIRA Administrator John Graham at the National Academy of Sciences Workshop #1 Ensuring the Quality of Data Disseminated by the Federal Government (March 21, 2002).

<sup>8</sup> See § 2.3 EPA's Commitment to Public Access, Draft Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency.

will have an impact so far beyond anything people can imagine." Jim Tozzi, through his Center for Regulatory Effectiveness, has made no secret of his plans to push for judicial review of agency decisions under the Data Quality Act. In light of regulated industry's undisguised intent to aggressively exploit the Data Quality Act and agencies' enacting guidelines, it is imperative that the DOL clearly and carefully define the scope of its final guidelines.

The DOL addressed this issue head-on in its draft guidelines, correctly balancing Congressional goals of data quality with OMB's enacting guidelines. The Department states that the guidelines are:

[N]ot intended to impose any binding requirements or obligations on the Department or the public or to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, officers, or any person. They are not intended to provide any right to judicial review. A Department agency may vary the application of information quality guidelines in particular situations where it believes that other approaches will more appropriately carry out the purpose of these guidelines or will help an agency to meet its statutory or program obligations.

The DOL should retain this statement in its final guidelines, because it demonstrates the Department's commitment of ensuring the accuracy of disseminated information while properly prioritizing its more fully developed Congressional mandates. It further emphasizes that Congress did not call for judicial review of agency decisions under the guidelines.

Since the Data Quality Act applies to information disseminated by federal agencies, the definition of these terms is of primary importance. The DOL incorporated OMB's definitions of "information" and "dissemination" in its draft guidelines, and enumerated specific exceptions to the guidelines, including those exceptions contained in OMB's guidelines. The Department states that the guidelines do not apply to "agency citation to or discussion of information that was prepared by others and considered by the agency in the performance of its responsibilities." Public Citizen suggests that the DOL clarify this provision and state that the guidelines do not apply when the Department acts as a conduit to disseminate information originating from the public, as it does during the notice and comment stage of rulemaking.

### **Risk Analysis**

The implications of the data quality guidelines for agency risk assessments, which generally serve as the foundation and justification for health, safety and environmental regulation, are of particular concern to Public Citizen. In crafting government-wide parameters for information quality, OMB attempted to accomplish by guideline what Congress has never done by statute—direct agencies to "adopt or adapt" principles for risk assessment laid out in the Safe Drinking Water Act (SDWA). Apparently, OMB overlooked or ignored the fact that OSHA, (like other federal agencies) already has an authorizing statute that, in OSHA's case, prescribes the procedure by which it must promulgate worker safety standards. <sup>11</sup> As previously discussed, Congress did not intend for the Data Quality Act to supercede or

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Andrew C. Revkin, Law Revises Standards for Scientific Study, N.Y. Times, March 21, 2002, at A-24.

Regulatory Reform, OMB Guidelines on Quality of Information Seen as Having Profound Impact on Agencies, Daily Environmental Report, January 14, 2002, at B-1 ("Tozzi said he thinks a refusal to correct information can be challenged in court. His organization intends to test that theory by filing a lawsuit soon after EPA implements OMB's guidelines in October"); see also, <a href="http://www.thecre.com/index.html">http://www.thecre.com/index.html</a> ("Executive Officials Opine that Agency Denials of Data Quality Act Petitions Are Judicially Reviewable.")

<sup>29</sup> U.S.C. § 655(b)(5). When promulgating standards dealing with toxic materials or harmful physical agents, Congress directs OSHA to "set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his

supplant existing authorizing statutes. As a result, to the extent that it contradicts any of the Department's preexisting authorizing statutes, the DOL is prohibited from adopting or adapting the SDWA.

OMB's guidelines ask agencies to "adopt or adapt" the SDWA quality standards, though the standards may be temporarily waived in "urgent situations." The provisions in the SDWA embraced by OMB's final guidelines apply to agency action based on science and agency dissemination of information to the public involving risk effects. When an agency takes action based on science, the SDWA directs agencies to "use (i) the best available, peer reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies uses of the data)."13

When presenting information on public health effects, the SDWA requires agencies to ensure that information is comprehensive, informative and understandable.<sup>14</sup> The SDWA further requires agencies "in a document made available to the public in support of a regulation promulgated under this section, [to] specify, to the extent practicable (i) each population addressed by any estimate of public health effects; (ii) the expected risk or central estimate of risk for the specific populations; (iii) each appropriate upperbound or lower-bound estimate of risk; (iv) each significant uncertainty identified in the process of the assessment of public health effects and studies that would assist in resolving the uncertainty; and (v) peerreviewed studies known to the Administrator that support, are directly relevant to, or fail to support any estimate of public health effects and the methodology used to reconcile inconsistencies in the scientific data."15

The SDWA provisions cited by OMB are far more restrictive on agency action than the provisions contained in OSHA's authorizing statute. The SDWA squeezes information through progressively smaller hoops beginning with "best available" science and further requiring "peer review," "studies conducted in accordance with sound and objective scientific practices," and "data collected by accepted methods or best available methods." Further complicating matters is the fact that each of these hoops contains terms that are vague and undefined. Much of the information OSHA relies upon during a rulemaking process cannot pass through each and every one of these hoops, and indeed, Congress makes no such requirement. Given that Congress has enacted an operating statute for OSHA with respect to actions based on risk analysis, it would not be legal for OSHA to adopt the more restrictive standards of the SDWA. OSHA must abide by its authorizing statute—it is not free to adopt the standards OMB attempts to foist upon it.

This is not the first time OMB has sought to extend the application of the Safe Drinking Water Act. In a September 20, 2001 memorandum to the President's Management Council, OIRA Administrator Graham "recommended" that agencies "consider adopting or adapting these basic congressional standards for judging the quality of scientific information about risk it uses and disseminates." This statement is misleading at best, since Congress has never adopted basic cross agency standards for information

working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws."

OMB's Final Data Quality Guidelines, section V(3)(b)(ii)(C). 12

<sup>42</sup> U.S.C. § 300g-1(b)(3)(A). 13

<sup>14</sup> Id. at  $\S 300g-1(b)(3)(B)$ .

<sup>15</sup> Id.

<sup>16</sup> Memorandum, Presidential Review of Agency Rulemaking by OIRA, September 20, 2002 (available on the Internet at http://www.whitehouse.gov/omb/inforeg/oira\_review-process.html).

quality. Indeed, the provision of the SDWA cited by Administrator Graham in the memorandum says specifically that the quality standards apply only "in carrying out this section." <sup>17</sup>

EPA's recent record for safeguarding our drinking water hardly recommends exporting the SDWA quality standards to other programs or agencies. Since the SDWA scientific data quality standards went into effect in 1996, EPA's drinking water program has been crippled by delays, in part due to the extraordinary and inappropriate new scientific hurdles. EPA has not adopted a single safeguard for a new contaminant from its "contaminant candidate list" in the nearly six years since the 1996 law passed. The agency's only new or revised standards issued during that period were a handful that were issued in response to explicit Congressional deadlines (and even those generally were issued after the statutory deadlines had passed, in one case only after a deadline lawsuit). Maximum contaminant levels mandated by Congress under the SDWA limiting the level of radon and emerging contaminants in drinking water are long overdue. Furthermore, in 2000, the D.C. circuit court struck down EPA's maximum contaminant level goal for chloroform, in large part because it found that the quality standards of the SDWA were not met. While the SDWA quality standards are not solely to blame for this abysmal state of affairs at EPA, it is reason to be concerned that other agencies may be similarly hamstrung by the standards.

The DOL delegated to OSHA and MSHA the responsibility for drafting guidelines for conducting health and safety risk analyses. OSHA/MSHA wisely chose to adapt the SDWA standards rather than closely follow OMB guidelines, as did every other federal agency, including the EPA. After describing the adaptations, OSHA/MSHA describes in the draft guidelines how their respective authorizing statutes address risk analyses and explains how current practice fits with the principles of the Safe Drinking Water Act. Public Citizen suggests that the DOL reverse the order in which this information is presented in the final guidelines to clarify that the Data Quality Act and OMB's guidelines do not trump the standards of OSHA and MSHA, and to emphasize that DOL's first responsibility is to act pursuant to its own relevant authorizing statutes.

We also recommend that DOL include one of the most important adaptations of the SDWA we have seen. EPA – the agency that operates under the SDWA and its risk assessment principles – defined "best available" as the best available at the time. We strongly advise DOL to do the same. This provision is essential to ensure that the DOL can act based on the best scientific studies available at the time it is engaged in rulemaking.

# **Information Categories**

Like OMB's guidelines, the DOL has divided the universe of disseminated information into two categories, "influential" and "non-influential." The DOL states that "[w]hether information is influential is to be determined on an item-by-item basis rather than by aggregating multiple studies, documents or other informational items that may influence a single policy or decision." Public Citizen agrees with this approach, however, we strongly advise the DOL not to label information as "influential" or "not influential" prior to dissemination.

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Administrator Graham cites the Safe Drinking Water Act at 42 U.S.C. § 300g-1(b)(3)(A) & (B) to support his contention that Congress "adopted" government wide quality standards for the use of science in agency decision making. A plain reading of the text of the statute clearly evinces his mistaken understanding of Congress' intent. Section 300g-1(b)(3)(A) states in relevant part, "Use of science in decision making. *In carrying out this section*, and, to the degree that an Agency action is based on science, the Administrator shall use . . ." Similarly, Section 300g-1(b)(3)(B) states in relevant part, "Public information. *In carrying out this section*, the Administrator shall ensure that the presentation of information on public health effects is comprehensive, informative, and understandable."

In contrast, regulated industry has vigorously urged federal agencies to label information as "influential" or "not influential" prior to dissemination. Agencies should avoid this time consuming, burdensome exercise because it would divert scarce agency resources away from other more important and fully developed mandates, and it would interfere with information dissemination efforts. Instead, we recommend that the DOL employ a high threshold for meeting the definition "influential." By limiting the coverage of these guidelines, DOL can maximize its flexibility and preserve its ability to effectively carry out its statutory mission and act in a timely fashion.

## **Information Quality Assurance Techniques and Methods**

### Peer Review

OMB pressures agencies to subject all scientific, financial and statistical information to peer review in order to meet standards of objectivity. OMB's guidelines state that when data and statistical results have been subjected to "formal, independent, external peer review, the information may generally be presumed to be of acceptable objectivity." While independent external peer review of research may at times be a useful tool for ensuring the accuracy of information, there is no statutory or other basis for establishing peer review as a guarantor of quality. The Data Quality Act does not specifically call for peer review, nor has Congress ever imposed such a universal peer review requirement on agencies. In fact, Congress has repeatedly failed to pass regulatory "reform" legislation with such a requirement.

The DOL should, and does, reserve the option to bypass peer review when it is unlikely to enhance information quality (except, of course, when peer review is mandated by statute). For example, agencies often rely upon information published in scientific journals and already subjected to the rigorous peer review requirements of the scientific community. It is superfluous for agencies to initiate a second peer review process that is unlikely to improve information quality. The Department recognizes this and takes a common sense approach that enables sub-agencies to use the most beneficial means of ensuring high quality information. The DOL's draft guidelines direct sub-agencies to "use information quality assurance techniques and methods that they determine are most appropriate for their information products." Public Citizen agrees that agencies must be permitted to exercise their discretion to use the most appropriate method of quality assurance. However, there are a number of points the DOL should clarify with respect to peer review.

The standards of what constitutes peer review are directly proportional to the usefulness of the process, i.e., the higher the standards, the more likely the process is to enhance the quality of the information at issue. Therefore, when the DOL chooses to utilize peer review, the agency should go beyond the peer review "recommendations" referred to in OMB's final guidelines.<sup>19</sup> OMB refers to the September 20, 2001 memorandum to the President's Management Council, wherein Administrator Graham makes the following "recommendations" to federal agencies:

For economically significant and major rulemakings, OMB recommends that agencies subject RIAs [Regulatory Impact Analysis] and supporting technical documents to independent, external peer review by qualified specialists. Given the growing public interest in peer review at agencies, OMB recommends that (a) peer reviewers be selected primarily on the basis of necessary technical expertise, (b) peer reviewers be expected to disclose to agencies prior technical/policy positions they may have taken on the issues at hand, (c) peer reviewers be expected to disclose to agencies their sources of personal and

OMB's Final Data Quality Guidelines, section V(3)(b)(i).

<sup>19</sup> See id.; see also 67 FR 8454-55 (OMB's discussion of the peer review "recommendations" contained in the September 20, 2001 memorandum to the President's Management Council).

institutional funding (private or public sector), and (d) peer reviews be conducted in an open and rigorous manner. OIRA will be giving a measure of deference to agency analysis that has been developed in conjunction with such peer review procedures.<sup>20</sup>

There are a number of problems with peer review that are glaringly overlooked by OMB's final guidelines. First, the "recommendations" do not ensure unbiased review because information about the peer reviewers is *only* disclosed to the agencies. Peer reviewers are only required to disclose information regarding their prior technical/policy positions and their sources of personal and institutional funding *to agencies*, not to the public. <sup>21</sup> Also, the recommendations do not provide for any public participation, nomination or review of the peer reviewer selection process. Finally, there is no requirement that peer reviewers be free of any conflict of interest.

Public Citizen strongly advises the DOL to incorporate provisions to ensure that peer reviewers meet the highest standards of impartiality and fairness. Information about peer reviewers should be made available to the public and peer reviewers should be required to affirm the absence of any conflicts of interest. In the event that it is impossible to empanel impartial peer reviewers, all conflicts of interest must be published alongside their reports. Unless these precautions are taken, the peer review process will be highly susceptible to becoming a puppet of regulated industry.

## **Information Complaint Process**

The Data Quality Act and OMB's implementing guidelines each require agencies to create an administrative review mechanism whereby affected persons can seek correction of information that does not comply with OMB's data quality guidelines. The design of this mechanism and the procedures by which it will operate are critical.

As an initial point, a plain reading of the Data Quality Act requires that agencies create an administrative review mechanism "allowing affected persons to seek and obtain correction of information maintained and disseminated by agencies that does not comply with [OMB's] guidelines (emphasis added)."<sup>22</sup> OMB's guidelines echo the Congressional language in section II(2) of its final guidelines, directing agencies to "establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with these OMB guidelines (emphasis added)." However, later in the final guidelines, OMB extends the review mechanism to apply to OMB or agency guidelines (emphasis added).<sup>23</sup> Due to this contradictory language, the DOL should be careful not to promise more than it is required to with respect to the scope of the review mechanism, or it will create new rights under administrative law.

The Review Mechanism Must Be Carefully Constructed

In the guidelines the DOL does a good job of carrying out its responsibility in complying with the review requirement without creating duplicative, cumbersome new mechanisms. The Department first

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Memorandum, Presidential Review of Agency Rulemaking by OIRA, September 20, 2002 (available on the Internet at http://www.whitehouse.gov/omb/inforeg/oira\_review-process.html).

The General Accounting Office concluded last summer that EPA's Science Advisory Board panels, a model suggested by peer review proponents, were plagued by undisclosed conflicts of interest and that the public was consequently left uninformed about the nature of the panelists backgrounds in a manner that thwarted the intent and importance of conflicts laws and rules. See General Accounting Office, EPA's Science Advisory Board Panels: Improved Polices and Procedures Needed to Ensure Independence and Balance, GAO-01-536, June 2001.

<sup>22</sup> Data Quality Act, PL-106-544, section 515(b)(2)(B).

OMB's Final Data Quality Guidelines, section III(3).

acknowledges the importance of public input and encourages the public to suggest improvements informally. Then, at the outset of describing the formal complaint process, the DOL clearly states that the purpose of the process is "to deal with information quality, not to resolve underlying substantive policy or legal issues." The DOL should retain this important statement of purpose in its final guidelines.

The Department should also retain the language limiting the scope of the complaint process, underscoring as it did at the beginning of its draft guidelines, that the complaint process

[I]s not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, officers or any persons. It is not intended to provide any right of judicial review. Moreover, this process is not intended to substitute for other legally authorized processes, such as the Privacy Act or the rulemaking process. Concerns regarding information in a rulemaking must be presented in the rulemaking in accordance with the rulemaking's procedures.

#### Access to the Review Mechanism

The Department specifically requests comments regarding "whether the information requested from complainants is adequate to assure that complaints can be properly evaluated." The DOL identifies certain information complainants must provide, including identification and contact information. Additionally, complainants must "identify, as specifically as possible, the information in question and carefully describe the nature of the complaint, including an explanation of why they believe the information does not comply with OMB, Departmental, or agency-specific guidelines, and the reason why the agency should make the change."

First, it is unclear whether the review mechanism applies with respect to agencies' data quality guidelines. As mentioned previously, OMB's final guidelines are inconsistent with the Data Quality Act.<sup>24</sup> Given this inconsistency, the Department should not unnecessarily enlarge the scope of the review mechanism. To avoid doing so, the DOL should omit any reference to Departmental or agency-specific guidelines, so that its final guidelines read ". . . including an explanation of why they believe the information does not conform with OMB guidelines."

Also, in addition to simply listing the information a complainant must provide, the DOL's final guidelines should include a clear statement that the "burden of proof" rests upon the party requesting correction of information— both to demonstrate that they are an "affected person," as that term is used in the Data Quality Act, <sup>25</sup> and that a change is necessary. Since the DOL is not required to defend the quality of disseminated information, the burden of proof plainly rests with the complainant to demonstrate that the challenged information does not comply with OMB's guidelines and that corrective action is warranted.

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Compare PL 106-554, section 515(b)(2)(B) ("establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines issued under subsection (a)." Subsection (a) requires the Director of OMB to issue data quality guidelines for federal agencies.), and OMB's Final Data Quality Guidelines, section II(2) ("Establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with these OMB guidelines), with OMB's Final Data Quality Guidelines, section III(3) ("agencies shall establish administrative mechanisms allowing affected persons to seek and obtain, where appropriate, timely correction of information maintained and disseminated by the agency that does not comply with OMB or agency guidelines (emphasis added).").

It should be noted that the Data Quality Act calls for an administrative mechanism that allows "affected persons to seek and obtain correction of information." PL 106-554, section 515 (b)(2)(B) (emphasis added). Since OMB's final data quality guidelines fail to define "affected person" agencies must do so for themselves.

## Balancing the Department's Obligations

Public Citizen strongly endorses the Department's recognition that "agencies should be especially mindful of their legal obligations, program priorities, resource constraints, and their duty to use resources efficiently" and that agencies "must administer the complaint and appeal process consistent with these obligations and their responsibilities to carry them out in an expeditious manner." The Department reiterates this commitment to balance at the conclusion of its draft guidelines, stating that "in processing initial complaints and appeal requests, agencies should be flexible and take into account, among other things, the nature, significance, and volume of complaints, the agency's particular program needs, and available review mechanisms."

The DOL effectuates this language in the following paragraph of its draft guidelines

Any structured process would not apply to agency's archival information or to public filings. Agencies may choose not to respond to complaints about claimed defects that are frivolous or unlikely to have substantial future impact. It may not be in the public interest for agencies to devote significant resources to correcting information where the expenditure of such resources is not, in the agency's view, cost effective in light of the significance of the asserted error, the benefits that are likely to be derived from such a correction, the costs of the correction, and the agency's more pressing priorities and obligations.

To supplement this provision, we suggest that the DOL state specifically that its response to a correction request will be calibrated to take proportional account of the significance of the information in question. This will enable DOL to carry out a correction if it finds such correction appropriate given other competing duties. Also, the Department should acknowledge the distinction between incremental improvements to scientific understanding, which separately may not justify a correction, from substantial changes in the totality of the science, which likely do, and limit complaints accordingly.

## Timeliness of Complaints

The Department provides that it will "try to respond to complaints and appeals within 90 days of their receipt, unless they deem a response within this time period to be impracticable, in light of the nature of the complaint and the agency priorities." Public Citizen agrees that the agency should strive to respond to complaints in a timely manner while at the same time preserving its ability to adjust this schedule to accommodate other statutory priorities. However, to avoid criticism, the Department should notify complainants when it cannot take immediate action on their correction request and inform them of when action will be taken, as agencies do with respect to FOIA requests.

# Maintenance of a Public Docket

Keeping the public properly informed of the use of the administrative mechanism for review is essential for evaluating its progress and usefulness, as well as for ensuring the transparency that OMB's final data quality guidelines purport to advocate. Public Citizen suggests that the DOL establish a running public docket of requests for information correction and any changes to information made in response to a request. The docket should include information about the affected person requesting a change, the nature of the request, any specific changes made, and why they were made. Any changes made to publicly accessible databases should contain flags noting the information above so that the public has a log of requests and content that is changed.

## **Information Reconsideration Process**

The Department states at the outset of its draft guidelines that the purpose of its draft guidelines is in part "to describe the information quality complaint and *appeal process* required by law and OMB guidelines (emphasis added)." This statement is inaccurate and must be eliminated from the DOL's final guidelines. The Data Quality Act, which directs OMB's guidelines, does not in fact require an appeals process. It states simply that OMB's interpretive guidelines shall "establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with OMB's guidelines." Simply put, OMB exceeded its authority by including an extrastatutory appeals process in its guidelines.

A careful reading of OMB's final guidelines reveals that the "appeal" process is more accurately a "reconsideration" process. OMB states, "the agency shall establish an administrative appeal process to *review* the agency's initial decision, and specify appropriate time limits in which to resolve such requests for *reconsideration* (emphasis added)." As a result, the DOL's reconsideration process should remain fairly informal and limited in scope, with the primary purpose of ensuring that the initial agency review was conducted with due diligence.

Public Citizen agrees with the Department that reconsideration requests should be conducted by a different official than that which conducted the original review. We also approve of the Department's provision allowing designated agency officials to consult with "other agency or Departmental offices, as the agency may deem appropriate to the resolution of the complaint." The ability to consult with agency officials having expertise regarding the information at issue will reduce the likelihood that resources will be wasted and increase the ability of the agency to provide timely responses.

The Department treats requests for reconsideration as it does original correction requests, allowing itself 90 days within which to respond, unless circumstances do not permit. Again, as with FOIA requests, we suggest that the Department notify complainants when there will be a delay and advise them as to when they might expect a resolution.

Finally, the DOL permits complainants to request review during the 30-day window following the resolution of a complaint, or 120 days following the date on which the agency received the complaint, whichever is later. This time frame allows a complainant ample time to request reconsideration and allows the agency to "close the book" on a particular complaint after a reasonable time.

### **Tracking and Reporting Information Complaints and Appeals**

Both the Data Quality Act and OMB's final guidelines require agencies to report to the director of OMB the number and nature of complaints received by the agency and how such complaints were resolved. Public Citizen suggests that the Department additionally include in this report to OMB the quantitative and qualitative cost to the agency and the public imposed by the Data Quality Act and OMB's final guidelines (to the extent costs can be calculated without further disrupting the Department's agenda). As mentioned previously, the Data Quality Act is an enormous unfunded mandate, yet, contrary to the OMB's emphasis on cost-benefit analysis as the arbiter of effective government action, no such analysis of the Data Quality Act has been conducted. Providing a cost accounting to OMB will enable Congress to determine whether it is in the public's best interest to distract federal agencies with arbitrary quality standards and correction requests. If Congress determines that the data quality guidelines are an

OMB's Final Data Quality Guidelines, section III(3)(ii).

<sup>26</sup> PL 106-554, section 515(b)(2)(B).

<sup>28</sup> See PL-1-6-554, section 551(b)(2)(C) and OMB's Final Data Quality Guidelines, section IV(6).

appropriate use of agency resources, perhaps an accounting will encourage Congress to fund the Data Quality Act as it does other authorizing statutes.

# Conclusion

We appreciate the opportunity to comment on the DOL's draft guidelines. It is clear that the Department approached this task with thoughtfulness and seriousness. It is our hope that these comments will be helpful and carefully considered.

Sincerely,

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