



September 29, 2008

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SUBMITTED ELECTRONICALLY VIA WWW.REGULATIONS.GOV

Office of the Assistant Secretary for Policy  
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Washington, DC 20210  
ATTN: Risk Assessment Policy

**Advisory Council**

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**Re: The Center for Progressive Reform's Comments on DOL's  
Proposed Risk Assessment Rulemaking (RIN 1290-AA23)**

Dear Assistant Secretary Sequeira:

The Center for Progressive Reform (CPR) appreciates the opportunity to submit these comments on the Department of Labor's (DOL's) proposed "Requirements for DOL Agencies' Assessment of Occupational Health Risks" (RIN 1290-AA23). CPR's President, Professor Rena Steinzor, along with 38 other public health professionals and academics, submitted a letter to you on September 5, 2008 requesting an extension of the comment period and hearings on this proposed rule. We have received your letter denying those requests, but based on the enclosed comments on the substance of the rule, we renew the requests and urge DOL to withdraw the proposal.

Founded in 2002, the Center for Progressive Reform is a 501(c)(3) nonprofit research and educational organization comprising a network of scholars across the nation dedicated to protecting health, safety, and the environment through analysis and commentary. CPR believes sensible safeguards in these areas serve important shared values, including doing the best we can to prevent harm to people and the environment, distributing environmental harms and benefits fairly, and protecting the earth for future generations. CPR rejects the view that the economic efficiency of private markets should be the only value used to guide government action. Rather, CPR supports thoughtful government action and reform to advance the well-being of human life and the environment. Additionally, CPR believes that the public plays a crucial role in ensuring both private and public sector decisions that result in improved protection of consumers, public health and safety, and the environment; accordingly, CPR supports ready public access to the courts, enhanced public participation and improved public access to information.

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Our attached comments address numerous aspects of the proposal, each with serious implications for worker health and safety. Of our many concerns, one stands out for its immediate harmful impact on worker health: the requirement that DOL agencies publish an Advance Notice of Proposed Rulemaking (ANPRM) for each new safety standard, with the accompanying requirement that the ANPRM solicit information aimed at altering the 45-year “working life” assumption. The historical 45-year assumption is rooted in Congress’s intent to protect all workers from occupational hazard, regardless of how many years they stay on the job. Altering the assumption will leave some longtime employees inadequately protected. For example, if workers in a plant that produces hazardous chemicals stay an average of 20 years, any individual worker will receive only the protection from cancer and other long-latency diseases that he would need to avoid adverse health effects for this period. But because an uncounted number of workers will remain for longer periods – the 20 years would be an average, after all, with outliers on both sides of this number – they will not receive adequate protection. Regulated industries have long demanded such liberal revisions to traditionally conservative “default assumptions” and with this notice DOL satisfies this demand.

We thank you for the opportunity to comment, urge DOL to abandon this rulemaking, and reiterate our request for hearings and an extension of the comment period.

Sincerely,

A handwritten signature in black ink that reads "Rena I. Steinzor". The signature is written in a cursive, flowing style.

**Rena I. Steinzor**  
President, Center for Progressive Reform  
Professor, University of Maryland Law School

**Matthew Shudtz**  
Policy Analyst, Center for Progressive Reform

## ***Summary***

CPR urges DOL to withdraw the proposed risk assessment rules for four reasons. First, the new rules suggest changes to DOL standard-setting processes that endanger the health and safety of American workers. Second, the new rules ignore statutory mandates and longstanding agency policy. Third, given the evolving nature of the best practices for risk assessment, DOL's guidelines on the subject should be published in a less formal, more easily amended format. That is, DOL should not publish these guidelines as regulations, but rather as a guidance document or series of guidance documents. Finally, Department-wide policies on risk assessment deserve a more robust and transparent vetting process than DOL used in this instance. As suggested by the National Academy of Sciences' National Research Council (NRC), DOL should develop technical guidance by establishing an advisory committee of experts on all aspects of DOL risk assessment, including regulatory staff from the Occupational Safety and Health Administration (OSHA) and Mine Safety and Health Administration (MSHA).

DOL claims that this proposal "implements the [Presidential/Congressional Commission on Risk Assessment and Risk Management's] recommendation by explaining the agency's existing best practices related to risk assessment in one easy-to-reference regulation." But DOL has failed in that endeavor. What the Commission on Risk actually said was that "OSHA should publish, after appropriate public involvement and review, one or more sets of guidelines that lay out its scientific and policy defaults."<sup>1</sup> At a minimum, the Commission intended for DOL's guidelines to cover four points:

- "An explicit rationale for choosing the defaults and an explicit standard for how and when to modify them;"
- "Methods for assessing risk for noncancer health effects of concern in occupational settings;"
- "Methods for quantifying and expressing uncertainty and individual variability in risk; and"
- "A statement of the magnitude of individual risk that it considers negligible for the various adverse health effects."<sup>2</sup>

DOL in this proposal has failed to accomplish any of these recommendations. We therefore urge the agency to withdraw the proposal and develop a strategy for actively engaging a broad group of experts to help DOL implement the Commission on Risk's recommendations.

More specific objections to DOL's proposal follow.

## ***DOL should eliminate the requirement that agencies always publish Advanced Notices of Proposed Rulemaking***

Breaking from long-established precedent, this proposal would require that DOL agencies publish an advance notice of proposed rulemaking (ANPRM) when developing *any*

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<sup>1</sup> Presidential/Congressional Commission on Risk Assessment and Risk Management, *Final Report, Volume 2: Risk Assessment and Risk Management in Regulatory Decision-Making* 133-34 (1997).

<sup>2</sup> *Id.*

health standard regulating occupational exposure to a toxic substance or hazardous chemical. We urge DOL to abandon this proposal.

### 1. Paralysis by Analysis

Requiring an ANPRM at the early stages of any standard-setting process will cause delay in promulgation of the final rule, delay that has real costs in terms of workers' health and safety. As explained in the preamble, "[a]ny public comments received in response to the ANPRM shall be reviewed by the agencies, and the strength or weakness of any data received shall be carefully evaluated by agency scientists and experts in the same manner that comments in response to an NPRM are reviewed."<sup>3</sup> In other words, DOL agencies will have to complete a full notice-and-comment rulemaking *twice* for each new proposal. Such procedural complication of the rulemaking process is entirely unnecessary and will lead to delays in implementation of protective standards that should not be tolerated – much less encouraged – by an agency whose responsibility it is to act aggressively to protect American workers.

DOL notes that OSHA has occasionally used ANPRMs in past rulemakings and that "[t]he Department believes the risk assessment and rulemaking process will be strengthened by consistent opportunities for public input through an ANPRM."<sup>4</sup> However, DOL has failed to provide any evidence to support this belief. Before adding mandatory (and inevitably dilatory) procedures to its rulemaking process, DOL should develop a set of objective criteria for measuring the relationship between the use of an ANPRM and the ultimate quality of a rulemaking. These criteria should then be used to analyze past rulemakings and determine if there is positive and causative relationship between use of an ANPRM and the quality of the final rule.

### 2. Working Lives

If DOL finds based on objective criteria that use of an ANPRM improves the quality of safety standards, the regulatory text proposed for 29 C.F.R. § 2.9(c)(1) should be changed. The proposed language states that DOL agencies should use ANPRMs to solicit public input on "data regarding the frequency, intensity, duration and other parameters of worker exposure in the affected industries." As explained in Footnote 33 and the accompanying text of the preamble, the purpose of soliciting this data is to adjust agency assumptions about "working life." DOL agencies have for decades operated under the assumption that occupational safety and health standards should be designed to protect a worker exposed to hazards over the full course of a 45-year "working life." Abandoning the 45-year working life assumption based on this regulation runs counter to OSHA's and MSHA's statutory mandate to assure "that no [employee or miner] will suffer material impairment of health or functional capacity *even if such [employee or miner] has regular exposure to the hazards dealt with by such standard for the period of his working life.*"<sup>5</sup> Congress used the term "working life" to make it abundantly clear that Congress intended

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<sup>3</sup> DEPT. OF LABOR, *Requirements for DOL Agencies' Assessment of Occupational Health Risks*, 73 Fed. Reg. 50909, 50914 (Aug. 29, 2008) (hereinafter, "DOL FR notice").

<sup>4</sup> *Id.*

<sup>5</sup> 29 U.S.C. § 655(b)(5) (OSH Act § 6(b)(5)); 30 U.S.C. § 811(a)(6)(A), (Mine Act § 101(a)(6)(A)) (emphasis added).

for DOL agencies to make conservative assumptions about how long workers would be exposed to occupational hazards, in order to protect all workers.

In addition to violating OSHA and MSHA legal mandates, abandoning the 45-year working life assumption is bad risk assessment policy. Generally referred to as “default options,” standardized assumptions about certain aspects of a risk assessment play an integral role in good risk assessment practice because they provide a useful tool for working around uncertainties and variability, enabling regulators to fulfill their statutory obligation to protect public health through the enactment of protective standards despite incomplete knowledge. NRC’s influential 1983 report on risk assessment, known as the *Red Book*, lists seven important advantages of using default options in risk assessment:<sup>6</sup>

- Separation of risk assessment from risk management;
- Quality control;
- Consistency;
- Predictability;
- Evolutionary improvement of the risk assessment process;
- Improved public understanding of risk assessments, and;
- Administrative efficiency.

More recently, NRC has described default options as “critical if one is to avoid case-by-case manipulations of individual risk assessments to achieve predetermined risk management outcomes.”<sup>7</sup>

The 45-year working life default option represents good risk assessment practice because it is a plausible estimate of the “real” duration of a working life that takes into account applicable legal mandates and is ultimately based on an explicit rationale clearly articulated by the agency. DOL’s proposal to alter the working life default option is poorly designed. The utility of default options is compromised when modifications to the defaults are not based on explicit standards for how and when the default option should be altered. Indeed, in its review of the 2006 OMB Proposed Risk Assessment Bulletin, NRC wrote:

Although recognizing the need for defaults to achieve consistency and to avoid case-by-case manipulations of risk assessments, the *Red Book* committee and other committees have urged that the agencies incorporate procedures that allow departures from the defaults in specific cases in which a scientific basis for alternative assumptions or models can be found. Flexibility to incorporate new scientific knowledge, when it becomes available, is urged in most expert studies of risk assessment.<sup>8</sup>

In the proposed rule, DOL has put the cart before the horse by making simplistic, unrefined requests for “data regarding the frequency, intensity, duration and other parameters of worker

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<sup>6</sup> NRC, *Risk Assessment in the Federal Government: Managing the Process* 69-74 (1983).

<sup>7</sup> NRC, *Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget* 11 (2007).

<sup>8</sup> *Id.* at 12.

exposure” without first adopting clearly defined standards for determining when and how to modify the existing 45-year default option.

DOL has failed to answer the most obvious question: Why is the 45-year working life default assumption not valid anymore? If workers are not staying in one occupation for their entire working life, might not the reason be that existing health standards are inadequately protective, leading to injuries that force them out of the profession or out of work completely? Without first knowing *why* workers are not remaining with particular employers or in particular occupations, altering the working life default option may result in broad-scale adverse consequences for public health.

Explicit and objective standards for modifying the definition of working life are particularly important given the public health consequences of modifying the default option to anything shorter than 45 years. In terms of the standard risk assessment model, the duration of a working life is one parameter in the exposure assessment step in the model. If all other aspects of the model are held constant, reducing the working life parameter will result in a reduced value for overall risk posed by a particular hazard. Risk management decisions will reflect this reduced risk in the form of more lax regulatory standards. These standards will result in over-exposure to occupational hazards for any worker who remains on the job longer than DOL’s new working life default option. With that excess exposure comes an excess risk of injury, illness, or death.

Less stringent regulatory standards create a disincentive for workers to stay in an industry, effectively penalizing longtime employees for their loyalty to their profession. The consequent increase in employee turnover will result in an increase in the total number of workers exposed to the hazard, eventually increasing the total public health risk. The potential adverse consequences for public health are magnified in areas where DOL regulates acute hazards (e.g., hazards in slaughterhouses or logging operations). In those situations experienced workers leaving the job opens the door for novice employees who are more likely to injure themselves due to a lack of familiarity with hazardous working conditions.

For all of these reasons, if the requirement for an ANPRM remains in the final rule, DOL should remove from the proposed language for 29 C.F.R. § 2.9(c)(1) the requirement that DOL agencies solicit data related to the 45-year working life assumption. Incidentally, DOL should also remove the proposed 29 C.F.R. § 2.9(c)(3), which requires that DOL agencies’ risk assessments use “industry-by-industry evidence relating to working life exposures.”

### 3. Other Default Values

The requirement that ANPRMs solicit public input on all “key default factors and assumptions” will do nothing more than add confusion to the standard-setting process. Again, changes to default options should only occur when there are predetermined, objective criteria and procedures for determining when an existing default is no longer valid and what types of information are needed to improve the default option. Before finalizing a requirement that DOL agencies use ANPRMs to collect data on current default options, DOL should establish

guidelines that agency staff can use to formulate procedures for assessing the validity of and improving default options.

As with any important aspect of the risk assessment process, the task of gathering public input requires clear, precise, and upfront guidance for both agency staff and the interested public. In NRC's words:

The more precisely the risk manager frames the questions to be addressed by the risk assessment at the outset, the less ambiguity there will be as to what data are required to answer the questions, the less need for judgment in data-gathering, and the lower the likelihood that inappropriate or insufficient data will be gathered.<sup>9</sup>

In fact, NRC suggested that data collection and data evaluation processes should be governed by guidelines that are developed by a panel of experts.<sup>10</sup>

DOL's proposal to require an information-soliciting ANPRM suffers from the fatal flaw that it lacks the detail necessary to ensure that the ANPRM will prompt useful data submission. Far from NRC's suggestion of expert-designed guidance, the regulatory text simply instructs DOL agencies to solicit public input on a wide variety of issues generally related to risk assessment.

CPR urges DOL to abandon the requirement that agencies publish an ANPRM prior to development of any health standard.

***Requirements regarding the electronic posting of rulemaking information are inadequate***

The proposal to improve public access to DOL rulemaking information through increased use of electronic dockets is a laudable goal, but we suggest that the proposed regulations could use some fine-tuning. In the current proposal, 29 C.F.R. § 2.9(d)(1) requires publication of certain information "no later than fourteen days after the conclusion of the relevant step in the rulemaking process." If the Department wants to facilitate better commentary on proposed rules, and not just provide fodder for subsequent litigation, the proposed text should be modified to require that information be published online (at [www.regulations.gov](http://www.regulations.gov)) before the conclusion of "the relevant step in the rulemaking process."

***Many aspects of the proposed regulations will cause confusion, not clarity or consistency***

The proposed regulations contain a number of requirements that DOL has framed as "existing best practices related to risk assessment" that in fact involve significant policy choices and so deserve public comment. Because we recognize the powerful implications of DOL's decision to codify these "best practices" in formal regulation we provide these unsolicited comments on certain problematic aspects of the rule. We would also like to reiterate a point made in CPR President Rena Steinzor's September 5, 2008 letter to you: the complexity of the issues involved in this rulemaking warrant a more detailed analysis than can be accomplished in

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<sup>9</sup> NRC, *Science and Judgment in Risk Assessment* 144 (1994).

<sup>10</sup> *Id.* at 158.

the allotted 30-day comment period, we therefore request a 60-day extension and public hearings to vet the proposal. In the meantime, we are providing comments on the following aspects of the Department's "best practices," all of which support our ultimate recommendation that DOL withdraw this proposal.

## 1. Uncertainty Analysis

The proposed 29 C.F.R. § 2.9(c)(2) instructs DOL agencies to discuss in each proposed and final rule various issues related to uncertainty analysis "not limited to the reliability of data [and] significant uncertainties." And, in the proposed 29 C.F.R. § 2.9(c)(5), the text instructs DOL agencies to perform all risk assessments "in accordance with the Department's information quality and peer review guidelines." These guidelines repeatedly insist that DOL agencies specify "significant uncertainties" in risk assessments made available to the public.<sup>11</sup>

NRC committees over the years have repeatedly written about the potential utility of well-designed uncertainty analyses. The 1983 *Red Book*, the 1994 *Science and Judgment in Risk Assessment*, and 1996's *Understanding Risk: Informing Decision in a Democratic Society* all highlight the fact that an understanding of the uncertainties inherent in a risk assessment is a critical precursor to proper risk management decisions. In essence, a good characterization of a full uncertainty analysis will frame the expansive "gray area" in which risk managers must regulate, creating a backdrop against which risk managers and various stakeholders can debate the policy considerations that ultimately help shape regulatory decisions.

However, each NRC statement in support of uncertainty analysis has been accompanied by a strong caveat warning against devoting too many agency resources to uncertainty analysis. The warnings are based on the fact that while techniques used to analyze uncertainty have improved dramatically over the years, guidelines for communicating uncertainty to risk managers and tools for incorporating uncertainty analysis into risk management decisions have developed more slowly.<sup>12</sup> For instance, in its review of the OMB Risk Assessment Bulletin, NRC wrote:

The ability to quantify and propagate uncertainty is still in development. However, uncertainty analysis has developed further and faster than our ability to *use* the tools in decision-making. Questions, such as how uncertainty analysis should be used to set action levels and make regulatory decisions, deserve more attention.<sup>13</sup>

And in the 1994 report *Science and Judgment in Risk Assessment*, NRC warned:

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<sup>11</sup> DOL, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Department of Labor* 15-17 (2002), available at <http://www.dol.gov/cio/programs/InfoGuidelines/InfoQualityGuidelines.pdf> (accessed Aug. 20, 2008).

<sup>12</sup> Advances in uncertainty analysis can probably be linked to efforts by anti-regulatory advocates to "manufacture" uncertainty as a way of forestalling additional public health protections. *See generally*, David Michaels, DOUBT IS THEIR PRODUCT: HOW INDUSTRY'S ASSAULT ON SCIENCE THREATENS YOUR HEALTH (2008).

<sup>13</sup> NRC, *Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget* 54 (2007).

[U]ncertainty analyses should be refined only so far as improvements in the understanding of risk and the implications for risk management justify the expenditure of the professional time and other resources that are required.<sup>14</sup>

This statement highlights the essential problem with DOL’s proposal with respect to uncertainty analysis: the proposal mandates uncertainty analysis (“agencies *shall* identify and discuss ... significant uncertainties”) without acknowledging that the type and extent of uncertainty analysis should vary from one risk assessment to another. The proposed preamble provides no clarification. It simply states that “[q]uantitative uncertainty analysis, sensitivity analysis, and a discussion of model uncertainty are utilized when possible.”<sup>15</sup> The science supporting regulatory action is always uncertain, and DOL agencies should recognize this by using precautionary rulemaking procedures. Risk assessors who are developing an assessment in support of a protective regulation should only be required to analyze uncertainty in the supporting science to the extent that the analysis will improve subsequent risk management decisions.

The proposed preamble text suggests that DOL agencies should undertake uncertainty analysis on the models used in risk assessment, despite NRC’s criticism of OMB’s previous call for model uncertainty analysis. NRC stated that OMB’s proposal – the precursor to the DOL proposal – suffered from the “key limitation” that:

although methods exist for addressing model uncertainty, there are no standard methods, and some methods are still in the initial stages of development. Furthermore, model uncertainty may dominate parameter uncertainty in many situations and, as indicated by the lack of standard methods, may be more difficult, if not impossible, to quantify.<sup>16</sup>

In addition, the Department’s Information Quality Guidelines, which DOL agencies are required to follow in developing risk assessments under the proposed 29 C.F.R. § 2.9(c)(5), blithely state that uncertainty analyses should be included in a risk assessment “to the extent practicable.” NRC criticized OMB for its proposal to require uncertainty analysis in government risk assessments “where feasible” because the qualification “is too vague to serve as technical guidance.”<sup>17</sup> The DOL qualification, “to the extent practicable,” is no less vague and fails to answer NRC’s important questions: How is practicability determined? Could studies with unwelcome results be held to higher practicability standards? DOL should establish objective criteria that risk assessors could use to determine when uncertainty analysis will be useful in the risk management process and what level of uncertainty analysis is warranted.

DOL itself previously has questioned the utility of uncertainty analysis in response to questions from NRC regarding potential problems with implementing OMB’s Proposed Risk Assessment Bulletin. NRC asked DOL to “please specify provisions in the Bulletin that can be

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<sup>14</sup> NRC, *Science and Judgment in Risk Assessment* 185 (1994).

<sup>15</sup> DOL FR Notice, *supra* note 3, at 50912.

<sup>16</sup> NRC, *Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget* 33-34 (2007).

<sup>17</sup> *Id.* at 33.

expected to have a substantial negative effect on the quality, conduct, and use of risk assessments undertaken by [DOL].”<sup>18</sup> DOL responded:

The Bulletin’s provisions for deriving quantitative distributions of model uncertainty and variability, wherever feasible, could add significant time to some risk assessments where such analyses are not critical to fully inform regulatory decision makers. In particular, such analyses have not been necessary to adequately characterize safety risks.<sup>19</sup>

The fact that DOL’s proposed risk assessment regulations do not comport with recent statements on the same subject raises concerns about the identity and qualifications of the authors of this new proposed policy, as well as the degree of participation in its development by career staff.

2. Requiring risk characterization in terms of “a range of plausible risk estimates”

Uncertainty analysis, when done correctly, is designed to improve risk characterization. The proposed preamble text states that “[w]hen a quantitative characterization of risk is provided, a range of plausible risk estimates should be provided”<sup>20</sup> and that “[r]isk descriptors should be presented as estimates of central tendency along with the appropriate upper and lower bounds.”<sup>21</sup> These requirements seem to reflect the legitimate concerns that the “[u]se of a single point estimate [to characterize risk] suppresses information about sources of error”<sup>22</sup> and that a range of values can help stakeholders better understand the extent of conservatism in the risk estimate and consequent regulatory actions. However, NRC has repeatedly noted that there are thorny technical considerations that must be addressed when replacing point estimates of risk with other characterizations, and “the challenge is in the operational definitions of such words as *central ... and plausible*.”<sup>23</sup>

NRC, in critiquing OMB’s proposal to require similar risk characterizations across the federal government, concluded that the OMB standard “does not provide clear guidance on how such a range is to be defined” and “may produce confusion that could erode the quality of risk assessment.”<sup>24</sup> Similarly, the DOL proposal lacks clear and detailed definitions of the operative terms and, therefore, will not improve the quality of agency risk assessments.

The statutory mandates of the OSH Act and Mine Act establish a framework that highlights the complexity of characterizing risks in relevant ranges. As noted previously, DOL is responsible for crafting standards adequate to assure “that no [employee or miner] will suffer material impairment of health or functional capacity even if such [employee or miner] has

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<sup>18</sup> *Id.* at 196.

<sup>19</sup> *Id.*

<sup>20</sup> DOL FR notice, *supra* note 3, at 50912.

<sup>21</sup> *Id.*

<sup>22</sup> NRC, *Science and Judgment in Risk Assessment* 184 (1994).

<sup>23</sup> NRC, *Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget* 24 (2007).

<sup>24</sup> *Id.* at 39.

regular exposure to the hazards dealt with by such standard for the period of his working life.”<sup>25</sup>  
As NRC notes,

Often in public-health practice and prevention, the goal is to protect the *most vulnerable* in the population – children, the elderly, people with illnesses (such as respiratory or cardiac disease), the developing fetus, and workers. Using the mean or central estimate [of risk] would not accomplish that goal unless it reflected the mean response of the distribution of vulnerable or susceptible individuals.<sup>26</sup>

So not only is DOL’s proposal insufficiently precise to improve risk assessment practice, it also undercuts the agency’s ability to accomplish its own mission of protecting the most vulnerable workers.

### 3. Only analyzing “adverse” responses to hazards

The proposed 29 C.F.R. § 2.9 (c)(4)(ii) suggests that DOL risk assessments need only model relationships between occupational hazards and “an adverse health outcome,” a restrictive analysis that would fail to adequately protect workers and has received strong criticism from NRC. When NRC reviewed the OMB Proposed Risk Assessment Bulletin, it explained:

The core task of risk assessment is the analysis of risks associated with a particular activity, outcome, or event. The choice of the end point of interest is a critical step in risk assessment.<sup>27</sup>

NRC went on to explain that the appropriate end point must always be chosen in light of the fact that “the goal of public health is to control exposures before the occurrence of functional impairment of the whole organism.”<sup>28</sup> NRC’s statement reflects a widely accepted view that the federal government should act with precaution when regulating to protect public health.<sup>29</sup> Thus, “[d]ividing effects into dichotomous categories of adverse and nonadverse is problematic.”<sup>30</sup> NRC notes that the relationship between risk assessment end points and adverse effects “is one of many scientifically difficult matters that must be confronted in the conduct of risk assessment,” not in general guidance documents.

To provide a concrete example of the problem, NRC explained that carbon monoxide (CO) risk assessment focuses on an endpoint that does not necessarily lead to adverse health outcomes. For CO, dose-response assessments focus on carboxyhemoglobin concentrations.

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<sup>25</sup> 29 U.S.C. § 655(b)(5) (OSH Act § 6(b)(5)); 30 U.S.C. § 811(a)(6)(A), (Mine Act § 101(a)(6)(A)).

<sup>26</sup> NRC, *Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget* 27 (2007).

<sup>27</sup> *Id.* at 34.

<sup>28</sup> *Id.* at 35.

<sup>29</sup> See *Lead Industries Ass’n. v. Environmental Protection Agency*, 647 F.2d 1130 (D.C. Cir. 1980) (holding that EPA did not exceed its statutory authority when it set ambient air quality regulations that were based on subclinical effects of lead exposure.)

<sup>30</sup> NRC, *Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget* 35 (2007).

At very low concentrations, such as current background concentrations (1-2%), enough oxygen is usually brought to the tissues for there to be no discernible clinical or subclinical effects. However, even mild increases (to 4-6%) can cause symptoms in vulnerable populations. For example, those with underlying heart conditions can experience an increase in cardiac arrhythmias and a decrease in exercise performance. The developing fetus is also more susceptible to decreases in oxygen content and increases in CO.

As another example, risk assessors investigating the effects of endocrine-disrupting chemicals may find it more useful to model dose-response relationships that describe the chemicals' effect on hormone levels (changes which may not, in themselves, be considered "adverse health outcomes"), as opposed to some adverse change in a physiological process brought on by the changing hormone levels.

As NRC suggested to OMB, DOL should not use this general policy to restrict risk assessments. Instead of limiting dose-response analysis to the relationship between occupational hazards and "adverse health outcomes," DOL should allow risk assessors to choose appropriate end points on a case-by-case basis. If a restrictive approach is necessary (e.g., to increase the speed of risk assessment), DOL should adopt relevant technical guidelines through an open, peer-reviewed process led by agency scientists.

#### 4. Subjecting risk assessments to DOL and OMB peer review guidelines

The proposed 29 C.F.R. § 2.9(c)(5) states that DOL risk assessments "shall be performed in accordance with [OMB's and DOL's] ... peer review guidelines." NRC criticized OMB's earlier attempt to saddle risk assessors with the burden of complying with agency peer review guidelines. While acknowledging that peer review "is the standard course for ensuring good scientific standards," NRC recognized that the agencies' peer review guidelines would require risk assessments to "be handled through the process designed for the [Information Quality Act], a process that is more a legal or policy process than a scientific one."<sup>31</sup> NRC worried that "to the extent that the implementation of the technical aspects of risk assessment will be overseen by OMB and not by the peer-review process or by agency technical managers, scientific issues may be superseded by policy considerations."<sup>32</sup>

#### 5. Using the risk management process to undercut the risk assessment process

In describing DOL's "best practices" with respect to risk management, the proposal states that DOL views risk management as a process of integrating "risk characterization results with Department policies and directives, and other information to assess policy options and recommend regulatory action."<sup>33</sup> This is reasonable, but the sentence that follows is not. DOL goes on to suggest that the risk management process "may include consideration of both positive

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<sup>31</sup> *Id.* at 63.

<sup>32</sup> *Id.* at 63-64.

<sup>33</sup> DOL FR notice, *supra* note 3, at 50913.

and negative studies” in weight-of-evidence evaluations.<sup>34</sup> In essence, DOL is suggesting that risk managers go back and do their own assessment of the studies and data that their staff used to create the risk assessment. This practice would invite political manipulation of science and should not be condoned in rulemaking.

### ***Conclusion***

The overarching problem with DOL’s proposed risk assessment regulations is that the Department has failed to heed the sage advice of the NRC committee that dutifully reviewed and provided suggestions for improvement upon the OMB Proposed Risk Assessment Guidelines. That committee suggested that each regulatory agency develop a set of risk assessment guidelines that provide clear and technical guidance on the proper conduct of regulatory risk assessment. The DOL proposal is a start in that direction, but does not go nearly far enough. DOL should refrain from promulgating any risk assessment-related regulations until it has first developed (through a peer reviewed and transparent process) technical risk assessment guidelines.

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<sup>34</sup> *Id.*