August 14, 2008

The Honorable Elaine Chao
Secretary of Labor
U.S. Department of Labor
Suite S-2018
200 Constitution Avenue NW
Washington, DC 20210

By fax: 202-693-6111
and regular mail

Dear Secretary Chao:

We are writing to urge you to withdraw the proposed rule "Requirements for DOL Agencies' Assessment of Occupational Health Risks" (RIN 1290-AA23), which is pending review at the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs. The proposed rule fails to provide any validated guidance that would improve the current risk assessment approaches used by MSHA and OSHA, and has serious flaws that would weaken current procedures and undermine occupational health rules. Furthermore, the draft proposal would add an additional step to the rulemaking process, further delaying the development and issuance of needed health and safety protections for workers.[1]

If the Department of Labor (DOL) is serious about improving its risk assessment approaches, it should be guided by recommendations of the National Academies' National Research Council (NRC) and other authoritative bodies, rather than a scattered approach that fails to incorporate advice from agency experts, practitioners, worker advocates, and the public.[2] The NRC panel charged with reviewing the 2006 OMB Risk Assessment guidelines issued its scathing report in January 2007, concluding "that the OMB bulletin is fundamentally flawed" and recommending that "it be withdrawn."[3] Nonetheless, many of the faulty OMB recommendations have re-emerged in this DOL proposal.

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[1] Original documents and chronology of events can be accessed at: http://www.defendingscience.org/case_studies/Secret-DOL-Rule.cfm.

[2] The National Research Council (NRC) Report, *Scientific review of the proposed risk assessment bulletin from the Office of Management and Budget* (2007), pointed out that, "the major recommendations that have emerged from nearly 25 years of study of risk assessment have much in common", including the following: the *Red Book* (NRC, 1983); *Science and Judgment in Risk Assessment* (NRC, 1994); *Understanding Risk: Informing Decisions in a Democratic Society* (NRC, 1996), and *Review of the Proposed OMB Risk Assessment Bulletin* (NRC, 2007).

[3] NRC. *Scientific review of the proposed risk assessment bulletin from the Office of Management and Budget*. National Research Council, 2007. http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=11811.

Moreover, it is ironic that your proposal will require MSHA and OSHA to issue an Advance Notice of Proposed Rulemaking (ANPRM) soliciting public input, but you failed to follow this same mandate with respect to this proposal. It was developed without any opportunity for early public input.[4] In fact, the secrecy of this proposal resulted in a front-page story in the *Washington Post*[5] and a request from Senator Edward Kennedy (D-MA) and Congressman George Miller (D-CA) to be briefed by DOL about its proposal.[6]

We discuss three major flaws with the document: 1) altering the definition of a working life from 45 years to an average number of years, 2) calling for uncertainty analysis without providing any guidance that would actually improve the quality, reliability, or utility of such an analysis, and 3) taking regulatory action only where clinical adverse health outcomes have been demonstrated.

1) Altering the definition of a working life

The proposed rule seeks to reduce the definition of a working life from as many as 45 years to an *average* number of years, justifying this move with data tables showing that most workers stay with the same employer for much less time than 45 years. While workers do change jobs, they are much less likely to change into a job that significantly reduces their risks. Individuals who learn a skilled trade like welding, for example, may indeed change employers over their careers, but most practice their welding trade for their entire working lives. Furthermore, an expert panel of the National Academies issued a report in 1994 that recommended against this unvalidated and unrealistic approach in their discussion of ambient exposures to the general public over a lifetime, notwithstanding the data that show multiple changes of residences over a lifetime.[7]

The attempt to weaken the definition of a working life is contrary to the health-protective frameworks mandated in the Occupational Safety and Health Act of 1970 and the Federal Mine Safety and Health Act of 1978, which specifically direct the Department of Labor to issue standards on toxic agents that assure workers' health is protected even if an employee "has regular exposure to the hazard…for the period of his working life."[8] Congress wanted OSHA and MSHA to set standards that would protect people who choose to work in the same industry for 45 years.

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[4] Monforton, C. Secret rule on OSHA risk assessment? The Pump Handle. July 8, 2008. http://thepumphandle.wordpress.com/2008/07/08/secret-rule-on-osha-risk-assessment/.

[5] Leonnig, CD. U.S. rushes to change workplace toxin rules. *Washington Post*. July 23, 2008; Page A01.

[6] Monforton, C. Congress demands briefing on Chao's mystery proposal for risk assessment. July 10, 2008. http://thepumphandle.wordpress.com/2008/07/10/congress-demands-briefing-on-chaos-mystery-proposal-for-risk-assessment/.

[7] NRC. *Science and Judgment in Risk Assessment*. 1994. p. 217.

[8] OSH Act of 1970, Section 6(b)(5); Mine Act of 1977, Section 101(a)(6)(A).

2) Calling for uncertainty analysis without providing any guidance that would actually improve the quality, reliability, or utility of such an analysis

The proposal calls for a rigorous uncertainty analysis, but provides no clear guidance on how to conduct one. The NRC report criticizes this same failure in the OMB Risk Assessment Bulletin, saying,

> "In the absence of clear guidance regarding the conduct of uncertainty analysis, there is a serious danger that agencies will produce ranges of meaningless and confusing risk estimates, which could result in risk assessments of reduced rather than enhanced quality and objectivity."[3]

Because risk assessors must rely on imperfect and incomplete data, decisions are informed by various guidance documents that are publicly available and publicly documented, and have been publicly vetted. Reliance on guidance documents helps to ensure that evaluations are consistent across substances and as objective as possible. This proposal fails to provide any useful guidance for important questions such as what default assumptions agencies will use, how agencies will decide when available data is robust enough to move away from default assumptions, and how incomplete exposure data should be used to support dose-response estimates.

3) Taking regulatory action only where clinical adverse health outcomes have been demonstrated

Finally, the draft regulatory text suggests the Department seeks to reserve its regulatory action for hazards associated solely with clinically apparent adverse health outcomes, by saying that, "The dose-response step determines a quantitative model that accounts for the relationship between a hazard and an <u>adverse health outcome</u>" (emphasis added). OMB in its Risk Assessment Bulletin was admonished for failing to specifically define the term "adverse." The NRC (2007) panel wrote:

> "The bulletin's definition of *adverse effect* implies a *clinically* apparent effect, which ignores a fundamental public-health goal to control exposures well before the occurrence of any possible functional impairment of an organism. Dividing effects into 'adverse and 'nonadverse' ignores the scientific reality that adverse effects may be manifest along a continuum."[3] (emphasis in original)

By oversimplifying the risk assessment process, demanding an unachievable quantification of uncertainty, and defining adverse effects in a narrow manner that overlooks medical reality, the Department has created a proposed regulation that will hamper the OSHA and MSHA in their Congressionally-mandated duties to protect workers' health from toxic agents.

In conclusion, this proposed rule will significantly weaken current risk assessment approaches without offering any improvements and will undermine worker health protections.

There are scores of workplace health and safety hazards for which the regulation needs to be updated, and hundreds more that have not yet been regulated. The Department of Labor should turn its attention and direct resources to such hazards as silica, diacetyl and beryllium – not to a deeply flawed rule that will make future efforts to safeguard the health of U.S. workers more difficult.

As industrial hygienists, physicians, epidemiologists, toxicologists, and other practitioners involved in workers' safety and health research and prevention programs, we urge you to withdraw this proposed rule.

Sincerely,

Affiliations for identification purposes only, and do not constitute an endorsement on the part of the institution of information contained in this letter.

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cc: The Honorable Edward M. Kennedy, Chairman, U.S. Senate Committee on Health, Education, Labor and Pensions

The Honorable George Miller, Chairman, House Committee on Education and Labor