THE SECRET RULE: IMPACT OF THE DEPARTMENT OF LABOR'S WORKER HEALTH RISK ASSESSMENT PROPOSAL

HEARING

BEFORE THE

SUBCOMMITTEE ON WORKFORCE PROTECTIONS

COMMITTEE ON

EDUCATION AND LABOR

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C O N T E N T S

THE SECRET RULE: IMPACT OF THE DEPARTMENT OF LABOR'S WORKER HEALTH RISK ASSESSMENT PROPOSAL

Wednesday, September 17, 2008
U.S. House of Representatives
Subcommittee on Workforce Protections
Committee on Education and Labor
Washington, DC

The subcommittee met, pursuant to call, at 10:05 a.m., in room 2175, Rayburn House Office Building, Hon. Lynn Woolsey [chairwoman of the subcommittee] presiding.

Present: Representatives Woolsey, Payne, Hare, and Wilson.

Also Present: Representative Scott.

Staff Present: Aaron Albright, Press Secretary; Tylease Alli, Hearing Clerk; Jordan Barab, Senior Labor Policy Advisor; Jody Calemine, Labor Policy Deputy Director; Lynn Dondis, Senior Policy Advisor, Subcommittee on Workforce Protections; David Hartzler, Systems Administrator; Jessica Kahanek, Press Assistant; Brian Kennedy, General Counsel; Therese Leung, Labor Policy Advisor; Sara Lonardo, Junior Legislative Associate, Labor; Joe Novotny, Chief Clerk; Meredith Regine, Junior Legislative Associate, Labor; Michele Varnhagen, Labor Policy Director; Robert Borden, Minority General Counsel; Cameron Coursen, Minority Assistant Communications Director; Ed Gilroy, Minority Director of Workforce Policy; Rob Gregg, Minority Senior Legislative Assistant; Alexa Marrero, Minority Communications Director; Jim Paretti, Minority Workforce Policy Counsel; Chris Perry, Minority Legislative Assistant; Linda Stevens, Minority Chief Clerk/Assistant to the General Counsel; and Loren Sweatt, Minority Professional Staff Member.

Chairwoman WOOLSEY. A quorum is present. The hearing of the Subcommittee on Workforce Protection will come to order, and I will begin with my opening remarks and then I will yield to my ranking member.

Thank you all for being here. It is sort of the end of the school year around here. Everybody is excited and forgetting to come to their committee meeting, yes, but they will be here. I was assured of that. And I thank you because this is more important to you than our getting out of here for the next few months.

I have called this hearing today on the Department of Labor's proposed risk assessment regulation because, quite frankly, I am troubled by the Agency's attempt to rush through this rule without

a full consideration of its effect on the health and safety of the American worker. This proposed rule has, without explanation, leapfrogged ahead of many other worker protection standards that OSHA should have been working on for the last eight years, including a standard for diacetyl, the long delayed silica standard, the long delayed beryllium standard and the long delayed crane standard.

By now most of you know why the proposed rule has been dubbed the secret rule. That is what we call it around here, and now it has become the name of the rule. Because the secret rule was developed by DOL's Office of Policy with little input from anyone, not even its own experts at OSHA and MSHA. And according to documents recently provided by the committee throughout the process, DOL consulted with only one outsider during its consideration of the proposal. This was a lawyer representing industry. When the Secretary's office finally showed the rule to its own experts at OSHA and MSHA, those experts disapproved the rule and urged DOL not to proceed. But the DOL policy department ignored their input, pushed ahead anyway.

The Department was so determined to put this rule in place that it even ignored a deadline set by White House Chief of Staff Josh Bolten. Chief Bolten prohibited all Agencies from proposing regulations after June 1, 2008, except in extraordinary circumstances. I am hoping that Mr. Sequeira is prepared to explain to us why extraordinary circumstances exist to justify this rule.

Now, it is important to note that this proposed rule developed in secret—we are going to say this many times today—was only brought to the public's attention in early July when the Office of Management and Budget, OMB, which reviews all proposed rules posted the rule on its Web site. Actually it did not post the rule. It only posted the title. Uh-huh, secret. So Chairman Miller and Senator Kennedy wrote to DOL and asked for specific information on the rule and how it came about. But no documents were forthcoming until the day before the rule was published in the Federal Register on August 29. So, many of us have spent the summer scratching our heads about the content of the proposed rule.

Now we have the really bad news. Only 30 days to comment on this misguided proposal. Only 30 days to comment on a risk assessment regulation that would significantly lengthen the many years that it currently takes to issue standards. And only 30 days to comment on a regulation that will significantly affect the ability of OSHA and MSHA to protect workers from deadly health hazards.

In addition, DOL has decided not to provide an opportunity for a public hearing. This is unprecedented in the history of significant OSHA and MSHA standards. We have a chart up there on the screen which shows the usual procedures DOL has chosen to ignore in quickly pushing through this proposed regulation. These procedures, as you can see, include Executive Order 12866, the Regulatory Flexibility Act, the Administrative Procedure Act, the OSH Act, the Mine Safety and Health Act and the Bolten memo.

Chairman Miller and Senator Kennedy and Senator Murray and I have recently sent a letter to DOL asking for a public hearing and for an extension of the comment period, and other groups have

done so as well. I hope that the Assistant Secretary will have some good news for us on that front.

Of course the irony of all of this is that during the entire Bush administration OSHA has not issued a single new health standard except for one that was issued under a court ordered deadline. And MSHA has issued only one new health standard, and that was on asbestos that belatedly brought the mine standard up to the level that other American workers have enjoyed for over 20 years.

In April 2007, this subcommittee had a hearing on OSHA's failure to issue standards. And a young man, Eric Peoples, who is a former worker in a popcorn factory, testified about his losing struggle with popcorn lung disease caused by his exposure to diacetyl, a chemical that is used in the microwave popcorn manufacturing process. Sitting beside Eric at the hearing was OSHA Administrator Ed Foulke, who assured us that the Agency was fully committed to achieving its regulatory goals. Following the April 2007 hearing, many of us concluded that OSHA intended to take no action to prevent workers from exposure to diacetyl.

So I introduced legislation that would require OSHA to issue an interim standard within 90 days and a final standard within no less than two years. As we were about to vote on the bill, which passed in the House, OSHA announced that it would begin rulemaking and shortly thereafter promised to have a draft ready for Small Business review by January 2008. But here we are September with no draft of a standard for diacetyl. But we have the secret rule which is being propelled forward at lightning speed. Sadly, we know where this administration's priorities are and they are not with the American people.

Our witness will further explain this secret rule, we hope, and we look forward to hearing all of our witnesses' testimony. With that, I defer to Ranking Member Joe Wilson for his opening statement.

[The statement of Ms. Woolsey follows:]

Prepared Statement of Hon. Lynn C. Woolsey, Chairwoman, Subcommittee on Workforce Protections

I've called this hearing today on DOL's proposed risk assessment regulation because, quite frankly, I am troubled by the Agency's attempt to rush through this rule without a full consideration of its effect on the health and safety of the American worker.

This proposed rule has without explanation leapfrogged ahead of many other worker protection standards that OSHA should have been working on for the last 8 years, including:

- A standard for diacetyl,
- The long delayed silica standard,
- The long delayed beryllium standard, and
- The long delayed crane standard. By now most of you know why the proposed rule has been dubbed the "secret rule." It was developed by DOL's Office of Policy with little input from anyone, not even its own experts at OSHA and MSHA.

And according to documents recently provided to the Committee, throughout the process, DOL only consulted with one outsider. And this was a lawyer representing the industry. When the Secretary's office finally showed the rule to its own experts at OSHA and MSHA, those experts disapproved the rule and urged DOL not to proceed. But the DOL Policy Department apparently ignored them and pushed ahead anyway.

Now, it is important to note that this proposed rule—-developed in secret—-was only brought to the public's attention in early July when the Office of Management and Budget (OMB), which reviews all proposed rules, posted the rule on its website.

Actually, it did not post the rule, but only its title.

And so, Chairman Miller and Senator Kennedy wrote to DOL and asked for specific information on the rule and how it came about. But no documents were forthcoming until the day before the rule was published in the Federal Register on August 29.

So many of us have spent the summer scratching our heads about the content of the proposed rule. Well, now we have the bad news, but only 30 days to comment on this misguided proposal. Only 30 days to comment on a risk assessment regulation that would significantly lengthen the many years it takes currently to issue standards.

And only 30 days to comment on a regulation that will significantly affect the ability of OSHA and MSHA to protect workers from deadly health hazards. The Department was so determined to put this rule in place that it even ignored a deadline set by

White House Chief of Staff John Bolten who prohibited all agencies from proposing regulations after June 1, 2008, except in extraordinary circumstances. In addition, DOL has decided not to provide an opportunity for a public hearing.

This is unprecedented in the history of significant OSHA or MSHA standards. We have a chart, which shows the usual procedures DOL has chosen to ignore in its effort to quickly push through this proposed rule.

In addition to Mr. Bolten's memo, DOL has ignored the orderly processes set outlined in Executive Order 12866, the Regulatory Flexibility Act, the Administrative Procedure Act, the OSH Act and the Mine Safety and Health Act.

Chairman Miller, Senator Kennedy, Senator Murray and I have recently sent a letter to DOL asking for a public hearing and for an extension of the comment period. Other groups have done so as well. I hope that Assistant Secretary Sequeira will have good news for us on that front.

Of course, the irony of all of this is that during the entire Bush Administration, OSHA has not issued a single new health standard, except for one that was issued under a court-ordered deadline.

And MSHA has issued only one new health standard—on asbestos—that belatedly brought the mine standard up to the level that other American workers have enjoyed for over 20 years.

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As we were about to vote on the bill, which passed in the House, OSHA announced that it would begin rulemaking and shortly thereafter promised to have draft ready for small business review by January 2008.

But here we are in September with no draft of a standard for diacytel but we have the secret rule, which is being propelled forward at lightning speed.

Sadly, we know where this Administration's priorities are, and they are not with American workers.

Our witnesses will further explain this "secret rule," and I look forward to their testimony.

With that, I defer to the ranking member, Joe Wilson, for his opening statement.

Mr. WILSON. Good morning, Chairwoman Woolsey. And thank you for recognizing me. I want to thank you for holding this hearing today and thank our witnesses for taking the time to appear before us. Today is Constitution Day, and it is only right that we have a hearing ensuring that citizens are able to redress their government. I hope we will all take a few moments today to reflect on the importance of this document to our lives.

On August 29, 2008, the Department of Labor formally proposed to change its internal risk assessment policy and provided that proposal for stakeholder input. Prior to this action, however, there was

an unnecessary conflict over so-called secret rulemaking, to include the chairman of this committee introducing legislation to halt a draft proposal leaked to the Washington Post. The Department should be commended for subjecting internal policy to outside scrutiny when it simply could have changed the policy without any notice. That, ladies and gentlemen, would have actually been secret rulemaking.

While I will not prejudge the outcome of this rulemaking, I will say that I support the concept of greater transparency in the rulemaking process. The Department's risk assessment proposal will require an Advanced Notice of Proposed Rulemaking, ANPRM—and so here we go another acronym, Madam Chairwoman, for us to learn—in order for all stakeholders to provide input during the regulatory process. This will ensure that all of the studies used as a foundation for rulemaking are available for review and I hope will serve to improve rulemaking in the future.

I welcome our witnesses today and look forward to a discussion on how to improve the use of risk assessment in Federal regulations.

[The statement of Mr. Wilson follows:]

Prepared Statement of Hon. Joe Wilson, Ranking Republican Member, Subcommittee on Workforce Protections

Good morning Chairwoman Woolsey. I want to thank you for holding this hearing today and thank our witnesses for taking the time to appear before us. Today is Constitution Day and it is only right that we have a hearing ensuring that citizens are able to redress their government. I hope we will all take a few moments today to reflect on the importance of this document in our lives.

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I welcome our witnesses today and look forward to a discussion on how to improve the use of risk assessment in federal regulations.

Chairwoman WOOLSEY. Thank you, Mr. Wilson. Without objection, all Members will have 14 days to submit additional material for the hearing record.

Now I would like to introduce our very distinguished panel of witnesses that are with us today, and I will read their biographies in the order that they will present. And then after their biographies, we will get started.

But let's talk about the lighting system, which is not new to any of you up there, I believe. But we have a lighting system that is the fiveminute rule. Everyone, including Members, is limited to five minutes of presentation or questioning. The green light is illuminated when you begin to speak. The yellow light goes on when you have a minute left. And when the red light turns on in front of

you—you each have your own little lighting system—you will know that it is time to wrap up or conclude. Now we don't, you know, open the floor and you drop through it at the red light, but we do know that that is about time to end. And the same thing goes for the Members up here. If we choose to use our whole five minutes making a speech, then there is no time left to ask questions. So we will go from there.

So first let me introduce all of you. Leon Sequeira, Assistant Secretary for Policy at the U.S. Department of Labor, a position he has held since February of last year. He previously served as Deputy Assistant Secretary of Policy at DOL and as Counsel to the Senate Rules Committee. Mr. Sequeira holds a Bachelor's Degree from Northwest Missouri State University and a J.D. from the George Washington University.

Celeste Monforton is a lecturer and researcher at the George Washington University School of Public Health. Dr. Monforton worked at OSHA from 1991 to 1995 as a Policy Analyst and at MSHA as a Special Assistant to the Assistant Secretary of Labor from 1996 to 2001.

She earned her Master's of Public Health in 2004 and her doctorate of public health in 2008 from George Washington's School of Public Health.

Randel Johnson is Vice President for Labor, Immigration and Employee Benefits at the U.S. Chamber of Commerce. Before joining the Chamber, Mr. Johnson was the Republican Labor Counsel and Coordinator for the full Education and Labor Committee here in the House. He is a graduate of Denison University and the Maryland University School of Law and received his Master's of Law in labor relations from the Georgetown University Law Center.

Margaret Seminario is the Director of Occupational Health and Safety for the AFL-CIO, where she has worked since 1977. Ms. Seminario has directed the organization's efforts on safety and health since 1990. She served on the National Advisory Committee on Occupational Safety and Health and was trained as an industrial hygienist at the Harvard School of Public Health.

We will now begin with you, Mr. Secretary.

STATEMENT OF HON. LEON R. SEQUEIRA, ASSISTANT SECRETARY FOR POLICY, U.S. DEPARTMENT OF LABOR

Mr. SEQUEIRA. Good morning, Madam Chair and members of the subcommittee. Thank you for the opportunity to appear before you today to discuss the Department of Labor's recent notice of proposed rulemaking regarding our internal procedures for conducting rulemakings that involve the regulation of potential workplace exposure to toxins. I appreciate the opportunity to testify today to offer some facts about the Department's proposal, especially given the widespread inaccurate speculation and misleading descriptions of this rulemaking.

The Department's proposed rule is short and simple. It codifies existing best practices into a single easy-to-reference regulation and includes two provisions to establish consistent procedures that promote greater public input and awareness of the Department's health rulemakings. Specifically, those provisions are, one, the

issuance of an Advanced Notice of Proposed Rulemaking as part of the health standard rulemaking involving the regulation of workplace toxins and, two, the electronic posting of all documents the Department relies upon when developing these health standards.

It is important to note, contrary to many misleading reports, that this proposal does not affect the substance or methodology of risk assessments and it does not weaken any health standard. Much of the criticism of this proposal appears to reflect either a profound misunderstanding of the Federal rulemaking process or a deliberate mischaracterization of the Department's proposal.

The Department's use of an Advanced Notice of Proposed Rulemaking is not new. In fact, OSHA frequently issues an Advanced Notice of Proposed Rulemaking when regulating workplace exposure to toxins, and it has done so since the early 1970s. In fact, several of the health standards most recently issued by the Department began with an Advanced Notice of Proposed Rulemaking. So those who would suggest that this is some sort of unheard of new process are being, well, at the very least, disingenuous.

Currently the Department does not have a comprehensive regulation or guidance governing our proceedings for conducting the rulemakings that involve the regulation of workplace toxins. That topic has long been discussed within the Department, within the Federal Government and among public stakeholders. Specifically, the Clinton era bipartisan presidential and congressional Commission on Risk Assessment and Risk Management thoroughly studied Federal risk assessment and management policies. In its 1997 final report, that bipartisan commission on risk made specific findings with respect to the Occupational Safety and Health Administration. In particular, it found—and I quote—OSHA seems to have relied upon a case-by-case approach for performing risk assessment and risk characterization. The commission further recommended that the Agency publish and describe its scientific and policy defaults with regard to risk assessment and risk characterization in support of risk management.

Finally, let me say the Department's proposal was developed with a full participation of numerous career professionals within several Agencies in the Department, including all experts with knowledge on this topic. The Department believes it is critical that the process for regulating workplace exposure to toxins is fully transparent and accountable to the public, and that is what this proposal seeks to do.

Thank you again for the opportunity to testify today. I would be happy to answer questions from you.

[The statement of Mr. Sequeira follows:]

LEON R. SEQUEIRA
ASSISTANT SECRETARY FOR POLICY
U.S. DEPARTMENT OF LABOR
BEFORE THE
HOUSE COMMITTEE ON EDUCATION AND LABOR
SUBCOMMITTEE ON WORKFORCE PROTECTIONS

September 17, 2008

Good morning Madam Chair and Members of the Subcommittee, thank you for the opportunity to appear before you today to discuss the Department of Labor's recent Notice of Proposal Rulemaking (NPRM) regarding our internal procedures for conducting rulemakings that involve the regulation of potential workplace exposure to toxins. The goals of this proposed rule are to increase the transparency, consistency and scientific reliability of the Department's health standard rulemakings that include risk assessments.

The Department's proposed rule codifies existing best practices into a single, easy to reference regulation, and includes two provisions to promote greater public input and awareness of Department rulemakings. Specifically, those provisions are the issuance of an Advanced Notice of Proposed Rulemaking (ANPRM) as part of the health standard rulemaking, and the electronic posting of all documents the Department relies upon when developing the health standard. It is important to note that this proposal does not affect the substance or methodology of risk assessments and does not impose additional standards or compliance obligations on the regulated community.

Commission on Risk

Currently, the Department does not have comprehensive regulations or guidance governing our procedures for conducting rulemakings that involve the regulation of workplace exposure to toxins. Federal risk assessment and management policies were thoroughly studied by the bipartisan Presidential/Congressional Commission on Risk Assessment and Risk Management (Commission on Risk), which was created by the 1990 Clean Air Act Amendments, "to make a full investigation of the policy implications and appropriate uses of risk assessment and risk management in regulatory programs under various Federal laws to prevent cancer and other chronic human health effects which may result from exposure to hazardous substances."[1]

In its 1997 final report, the bipartisan Commission on Risk made specific findings with respect to the Occupational Safety and Health Administration (OSHA). In particular, it found that, "OSHA seems to have relied upon a case-by-case approach for performing risk assessment and risk characterization," and recommended that the agency publish and describe its scientific and policy defaults with regard to risk assessment and risk characterization in support of risk management.[2] This NPRM implements the Commission on Risk's recommendation by explaining the agency's existing best practices related to risk assessment in one easy-to-reference regulation, and by including two provisions to establish consistent procedures that promote greater public input into and awareness of the Department's health rulemakings.

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[1] 42 U.S.C. 7412 note, Pub. L. 101-549, § 303, Nov. 15, 1990.
[2] Presidential/Congressional Commission on Risk Assessment and Risk Management, *Framework for Environmental Health Risk Management*, 2 Final Report 131-36 (1997) (Commission on Risk Report).

Principles Underlying this Proposal

This proposed regulation is a compilation of basic principles and practices related to risk assessment. As such, it ensures that DOL's scientists have the necessary latitude to exercise their professional discretion and to modify their assessments as science evolves, while assuring that the Department's process is fully accountable to the public.

The principles underlying this rulemaking are:

1. Transparency

The reasoning, assumptions, calculations, methods and data on which risk assessment findings and risk management decisions are made should be presented in an open and readily accessible format to enable members of the public to review, critique, and replicate the process leading to the Department's findings and decisions. Where results embody uncertainty, the degree of uncertainty should be clearly stated and quantified in probabilistic terms if adequate data are available, and the analysis adds value to the risk management decision process.

2. Consistency

The approaches used to assess risk should conform to accepted scientific practice and strive to be consistent with approaches used in previous occupational standards that address similar hazards and agents. A justification should be provided when alternate approaches are employed. The choice of methods, procedures and approaches should be based on objective criteria and adhere to basic principles that have achieved general scientific acceptance. While consistency is a key objective, risk analysis is an evolving scientific process and agencies must retain sufficient flexibility to incorporate methodological and analytical advances. In addition, to the extent risk analyses must be

tailored for particular projects, the Department's agencies should clearly articulate the reasons for selecting the methodologies used.

3. Reliability

Analyses and calculations must be based on the best available scientific data and practices consistent with the Federal Government's directives on information quality and peer review.

Summary of the Proposal

DOL is proposing this rulemaking pursuant to the Secretary's authority at 5 U.S.C. Section 301 to prescribe regulations related to the performance of the agency's business and the conduct of its employees. Although the Department is not required to seek public comment on its internal procedures under the Administrative Procedure Act (APA), the agency has chosen to do so in order to gain public input and in the interests of full transparency and accountability. In addition, because this rulemaking merely communicates to the public how the Department will regulate itself, and does not require the regulated community to provide conditions or adopt practices to provide safe or healthful employment, it does not constitute an occupational safety and health standard.

The Secretary of Labor is charged with ensuring safe and healthful working conditions for working men and women. To that end, the Secretary has broad authority to promulgate health standards. In Section 6(b) (5) of the Occupational Safety and Health Act of 1970 (OSH Act) and Section 101(a) (6) (A) of the Federal Mine Safety and Health Act of 1977 (Mine Act) Congress required the Secretary to set health standards "on the basis of the best available evidence." The Acts also state that, "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." In sum, the OSH Act and Mine Act reflect a basic principle that agency actions should be based on the best scientific information available at the time of the agency action. The Government-wide Office of Management and Budget (OMB) Information Quality Guidelines, internal U.S. Department of Labor Information Quality Guidelines, and the OMB/ Office of Science and Technology Policy 2007 Memorandum on Updated Principles for Risk Analysis further reflect this principle. This proposal will help ensure that the best available evidence and latest scientific data in the field, including industry-specific information when available, is utilized in agency risk assessments.

The proposed regulation requests public comment on two matters. First, the rule seeks comment on the Department's issuance of an ANPRM before publishing an NPRM or other regulatory action in a health standard rulemaking. An ANPRM would permit the agency to cast a wide net for available information from the public, before proposing a health standard. Further, including an ANPRM in health rulemakings helps to ensure that the Department has the best information necessary to produce a thorough and accurate risk assessment; the ultimate purpose of which is to effectively protect workers. The Department has frequently utilized an ANPRM in its health standard rulemakings since the early 1970s when it began regulating exposure to workplace toxins. In fact, two of the last three health standard rulemakings began with an ANPRM and the third began with a Request for Information before the NPRM. The publication of the ANPRM, submission of public comments and agency review of comments will occur simultaneously with the ordinary development of a health standard. The proposal

suggests that the ANPRM could occur soon after the proposed standard is placed on the regulatory agenda, which is the period of time when the agency would typically be gathering information related to the proposed rulemaking, or concurrently with the Small Business Regulatory Fairness Act (SBREFA) process. The Department believes the risk assessment and rulemaking process will be strengthened by consistent opportunities for public input through an ANPRM.

Second, the Department requests comment on the electronic posting of all information associated with the development of regulations addressing occupational exposure to toxic substances and hazardous chemicals. This information would include for example, scientific studies relied upon in the rulemaking, risk assessment analyses underlying the NPRM and Final Rule, public hearing transcripts and briefs, SBREFA process documents, and public comments. The Department believes electronic posting of all documents related to a health standard rulemaking will promote greater public input, awareness, and transparency of the information underlying the Department's health rulemakings.

This proposed rule impacts only internal agency procedures for conducting health standard rulemakings. It does not affect the methodologies or substance of risk assessments and does not impose additional standards or compliance obligations on the regulated community. The proposal was published in the *Federal Register* on August 29, 2008 with a thirty (30) day public comment period.

Conclusion

The Department's proposal codifies the agency's existing best practices by compiling the Department's procedures for health standard rulemakings, into a single, easy to reference regulation. In addition, consistent with the agency's commitment to public participation in the rulemaking process, the proposal includes the issuance of an open call for relevant data through an Advance Notice of Proposed Rulemaking and provides the public with electronic access to all materials relied upon in those health rulemakings. Contrary to numerous erroneous reports and speculation, the Department's proposed rule is not a health rulemaking; it does not weaken any health standard; and it does not change the methodology for conducting risk assessments.

Thank you for the opportunity to testify today. I would be pleased to answer questions from the Subcommittee.

Chairwoman WOOLSEY. Thank you.
Dr. Monforton.

STATEMENT OF DR. CELESTE MONFORTON, PH.D., MPH, GEORGE WASHINGTON UNIVERSITY SCHOOL OF PUBLIC HEALTH

Ms. MONFORTON. Chairwoman Woolsey, Ranking Member Wilson, and other members of the subcommittee, I am Celeste Monforton and a researcher at the George Washington University School of Public Health, and I appreciate the opportunity to be here today and ask that my full statement be made a part of the record.

On its face, I understand how some individuals might ask, who could be against the Labor Department having requirements for risk assessment, or others might wonder why a large group of health scientists and the American Public Health Association urge the Secretary to withdraw this proposal.

Here is the problem: Our Nation's system for protecting workers from harmful substances that causes injury and illnesses is paralyzed. Thousands of workers are exposed every day to chemical compounds and physical hazards that are known to be harmful, yet these exposures are permitted by outdated and nonexistent OSHA and MSHA standards.

As the former chairman of this subcommittee, the late Congressman Norwood, acknowledged, there are many occupational health standards that need to be updated in order to achieve safe and healthful workplaces. The public health and worker rights communities would have welcomed a Department of Labor effort to improve the efficiency and effectiveness of the rulemaking process.

The OSH Act and Mine Act are robust, well-crafted statutes that give broad authority to the Secretary to regulate workers' exposure to toxic materials, and both were clearly grounded in the public health principle of prevention. The overarching goal of both statutes was to identify, mitigate, and/or control hazards before they cause harm. But instead of being motivated by prevention, the Labor Department is sponsoring changes that will make it more difficult to issue health protective rules, and the longer workers are exposed to harmful levels of toxic materials, the greater the risk of harm.

In the simplest terms, conducting a risk assessment means using the best information available to describe or estimate the risk of an adverse event. A risk assessment is a decision making tool that allows users to make informed decisions. In the context of occupational health standards, a risk assessment is prepared by OSHA to determine if exposure to a toxic material poses a significant risk to workers. If the hazard does not pose a significant risk, the Agency does not have the authority to regulate it.

Since the 1980s, when the Labor Department began preparing quantitative risk assessments, the Agency's products have consistently withstood vigorous scientific and public scrutiny and legal challenges. No matter the contaminant, asbestos, vinyl chloride, lead, diesel particulate, the assessments were based on the best available evidence determined with little room for doubt that the levels of exposure experienced by workers place them at a significant risk of material impairment of health or functional capacity.

Furthermore, these risk assessments are not the only factors used in OSHA and MSHA regulatory decisions. The Agencies must also conduct analyses to determine if a proposed regulation is economically and technologically feasible. This means that even if the Agency's risk assessment for chemical x suggests that an exposure limit should be set at y in order to protect workers' health, the Agency is required to set the exposure limit at a level that is feasible. This means that a final exposure limit might be set at y times two or y times five, even when the risk assessment suggested a much lower level was warranted.

In my written statement, I outline a number of problems with the Department's proposed rule, including its misreading of the 1997 commission report, the way it says it values public input but fails to allow adequate time for it, and its incomplete appraisal of key documents that already exist in the Department for standard setting and risk assessment. In my remaining time, however, I would like to draw your attention to the pitfalls of preparing a proposed rule on risk assessment in haste and without the benefit of experienced career Federal employees in the Department.

Just last year a panel of scientists for the National Academies offered a harsh critique of a comparable effort by OMB, and the NAS made specific recommendations for administrative Agencies for the content of and procedures for developing risk assessment guidelines. The Labor Department ignores the NAS report in numerous respects, including the recommendation that any proposed guidance draw on expertise and Federal Agencies and be subjected to peer review.

Curiously, the Department indicates that, quote, it does not have comprehensive regulations or formal internal guidance outlining consistent risk assessment procedures, end quote. Yet in 2002 it issued a special appendix under its information quality guidelines which specifically describe the procedures to be used by OSHA and MSHA when conducting risk analyses for health and safety rules.

The Labor Department's proposal is a sloppy piece of work that will impede, not improve health protections for workers. It is imperative that this committee use its oversight role to ensure that the promise of the OSH Act and the Mine Act are upheld for the sake of our Nation's working people. These are the men and women who create the wealth for our businesses and for our entire economy.

Thank you.

[The statement of Ms. Monforton follows:]

Prepared Statement of Celeste Monforton, MPH, DrPH, Researcher, Department of Environmental and Occupational Health, George Washington University School of Public Health & Health Services

Chairwoman Woolsey and Members of the Subcommittee: I am Celeste Monforton, a researcher in the Department of Environmental and Occupational Health at the George Washington University School of Public Health & Health Services. I appreciate the opportunity to appear before the subcommittee to share my views on the Department of Labor's proposed rule on MSHA and OSHA risk assessment procedures for occupational health hazards.[1]

On its face, I understand how some individuals might ask "who could be against the Labor Department having requirements for risk assessment?" In fact, this proposal is so potentially damaging to worker health that 80 epidemiologists, physicians, and other health scientists,[2] including the American Public Health Association,[3] urged the Secretary of Labor to withdraw her plan to issue a regulation on how occupational health risks are assessed.

I am currently preparing my detailed written comments on the proposed rule, which I plan to submit to the Labor Department by the September 29 deadline, but I am pleased to share my big-picture concerns about it, concerns that are shared by other public health scientists and proponents of health-protective standards for working men and women in our country.

Our nation's system for protecting workers from harmful substances that cause injuries, illnesses, and deaths is paralyzed. Thousands of workers are exposed every day to chemical compounds and physical hazards that are known to be harmful, yet these exposures are permitted by outdated or non-existent OSHA and MSHA standards. Hazards such as respirable coal mine dust and crystalline silica, diesel particulate, and noise,[4] to name just a few, have damaged the health of generations of

workers and continue to do harm today—even though we have known about these problems for decades.

The Department of Labor's record over the last 20 years is dismal with respect to issuing health standards to protect workers from these age-old contaminants, and it is particularly appalling for emerging health hazards. The overwhelming majority of the permissible exposure limits currently on OSHA's and MSHA's books date back to 1968 and 1973, respectively. These current limits are based on science from the 1960's, meaning the last 4050 years of scientific understanding of how chemicals affect human health are not reflected in most OSHA or MSHA standards.[5] For many of these compounds, the health science data suggests that the existing permissible exposure limits should be amended if we want to reduce workers' risk of adverse health effects. As the former chair of this subcommittee, the late Congressman Charlie Norwood, acknowledged, there are many OSHA standards that are out of date and need to be updated in order to achieve safe and healthful workplaces for American workers.[6] It should be a grave concern to all of us, no matter what our political views, that the promise of the OSH Act and the Mine Act is not being upheld for workers who are made ill due to harmful on-the-job exposures.

While we know of many as-yet-unregulated workplace hazards, there are likely many others that we will become aware of in the future. There are 82,000 chemicals listed in U.S. EPA's TSCA inventory,[7,8] of which nearly 3,000 are compounds manufactured or imported annually in quantities greater than 1 million pounds, and another 6,000 compounds used in quantities between 10,000 and just below 1 million pounds.[9] Many of these chemical compounds, especially in their final form, have improved our way of life. We must also recognize, however, that under current workplace standards, we have no systematic way to monitor the exposure of workers who manufacturer or work downstream with these thousands of compounds, nor do we have a mechanism to assess the adverse health consequences that may be associated with exposure to them individually or in combination with other chemicals.

The public health and workers' rights communities would have welcomed a Department of Labor effort to improve the efficiency and effectiveness of the rulemaking process, or even to address one of the many hazards that continue to put workers' lives and health at risk. Instead, the Labor Department is sponsoring changes that will further paralyze the rulemaking process. Future OSHA and MSHA administrators who may be more inclined to pursue new standards to protect workers from harmful exposures will find themselves facing new obstacles. These obstacles mean additional months and years of exposure for workers, during which some of them will develop life-threatening conditions.

Standard-Setting under MSHA and OSHA: Prevention-Based Statutes

The Mine Act of 1977 [10] and the OSH Act of 1970 [11] are robust, well-crafted statutes that give broad authority to the Secretary of Labor to regulate workers' exposure to toxic materials, and were clearly grounded in the public health principle of prevention. The overarching goal of both statutes was to identify, mitigate, and/or control hazards before they cause harm. Both statutes include the following prevention framework:

"The Secretary, in promulgating standards dealing with toxic materials * * * shall set the standard * * * that no employee will suffer material impairment of health * * * even if the employee has regular exposure to the hazard * * * for the period of his working lifetime." [12]

It might be worthwhile to explain how risk assessment informs the Department of Labor's standard-setting process, but first let's simply review what "risk assessment" is. The term "risk assessment" has a variety of meanings depending on the context of the "risk" and the perspective of the assessor. Risk assessments are conducted by investors in the financial markets, by fire chiefs in command centers during emergency response, and by environmental scientists trying to estimate the impact of a commercial development on the habitat of a native species. They may rely on quantitative data, qualitative data, or both.[13] In the simplest terms, a risk assessment is the process of using the best information available to describe or estimate the risk of an adverse event. A risk assessment is a decisionmaking tool that allows users to make informed decisions; it does not dictate what the final decision will be.

In the context of occupational health standards, a risk assessment is prepared by OSHA to determine if exposure to a toxic material poses a significant risk to workers.[14] If the hazard does not pose a significant risk, the agency does not have the authority to regulate it. OSHA is required to make a significant-risk finding which, based on the U.S. Supreme Court's 1980 suggestion,[15] is a risk of about 1 in 1,000. This means that when there is evidence that a particular substance is causing harm to workers, OSHA will gather the best available information to estimate if workers

exposed to the substance face a higher risk of harm compared to individuals who are not exposed. If, for example, the epidemiological evidence suggests that for every 1,000 exposed workers, at least 6 excess cases of bladder cancer will occur, this information provides OSHA with its finding of "significant risk." On the other hand, if the available evidence suggests that the number of excess cases of bladder cancer is 1 out of 5,000 workers, then this estimate would not meet the threshold finding of a significant risk. For OSHA, the written output of using the available evidence to characterize the exposed workers' risk is the agency's "risk assessment."

Since the 1980's, when the Labor Department began preparing quantitative risk assessments to support health standards for toxic substances, the agency's assessments have consistently withstood vigorously scientific scrutiny and legal challenges. Whether the contaminant regulated was asbestos, lead, vinyl chloride, formaldehyde, butadiene, or diesel particulate matter, the assessments have been based on the best available evidence and determined, with little room for doubt, that the levels of exposure experienced by workers placed them at significant risk of "material impairment of health or functional capacity." [16]

We must remember that risk assessments are not the only factors in regulatory decisions; OSHA and MSHA must also conduct economic analyses and ensure that their regulations are economically and technologically feasible. This means that even if the agency's risk assessment for chemical X suggests that an exposure limit should be set at Y in order to protect workers from disease (e.g., lung cancer, lead poisoning,) the agency has to set the exposure limit as a level that is feasible. This might mean an exposure limit of Y*2, Y*5, or whatever level is determined feasible. The permissible exposure limits incorporated into OSHA standards are driven by a combination of the risk assessments and the feasibility data.

If the Department of Labor is spending its finite resources on this risk assessment proposal it ought to be in response to a critical flaw in the current risk assessment process. No evidence is presented in the preamble to this proposed rule (or elsewhere, to my knowledge) to suggest fundamental flaws in OSHA's or MSHA's risk assessment practices.

DOL's Rationale Based on Misreading of 1997 Commission Report

The rationale DOL gives for this proposed rule, both in the document itself and in statements made by Department officials, is largely based on a misreading of a recommendation made more than 11 years ago in a report by a Presidential/Congressional Commission.[17] The Department has cherry-picked a single sentence from the Commission's report and ignores its key recommendation. The part of the 1997 Commission report DOL seizes on says that:

"OSHA seems to have relied upon a case-by-case approach for performing risk assessment and risk characterization in support of risk management policy decisions."

This phrase "case-by-case approach," is conveniently described by the Labor Department as a "criticism," [18] although the 1997 report never labels it that way. What DOL fails to mention in its proposal is the specific recommendation from the Commission's report, which states:

"OSHA should publish, after appropriate public involvement and review, one or more sets of guidelines that lay out its scientific and policy defaults. At a minimum, the guidelines should cover 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. The guidelines should help OSHA decide how extensive a risk assessment is needed in different situations. Finally, OSHA should explain and justify its actions when it evaluates or regulates a substance differently than other federal agencies that regulate the same substance." [19]

Note that the Commission's recommendation was for OSHA to develop guidelines, not some other office within DOL that does not have experts in epidemiology, biostatistics or other health sciences, or experience preparing risk assessments on workplace chemical hazard exposure and health effects. An appropriate question for this committee to explore is determining the extent of involvement, if any, of the career federal employees at MSHA and OSHA in the development of this proposal. These individuals are the most expert at preparing occupational health risk assessments and would be best able to identify the agencies' best practices.[20]

Other substantive parts of the 1997 Commission's recommendation are curiously absent from DOL's proposal, such as the suggestions to:

• do more to address non-cancer health effects (e.g., cardiovascular, cardiopulmonary, neurological, reproductive)

• do more to address individual variability (e.g., protection factors for susceptible subpopulations)
• develop guidelines with sufficient flexibility to allow for different types of risk assessments depending on the nature of the hazard

If the DOL had truly paid attention to the Commission's recommendations rather than focusing on a single sentence and misinterpreting that sentence as a criticism, its risk-assessment proposal would have looked very different.

DOL's Disregard for 2007 National Academies' Report

Even more troubling than misreading the 1997 Commission's report is the Department's disregard for the much more recent 2007 report the National Research Council of the National Academies entitled "Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget." This report offered a harsh critique of the White House Office of Management and Budget's proposed risk assessment guidelines, including the conclusion that OMB's product was "fundamentally flawed."[21,22] In the NRC's report, the scientific committee recommended to OMB that any risk assessment guidance documents prepared by the Administration: "outline goals and general principles of risk assessment designed to enhance the quality, efficiency, and consistency of risk assessment * * * [that would] be consistent with each agency's legislative mandates and missions, and draw on the expertise that exists in federal agencies and other organizations. The technical guidance developed by or identified by the agencies should be peer-reviewed and contain procedures for ensuing agency compliance with the guidance."[23]

The Department of Labor has failed to fulfill this recommendation by neglecting to:

• "outline goals and general principles of risk assessment";
• develop guidelines that would "enhance the quality, efficiency and consistency of risk assessment";
• "draw on the expertise in federal agencies and other organizations"; and
• subject the proposed rule to "peer review"

I would respectfully request Chairwoman Woolsey or other members of the subcommittee to ascertain from Assistant Secretary Sequeira why this proposed rule on risk assessment does not meet the standards recommended just last year by the National Academies' panel.

"Best Practices": Missing in Action in DOL's Proposed Rule

There is a fundamental disconnect between what the Department of Labor says about this proposed rule and their actions.

1) Their timing discourages the input they claim to value

First, the proposed rule says they are seeking public comment "* * * in order to gain valuable public input and in the interests of full transparency and accountability."[24]

Yet, the time allowed to submit written comments is only 30 days (the deadline is September 29), hardly consistent with the Department's claim of wanting to receive "valuable public input." Similarly, Secretary Chao's spokesperson said the public would "have plenty of opportunity"[25] to examine and debate the proposal. It is hard to believe he actually thought that a robust debate could occur in such a short time span.

2) They made a feeble attempt to compile OSHA's actual best practices

The preamble to the proposed rule suggests that the regulation is simply about assembling the Department's "best practices" for risk assessment into a single document. OSHA has nearly 30 years of history developing risk assessments, and had the Department truly wanted to compile the agency's "best practices" it could have evaluated methodically the scientific assumptions, controversies, and other issues encountered by OSHA and MSHA over the years. In DOL's proposed rule, however, one will find very little in the regulatory text that could be characterized as a "best practices." Instead the proposal offers the most elementary definitions of "hazard identification," "dose-response assessment," and "exposure assessment," and completely neglects to mention the Department's own five-page appendix issued in 2002 under its Information Quality Guidelines describing procedures to be used by OSHA and MSHA when conducting risk analyses for health and safety rules.[26] Likewise, the news release issued by the Department stated "the department does not have comprehensive regulations or formal internal guidance outlining consistent risk assessment procedures,"[27] again, forgetting about its written procedures already on the books.

3) They describe the ANPRM as a best practice when it is not

While overlooking practices developed by OSHA and MSHA experts over the past several decades, the Department's proposal identifies one practice that it identifies erroneously as a "best practice": Advanced notice of proposed rulemaking (ANPRM). The Department offers no evidence to support its assertion that ANPRM represents a best practice for risk assessment. To the contrary, I would suggest that that available data indicates that adding the mandatory step of an ANPRM delays significantly the completion of a standard to protect workers' health. In the case of OSHA's rule on butadiene, the agency issued an

ANPRM in 1986 and the final rule was not completed until 1996. For methylene chloride, OSHA published an ANPRM in 1986 and the final rule was issued in 1997. In contrast, OSHA's did not issue an ANPRM for hexavalent chromium, it proposed a rule in 2004 and the final was issued in 2006. Likewise, MSHA proposed its diesel particulate matter rule in 1998 and completed it in January 2001. I suppose a "best practice" is in the eyes of the beholder. If the objective is to delay health protective rules as long as possible, an ANPRM would be a "best practice." But for the workers who are exposed to a hazardous substance and whose health would be protected by a workplace standard, the extra years of delay associated with an ANPRM are anything but a best practice. There are costs associated with such delays, costs in terms of additional years of exposure and harm incurred.

4) They fail to follow their own proposed rule for posting documents promptly

In its proposed rule, DOL is requiring MSHA and OSHA to post all relevant documents at Regulations.gov within 14 days of each key steps in the rulemaking process (e.g., issuing a proposed rule). As of September 15, 2008 (17 days after DOL's proposed rule was published in the Federal Register—and more than halfway through the comment period) the Department has not yet posted any supporting documents or background materials in the public docket for this rule.28 The double standard is striking.

The Department of Labor's entire process for developing and issuing the proposal has disregarded recent reports and decades of MSHA and OSHA practices, while ignoring the standards of openness and transparency that the Department claims to value. Most distressing, however, is the content of the rule. The Department of Labor is proposing changes to MSHA's and OSHA's risk assessment procedures that will impede, not improve, health protections for workers. It is imperative that this Committee use its oversight role to ensure that the promises of the OSH Act and the Mine Act are upheld for the sake of our nation's workers—the individuals who create the wealth for businesses and our entire country.

REFERENCES

[1] U.S. Department of Labor, Assistant Secretary for Policy. "Requirements for DOL Agencies' Assessment of Occupational Health Risks," (RIN: 1290-AA23), 73 Federal Register 50909, August 29, 2008.

[2] Letter from scientists to Secretary of Labor Elaine Chao, August 14, 2008, (Attachment A)

[3] Letter from Georges Benjamin, MD, Executive Director, American Public Health Association, to Secretary of Labor Elaine Chao, August 12, 2008 (Atachment B)

[4] The gaps in worker protections for well known hazards are glaring. Neither OSHA nor MSHA have comprehensive occupational health standards to protect workers from respirable coal mine dust or respirable crystalline silica. In 1974 NIOSH recommended an exposure limit for silica of 0.05 mg/m3 (for up to a 10-hr workday during a 40-hr workweek) [National Institute for Occupational Safety and Health, U.S. Department of Health, Education and Welfare. "Criteria for a recommended standard: occupational exposure to crystalline silica," 1974] and reiterated this recommendation in 2002 [National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, "NIOSH Hazard Review: Health Effects of Occupational Exposure to Respirable Crystalline Silica," 2002.] In 1995, NIOSH recommended that coal miners' exposure to respirable coal mine dust be reduced from 2 mg/m3 to 1 mg/m3 (time-weighted concentration for up to 10 hours/day) [National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, "Criteria for a recommended standard: occupational exposure to respirable coal mine dust," 1995] yet the outdated standard remains on MSHA's books. A comprehensive OSHA standard to protect many workers from noise-induced hearing loss was issued in 1983, but there is no equal health protection for construction workers. In January 2001, MSHA issued a health standard to protect underground mine workers from exposure to diesel particulate matter (which is associated with cardiovascular and cardiopulmonary disease, and lung cancer,) but workers in all other industries (e.g., industrial operations, construction sites, bus/truck depots and repair platforms, shipyards and ports, etc.) are not protected adequately from this hazardous exposure.

[5] Occupational Safety and Health Administration, U.S. Department of Labor. Air contaminants proposed rule. 53 Federal Register 20960, June 7, 1988; 30 Code of Federal Regulations, Subpart D: Air quality and physical agents, 56.5001.

[6] The Honorable Charlie Norwood, Opening Statements at hearings of the Subcommittee on Workforce Protections: "Making Sense of OSHA Rulemaking: A Thirty Year Perspective," June

14, 2001; "The Role of Consensus Standard Setting Organizations," November 1, 2001; "Can a Consensus be Reached to Update OSHA's PELs," July 16, 2002.

[7] A list maintained by EPA based on submissions from manufacturers which provides information on chemicals in commerce, called the TSCA inventory, referring to the Toxic Substances Control Act of 1976 which authorized EPA to collect this information.

[8] U.S. General Accountability Office. "Chemical Regulation: Comparison of U.S. and Recently Enacted European Union Approaches to Protect against the Risks of Toxic Chemicals," Report No. GAO-07-825, August 2007.

[9] Lowell Center for Sustainable Production, University of Massachusetts, Lowell. "The Promise and Limits of the United States Toxic Substances Control Act," October 2003. Available at: www.chemicalspolicy.org/downloads/Chemicals—Policy—TSCA.doc

[10] 29 U.S.C. §651

[11] 30 U.S.C. §801, et seq 12 Section 6(b)(5) of the Occupational Safety and Health Act of 1970 (29 U.S.C. §651), and Section 101(a)(6)(A) of the Federal Mine Safety and Health Act of 1977 (30 U.S.C. §801, et seq).

[13] In 1983, the National Research Council issued the legendary "Red Book," which defined [chemical] risk assessment as "the qualitative or quantitative characterization of the potential health effects of particular substances on individuals or populations." National Research Council. Risk Assessment in the Federal Government: Managing the Process. 1983.

[14] Under the U.S. Supreme Court's decision in Industrial Union Department v. American Petroleum Institute, [448 U.S. 607 (1980)], OSHA is required to find "as a threshold matter, that the toxic substance in question poses a significant health risk in the workplace and that a new, lower standard is therefore 'reasonably necessary or appropriate' to provide safe or healthful employment and places of employment."

[15] Industrial Union Department v. American Petroleum Institute, 448 U.S. 607 (1980).

[16] Section 6(b)(5) of OSH Act.

[17] The Presidential/Congressional Commission on Risk Assessment and Risk Management. "Risk Assessment and Risk Management in Regulatory Decision-Making." Final Report, Vol. 2, 1997.

[18] OSHA News Release. "Notice of Proposed Rulemaking on U.S. Department of Labor's risk assessment procedures published in Federal Register," Release Number: 08-1242-NAT, 08/29/2008.

[19] The Presidential/Congressional Commission on Risk Assessment and Risk Management. "Risk Assessment and Risk Management in Regulatory Decision-Making." Final Report, Vol. 2, 1997. (p. 133-134)

[20] The proposal also fails to mention the comprehensive report prepared by the National Advisory Committee on Occupational Safety and Health which was commissioned precisely to examine and make recommendations on OSHA's standards development process. The report was released on June 6, 2000.

[21] National Research Council of the National Academies. "Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget," 2007.

[22] National Academies. News Release: "Report Recommends Withdrawal of OMB Risk Assessment Bulletin," January 11, 2007.

[23] The Presidential/Congressional Commission on Risk Assessment and Risk Management. "Risk Assessment and Risk Management in Regulatory Decision-Making." Final Report, Vol. 2, 1997. (p. 105)

[24] U.S. Department of Labor, Assistant Secretary for Policy. "Requirements for DOL Agencies' Assessment of Occupational Health Risks," (RIN: 1290-AA23), 73 Federal Register 50909, August 29, 2008, at 50910.

[25] Lewis R. Bush Administration Tries To Slow Workplace Toxin Rules. ProPublica, July 23, 2008. At: *http://www.propublica.org/article/bush-administration-tries-to-slow-workplacetoxin-rules-723/*

[26] U.S. Department of Labor. "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Department of Labor," October 1, 2002.

[27] OSHA News Release, Release Number 08-1242-NAT, 08/29/2008. 28 Public docket available at *http://www.regulations.gov*

ATTACHMENT A

August 14, 2008.

Hon. ELAINE CHAO, *Secretary of Labor,*
U.S. Department of Labor, Suite S-2018, 200 Constitution Avenue N.W., Washington, DC.

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.

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.

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,

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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.*

[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-chaosmystery-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).

"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."

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 adverse health outcome" (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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ATTACHMENT B

August 12, 2008.

Hon. ELAINE CHAO, *Secretary of Labor,*
U.S. Department of Labor, Suite S-2018, 200 Constitution Avenue N.W., Washington, DC.

DEAR SECRETARY CHAO: On behalf of the American Public Health Association (APHA), the nation's oldest and most diverse organization of public health professionals in the world, I write to express our opposition to Department of Labor's (DOL) proposed regulation that would significantly alter the preventive health framework embodied in the Occupational Safety and Health Act of 1970 (OSH Act) and the Mine Safety and Health Act of 1978 (Mine Act). The proposed "Requirements for DOL Agencies' Assessment of Occupational Health Risks," which is pending review at the White House's Office of Management and Budget, is contrary to the most fundamental public health principle of prevention.

Occupational diseases can best be prevented by reducing exposure levels of workers to toxic agents and processes. The DOL proposed rule seeks to alter the definition of a working life to an arbitrary average number of years—a notion and that is wholly inconsistent with public health and risk science standards. The document also makes erroneous characterizations of uncertainty, risk, and adverse health effects, in direct opposition to recommendations made by the National Academies of Science (NAS) in their 2007 report.

The DOL draft proposal also would require that the Occupational Safety and Health Administration (OSHA) and the Mine Safety and Health Administration (MSHA) issue an Advanced Notice of Proposed Rulemaking for all health-based standards. This new mandatory step in the process will further delay protective

rules, even those with well-understood adverse health effects, such as respirable coal mine dust and silica. Although the DOL is charged with worker health and safety protection, it has only issued one health standard over the last 10 years. The latest DOL proposal would only add steps to the rulemaking process, and thus delay health protections for workers even further.

APHA urges you to withdraw this proposed rule immediately.

GEORGES C. BENJAMIN, MD, FACP, FACEP *(Emeritus),*
Executive Director.

Chairwoman WOOLSEY. Thank you.

Mr. Johnson.

STATEMENT OF RANDEL JOHNSON, VICE PRESIDENT, LABOR, IMMIGRATION, EMPLOYEE BENEFITS, U.S. CHAMBER OF COMMERCE

Mr. JOHNSON. Thank you, Madam Chairwoman. Let me try to put this a little bit in context. Before I joined the committee, where I did work for 10 years, I also worked handling many OSHA regulations at the Department of Labor——

Chairwoman WOOLSEY. Mr. Johnson, a little closer.

Mr. JOHNSON. Let's turn the tape back there so I can get my time back.

Before joining the committee, where I did work for 10 years, Madam Chairwoman, I did spend some time at OSHA working on many rulemakings, including benzene, formaldehyde, nonasbestisform tremolite, the Personal Exposure Limit project, which was a personal disappointment where we did regulate 438 chemicals in a very swift rulemaking over seven months. Unfortunately, the court struck that down. I think we could have done that, however, if we had taken four or five more months and done it properly. But I have had some experience in this area, although I meant to be a generalist.

But this rulemaking needs to be put in the context of, look, this is an Advanced Notice of Proposed Rulemaking. There is going to be ample time for the public and other experts to comment on this. It will then become a Notice of Proposed Rulemaking before it becomes a final rule. I use the rule loosely here, because I know the Agency is not formally calling this a rule. An administrative procedure act, but it's an agency action. And I still believe it would be challengeable in court in one way or another, although the DOL solicitor's office may disagree with me on that. But there is a check and balance built into this.

Secondly, there is nothing secret about this going on. It is an Advanced Notice of Proposed Rulemaking. What could be more open?

Third, I think it is important to note that the courts recognize that much deference must be given to OSHA once it determines what a significant risk is. And I can quote from the court cases. You can look at the benzene decision and other cases. The point is, this is not a math—the courts do not hold OSHA to a mathematical straitjacket. Once OSHA makes a decision as to risk or hazard, the courts will defer to that absent as long as it is supported by substantial evidence.

So it is important to get that initial risk assessment right the first time out. An Advanced Notice of Proposed Rulemaking allows the experts and OSHA to sort through the weeds and the long

grass before it gets to an NPRM. And what can be wrong with that?

And let me come back to the question of notice; the 30-day comment period, Madam Chairwoman, which you hit on. Frankly 30 days is a short period of time. However, there are certainly many times in the history of OSHA where it has used that kind of a time period for even more significant regulations.

For example, I am holding up here the proposed regulation on ergonomics, which was issued November 23, 1999, Thanksgiving week, in which we had 60 days to comment on it with 800 pages of regulations which is right here as comparative to this regulation, which is about 6 pages. Now we did ask the Clinton administration for a 30-day extension, which we got after selling our first born, but that was a massive piece of rulemaking stretching over many, many issues, many pages. This is six or seven pages. So maybe 30 days is not enough. Maybe the Department will give another 30 days. I am not sure. The point is it can be done. People can focus on it, and it is just an Advanced Notice of Proposed Rulemaking.

Lastly, I think you know if a final rule comes out and it is not to the satisfaction of this committee, Congress always has oversight powers to reign in an Agency that has gone too far, and who knows what will happen in the next election. But I think the proper role for the committee might be to look at this when it comes out as a final rule rather than to be interfering with the Agency process now, which of course the Administrative Procedure Act and OSHA rulemaking process contemplated that the Agency would apply its expertise—that is why it is created—before Congress steps in.

So you know with regard to transparency, posting things on the Internet, duh, I mean of course those kinds of things can be done. I can say in the past, such as ergonomics, the Agency failed to do several of those things, which is why we certainly support this regulation. Key studies were left out. We had to send law clerks over to the Department of Labor. I believe Senator Enzi had to go over there and go through the rulemaking record and find the studies we needed. Posting it on the Internet, what could be wrong with that? It certainly should be done at the same time that the NPRM is posted and not two weeks into that. And I think I will just—these are—there will be lots of time to sort through these issues. I think it is a rulemaking that needs to be done.

The process of a risk assessment down at OSHA is confusing. I met—I know less about MSHA, but this is just to try to pull it together in one useful document for the public to look at. Is it a tempest in a teapot? I am not sure. It is more important than that. But I think it is something that has perhaps been blown out of proportion. But nonetheless, I appreciate the opportunity to testify. And hopefully we will all comment seriously on this proposal if it becomes a final rule.

Thank you, Madam Chairwoman.

[The statement of Mr. Johnson follows:]

Prepared Statement of Randel K. Johnson, Vice President of Labor, Immigration and Employee Benefits, U.S. Chamber of Commerce

Madame Chairwoman, members of the committee, I am Randy Johnson, Vice President for Labor, Immigration and Employee Benefits at the U.S. Chamber of Commerce. Before coming to the Chamber, I was the Labor Policy Coordinator and

Counsel for this committee when it was chaired by Representative Goodling from Pennsylvania. Prior to working for this committee, I was at the Department of Labor working in the Solicitor's Office on regulatory matters, including OSHA regulations such as benzene, formaldehyde, the Hazard Communication Standard, asbestos/non-asbestisform tremolite and the Personal Exposure Limit (PEL) project rulemaking. It was one of my personal disappointments that the PEL rulemaking was struck down by the courts. Based on my experience, what the Department of Labor has proposed for comment appears useful to all parties interested in OSHA and MSHA rulemakings, and is consistent with the principles of sound rulemakings as expressed during this and previous administrations.

An agency of the federal government shall only have the power to impose a requirement on a private citizen through a regulation, either an individual, or in the case of OSHA and MSHA an employer, where it has made a compelling and public case for the need for the regulation, and demonstrating that the best available science and data support such a regulation. While taken for granted in Washington, DC, the power to regulate is an awesome one, and often underappreciated by decision makers who rarely have to live under these regulations. Inherent in these principles is that the public shall have the opportunity to examine and critically review the materials supporting the agency's intended action. OSHA's and MSHA's rulemaking processes as well as the broader Administrative Procedure Act are built on this foundation. The Department of Labor is proposing to ensure that, to the greatest degree possible, these principles of best data underlying a regulation and maximum transparency are achieved, and the U.S. Chamber unequivocally supports this proposal.

As a preliminary matter, I wish to emphasize what should be obvious in all regulations, but often goes unnoticed—which is that the burdens and costs of this proposal (along with its benefits) should be viewed in the context of the numerous and complex regulations businesses must already comply with. Currently, there are more than 100,000 regulations on the books with an estimated cost of over $1.11 trillion to the public. Thousands of pages of fine print of the Code of Federal Regulations, which are then interpreted by agency directives, and ultimately by the courts against the backdrop of numerous statutes, truly present a huge compliance burden to business which is daunting to any employer. State and local laws add to the confusion. Even the best intentioned employer and even those well staffed by lawyers can make good faith compliance errors which agencies and plaintiffs' lawyers will make much ado over, to say the least. OSHA regulations are but one small part of this gigantic puzzle and all the more reason they should be carefully justified before issuance.

To the extent that a risk assessment by OSHA or MSHA is not adequately supported by scientific data and results in a new regulation that imposes more burdens on employers without producing a commensurate improvement in worker protection, employers will be further disadvantaged and have that many fewer resources for creating new jobs and compensating employees. Indeed, much will be expended on attorney fees to determine, in good faith, if there even was an error, given the vagueness of many legal requirements.

Unfortunately, one of the major problems of government and its enforcement agencies is that its initiatives tend to be read in isolation and silos, rather than against this backdrop of the huge existing panoply of regulations. Who among us envies the small business person faced with these challenges? Who among us even dare open such a business and putting our assets on the line? We ask that you keep this entire picture in mind as you consider whether to support the Department of Labor's proposal to implement a consistent and transparent risk assessment process.

That being said, what constitutes the level of risk necessary for regulating by OSHA or MSHA is still an issue of debate. The Supreme Court in the "Benzene" decision in 1980 ruled that OSHA must establish that a significant health risk is presented, and that this risk can be lessened or eliminated through some change that can be imposed through regulation.[1] While the Supreme Court established the requirement for finding significant risk, it did not spell out how OSHA was to do so. The Court mused that a one in a billion chance of someone dying from cancer because of drinking chlorinated water would not be significant, but a one in a thousand risk of dying from inhalation of benzene would be significant. Although it may be tempting to mandate such a specific statistical threshold as identifying significant risk, the Chamber believes this would be unwise. The essence of risk assessment is flexibility, as risks need to be evaluated in context. The National Research Council's report on OMB's Proposed Bulletin on Risk Assessment in criticizing OMB's proposal stated that "risk assessment is not a monolithic process or a single method. Different technical issues arise in the probability of exposure to a given

dose of a chemical. * * * Thus, one size does not fit all, nor can one set of technical guidance make sense for the heterogeneous risk assessments undertaken by federal agencies."[2]

A sound risk assessment is necessary for a good regulation, but getting a poorly supported risk assessment overturned in court is extremely difficult. Courts almost always defer to agencies with respect to their determinations, and in particular to OSHA risk assessments. This heightens the need for OSHA and MSHA to ensure that the science and data underpinning a regulation is adequate.

The principles for good risk assessments have been expressed by a variety of sources over several administrations. Among them, the Presidential/Congressional Commission on Risk Assessment and Risk Management, created under the Clean Air Act Amendments of 1990, concluded that OSHA has "relied upon a case-by-case approach for performing risk assessment and risk characterization."[3] The Department of Labor's proposal seeks to systematize this process, moving beyond the "case-by-case" approach cited by the Commission.

Another source for the principles of risk assessment is the Memorandum for Heads of Executive Departments and Agencies issued by OMB and the Office of Science and Technology Policy last September. The Department's proposal reflects the principles stated in that memo closely. The top principle is that agencies "should employ the best reasonably obtainable scientific information to assess risks to health, safety and the environment,"[4] which is the central thrust of the Department of Labor's proposal. The memo also makes clear that assumptions and uncertainties should be stated explicitly. This is also one of the provisions of the Department of Labor's proposed risk assessment regulation.

Furthermore, the proposal reflects the recommendations of the National Research Council in its review of OMB's proposed risk assessment bulletin. The NRC concluded that agencies "describe, develop, and coordinate their own technical risk assessment guidance,"[5] instead of OMB trying to institute a generic risk assessment process. The NRC stated that "longestablished concepts and practices that have defined risk assessment as a process * * * involve hazard identification, hazard characterization or dose-response assessment, exposure assessment and risk characterization."[6] These terms are the exact requirements for a risk assessment in the proposed regulation under section 2.9(c)(4).

The proposal is also consistent with the Administration's and Department of Labor's guidelines on Information Quality, all of which stress the use of the best available data at the time of the rulemaking. Among the areas where the best available data is to be used is how long an employee stays at a specific job. While the Department has retreated from the position taken in the draft proposal that was leaked, which explicitly moved away from the assumption that workers stay at their jobs for 45 years, the published proposal still makes clear that OSHA and MSHA are to use best available scientific data including industry-by-industry evidence describing working life exposures. Relying on a stale, inaccurate assumption when better, more current data is available simply makes no sense.

The proposed regulation also codifies the 1980 "benzene" decision by the Supreme Court, which established the principle that OSHA must find a "significant risk" that can be lessened or eliminated by a change in practices before promulgating any health standard. As mentioned above, the Supreme Court did not define "significant risk," leaving that up to OSHA. In this proposed regulation, DOL is establishing a consistent process by which OSHA and MSHA will describe how significant risk was determined for any given health standard.

Not only is this proposal well reasoned, necessary, and overdue, but the Department should be commended for its approach to implementing it. As this is only an internal policy guideline, it could have been implemented without seeking public comment through a notice of proposed rulemaking as they have done. If the Department had pursued that approach, the title of today's hearing might have been appropriate—this could have been seen as a "secret" rulemaking. As they have chosen to do this through a fully public procedure, soliciting comments and input as with any other regulation, calling this a secret regulation is unwarranted and suggests a desperate intent to find something wrong with the proposal.

What the Department has proposed is very simple—provide more information to the public and those interested in a specific health standard rulemaking, make sure that any assumptions and uncertainties are identified and explained, and give interested parties the opportunity to review and comment on the science and data upon which the agency is relying. These goals would be achieved through the use of mandatory Advanced Notice of Proposed Rulemakings (ANPRMs), except in the case of an emergency temporary standard.[7] Requiring ANPRMs and thus opening up OSHA's and MSHA's scientific and data support to public scrutiny is similar to the way that OSHA must disclose its support for a regulation during the Small Busi-

ness Regulatory Enforcement Fairness Act (SBREFA) review panels that are required if a regulation is determined to have a significant economic impact on a substantial number of small entities. The SBREFA process has been criticized by organized labor as giving small businesses too much access to the rulemaking process. By requiring that OSHA and MSHA issue ANPRMs for health standards (not safety standards), the Department is giving the unions and all others not part of the SBREFA review process the same opportunity to review the science and data upon which the agencies are relying and comment on these materials at a time before the regulation has been drafted and all but formed. Commenting at that point in the process is essential, since once a regulation is drafted and proposed, getting OSHA or MSHA to significantly revise a regulation or withdraw it because of inadequate scientific support is all but impossible.

The Department is also requiring that all relevant documents related to the rulemaking be posted in an easily accessed and well organized format at www.regulations.gov—the federal government's central internet rulemaking portal. This sounds so fundamental in this era of instant electronic access to an enormous array of authorities and data that specifying this would seem redundant or unnecessary. However, there are examples where OSHA did not make key materials available in a timely manner during major rulemakings. The most egregious of these was during the ergonomics rulemaking when key studies were not made available for review during the comment process, frustrating those who were trying to develop statements and questions in preparation for the administrative hearings held by OSHA.

The proposed regulation from the Department of Labor specifying how risk assessments for health standards are to be done and providing greater transparency and opportunity for public input is absolutely consistent with the principles of risk assessments, sound rulemaking, and above all, good government. The risk assessment drives the entire process of regulation from the go/no go decision to what level of protection and remedial action may be required. It is imperative the risk assessment be done using the best available and most current data. The Department's proposal establishes a process that will yield sound and credible risk assessments. I look forward to responding to your questions.

ENDNOTES

[1] Industrial Union Department v. American Petroleum Institute, 448 U.S. 642 (1980).
[2] 2007 NAS Report on the Proposed Risk Assessment Bulletin, Executive Summary, page 7.
[3] Presidential/Congressional Commission on Risk Assessment and Risk Management, Framework for Environmental Health Risk Management, 2 Final Report 133 (1997).
[4] OMB/OSTP Memorandum for the Heads of Executive Departments and Agencies, Updated Principles for Risk Analysis (2007) M—07—24.
[5] 2007 NAS Report on the Proposed Risk Assessment Bulletin, Executive Summary, page 7.
[6] Id. at 3.
[7] Criteria and procedures for emergency temporary standards are found under section 6(c) of the OSH Act, and section 101 (b)(1) of the Mine Act.

Chairwoman WOOLSEY. Thank you. I think you heard the bells ring. We are going to have three votes. So Ms. Seminario, if you will complete and then we are going to try to have a series of questions up here because we really have 20 minutes. We know that. It says 13 but we know how it works. The first vote. So let's complete the witnesses and then we will ask some questions.

Mr. WILSON. The chairman runs very fast.

STATEMENT OF MARGARET SEMINARIO, DIRECTOR, DEPARTMENT OF OCCUPATIONAL HEALTH AND SAFETY, AFL–CIO

Ms. SEMINARIO. Thank you very much. My name is Peg Seminario. I am Safety and Health Director for the AFL-CIO, and I appreciate the opportunity to testify today. I have been doing this work for over 30 years and have worked on virtually every major rule that has come through the Occupational Safety and Health Administration.

On August 29, just before Labor Day, the Department of Labor published a proposed rule in the Federal Register imposing new re-

quirements on OSHA and MSHA for conducting occupational risk assessments in developing health rules. It is our view that it is actually a proposed rule, unlike what Mr. Johnson said. He thinks it is an Advanced Notice of Proposed Rulemaking, which indeed are different. So getting some clarification on that would be helpful.

This new rule was developed in secret without any consultation by political appointees in the Office of Assistant Secretary of Policy during the last months of the Bush administration. In our view, it would significantly delay and potentially weaken future occupational health protections. We are greatly concerned, seeing this rule being pushed through by an administration that unfortunately for the past 7½ years has refused and has failed to set any new OSHA health rules to protect workers. Now the administration is rushing to lock in place requirements to make it more difficult for the next administration to act to protect workers from known health risks.

In our view, the Department of Labor risk assessment rule is unnecessary and unsound. According to the Department, the purpose of the rule is to compile its existing best practices related to risk assessment into a single easy-to-reference regulation. But as noted above and explained in greater detail in my written testimony, the rule does more than codify existing practices. It changes existing practices and does impose new burdens on both OSHA and MSHA. We believe that the rule is unnecessary. As Dr. Monforton pointed out, OSHA has conducted risk assessments for years and those risk assessments have been very robust and have withstood court challenges and have been found to have been sound.

We also believe that the rule is inappropriate. The Department already has risk assessment guidelines that were adopted in 2002. But guidance is meant to be just that, guidance, which is nonmandatory, a flexible directive that can be changed. Indeed, when you look across the government, everything that has been done on risk assessment, including those directives out of OMB, are done as guidance. This is different. It is codifying these procedures in the Federal Register and, with that, the administration's attempt to impose its policies on the next administration. We don't see that in the next four months this administration is going to issue any new rules. They haven't done so to date. So what is the purpose of this rather than putting in place its views, its policies on the next administration?

We think that the rule would add years of delay to both OSHA and MSHA rulemakings. And with it, it will put workers at risk. It adds a new step, the Advanced Notice of Proposed Rulemaking, to the rulemaking process. Indeed, in some cases OSHA has used ANPRs but they use other procedures for gathering information as well. They have advisory committees. They have requests for information. They may conduct public meetings. This proposal would lock in this one particular procedure rather than leaving it to the discretion and judgment of the Agencies as to how to proceed. And it changes the rulemaking procedures that are set forth in the Occupational Safety and Health Act, in the Mine Safety and Health Act, and essentially it attempts to amend those rules. So we don't think this one method should be imposed in a one size fits all when rules differ and the mechanisms for gathering information and what is appropriate should be flexible.

It is important to point out or worth pointing out because of such delays that ANPRs bring to rulemaking, and we estimate it will be about two years of additional time. In 1987 the Administrative Conference suggested and recommended that OSHA not use ANPRs.

It is important to point out this delay has real impact on workers. The proposal doesn't apply only to future rules. It applies to those in process as well. We have three important health rules moving along at OSHA. One on silica, one on beryllium, another on diacetyl. None of those have had an ANPR. Not one of them. They have had other ways of gathering the information. This rule requires that OSHA go back to square one and start all over. You know, silica has been under development for 10 years, beryllium the same. And this will result in dozens and dozens of unnecessary deaths.

So in conclusion, let me just say that this proposal is flawed. It is unnecessary. It is unsound, and it will harm the health of workers in this country. It should be withdrawn by the Department of Labor. And if it is not, we would highly support efforts by the Congress to stop it.

Thank you.

[The statement of Ms. Seminario follows:]

Prepared Statement of Peg Seminario, Director of Safety and Health, AFL–CIO

Chairwoman Woolsey, Ranking Member Wilson, and members of the committee: Thank you for the opportunity to testify today on the Department of Labor's proposed rule on occupational risk assessment. My name is Peg Seminario, and I am Safety and Health Director for the AFL-CIO. In my more than 30 years working on safety and health issues, I have been involved in dozens of rulemakings on safety and health standards and regulations promulgated under the Occupational Safety and Health Act.

On Friday, August 29, 2008, just before Labor Day, the Department of Labor (DOL) published a proposed rule in the Federal Register imposing new requirements on the Occupational Safety and Health Administration (OSHA) and Mine Safety and Health Administration (MSHA) for conducting occupational risk assessments in developing workplace health rules. This new rule, developed in secret by political appointees in the Office of the Assistant Secretary of Policy (OASP) during the last months of the Bush Administration, would significantly delay and potentially weaken future occupational health protections.

This new rule is being pushed through by an Administration that for the past seven and one-half years has refused and failed to set any new OSHA health rules to protect workers, except for one rule that was issued pursuant to court order. Now, the Administration is rushing to lock in place requirements to make it more difficult for the next administration to protect workers from known health risks. This cynical measure is unfounded, unsound, and harmful to workers. We fully support HR 6660, legislation that would stop the adoption or implementation of this rule.

The risk assessment rule proposed by DOL would do the following:

- Add a new step to the rulemaking process for setting occupational health standards by requiring both OSHA and MSHA to issue an advanced notice of proposed rulemaking (ANPR) for every occupational health standard to solicit scientific studies and other information on health risks and exposures. This would add years of delay to an already glacial process and result in unnecessary death and disease for workers.
- Require OSHA and MSHA to respond to every public comment submitted on the risk assessment issues, regardless of the validity or merit of the comment, before issuing a proposed or final rule.
- Require the agencies to gather and analyze available industry-by-industry evidence related to working life exposures, which neither OSHA nor MSHA now do, which will add significant time to the rulemaking process and which could result in weaker protections for workers.

• Codify existing Office of Management and Budget (OMB) and DOL informational quality and peer review guidelines, locking into place by rule controversial regulatory policies of the Bush Administration, many of which have been criticized or rejected by the National Academy of Sciences.

• Require OSHA and MSHA to post all relevant documents related to an occupational health standard, including all underlying studies and analyses, on www.regulations.gov within 14 days after the conclusion of the relevant step in the rulemaking process. On this point, it is worth noting that 16 days after the DOL risk assessment rule was published in the Federal Register, DOL had failed to make any of the underlying documents related to this rulemaking part of the public docket.

The DOL Risk Assessment Rule is Unnecessary and Unsound

According to DOL, the purpose of this rule is "to compile its existing best practices related to risk assessment into a single, easy to reference regulation." But as noted above, and explained in greater detail below, the rule does more than codify existing practices—it changes existing practices and imposes new burdens on OSHA and MSHA.

The rule is unnecessary. OSHA has conducted risk assessments for its occupational health rules for decades, and recently MSHA has done so as well. OSHA's risk assessments have withstood court challenges and have been found to be sound.

And the rule is inappropriate. The Department of Labor already has risk assessment guidelines that were adopted in 2002 as part of DOL's information quality guidelines to implement Bush Administration policies on peer review and data quality. (Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Department of Labor, October 1, 2002.) Guidance is meant to be just that—non-mandatory, flexible directives that reflect the views, policies and practices of an agency, department or administration, and that can be changed. By proposing to codify these risk assessment practices into a formal rule, the Bush Administration is attempting to impose its policies and practices on the next administration.

The Rule Will Add Years of Delay to OSHA and MSHA Rulemaking and Delay Needed Protections

The DOL rule would require OSHA and MSHA to issue an ANPR for every occupational health rule, except for emergency rules. This new mandatory step for every rulemaking is not needed and will delay needed protections.

The OSHA and MSHA standard setting processes already provide for much more extensive public input and participation than virtually all other government agencies. Both agencies routinely cast a wide net, soliciting information using a variety of mechanisms such as Requests for Information published in the Federal Register, public meetings, stakeholder meetings, workshops, advisory committees, and negotiated rulemaking committees, in addition to publishing a formal ANPR in the Federal Register. ANPRs may be appropriate for some rules, but rules vary in their complexity and approach, and it is unsound to impose a one-size fits all process and methodology on all rules.

Mandating an additional formal step in the rulemaking process for every occupational health rule, and requiring OSHA and MSHA to respond to all comments on the risk assessment issues before even issuing a proposed rule, will add approximately two years to a process that already takes eight or more years to complete. For this reason, in 1987 the Administrative Conference of the United States recommended that OSHA not routinely use ANPRs. ACUS Recommendation 87-10, Regulation by the Occupational Safety and Health Administration, 52 Fed. Reg. 49,147 (1987).

It is important to point out that this delay in protection has real impacts on worker health. Every month or year of delay results in unnecessary exposure by workers to harmful substances, and results in deaths and illnesses that could have been prevented. For example, according to OSHA's risk assessment on hexavalent chromium, every year of delay in the adoption of the new 5.0 ug/m3 standard resulted in 40 to 145 lung cancer deaths. Similarly, OSHA's preliminary risk assessment on silica estimates that reducing the permissible exposure limit to 50 ug/m3 will prevent 41 silicosis deaths and 19 lung cancer deaths annually. Every year of delay in setting a silica rule results in 60 unnecessary deaths.

The proposed new risk assessment rule includes rules currently under development within its reach. This means that for rules that have been under development for years, OSHA will have to go back to square one and start anew under the new risk assessment rules. So, for example, an OSHA rule on silica that has been under development since 1997 will be delayed even further. It is worth noting that the sili-

ca rule has been designated by the Bush Administration as a priority for action on the Regulatory Agenda since 2002, and that OSHA completed the required small business review on the draft silica rule in 2003. But for the past 4 years the OMB required peer review of the silica risk assessment has been repeatedly delayed. It is our understanding that this rule, like other pending OSHA rules, has been held up by the Office of the Secretary. And now, with this new rule the Department would require OSHA to start all over and issue an ANPR for silica, delaying this important standard for many more years.

The risk assessment rule would also delay action on an OSHA standard to protect workers from diacetyl, a food flavoring chemical that causes a disabling deadly lung disease. As you know, last year the House of Representatives passed legislation requiring OSHA to issue a final standard on diacetyl within two years of enactment. The Bush Administration opposed the legislation and refused to issue an emergency rule, but promised to move expeditiously to develop a diacetyl standard through normal rulemaking procedures. But there has been no such action. A small business review on a draft diacetyl rule, scheduled to be initiated in January, has yet to happen, and there is no sign that the Administration has any intention of acting. If the next Administration decides to move quickly on diacetyl, they can't. The new DOL risk assessment rule would require OSHA to issue an ANPR and respond to all comments before moving forward with a proposed rule.

It is shameful that after refusing to take action to protect workers from serious well-recognized health hazards for 7 1/2 years, that the Bush Administration is spending its lasts months and taxpayer money to lock in place rules that would prevent the next administration from taking prompt action.

The DOL Rule Would Change the Way OSHA and MSHA Assess Worker Health Risks and Could Result in Weaker Protections

The new DOL rule would require OSHA and MSHA to gather and analyze available industry-by-industry evidence related to working life exposures in evaluating risk, which neither OSHA nor MSHA now do. Changing OSHA and MSHA's risk assessment practice in this manner is inappropriate and could lead to weaker protections for workers.

The current practice of both agencies is to evaluate the risk of exposure posed to the overall population of workers exposed to the hazard in question at the level of exposure under an existing rule or conditions, and to assess how a reduction in exposure to lower levels would reduce that risk. Both the OSHAct and the MSHAct require that the agencies protect workers against health risks even if they are exposed over the course of a working lifetime. In keeping with this statutory requirement, both agencies have adopted a practice of assessing workplace health risks based upon exposure over 45 years.

In regulating occupational health risks, both agencies usually set a single permissible exposure level for all workers exposed to the hazard. This limit applies to all industries covered by the rule. The agencies appropriately assume that exposure to similar levels of a chemical pose the same risk to workers, regardless of the sector where the exposures occur. Thus, the proposed industry-by-industry assessment of health risks—and the idea that different exposure limits could be set for workers in different sectors—makes no sense for rules that cover many groups of workers.

In addition, the proposal appears to potentially open the door to changing OSHA and MSHA's longstanding assumption of a 45 year working lifetime exposure. An earlier version of the proposal explicitly made this change, and the new proposal is murky on this point. Such a change would be unsound. In many industries such as coal mining and construction, a large number of workers are employed in the industry or the occupation over their entire working life. These long-term workers are at the greatest risk and deserve to be protected. Basing risk determinations and exposure levels on the average time in an occupation or industry will reduce the level of protection and leave all workers at greater risk. For example, if OSHA's hexavalent chromium standard was based on the assumption that workers were on average employed for 10 years, the permissible exposure level would be 4.5 times higher than that set by OSHA, creating a greater risk for all workers, and allowing much greater cumulative exposures and risk for long-term workers. This approach is unsound and contrary to the directive in the Occupational Safety and Health Act and Mine Safety and Health Act that protections be set at a level that will protect workers who are exposed for a "working lifetime."

The Process by Which DOL Has Developed the Risk Assessment Rule is Highly Irregular and Flawed

The proposed risk assessment rule has been developed in secret by political appointees in the Department of Labor's Office of Assistant Secretary for Policy

(OASP), with little involvement by OSHA and MSHA and with no public notice prior to its publication. OASP has no expertise in risk assessment and no authority under the Occupational Safety and Health Act or Mine Safety and Health Act for the development or issuance of occupational safety and health rules. It is our understanding that the background for the rule was developed by an outside contractor, not by the agencies or OSHA or MSHA experts on risk assessment and occupational health standards.

This is in direct contradiction to the recommendation by the National Academy of Sciences that risk assessment guidelines be developed by the individual agencies with the technical expertise and knowledge of legislative requirements. (National Academy of Sciences, Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget, 2007).

The risk assessment rule was not included in the Department of Labor's semi-annual regulatory agenda published in April 2008, despite a requirement under Executive Order 12866 that all rules under development be listed on the agenda. The first public indication that this rule was even under consideration came on July 7, when a notice was posted on www.reginfo.gov, that the draft proposed rule was at OMB for review under Executive Order 12866. No explanation or information about the rule was posted, and the Department refused to provide any information to the Congress, the press or public when asked. Information about the content of the rule only became public when the Washington Post obtained an earlier draft and published a story on July 23. Subsequently, the Post and other media outlets obtained a copy of the draft that had been submitted to OMB for review, and posted the document on their respective websites.

Many in the scientific, labor, and occupational safety and health communities objected to the Department of Labor's draft proposal and the process by which it was developed. The American College of Occupational and Environmental Medicine, the American Industrial Hygiene Association, the American Public Health Association and a group of over 75 scientists all wrote to Secretary of Labor Elaine Chao urging her to withdraw the draft rule.

Despite these objections, the Department forged ahead. The draft proposal was cleared by OMB on August 25th, and published in the Federal Register on August 29, 2008, the Friday before Labor Day.

The proposed rule violates the policy announced by White House Chief of Staff Josh Bolten on May 9, 2008, which states that except for "extraordinary circumstances," agencies were supposed to issue any new proposed rules by no later than June 1, 2008. No "extraordinary circumstances" exist to justify DOL's last-minute rule.

The Department is trying to rush the proposal through and is depriving the public of an opportunity to meaningfully participate in this rulemaking process. DOL is giving the public only 30 days to comment on the proposed rule—an unusually short comment period that started on the Friday before a three-day holiday weekend.

The 30 day time period for comment on a rule with such significant impact is unusual and inadequate. OSHA and MSHA typically provide a far longer comment period on their proposed rules, and Executive Order 12866, under which the proposal was supposedly reviewed, says that agencies should ordinarily provide at least 60 days' notice.

For example, in 1996, when OSHA was adopting new rules on Recording and Reporting Occupational Injuries and Illnesses, the agency initially provided 90 days for comments and extended the comment period twice for a total comment period of 150 days. In addition, six days of public meetings were held to provide full opportunity for public input.

Even for non-mandatory guidance, agencies have generally provided much longer comment periods than 30 days. When OMB proposed its Bulletin on Peer Review and Information Quality in 2003, an initial 90-day comment period was provided and a public workshop was convened at the National Academy of Sciences. In response to comments, in 2004, a revised draft bulletin was re-proposed and an additional 30 days were provided for comments. Recently, OSHA published Proposed Guidance on Workplace Stockpiling of Respirators and Facemasks for Pandemic Influenza and provided 60 days for public comments. Prior to this in 2007, OSHA had circulated a draft for public comment and with CDC convened a series of public meetings soliciting input from interested stakeholders.

Moreover, while the proposed DOL risk assessment rule requires OSHA and MSHA to post documents in the public docket within 14 days, as of September 15, 2008, 16 days after the proposal was published, the Department had failed to post any of the background documents and analyses related to this rule.

Finally, and importantly, because the proposed risk assessment rule will affect the substance and process of standard-setting under the Occupational Safety and

Health Act and the Mine Safety and Health Act, it is the AFL-CIO's view that the Department of Labor must hold a public hearing on the proposal if requested. The AFL-CIO and others have requested such a hearing, but the Department has given no indication that it intends to schedule one.

Conclusion

The Bush Administration started its tenure in 2001 by repealing OSHA's ergonomics standard, and for the past 7 1/2 years it has refused to take action to issue new safety and health protections unless under court order or in response to Congressional mandates. Now in its waning days, the Administration is attempting to put in place new regulatory requirements that would make it much more difficult for the next administration to take action to protect workers. DOL's proposed risk assessment rule is unsound, unnecessary and will result in unnecessary deaths and disease among workers. If the Department of Labor does not withdraw this harmful measure, we urge the Congress to enact legislation to stop it.

Chairwoman WOOLSEY. Thank you. I am going to yield to Mr. Payne.

Mr. PAYNE. Thank you very much. I will just be brief since we are going to have to leave.

Let's see. Mr. Sequeira, this proposal we are talking about has not been peer reviewed. Why did your office disregard the recommendation from the National Academies made in 2007 which states that technical guidance developed by Agencies should be peer reviewed?

Mr. SEQUEIRA. The Department's proposal is not required to be peer reviewed. The proposed rulemaking and what we are seeking comment on is not technical and is not guidance and therefore is not subject to peer review.

Mr. PAYNE. Okay. Therefore, because it is not subject to peer review, therefore you discount the fact that, you know, that it shouldn't be? I mean, your answer is that it is not required, therefore a lot of things weren't required. That is why AIG had to get $85 billion from the government yesterday. You know, things that are required and not required as opposed to what should be done to prevent things from happening are what we are concerned about. And there seems to be a nonchalant sort of cavalier attitude by the Department of Labor that these things are not required, therefore, it is like water off a duck's back.

Mr. SEQUEIRA. Well, Congressman, as I understand it, the process of peer review applies to technical information studies, reports in the academic sense that articles are peer reviewed. This proposal, the Department's proposal doesn't represent anything of that kind. I am not sure what there is in the proposal to be peer reviewed, frankly.

Mr. PAYNE. Okay. Would any of the other witnesses like to express their point of view? Yes, Doctor.

Ms. MONFORTON. Thank you. Your question is excellent in terms of the requirement for peer review. Yes, it is not a requirement. But the Department of Labor says over and over again that this is something about best practices, and I don't think there is anyone here that would suggest that recommendations coming out of the National Academies would not be considered best practices. And the National Academies specifically said that any risk assessment, guidance, document prepared by the administration should meet certain criteria and it should be subject to peer review.

Mr. PAYNE. Yes.

Ms. SEMINARIO. I would just support what Dr. Monforton has said. The Department can't have it both ways. They can't be proposing by rule to make law certain, they say existing best practices, but some changes in practices, say that on the one hand but on the other hand say that it shouldn't be peer reviewed or they don't need public comment on it. They also shouldn't be saying, quite frankly, when they are attempting to change the way standards are set in the standard setting process, change the Administrative Procedures Act, change the Occupational Safety and Health Act and Mine Safety and Health Act requirements for how you set rules. Both those laws say you issue a proposal and then you issue a final. Both of them also provide for advisory committees. And suddenly, lo and behold, we have a whole new proposal to say we have a whole new formal step for every occupational health rule. You can't do that and say that, no, we don't think we should take public comment or no, we don't think that peer review is needed. It just doesn't make any sense.

Mr. PAYNE. Yes.

Mr. JOHNSON. Normally the employer can be very strong supporters of peer reviewed studies, and we would certainly join with the unions here on requiring peer reviewed studies generally in OSHA standard-setting processes which are so important here. I think whether or not they had to be done here, I think your point is perhaps they should have been done.

I am not quite sure of the legal requirements of this proposal. It appears to be not the kind of methodological studies that are normally subject to a peer review process. But I am not quite sure. With regard to Peg Seminario's—these changes in the rulemaking process, look, an ANPR is not recognized under the Administrative Procedures Act, that is true, or the rulemaking process under OSHA. However, the APA has not been amended since 1940—well, in this area since 1947. The OSHA act has not been amended since 1972. Surely there is some room for some novelty and reflection in terms of improving the rulemaking process in those 40 years.

The ANPRMs are commonly used by Agencies. They are not some strange creature, and they can be used quickly by Agency to clear out their underlying brush and move quickly to an ANPRM. What Agencies often do, unfortunately, is use ANPRMs as an excuse to get their political overseers on Capitol Hill off their back or the courts, and that is unfortunate but it is used by both Republican and Democratic administrations.

If they are not used as an excuse, and they are used as good faith mechanisms to get to conclusions quickly and allow public comment, then they are very useful. But they shouldn't be used as a shield, which is a problem.

Chairwoman WOOLSEY. Thank you very much. Thank you, Mr. Payne. The ranking member and I will be back after the votes, and I will try to get the rest of our committee back up here too. All right. So hang on. We will be back.

[Recess.]

Chairwoman WOOLSEY. Thank you for waiting for us. The vote is still not quite over; so our Ranking Member will get here soon. I will take this opportunity to ask my questions.

I am very concerned, Mr. Sequeira, that we are kind of missing the point here. In this rulemaking, we are adding a new step to rulemaking, which will lengthen rulemaking, and in all of the language regarding hearings and review, it refers to exceptional circumstances in order to skip the steps necessary.

So my question, and this is after I introduced the popcorn lung bill regarding diacetyl, and that was just out of sheer frustration because of OSHA's inaction, and it just leads me to asking you questions of why adding this step is more important than the three OSHA examples that Dr. Monforton talked about and I talked about in my opening statement. Why do we need this standard so urgently that you operated in an opaque fashion, leapt ahead of all other OSHA and MSHA regulations? What in your standards and in this process is going to save lives?

Mr. SEQUEIRA. Madam Chair, there is nothing in the Department's proposal here that necessarily lengthens rulemaking. And ANPRM, as I mentioned earlier, is not a new process. It is used often by OSHA already. In fact, the recent standards issued by OSHA began with ANPRMs.

It is no secret that OSHA rulemakings take a long time. That is due to a number of factors, not the least of which are the statutory requirements that Congress has put on the agency. OSHA has to comply with no fewer than eight statutes when it conducts a rulemaking. That more than anything is responsible for the length of time.

Chairwoman WOOLSEY. And this rule—and, Ms. Seminario and Dr. Monforton, respond to this and see if maybe I am wrong—this is going to add steps to the process, it is going to make it longer if you prevail in what you are aiming at.

Mr. SEQUEIRA. Actually I don't think that that has the case. An ANPRM can be conducted during the already statute-required SUBREFA process.

Chairwoman WOOLSEY. Let me reclaim my time and turn it over to Ms. Seminario.

Ms. SEMINARIO. Again, let us look at the rules that are pending that we are concerned about: Diacetyl scheduled for a SUBREFA review that was supposed to start in January; silica, a peer review requirement which comes from the Bush administration directive that they have to conduct peer review. It is not a statutory requirement, it is a Bush administration policy which this rule would now codify. That peer review has been pending for four years. SUBREFA review on silica took place in 2003. So on its face this rule says that OSHA has to go back now and conduct an ANPR, start all over, collect data, respond to all the comments, redo their risk assessment which is ready for peer review. So again, it does add a new step and particularly is problematic for those things which have been in the pipeline for years which are underway. And again, it is not appropriate to use this mechanism for every rule.

Ms. MONFORTON. I would also like to just state again that in terms of best practices, I don't see anything in the preamble to the rule that suggests that an ANPRM has been demonstrated to be a best practice. I think it would be really useful for someone to look at perhaps two OSHA rules where an ANPRM was issued and two

OSHA rules when it wasn't issued, and look at the real quality of the information that comes in from the ANPRM.

When the agency issues an ANPRM, there is no requirement. It doesn't have subpoena power to require information from companies or scientists to get information, and you are kind of at the mercy of whoever wants to send in information. So you could actually look at what is submitted during that process and find out does it really add anything to the quality of the product that ultimately comes out?

Chairwoman WOOLSEY. Mr. Johnson.

Mr. JOHNSON. Just, Madam Chair, I know time is limited, but just very quickly, ANPRM is a generalized way of gathering data because it asks generalized questions. It gets it in the hopper for people to look at it and analyze it.

The problems with an ANPRM are traditionally it is actually a proposed regulation, very specific, so by definition it narrows the constraints of those who can comment to that regulation. And the range of changes between ANPRM and the final rule as a practical matter are very small for APA reasons. So an ANPRM is a useful way to collect data upfront, look at it carefully. And you are going to have to deal with those issues anyways. I don't really think it is going to result in delays in and of itself, but an agency can use that excuse for a delay. It really comes down to not the process itself, but, I think, the desire of the agency to move forward for other reasons.

Chairwoman WOOLSEY. Well, it is my understanding all of those questions have to come out in the final review, so why would we have it at the front and the back end? It does add steps to the process.

Mr. JOHNSON. It is all going to wind up in court. You may as well try to deal with some upfront early on rather than later.

Chairwoman WOOLSEY. Well, and then again later. I am sorry. My time is up, and I am going to yield to Mr. Wilson for the purpose of questioning the witnesses.

Mr. WILSON. Thank you again for being here and staying over, too.

Additionally, Mr. Secretary, I appreciate your explanation about the open process that is under way, not a secret, one that can be intelligible and very helpful in receiving information to truly help the people who are working in our country and who understand the significance of safety.

In written questions which were sent to the Department by the Majority, you provide an answer to this question, but can you explain for the record today upon what authority the Department of Labor took this policy change? Furthermore, why did the Department decide to seek public comment on the proposed policy change?

Mr. SEQUEIRA. The proposals issued under the Secretary's general authority at 5 U.S.C. 301, this proposal is not a health standard. It is not a rulemaking. It is not issued pursuant to the Occupational Safety and Health Act or the Mine Safety and Health Act. It is issued pursuant to the Secretary's general authority to prescribe Departmental procedures and process.

As you noted, we weren't required under the Administrative Procedure Act to seek public input or comment on this, but the De-

partment thought that that was important to do. So we expressly affirmatively made that decision to put this proposal out and seek public comment on it, which is ironic that some would call it secret, by the way. Anybody who is familiar with the Administrative Procedure Act knows that by definition a rulemaking is a public process. It is impossible to be secret.

Mr. WILSON. And, further, I think you have explained this in letters of July 17, 2008, and September 5, 2008, to the Chairman.

I would like to submit these for the record.

Chairwoman WOOLSEY. Without objection.

[The information follows:]

U.S. Department of Labor

Assistant Secretary for Policy
Washington, D.C. 20210

JUL 17 2008

The Honorable George Miller
Chairman
Committee on Education and Labor
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Miller:

This letter is in response to the July 10, 2008 letter from you and Chairman Kennedy requesting information about the Department of Labor's draft Notice of Proposed Rulemaking (NPRM) titled, "Requirements for DOL Agencies' Assessment of Occupational Health Risks" that is currently under review at the Office of Management and Budget (OMB). The Department's responses to your specific questions are as follows:

1. A copy of the proposed regulation.

The draft NPRM is currently under review at OMB. Consistent with historical agency practice under the Administrative Procedure Act, a draft NPRM is not shared outside the Executive Branch until interagency review is completed and the NPRM is published in the *Federal Register*.

2. The legal authority under which the Department expects to promulgate this regulation.

The Department is proposing to promulgate this draft NPRM under the Secretary's authority at 5 U.S.C. § 301 to prescribe regulations related to the performance of the agency's business.

3. The reason that this proposed regulation was not listed in the Department's Regulatory Agenda as required by E.O. 12866.

The draft NPRM was not listed in the Department's most recent regulatory agenda because when that agenda was issued, the Department had not determined it would pursue an NPRM. Occasionally, the Department decides to pursue a particular regulatory action in the interim between the publication of each bi-annual regulatory agenda. As you may know, in addition to this item, OMB is currently reviewing a Department of Labor draft NPRM entitled, "Proposed Class Exemption for the Provision of Investment Advice to Participants and Beneficiaries of Self-Directed Individual Account Plans and Individual Retirement Accounts," which

was also not listed in our Spring Regulatory Agenda and for which no abstract or other details appear on the OMB website.

For your information, the abstract for the risk assessment-related NPRM that we provided to OMB is:

> The Department of Labor is proposing requirements for its Agencies to follow when preparing risk assessments in conjunction with the development of health standards governing occupational exposure to toxic substances and hazardous chemicals. The proposed rule requires DOL agencies to follow a consistent, reliable, and transparent set of procedures when conducting risk assessments, outlines the components that should be included in a risk assessment, and provides for improved public access to rulemaking information.

4. The date on which the Department expects to issue its Notice of Proposed Rulemaking for this regulation.

The Department has not identified a specific date for publishing an NPRM. An NPRM publication date can vary depending on a number of factors, including the length of time OMB needs to complete its review of the draft.

5. The date upon which the Department expects to promulgate the final regulation.

The Department has not identified a specific date for publishing a final regulation. The date for publishing a final regulation can vary depending on a number of factors, including the content of public comments received and any resulting modifications to the proposed rule.

6. Whether the Department intends to hold hearings on this proposal.

At this time, the Department has not made a determination on whether it will hold hearings on this proposal.

If you have additional questions, please feel free to contact my office at (202) 693-6151.

Sincerely,

Leon R. Sequeira

Leon R. Sequeira
Assistant Secretary for Policy

U.S. Department of Labor

Assistant Secretary for Policy
Washington, D.C. 20210

SEP - 5 2008

The Honorable Edward M. Kennedy
Chairman
Committee on Health, Education, Labor, and Pensions
United States Senate
Washington, DC 20510-6300

Dear Chairman Kennedy:

The Department recently published in the *Federal Register*, a Notice of Proposed Rulemaking (NPRM) entitled, "Requirements for DOL Agencies' Assessment of Occupational Health Risks," and we are now able to more fully respond to the request from you and Chairman Miller for information concerning the Department of Labor's NPRM.

Pursuant to your request, we asked Departmental employees who worked on, attended meetings regarding, or were otherwise involved with the proposed regulation for information regarding meetings or contacts with entities outside of the federal government.

There was one meeting responsive to your request that was held on May 7, 2008. There was no agenda, other than to discuss David Sarvadi's general views on current risk assessment practices; no minutes were taken; and there was no discussion of any specific plans or proposals regarding the Department's risk assessment methodologies. The following people were invited to the meeting (attendees in bold):

Kevin Burns (MSHA)
Peter Montali (MSHA)
Dorothy Doughterty (OSHA)
Bill Perry (OSHA)
Mandy Edens (OSHA)
Ron Bird (OASP)
Kathleen Franks (OASP)
Deborah Misir (OASP)
Joe Woodward (SOL)
Ian Moar (SOL)
Amanda Walker (SOL)
Jonathan Snare (SOL)
David Sarvadi (Keller Heckman LLP)
Scott Mugno (Mr. Sarvadi invited and brought Mr. Mugno, of Federal Express, to the meeting).

The Department considered holding a second meeting with Public Citizen, but decided not to when OSHA staff pointed out that OSHA is currently in litigation with Public Citizen on an issue that touches on risk assessment.

In addition, Deborah Misir spoke by telephone with David Sarvadi a few weeks prior to May 7, 2008, to invite him to present views on risk assessment practices to DOL staff.

Lastly, a copy of the solicitation contract order and the contractor's final report is also enclosed as you requested.

If you have any further questions regarding this matter, please contact my office at (202) 693-6151.

Sincerely,

Leon R Sequeira

Leon R. Sequeira
Assistant Secretary for Policy

Enclosures

Identical letter to: The Honorable Edward M. Kennedy

cc: The Honorable Howard P. "Buck" McKeon
The Honorable Michael B. Enzi

U.S. Department of Labor

Assistant Secretary for Policy
Washington, D.C. 20210

SEP - 5 2008

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Chairman
Committee on Education and Labor
U.S. House of Representatives
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The Department recently published in the *Federal Register*, a Notice of Proposed Rulemaking (NPRM) entitled, "Requirements for DOL Agencies' Assessment of Occupational Health Risks," and we are now able to more fully respond to the request from you and Chairman Kennedy for information concerning the Department of Labor's NPRM.

Pursuant to your request, we asked Departmental employees who worked on, attended meetings regarding, or were otherwise involved with the proposed regulation for information regarding meetings or contacts with entities outside of the federal government.

There was one meeting responsive to your request that was held on May 7, 2008. There was no agenda, other than to discuss David Sarvadi's general views on current risk assessment practices; no minutes were taken; and there was no discussion of any specific plans or proposals regarding the Department's risk assessment methodologies. The following people were invited to the meeting (attendees in bold):

Kevin Burns (MSHA)
Peter Montali (MSHA)
Dorothy Doughterty (OSHA)
Bill Perry (OSHA)
Mandy Edens (OSHA)
Ron Bird (OASP)
Kathleen Franks (OASP)
Deborah Misir (OASP)
Joe Woodward (SOL)
Ian Moar (SOL)
Amanda Walker (SOL)
Jonathan Snare (SOL)
David Sarvadi (Keller Heckman LLP)
Scott Mugno (Mr. Sarvadi invited and brought Mr. Mugno, of Federal Express, to the meeting).

The Department considered holding a second meeting with Public Citizen, but decided not to when OSHA staff pointed out that OSHA is currently in litigation with Public Citizen on an issue that touches on risk assessment.

In addition, Deborah Misir spoke by telephone with David Sarvadi a few weeks prior to May 7, 2008, to invite him to present views on risk assessment practices to DOL staff.

Lastly, a copy of the solicitation contract order and the contractor's final report is also enclosed as you requested.

If you have any further questions regarding this matter, please contact my office at (202) 693-6151.

Sincerely,

Leon R Sequeira

Leon R. Sequeira
Assistant Secretary for Policy

Enclosures

Identical letter to: The Honorable George Miller

cc: The Honorable Howard P. "Buck" McKeon
The Honorable Michael B. Enzi

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Mr. WILSON. And indeed in terms of workers' safety, I am pleased that for the last six out of seven years, there has been a reduction in the number of persons injured and killed in the workplace across America. And a person who I greatly admire is my fellow home stater Ed Foulke. So be sure to tell Secretary Foulke hello for me.

Mr. SEQUEIRA. I will. And, Congressman, I would note, if I may, that not only are injury and illness rates declining, they are at the lowest level in recorded history under this administration.

Mr. WILSON. And I appreciate this coming out, because part of my service, I have visited the different manufacturing facilities across the district, and we are really very pleased, in particular for-

eign direct investment. I have got three Michelin plants in the district I represent. We have Bridgestone Tire next door, which is Japanese. We have Westinghouse Nuclear Fuels, which is also Japanese. We have significant German, Swiss, Swedish investments in the district that I represent. And going by and visiting the different manufacturing facilities of flooring, of oriented strand board, Canadian investment, everywhere I go, obviously the very first point that I see is safety.

And it is completely understanding that businesses cannot be successful without a healthy and safe workforce, in addition to the fact, obviously, that the people who work at the manufacturing facilities live, work, and play with the families of the people who are the managers. So over and over again I have seen a positive step.

Mr. Johnson, in your testimony you reflect the Chamber of Commerce's support for this regulation. How do you believe this regulation improves the regulatory process for stakeholders?

Mr. JOHNSON. Well, I think it just brings together in one document all the different procedures that the Department of Labor can look at in setting risk assessment. For example, I have an article here on the carcinogen policy, which mentions that traditionally the current collection of policies and regulations is remarkable for the inconsistent and incomplete way in which suspect chemicals are treated. It is—my experience at the Department of Labor was that it is a very confusing decision-making process, who makes what decision on risk, what are they looking at. This tries to bring in one document for the public to understand. But more importantly, it is just very simple and requires, for example, all documents to be up on the Web and be transparent and easily accessible. It used to be companies would have to hire law clerks to go down to the Department of Labor, Xerox records and bring them back in a paper file, and this makes it all much easier and commonsense.

Ms. SEMINARIO. I might just say that OSHA has always had a very robust docket, even before there was regulations.gov. They have had an electronic docket with information up there. It is also worth pointing out that this particular rule was posted on August 29 on regs.gov, which is—I guess now is 18 days ago, and none of the documents related to this rule and its underpinnings had been posted as of this morning. So all that appears on that public docket is the rule and then a number of submissions of requests for extensions, but none of the underlying dockets—there was a big contractor's report that was done. Taxpayers spent $350,000 in support of this, and none of that information, none of the background behind this rule is on the Web, and we have 12 days left to comment on it.

Mr. WILSON. And I would say that we are in the age of Internet, which makes access so readily available worldwide. So I would hope and expect that whatever shortcomings you see, that you can bring them to the attention of good Members of Congress like Chairwoman Woolsey or me, and we will be happy to make inquiry. And I would think, again, transparency truly is beneficial. It is not negative.

And I yield.

Chairwoman WOOLSEY. Thank you.

Mr. Payne, Congressman Payne.

Mr. PAYNE. Thank you very much.

I think that there is some dispute perhaps in certain industries, and the one that the Assistant Secretary is mainly familiar with, there has been a superb record of safety. However, I just want to bring out that perhaps you are not involved with the cleaning industry. For example, Cintas, which is a large industry of uniform cleaning and cleaning of large laundries, have had several deaths, two actually in my district about a year ago, unsafe conditions where workers were not given safety equipment to clean out these big vats.

Secondly, I am not sure that anyone—and maybe the building industry is not under your jurisdiction specifically, but you had a tremendous number of deaths in the construction industry this year in New York City alone. I mean, you have had almost one a month easily, even more than that, crane safety, safety of employees. We have had an epidemic. So maybe in South Carolina things are great, but I know up in New Jersey and New York, we have had bad luck. Perhaps we don't get the hurricanes, but evidently we have other kinds of disasters that impact on human beings.

I might just ask a question of Mr. Johnson, where you object to the designation of this program as a secret regulation because DOL "has chosen to do this thoroughly through a full public procedure, soliciting comments and input as with any other regulation." That was a quote. So I just kind of find it astonishing actually that you claim that the Department has solicited as much input as with any other regulation. So I don't know if you would perhaps bring to my attention any other regulations or any other regulation which will significantly affect OSHA or MSHA standards as this does that did not have a hearing or more than a 30-day period of comment.

Mr. JOHNSON. Well, as I mentioned earlier, the ergonomics regulation, which is right here, hundreds of pages long, only had a 60-day comment period, and that was issued during Thanksgiving week of 1990, and we eventually got an extension from that. I am not—Congressman, whether 30 days is appropriate to this as distinguished to 60, I will say we often ask for an extension on comments. And perhaps an extension from 30 days to 60 may be appropriate in this case. We asked for an extension—actually, we didn't. But formaldehyde, benzene, hazard communication standards, I have worked on all of those, and traditionally their initial rulemaking period is quite short, and then traditionally there is an extension of comment.

Which had hearings or which did not, frankly I would have to go back and take a look at that. Whether or not a hearing is appropriate in this case, I am not going to hazard a position on this and wouldn't take one.

Ms. SEMINARIO. Let me just say with respect to comment periods on ergonomics, the ergonomic rule was under development for years. There was a draft proposal with all of the background that was circulated to interested parties back in 1993. There were public meetings. This went on for years and years and years. So the notice that came out in 19 whatever—in 1999 originally was one that had, you know, lots of public input prior to that.

This rule came out of nowhere. This rule came out of nowhere. It wasn't in the regulatory agenda. We had no notice that it was coming. The first we saw was when—the fact that it had gone to OMB on July 7.

Mr. JOHNSOn talked about when OSHA did its cancer policy. That was done under the Occupational Safety and Health Act. There were extensive hearings. I went to every day of those hearings. I think it was my first year at the AFL-CIO, three months of public hearings at the Department of Labor on that policy. Ergonomics, we had months and months, weeks of public hearings on that.

So the bottom line is 30 days is basically the shortest time possible for comment. It certainly is not providing for the robust public comment which the Bolten memo said agencies should be following in the final months of the administration.

And also we think that a hearing on this is required, given the way the Department is doing it. They are essentially changing standards and standard setting under the Occupational Safety and Health and Mine Safety and Health Act, and both those laws say when a party objects and requests a hearing, they have to be granted a hearing. We put that question, and we would expect that the Department would follow the law.

Mr. JOHNSON. I believe as a technical matter that this is the Department saying, this is not our standard, this is not a regulation; it is an internal agency practice, therefore not technically subject to some of those requirements. But that is a separate—what might be the right thing to do, which is more public input.

Chairwoman WOOLSEY. The gentleman's time has expired.

Mr. PAYNE. Just if I might mention, I do recall also those hearings on ergonomics and how I was wondering when we were ever going to pass anything, they had so many hearings on it. So I think to say, well, you have got 60 days, is kind of not—is far from the truth. I thought it went too long before the regulations came out. Thank you.

Chairwoman WOOLSEY. Congressman Hare.

Mr. HARE. Thank you, Madam Chairman. My apologies. I was in a markup on Veterans, so I didn't get to hear the testimony.

But I am troubled here, Mr. Sequeira, and maybe you can help me out. Was anyone on OSHA or MSHA consulted on this proposed rule?

Mr. SEQUEIRA. Yes.

Mr. HARE. Did they ask you to issue the rule?

Mr. SEQUEIRA. I am sorry?

Mr. HARE. Did the agencies ask you to issue the rule after you consulted with them? The reason is I am curious why the rule is coming out of the DOL policy office and not the health and safety agencies.

Mr. SEQUEIRA. Yes. I understand that you weren't here for the earlier testimony, Congressman, but as I mentioned earlier, this proposal is issued pursuant to the Secretary's general authority to issue regulations related to the Department procedures. It is not issued pursuant to the Occupational Safety and Health Act or the Mine Act.

Mr. HARE. Well, in my opinion, it seems like it is going to be tying the hands of any future administration, which, to be candid with you, I would consider shameful because of how long it currently takes OSHA and MSHA to issue standards, and the fact that OSHA has issued only one major standard during this administration and they were ordered to do so under court order. So I do have a concern about that.

My other couple of concerns is why move forward on this proposal after 80 epidemiologists, as I understand it, physicians in the American Public Health Association, advised the Secretary of Labor to withdraw the proposal for reasons that it would be damaging to workers' health? I mean, doesn't that kind of fly in the face of what the experts are saying? Maybe you can help me try to understand why you folks know more than these epidemiologists, physicians in the American Public Health Association?

Mr. SEQUEIRA. I don't know precisely which experts you are referring to or what their specific argument is. People may have different views about the regulation. That is the purpose of a notice-and-comment period, so that we can collect those views from the public.

As for delays, we discussed earlier an ANPRM and a health rulemaking does not necessarily lengthen the time it takes to do an OSHA rulemaking. Those rulemakings take a long time. Much of that time is required by Congress because of statutes Congress has passed, and in addition they take a long time because of the inevitable lawsuits. There have been nearly two dozen lawsuits including some filed by members on this panel against OSHA in rulemaking.

Mr. HARE. But didn't you bypass standard procedure for following the rule? For example, it was not announced in the most recent semiannual DOL regulatory agenda, and which is in violation of Executive Order 12866. You only provided 30 days for public comment rather than the customary 60 days that is laid out under the Executive Order. So there are no public hearings. You have not made any of the underlying documents relating to the rule part of the public docket. So can you explain to me why that happened?

Mr. SEQUEIRA. My understanding is some people have requested a public hearing. The Department will consider those requests. Again, unlike the OSH Act and the Mine Act, there is no requirement for the Department to conduct a public hearing. The item was not listed on the spring regulatory agenda of the Department, and that is for a simple reason. The spring regulatory agenda lists regulations that the Department is pursuing.

Mr. HARE. So you are comfortable with the 30 days instead of the 60 days for comments and people being able to testify about it?

Mr. SEQUEIRA. Congressman, we are in the middle of an open rulemaking and a notice-and-comment procedure, and I am not going to prejudge at this point what the appropriate time for comments is. The Department in its initial proposal said 30 days. As I understand it, we have received requests, but I am not prepared here today to judge requests that I haven't even seen about whether we should extend that comment period.

Mr. HARE. Well, I understand that, but I don't understand why standard procedure proposing the rule, which is in violation of Ex-

ecutive Order 12866, and I am just wondering if you are comfortable with going against Executive Order 12866.

Mr. SEQUEIRA. Congressman, I respectfully disagree with your characterization that it is not in compliance with Executive Order 12266.

Mr. HARE. Dr. Monforton, you mentioned in your testimony—I am sorry if I mispronounced your name.

Ms. MONFORTON. No. That is correct.

Mr. HARE. Thank you. I am getting something right here today.

You said in your testimony that the proposed rule would be quite damaging to workers by further paralyzing the rulemaking process. I wonder if you could go into more detail on how it would do that.

Ms. MONFORTON. I would be happy to. As numerous people have said here, regulating occupational health hazards takes a long time. There are numerous steps in the process, including numerous steps that have been instituted by this administration and under the previous Congress under SUBREFA, and it is my feeling that probably the best thing to do would take a step back and look at all of these requirements for SUBREFA panels, for peer review and all of that, and really decide if those things are necessary and add to the quality of the final product.

The objective here for these statutes is to prevent harm, prevent workers from developing disease and disabilities, and if we have too many steps along the process, we never get to the final product. And it is not about the process. It is about the workers in the end who are harmed and develop diseases or die because of exposures at work.

Mr. HARE. Thank you.

Ms. SEMINARIO. Can I just add to that? When the National Academy of Sciences looked at what OMB had proposed on risk assessment—they put out a proposed bulletin. It went through public comment. It had an NAS panel. They had a lot of criticisms of the bulletin, but one of the main criticisms that they had was that bulletin, with all of its additional requirements, that the administration hadn't done its own sort of cost-benefit analysis as to whether or not adding all these additional requirements had any benefit, had any benefit with respect to the outcome, and the benefit being not one of processing.

The Occupational Health and Safety and Mine Acts are, as Dr. Monforton said, to protect workers. All right? That should be the main goal. So how does this add to the protection of workers? And I would say that in looking at this proposal here, it does nothing in that regard and would be quite detrimental. So, again, I think imposing additional requirements is not needed.

And as I said, NAS also said that agencies needed to look at that when they were developing their risk assessment approaches to see if it added anything and was necessary and shouldn't lose sight of what essentially the purposes of their statutes were.

Chairwoman WOOLSEY. The gentleman's time has expired.

I am going to ask a question, and then the Ranking Member is going to give us his closing remarks, and then I will give my closing remarks, and you will all be excused. But let us get to what I think the main question is, Mr. Secretary. The White House Chief of Staff, Josh Bolten, issued a memo in May stating that no new

regulations should be proposed after June 1, 2008, absent extraordinary circumstances. Can you describe why—well, describe the extraordinary circumstances in this case. Why is this extraordinary?

Mr. SEQUEIRA. Madam Chairman, respectfully I disagree with your characterization of the Bolten memo. It, in fact, does not say that agencies cannot issue regulations after June 1.

Chairwoman WOOLSEY. What does it say?

Mr. SEQUEIRA. I don't have a copy in front of me.

Chairwoman WOOLSEY. Read it, please.

Mr. SEQUEIRA. I said I don't have a copy.

Ms. SEMINARIO. I have a copy.

Chairwoman WOOLSEY. And that is what it says, right?

Ms. SEMINARIO. It says, "Except in extraordinary circumstances, regulations to be finalized in this administration should be proposed no later than June 1, 2008, and final regulations should be issued no later than November 1, 2008." So either they are——

Mr. SEQUEIRA. I am sorry. She is asking the——

Ms. SEMINARIO. They are out of compliance with the memo, or they don't intend to finalize it by the end of this administration.

Chairwoman WOOLSEY. So my question to you, what are the extraordinary circumstances in this case other than putting one more roadblock into OSHA procedures to save life and health of workers?

Mr. SEQUEIRA. The Department has not cited any extraordinary circumstances with regard to this rulemaking.

Chairwoman WOOLSEY. Then why is this rulemaking more important than diacetyl, for example?

Mr. SEQUEIRA. I have never said that it is, Madam Chairman.

Chairwoman WOOLSEY. Well, it is preempting other actions that should be taken.

Mr. SEQUEIRA. Actually I don't believe that it is. This regulation is rather short. I think in a Word document, it is maybe 25 pages long. The three most recent standards issued by OSHA, I believe, were somewhere in the order of 400 to 700 pages long. The cranes and derricks rule that they are currently working on is in excess of 1,200 pages.

Chairwoman WOOLSEY. It doesn't matter how many pages. Whose life is being saved, whose health is better because of what we are doing?

Mr. Johnson, you had something you wanted to say. Then I am going to ask our two women witnesses——

Mr. JOHNSON. Just on the last round of questions, it is true that obviously the OSHA Act was intended to protect workers. It was not a limitless grant of discretion to OSHA to create a risk-free environment.

The OSHA Act also contains, quote, "that the Secretary in promulgating regulations must use the best available evidence and the latest available scientific data in the field." Best available evidence, latest scientific data in the field, those concepts are from the statute. They are in the quality guidance——

Chairwoman WOOLSEY. Okay. Thank you, I don't see how that relates to new standards, but we will see.

Ms. Seminario, and then Dr. Monforton are going to be our clean-up batter for the witnesses.

Ms. Seminario, you are first.

Ms. MONFORTON. I just want to reiterate and make sure the committee understands that in the regulation, it specifically says that when MSHA and OSHA make major steps in rulemaking such as proposing a rule, that documents are to be published on regulations.gov within 14 days. This proposal purports to be something about best practices, but they don't follow their own because there is nothing in regulations.gov that supports this rulemaking. They haven't even followed their own best practices that they are proposing in this rule. It is very problematic when you are trying to comment on a proposed rule when you don't have any of the substantive documents that were used to develop it.

Chairwoman WOOLSEY. Okay, thank you.

Ms. Seminario, you are our clean-up batter.

Ms. SEMINARIO. Just to say that, again, this rule is being put forward in the name of improved transparency and notice to the public, but with the rule no notice was given that it was even under development, and certainly as far as transparency, we have had a little information, and as far as opportunity for comment, there is virtually none. So it violates, as Dr. Monforton said, what is being proposed here, but more importantly it will hurt workers. It will delay rules, very important rules like diacetyl and silica, which would mean that workers will be exposed.

We have gone through 7½ years, it will be eight years come January 2009, with only one occupational health rule being issued, and we would like the next administration to move forward quickly to put those standards in place to propose the silica rule, the diacetyl rule so workers aren't exposed and their lives can be saved. That has what we think the priority of the next administration should do, not starting all over at the beginning of the process. Thank you.

Chairwoman WOOLSEY. Mr. Wilson.

Mr. WILSON. Thank you, Chairwoman Woolsey, for this hearing today. And I appreciate all of the witnesses, your input. I want to thank the Secretary and the Department. I wish you well as we are all working somewhat together and working on behalf of reducing workplace accidents and deaths. So I thank all of you for being here today, and I want to thank the staff, too. I will tell you Loren Sweatt is an amazing person putting up with us. Thank you.

Chairwoman WOOLSEY. Thank you, Mr. Wilson.

I want to thank all of you for being here today. You are excellent witnesses. It was very informative, and I believe there is one issue in all of these discussions that we can agree on, that there are major problems at OSHA and MSHA when it comes to issuing protective standards. However, we do differ on the nature of the problem. DOL seems to think that the paralyzed regulatory process requires even more years of review and even more delay. However, for those of us who believe that OSHA's and MSHA's job is to protect America's workers, the real problem is the inexcusable delays in standard setting which is actually leaving workers exposed to deadly hazards.

Congress gave OSHA and MSHA broad authority to issue enforced, strong workplace safety and health standards. Over the years the courts and this administration also have made it tougher to issue these standards, adding even more time to the process. We need to look at ways to reform the standard-making process so that

it actually provides workers with the protection that they need on a timely basis.

But this administration has utterly failed to fulfill its obligation to the American worker. While it should have been working full speed ahead to issue protective standards, it has instead been busy with this secret rule, a rule that subverts congressional intent to help workers, and it is being rushed through without proper consideration.

Again, I want to thank the witnesses for your testimony, particularly coming to us on such short notice, and I want to assure you that we will continue to fight right here for American workers to ensure that any ill-conceived proposal won't see the light of day, particularly this one.

So as previously ordered, Members will have 14 days to submit additional materials for the hearing record. Any Member who wishes to submit follow-up questions in writing to the witnesses should coordinate with Majority staff within 14 days.

Without objection, the hearing is adjourned.

[Whereupon, at 11:50 a.m., the subcommittee was adjourned.]