THE OSHA RULEMAKING PROCESS

HEARINGS

BEFORE THE

SUBCOMMITTEE ON WORKFORCE PROTECTIONS

OF THE

COMMITTEE ON EDUCATION AND THE WORKFORCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED SEVENTH CONGRESS

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"MAKING SENSE OF OSHA RULEMAKING:

A THIRTY-YEAR PERSPECTIVE"

Thursday, June 14, 2001

Subcommittee on Workforce Protections

Committee on Education and the Workforce

U.S. House of Representatives

Washington, D.C.

The Subcommittee met pursuant to notice at 10:03 a.m., in Room 2175, Rayburn House Office Building, Honorable Charlie Norwood, Chairman of the Subcommittee presiding.

Present: Representatives Norwood, Ballenger, Keller, Culberson, Owens, Kucinich, and Mink.

Staff present: Victoria Lipnic, Workforce Policy Counsel; Molly Salmi, Professional Staff Member; Stephen Settle, Professional Staff Member; Heather Oellermann, Legislative Assistant; Heather Valentine, Press Secretary; Michael Reynard, Deputy Press Secretary; Patrick Lyden, Professional Staff Member; Deborah L. Samantar, Committee Clerk/Intern Coordinator; Peter Rutledge, Minority Senior Legislative Associate; Maria Cuprill, Minority Legislative Associate; Brian Compagnone, Minority Legislative Aide;

Chairman Norwood. A quorum being present, the Subcommittee on Workforce Protections will now come to order. The Subcommittee is meeting today to hear testimony on "Making Sense of OSHA Rulemaking: A Thirty Year Perspective."

Under Rule 12(b) of the Committee rules, any oral opening statements at hearings are limited to the Chairman and Ranking Minority Member. This will allow us to hear from our witnesses sooner and help Members keep to their busy schedules. Therefore, if other Members have statements, they can be included in the hearing record. Without objection, the record will be held open for 14 days so that all statements, testimony, and other material referenced during the hearing may be inserted in the hearing record.

OPENING STATEMENT OF CHAIRMAN CHARLIE NORWOOD, SUBCOMMITTEE ON WORKFORCE PROTECTIONS, COMMITTEE ON EDUCATION AND THE WORKFORCE

We are here today to discuss a topic of endless fascination, frustration, and complexity, OSHA's standard rulemaking process. I say fascination because it has been a constant source of wonder to me how everything Congress manages to legislate seems to get turned on its head in the regulatory process. I say frustration because it seems to me there isn't anyone, I dare say, on either side of the aisle that is completely satisfied with OSHA's rulemaking efforts.

It is no secret that I have been an outspoken critic of OSHA. It will further come as no surprise that I am not a fan of excessive legislation. That being said let me note this. Today marks the first time our Subcommittee has met this Congress to address an OSHA matter. I hope that this will be a first step in trying to find some common agreement about OSHA, and I don't expect that to be easy, but I, for one, am willing to try.

It seems to me that the easiest thing for all of us in this room to do is accept the status quo of our constant disagreement about OSHA matters. That does not strike me as a very responsible way to discharge our duties with respect to this agency. It certainly will do nothing to advance the larger and more important issue of achieving safe and helpful workplaces for American workers. I am hopeful that Mr. Owens and our Committee colleagues on both sides of the aisle will look for ways we can work together to bring about meaningful improvements to the safety of our nation's workplace.

I would also like to take a moment to welcome our witnesses. We appreciate their willingness to take time out of their busy schedules to testify before this Subcommittee. I note that we have an abundance of lawyers on our panel today. Since my background is in science, I especially want to thank Mrs. Seminario for being here to offer a perspective from beyond the bar. We are obviously lacking a participant from OSHA on our panel today. I am pleased to see that the Bush administration yesterday announced the nomination of the new Assistant Secretary. Once Mr. Henshaw is in place, I'll look forward to having him here to provide his observations about today's topic as well as his goal for this agency.

When we first thought to review and try to make sense of OSHA's rulemaking effort, the immediate reaction from some was that would be a bit like watching paint dry. Now, I admit that the workings of the regulatory process are not the liveliest topics. However, let me suggest for you three reasons why this is an important subject for Congress to review.

First, in fiscal year 2001, OSHA will spend nearly $15 million as a line item in its budget on safety and health standards. We certainly have some obligation to determine if that is taxpayer money well spent. Moreover, in its recently published unified regulatory agenda, OSHA lists no less than 45 items at some stage in the rulemaking process.

Second, in April we passed the 30th anniversary of the effective date of the OSH Act. Anniversary dates always provide a nice focal point for reflection and observation. It also strikes me that this past March we may have passed a point of critical mass when it comes to OSHA rulemaking. I refer, of course, to the congressional action on the ergonomics rule.

It has been a great temptation for this hearing to be a rehash of everything wrong about the ergonomics rulemaking. I have every expectation that each of our witnesses today could express some fairly strong opinions about that subject. That is not our intent today. Rather, given that we have 30 years' worth of OSHA rulemaking to reflect upon, I hope we can consider some observations in a fair, objective, and honest manner about what has worked well in OSHA rulemaking and what has not, and about what the current state of affairs is.

There is a third reason we should review this area of OSHA activity. When Congress passed the OSH Act in 1970, it gave OSHA the authority, under Section 6 of the Act, to adopt national consensus standards and to issue through rulemaking safety and health standards for the protection of American workers. It gave OSHA the authority to enforce those standards in the workplace. That is an extraordinary exercise of power and of responsibility. When it comes to rulemaking, we should be very, very mindful of that.

We're all aware that OSHA deals with complex, often controversial, issues within a complicated regulatory process, but complexity and controversy should not be things we shy away from, given the charge to this agency. In order to maintain a necessary level of trust and confidence between the agency and the regulated community, the responsibility given to OSHA requires a degree of transparency and vigilance about the process. We have a role in that, Congress included. It is entirely appropriate after 30 years of effort that we look at how it is OSHA goes about discharging its authority and responsibility.

I look forward to this hearing today, to a thorough and informative discussion. I would now like to yield the floor to the distinguished Ranking Member, Mr. Owens, for his opening statement.

WRITTEN OPENING STATEMENT OF CHAIRMAN CHARLIE NORWOOD, SUBCOMMITTEE ON WORKFORCE PROTECTIONS, COMMITTEE ON EDUCATION AND THE WORKFORCE – SEE APPENDIX A

OPENING STATEMENT OF RANKING MEMBER MAJOR OWENS, SUBCOMMITTEE ON WORKFORCE PROTECTIONS, COMMITTEE ON EDUCATION AND THE WORKFORCE

Thank you, Chairman Norwood. Again, I'm quite impressed with the broad and deep insight of your opening statement. I want to welcome today's witnesses. There's no question that we can benefit from a clearer understanding of the rulemaking process. I

look forward to your testimony.

Anyone who's concerned about the health and safety of workers has to be concerned about the degree of difficulty and the excessive time that it takes OSHA to promulgate safety and health standards. I suppose we could also say that the long time period guarantees thoroughness. On average, it takes OSHA ten years to develop and promulgate a standard.

The advance notice of proposed rulemaking for the respiratory protection standard was issued in 1982. The final rule was not issued until 1998. The Construction Advisory Committee recommended the development of a standard for scaffolds in 1977. A notice of proposed rulemaking was not issued until 1986, and the final standard was not issued until 1996. The lock-out/tag-out standard took nine years from the time that the notice was issued to the final rule. The confined space entry standard took 18 years from the first notice to the final rule. The most important point to remember is that workers are continuing to be killed or injured during the period that the agency is developing the standard.

We limit the amount of time that any individual can serve as President to eight years. The average tenure of an Assistant Secretary for OSHA is only two and a half years. It should be obvious to everyone that there will be problems with continuity when it typically requires four different OSHA administrations and three different presidential administrations to work on and develop a single standard. I'm therefore particularly interested in any ideas the witnesses may have that might help to formalize or regularize the manner in which OSHA establishes priorities.

Last year the Congress, at least implicitly, acknowledged the breakdown of the standard-making process at OSHA when we enacted the needlestick legislation. Recognizing that it would take years for OSHA to amend the blood-borne pathogen standard, the Congress stepped in and did so directly. As a result, safer needles will be widely used more quickly, and health workers who may otherwise have been exposed to hepatitis or HIV will be protected.

I'm not optimistic that this Committee or this Congress is likely to be able to do much to improve the standard-making process, but there may well be specific areas, similar to the blood-borne pathogen standard and the needlestick bill, where we can act in a timely bipartisan manner to update a specific standard. I want to go on record now to express my willingness to work with Chairman Norwood toward that end.

There is one aspect of today's hearing, however, that I find to be unseemly. Mr. Chairman, you've chosen to invite Mr. Chajet to testify today. Mr. Chajet is here to reiterate allegations that have been made in a pending lawsuit, Anchor Glass Container Corporation, et al., v. ACGIH, U.S. DOL, and U.S. DHHS. In my view, it is, as a general matter, inappropriate for a Congressional Committee to involve itself in pending litigation. The matter is before the court. Let the court have its say, and when they are done, if we disagree, we can act.

However, what is questionably irresponsible and inappropriate is to provide a forum for only one side in that pending litigation to present its views while denying the other side that same opportunity. In order that the record might be just a little balanced, I ask unanimous consent to enter into the record a letter from Chairman Norwood to the Secretary of Labor regarding ACGIH guidelines, a letter from ACGIH to the Secretary of Labor responding to the concerns raised by Mr. Norwood, and several articles from ACGIH regarding the legislation. Finally, Mr. Chairman, I ask that the record be held open in the event that ACGIH wishes to submit a statement in response to Mr. Chajet's statement.

Let me be clear, however, that I do not think that such a submission evens the score. Inviting Mr. Chajet to testify without affording a similar opportunity to ACGIH is clearly an ambush, and this kind of ambush, particularly when it involves pending litigation, is, in my view, a misuse of the Committee and a disservice to the Congress.

I yield back the balance of my time.

WRITTEN OPENING STATEMENT OF RANKING MEMBER MAJOR OWENS, SUBCOMMITTEE ON WORKFORCE PROTECTIONS, COMMITTEE ON EDUCATION AND THE WORKFORCE – SEE APPENDIX B

Chairman Norwood. I thank you, Mr. Owens.

As you know, the record is open for 14 days, and what is entered into it is up to the discretion of the Chairman. I'm certainly happy, though, to have the letter I wrote entered into the record. I wish everybody I know could read it.

Now I would like to introduce our panel of witnesses:

Mr. Victor Rezendes from the General Accounting Office. Thank you, sir, for being here.

Mr. Willis J. Goldsmith from Jones, Day, Reavis & Pogue, thank you, sir.

Mr. Frank White, Organization Resources Counselors, Inc. Thank you, sir, for being here.

Ms. Margaret Seminario, Department of Occupational Safety and Health. We thank you, ma'am, for being here.

Mr. Henry Chajet from Patton Boggs. Thank you, Mr. Chajet. I'm delighted that you're with us, too.

Let me remind the witnesses that under our Committee rules they must limit their oral statements to five minutes, but their entire written statement will appear in the record. We will also allow the entire panel to testify before we question the witnesses.

With that said, Mr. Rezendes, would you please begin your testimony?

STATEMENT OF VICTOR REZENDES, MANAGING DIRECTOR FOR STRATEGIC ISSUES, U.S. GENERAL ACCOUNTING OFFICE, WASHINGTON, D.C.

Mr. Chairman, I'm pleased to be here today to discuss the federal rulemaking.

In brief, the congressional and executive branch rulemaking requirements are clearly voluminous and require a wide variety of actions. This is not my visual aid here, but someone put up the **ICF Consulting chart of The Regulatory Process (www.icfconsulting.com)**, and I think it gives you a sort of a flavor of the kinds and complexities of actions and requirements that are out there.

While it's also clear that the federal agencies sometimes take years to develop a final rule, we have not examined the extent to which the rulemaking requirements are responsible for the long time frames. Our reviews do, however, demonstrate that the requirements are frequently not as effective as they could be. In some cases the lack of effectiveness can be traced to how the requirements are being implemented at the agencies. In other cases, though, the requirements themselves are the problem.

Let me briefly identify some of the major statutory requirements. The most longstanding and broadly applicable is the Administrative Procedures Act, which generally requires agencies to publish a notice of proposed rulemaking and obtain comments. However, we reported that about half of the over 4,000 final regulatory actions published in 1997 were issued without a notice of proposed rulemaking.

The notice and comment procedures do not apply when an agency finds, for good cause, that it would be impracticable, unnecessary, or contrary to the public interest. Without a notice and comment period, however, the public's ability to participate in the rulemaking process is limited.

Another major requirement is the Paperwork Reduction Act. Under the Act, agencies must justify collection of information from the public. The Act also requires OMB to set burden reduction goals. However, we've reported that the government-wide paperwork burden has gone up, not down, since the Act has been passed.

The Regulatory Flexibilities Act and the Small Business Regulatory Enforcement Fairness Act focus on the effect that regulations have on small entities. The trigger for action for both statutes is an agency's determination that a rule may have a significant economic impact on a substantial number of small entities. Agencies' interpretation of

this requirement varies, with some agencies establishing a high threshold that limits the Act's effectiveness.

The crosscutting statutory requirements that I've just listed are by no means the only ones that guide an agency's rulemaking. Regulations generally start with an act of Congress, and are the means by which are laws are implemented.

We examined the issue of regulatory discretion and found that in many cases the agencies had little or no discretion in establishing regulatory requirements that businesses viewed as burdensome. For example, we concluded that the Occupational Safety and Health Act gave OSHA no discretion whether to hold companies rather than individuals responsible for violations of health and safety rules.

OSHA also follows numerous procedural and consultative steps for issuing a rule that may or may not be statutorily driven. For example, interested parties who comment on proposed OSHA rules may request a public hearing when none has been announced. When such a hearing is requested, OSHA says it will schedule one.

Similarly, agency rulemaking is often significantly influenced by court decisions, and OSHA rulemaking is a good case in point. For example, in the 1980 benzene decision, the Supreme Court ruled that before promulgating new health standards, OSHA must demonstrate that the particular chemical regulated poses as a significant risk, and that the new proposed limit will substantially reduce that risk. This decision effectively requires OSHA to evaluate the risk associated with exposure to a chemical and to determine that the risks are significant before issuing a standard.

Other court decisions have required OSHA rulemaking to demonstrate the technical and economic feasibility of its requirements.

Finally, Mr. Chairman, the Congressional Review Act gives Congress an opportunity to review rules before they become effective and to disapprove those that they find objectionable. GAO's role under the Act is to provide the Congress with information on how agencies have satisfied the procedural requirements of these acts.

Thank you, Mr. Chairman.

WRITTEN STATEMENT OF VICTOR REZENDES, MANAGING DIRECTOR FOR STRATEGIC ISSUES, U.S. GENERAL ACCOUNTING OFFICE, WASHINGTON, D.C. – SEE APPENDIX C

Chairman Norwood. Thank you, Mr. Rezendes. I'll be anxious to ask questions.

Mr. White, you're up, sir. Five minutes.

STATEMENT OF FRANK WHITE, VICE PRESIDENT, ORGANIZATION RESOURCES COUNSELORS, INC., WASHINGTON, D.C.

Thank you, Mr. Chairman. I'm extremely pleased to appear here in a bipartisan spirit to explore OSHA's rulemaking process and what might be done to make it more effective and credible as OSHA enters its fourth decade.

To set the stage, I'd first observe that in enacting the Occupational Safety and Health Act, as well as the Mine Safety and Health Act, Congress established criteria for standards-setting that were really designs to optimize worker protection. Indeed, OSHA has largely succeeded, in my view, in issuing and defending the kinds of protective standards that Congress envisioned, resulting in landmark protections for workers on a wide array of serious health and safety risks.

Certainly over the years, OSHA rulemaking has always been controversial and adversarial, but in recent years it does seem to have become more contentious, politicized, cumbersome, and time-consuming, almost to the point of complete stagnation. The problems are not solely ones of timeliness, but increasingly seem to be related to the credibility of both the process and the products themselves.

As a way of beginning to assess the rulemaking process and what improvements might be considered, let me make two observations. First, each new Secretary of Labor and head of OSHA have extremely broad authority to determine which issues they choose to address through rulemaking, in what order, and at what pace to address them.

A close examination of many of the OSHA standards that have taken the longest to issue, and Mr. Owens has reviewed some, will reveal that somewhere during the course of the rulemaking express or tacit changes in priorities, resource allocations, political leadership and philosophy had much to do with the cumulative delay.

The second observation I'd make is that there's clearly an important balance to be struck between the need to complete the rulemaking in a timely manner and the need for full participation of the affected parties and full consideration in the record. The OSHA rulemaking process has become extraordinarily complex, demanding, and encumbered, more so than it even was five years ago.

It's also important to recognize that a great many, and perhaps the vast majority of requirements related to the OSHA rulemaking process are not even within the authority of OSHA to control or alter, and Mr. Rezendes has discussed some of those. Even revisions to the Occupational Safety and Health Act itself would leave unaffected many of those requirements. A host of other statutory mandates as well as executive branch requirements for regulatory analyses and review must be followed during the rulemaking process. In addition, well-established court law requires OSHA to undertake the kinds of extensive analyses of rulemaking records that result in preambles to OSHA rules of 300 pages or more.

Now, with this background, I'd like to offer a few possible starting points for improvements of OSHA's process that may, at least in part, assist in improving both its credibility and timeliness. I point to at least six general stages of the rulemaking process:

Stage one would be determining priorities. This is a perennial weakness for OSHA. The historical lack of any credible, rational, priority-setting process or subtle criteria for determining which safety and health issues should be addressed through standard-setting has allowed OSHA to shift its priorities almost on a dime, as I've mentioned earlier, with almost no accountability.

I would suggest using a model similar to that used by NIOSH in developing its National Occupational Research Agenda. This was a process that involved the participation of a wide spectrum of agency stakeholders, not only in the initial selection phrase of priorities, but in the ongoing development of those priorities and the execution and the resulting research activities themselves. It's this ongoing stakeholder participation in the process that was missing from OSHA's failed attempt at prioritization in 1994.

Stage two of the process I call initiation of rulemaking and collection of evidence. These, too, are critical steps in the process and mishandling of them frequently gets OSHA off on the wrong foot, at least as far as the affected stakeholders are concerned. While there's certainly no best or right way to proceed, I would agree with NACOSH that, in general, advance notices of proposed rulemaking should be discouraged and used only on a very limited basis.

I do believe that the issuance of pre-proposal drafts of standards can be a useful device for receiving early input. I also believe that pre-proposal stakeholder meetings can be valuable if there's a more robust and, again, an ongoing process that would include prompt feedback and follow-up to the stakeholders; another example of the ongoing involvement of the stakeholders.

Now we come to three stages that are really internal stages by OSHA, and those are: evaluating the evidence, making scientific and policy decisions, and writing the standard itself. It's with these three intertwined, but distinct, internal steps that OSHA can make the greatest strides in terms of improving timeliness.

Again, OSHA has struggled with this for many years. But, frankly, the key to making a rulemaking process work internally is really management commitment and leadership, the same things that make safety and health programs work. There must be a clear focus and commitment to getting the job done. OSHA leadership must understand the process, have somebody in the front office who can guide and control the process, and there must be an internal process that allows top officials to really know what's going on at all times, and to make decisions on critical issues as the process goes forward.

Finally, the sixth stage is what I call the rollout and follow-up process, and this stage I think offers the greatest opportunity for improvement related to the credibility of OSHA standards. I would argue that this is the area in which OSHA has simply dropped the ball on too many occasions. By that I mean that the agency has done relatively little in a proactive way to truly prepare the affected public for the implementation of many of

its new standards.

It should be apparent that the issuance of a new standard should be part of a broader strategy of assistance and outreach and training. Yet OSHA really does very little of that, and needs to do it in a much more timely manner so that clients' directives and training materials simply must be issued concurrently with the standard.

The last sort of significant deficit at this back end of the rulemaking process is the almost uniform failure to evaluate the effectiveness of a new standard once it's issued, so that OSHA doesn't go back three or five years later and say this standard has worked, or here's what we could have done more effectively.

This concludes my prepared remarks.

WRITTEN STATEMENT OF FRANK WHITE, VICE PRESIDENT, ORGANIZATION RESOURCES COUNSELORS, INC., WASHINGTON, D.C. – SEE APPENDIX D

Chairman Norwood. Thank you very much, Mr. White. We appreciate you being here.

Mr. Chajet, you're recognized for five minutes.

STATEMENT OF HENRY CHAJET, ESQ., PARTNER, PATTON BOGGS, LLP, WASHINGTON, D.C.

Thank you, Mr. Chairman, and Members of the Committee. Good morning to you. It's my pleasure and honor to appear before you this morning to talk about the rulemaking process on issues that affect all of our employees and the workers around the country. The power of the Federal Government to regulate workplaces is a vast and important power that the Congress of the United States entrusted to several different agencies. The entrusting of that power comes with a tremendous amount of responsibility, Mr. Chairman, that the power not be abused.

The power to create rules and enforce them is a matter on which the United States probably spends in excess of a billion dollars a year, if you add up the OSHA budget, the MSHA budget, the NIOSH budget, and other related Institutes that work on the creation and enforcement of health and safety standards. It's a huge resource that needs to be properly utilized.

I'm here to talk about one particular part of that effort. There's no question in my mind, after working on rulemakings in health and safety for my entire career that the system is broken and needs to be fixed. The one part that I would like to focus on, Mr. Chairman, is the use of privately created standards by the Federal Government that are

not subject to the review of our elected officials or of the court system.

We have in place a system that demands from our Congress an open, transparent, and fair process to create rules. It demands review by the courts. It demands review by the Congress when appropriate. Federal agencies use standards that are developed in secret by outside groups, and federal employees participate in those standard-setting activities behind closed doors without giving all parties access to the information, the materials, the meetings, or the activities. Then they come back and create a standard in those private situations, and those standards are then incorporated by reference or used by the federal agencies and enforced. It avoids the openness, the transparency, the fairness and the judicial review that's available for standard setting as intended by this Congress. It's this part of the rulemaking system that I would like to focus on, the use of non-consensus standard-setting organizations.

There are excellent standard-setting organizations that operate in the open, with consensus by all parties, and produce very important work to protect our country. The National Fire Protection Association, and the ANSI standards do a superb job.

On the other hand, there are a couple of organizations that are directly incorporated by reference in our regulations. One of them is the American Conference of Governmental Industrial Hygienists, ACGIH. OSHA's rules and MSHA's rules incorporate by reference the standards that this organization produces. In the hazard communication rules, if ACGIH labels a substance as hazardous, that tag must be repeated on the training materials and on the material safety data sheets and products. The reputation of those products can be defamed and industries can be harmed. On the other hand, if they publish a standard that is too high, employees can be harmed.

This process of government employees participating in standard setting outside the agencies, and the use of and reliance on those standards, is an avoidance of the rulemaking process that's mandated by Congress. Secret standard setting has to be examined closely for its impact on how the process works. There is a role, but perhaps that role is in a formalized advisory committee, open to all parties. Perhaps time limits are needed for the process, but the existing system needs to be carefully looked at for the abuse that it allows.

Thank you, Mr. Chairman.

WRITTEN STATEMENT OF HENRY CHAJET, ESQ., PARTNER, PATTON BOGGS, LLP, WASHINGTON, D.C. – SEE APPENDIX E

Chairman Norwood. Mr. Goldsmith, you are recognized for five minutes, sir.

STATEMENT OF WILLIS J. GOLDSMITH, ESQ., PARTNER, JONES, DAY, REAVIS & POGUE, WASHINGTON, D.C.

Thank you, Mr. Chairman, and Members of the Subcommittee. I appreciate the opportunity to testify before you this morning. I think there are basically two main flaws in OSHA's rulemaking process about which everyone agrees.

The first is that it has become intensely political, much more so than it ever has been. Of course, the political aspect of the rulemaking process is inevitable, and it's a good thing to a point, but to the degree to which the process becomes so highly politicized, it decreases stakeholder confidence and trust in the process. This, of course, increases as the process itself becomes less transparent.

As a general matter, as Ranking Member Owens pointed out, the process is far too slow. In its 30-year history the agency has promulgated approximately 45 standards in the safety area and approximately 30 health standards. They take years in certain instances to promulgate, indeed, decades.

Unfortunately, the negotiated rulemaking process is really not much better. The negotiated standards for the steel erection process in the construction industry, which I think it's fair to say is a fairly simple and straightforward process, took seven years to come to a conclusion. Of course, most standards that are promulgated in the rulemaking process are challenged by one party or another in court, and that, of course, adds time to the entire process. There are, I believe, possible solutions to this problem. The key is to make things both quicker and less politically driven.

One suggestion would be to consider amending the Act to create an independent agency outside of the Department of Labor to set standards. One version of the OSH Act as originally proposed and introduced in Congress, and, in fact supported by Congressional Republicans, included provisions to place the authority for establishing occupational safety and health standards in an independent agency.

Now, as an example, the Consumer Product Safety Commission is an independent agency made up of three members appointed by the President that must have members from both political parties. All rulemaking activities must be approved by a majority vote of the Commission.

A second proposal would be a process of peer review to ensure that the standards have a scientific basis. OSHA is often criticized for failing to properly analyze the scientific evidence underlying a problem. One way to minimize these criticisms is for all controversial scientific issues to be examined by an objective, independent group of individuals who clearly are qualified in the relevant field.

Selection of the individuals, of course, would be key, and there must be a way to select qualified, objective persons who have no financial or other interest in the outcome of any proposed rule. More to the point, I believe, these individuals have to be provided with some standard by which to judge scientific evidence, and, under any circumstances, whether the Act is amended or the rulemaking process is changed in any way, the agency should be held to some standard in judging scientific evidence.

What I would propose in that regard is a Daubert type of standard, as has been imposed by the courts under the Federal Rules of Evidence. The Daubert standard requires the trial courts to evaluate scientific evidence and scientific theories to determine whether they're reliable and relevant. The analysis depends on a theory or a technique's ability to satisfy a number of tests. Whether the technique, for example, enjoys general acceptance within the scientific community, whether the methodology has been tested, and so on.

There is no reason not to hold the Department of Labor or an independent agency to these standards, no matter what happens with any amendments to the Act. The best available evidence of Section 65 of the Act, I believe, is too low a bar, allowing the agency to regulate based on virtually no evidence at all if it chooses to do so.

Finally, I would suggest that there be better defined rules and processes in terms of how the rulemaking is itself conducted, no matter if it proceeds under the Act as we currently know it or whether the Act is amended.

One way to eliminate some of the political influence from the rulemaking process and to speed up the process is to have better defined procedural rules, and a person involved in the rulemaking process that can actually enforce those rules. The administrative law judge who is now designated to preside over an OSHA rulemaking really has no meaningful function at all. He or she simply marks exhibits and watches the clock to see how much has been used by witnesses.

There are regulations that govern the rulemaking process. I believe those regulations are too vague, and need to be substantiated with specific rules. Strengthening the procedural rules and allowing the administrative law judge who presides over the hearing to actually enforce those rules, and to deviate from them if necessary, basically to act like a judge, would go a long way toward fixing this process.

Thank you, Mr. Chairman, for this opportunity to present my views.

WRITTEN STATEMENT OF WILLIS J. GOLDSMITH, ESQ., PARTNER, JONES, DAY, REAVIS & POGUE, WASHINGTON, D.C. – SEE APPENDIX F

Chairman Norwood. Thank you very much, Mr. Goldsmith.

Ms. Seminario, would you begin?

STATEMENT OF MARGARET SEMINARIO, DIRECTOR, DEPARTMENT OF OCCUPATIONAL SAFETY AND HEALTH, AFL-CIO, WASHINGTON, D.C.

Yes, thank you very much, Mr. Chairman and Members of the Committee, for the opportunity to testify today on OSHA's standard-setting process.

The AFL-CIO has been involved with OSHA standard-setting for many, many years. I personally have been involved in this activity for the 24 years that I've been at the AFL-CIO, and am also serving as a member of NACOSH. I was involved in the review by the advisory committee to the Secretary of Labor on the standard-setting process that occurred last year. So I'd like to offer my observations, comments, and some recommendations.

First, it's important to recognize that, indeed, when OSHA standards have been set, they have been very effective at reducing hazardous exposures and work-related injuries, illnesses, and fatalities. Looking at OSHA's cotton dust standard, when it was adopted, 12 percent of textile workers suffered byssinosis. Today it's less than one percent of workers. Similarly, before the confined space entry standard was issued, there were a couple of hundred workers being killed every year in confined space incidents. Today, thankfully, that number is much lower.

In my testimony in the back we've developed a list of the standards that have been issued by OSHA. Even though many of these have been controversial, I think in retrospect what we see is that the things that OSHA has regulated generally have been major hazards. When you look at their impact, they have indeed been effective and have also been feasible to comply with.

We go through every rulemaking with claims that there's no science that the costs will be too high, that it isn't feasible to comply with these standards. While there haven't been reviews of every standard OSHA has issued, there have been reviews of some.

In 1995 OTA did an in-depth assessment of eight OSHA standards and found that, indeed the agency's assessments on feasibility and cost generally were correct. If anything, the agency had overestimated the cost. So the reality of the cost of the rules has ended up usually to be less, and that's often because employers and industries figure out ways to comply with these that weren't really contemplated at the time the standard was under consideration.

As many have said, OSHA standards have been controversial and most have been challenged in court, but in the majority of cases the reviewing courts have not only upheld the standards, but in many cases they have ordered the agency to go further and add protections to standards so that workers are provided a higher level of protection.

As far as the process is concerned, it is one that is open, it is accessible, and it provides many opportunities, as we see from the charts here, and from others' testimony, for the public to participate. I would argue that the process for setting standards at OSHA probably is about the most open process that exists in the Federal Government today for

getting input from all interested parties on actions of the Federal Government. I'm not going to review all those steps. They've been reviewed in others' testimony. But it is indeed a very, very open process, with a lot of opportunity for input and comment, and that process has existed since the Act was passed.

But since the Act was passed there have been numerous other requirements that added which have increased the length of the process. When you look back at the process in the early years, it took OSHA about two years to set major rules on vinyl chloride, asbestos, and 14 carcinogens. Every decade the process has gotten longer, and there are a number of reasons for that. The other thing that's happened, as Mr. White said, is that the preambles have gotten a lot longer as well additional requirements to comply with.

I think one could argue that the faster, less complicated process that existed in the early 1970s produced standards that are probably similar to the ones that are produced by the very long process today. If one did a cost benefit analysis on the time versus getting a better standard and all the steps, the earlier, less cumbersome process was one that resulted in more protective standards in a more timely way.

As many have said, there has been increased political and industry opposition to safety and health standards, and, in our view, this has greatly impeded and delayed worker protections. Since the beginning OSHA standards have been controversial and they have been challenged, but that controversy and that level of challenge has increased. I think there's a different political environment today. It is one that actually is much more opposed to government action and regulation. The actions that may be proposed by OSHA may be quite similar to what were being proposed in the 1970s and 1980s, but the political climate is different today. And that's a fact of life, that's a fact of reality. We see virtually everything the agency tries to do being challenged, whether it's putting out a hazard alert, whether it's trying to gather information. When they circulate draft rules, those draft rules are attacked.

So that's the reality that we're dealing with. I think that Congress has to recognize that becoming involved in every stage of activity is one of the main reasons why the standard-setting process, indeed, has slowed down.

WRITTEN STATEMENT OF MARGARET SEMINARIO, DIRECTOR, DEPARTMENT OF OCCUPATIONAL SAFETY AND HEALTH, AFL-CIO, WASHINGTON, D.C. – SEE APPENDIX G

Chairman Norwood. Thank you very much. We're going to recess for 20 minutes and go vote. We'll be back just as fast as we can.

The Committee is recessed.

[Recess]

Chairman Norwood. I thank the witnesses. I apologize that we were gone for a while, but I'll begin with the questions.

Mr. Rezendes, you made a statement in your remarks that half of the standards issued at OSHA were outside of the rulemaking process. Does that mean without public comment?

Mr. Rezendes. Actually my statement was we looked at 1997, and of the 4,000 rulemaking that were done in 1997, half did not have notice of proposed rulemaking. I did look back in preparation for this hearing at OSHA's rulemaking since 1996, and as best as I can figure, there were 28 rulemakings of which eight did not have notices of proposed rulemaking.

Most of those eight though probably need to put in context. They were not major rules. They tend to be technical clarifications, basically conforming language, although one was a direct final rule that involved cotton dust related to a washing technique, and they were allowing that. Another one was the needlestick rule that was mentioned already, that Congress basically directed them to issue without going through the regulatory process.

Chairman Norwood. Does this include standards that have been incorporated by reference?

Mr. Rezendes. I didn't look at each of the individual rules. I'm only looking at the rulemaking process. So I'm not sure if I understand the question.

Chairman Norwood. There are standards that are placed into the rules and regulations.

Mr. Rezendes. Yes, right.

Chairman Norwood. These are simply referred to or incorporated by reference to someone else, and I'm trying to find out if in this process you're including them, too.

Mr. Rezendes. No, we didn't look at each of the rulemaking that OSHA did in detail, we just looked at the overall process.

Chairman Norwood. Would you do that for me?

Mr. Rezendes. I'll be happy to do it and talk to you about it.

Chairman Norwood. Do you feel in your observation that OSHA is indeed failing to comply with the law, as the Act was originated?

Mr. Rezendes. The OSH Act?

Chairman Norwood. Yes.

Mr. Rezendes. Fortunately, most of my testimony is really focused on the regulatory rulemaking process, the crosscutting pieces. We've never really frontally addressed the OSH Act and how OSHA is implementing it.

We do have a report we've done for the Energy and Commerce Committee that's coming out next month, comparing the risk process in terms of the policies and procedures and the methodology that OSHA and EPA and FDA have used in terms of making those decisions.

Chairman Norwood. Well, we'll take great interest in reading that.

Mr. Rezendes. Great.

Chairman Norwood. Mr. Goldsmith, you made a statement that the rulemaking process is very political today. I would like for you to expound on that. I'd like to hear about your observations.

Mr. Goldsmith. Well, Mr. Chairman, I think that what has happened, because so many of the recent rules have been far-reaching and therefore very controversial, is that interest groups on all sides have lined up and have made what is always going to be a political process much more intensely political than it ever was.

I'm very mindful of your comment at the opening of the hearing, that this isn't a hearing on ergonomics, but it's difficult to put that completely out of one's mind as an example of the politicization of the standard-setting process.

Chairman Norwood. You cited some solutions, and I found them very interesting. One was that an agency outside of the DOL would set the standards, leaving the enforcement to OSHA, I gather.

Mr. Goldsmith. That's correct.

Chairman Norwood. You also spoke of scientific evidence being reviewed outside of OSHA while leaving the enforcement to OSHA. Do you envision the same agency setting the standards outside of DOL also dealing with the scientific evidence?

Mr. Goldsmith. Yes. I think that you would have the entire standard-setting process outside of the Department of Labor. This was not a novel idea. It's one that was part of the original debate over the statute in 1970. That outside agency would act with as much independence as could possibly be arranged for.

That’s not to say that I'm naive enough to believe that there would be no political back-and-forth. But once you take the standard-setting agency out of the enforcement branch, I think that alone will do much to make the standard-setting process much more even-handed.

Then if, on top of that, you guide that independent agency with standards much like the standards that federal judges apply every single day in making rulings on expert

witnesses and on the reliability and relevance of expert testimony, you've taken it yet another step away from overly political action and focused on really getting to the truth of the scientific issues that have been raised.

Chairman Norwood. That's an interesting concept, and of course the purpose of the first of these hearings. It's a learning process, and we all ought to think about what you're proposing.

I see the red light is on, Mr. Owens. I'd like to yield five minutes to you for questioning.

Mr. Owens. Thank you.

Mr. Rezendes?

Mr. Rezendes. Yes, sir.

Mr. Owens. Just for clarity, when you talk about thousands of rulemaking situations, for the sake of the audience and the record, you're not talking about standards?

Mr. Rezendes. No, we're talking about the rule.

Mr. Owens. Technical adjustments, what we call when we're making legislation technical amendments?

Mr. Rezendes. Well, actually, in 1997, what we looked at was all the rulemaking that went on in 1997, and there were over 4,658, if I recall the number correctly.

Mr. Owens. 4,658?

Mr. Rezendes. Rules.

Mr. Owens. Technical adjustments?

Mr. Rezendes. No, rules; rules and rulemaking. Some of them were technical adjustments; some of them were major rules.

Mr. Owens. Can you make a distinction? A standard, when you finalize a standard, that's different from what you're talking about, right?

Mr. Rezendes. Yes, correct. We did not look at the standard-setting process within OSHA or anyplace. We looked at the rulemaking process.

Mr. Owens. Did you look at the total rulemaking process?

Mr. Rezendes. Absolutely, correct.

Mr. Owens. Which includes standards, in the final analysis, right?

Mr. Rezendes. It could, yes.

Mr. Owens. I just want to make that clear.

Mr. Rezendes. Yes, thank you.

Mr. Owens. We were talking about some 40 standards in the history of the agency?

Mr. Rezendes. Thousands.

Mr. Owens. Thank you.

Mr. White, you set out a very logical procedure there, but you just chose to leave out the interference of the political process. You don't think that has any bearing on the process?

Mr. White. Well, I think that can occur at any of the stages that I laid out. So I didn't lay it out separately. In fact, political interference does occur.

Mr. Owens. Would you comment on my statement about the number of Administrations and the number of Labor Secretaries that could go by?

Mr. White. Well, I think that's exactly part of the problem. As you've said, and I said in my written testimony, the average shelf life of an Assistant Secretary is about two and a half years. So you have new people, new administrations, new political philosophies coming in during the course of a variety of rulemakings, and one person's priority is another person's very low priority.

It's so easy for a new Administration not to want to work on confined spaces, but on permissible exposure limits, so confined spaces go on the back burner. There's nothing to prevent the Agency, or hold the new Administrator accountable for saying, "Why are you moving what was a high priority to a low priority and putting something else on that burner?"

Mr. Owens. Would you say that it's not stretching matters to say that when you develop standards you're dealing with a fundamental clash between management and labor, management and workers? It's the safety of the workers usually that's of concern to OSHA. It's management that challenges more and more in an attempt to make the workplace safe.

Mr. White. Well, I think that the rulemaking process has always been adversarial, and every one of OSHA's health standards save one, and most of OSHA's safety standards have been challenged by some segment of industry because there's some dissatisfaction with the result.

So it's always going to be an adversarial process.

Mr. Owens. Mr. Goldsmith, would you say that there's a correlation between the complexity of the rule or standard and the amount of controversy? I mean, when you were setting standards for the building trades, it's obvious what makes a situation an unsafe workplace; far more obvious than many more instances. But when you're talking about ergonomics or certain chemicals, it becomes more complex, and the controversy has increased in relation to the complexity. Am I correct?

Mr. Goldsmith. Yes, I think that's right. I think to the extent that a proposed standard or standards are increasingly complicated and far-reaching, as was the case with ergonomics that is certainly going to create some controversy.

Mr. Owens. But management has disputed the evidence, in other words?

Mr. Goldsmith. Well, if I may, with all due respect, I don't think it lines up as management always opposing having a safe workplace. I think that is not the case at least in my experience of almost 30 years of representing employers in this area. Indeed, I think much of what transpired in the ergonomics and other rulemakings makes that clear.

What you have are legitimate disputes about whether or not a standard addresses a problem and how it should address a problem and what the enforcement implications are and so on. I don't think that this is a matter of management wanting to have unsafe workplaces.

Mr. Owens. Ms. Seminario, Mr. White has suggested that OSHA should adopt the same process that NIOSH uses to develop the National Occupational Research Agenda. How does that process work, and how would that help to bring consensus to this regulatory agenda?

Ms. Seminario. The process was one of bringing together the interested parties, the health and safety community, to set an agenda of priorities particularly for research activity. It's the National Occupational Research Agenda, and it was one that identified key areas of concern and developed working groups to continue the input on the research in those areas.

I would agree with Mr. White that having a process for setting priorities that involves interested parties in the broad community is a good thing. OSHA did that in 1994 in its priority planning process, which I think was generally a good process.

Mr. Owens. That process would be more acceptable to management and to industry?

Ms. Seminario. Well, I think, again, having some clear priorities are important and getting input on them is important.

What you want to do with whatever process you're setting up is have it be one that leads to something, and not just endless discussion. I think in setting up any new steps or new ways of doing rulemaking that we have to be very thoughtful and careful about the

result being better, timelier protection for workers because that's the point of this. It isn't about the process, it's about the protections, and I think we have to keep that in mind. Right now we have a process that isn't working to protect workers.

I don't agree Mr. Goldsmith's recommendations that that would make the process of putting protections in place better. We have a different view on that. But having some processes to set some priorities that are ongoing, I don't think is a bad idea.

Mr. Owens. Thank you for the additional time, Mr. Chairman.

Chairman Norwood. Thank you, Mr. Owens.

I'd like to recognize Mr. Keller for five minutes.

Mr. Keller. Thank you, Mr. Chairman.

Mr. Goldsmith, I have a couple questions for you along the lines of the Daubert standard, and the use of peer review. I have tried a few cases in my day in Florida. We call it "Dolber." We're not these fancy big city lawyers. I understand now that it's Daubert. We've been messing this up.

I was very intrigued by your testimony, regarding scientific review by OSHA using the Daubert standards, and specifically making sure whatever standard is adopted is generally accepted in the scientific community. In my own private practice experience I have seen that make a lot of sense.

Down in Florida, for example, there's a form of junk science called multiple chemical sensitivity. Someone will go and spray a house for bugs, or they may paint that same house, and the next thing you know, you're facing a $20 million lawsuit. "I have to live in a spacesuit now because I have multiple chemical sensitivity, and I'm allergic to everything, and here's the $700 an hour expert that I've flown in from Los Angeles to testify that." As a matter of practice, we routinely have these hearings, and their testimony is thrown out of court; not allowed to testify.

I'm concerned that in the workplace setting we don't have these same safeguards, because workers' compensation judges are allowing these judgments. I want your ideas about how OSHA can implement some sort of Daubert type procedure to make sure that proposed regulations are based on sound science.

Mr. Goldsmith. I used to call it "Dolber" until a judge corrected me, so I could go either way, Daubert or "Dolber."

The easiest and most direct way to do it is to simply tell OSHA that the standards that the United States Supreme Court, and any number of federal judges apply on a daily basis have to apply to this process. It's easy enough to take the decisions and summarize them in very objective terms, just as you would in trying a case or contesting the relevance and reliability of an expert's testimony. These are the rules, and they either follow them or they don't. If they don't, presumably that would be a basis for challenging

a standard. But at least they would have an understanding from Congress that this is the way you analyze scientific evidence.

Mr. Keller. The second question along the same lines relates to peer review. It's my understanding that the only time OSHA has utilized peer review was during the tuberculosis standard, and that unlike EPA or FDA, OSHA refuses at this point to utilize the independent scientific peer review.

Do you think that peer review is something that OSHA should consider in the future?

Mr. Goldsmith. Absolutely. Peer review is certainly a staple of the medical research that is done at universities and in hospital centers all over the country. I just don't understand why there would be any reluctance to have some formalized peer review system in place to make sure that the evidence that's being put forward, among other things, meets the relevance or reliability tests and is otherwise probative and reliable. It doesn't make any sense to avoid some sort of peer review process.

Mr. Keller. What we're talking about is really getting back to the same issue: Sending this research to folks at Harvard or Duke or Vanderbilt or California Tech and asking, "You're an expert. In your belief is this generally accepted in the scientific community?"

Mr. Goldsmith. That would certainly be one way of doing it. I think there are any number of ways that could be devised to have effective peer review. But just to ignore it makes no sense at all, in my judgment.

Mr. Keller. Thank you. Ms. Seminario, is there a need for OSHA to use independent scientific peer review?

Ms. Seminario. Yes, in certain cases, and they certainly do. Routinely OSHA does have their risk assessments reviewed by outsiders and receives comments on that. They do that fairly routinely with their economic analyses as well. As far as adding a whole formal procedure and setup, such as exists at EPA, I wouldn't support that. I think it would just add a lot more time to the process.

As I said before, OSHA standard setting is among the most open process that exists right now. The Agency's scientific findings and evidence are all put forward. Everyone has a chance to come forward, and not only to comment, but to cross-examine witnesses as well. So, for example, we at the AFL-CIO have a chance to ask the Agency and the people who actually prepare these documents questions that we get on the record. It's a very, very open process, and I would say that it allows for peer review that is much broader than the kind of open peer review that exists in any other Agency. It's a different form, but I think it does already exist.

Mr. Keller. Mr. Chairman, am I out of time?

Chairman Norwood. You're out of time.

Mr. Keller. Okay. I yield back then. Thank you.

Chairman Norwood. I'd like to recognize Mr. Ballenger, former Chairman of the Subcommittee, for five minutes.

Mr. Ballenger. Thank you, sir.

Mr. White, the last Congress proposed legislation that would change the way OSHA proposes such safety and health standards. The bill that I introduced would simply require OSHA to include risk assessments and cost benefit analysis that are industry specific in any proposed regulation. To my way of thinking, almost every business that operates today does this. What do you believe would be the benefit of the legislation? Could you express an opinion on that?

Mr. White. Mr. Ballenger, maybe my memory is shorter as I get older. I don't remember the particulars of your bill, but certainly the issues of risk assessment and economic analysis are critical to OSHA's rules today.

I think one of the big failures of OSHA's process, though, is that you can't find anywhere in the Agency a set of guidelines that tells you how OSHA goes about the process. You can figure it out if you sort through various standards and preambles and court cases, but I think it would be extremely valuable for OSHA to have a valid, clear-cut, open set of criteria for peer review and economic analysis. I think part of the issue is that it's sort of a mystery to the rest of the public as to how this happens.

Mr. Ballenger. Right.

Mr. White. Whether you need to do that by legislation or whether you could accomplish the same thing administratively I think is open to some question. But certainly the concept of clear-cut criteria for peer review, and certainly for economic analysis that must be done industry by industry is an essential part of the process.

Mr. Ballenger. Right, and I think ergonomics proved how wild and wooly it can get depending on the side you happen to be on in that issue. I don't know how many billions of variations there was, but there were billions and billions and billions.

Let me ask you another question. It seems that every time OSHA develops a standard, its fate is decided in the courts. Do you believe that this is the most effective rulemaking procedure? What do you think we could do about this final step to keep it from going into the courts? Is there a way?

Mr. White. Well, I'd like to think that there is. I think OSHA can do a better job of collaboration and consensus building from the first stage of the process as I indicated. That is in the prioritization phase, through the implementation phase.

Part of the problem with the process is that the stakeholders, the interested parties are not really involved. I think that despite the various legal requirements there needs to be a better way to make sure that stakeholders are involved throughout the process so that

they can provide input. There is some way to build more consensuses about the product so that there isn't so much litigation.

Now, all that having been said, it would be great if every rule could be done by negotiation. I don't think the process lends itself to that, particularly in these mega rules where there are many interested parties and many issues. But OSHA needs to find those areas where there could be some agreement, enter into negotiation, and have a negotiated rule, which then would not lead to litigation.

In general, litigation is sort of part of the history of OSHA rulemaking, unfortunately, and OSHA will just have to do a better job, I think, of collaborating everywhere from the front end to the back end in order to try to minimize that.

Mr. Ballenger. We might, if we figured out an answer to that question, put a lot of lawyers out of business, and that wouldn't be nice at all.

Mr. White. That's right, and I certainly wouldn't want to do that to my colleagues on the panel here.

Mr. Ballenger. Mr. Rezendes?

Mr. Rezendes. Yes, sir.

Mr. Ballenger. In 1996 we passed a law that requires OSHA to convene small businessmen to consider the impact of rules on small businesses during the rulemaking process. I'm a small businessman myself.

Has this affected the process?

Mr. Rezendes. Actually, when we looked at it, most of our critique was that the ambiguity in terms of defining what is a significant economic impact on a substantial number of small entities was so vague that each of the agencies were using their own interpretation. Some, like EPA, were using a rather high threshold.

Our critique has been not so much in terms of how it slowed down the regulatory process, but that the objective that Congress had in terms of clearly analyzing the impact of a regulation on small business has not been achieved because the definitions have not been clearly defined. We've recommended numerous times that either Congress amend the Act or that somebody, like the Small Business Advocate at SBA be given the authority to define and help the Agencies clarify when those assessments need to be done.

Mr. Ballenger. Thank you.

Ms. Seminario, I've known your name off and on for years and years and years, and I don't think we've ever testified either for or against each other, have we? Well, let me just say I welcome you here. I love your charts. I was involved with regulatory legislation of chemicals that you mentioned in the early part of OSHA's existence. All the

easy stuff seems to be done, and now nothing is left but hard stuff. We're keeping a lot of rich lawyers involved, and as you have heard me say many, many, many times, or maybe you haven't heard, I'm not their best friend. I'd love to see this legal practice shrink somehow if that could happen.

However, it seems that you don't think the easiest part has been done. I mean ethylene chloride was one of the later ones. But those of us that happened to live in close proximity to the foam-manufacturers and were complaining about the smell in our neighborhoods, we're very happy to see that regulation come along

Ms. Seminario. Well, I think you raise a very good point. I don't think all the easy ones have been done. The issues that are confronting the employers' unions and OSHA are more complex. There's no doubt about it. Ergonomics is a complex issue, but it's also a serious one. So how do you define a government response?

Again, as Mr. Goldsmith said, the regulation was far-reaching, but the problem is very broad, and so these are the realities that we have to deal with. I would suggest that there are some areas, which maybe aren't so hard that we could deal with. In my summary I didn't get to talk about the need to update certain standards.

The permissible exposure limits that exist for many chemicals were adopted back in 1971 at the direction of Congress, and so for most toxic chemicals that workers are exposed to, the standards are very out of date. They were based upon 1968 limits and really dated from the '40's and '50's. So for most chemical exposures in the workplace today, the scientific evidence that they are based on is 50 years old, and there's agreement on a lot of those chemicals and a lot of those limits.

I think we should try a process that would allow us to raise the baseline on things that people agree about, but look at some new processes to keep those limits up to date. That allows you to narrow the definition of what you're trying to do, so maybe it's manageable. I think maybe one of the things that we need to do is look at how we can break this up into parts that are more manageable and are still significant actions. It's something that a number of us in the safety and health community have had discussions about.

What are the ways we could move forward to try to update these limits? Mr. White's been involved in those discussions over the years, and it's something that we'd like to try to explore with the new Assistant Secretary, folks in the business community, and yourselves as well.

Mr. Ballenger. I see my time has expired.

Chairman Norwood. That's all right. I still have some unanswered questions, and I'm sure Major Owens does, too.

One of the things I want to correct for the record is the comment my friend from New York made about the clash between management and labor over OSHA standards. What I think we're talking about is the management of big business, clashing with the

management of the AFL-CIO. I would like to set the record straight in saying that probably for 80 percent of the workforce who works in small business and in mom and pop businesses, management and labor often is the same thing. There are people in this room who make their living as managers, working side by side with their employees. So some of these standards aren't necessarily a clash between management and labor. It just seems to be so at the higher levels.

I also think that it's important to point out that this clash between the AFL-CIO and big business management generally represents about 10 percent of the workforce. I think we get into more trouble at OSHA because over and over again "one size fits all." When you do that, it may work really well for big, big business but it is devastating to small business. I would submit to you that "one size fits all" slows down the process.

Now, Mr. Chajet, I have some questions I've got to ask because at our upcoming hearings, we certainly want to hear from the American Council of Governmental Industrial Hygienists. I need to ask you some questions so I can question them better at a later hearing.

My understanding is that the ACGIH is a private organization that receives government money, and they go about the business of setting standards for this country. On frequent occasions OSHA will look at their standards and incorporate them by reference into OSHA rules, which, in effect, changes the law.

Have I got that right so far?

Mr. Chajet. I think you do, Mr. Chairman, in the sense that this organization is portrayed as a private organization. However, there are often different layers of an onion as you peel it.

When you look at the organization, what you find is that Public Health Service employees with Social Security funding created it. It is staffed now and has been staffed for many years, by active federal employees who took it on as a "volunteer effort" and ran it out of their government offices in NIOSH in Cincinnati.

Chairman Norwood. Are there other private groups in the country that set standards?

Mr. Chajet. There is, Mr. Chairman, but they're not of the same character or nature. There are many consensus standards groups that are open, that seek industry, labor, academic, and expert input and arrive at consensus standards.

Chairman Norwood. Does OSHA incorporate by reference from these other groups, or is it particularly the ACGIH?

Mr. Chajet. They do incorporate by reference standards from consensus-setting groups, but not in an overwhelming nature. For example, OSHA has a communication rule that simply says that if the ACGIH or a couple of other organizations tag a substance as hazardous, it is therefore automatically tagged as hazardous for purposes of the federal

program.

This labeling process, as you can imagine, tags a product as hazardous and places a level on it that states that anything above this level is unsafe. That number and that tag is produced by a private organization and it's incorporated by reference

Chairman Norwood. Does the public get to comment on that?

Mr. Chajet. No, Mr. Chairman, they do not.

Chairman Norwood. Is that what the OSH Act is? Something's wrong here.

Mr. Chajet. There's something very wrong with this process. The standards that they adopt are put up as a notice of intended change and are published in their publication, and circulated within the hygiene community. But there's no notice and comment, as the law requires. The government is using this group as an advisory committee. This Congress passed a Federal Advisory Committee Act to control that very kind of problem, and this process somehow escaped the overview of how the Federal Advisory Committee Act has been implemented.

We have a law that says if you're going to use or rely on an advisory committee, Congress has to charter that advisory committee. You have to have open meetings, you have to have notices in the Federal Register, and you have to take minutes. But that has not been applied to the use of and reliance on ACGIH. It is a very significant denial of our due process, and all of the things you've heard here today about open and transparent rulemaking that we want, doesn't happen.

Chairman Norwood. Is Mr. Chajet right about this? Is it an open process or not? Does the public get to comment or not?

Yes, ma'am?

Ms. Seminario. I don't really think the focus should be on ACGIH. It is a private organization, and we can have discussions about their standards and their processes. But we're really focusing on OSHA and their rulemaking, and their rulemaking is very open.

Chairman Norwood. No, my question wasn't about OSHA. My question is, does this private agency set standards that are incorporated by reference where there is no public comment? That's my question.

Ms. Seminario. I was getting to that point. Regarding the hazard communication standard, which incorporates the ACGIH standards, there's a presumption that if they are indeed on the ACGIH list, those substances or materials are captured, and an ACGIH data sheet has to be provided.

That rule was subject to very open rulemaking for many, many years. So the incorporation of the ACGIH as one element of that standard was one piece of information when the hearings were going on. I was not aware of anyone during that process nearly

20 years ago that objected to that, and indeed it was regular practice by manufacturers to include that information on their data sheets.

Chairman Norwood. My understanding, is that 20 years ago they did it a lot better than today. What I would suggest to you is that you come to the next hearing and we'll bring some people in who have been affected by "incorporated by reference" and had not one word of input.

My time has expired but Major Owens you're certainly recognized.

Mr. Owens. Ms. Seminario, would you like to finish your statement?

Ms. Seminario. I would. I didn't come to testify on the ACGIH process. I came to testify on the OSHA standard-setting process. To get a fuller picture, it would make sense to have ACGIH and OSHA here and not just hear from one party. Perhaps then you would get a fuller picture of that.

Chairman Norwood. Keep the faith. I promise you I'm going to have them in.

Mr. Owens. I claim my time, Mr. Chairman.

I ask unanimous consent to have submitted for the record a letter from ACGIH as well as other documents.

Chairman Norwood. I agree, if you'll yield. We'll put it in the record.

Mr. Owens. I think it's important to note that one of those documents is from the ACGIH, which says quite clearly that ACGIH received no government funding.

In a statement you made a few minutes ago you seemed to have some doubts about them receiving no government funding. Government employees participate in some ACGIH activities, just as I'm sure some government-employed lawyers participate in the American Bar Association and American Medical Association and various other organizations that do have an impact on government decision-making.

I don't know whether this Administration is going to do it or not, but most previous Administrations have used the Bar Association in making recommendations for federal judges, but it doesn't make them advisory committees for the Federal Government, and it does not rule out them having some lawyers who might work for the government.

I'd like to also point out that the ACGIH has 42,000 members who are scientists, toxicologists, epidemiologists, physicians, and industrial hygienists who are concerned with issues involving workplace health and safety. Our members are employed by academic institutions, major corporations, labor organizations, and federal, state and local agencies, and I'm not sure we should deny a federal employee the right to belong to such an association because there's some possibility that the government would use their

expertise or their advice in making decisions somewhere in the future.

I would just like to say that it's clear that OSHA is in the business of making rules and of doing other things to protect the health and safety of workers. I didn't mean to sound as if I am anti-management or anti-employer or anti-corporations, but that happens to be the business that it's in: workers.

There may be some situations in the future where both will obviously benefit; management as well as workers. There's some controversy about the radioactivity of cell phones, for example, and some millionaires have died and some of their relatives have sued cell phone companies. There are some pending suits out there that nobody talks about. That may be an area where safety of the executives is even more of an issue than the safety of the workers. So there may be such situations.

But in general OSHA does not deal with protecting the health and safety of management and employees. It's workers. And when these challenges are made, we are challenging a governmental effort to make the workplace safe for workers, and we can't get away from that. There's a moral issue here.

Ms. Seminario, and maybe some others would comment, too, what are your views regarding the establishment of a completely independent agency to develop standards? You know, take it out of the Department of Labor and have it become completely independent, without the political overtones of having appointments made as Administrations change and some other kinds of things that happen as a result of it being a part of the Department of Labor.

Ms. Seminario. I don't think that would make it any better. I mean, look at what we just went through on ergonomics. We had two NAS studies with the best experts in the world. We had nothing to do with who was selected on that panel. It was the NAS, the Institute of Medicine. But even with those determinations that were made, they weren't accepted.

So I don't think that.

Mr. Owens. You're not sure Congress should get more involved? I implied in my opening statement, that in some cases Congress might get more involved as we did in the needlestick legislation, but you're not so sure that that's a good idea.

Ms. Seminario. No, and I don't think setting up an independent group really deals with the issues. Look at what OSHA has produced over the years in the way of its standards. They've been pretty good standards. I mean, after they're issued, for the most part, they've been accepted; they've been put in practice. There isn't a track record that these rules were so off the wall, so off base, causing all these various catastrophes with respect to job loss and feasibility. That hasn't been the case.

So I don't think setting up an independent board that has no relationship to the workplace or to enforcement, makes a lot of sense at all, because feasibility issues actually are very, very key in OSHA standard setting. They're as key as the risk side of the equation. Having those standards developed by an agency that's familiar with the

workplace actually is very, very helpful. Putting in a separate organization that has no relationship to the workplace I think would be a very bad thing.

Mr. Owens. Mr. White?

Mr. White. I think it's an issue worth considering, but I guess after working in this area for 25 years, I've also become sort of a political pragmatist, and I doubt that people are going to be able to come together on this issue and agree that we need to fundamentally restructure the Occupational Safety and Health Act.

What I think, as Ms. Seminario states, is the results are uncertain. We don't know that, and I don't think we can predict very well that an independent agency would be any better, more effective, or less controversial than what we've got now. I think, though, that maybe it's something worth considering. I don't think it is a silver bullet, and I think we ought to be very cautious about fundamentally amending the Act.

Let me volunteer something about the ACGIH. I would just caution about throwing the baby out with the bath water. While there are certainly issues surrounding the way ACGIH sets its own limits, I think business has some concerns about that, as labor did 10 or 15 years ago. I think ACGIH has served a valuable function, both for business and for labor. Where, as Ms. Seminario pointed out, OSHA has not been successful in updating its limits over the past 30 years, ACGIH limits have served a valuable role.

So I think if we're going to focus our attention on ACGIH, it ought to be a specific issue as Mr. Chajet's raised, and not about the value of ACGIH and their limits, which I think has been there over the years.

Mr. Owens. I want to thank you for that valuable information.

Mr. Goldsmith?

Mr. Goldsmith. Mr. Owens, if I might, just on the issue of an independent agency. It seems to me that one of the problems that OSHA, has had over the years is an increasing lack of trust on all sides. Labor lacks trust in what the agency does, management lacks trust in what the agency does, and so on.

A way I think to give the Agency more credibility within the regulated community is to establish independent agencies, like an independent standard-setting agency. The entire judiciary is predicated on the notion of being independent. The judiciary takes all kinds of cases. They become familiar with the workplace. They become familiar with all kinds of things.

There's no reason why an independent agency couldn't address all of the issues that need to be addressed in the context of making standards, and I think if you take it away from the enforcement arm of the Department of Labor, you will almost immediately increase the credibility of the standard-setting process. I think that would result in fewer lawsuits challenging standards, and I think that the basic notion that

independence is generally a good thing is hard to argue with. Yes, there are questions about how you would appoint people and so on, but those are in effect details that can be dealt with.

Mr. Owens. So you would recommend an independent agency, isolated from Congressional interference. Congress would not be allowed to threaten budget cuts or do other things that might intimidate the agency.

Mr. Goldsmith. I don't know exactly how Congress would work with such an agency, but I think a certain amount of independence is a good thing.

How it would come about politically and what the role of this Committee or the Congress would be in moderating the agency's activities are obviously something that should be looked at.

Mr. Owens. Thank you.

Mr. Chajet. Mr. Chairman, if I might?

Mr. Owens. I have no further questions. You wanted to comment, sir?

Mr. Chajet. I would on two points, if the Chair and Mr. Owens would permit.

First of all, I would hate to live in a country where Congress couldn't look at agencies making decisions that affect my life. I very much appreciate the role of the Congress in examining and overseeing regulatory agencies that affect my family's small business activities in Florida, and I hope that will continue.

On the ACGIH issue I also wanted to add that it is very important to realize this is an Agency that's done a lot of good over the year. They've kind of lost their way. They've had very good intentions and they're good people that are trying to do the right thing. I agree with Mr. White, we don't want to throw the baby out with the bath water, but we want to make sure that there are no conflicts of interest. Open, transparent, fair processes are inherent in our system of government.

So an ACGIH federal employee who is writing a standard for diesel exhaust shouldn't be writing an ACGIH standard for diesel exhaust. There is a crossover of materials and philosophy that's a subject matter conflict. Similarly, there are potential financial conflicts as well. ACGIH money should not be paid to a committee member who is writing a standard at his university, and then that standard is used in the OSHA or MSHA rules.

Mr. Owens. Thank you, sir. I understand you have a case where you're making all these arguments, and I choose not to have them made here in response to my question. Thank you.

Chairman Norwood. Let me summarize and close this hearing, which is for informational purposes. I hope everybody understands that. There will be others.

I am going to work very hard to make sure that this Committee understands the rulemaking process, and we do understand, I think, all of us on both sides, that it is not functioning correctly. One of the things that I want to be sure of is that in 100 years we are never accused of dereliction of duty by not overseeing the appropriations process for a federal agency. We certainly want Congress to do its constitutional duty, and that is one of our constitutional duties.

I am inclined to correct the record about some of the things that were said, particularly about NAS and their relationship with OSHA. I'm reminded that the ERGO Rule was finalized before the NAS study was actually published, so it makes you wonder how that fit in together.

Lastly, I am concerned, frankly, about this process being closed down to the very people that it bothers, and I intend to find answers to that, and I'm going to ask a lot of other people about it.

But I think regulation without representation is the worst possible thing we can allow to happen, and I for one am going to be absolutely certain that agencies such as OSHA that are using regulation without following the actual open process laws Congress gave them stop. There is no reason, for example, we shouldn't use public entities that are producing standards. But we have to be very, very concerned if there is any interconnection at work between federal employees and private agencies to avoid due process of law.

So with that, let me thank each one of you for your time. I have a lot of additional questions, and I hope all of you will consider responding to my questions in writing. I'd like to put your answers into the record because we are out of time.

I invite you to come back to our next hearings on this subject, because we're going to stay on this subject until we get the air cleared and determine what we can do to improve OSHA and make sure the government does its duty in trying to protect Americans in terms of safety and health. I agree with Major Owens on that process.

Mr. Owens. Can I ask you to share the questions with us?

Chairman Norwood. I'll be delighted.

Mr. Owens. Thank you very much.

Chairman Norwood. So granted. This hearing is now adjourned. Thank you all.

Whereupon, at 12:12 p.m., the Subcommittee was adjourned.

APPENDIX A - WRITTEN OPENING STATEMENT OF CHAIRMAN CHARLIE NORWOOD, SUBCOMMITTEE ON WORKFORCE PROTECTIONS, COMMITTEE ON EDUCATION AND THE WORKFORCE

The Honorable Charlie Norwood
Chairman

Subcommittee on Workforce Protections
Hearing on
"Making Sense of OSHA Rulemaking: A Thirty Year Perspective"

June 14, 2001

We are here today to discuss a topic of endless fascination, frustration and complexity – OSHA's standards rulemaking process. I say fascination because it has been a constant source of wonder to me how it is that everything Congress manages to legislate seems to get turned on its head in the regulatory process. I say frustration because it seems to me there isn't much of anyone these days, I dare say on both sides of the aisle, who is completely satisfied with OSHA's rulemaking efforts.

It is no secret that I have been an outspoken critic of OSHA. It will further come as no surprise that I am not a fan of excessive regulation. That being said, let me note this: today marks the first time our Subcommittee has met this Congress to address an OSHA matter. I hope that this will be a first step in trying to find some common agreement about OSHA. I don't expect it to be easy. I am willing to try.

It seems to me that the easiest thing for all of us in this room to do is to accept the status quo of our constant disagreement about OSHA matters. That does not strike me as a very responsible way to discharge our duties with respect to this agency. It certainly will do nothing to advance the larger and more important issue of achieving safe and healthful workplaces for American workers. I am hopeful that Mr. Owens and our Committee colleagues on both sides of the aisle will look for ways we can work together to bring about meaningful improvements to the safety of our nation's workplaces.

I would also like to take a moment to welcome our witnesses. We appreciate their willingness to take time out of their busy schedules to testify before the Subcommittee. I note that we have an abundance of lawyers on our panel today. Since my background is in science, I especially want to thank Ms. Seminario for being here to offer a perspective from beyond the bar. We are obviously lacking a participant from OSHA on our panel today. I am pleased to see that the Bush Administration yesterday announced the nomination of the new Assistant Secretary. Once Mr. Henshaw is in place, I look forward to having him here to provide his observations about today's topic, as well as his goals for the agency.

When we first thought to review and try to make some sense of OSHA's rulemaking efforts, the immediate reaction from some was that would be a bit like watching paint dry. I admit that the workings of the regulatory process are not the most lively topic. However, let me suggest three reasons why this is an important subject for the

Congress to review.

First, in Fiscal Year 2001 OSHA will spend nearly $15 million as a line item in its budget on Safety and Health standards. We certainly have some obligation to determine if that is taxpayer money well spent. Moreover, in its recently published unified regulatory agenda, OSHA lists no less than 45 items at some stage in the rulemaking process.

Second, in April we passed the thirtieth anniversary of the effective date of the OSH Act. Anniversary dates always provide a nice focal point for reflection and observation. It also strikes me that this past March we may have passed a point of critical mass when it comes to OSHA rulemaking. I refer, of course, to the Congressional action on the ergonomics rule. There has been a great temptation for this hearing to be a rehash of everything wrong about the ergonomics rulemaking. I have every expectation that each of our witnesses today could express some fairly strong opinions about that subject. That is not our intent here today. Rather, given that we have thirty years worth of OSHA rulemaking to reflect upon, I hope we can consider some observations, in a fair, objective, and honest manner, about what has worked well in OSHA rulemaking and what has not, and about what the current state of affairs is.

There is a third reason we should review this area of OSHA activity. When Congress passed the OSH Act in 1970 it gave OSHA the authority to under Section 6 of the Act to adopt national consensus standards and to issue, through rulemaking, safety and health standards for the protection of American workers. It gave OSHA the authority to enforce those standards in the workplace. That is an extraordinary exercise of power – and of responsibility. When it comes to rulemaking, we should be extraordinarily mindful of that.

We are all aware that OSHA deals with complex, often controversial issues within a complicated regulatory process. But complexity and controversy should not be things we shy away from given the charge to the agency. In order to maintain a necessary level of trust and confidence between the agency and the regulated community, the responsibility given to OSHA requires a high degree of transparency and vigilance about the process. We all have a role in that – Congress included. It is entirely appropriate, after thirty years of effort, that we look at how it is OSHA goes about discharging its authority and responsibility.

I look forward to a thorough and informative discussion today.

APPENDIX B - WRITTEN OPENING STATEMENT OF RANKING MEMBER MAJOR OWENS, SUBCOMMITTEE ON WORKFORCE PROTECTIONS, COMMITTEE ON EDUCATION AND THE WORKFORCE

Statement of the Hon. Major R. Owens
Hearing on: "Making Sense of OSHA Rulemaking: A 30 Year Perspective"
Subcommittee on Workforce Protections
June 14, 2001

Thank you Chairman Norwood for yielding to me. I want to welcome most of today's witnesses. There is no question that we can benefit from a clearer understanding of the rulemaking process. I look forward to your testimony.

Anyone who is concerned about the health and safety of workers has to be concerned about the degree of difficulty and the excessive time that it takes OSHA to promulgate safety and health standards. On average it takes OSHA ten years to develop and promulgate a standard. The Advance Notice of Proposed Rulemaking (ANPR) for the Respiratory Protection standard was issued in 1982. The final rule was not issued until 1998. The Construction Advisory Committee recommended the development of a standard for scaffolds in 1977. A Notice of Proposed Rulemaking (NPR) was not issued until 1986 and the final standard was not issued until 1996. The Lock-out/Tag-out standard took nine years from the ANPR to the final rule. The Confined Space Entry standard took 18 years from the first ANPR until the final rule. The most important point to remember is that workers are continuing to be killed or injured during the period that the agency is developing the standard.

We limit the amount of time that any individual can serve as President to 8 years. The average tenure of an Assistant Secretary for OSHA is only two-and-a-half years. It should be obvious to everyone that there will be problems with continuity when it typically requires 4 different OSHA administrations and three different Presidential administrations to work on and develop a single standard. I am, therefore, particularly interested in any ideas the witnesses may have that might help to formalize or regularize the manner in which OSHA establishes priorities.

Last year, the Congress at least implicitly acknowledged the breakdown of standard making process at OSHA when we enacted the needlestick legislation. Recognizing that it would take years for OSHA to amend the bloodborne pathogen standard, the Congress stepped in and did so directly. As a result, safer needles will be more widely used more quickly and health workers, who may otherwise have been exposed to hepatitis or HIV, will be protected. I am not optimistic that this Committee or this Congress is likely to be able to do much to improve the standard making process; but there may well be specific areas, similar to the bloodborne pathogen standard and the needlestick bill, where we can act bipartisanly in a timely manner to update a specific standard. I want to go on record now to express my willingness to work with Chairman Norwood toward that end.

There is one aspect of today's hearing, however, that I find to be unseemly. Mr. Chairman, you have chosen to invite Mr. Chajet to testify today. Mr. Chajet is here to reiterate allegations that have been made in a pending law suit, Anchor Glass Container Corp., et al vs. ACGIH, U.S. DOL, and U.S. DHHS. In my view it is, as a general matter, inappropriate for a Congressional Committee to involve itself in pending litigation. The matter is before the court, let the court have its say and when they are done, if we disagree, we can act. However, what is

unquestionably irresponsible and inappropriate is to provide a forum for only one side in that pending litigation to present its views while denying the other side that same opportunity.

In order that the record might be just a little balanced, I ask unanimous consent to enter into it a letter from Chairman Norwood to the Secretary of Labor regarding ACGIH guidelines; a letter from ACGIH to the Secretary of Labor responding to the concerns raised by Mr. Norwood; and several articles from ACGIH regarding the litigation. Finally, Mr. Chairman I ask that the record be held open in the event that ACGIH wishes to submit a statement in response to Mr. Chajet's statement. Let me be clear, however, that I do not think that such a submission evens the score. Inviting Mr. Chajet to testify without affording a similar opportunity to ACGIH is clearly an ambush and this kind of ambush, particularly when it involves pending litigation, is in my view a misuse of the Committee and a disservice to the Congress.

APPENDIX C - WRITTEN STATEMENT OF VICTOR REZENDES, MANAGING DIRECTOR FOR STRATEGIC ISSUES, U.S. GENERAL ACCOUNTING OFFICE, WASHINGTON, D.C.

United States General Accounting Office

GAO

Testimony
Before the Committee on Education and the Workforce, House of Representatives

For Release on Delivery
Expected at 10 a.m., EDT
Thursday June 14, 2001

FEDERAL RULEMAKING

Procedural and Analytical Requirements at OSHA and Other Agencies

Statement of Victor Rezendes, Managing Director, Strategic Issues

GAO-01-852T

I am pleased to be here today to discuss the procedural and analytical rulemaking requirements applicable to the Occupational Safety and Health Administration (OSHA) and, in many cases, other federal regulatory agencies. The requirements are contained in a number of statutes and executive orders governing the rulemaking process, and the scope of the requirements varies dramatically. Various actors are involved in this process, including Congress, the president, the Office of Management and Budget (OMB), and, most recently, GAO.

First, I would like to identify and describe the major statutory rulemaking requirements that apply to many, and in some cases all, federal agencies. These requirements are contained in such statutes as the Administrative Procedure Act, the Paperwork Reduction Act, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act. Then I would like to identify and describe some of the executive branch requirements that apply to the rulemaking process, most notably Executive Order 12866 on regulatory planning and review. As I mentioned previously, we have examined the implementation of many of these statutory and executive branch rulemaking requirements, and I will discuss the results of our reviews in the process of listing the requirements. Finally, I will note a relatively recent statute that involves the legislative branch in the rulemaking process.

In brief, the rulemaking requirements that have been placed on OSHA and other agencies over the years are clearly voluminous and require a wide range of procedural, consultative, and analytical actions on the part of the agencies. It is also clear that federal agencies sometimes take years to develop final rules. For example, last year, the National Advisory Committee on Occupational Safety and Health noted that it takes OSHA an average of 10 years to develop and promulgate a health or safety standard.[1] Although we have reported on many federal rulemaking requirements, we have not examined the extent to which those requirements are responsible for the long time frames that are sometimes required to develop and publish final rules. Our reviews do, however, demonstrate that the requirements are frequently not as effective as expected or as they could be. In some cases that lack of effectiveness can be traced to how the requirements have been implemented by the agencies. In other cases, though, the requirements themselves seem to be the problem. Specifically,

[1]National Advisory Committee on Occupational Safety and Health, *Report and Recommendations Related to OSHA's Standards Development Process*, June 6, 2000.

the requirements were written in such a way that they do not apply to many rules, do not require substantial additional effort by the regulatory agencies, or give the agencies broad discretion in how key terms could be defined and, therefore, whether certain rulemaking actions are required.

Statutory Rulemaking Requirements

Some of the statutory rulemaking requirements that Congress has enacted over the years apply to all agencies, but some of the requirements are applicable only to certain agencies. Some of these requirements have been in place for more than 50 years, but most have been implemented within the past 20 years or so.

Administrative Procedure Act

The most long-standing and broadly applicable federal rulemaking requirements are in the Administrative Procedure Act (APA) of 1946. The APA provides for both formal and informal rulemaking. Formal rulemaking is used in ratemaking proceedings and in certain other cases when rules are required by statute to be made "on the record" after an opportunity for a trial-type agency hearing. Informal or "notice and comment" rulemaking is used much more frequently, and is the focus of my comments here today.

In informal rulemaking, the APA generally requires that agencies publish a notice of proposed rulemaking (NPRM) in the *Federal Register*.[2] The notice must contain (1) a statement of the time, place, and nature of public rulemaking proceedings; (2) reference to the legal authority under which the rule is proposed; and (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved. "Interested persons" must then be given an opportunity to comment on the proposed rule. The APA does not specify the length of this comment period, but agencies commonly allow at least 30 days. After considering the public comments, the agency may then publish the final rule in the *Federal Register*. According to the APA, a final rule cannot become effective until at least 30 days after its publication unless (1) the rule grants or recognizes an exemption or relieves a restriction, (2) the rule is an interpretative rule or statement of policy, or (3) the agency determines that the rule should

[2]Some agencies begin the rulemaking process by publishing an "advance notice of proposed rulemaking" or ANPR in which the agency notifies the public that it is considering an area for rulemaking and often requests comments on the appropriate scope or topics of the rule. The APA does not require the use of ANPRs, but some other statutes require it for particular types of rules.

take effect sooner for good cause and publishes that determination with the rule.

The APA also states that the notice and comment procedures generally do not apply when an agency finds, for "good cause," that those procedures are "impracticable, unnecessary, or contrary to the public interest."[3] When agencies use the good cause exception, the act requires that they explicitly say so and provide a rationale for the exception's use when the rule is published in the *Federal Register*. Two procedures for noncontroversial and expedited rulemaking actions have been developed that are essentially applications of the good cause exception. "Direct final" rulemaking involves agency publication of a rule in the *Federal Register* with a statement that the rule will be effective on a particular date unless an adverse comment is received within a specified period of time (e.g., 30 days). If an adverse comment is filed, the direct final rule is withdrawn and the agency may publish the rule as a proposed rule. In "interim final" rulemaking, the agency issues a final rule without an NPRM that is generally effective immediately, but with a post-promulgation opportunity for the public to comment. If the public comments persuade the agency that changes are needed in the interim final rule, the agency may revise the rule by publishing a final rule reflecting those changes.

In August 1998, we reported that about half of the 4,658 final regulatory actions published in the *Federal Register* during 1997 were issued without NPRMs.[4] Although most of the final actions without NPRMs appeared to involve administrative or technical issues with limited applicability, some were significant actions, and 11 were "economically significant" (e.g., had at least a $100 million impact on the economy). Some of the explanations that the agencies offered in the preambles to their rules for using the good cause exception were not clear. For example, in several cases, the preambles said that an NPRM was "impracticable" because of statutory or other deadlines that had already passed by the time the rules were issued. In other cases, the agencies asserted in the preambles that notice and comment would delay rules that were, in some general way, in the "public

[3]The APA also provides exceptions to the NPRM requirement for certain categories of regulatory action (e.g., rules dealing with military or foreign affairs). It also states that the notice and comment procedures do not apply to interpretive rules; general statements of policy; or rules of agency organization, procedure, or practice.

[4]*Federal Rulemaking: Agencies Often Published Final Actions Without Proposed Rules* (GAO/GGD-98-126, Aug. 31, 1998).

interest." For example, in one such case, the agency said it was using the good cause exception because the rule would "facilitate tourist and business travel to and from Slovenia," and therefore delaying the rule to allow for public comments "would be contrary to the public interest." In another case, the agency said that soliciting public comments on the rule was "contrary to the public interest" because the rule authorized a "new and creative method of financing the development of public housing."

The APA recognizes that NPRMS are not always practical, necessary, or in the public interest. However, when agencies publish final rules without NPRMs, the public's ability to participate in the rulemaking process is limited. Also, several of the regulatory reform requirements that Congress has enacted during the past 20 years use as their trigger the publication of an NPRM. Therefore, it is important that agencies clearly explain why notice and comment procedures are not followed. We recommended in our report that OMB notify executive departments and agencies that (1) their explanations in the preambles to their rules should clearly explain why notice and comment was impracticable, unnecessary, or not in the public interest, and (2) OMB would, as part of its review of significant final rules, focus on those explanations.

Paperwork Reduction Act

Another statutory requirement that is applicable to both independent and non-independent regulatory agencies is the Paperwork Reduction Act (PRA), which was originally enacted in 1980 but was amended and recodified in 1995. The original PRA established the Office of Information and Regulatory Affairs (OIRA) within OMB to provide central agency leadership and oversight of governmentwide efforts to reduce unnecessary paperwork and improve the management of information resources. Under the act, agencies must receive OIRA approval for each information collection request before it is implemented. The act generally defines a "collection of information" as the obtaining or disclosure of facts or opinions by or for an agency by 10 or more non-federal persons. Many information collections, recordkeeping requirements, and third-party disclosures are contained in or are authorized by regulations as monitoring or enforcement tools, while others appear in separate written questionnaires.

Under the PRA, agencies must generally provide the public with an opportunity to comment on a proposed information collection by publishing a 60-day notice in the *Federal Register*. For each proposed collection of information submitted to OIRA, the responsible agency must certify and provide a record of support that the collection, among other

things, is necessary for the proper performance of the functions of the agency, is not unnecessarily duplicative of other information, reduces burden on the public to the extent practicable and appropriate, and is written in plain and unambiguous terminology. The agency must also publish a notice in the *Federal Register* stating that the agency has submitted the proposed collection to OIRA and setting forth, among other things, (1) a description of the need and proposed use of the information, (2) a description of the likely respondents and their proposed frequency of response, and (3) an estimate of the resultant burden.

For any proposed information collection that is not contained in a proposed rule, OIRA must complete its review of an agency information collection request within 60 days of the date that the proposed collection is submitted. OIRA approvals can be for up to 3 years, but can be renewed by resubmitting their information collection requests to OIRA. Agency information collections that have not been approved by OIRA or for which approvals have expired are considered violations of the PRA, and those individuals and organizations subject to these collections' requirements cannot be penalized for failing to provide the information requested.

The PRA also requires OIRA to set governmentwide and agency-specific burden reduction goals. The act envisioned a 35-percent reduction in governmentwide paperwork burden by the end of fiscal year 2000. However, earlier this year we testified that governmentwide paperwork burden has gone up, not down, since 1995.[5] Federal agencies often indicate that they cannot reduce their paperwork burden because of existing and new statutory requirements that they collect more information. Nevertheless, some agencies do appear to be making progress. For example, the Department of Labor's paperwork estimate dropped from more than 266 million burden hours at the end of fiscal year 1995 to about 182 million burden hours at the end of fiscal year 2000—a 32 percent decrease.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), enacted in 1980 in response to concerns about the effect that federal regulations can have on small entities, is another example of a broadly-based rulemaking requirement. Under the RFA, independent and non-independent regulatory agencies

[5] *Paperwork Reduction Act: Burden Estimates Continue to Increase* (GAO-01-648T, Apr. 24, 2001).

must prepare an initial regulatory flexibility analysis at the time proposed rules are issued unless the head of the issuing agency determines that the proposed rule would not have a "significant economic impact upon a substantial number of small entities."[6] The regulatory flexibility analysis must include a description of, among other things, (1) the reasons why the regulatory action is being considered; (2) the small entities to which the proposed rule will apply and, where feasible, an estimate of their number; (3) the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, and (4) any significant alternatives to the proposed rule that accomplish the statutory objectives and minimize any significant economic impact on small entities. The RFA also requires agencies to ensure that small entities have an opportunity to participate in the rulemaking process, and requires the Chief Counsel of the Small Business Administration's (SBA) Office of Advocacy to monitor agencies' compliance with the Act. Section 610 of the RFA requires agencies to review those rules that have or will have a significant impact within 10 years of their promulgation to determine whether they should be continued without change or should be amended or rescinded to minimize their impact on small entities.

We have reported on the implementation of the RFA on several occasions in the past, and a recurring theme in our reports is the varying interpretation of the RFA's requirements by federal agencies. For example, in 1991, we reported that each of the four federal agencies that we reviewed had a different interpretation of key RFA provisions.[7] The report pointed out that the RFA provided neither a mechanism to enforce compliance with the act nor guidance on implementing it. We recommended that Congress consider amending the RFA to require that SBA develop criteria for whether and how federal agencies should conduct RFA analyses.

In 1994 we examined the 12 SBA annual reports on agencies' RFA compliance that had been issued since 1980.[8] The reports indicated that

[6]The agency must prepare a final regulatory flexibility analysis at the time the final rule is issued unless the agency head makes a determination that the rule will not have a significant economic impact on a substantial number of small entities.

[7]*Regulatory Flexibility Act: Inherent Weaknesses May Limit Its Usefulness for Small Governments* (GAO/HRD-91-16, Jan. 11, 1991).

[8]*Regulatory Flexibility Act: Status of Agencies' Compliance* (GAO/GGD-94-105, Apr. 27, 1994).

agencies' compliance with the RFA varied widely from one agency to another, and that some agencies' compliance varied over time. We noted that the RFA does not expressly authorize SBA to interpret key provisions of the statute, and does not require SBA to develop criteria for agencies to follow in reviewing their rules. As a result, different rulemaking agencies were interpreting the statute differently. We said that if Congress wanted to strengthen the implementation of the RFA it should consider amending the act to provide SBA with clearer authority and responsibility to interpret the RFA's provisions and require SBA to develop criteria on whether and how agencies should conduct RFA analyses.

We essentially repeated this recommendation in our 1999 report on the review requirements in section 610 of the RFA that the agencies we reviewed differed in their in their interpretation of those review requirements.[9] We said that if Congress was concerned about these varying interpretations it might wish to consider clarifying those provisions. Last year we reported on the implementation of the RFA at EPA and concluded that, although the agency had established a high threshold for what constitutes a significant economic impact, the agency's determinations were within the broad discretion that the statute allowed.[10] We again said that Congress could take action to clarify the act's requirements and help prevent concerns about how agencies are implementing the act. Earlier this year we testified on the need for congressional action in this area, noting that the promise of the RFA may never be realized until Congress or some other entity defines what a "significant economic impact" and a "substantial number of small entities mean in a rulemaking setting.[11] To date, Congress has not acted on our recommendations.

Small Business Regulatory Enforcement Fairness Act

The RFA was amended in 1996 by the Small Business Regulatory Enforcement Fairness Act (SBREFA) to, among other things, make certain agency actions under the act judicially reviewable. For example, a small entity that is adversely affected or aggrieved by an agency's determination that its final rule would not have a significant impact on small entities

[9] *Regulatory Flexibility Act: Agencies' Interpretations of Review Requirements Vary* (GAO/GGD-99-55, Apr. 2, 1999).

[10] *Regulatory Flexibility Act: Implementation in EPA Program Offices and Proposed Lead Rule* (GAO/GGD-00-193, Sept. 20, 2000).

[11] *Regulatory Flexibility Act: Key Terms Still Need to Be Clarified* (GAO-01-669T, Apr. 24, 2001).

could generally seek judicial review of that determination within 1 year of the date of the final agency action. In granting relief, a court may remand the rule to the agency or defer enforcement against small entities. SBA's Office of Advocacy noted in a report marking the 20th anniversary of the RFA that the addition of judicial review has been an incentive for agencies to comply with the act's requirements, and that small entities are not hesitant to initiate court challenges in appropriate cases.[12]

Another provision of SBREFA requires OSHA and the Environmental Protection Agency (EPA) to convene advocacy review panels before publishing an initial regulatory flexibility analysis. Specifically, the agency issuing the regulation (OSHA or EPA) must notify the SBA Chief Counsel for Advocacy and provide information on the draft rule's potential impacts on small entities and the type of small entities that might be affected. The Chief Counsel then must identify representatives of affected small entities within 15 days of the notification. SBREFA requires the panel to consist of full-time federal employees from the rulemaking agency, OIRA, and SBA's Chief Counsel for Advocacy. During the advocacy review panel process, the panel must collect the advice and recommendations of representatives of affected small entities about the potential impact of the draft rule. SBREFA also states that the panel must report on the comments received and on the panel's recommendations no later than 60 days after the panel is convened, and the panel's report must be made public as part of the rulemaking record.

In 1998 we reported on how the first five advocacy review panels were implemented, including OSHA's panel on occupational exposure to tuberculosis.[13] Agency officials and small entity representatives generally agreed that the panel process was worthwhile, providing valuable insights and opportunities for participation in the rulemaking process. However, some of the small entity representatives believed that the panels should be held earlier in the process, that the materials provided to them and the amount of time provided for their review could be improved, and that the agencies should improve the means by which they obtain comments. We noted that the trigger for the panel process is an agency's initial determination that a rule may have a significant economic impact on a

[12]U.S. Small Business Administration, *20 Years of the Regulatory Flexibility Act: Rulemaking in a Dynamic Economy* (Washington, DC, 2000).

[13]*Regulatory Reform: Implementation of the Small Business Advocacy Review Panel Requirements* (GAO/GGD-98-36, Mar. 18, 1998).

substantial number of small entities, and again recommended that Congress give some entity clear authority and responsibility to interpret the RFA's provisions.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (UMRA) is an example of a statutory requirement that appears to have had little substantive effect on agency rulemaking. For example, title II of UMRA generally requires covered federal agencies to prepare written statements containing specific information for any rule for which a proposed rule was published that includes a federal mandate that may result in the expenditure of $100 million or more in any 1 year by state, local, and tribal governments, in the aggregate, or by the private sector. The statute defined a "federal mandate" as not including conditions imposed as part of a voluntary federal program or as a condition of federal assistance.

We examined the implementation of title II of UMRA during its first 2 years and concluded that it appeared to have only limited direct impact on agencies' rulemaking actions.[14] Most of the economically significant rules promulgated during that period were not subject to the act's requirements for a variety of reasons (e.g., no proposed rule, or the mandates were a condition of federal assistance or part of a voluntary program). There were only two rules without an UMRA written statement that we believed should have had one (EPA's proposed national ambient air quality standards for ozone and particulate matter), but even in those rules we believed that the agency had satisfied the substantive UMRA written statement requirements. Also, title II contains exemptions that allowed agencies not to take certain actions if they determined that they were duplicative or not "reasonably feasible." The title also required agencies to take certain actions that they already were required to take or had completed or that were already under way.

National Environmental Policy Act

Another crosscutting rulemaking requirement of note is the National Environmental Policy Act of 1969 (NEPA). NEPA requires federal agencies to include in every recommendation or report related to "major Federal actions significantly affecting the quality of the human environment" a detailed statement on the environmental impact of the proposed action.

[14] *Unfunded Mandates: Reform Act Has Had Little Effect on Agencies' Rulemaking Actions* (GAO/GGD-98-30, Feb. 4, 1998).

According to the act and its implementing regulations developed by the Council on Environmental Quality, the statement must delineate the direct, indirect, and cumulative effects of the proposed action.[15] Agencies are also required to include in the statement (1) any adverse environmental effects that cannot be avoided should the proposal be implemented, (2) alternatives to the proposed action, (3) the relationship between local short-term uses of the environment and the maintenance and enhancement of long-term productivity, and (4) any irreversible and irretrievable commitments of resources that would be involved if the proposed action should be implemented. Before developing any such environmental impact statement, NEPA requires the responsible federal official to consult with and obtain comments of any federal agency that has jurisdiction by law or special expertise with respect to any environmental impact involved. Agencies must make copies of the statement and the comments and views of appropriate federal, state, and local agencies available to the president, the Council on Environmental Quality, and to the public. The adequacy of an agency's environmental impact statement is subject to judicial review.

Other Statutory Requirements

The crosscutting statutory requirements that I have just listed are by no means the only statutory requirements that guide agency rulemaking. Regulations generally start with an act of Congress and are the means by which statutes are implemented and specific requirements are established. The statutory basis for a regulation can vary in terms of its specificity, from very broad grants of authority that state only the general intent of the legislation to very specific requirements delineating exactly what regulatory agencies should do and how they should do it. In 1999, we issued a report that examined this issue of regulatory discretion, and we reported that in many of the cases that we examined the statutes gave the agencies little or no discretion in establishing regulatory requirements that businesses viewed as burdensome.[16] For example, we concluded that the Occupational Safety and Health Act gave OSHA no discretion in whether to hold companies (rather than individual employees) responsible for health and safety violations. Also, as other witnesses today will likely describe in detail, OSHA also follows numerous procedural and consultative steps before issuing a rule that may or may not be statutorily

[15]The NEPA regulations are codified at 40 CFR Parts 1500-1508.

[16]*Regulatory Burden: Some Agencies' Claims Regarding Lack of Rulemaking Discretion Have Merit* (GAO/GGD-99-20, Jan. 8, 1999).

driven. For example, interested parties who comment on proposed OSHA rules may request a public hearing when none has been announced in the notice. When such a hearing is requested, OSHA says it will schedule one, and will publish in advance the time and place for it in the *Federal Register*. Therefore, federal agencies must be aware of the statutory requirements underlying their regulations, and must craft rules that are consistent with those requirements.

Similarly, agency rulemaking is often significantly influenced by court decisions interpreting statutory requirements, and OSHA rulemaking is a good case in point. For example, in its 1980 "Benzene" decision, the Supreme Court ruled that, before promulgating new health standards, OSHA must demonstrate that the particular chemical to be regulated poses a "significant risk" under workplace conditions permitted by current regulations.[17] The court also said that OSHA must demonstrate that the new limit OSHA proposes will substantially reduce that risk. This decision effectively requires OSHA to evaluate the risks associated with exposure to a chemical and to determine that these risks are "significant" before issuing a standard. Other court decisions have required OSHA rulemaking to demonstrate the technical and economic feasibility of its requirements.[18]

Executive Orders/Presidential Directives

During the past 20 years, each president has issued executive orders and/or presidential directives designed to guide the federal rulemaking process, often with the goal of reducing regulatory burden. Although independent regulatory agencies are generally not covered by these requirements, they are often encouraged to follow them.

Regulatory Planning and Review

One of the most important of the current set of executive orders governing the rulemaking process is Executive Order 12866, "Regulatory Planning and Review," which was issued by President Clinton in September 1993. Under the order, non-independent regulatory agencies are required to submit their "significant" rules to OIRA before publishing them in the *Federal Register* at both the proposed and final rulemaking stages. OIRA must generally notify the agency of the results of its review of a proposed

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

[18] See, for example, *American Textile Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490 (1981) and *United Steelworkers v. Marshall*, 647 F.2d 1189 (D.C. Cir. 1980), cert. denied, 453 U.S. 913 (1981).

or final rule within 90 calendar days after the date the rule and related analyses are submitted.[19] The agencies are required to submit the text of the draft regulatory action and an assessment of the potential costs and benefits of the action to OIRA. They are required to submit a detailed economic analysis for any regulatory actions that are "economically significant" (e.g., have annual effects on the economy of $100 million or more).[20] According to the executive order, the analyses should include an assessment of the costs and benefits anticipated from the action as well as the costs and benefits of "potentially effective and reasonably feasible alternatives to the planned regulation." The order also states that, in choosing among alternatives, an agency should select those approaches that maximize net benefits and "base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation."

In January 1996, OMB issued "best practices" guidance on preparing cost-benefit analyses under the executive order. The guidance gives agencies substantial flexibility regarding how the analyses should be prepared, but also indicates that the analyses should contain certain basic elements and should be "transparent"—disclosing how the study was conducted, what assumptions were used, and the implications of plausible alternative assumptions.

At the request of Members of Congress, we have examined agencies' economic analyses both in our reviews of selected federal rules issued by multiple agencies and in the context of particular regulatory actions. In one of our reviews, we reported that some of the 20 economic analyses from five agencies that we reviewed did not incorporate all of the best practices set forth in OMB's guidance.[21] Five of the analyses did not discuss alternatives to the proposed regulatory action, and, in many cases, it was not clear why the agencies used certain assumptions. Also, five of the analyses did not discuss uncertainty associated with the agencies' estimates of benefits and/or costs, and did not document the agencies' reasons for not doing so. We recommended that OMB's best practices

[19]OIRA must complete its review within 45 days if it has previously reviewed the rule and the facts and circumstances are substantially unchanged.

[20]Similar economic analysis requirements had previously been in place under Executive Order 12291, issued by President Reagan in 1981.

[21]*Regulatory Reform: Agencies Could Improve Development, Documentation, and Clarity of Regulatory Economic Analyses* (GAO/RCED-98-142, May 26, 1998).

guidance be amended to provide that economic analyses should (1) address all of the best practices or state the agency's reason for not doing so, (2) contain an executive summary, and (3) undergo an appropriate level of internal or external peer review by independent experts. To date, OMB has not acted on our recommendations.

Executive Order 12866 also includes several other notable requirements. For example, section 5 of the order requires agencies to periodically review their existing significant regulations to determine whether they should be modified or eliminated. In March 1995, President Clinton reemphasized this requirement by directing each agency to conduct a page-by-page review of all existing regulations. In June 1995, the President announced that 16,000 pages had been eliminated from the Code of Federal Regulations. We reported on this review effort in October 1997, noting that the page elimination totals that four agencies reported did not take into account pages that had been added while the eliminations took place.[22] We also said that about 50 percent of the actions taken appeared to have no effect on the burden felt by regulated entities, would have little effect, or could increase regulatory burden.

Another part of the executive order requires agencies to prepare an agenda of all regulations under development or review and a plan describing in greater detail the most important regulatory actions that the agency expects to issue in proposed or final form in the next fiscal year or thereafter. The order also requires agencies to identify for the public in a complete, clear, and simple manner the substantive changes that are made to rules while under review at OIRA and, separately, the changes made at the suggestion or recommendation of OIRA. In January 1998 we reported on the implementation of this requirement, and concluded that the four agencies we reviewed had complete documentation available to the public of these changes for only about one-quarter of the 122 regulatory actions that we reviewed.[23] OSHA had complete documentation available for one of its three regulatory actions, but the information was contained in files separate from the public rulemaking docket to ensure that it did not become part of the official rulemaking record and, therefore, subject to litigation.

[22] *Regulatory Reform: Agencies' Efforts to Eliminate and Revise Rules Yield Mixed Results* (GAO/GGD-98-3, Oct. 2, 1997).

[23] *Regulatory Reform: Changes Made to Agencies' Rules Are Not Always Clearly Documented* (GAO/GGD-98-31, Jan. 8, 1998).

Federalism Executive Order

Executive Order 12612 on "Federalism," issued by President Reagan in 1987, was similar to the RFA in that it gave federal agencies broad discretion to determine the applicability of its requirements. The executive order required the head of each federal agency to designate an official to be responsible for determining which proposed policies (including regulations) had "sufficient federalism implications" to warrant preparation of a federalism assessment. If the designated official determined that such an assessment was required, it had to accompany any proposed or final rule submitted to OMB for review.

We examined the preambles of more than 11,000 final rules that federal agencies issued between April 1996 and December 1998 to determine how often they mentioned the executive order and how often the agencies indicated that they had prepared a federalism assessment.[24] Our work indicated that Executive Order 12612 had relatively little visible effect on federal agencies' rulemaking actions during this time frame. The preambles to only 5 of the more than 11,000 rules indicated that the agencies had conducted a federalism assessment.

Most of these rules were technical or administrative in nature, but 117 were economically significant rules. However, the agencies prepared a federalism assessment for only one of these economically significant rules. The lack of assessments for these rules is particularly surprising given that the agencies had previously indicated that 37 of the rules would affect state and local governments, and said that 21 of them would preempt state and local laws in the event of a conflict.

Federal agencies had broad discretion under Executive Order 12612 to determine whether a proposed policy has "sufficient" federalism implications to warrant the preparation of a federalism assessment. Some agencies have clearly used that discretion to establish an extremely high threshold. For example, in order for an EPA rule to require a federalism assessment, the agency's guidance said that the rule must, among other things, have an "institutional" effect on the states (not just a financial effect), and affect all or most of the states in a direct, causal manner. Under these standards, an EPA regulation that has a substantial financial

[24] *Federalism: Previous Initiatives Have Had Little Effect on Agency Rulemaking* (GAO/T-GGD-99-31, June 30, 1999).

effect on all states, but does not affect the "institutional" role of the states, would not require a federalism assessment.

Executive Order 12612 was revoked by President Clinton's Executive Order 13132 on "Federalism," which was issued August 4, 1999, and took effect on November 2, 1999. Like the old executive order, the new order provides agencies with substantial flexibility to determine which of their actions have "federalism implications" and, therefore, when they should prepare a "federalism summary impact statement."

Other Executive Orders and Directives

Non-independent regulatory agencies are also covered by an array of other executive orders and presidential directives or memoranda. These executive requirements include:

- Executive Order 13175, which requires consultation and coordination with Indian tribal governments. Agencies submitting final rules to OIRA under Executive Order 12866 must certify that this order's requirements were "met in a meaningful and timely manner."
- Executive Order 12988 on civil justice reform, which generally requires agencies to review existing and new regulations to ensure that they comply with specific requirements (e.g., "eliminate drafting errors and ambiguity" and "provide a clear legal standard for affected conduct") to improve regulatory drafting in order to minimize litigation.
- Executive Order 12630 on constitutionally protected property rights, which says each agency "shall be guided by" certain principles when formulating or implementing policies that have "takings" implications. For example, the order says that private property should be taken only for "real and substantial threats," and "be no greater than is necessary."
- Executive Order 12898 on environmental justice, which says (among other things) that each agency must develop a strategy that identifies and addresses disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low income populations. It also says that agencies should identify rules that should be revised to meet the objectives of the order.
- Executive Order 13045 on protection of children from environmental health risks and safety risks. The order says that for any substantive rulemaking action that is likely to result in an economically significant rule that concerns an environmental health risk or safety risk that may disproportionately affect children, the agency must provide OIRA (1) an evaluation of the environmental or safety effects on children and (2) an explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives.

- Executive Order 12889 on the North American Free Trade Agreement, which generally requires agencies subject to the APA to provide at least a 75-day comment period for any "proposed Federal technical regulation or any Federal sanitary or phytosanitary measure of general application."
- Various presidential memoranda or directives. For example, a March 4, 1995, presidential memorandum directed agencies to, among other things, focus their regulatory programs on results not process and expand their use of negotiated rulemaking. A June 1, 1998, presidential directive required agencies to use plain language in proposed and final rulemaking documents.

Congressional Review Act

One statutory requirement that I did not mention previously but that can clearly affect agency rulemaking is the Congressional Review Act (CRA), which was included as part of SBREFA in 1996. Under the CRA, before a final rule can become effective it must be filed with Congress and GAO. If OIRA considers the rule to be "major" (e.g., has a $100 million impact on the economy), the agency must delay its effective date by 60 days after the date of publication in the *Federal Register* or submission to Congress and GAO, whichever is later. Within 60 legislative or session days, a Member of Congress can introduce a resolution of disapproval that, if adopted by both Houses and signed by the president, can nullify the agency's rule.

GAO's major role under CRA is to provide Congress with a report on each major rule concerning GAO's assessment of the issuing agency's compliance with the procedural steps required by the various acts and executive orders governing the rulemaking process. Our report must be sent to the congressional committees of jurisdiction within 15 calendar days, so our review is limited to a description of the issuing agency's rulemaking actions.[25] We also collect basic information about the nonmajor rules that agencies issue. Information about both major and nonmajor rules is available on our web site *(www.gao.gov)*. As of last

[25]Last year, Congress gave GAO a new and more substantive regulatory oversight responsibility through passage of the Truth in Regulating Act of 2000 (TIRA). Under TIRA, the chairman or ranking member of any committee of jurisdiction can request an in-depth review of the agency's estimate of a proposed or final economically significant rule's costs and benefits, an analysis of the alternatives that the agency considered, and the agency's compliance with relevant procedural and analytical requirements. Federal agencies are required to "promptly cooperate" with GAO in carrying out the act. However, TIRA established a 3-year pilot project that became effective upon the specific annual appropriation of $5.2 million (or the prorated portion thereof). To date, Congress has not provided that appropriation.

week, GAO had received more than 22,000 rules since the CRA took effect in March 1996, of which nearly 350 have been considered major under the act. OSHA had issued only 28 rules since March 1996, of which 6 were major rules.

Although the CRA has only a modest direct impact on regulatory agencies' rulemaking processes, Congress' use of the statute to disapprove rules may have a decided indirect impact on how other rulemaking requirements are implemented. To date, Congress has used its disapproval power only one time—the disapproval of OSHA's ergonomics standard earlier this year.

Mr. Chairman, this completes my prepared statement. I would be pleased to answer any questions.

APPENDIX D - WRITTEN STATEMENT OF FRANK WHITE, VICE PRESIDENT, ORGANIZATION RESOURCES COUNSELORS, INC., WASHINGTON, D.C.

STATEMENT OF
FRANK A. WHITE
VICE PRESIDENT
ORGANIZATION RESOURCES COUNSELORS, INC.

BEFORE THE

SUBCOMMITTEE ON WORKFORCE PROTECTIONS
COMMITTEE ON EDUCATION AND THE WORKFORCE
U.S. HOUSE OF REPRESENTATIVES

June 14, 2001

Mr. Chairman and Members of the Subcommittee:

I want to sincerely thank the Chairman and the Committee for their invitation. I am extremely pleased to appear today, in a bipartisan spirit, to discuss the Occupational Safety and Health Administration's (OSHA's) rulemaking process and what might be done to make it more credible and effective as OSHA enters its fourth decade. I congratulate the Committee for recognizing the importance of this vexing issue to the future success of OSHA and for addressing it forthrightly and early in the 107th Congress.

I will try to bring a balanced perspective to this inquiry, first based on my current work for Organization Resources Counselors, Inc. (ORC), a business organization that for almost 30 years has been involved in virtually every significant OSHA rulemaking, during which time it has been ORC's mission to provide constructive and specific input on the agency's standards. In addition, I will try to provide the viewpoint of someone who for more than a decade during the 1970's and 1980's had as a primary responsibility at the Labor Department as both lawyer and administrator the development of safety and health regulations first for the Mine Safety and Health Administration and then for OSHA.

I would first observe that in enacting the Occupational Safety and Health Act (the "Act"), as well as the Mine Safety and Health Act, Congress established criteria for standards-setting that were intentionally designed to "stack the deck" in favor of optimizing worker protection, such as allowing most uncertainties involving matters of science and policy to be resolved in favor of a more protective standard, subject to considerations of "feasibility," itself a narrowly drawn limitation. In addition, the courts have generally deferred to OSHA's policy and scientific judgments as long as the agency demonstrates that it has analyzed all of the relevant evidence in the rulemaking record and has provided plausible explanations for the choices and judgments it makes. And, indeed, OSHA has largely succeeded in issuing and defending the kinds of protective standards that Congress envisioned, resulting in

many cases in landmark protections for workers on a wide array of serious health and safety risks, from asbestos, lead, arsenic and cotton dust to grain handling, confined spaces and lockout of hazardous energy sources. Virtually all of these and other far-reaching OSHA standards were controversial and the rulemaking process has always been adversarial, frequently including years of litigation. However, for the most part, I believe that OSHA's standards over the years have delivered the kinds of protections that Congress contemplated.

At the same time, it is also true that in recent years the rulemaking process has become even more contentious and laden with hostility and rancor than in years past. The process has become even more cumbersome and time-consuming, almost to the point of complete stagnation. The problems, however, are not solely ones of timeliness, but also, increasingly, are related to the credibility of both the process and the product.

As a way of beginning to assess what factors have contributed to this heightened concern about the rulemaking process and what improvements might be considered, let me make two observations that on the surface might appear to be rather obvious and noncontroversial but that in reality are at the heart of the dilemma we are addressing here today. In order to reach some consensus on the problems and the solutions, it might be useful to understand and explore these two assertions.

> *First, issuing safety and health standards is an essential function of OSHA under the Act;*
>
> *Second, a balance must be struck between the speed with which standards are issued by OSHA and the need for the agency to assure open and full participation of the parties affected by a standard, full consideration of the available evidence and full compliance with applicable legal obligations.*

Let's talk about Point 1. Although it is certainly true as a general proposition that the issuance of safety and health standards is one of OSHA's most important obligations, it has been clearly established under the Act that the Secretary of Labor and through her, OSHA, have not quite limitless -- but certainly very broad -- authority to determine which issues it chooses to address through rulemaking, and in what order and pace to address them. And while it is also settled that once the choice is made to initiate rulemaking on a particular subject, OSHA cannot "unreasonably" delay action, even here much deference is given to the Secretary's plausible explanations for delays that may often extend for years. It has been the regular and predictable practice of OSHA administrators, whose average tenure is roughly two and a half years each, to identify new priorities for rulemaking and to delay or halt action altogether on rulemakings already in the pipeline.

The point is that the choice to address safety and health issues through rulemaking is essentially a policy determination over which agency leadership has broad discretion. As often as not, what may be perceived by some as inefficiency or sluggishness or poor management of the OSHA rulemaking process may have as much to do with the

express or tacit choices of agency leadership at a particular point in time not to act or to delay action or to re-prioritize actions. A close examination of many of the OSHA standards that have taken the longest to issue will reveal that somewhere during the course of the rulemaking, changes in priorities, resource allocation, political leadership and philosophy, etc., had much to do with the cumulative delay. While these factors will forever remain "facts of life" at OSHA and other agencies, we may be able to look for ways, a few of which are discussed further below, to reduce their undesirable impact.

On to Point 2 -- balancing the need to complete a rulemaking in a timely manner against the need for full participation of affected parties and full consideration of the record. Embedded in this fairly straightforward principle are the sources of many of the more controllable, unintentional factors that result in rulemaking delays. This principle also controls the issue of the perceived fairness and credibility of both the process and the product. At the outset, it is necessary to recognize and acknowledge how extraordinarily complex, demanding and encumbered the OSHA rulemaking process has become. In reviewing the June 2000 Report of the National Advisory Committee on Occupational Safety and Health (NACOSH) on OSHA=s Standard Development Process, I noted that OSHA identified over 100 major steps to the process. Although I do not have a copy of that list, I have every reason to believe that only a very few of the steps themselves could be considered optional or dispensable and that they all could to be said to serve legitimate legal and policy purposes.

It is also important to recognize that a great many, perhaps the vast majority of requirements related to the OSHA rulemaking process, are not even within the authority of OSHA to control or alter. Even revisions to the Occupational Safety and Health Act itself would leave unaffected many of these requirements. A host of other statutory mandates, e.g., the Regulatory Flexibility Act, the Small Business Regulatory Enforcement Fairness Act, the Paperwork Reduction Act, as well as Executive Branch requirements for Regulatory Analyses and review must be followed during the rulemaking process. In addition, more than twenty years of court-made law require OSHA to undertake the kinds of extensive analyses of the rulemaking records that result in preambles of 300 page or more to OSHA rules. In many cases, OSHA would compromise its legal positions on important issues by cutting back on its seemingly interminable preamble explanations.

In a process with this many interconnected steps and with the vast number of scientific, policy and other decisions that must be made in order to produce first a proposed rule and then a final rule, it should not come as a surprise that the opportunities for slippage and inefficiencies are myriad. In addition, there are several layers of review that many of these decisions, as well as the written product itself, must go through before the rule emerges. In the Department of Labor alone, a rulemaking document drafted by OSHA standards-writers must undergo review, at a minimum, by staff and officials in the Office of the Solicitor, the Office of the Assistant Secretary for OSHA and the Assistant Secretary for Policy, followed by extensive review by the Office of Management and Budget. At each of these stages, critical decisions related to science, economics, policy and law may be revisited and modified, frequently more than once.

As has been mentioned, the problems associated with these multi-layered demands of the rulemaking process do not affect merely the speed and efficiency with which standards are developed; they also relate to the credibility of the process itself and of the resulting product.

With this background, I would like to offer a few possible starting points for improvement of OSHA's rulemaking process that may, at least in part, assist in improving both its credibility and timeliness. There are at least six key general stages of the process in which improvements should be evaluated. The six areas are: (1) Determining the agency's rulemaking priorities; (2) Initiation of the rulemaking process and collection of the evidence through public comment and hearings; (3) Evaluating the evidence in the rulemaking record; (4) Making the necessary scientific and policy decisions; (5) Writing the standard; and (6) "Rolling out" and "follow up" of the standard. Each of these areas could be the subject of separate congressional hearings, but I will attempt to highlight a few recommendations that could lead to improvements in each phase.

> (1) Determining Priorities: This is an area of perennial weakness for OSHA. The historical lack of any credible, rational priority-setting process or criteria for determining which safety and health issues should be addressed through standards-setting has allowed OSHA to shift its priorities "on a dime" with virtually no accountability whatsoever except to reassure the advocates of whichever project gets slid to the back burner. As indicated, the law sanctions such shifts in priorities by providing broad discretion and deference to the agency. While OSHA has in the past, most notably once in the late 1970's and again in the early 1990's, tried unsuccessfully to develop a rational process, it needs to try again.
>
> I would suggest using a model similar to that used by the National Institute for Occupational Safety and Health in developing its National Occupational Research Agenda (NORA). This was a process that involved the participation of a wide spectrum of agency stakeholders not only in the initial priority-selection phase, but in the ongoing development of those priorities and in the execution of the resulting research activities themselves. It is this ongoing stakeholder participation in the process that was missing from the failed prioritization effort by OSHA in 1994. To be sure, there are hurdles to adapting this type of approach to priority-setting for OSHA rulemaking, and it would not prevent arbitrary priority-shifting in future years. In addition, it would be important to agree on some criteria for evaluating the priority candidate list. However, with sufficient "buy-in" and ongoing involvement by the stakeholder community, it could generate a measure of bipartisan support and congressional endorsement (as NORA has) that might, in turn, result in

more continuity across administrations and in more accountability for change.

(2) Initiation of Rulemaking and Collection of Evidence: These are critical steps in the process and mishandling them frequently gets OSHA off on the wrong foot, at least as far as the affected stakeholders are concerned. OSHA has historically "initiated" rulemaking in several ways, e.g., issuance of Advance Notices of Proposed Rulemaking (ANPRs), issuance of Proposed Rules (NPRs), establishment of advisory committees, conducting stakeholder meetings and informal issuance of draft proposals or "concepts." While there is no "best" or "right" way to proceed, I agree with NACOSH that, in general, ANPRs should be discouraged. I also believe that the issuance of "pre-proposal drafts" can be a useful device for receiving early input. In the past, MSHA has used this approach successfully.

Up to now, I do not believe that the stakeholder meetings that OSHA has held in conjunction with some of its rulemakings have been as effective as they might have been. They may even have been counterproductive in the sense that there was a widespread perception that although they were undertaken in good faith, they amounted to little more than "window-dressing" because there was no effective mechanism for follow-up with and feedback to the stakeholders, i.e., no real sense that OSHA actually heard and acted on the input. I believe that pre-proposal stakeholder input can be valuable if there is a more robust process that includes such feedback and follow-up.

With respect to the issue of information collection during the rulemaking process itself through public comment and hearings, OSHA has, in general, a well-developed, highly-structured process for assuring full public input. Although questions have recently arisen in the context of the ergonomics proceedings about whether some parties had an equal opportunity to present evidence and about OSHA's witness preparation activities, I would argue that over the years, OSHA has put in place an information gathering process that is fair and thorough. Frankly, when compared to MSHA's less structured and formalistic process, arising out of nearly identical statutory provisions, OSHA appears to bend over backwards to assure "due process." However, now may be a good time for OSHA to reexamine some of these procedures to see whether and how they might be adjusted both to enhance efficiency and fairness.

There is one area of information collection that I would like to address briefly and that is the gathering of economic and feasibility data. This has been an area of perennial weakness for the agency from an industry perspective. OSHA's traditional use of contractors who conduct telephone surveys of a sample of employers as a primary data-collection source almost never yields adequate or accurate economic information. To be fair, industry is often not forthcoming about such data, and there are opportunities during the rulemaking to supplement the record. However, this is an issue that affects the credibility of the process and one that needs to be addressed.

(3),(4),(5)Evaluating the Evidence; Making Scientific and Policy Decisions; Writing the Standard: I will discuss these three intertwined but distinct "internal" steps in the process together, because it is here that collectively OSHA can make the greatest strides in terms of improving the timeliness of the rulemaking process. There is surely no panacea, because OSHA has struggled for many years with trying to make the analytical, decision-making and writing phases of the rulemaking process more efficient.

Like a successful safety and health program, the key to making the rulemaking process work internally is "management commitment and leadership." There must be a clear focus and commitment to "getting the job done" that begins at the very top of the agency. It is ultimately the agency head that must drive the process and make the critical policy choices. But even OSHA leaders that have had the "will" to move forward have allowed the process to become bogged down, in my opinion because of a few key factors.

First, OSHA leadership must understand both the rulemaking process itself and the nature of and criteria for making the critical policy decisions that must be made. That is not to say that the head of OSHA must personally be an expert in the intricacies of OSHA rulemaking, but he or she must have a deputy (someone with authority at the most senior level in the immediate "front office") who does understand OSHA rulemaking and whose primary responsibility is to drive the process.

Second, there must be a clearly defined process, again driven from the Assistant Secretary's office, that (a) allows top officials to know at all times where the process for each significant rule stands and (b) contains a well-understood and mandatory procedure for issue resolution. Too often, the

internal process gets bogged down because of staff or inter-office conflicts about issues. Briefings and meetings between the standards team and OSHA leadership should be regular and frequent in order to assure that there is a common understanding of where the process stands, what the next steps are and where the bottlenecks are occurring.

Another area that has drawn recent attention is the lack of a formalized "peer review" method as a part of the OSHA rulemaking process in order to examine the agency's scientific analysis of the evidence and the conclusions that it reaches about the science. It is true that the courts have almost uniformly upheld OSHA's scientific judgments and, as OSHA has claimed, the rulemaking process itself allows for a robust form of peer review. However, it may be time for the agency to consider the potential benefits to the credibility of the process and to its conclusions that establishing a peer review process could bring, especially on those issues that OSHA is addressing with greater regularity where the science is still evolving and the uncertainties are greatest.

One of the most overlooked but vitally important areas of the rulemaking process is that of the drafting of the standard itself and the accompanying preamble. The combination of skills required to be a successful standards-writer would intimidate even a James Joyce, although *Ulysses* may be a less challenging "read" than some of OSHA's standards. The need to be thorough in reviewing the evidence and at the same time precise, clear and succinct is a daunting responsibility. OSHA needs to do a better job in two areas: First, it needs to focus more effort on assuring that its standards staff have the necessary sophisticated writing skills that are necessary to avoid the need -- often entailing enormous investments of time and effort -- to rewrite and heavily edit portions of OSHA rules by more senior staff, often more than once. Second, the internal standards review process should rely less on "sequential" supervisory reviews and be more "vertical" in nature, involving some supervisory involvement during the drafting phase itself. This would apply both to OSHA and Office of the Solicitor review. This is easier said than done, but a comprehensive, clearly defined internal process, referenced above, should incorporate this concept.

(6) Roll Out and Follow Up: To understate the case, this stage of the rulemaking process offers a great deal of opportunity for improvement. I would argue that this is the area in which OSHA has simply "dropped the ball" on a regular basis. By that I mean that the agency has done very little, in a strategic

and proactive way, to truly prepare the affected public for the implementation of its new standards. From a philosophical standpoint, especially in an era in which there is increasing societal and political skepticism about relying primarily on regulatory approaches to solving problems, particularly with respect to broad and complex issues such as those OSHA increasingly confronts, it would seem apparent that the issuance of a new standard should be a part of a broader strategy of assistance and outreach and training and public information. Yet, it is barely and exaggeration to say that OSHA does very little of any of those important adjuncts to a new standard, and even more rarely does it in a timely manner. Compliance directives, training material and other guidance and information simply must be issued concurrently with the standard itself and OSHA must devote resources to the necessary outreach activities prior to the effective date of a new standard. The standard should be viewed as one part of an overall effort to address the covered hazard. This is one area where OSHA leadership will be the critical factor in making a change of this magnitude happen. The other significant deficit at this "back end" of the rulemaking process is the almost uniform failure of OSHA to evaluate the effectiveness of a new standard, an essential step in assuring that the protections of the standard are actually being delivered to the workers in the manner anticipated.

This concludes my prepared remarks. I want to again thank the Committee for this opportunity and would be pleased to respond to your questions.

APPENDIX E - WRITTEN STATEMENT OF HENRY CHAJET, ESQ., PARTNER, PATTON BOGGS, LLP, WASHINGTON, D.C.

WRITTEN TESTIMONY|
BEFORE THE UNITED STATES HOUSE OF REPRESENTATIVES
COMMITTEE ON EDUCATION AND THE WORKFORCE
SUBCOMMITTEE ON WORKFORCE PROTECTIONS
By

HENRY CHAJET, ESQ.
PATTON BOGGS LLP

WASHINGTON, DC
June 14, 2001

I. Introduction

Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to present testimony on the safety and health rulemaking process, a system that is broken and in need of reform. I reach this conclusion from the perspective of a partner at the law firm of Patton Boggs LLP, representing employers in safety and health matters since 1978, and with fifteen years of teaching experience as an Associate Professor of Safety and Health Law at the Johns Hopkins University Graduate School of Public Health. On behalf of hundreds of companies and major trade associations, I have participated in dozens of rulemaking proceedings, and represented industry clients in seven regulatory challenges in the United States Circuit Courts of Appeal, and literally thousands of enforcement actions for regulatory violations. My law practice includes regulatory counseling, crisis management, dispute resolution, and litigation at the trial and appellate levels. I have also had the privilege of working with this Subcommittee in years past to identify potential safety and health statutory and procedural improvements and serving on Congressman Paul Henry's Task Group for Safety Law Reform. I believe that Mr. Henry would be gratified that his commitment to achieving employee protections through sound law and public policy is being carried forward by this Congress.

While numerous problems have caused the deterioration of the rulemaking process, my focus today is the one of greatest concern to me and the one with the easiest achievable public policy solution. Rules and standards mandated by the federal government, or relied on or used by the federal agencies, should be the result of a transparent, open process. This process should provide meaningful input to the affected parties, prohibit conflicts of interest by those engaged in writing the rules, and be subject to the due process protections of the law and the oversight of our elected representatives. The OSHA and MSHA use of, and reliance on, declarations of hazards and standards not subject to meaningful private sector input or public accountability, in my opinion constitutes illegal rulemaking, a misuse of taxpayers dollars, and a conflict of interest that should be prohibited. OSHA and MSHA do this through groups such as the American of Governmental Industrial Hygienists (ACGIH), in private sessions, under the leadership of federal employees who have enforcement or rulemaking government

duties.

II. ACGIH – CREATED AND CONTROLLED BY FEDERAL OFFICIALS

Mr. Chairman, a renowned leader of ACGIH put the potential problem created by governmental "private" organizations best when, referring to ACGIH, he stated:

> An organization of this sort can very often accomplish things which an organization of more official character is unable to do, because of certain limitations imposed upon official organizations. . . . [An unofficial organization] very often makes statements and takes action on matters which [an official organization] would not dare to do, even though the same people are talking.

ACGIH was created in 1938 by employees of the Public Health Service, funded under the Social Security Act. *See generally* Jacqueline Karnell Corn, *Protecting the Health of Workers: The American Conference of Governmental Industrial Hygienists 1938-1988* (ACGIH 1989). The federal role in ACGIH continues today with U.S. Department of Labor and the U.S. Department of Health and Human Services personnel chairing and holding seats on the ACGIH Board and key ACGIH committees. Board members include two OSHA officials and two HHS officials. The current TLV committee has three DOL and HHS officials as voting members, all of whom have related responsibilities in their day-to-day federal jobs.

Threshold Limit Values (TLVs) have been published annually since 1946, and are credited with advancing the cause of employee health and safety by institutionalizing the concept that numerical exposure limits can be developed and used to protect workers, long before OSHA, MSHA and NIOSH were created. Today, there are TLVs for more than 700 chemical substances and physical agents, as well as fifty Biological Exposure Indices for selected chemicals. TLVs are adopted and used by governments around the world. The ACGIH even carries out its own foreign policy by working with other countries and governments towards "harmonization" of standards.

The ACGIH name and the TLV trademark are recognized and respected around the world, based on a fifty year history of advancing the health protection of the workforce. However, this well earned respect has been abused over the last decade, and ACGIH has risked its reputation and the institution itself by failing to solve significant structural problems that permit abuses of its power. The federal government contributes to these problems through the involvement of its personnel and its reliance and use of ACGIH TLVs.

It is an established fact that federal agency officials charged with developing, using, and enforcing government standards, develop ACGIH TLVs in their so-called "volunteer" ACGIH role, often while being paid by the federal government for ACGIH dedicated time and expenses, and while intermingling agency materials and opinions in

closed ACGIH deliberations. Although the ACGIH has several thousand members, the TLV process is controlled by a small group of non-elected people. A number of these individuals are federal employees. Some of these officials have stayed in key TLV committee positions for a decade or more and some for their entire careers. Others have selected their successors or been hired directly by ACGIH after their federal retirement, through an appointment process controlled by the existing leadership.

A new or proposed TLV is generally developed and documented by one person, acting independently on behalf of the TLV Committee and its Subcommittees. All TLV proposals are adopted in mass by the Board of Directors of the ACGIH, based upon recommendations of its committees. Board members readily acknowledge that, due to the amount of materials presented at Board meetings, they rely on the committees and subcommittees.

Previously, TLVs were voted on by the entire ACGIH membership at an open meeting permitting discussion. However, this practice has been eliminated in favor of a faster and more convenient process. While speed and convenience have been realized, transparency and reasoned decision-making have been sacrificed.

Yet TLVs are not widgets and based on the reputation they carry and their critical impact, they should be sound scientific determinations. Everyone should agree that TLVs should be carefully reviewed by experts and the process by which they are adopted should be transparent. After all, a defective TLV can either cause worker harm, if it is not a safe level, or industry dislocations and economic disaster for the communities and companies that produce a product improperly labeled as "hazardous."

The subcommittees that develop ACGIH TLVs assign the analysis of the scientific literature to one person to determine if a TLV is needed or if changes to an existing TLV are justified. There are no criteria published for making this crucial determination. There is no outside peer review by experts of the TLV proposal or the documentation that underlies it. Nor is there a public hearing for the recommendation to permit open discussion. While there is a generous one year opportunity for written comments on a proposed TLV, the opportunity for in person scientific discussions and presentations to the TLV Subcommittee and Committee, which at one time was routinely available, has been prohibited in recent years.

Recommendations for TLV adoption are formed by the TLV Subcommittees in closed session. There are no minutes of the meetings, and the documents and scientific evidence considered or rejected at the meetings are not revealed. Even the names of the members of the TLV Subcommittees are undisclosed. While our governmental institutions and professional organizations have become more open, the TLV process has grown more secretive and insular. At the same time, the number of chemicals and materials for analysis has grown along with the complexity of scientific determinations.

Yet, ACGIH funding for outside assistance and internal staff and technical resources for TLV development is severely limited, and the TLV process is hampered by a resource shortage. One recent TLV Committee chairman resigned due to the lack of

resources available for the development of sound TLVs. Unfortunately, an attempt by the leaders of the industrial hygiene professional community to cure the ACGIH problem, through the merger of ACGIH and the larger, more open American Industrial Hygiene Association, failed for many reasons, including the perceived desire of the TLV Committee to maintain closed sessions and government personnel control, described by some as "independence" and by me as illegal rulemaking.

IV. AGENCY USE, RELIANCE, AND ENFORCEMENT OF ACGIH TLVS

TLVs have been and are utilized by DOL (OSHA and MSHA) and HHS in many ways. First, HHS research agencies (*e.g.* NIOSH) routinely use TLVs as reference and as definitions of safe exposure levels. OSHA will enforce an ACGIH TLV for a substance under the General Duty Clause if there is no substance-specific OSHA standard (PEL) or if the ACGIH TLV is perceived as more protective. Some OSHA regulations require a TLV for a substance to be adhered to if there is no applicable OSHA-developed, substance-specific standard. OSHA regulations also adopt specific TLVs or TLV lists, promulgated in the year the regulation was adopted. Additionally, MSHA has acknowledged that it enforces ACGIH TLVs.

OSHA and MSHA have frequently utilized ACGIH TLVs to support new regulations and regulatory proposals and to give credibility to their regulations, actions and proposals. In fact, rarely has a new rule been proposed or promulgated without a supporting reference to the ACGIH TLV addressing the substance at issue. Both the massive OSHA PEL update project (still pending) and the corresponding MSHA TLV update project (pending) admitted their near complete reliance on the ACGIH TLVs for hundreds of substances in the original proposed rules.

OSHA and MSHA have directly incorporated the latest edition of the ACGIH TLVs into their generic training and hazard communication regulations. OSHA's Hazard Communication Standard requires that employers treat chemicals listed in the latest ACGIH TLV Booklet as "hazardous chemicals." MSHA's recently published Interim Final Rule entitled "Hazard Communication," also adopts by reference current and future ACGIH TLV lists. Thus, a single ACGIH action, if not reversed or prevented, could subject a vital U.S industry to a "hazardous substance" designation and new mandates that did not undergo any public scrutiny or MSHA or OSHA rulemaking.

Although ACGIH prints statements indicating that their TLVs are not intended to be used as regulatory standards, the ACGIH leadership, and its members, including the OSHA, MSHA, and NIOSH officials who vote on them, know full well that they are being used for that very purpose. A NIOSH official, who served as chairman of the ACGIH TLV committee for many years, wrote that the adoption by OSHA of some 400 TLVs in the early 1970s resulted in "the great satisfaction of the TLV committee members."

V. Diesel Exhaust and Trona: Examples of ACGIH and Rulemaking Problems

In 2001, ACGIH published in its TLV Booklet a proposed TLV for respirable diesel exhaust as elemental carbon of 0.02 mg/m^3 (milligrams per cubic meter of air). The

proposal was published as a "Notice of Intended Change." The booklet lists the reason for the proposed TLV as "cancer" and "lung" effects and with a notation that ACGIH considers diesel exhaust to be a suspected human carcinogen. The ACGIH originally published a proposed TLV for diesel exhaust as particulate less than one micrometer in the1999 and 2000 TLV Booklets. Those proposals listed a TLV of 0.05 mg/m^3 and the reason for the proposals as "cancer." The notation that ACGIH considered diesel exhaust to be a suspected human carcinogen was also included in the 1999 and 2000 proposals.

MSHA recently published a final rule on diesel particulate matter exposure of underground metal and nonmetal miners. 66 Fed. Reg. 5706 (January 19, 2001). The final rule includes "interim" and "final" concentration limits for total carbon as a surrogate for diesel particulate matter (dpm). Similar to ACGIH, the interim concentration limit for total carbon is equivalent to approximately 0.5 mg/m^3 of dpm, and the final limit is equivalent to approximately 0.2 mg/m^3 of dpm.

Remarkably, one federal official TLV Committee member did not consider it to be a conflict to be charged with developing the ACGIH diesel standard and also the MSHA diesel rule, intermingling the materials, and using government funds and time to support his ACGIH activities. In fact, the last Administration recommended him for a commendation for his diesel rulemaking efforts. This official has stated that there are no federal conflict of interest policies that address his dual role.

Another example of the ACGIH problem is the proposed trona TLV. Trona is a mineral found in deposits left behind by the evaporation of ancient water bodies. Trona is mined from the earth and processed to produce pure sodium sesquicarbonate, sodium carbonate (commonly known as soda ash) and/or sodium bicarbonate (commonly known as baking soda). It is principally mined in southwestern Wyoming and used throughout the Untied States.

Trona and its products are used in, among other things, commercial and household cleaners, animal feed, and baking soda. Sodium carbonate (soda ash) is used in the production of common consumer products, chemicals, and industrial materials, including glass, paper, detergents, cleaners, and water treatment supplies. Chemical producers use soda ash to manufacture products that sweeten foods and beverages (corn sweeteners) and improve foods and toiletries.

In 1999, 2000, and again in 2001 (as a result of court action that prevented final adoption), ACGIH published in its TLV Booklet for dissemination around the world a proposed TLV for respirable trona of 0.5 mg/m^3 (milligrams per cubic meter of air). The proposal was published as a "Notice of Intended Change." The proposed 0.5 mg/m^3 TLV is six times below (stricter than) the existing ACGIH TLV (for respirable nuisance dust) and ten times below the regulatory limits for respirable dust enforced by DOL in trona mines. The booklets list the reason for the proposed change as "irritation" and "pulmonary function," regardless of a NIOSH health study that found no decrease in lung function by employees exposed to high levels of dust over ten years in the 1970s.

In 1999, because the ACGIH acknowledged severe limitations of the evidence used to propose the trona TLV, ACGIH requested documentation concerning the health effects of trona from the industry. Information from animal toxicity studies and a literature search was provided to ACGIH which further demonstrated trona's lack of toxicity, even beyond that found by NIOSH. Notwithstanding the industry's cooperation, ACGIH repeatedly refused to permit the trona industry to make a scientific presentation to the TLV subcommittee that could have resulted in an open discussion and pointed out the fallacy of the TLV proposal, even though they acknowledged that the ACGIH evidence to support the TLV was "weak" and "flawed."

ACGIH, however, in conversations and correspondence, encouraged the trona producers to plan, fund, and perform a study of potential health effects, through the ACGIH TLV Subcommittee Chairman, an OSHA official, who agreed to wait to adopt a new TLV if the industry would conduct a study. The trona industry agreed and expended substantial sums of money to pursue the effort.

The ACGIH TLV Subcommittee then breached its agreement with the trona industry to wait for the pending study. The TLV Subcommittee Chairman reported at the end of October, 2000 that it had finalized its TLV recommendation to the ACGIH Board for adoption at its December 9, 2000 meeting and that it would be futile for the trona industry to try to overcome this recommendation.

In a November 14, 2000 letter to ACGIH, the industry again pointed out the lack of any scientific basis for the proposal, the ongoing study and prior agreement, and asked that ACGIH refrain from voting on the trona proposal at the December 9, 2000 meeting. ACGIH never responded to the letter, necessitating a lawsuit to prevent adoption of the flawed TLV.

Left with no other recourse, the industry sought a temporary restraining order to prevent the December 9 ACGIH Board vote. In a stipulation and agreement approved by the Court on December 4, 2000, ACGIH agreed to defer adopting the trona TLV until October 27, 2001. The permanent injunction and product defamation case is in the discovery phase, and a trial is expected in October. The Departments of Labor and Health and Human services are also defendants, due to Federal Advisory Committee Act violations.

VI. THE LACK OF TRANSPARENCY IN RULEMAKING MUST BE REMEDIED

A fundamental tenet of administrative rulemaking is transparency. The federal utilization of TLVs (and perhaps other, non consensus standards such as the designations of International Agency on Research on Cancer--IARC), which are promulgated in secret, under the leadership of federal employees, with unknown agendas and overlapping job duties, violates this fundamental tenet and should be stopped.

VII. THE FEDERAL ADVISORY COMMITTEE ACT IS THE SOLUTION

Mr. Chairman, I believe that given its current and historical role in influencing federal policies and regulations ACGIH serves as a *de facto* advisory committee to DOL and HHS within the meaning of the Federal Advisory Committee Act (FACA). However, it has never complied with the requirements of that Act. ACGIH is, therefore, under the provisions of FACA, without authority to meet or to perform such advisory committee functions, and DOL and HHS are prohibited from using or relying on ACGIH products. In its wisdom, Congress passed FACA to establish procedures for advisory committees. These procedures were designed to give credibility to government actions which rely on advisory committees and to make the process open and transparent.

New substance specific TLVs that have not been adopted by OSHA or MSHA rulemaking, or developed with FACA protections, should not be utilized in any way by DOL and HHS. Similarly, the incorporation by reference provisions of pending regulations should be suspended. Finally, until the ACGIH process is reformed, DOL and HHS should be prohibited from using or relying on any new ACGIH TLV not already incorporated by substance specific standards and from using federal funds to support ACGIH.

Furthermore, a new Federal Occupational Health Advisory Committee for the development of health standards for OSHA and MSHA could be created, in compliance with FACA, and ACGIH and AIHA could form the core of the professional contributions while work with industry and labor to provide the basis for expedited and sound development of new federal standards.

Unlike many other reforms to safety and health law that may be needed, no amendments nor new statutory provisions are needed to cure this serious problem. The law is already in existence to stop what amounts to clandestine, closed, private rulemaking. A reformed ACGIH, together with the rest of the industrial hygiene professional community, can continue to play a vital role in the protection of employees around the world. I urge the Congress and the Administration to work together to bring openness and transparency to the process by which DOL and HHS utilize ACGIH TLVs. A reformed process will restore ACGIH to its honored position and permit its membership to help preserve our nation's leadership in worker protection.

Thank you Mr. Chairman and Members. I look forward to working with you to help improve the safety and health regulatory system.

APPENDIX F - WRITTEN STATEMENT OF WILLIS J. GOLDSMITH, ESQ., PARTNER, JONES, DAY, REAVIS & POGUE, WASHINGTON, D.C.

TESTIMONY
ON THE OCCUPATIONAL SAFETY AND HEALTH ACT'S
RULEMAKING PROCEDURES
BEFORE
THE SUBCOMMITTEE ON WORKFORCE PROTECTIONS
OF THE
COMMITTEE ON EDUCATION AND THE WORKFORCE
OF THE UNITED STATES HOUSE OF REPRESENTATIVES
BY
WILLIS J. GOLDSMITH

JUNE 14, 2001

Good morning, Chairman Norwood and Members of the Subcommittee. My name is Willis Goldsmith. I am a partner in the law firm of Jones, Day, Reavis & Pogue, an international firm with approximately 1,300 lawyers in over 25 offices around the world, and Chair of the Firm's labor & employment law practice. I am pleased and honored to be here today to testify on the Occupational Safety and Health Administration's ("OSHA" or "Agency") rulemaking procedures; this is an important topic affecting industry, labor organizations, and the American workforce.

The Occupational Safety and Health Act of 1970, 29 U.S.C. §§ 651-678 (2000) (the "Act") contains procedures mandating public input into all proposed occupational safety and health standards. These procedures have been in place for decades and numerous law review articles and critiques have been written about them. Because it is such a comprehensive topic, and due to time constraints, the scope of my testimony is necessarily limited; my comments today will focus on what I have observed to be the two primary flaws in the OSHA rulemaking process, and on potential solutions to those problems.

By way of my background in the area, for over twenty-five years I have advised employers regarding their obligations under the Act, and have litigated cases under the statute. In addition, I have often written and lectured on the Act and related topics, including serving as one of four Associate Editors of *Occupational Safety and Health Law* (Bureau of National Affairs 1988), a treatise on the OSH Act prepared by the Labor and Employment Law Section of the American Bar Association through its Committee on Occupational Safety and Health. I have also taught a course on occupational safety and health law as an Adjunct Professor in the Graduate Program at the Georgetown University Law Center. With respect to OSHA rulemaking, I was lead counsel lead counsel for the U.S. Chamber of Commerce in OSHA's most recent rulemaking on its Ergonomics Program Standard. I also serve as a member of the Chamber's Labor Policy Committee. Finally, in July 1996 I testified regarding OSHA's use of directives and interpretations (as opposed to rulemaking) before Senator Bond's Committee on Small Business regarding the Small Business Regulatory Enforcement Fairness Act of 1996 ("SBREFA"), and in April 2000 I

testified on behalf of the U.S. Chamber of Commerce regarding the procedural infirmities in OSHA's ergonomics rulemaking before the Committee's Subcommittee on Oversight and Investigations. My experience has, I believe, provided me with insight as to how OSHA conducts itself in rulemaking proceedings, and of the positive and negative aspects of the substantive and procedural requirements governing that process.

The point of my testimony today is a simple but important one. OSHA's rulemaking process is broken. It has become so politicized over the past several decades that stakeholders on all sides have lost confidence in the Agency's ability to thoroughly and objectively review evidence, promulgate responsible standards with clear requirements, and to enforce those standards fairly and even-handedly. Much of the process occurs in secret, and without the opportunity for public input. And, finally, the process is far too slow — every standard takes years, and may take more than a decade, to promulgate, during which time employers are left to guess at what OSHA believes to be the best approach to protecting their employees, and therefore at what legal requirements are in effect, while employees are left without Agency guidance regarding safety and health improvements.

I. OVERVIEW OF THE OSH ACT'S RULEMAKING PROCESS

A. Standard Setting Under Section 6 of the OSH Act

The Occupational Safety and Health Act of 1970 ("Act") was signed into law on December 29, 1970 to "assure so far as possible every working man and woman in the Nation safe and healthful working conditions . . ." 29 U.S.C. § 651(b) (2000). Section 6 of the Act gives OSHA the authority to promulgate safety and health standards, and sets forth the procedures for doing so. OSHA is permitted to promulgate enforceable standards necessary to provide for safe and healthful workplaces, 29 U.S.C. §§ 655(b); 652(8) (2000), and may also issue emergency temporary standards to protect employees from grave danger. 29 U.S.C. § 655(c) (2000).

Although the Act undoubtedly gives OSHA broad regulatory authority, it also sets forth specific procedural and substantive criteria that the Agency's rules and rulemaking process must meet. Specifically, in promulgating standards, the Act requires OSHA to employ a hybrid form of rulemaking. The Act provides for publication in the Federal Register and the opportunity for written comment on any rule proposed by the Agency, it also specifically permits "any interested person" to "file with the Secretary written objections to the proposed rule" and to "request[] a public hearing on such objections." 29 U.S.C. § 655(b)(2), (3) (2000). If a public hearing is requested, the Act requires the Agency to respond by "specifying a time and place for such hearing." 29 U.S.C. § 655(b)(3). OSHA's regulations implementing these provisions recognize that the Agency must "provide more than the bare essentials of informal rulemaking," 29 C.F.R. § 1911.15(b), and that, in particular, because "fairness may require an opportunity for cross-examination on crucial issues," 29 C.F.R. § 1911.15(a)(3), "[t]he presiding officer *shall* provide an opportunity for cross-examination" on such issues. 29 C.F.R. § 1911.15(b)(2) (emphasis added).

Using these established rulemaking procedures, OSHA enacts two broad categories of standards: health standards, which generally cover latent, long-term risks such as occupational exposure to carcinogens, and safety standards, which typically address physical workplace hazards such as appropriate machine guarding. Based on the record generated by the Agency in a rulemaking hearing, in enacting a standard, OSHA must ultimately "show, on the basis of substantial evidence, the need for the challenged regulation." *Asbestos Information Association/North America v. Reich*, 117 F.3d 891, 893 (5th Cir. 1997) (citing *Industrial Union Dept., AFL-CIO v. American Petroleum Institute*, 448 U.S. 607, 653 (1980) ("*Benzene*")); *AFL-CIO v. OSHA*, 965 F.2d 962, 973 (11th Cir. 1992) ("*AFL-CIO*") ("OSHA ultimately bears the burden of proving by substantial evidence that such a risk exists and that the proposed standard is necessary") (citation omitted). To demonstrate the need for the regulation, the Agency must establish a number of facts based upon the record as a whole:

> (1) there must be a "significant risk of material harm" in the workplace. *Benzene*, 448 U.S. at 641-42; *see also* 29 U.S.C. § 655(b)(5) (limiting standards to those that assure that no employee "will suffer material impairment of health or functional capacity even if such employee has regular exposure");
>
> (2) the proposed standard must substantially reduce or eliminate that risk, *Benzene*, 448 U.S. at 641-42;
>
> (3) the proposed standard must be both technologically and economically feasible, *American Textile Mfrs. Institute, Inc. v. Donovan*, 452 U.S. 490, 513, n.31 (1981) ("*Cotton Dust*");
>
> (4) the proposed standard must be the most cost-effective means to substantially reduce or eliminate the risk, *id.*, at 514, n.32; and
>
> (5) the proposed standard must avoid other problems, such as unconstitutional vagueness, *Kropp Forge Co. v. Secretary of Labor*, 657 F.2d 119, 122 (7th Cir. 1981), or excessively broad discretion constituting an unconstitutional delegation of legislative power,

Benzene, 448 U.S. at 645-46;
International Union, UAW v. OSHA,
938 F.2d 1310 (D.C. Cir. 1991)
("*LOTO I*").

In addition to establishing these specific facts, Section 6(b)(5) of the Act requires the Agency, in establishing any health standard, to set a specific standard, rather than simply to list a series of vague measures and require employers to utilize those measures to achieve a prescribed outcome. Moreover, Section 6(b)(5) requires that this standard be set "on the basis of the best available evidence" and mandates that '[d] evelopment of standards under this subsection *shall be* based upon research, demonstrations, experiments, and such other information as may be appropriate," as well as "the latest available scientific data in the field." 29 U.S.C. § 655(b)(5) (emphasis added). In doing so, "Congress provided that OSHA regulate on the basis of knowledge rather than on the unknown." *American Petroleum Institute v. OSHA*, 581 F.2d 493, 504 (5th Cir. 1978), *aff'd sub. nom. Industrial Union Dept., AFL-CIO v. American Petroleum Institute,* 448 U.S. 607 (1980). This requires, among other things, that the Agency take into account the latest available scientific studies. *See Texas Indep. Ginners Ass'n v. Marshall,* 630 F.2d 396, 412, n.48 (5th Cir. 1980). Moreover, in choosing among studies reaching contrary results, OSHA does *not* have discretion to discount studies of "higher quality than those relied upon by the Secretary." *National Grain & Feed Ass'n v. OSHA*, 866 F.2d 717, 740 (5th Cir. 1989). Thus, although OSHA may operate on the "frontiers of scientific knowledge," *Public Citizen Health Research Group v. Tyson*, 796 F.2d 1479, 1486 (D.C. Cir. 1986), it may not go beyond.

In addition to these statutory requirements, the Agency must satisfy certain other criteria prior to promulgating a final standard. President Clinton issued Executive Order 12,866 in 1993, which requires OSHA to quantify and compare the costs and benefits of proposed standards and other available, feasible regulatory alternatives. The Small Business Regulatory Enforcement Fairness Act ("SBREFA") requires OSHA to provide Congress with a detailed analysis of each new standard for review, and requires the Agency to consider the effect any new rule may have on small businesses. The Unfunded Mandates Reform Act of 1995 requires the Agency to assess the impact of a standard on private sector employees and determine whether it imposes any "unfunded mandates" on state, local, or tribal governments. OSHA must also prepare an environmental impact statement for new regulations. And, finally, the Regulatory Flexibility Act requires OSHA to calculate compliance costs for small businesses and to determine whether any would be competitively disadvantaged by the new regulation.

A reviewing court will determine whether the Agency has satisfied these statutory and constitutional requirements, and established the need for the proposed rule, based on "substantial evidence" when the record is considered "as a whole." 29 U.S.C. § 655(f) (2000); *see also American Iron & Steel Inst. v. OSHA*, 182 F.3d 1261, 1267 (11th Cir. 1999); *Asbestos Information Ass'n/North America*, 117 F.3d at 893; *Industrial Union Dep't, AFL-CIO v. Hodgson*, 499 F.2d 467, 472 n.11 (D.C. Cir. 1974). Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to

support a conclusion." *Cotton Dust*, 452 U.S. at 522-23 (citation omitted); *American Iron & Steel Inst.*, 182 F.3d at 1267 (citation omitted). In considering the record "as a whole," a reviewing court will "take into account not just evidence that supports the agency's decision, but also countervailing evidence." *AFL-CIO*, 965 F.2d at 970. Although the courts will not decide the issues considered by the Agency *de novo*, *see id.*, it will determine whether OSHA has acted reasonably on the record before it. *See id.*; *Asbestos Information Ass'n/North America v. OSHA*, 727 F.2d 415, 421 (5th Cir. 1984).

B. Performance Standards and Specification Standards

In its efforts to establish standards governing different types of workplace hazards — i.e. health hazards and safety hazards — the Agency has typically drafted two different types of standards: "specification" standards and "performance" standards. In general terms, specification standards set forth either specific steps that an employer must implement to improve workplace safety and health, as permitted by Section 6(b)(7) of the Act, or set a specific goal, such as a permissible exposure limit for a given carcinogen, that an employer must achieve. The employer is often given a wide range of options, such as work practice, administrative, and/or engineering controls in order to achieve the established goal, and compliance with the standard is measured based upon whether the employer has, for example, reduced exposures to a level at or below the permissible exposure limit. Specification standards have most often been used in the health standards area, although there are certain safety standards that fall into this category — i.e. those governing ladder heights and ladder rung distance requirements. It is usually rather simple for employers and OSHA to determine whether or not an employer has complied with a specification standard, because there is an objective test, such as a specific, measurable distance or exposure limit, against which an employer's performance may be judged. On the other hand, specification standards provide little flexibility for employers who for whatever reason cannot comply with them to the letter; generally employers who cannot comply are left to pursue the rather cumbersome process of obtaining a formal variance to the standard or to remain non-compliant and hope that they do not get cited.

Performance standards are vastly different, and provide far more latitude in determining compliance objectives. These standards usually require an employer to take certain broad-based steps to improve safety and health, such as to "analyze" chemical processes and control chemical hazards (process safety management), or to analyze various job tasks and create procedures to prevent employees from being exposed to unexpected energization of equipment (lockout/tagout). Performance standards leave the details of compliance to the employer, who determines, for example, the type of analysis to be performed, the level of detail necessary, and the control measures that are appropriate. Obviously, these standards provide added flexibility to employers seeking to improve workplace safety and health, and are more easily applied in a wider variety of settings. However, that flexibility comes at a price: employers are often unable to judge whether and to what extent they have achieved compliance with a given standard until OSHA inspects the workplace. And OSHA's vast enforcement discretion with regard to these standards makes consistent enforcement nearly impossible.

In an ideal world, true performance standards, where employers are allowed to develop a sensible compliance plan and OSHA truly defers to an employer's reasonable exercise of discretion in doing so, are better for everyone. They are easier to draft, cover more situations, and give discretion to employers to tailor the standards to individual workplaces. However, in the real world there are a number of enforcement related issues that make performance standards suspect. Because the Agency has so much discretion in determining compliance, and because the measure of compliance is subjective, rather than objective, employers often have no way of knowing in advance whether or not their compliance plan will be deemed sufficient by the compliance officer who arrives at their door. Moreover, enforcement of performance standards can be — and, in my experience, often is — uneven; the vague terminology used in these standards allows OSHA and organized labor to target individual employers for stringent enforcement and to allow other employers to get by with a much more lenient program.

OSHA's efforts to alleviate this latter problem have only made things worse. The Agency drafts compliance directives for use by compliance personnel in enforcing various performance standards. However, as a practical matter, these compliance directives — which are not subject to the rulemaking provisions of the Act — impose additional substantive requirements upon employers, and often transform what was intended to be a performance standard into the equivalent of a specification standard, but without the benefit of notice and comment rulemaking on the specification issues.

II. FUNDAMENTAL FLAWS IN OSHA'S RULEMAKING PROCESS

As it stands now, there are two primary flaws in OSHA's rulemaking process upon which there should be little disagreement: the process is driven primarily by political concerns, and it is far too slow. In the end, both of these problems combine to create a situation that serves no one — not industry, not labor, and certainly not the health and safety of the American workforce, which is OSHA's primary objective.

A. OSHA Rulemaking Has Become Too Political

The U.S. system of government is such that, to some degree, all government actions are political; politicization is not necessarily bad, and is most certainly inevitable. However, it is important to recognize that politicization of the OSHA rulemaking process can at times be destructive, and thereby seriously undermine OSHA's ability to achieve its mandate. Moreover, an overtly political process diminishes stakeholder trust in the Agency, and therefore decreases stakeholder support for the Agency's actions. Over the last several decades of OSHA's existence, this failure of trust has occurred within both the management community and within organized labor, as OSHA personnel have changed from administration to administration. Stakeholder disenchantment with the process further increases as the process becomes less transparent, with Agency deliberations and decision-making occurring in private, rather than in the open.

Although this hearing is not about ergonomics, or OSHA's recent ergonomics

rulemaking, the experience in that rulemaking provides an apt example of how off track the process can get when it is overly politicized; after all, there can be no serious debate that the ergonomics rulemaking was perhaps the most politically-driven in OSHA's history and that, in the end, it was a colossal failure.

That the ergonomics rulemaking process was designed merely to achieve a political objective, rather than to consider seriously the myriad scientific and practical issues underlying the regulation, was apparent from the day immediately before Thanksgiving in 1999 when OSHA published its 300-page proposal in the Federal Register, and provided barely two months — later extended to three — for interested parties to digest an comment upon the massive, controversial proposal. Then, ignoring the text and the intent of its own rulemaking regulations, the Agency scheduled the public hearing to begin only 11 days after the close of the comment period, during which thousands of pages of comments from nearly 7,000 individuals and organizations were received. It scheduled more than 30 OSHA witnesses, including both Agency personnel and the crucial ergonomics "experts" testifying on its behalf, for the very first days of the hearing, thus affording the public virtually no time to prepare to cross-examine these individuals. This situation was greatly exacerbated by the Agency's inexplicable failure to identify its 29 proffered experts, who submitted more than 500 pages of written testimony, until less than two weeks before the hearing, and accompanying failure to disclose the names of the nine OSHA personnel who appeared, including two staff ergonomists and the Agency's lead economist on this project, until the very morning their testimony began. Participants were also given only minuscule amounts of time for cross-examination of witnesses, including the Agency's primary experts upon whose work much of the proposal was based.

Stakeholder concerns regarding OSHA's conduct of the ergonomics rulemaking were further exacerbated by OSHA's use of outside experts and consultants during the process. Although OSHA can — and in many cases should — utilize properly selected, objective experts from outside the Agency to assist with its analysis of particular issues, this should be done only with full disclosure to stakeholders regarding the identity of the outside experts, their qualifications, their fees, and their role in the process. OSHA's "hide-the-ball" approach to using consultants in the ergonomics rulemaking — and its use of consultants with a financial stake in the outcome of the rulemaking — only exacerbated stakeholder distrust of an already highly suspect process.

In the end, the ergonomics rulemaking illustrates why there are no winners when safety and health issues become polarized and politicized. The Agency's conduct of the ergonomics rulemaking — which Secretary Herman made clear from the first day of the hearings was designed to "mak[e] an ergonomics standard a reality" before the end of the Clinton Administration, seemingly irrespective of the record or the consequences — led to such disenchantment with the process and such a fundamental failure to explore the real issues underlying ergonomics regulation that Congress was forced to step in and invalidate a regulation in which the Agency had invested millions of taxpayer dollars, and sent OSHA back to square one in developing an ergonomics regulation.

B. OSHA's Rulemaking Process is Far Too Slow

In its entire 30 year history, OSHA has promulgated approximately 45 safety standards and approximately 30 health standards, many of which cover only a single industry, such as construction. On average, therefore, the federal Agency with sole responsibility for ensuring the safety and health of all workers in all American workplaces has managed to promulgate fewer than three standards per year. And, virtually without exception, the standards that have been promulgated have taken years to wend their way through the process from advance notice or notice of proposed rulemaking to final, enforceable rule. In recent years, this process has routinely taken more than a decade. For example, OSHA's methylene chloride standard, promulgated in 1997, took 11 years to complete; the respiratory protection standard, promulgated in 1998, took 16 years, and the confined space standard, promulgated in 1993, took an astonishing 18 years from advance notice of proposed rulemaking to final rule.

In recent years, in an effort to speed up its rulemaking process with respect to relatively simple, non-controversial rules, OSHA has developed a negotiated rulemaking scheme. However, as it turns out this process is little better from a timing perspective. For example, the first safety standard that was the product of a negotiated rulemaking — OSHA's recently promulgated standard for steel erection in the construction industry, which is a relatively simple, straightforward issue affecting a single industry — took seven years from start to finish. Many participants complained about OSHA's lack of involvement in the process and failure to provide clear direction and timetables to which the committee could adhere.

Finally, most standards that are promulgated are challenged, at least in part, in the Courts of Appeals by one or more parties, further delaying their effective date. As an example, before it was repealed by the Congressional Review Act, the Agency's highly controversial ergonomics standard was challenged in the Court of Appeals by dozens of separate parties, representing both industry and labor interests. These challenges are not always avoidable, of course, but increased stakeholder confidence in OSHA's rulemaking process could go a long way towards reducing the number and scope of such suits.

III. POSSIBLE SOLUTIONS

The key to improving OSHA's rulemaking process is to make it both quicker and less politically driven. While there may be many different ways to accomplish these objectives, a few suggestions follow.

A. Standard Setting as an Independent Agency Outside DOL and OSHA

During the Act's development, there was significant debate in Congress regarding how to structure the Act and, in particular, sharp debate over whether the Agency's enforcement and standard-setting functions should be placed within the Department of Labor or within an entirely independent agency. Before the final act was passed,

Congress debated over two versions of it; the primary difference between the two bills was the methods that each proposed for administering and enforcing legislation. Stephen A. Bokat & Horace A. Thompson III eds., Occupational Safety and Health Law, 41 (1988). The Williams bill, which was supported by organized labor, would have housed the three key functions of rulemaking, enforcement, and adjudication in the Department of Labor. S. 2193, 91st Cong. §§ 6, 7, 8, 10 (1969), *reprinted in Legislative History of the Occupational Safety and Health Act of 1970*, at 11-13, 16 (hereinafter *Legislative History*). Under this system, the Secretary of Labor would have developed the safety and health standards and issued them pursuant to informal rulemaking procedures, Department of Labor inspectors would have investigated alleged violations, and administrative law judges in the Department of Labor would have conducted hearings for adjudicating penalties and abatement orders. *Id.* at 42.

The substitute bill, however, which was supported by the Administration, sought to establish a separate agency or board to promulgate all safety and health standards, and a second separate agency or commission to adjudicate the enforcement cases. H.R. 19200, 91st Cong. § 6, 8, 10, 11 (1970), *reprinted in Legislative History*, at 989, 991. The supporters of the Administration's bill criticized the other bill for placing all power and authority in the hands of the Secretary of Labor, arguing that the concentration of power "raises the spectre of abuse" because "a single man is easier to harass than an independent standards board or quasi-judicial panel." *See Legislative History*, supra at 201. Also, this concentration of power would make the person subject to intense political pressure to act a certain way. *Id.* For these reasons, the proponents of the Administration's bill argued that the bill should provide for an independent standards-setting board composed of five members, and an independent commission to review enforcement orders; all members of both groups were to be appointed by the President. *Id.*; *see also*, Bokat, *supra* at 42.

The debate between labor and the Administration over the two bills resulted in a crisis that threatened the survival of the legislation. And although the Administration's proposal for an independent standards-setting board ultimately failed, it served as an important bargaining chip by which Congressional Republicans agreed to place authority for issuing and enforcing the standards with the Secretary instead of an independent entity, so long as the final bill provided for an independent Review Commission to adjudicate enforcement cases brought before it. *See* Bokat, *supra* at 43.

It is time to revisit the idea of create an independent standard setting board for OSHA. Depending upon how such a board was formulated, it could minimize the impact that political concerns are able to have upon occupational safety and health regulations. As suggested in the Act's legislative history, an individual "is easier to harass than an independent standards board or quasi-judicial panel," *see Legislative History*, *supra* at 201, thus increasing the potential for politicization and abuse. A five-member standards-setting board, as was originally proposed when the Act was drafted, could alleviate, though not eliminate, some of these concerns by bringing more objectivity to the process, which would in turn increase stakeholder trust and confidence. Other federal agencies have a similar structure. For example, the Consumer Products Safety Commission is an independent agency made up of three members appointed by the President which must have members from both political parties, and all rulemaking

activities must be approved by a majority vote of the commission. While the specific make-up and performance of this agency is beyond the scope of my expertise, its existence underscores the fact that such a structure is possible.

B. Incorporate Concepts of Peer Review to Ensure that All OSHA Rules Have a Sound Scientific Basis

OSHA has often been criticized for failing to analyze the scientific evidence underlying a problem thoroughly and objectively. Obviously the most recent, and most vehement, criticisms of OSHA in this regard occurred in connection with its ergonomics rulemaking, wherein the Agency hired consultants with a financial stake in the outcome of a final standard to analyze complex scientific and medical information and, many believe, ignored a number of significant variables regarding the potential causes of musculoskeletal disorders.

One way to alleviate criticisms of the Agency's failure thoroughly and objectively to analyze the complex scientific and medical data that is often central to OSHA rulemaking is to arrange for all controversial scientific issues to be examined by an objective, independent group of individuals qualified in the relevant field. Other federal agencies routinely engage in peer review prior to regulating; for example, before the Consumer Product Safety Commission regulates chronic chemical hazards, they consult a chronic hazard advisory panel nominated by the National Academy of Sciences. Moreover, it is my understanding that in the past two years, EPA has begun performing peer reviews prior to promulgating all regulations. Again, while the specific performance of these agencies is beyond my expertise or experience, the existence of such peer review models in other agencies plainly indicates that the concept is an accepted one. However, the key to the success of any such "peer review" process is two-fold: the selection process must be carefully circumscribed so that only truly qualified, independent individuals are selected, and those individuals must be given clear guidance as to the standards that they are to use to evaluate the evidence before them. Without such protections, peer review could be reduced to yet another politicized step in a process that often seems designed from the start to reach a pre-ordained conclusion.

With regard to selection of individuals, certain points are obvious. Those selected should be truly independent, without any financial or other stake in the outcome of OSHA's rulemaking efforts. Moreover, the individuals must be qualified, by relevant training or experience, in the area in which they are to give opinions. And there must be clear time limits placed upon the process during which the individuals selected review and analyze the evidence and report on their conclusions (with a dissent, if necessary). The Agency's role in such a process would be to provide those performing the peer review with a clear list of issues to be analyzed, with all information and data gathered by the Agency, and with appropriate resources to conduct independent searches for additional information if necessary.

In addition, any individual participating in a "peer review" process should be provided

with some clear standard by which to judge scientific evidence. (For its part, the Agency should always be held to some standard in judging evidence as well.) The OSH Act currently provides no real standard by which to judge the Agency's evaluation of scientific evidence. For health standards, the statute simply requires OSHA to rely upon the "best available evidence," which could be read to include reliance on very little, or very poor, evidence so long as it is the "best available." For safety standards, the Act contains virtually no guidance at all as to the level of evidence necessary to justify a regulation. The fact that the Agency has the authority to impose massive, costly regulations upon all of industry that affect millions of employees only highlights the importance of ensuring that these regulations are based upon sound science.

One possible way to impose standards upon the Agency where none presently exist is to incorporate a standard such as the one governing scientific evidence in the federal courts, as enunciated by the Supreme Court in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). The *Daubert* standard requires trial courts to evaluate scientific theories to determine whether they are "reliable" scientific evidence. This analysis depends upon a theory or technique's ability to satisfy a number of factors, including (1) whether the theory or technique enjoys general acceptance within the scientific community; (2) whether the methodology has been subjected to peer review and publication; (3) whether the methodology has been tested; (4) whether the theory or methodology has a known or potential error rate, and, if so, what that rate is; and (5) whether there are standards controlling the technique's operation and, if so, whether those standards have been followed. *Id.* at 592-94. This standard has been used successfully by the federal courts in evaluating scientific evidence for years, and provides a useful model for determining whether or not scientific evidence is, at bottom, "reliable."

Another possible way in which OSHA's vast discretion to set health and safety standards could be circumscribed is to require that all OSHA standards be justified on a cost-benefit basis. This would essentially permit the Agency to promulgate only those rules that will efficiently improve workplace health and safety. Suffice it to say that any measures, whether these or others, that would increase efficiency of OSHA regulations and ensure that they are based upon sound science would greatly increase stakeholder confidence in the process and substantially improve the Agency's credibility.

C. Better Defined Rules/Processes

Whether OSHA rulemaking continues to occur under the Act as presently structured, or whether Congress chooses to amend the Act's rulemaking provisions in certain respects, one thing that will certainly facilitate quicker, fairer rulemaking is to promulgate and enforce clear, objective rules to govern the process, and to designate an independent entity to enforce those rules. In the judicial process, the various rules governing discovery and trial procedures are designed to provide for fair, even-handed treatment of all involved parties. While the Agency should not be expected to conduct a full trial on the merits of every issue in every rulemaking, it is evident that more rules, and more objective rules, would significantly improve the process.

To be sure, there are provisions of the OSH Act that govern the rulemaking process, and the Agency has promulgated regulations relevant to the process as well. The content of these regulations is discussed in more detail in Section I, *supra*. Unfortunately those regulations are far too vague, and therefore provide OSHA with far too much discretion to manipulate the process for political reasons.

The ergonomics rulemaking again provides an apt example. Although the Agency's regulations governing rulemaking expressly provide that hearing participants "shall be provided an opportunity for cross-examination" on "crucial issues," OSHA effectively circumvented this process by compressing the time periods available for witness questioning to the point where any meaningful exploration of the issues, much less "cross-examination" was rendered impossible. For example, during the first six and a half days of the public hearings, and only during those days, OSHA offered over three dozen experts, outside consultants, and Agency personnel to testify and to answer questions. During the first two days, when OSHA personnel testified, hearing participants received only a brief questioning period — spread out over 15 or 20 minute segments — totaling under ten minutes per witness. During the four and a half days that OSHA offered its 29 outside consultants, the situation was little better. Although these consultants submitted more than 500 pages of written testimony on subjects ranging from medicine to engineering to economics to workers' compensation law, the Agency allowed only four and a half days for their testimony. For the first two days of consultant testimony, participants were given only ten minutes of questioning per panel of 3-4 consultants, which amounted to little more than *2-3 minutes per proffered expert*. While OSHA expanded that time in the following two and a half days, it still allowed no more than 10-15 minutes per proffered expert. Moreover, when OSHA offered a panel of experts from NIOSH, on whose 600-page report and analysis it heavily relies, it gave industry *as a whole* under two hours for cross-examination, or again less than 15 minutes per witness. While, as I have noted, nobody expects the Agency to conduct a full trial on the merits of the issues raised by any rulemaking, it is nonetheless clear that such brief question-and-answer sessions do not even come close to the "cross-examination" on undeniably "crucial issues" that OSHA's current regulations require. Promulgating clear rules providing for meaningful cross-examination and an opportunity for all participants to have their views heard and considered, and to explore the views of other participants, would help to prevent the Agency from manipulating the process to achieve its own politically-motivated objectives.

Strengthening these procedural rules is only part of what should be done to increase fairness in the process. In addition, there should be an independent, objective individual or entity available to enforce the rules, to provide for exceptions to them where necessary, and to ensure fairness. OSHA's rulemaking procedures already provide for such a person; typically, an administrative law judge presides over rulemaking hearings to ensure orderly collection of the record. However, as the Act and its regulations are currently structured, the administrative law judge does very little; in essence, he or she is permitted only to allocate time in the manner directed by the Agency, and to number exhibits as directed by the Agency. Providing this judge with more authority to act as a real judge and therefore to interpret and apply procedural rules, deviate from them as the circumstances warrant, and even-handedly

monitor the proceedings, without interference from the Agency, would greatly improve the process by ensuring that all participants were treated fairly. And, by taking these issues out of the hands of the Agency, the potential for politicization decreases and the potential exists to increase stakeholder trust in the process.

Thank you again for this opportunity to present my views to the Subcommittee.

APPENDIX G - WRITTEN STATEMENT OF MARGARET SEMINARIO, DIRECTOR, DEPARTMENT OF OCCUPATIONAL SAFETY AND HEALTH, AFL-CIO, WASHINGTON, D.C.

Testimony of Margaret Seminario, Director
AFL-CIO Department of Occupational Safety and Health
Before the
House Committee on Employment and Education,
Subcommittee on Workforce Protection on
OSHA's Standard Setting Process

June 14, 2001

Mr. Chairman and members of the Committee, I appreciate the opportunity to testify today on the Occupational Safety and Health Administration's standard setting process.

The AFL-CIO has a deep and long-standing interest and involvement in standard setting under the Occupational Safety and Health Act. We were key participants in the debate on the Occupational Safety and Health Act and its standard setting process in 1970. Since the Act's passage we have continually sought the adoption of standards to address serious workplace hazards, and have participated in almost all of OSHA's major rulemakings. During my 24 years with the AFL-CIO, I personally have participated in more than 20 rulemakings, including those on benzene, beryllium, lead, cancer policy, hazard communication, hearing conservation, formaldehyde, asbestos, air contaminants, respiratory protection, grain handling, hazardous waste operations, and ergonomics.

Since 1986, I have also served as a member of the National Advisory Committee on Occupational Safety and Health (NACOSH) providing advice to both the Secretary of Labor and Secretary of Health and Human Services on the OSHA and NIOSH programs. Last year, as a member of NACOSH, I participated in an extensive review of the OSHA's standard setting process that was requested by then OSHA Assistant Secretary Charles Jeffress, and contributed to the report on the OSHA Standards Development Process issued by the committee in June 2000.

Based upon my experience, I'd like to offer the following observations, comments and views on OSHA standards and their development, and recommendations for how the process can be improved to provide needed protection to workers in a more timely manner.

1. OSHA safety and health standards have been very effective at reducing hazardous exposures and work-related injuries, illnesses, and fatalities.

While during its 30-year history OSHA has issued only a relatively small number of standards, those that have been promulgated have been effective. OSHA standards have significantly reduced exposure to major occupational health hazards including exposures to asbestos, benzene, lead and formaldehyde and the diseases associated with these exposures. For example, in1978 when OSHA's cotton dust standard was adopted, 12 percent of textile workers suffered byssinosis. A 2000 evaluation of the

standard conducted by OSHA found that the prevalence rate for byssinosis in the textile industry has been reduced to less than one percent. Similarly in the 25 years prior to the issuance of OSHA's grain handling standard, there were 434 grain elevator explosions resulting in 776 injuries and 209 deaths. After the standard was issued, grain explosions and fatalities declined dramatically, from a high of 65 in 1977 to an average of just one fatality a year until 1997 and 1998 when there was a jump in explosions and fatalities as some employers' compliance with the standard became lax.

Prior to the issuance of OSHA's confined space entry standard 1993, there were 234 fatalities resulting from oxygen deficiency or toxic substance exposures in confined spaces identified from a sample of 20,000 industrial accident reports from 1974-1997. In 1999, according to the BLS Census of Fatal Occupational Injuries (CFOI), there were 23 deaths in confined space incidents, a number of these death were in construction where the confined space entry standard does not apply.

OSHA standards have also led to greater overall safety and health awareness and enhanced safety and health capabilities and efforts at the workplace. Even though most standards have addressed individual hazards, their issuance has often spurred broader safety and health activities and recognition. For example, OSHA's 1975 coke oven standard and 1978 cotton dust standard resulted in the development of programs, hiring of professionals and training in the steel industry and textile industry and enhanced safety and health programs in the unions in these sectors. Standards on ethylene oxide and blood borne pathogens spurred the development of broader and more comprehensive safety and health efforts in the health care industry. Thus, the positive impact of individual standards has been much greater than addressing the individual hazards they were designed to control.

2. Compliance with OSHA standards has proven to be feasible and in many cases at costs much lower than originally estimated by OSHA. Employer claims of infeasibility of standard and astronomical costs have proved to be false.

In setting standards, OSHA is required to consider both the technological and economical feasibility of the regulation. For virtually every major standard, employers have claimed that compliance with the proposed or final rule was not feasible or that the costs were excessive and in some cases would shut down many operations in an industry. For example, chemical manufacturers claimed that OSHA's vinyl chloride standard would shut down parts of the chemical and plastics industry. Textile employers claimed that OSHA's cotton dust standard would cost $2.3 billion and result in plant closures. Likewise, the grain industry claimed that OSHA's grain handling standard would result in the closure of all small grain elevators. However, none of these claims or projections was borne out.

In fact, in the case of vinyl chloride, measures to control exposures led to improvements in the process which resulted in increased profits. Similarly OSHA's cotton dust standard spurred investments in new technology which made the U.S. textile industry more productive and more competitive. The actual cost to comply with the cotton dust standard is estimated to have been about one-third of OSHA's predicted cost of $280.3 million annually.

An in-depth retrospective on the cost and feasibility of OSHA's standard conducted by the Congressional Office of Technology Assessment (OTA) in 1995 found that OSHA correctly judged the technological feasibility for seven of eight of the standards evaluated and correctly judged the economic feasibility for six of the eight. In fact for a number of the standards, OTA determined that OSHA had significantly overestimated actual compliance costs, usually because employers developed new technologies or found substitutes that cost much less than predicted control measures.

OTA found that the actual costs of control were far lower than those predicted by industry, which usually were based on unrealistic assumptions, inflated estimates and failed to take intro account process improvements and other efficiencies gained through experience, not to mention the benefits of reduced injuries and illnesses.

Unfortunately, industry practice of manufacturing wildly inflated cost estimates of rules continues as we saw more recently in the case of OSHA ergonomics rule, where exaggerated cost estimates were generated as part of employers' propaganda campaign against the rule.

3. While OSHA standards have been controversial and challenged in court, most have been upheld. In fact, in numerous cases, OSHA has been ordered by reviewing courts to strengthen or expand rules.

Over the 30-year history of OSHA, the vast majority of standards issued by the agency have been subject to challenge by employers and/or by unions. Employers have generally challenged rules on grounds that available evidence failed to demonstrate a significant risk or that required measures were too costly or not feasible. Union challenges have sought to have rules strengthened on grounds that evidence and the law support a more protective rule. Of the more than 80 final 6(b) standards issued by OSHA, three have been overturned by the courts B 4,4-methylene bis(2-chloraniline) (MOCA), benzene (1978 standard), and air contaminants.

OSHA's 1974 MOCA standard was overturned on procedural grounds. OSHA's 1978 benzene standard was overturned when the court ruled that OSHA had failed to show that reducing exposure to one part per million, as required by the standard, was reasonably necessary to protect workers from a significant risk of harm. (In 1987, OSHA issued a new benzene standard that reduced the permissible exposure level to 1 ppm, the same as the 1978 rule.) OSHA's 1989 air contaminants standard, which attempted to update permissible exposure limits of 376 substances by largely relying on consensus standards, was overturned because the agency failed to demonstrate that the revised limits were based on appropriate risk and feasibility determinations as required by the Act.

As indicated above in numerous cases, court review has resulted in standards being strengthened or expanded including the addition of a short-term exposure limit to the ethylene oxide standard, the expansion of the hazard communication standard to cover all sectors, the reduction of the asbestos exposure limit to .1 fiber/cubic centimeter, the reduction of the formaldehyde PEL to .75 ppm and the inclusion of medical removal protection in the rule.

The agency's overall record confirms that OSHA's standards have been sound measures, that if anything based on evidence and the law should be more protective of worker safety and health.

4. OSHA's standard setting process is open and accessible and provides many opportunities for involvement by all interested parties. The OSHA standards development process is one of the most open and accessible processes in the federal government.

For all of its rules, OSHA routinely publishes a request for information and/or advanced notice of proposed rulemaking requesting input early in the development process. For major rules, numerous stakeholder meetings are held in various locations around the country.

For rules with impacts on small business, OSHA is one of two agencies that establish a special panel to get early input from small entities, as required by the Small Business Regulatory Enforcement Fairness Act (SBREFA).

Once a proposed rule is issued, interested parties can submit written comments and evidence. In addition for most proposed rules, a public hearing is scheduled (and if one is not, can be requested by any interested party). During the public hearings, interested parties may not only present testimony, but also have the right to cross-examine the agency and other witnesses. These hearings are often held in several locations and last weeks or in some cases months to give all interested parties an opportunity to participate.

After the hearings conclude, participants are given time to submit post-hearing comments and additional evidence. Following these submission there is additional time for parties to submit post-hearing briefs to summarize their positions. And after a standard is issued, any affected party has the right to petition for review in the U.S. Court of Appeals.

By any measure, the process provides ample opportunity for any one who is interested to have their views and positions heard. For OSHA's ergonomics standard, for which some have claimed full input or participation, was not possible, there was an ANPR issued in 1992; stakeholder meetings held in 1994; a draft rule distributed for comment in 1995; another series of stakeholder meetings held in 1998; a new draft standard released in February 1999; a SBREFA panel review conducted February to April 1999; a proposed standard issued in November 1999, with a comment period of 100 days; nine weeks of public hearings from March 13, 2000-July 7, 2000, at four locations around the country where over 700 witnesses testified and provided the opportunity to cross-examine other witnesses; a 45-day period for post-hearing comments, and an additional 45-day period for the submission of post-hearing briefs.

There are few rules that have been subject to such an extensive process for public input.

5. Since the OSHAct was passed in 1970, the standard setting process has become

more cumbersome, complex and lengthy. When OSHA does regulate, it often takes more than 10 years to issue a major standard.

As outlined above, OSHA's standard setting process has always been quite involved both with respect to the evidence that must be gathered and the process for obtaining public input. But over the years the process has become more complex and burdensome as additional requirements have been imposed on the agency. The Paperwork Reduction Act, Regulatory Flexibility Act, Unfunded Mandates Reform Act, Small Business Regulatory Enforcement Fairness Act have required additional analyses and reviews. Executive orders on regulatory reform and federalism impose further analytical and process requirements. All of these are on top of the additional justification and analyses that have been required of the agency as a result of court reviews.

The impact of these requirements can be seen both in the increased time to develop and issue standards and the expansion of the preambles and analyses that accompany OSHA rules.

In the early 1970's, it took about six months to two years for the agency to develop and issue major rules such as those on asbestos and vinyl chloride even though these rules were controversial and contentious. The preambles for the standards were only five to ten pages, but the standards, evidence and material were upheld by reviewing courts.

In the mid- to late-1970's, the process was somewhat longer, taking three years for the promulgation of the lead standard, four years for standards on cotton dust and arsenic, all major regulatory initiatives. But during that time the agency developed and issued numerous other standards including those as benzene, acrylonitrile, DBCP, cancer policy, access to exposure and medical records, hearing conservation, fire protection, and guarding of roof perimeters.

In the early 1980's, as a result of the anti-regulatory philosophy of the Reagan Administration, the time for standards development and issuance became even longer as action was only taken in response to Congressional mandates or court orders. For example, it took six years and a lawsuit for OSHA to issue its formaldehyde standard and five years and a Congressional mandate for the issuance of the blood borne pathogens standard.

Other standards initiated during the Reagan Administration took much longer. Standards on 1,3 butadiene, methylene chloride and respiratory protection each took 12 years from start to finish and were not completed until the Clinton Administration.

Even standards developed through negotiated rulemaking take years to develop and issue. OSHA's standard on methylenedianilene (MDA) took a total of nine years, with five years between the formation of the negotiated rulemaking committee and issuance of a final rule. OSHA's standard on steel erection took 15 years, and was issued in final form in January 2001, seven years after the negotiated rulemaking process was initiated.

None of these time frames include the time period for litigation on final rules which can take years to resolve.

The delay in the issuance of rules means that workers continue to be exposed to serious recognized safety and health hazards which cause unnecessary injury disease and death.

6. Increased political and industry opposition to safety and health standards has greatly impeded and delayed important worker protections.

While OSHA standards have routinely and consistently been opposed by industry groups, in recent years opposition has increased. Similarly, political opposition to OSHA standards has also increased, most noticeably following the election of Republican majorities in Congress in 1994. Since that time more conservative members of Congress have sought to block, delay or weaken many OSHA rules through appropriations riders, legislation or intense oversight of agency actions. Congressional efforts to block and ultimately overturn OSHA's ergonomics rule are the most notable. But members of Congress have also sought to block or weaken rules on methylene chloride, tuberculosis and recordkeeping.

Congressional intervention has not been limited to OSHA rules. There have also been attempts to block a NIOSH Hazard Alert and an OSHA Technical Information Bulletin on latex allergies.

Similarly, industry efforts to oppose safety and health standards have now expanded to target voluntary standards as well. UPS and other industry groups are pushing to have the process to finalize the ANSI Z-365 standard on musculoskeletal disorders aborted. Efforts are also being made by industry to stop the development of a voluntary ANSI standard on safety and health program management. And industry groups are challenging the establishment of voluntary Threshold Limit Values (TLVs) by the American Conference of Governmental Industrial Hygienists (ACGIH). Unfortunately, it appears that some in industry don't want any standards B mandatory or voluntary B to protect workers from serious hazards.

7. OSHA's standard setting process has nearly ground to a halt. The combination of increased process and analytical requirements and strong political and industry opposition to virtually any and all standards had made it almost impossible to regulate.

As outlined above, it now regularly takes more than 10 years for OSHA to set a standard for a major hazard.

Completing the process and issuing a final rule is a huge undertaking, no matter how small or non-controversial the rule. Because the process takes so long, rulemaking spans from one administration to the next. There are changes in OSHA's leadership and staff. There is no continuity in policies or priorities.

Many rules which are initiated are never completed including OSHA's standards on

noise exposure, beryllium, trichlorethylene, toluene, sulfur dioxide, ammonia and glycol ethers B all recognized as serious hazards. Moreover, parties may reach consensus on a standard only to find that consensus disappears as time lapses, people change jobs, and the political environment changes. In summary the standard setting process simply does not operate in Areal time@ and produce standards in a time frame to address hazards of current concern.

8. OSHA's standard setting process is failing to protect workers from serious recognized hazards.

In the 30 years since passage of the Act, OSHA has issued about 80 safety and health standards. Today, many serious hazards are not regulated at all or subject to weak and out-of-date requirements. For example, OSHA has been unable to update permissible exposure limits for toxic chemicals. The levels that are in place are largely 1968 ACGIH limits that were adopted as 6(a) standards in 1971. Most of these limits were set by ACGIH in the 1940's and 1950's based upon the scientific evidence then available. Moreover, many chemicals now recognized as hazardous were not covered by the 1968 limits. OSHA's 1989 attempt to update these limits was overturned by the courts because the agency failed to make the risk and feasibility determinations for each chemical required by the Act.

Similarly, OSHA has issued standards on confined space entry, lockout/tagout and hearing conservation to protect workers in general industry. However, construction workers were not covered by these standards, and today have no standards to protect them from these hazards.

In some limited cases, OSHA will use the general duty clause to enforce against hazards where no standard exists or where a standard is not protective. But in most cases, particularly where a standard exists, the agency will not take action, even if workers are suffering illness or injury due to exposures. Employer compliance with existing OSHAct standards in no way means that workers are protected.

Recommendations for Improving the Process

The standard setting process has so many problems, deficiencies and complexities that making it efficient, effective and timely, particularly in the current political climate, is as a formidable task. However, several things could be done to improve the process so that workers are better protected. Some of these are a prerequisite for the process to work at all.

1. The Bush Administration and Secretary of Labor must demonstrate a clear commitment to setting worker safety and health standards, identify specific priorities and an agenda for action. Absent the commitment of top leadership the process simply will not work. The public will not take standard's initiatives seriously. Agency staff will not be motivated to act in a timely fashion. Internal disputes between the Department of Labor and

Office of Management and Budget (OMB), which always occur, will become more

significant if there is not direction from the top.

2. The Department of Labor must have the clear authority to develop proposed and final standards, without undue interference from the Office of Management and Budget. Under the Paperwork Reduction Act (PRA) and various executive orders, OMB has a major role in the review of proposed and final regulations, to assure that regulations are consistent with the PRA and Administration policy. However, the Department of Labor, not OMB, has the expertise on safety and health matters and the obligation to see that standards meet the high level of protection required by the OSHAct. The Department of Labor must be able to do its job.

3. The Department of Labor and OSHA should develop better systems for managing the standard setting process including setting clear priorities and meaningful deadlines for action, and keep to those deadlines.

4. Congress should consider legislation to make it possible to update permissible exposure limits on a regular basis. This could be done by mandating the adoption of current consensus or private standards, after public notice and comment, and setting up a process to keep PELs up to date. This process could involve the establishment of an advisory committee to provide advice to OSHA and changing evidentiary burdens where revised PELs are based on voluntary standards, existing industry standards or standards adopted in other countries.

These modest recommendations will not fix all of the problems with the OSHA standard setting process, but would if adopted and implemented improve protections for American workers.

Thank you.

OSHA HEALTH STANDARDS SINCE 1971

Date Final

Standard Standard Issued

Asbestos 1972

Fourteen Carcinogens 1974

Vinyl Chloride 1974

Coke Oven Emissions 1974

Benzene 1978

DBCP 1978

Arsenic 1978

Cotton Dust 1978

Acrylonitrile 1978

Lead 1978

Cancer Policy 1980

Access to Medical Records 1980

Hearing Conservation 1981

Hazard Communication 1983

Ethylene Oxide 1984

Asbestos (revised) 1986

Field Sanitation 1987

Benzene (revised) 1987

Formaldehyde 1987

Access to Medical Records (modified) 1988

Permissible Exposure Limits (PELs) Update (vacated) 1989

Chemical Exposure in Laboratories 1990

Bloodborne Pathogens 1991

4,4'-methylenedianiline 1992

Cadmium 1992

Asbestos (Partial Response to Court Remand) 1992

Formaldehyde (Response to Court Remand) 1992

Lead B (Construction) 1993

Asbestos (Response to Court Remand) 1994

1,3-Butadiene 1996

Methylene Chloride 1997

Respiratory Protection 1998

Ergonomics 2000

Bloodborne Pathogens (revised) 2001

Ergonomics (revoked) 2001

Source: Code of Federal Regulations

OSHA SAFETY STANDARDS SINCE 1971

Date Final

Standard Standard Issued

41675. Cranes/derricks (load indicators) 1972

41676. Roll-over protective structures (construction) 1972

41677. Power transmission and distribution 1972

41678. Scaffolding, pump jack scaffolding, and roof catch platform 1972

41679. Lavatories for industrial employment 1973

41680. Trucks, cranes, derricks, and indoor general storage 1973

41681. Temporary flooringBskeleton steel construction 1974

41682. Mechanical power pressesB(Ano hands in dies@) 1974

41683. Telecommunications 1975

41684. Roll-over protective structures of agricultural tractors 1975

41685. Industrial slings 1975

41686. Guarding of farm field equipment, farmstead equipment and cotton gins 1976

41687. Ground-fault protection 1976

41688. Commercial diving operations 1977

41689. Servicing multi-piece rim wheels 1980

41690. Fire protection 1980

41691. Guarding of low-pitched roof perimeters 1980

41692. Design safety standards for electrical standards 1981

41693. Latch-open devices (on gasoline pumps) 1982

41694. Marine terminals 1983

41695. Servicing of single-piece and multi-piece rim wheels 1984

41696. Electrical Safety in Construction (Part 1926) 1986

41697. General Environmental Controls B TAGS Part (1910) 1986

41698. Marine Terminals B Servicing Single Piece Rim Wheels (Part 1917) 1987

41699. Grain Handling Facilities (Part 1910) 1987

41700. Safety Testing of Certification of Certain Workplace Equipment and Materials (Laboratory Accreditation Revision) 1988

41701. Crane or Derrick Suspended Personnel Platforms (Part 1926) 1988

41702. Concrete and Masonry Construction (Part 1926) 1988

41703. Mechanical power presses B (Ano hands in dies@) B (Modified) 1988

41704. Powered Platforms (Part 1910) 1989

41705. Underground Construction (Part 1926) 1989

41706. Hazardous Waste Operations (1910) (Mandated by Congress) 1989

41707. Excavations (Part 1926) 1989

41708. Control of Hazardous Energy Sources (Lockout/Tagout) Part (1910) 1989

41709. Stairways and Ladders (Part 1926) 1990

41710. Concrete and Masonry Lift-Slab Operations 1990

41711. Electrical Safety Work Practices (Part 1910) 1990

41712. Welding, Cutting and Brazing (Part 1910) (revision) 1990

41713. Chemical Process Safety 1992

41714. Confined Spaces 1993

41715. Fall Protection 1994

41716. Electrical Power Generation 1994

41717. Retention of DOT Markings, Placards and Labels 1994

41718. Personal Protective Equipment 1994

41719. Logging Operations 1995

41720. Scaffolds 1996

41721. PPE for Shipyards 1996

41722. Longshoring and Marine Terminals 1997

41723. Powered Industrial Truck Operator Training 1998

41724. Confined Spaces (amended) 1998

41725. Dipping and Coating (plain language re-write) 1999

41726. Steel Erection 2001

Chronology of OSHA Safety and Health Standards

HEALTH STANDARDS

Asbestos

May 1971 Existing federal regulation under the Walsh-Healey Act adopted

Dec 1971 ETS (result of petition)

June 1972 Final rule

Fourteen Carcinogens

May 1972 RFI from NIOSH

July 1972 RFI from NIOSH (2)

Jan1973 ETS petition

Feb 1973 RFI

May 1973 ETS

June 1973 Standard advisory committee appointed

July 1973 NPRMM

Jan 1974 Final Rule

Vinyl Chloride

Apr 1974 ETS

May 1974 NPRM

Oct 1974 Final Rule

Exposure to Coke Oven Emissions

June 1971 Petition for standard

Aug 1974 Standards Advisory Committee established

July 1975 NPRMM

Oct 1976 Final rule

Occupational Exposure to Benzene (1) - Vacated

April 1971 OSHA adopts then current ANSI recommended 10 ppm without rulemaking under the OSHAct

May 1977 ETS

May 1977 ETS stayed

May 1977 NPRMM

Feb 1978 Final rule

1978 Standard is challenged. Court vacates standard

Exposure to DBCP

Aug 1977 NIOSH HHE

Sept 1977 ETS issued

Nov 1977 NPRMM

March 1978 Final Rule

Occupational Exposure to Inorganic Arsenic

Sept 1974 Informal fact finding hearing

Jan 1975 NPRM

May 1978 Final standard

Cotton Dust

Dec 1974 ANPR

Jan 1975 Petition

Dec 1976 NPRM

June 1978 Final Rule

Acrylonitrile

June 1977 RFI

Jan 1978 NPRM

Oct 1978 Final Rule

Lead

Oct 1975 NPRM

Sept 1977 NPRM (Medical Removal Protection)

Nov 1978 Final rule

Cancer policy

Jan 1977 Draft proposal to NACOSH for review and comment

Feb 1977 Draft proposal to NIOSH formal review and comment

Oct 1977 NPRM

Nov 1977 Comment period extended

Jan 1978 Comment period further extended

Jan 1980 Final Rule

Access to Employee Exposure Medical Records

July 1978 Interim Final Rule called "Preservation of Records"

July 1978 NPRM "Access to Employee Exposure and Medical Records"

May 1980 Final Rule

Aug 1981 OSHA published interpretations of the rule and a proposed interim modification of the rule

July 1982 NPRM to modify rule

Sept 1988 Modified Rule

Occupational Noise Exposure; Hearing Conservation Amendment

1971 Occupational exposure to noise standard adopted

1974 NPRM to revise the standard

Jan 1981 Final rule (hearing conservation amendment)

1981 Requests to reconsider the 1981 amendment and petitions to stay the amendment

May/July '81 Effective date of amendment deferred

Aug 1981 Administrative stay lifted on major portions of the rule and amendment goes into effect. Stay on other portions remain in effect and record is reopened for additional comment

March 1982 Informal public hearing

March 1983 Final rule (Revised)

Hazard Communication

Jan 1975 Advisory Committee Report

Jan 1977 ANPR

Jan 1981 NPRM 1

Feb 1981 NPRM withdrawn

Mar 1982 NPRM 2

Nov 1983 Final Rule

Ethylene Oxide

1977 NIOSH issues a "Special Occupational Hazard Review"

1979 ACGIH published a notice to lower its TLV for EtO

1981 ACGIH adopts lower TLV

May 1981 NIOSH issues a "Current Intelligence Bulletin"

Aug 1981 Petition for ETS (Public Citizen)

Sept 1981 OSHA denied petition

Jan 1982 ANPR

April 1983 NPRMM

June 1984 Final Rule

Asbestos (revised)

Oct 1975 ANPR

July 1976 NIOSH recommends reduced PEL

Nov 1983 ETS

March 1984 ETS ruled invalid

April 1984 NPRM

June 1986 Two Final rules (revision to 1972 rule, one general industry, one for

construction). Challenged in court.

Feb 1988 Court issues decision and remands 3 sets of issues back to OSHA for reconsideration

Sept 1988 Amendment (STEL)

Dec 1989 Final rule; partial response to court remand (Issue 1)

Feb 1990 Final rule; partial response to court remand (Issue 2)

July 1990 NPRM (result of remand Issue 3)

June 1992 Revision

Aug 1994 Final rule (Lowered PEL)

Field Sanitation

Sept 1972 Petition

Apr 1976 NPRM

Withdrawn

Mar 1983 ANPR

Mar 1984 NPRM (2)

April 1985 Final determination not to issue a federal standard

Oct 1985 Comment period reopened

May 1987 Final rule

Occupational Exposure to Benzene (Revised)

April 1983 ETS Petition

July 1983 Petition denied

July 1983 RFI

Dec 1985 NPRMM for revised standard

Sept 1987 Final Rule

Formaldehyde

Apr 1980 Federal Panel formed

Oct 1981 ETS Petition

Jan 1982 Petition denied

July 1984 District Court for the District of Columbia remanded the UAW's request for an ETS to the Agency for Reconsideration

Jan 1985 Petition denied again

Jan 1985 OSHA announced public meetings

Apr 1985 ANPR

Dec 1987 Final Rule

Nov 1988 Start-up date

Dec 1988 Administrative stay

Hazard Communication (revised)

1983 standard challenged in Court

May 1985 Court issues decision

Aug 1987 Final Rule (expansion of scope)

Access to Employee Exposure Medical Records (modified)

April 1981 Administrative stay for construction

Aug 1981 OSHA published interpretations of the rule and a proposed interim modification of the rule

July 1982 Proposal to modify the rule

Sept 1988 Final Rule (covers all industries)

PEL Update (Air Contaminants) - Vacated

Jan 1971 OSHA promulgates existing Federal and national consensus standards

June 1988 NPRM

Jan 1989 Final Rule

Chemical Exposure in Laboratories

Apr 1981 RFI

July 1986 NPRM

Jan 1990 Final Rule

Bloodborne Pathogens

Jan 1983 Voluntary Guidelines

Sept 1986 ETS Petition

Sept 1986 Petition

Oct 1987 Both petitions denied

Oct 1987 DOL and HHS publish a Joint Advisory Notice

Nov 1987 ANPR

May 1989 NPRM

Dec 1991 Final Rule

4, 4'-Methylenedianiline

Sept 1983 EPA ANPR for joint rulemaking

Oct 1985 Announcement of Mediated Rulemaking

May 1989 NPRM

Aug 1992 Final Rule

Cadmium

1986 ETS Petition

1987 Petition denied

1990 NPRMM

June 1993 Final Rule

Jan 1994 Corrections and technical amendments

Formaldehyde (Response to Court Remand)

1989 Court Decision

July 1991 Response to Court remand; proposed rule

Aug 1991 Administrative stay extended a second time

May 1992 Response to Court remand: final rule

Lead – Construction

1971 OSHA adopts existing standards

1978 Final Rule for General Industry

Nov 1978 OSHA requests that ACCSH review record and make recommendations for lead in construction

Oct 1992 Congress passes Sections 1031 and 1032 of Title X of the Housing and Community Development Act which requires the Secretary of Labor to issue an interim final lead standard covering the construction industry

May 1993 Final Rule

1, 3-Butadiene

Jan 1984 RFI

Jan 1984 ETS Petition

Mar 1984 Petition denied

Oct 1986 ANPR

Aug 1990 NPRM

Nov 1996 Final Rule

Methylene Chloride

1971 OSHA adopts ACGIH limit as a standard

July 1985 Petition

Nov 1986 ANPR

Nov 1991 NPRM

Jan 1997 Final Rule

Respiratory Protection

May 1982 ANPR

Sept 1985 Preliminary draft proposal

Nov 1994 NPRM

Jan 1998 Final Rule

Ergonomics

Aug 1990 Red Meat Guidelines Issued

July 1991 ETS Petition

June 1992 ANPR

Mar 1995 Draft proposal circulated

Feb 1999 New draft proposal sent for SBREFA review

Nov 1999 NPRM

Nov 2000 Final rule

Mar 2001 Rule revoked by use of CRA

April 2001 Petition for new rule

Bloodborne Pathogens (revised)

Sept 1998 RFI

Nov 1999 Revised compliance directive for the existing BBP standard

Nov 2000 The Needlestick Safety
and Prevention Act signed into law
directing OSHA to revise the BBP

standard in accordance with specific language in the Act within six months of enactment of the Act.

Jan 2001 Final Rule

SAFETY STANDARDS

Commercial Diving Operations

June 1976 ETS

Nov 1976 NPRM (ETS withdrawn)

July 1977 Final Rule

Fire Protection

April 1976 RFI on revisions fire protection standards

Dec 1978 NPRM

Sept 1980 Final Rule

Guarding of Low Pitched Roof Perimeters

1977/78 Agency consulted with ACCSH on draft proposal

Aug 1979 NPRM

Nov 1980 Final Rule

Design Safety for Electrical Systems

Sept 1979 NPRM

Nov 1979 Notice of correction and extension of comment period

Jan 1981 Final Rule

Latch-Open Devices

Jan 1981 ANPR

Mar 1982 NPRM

Sept 1982 Final Rule

Marine Terminals

Jan 1981 NPRM

July 1983 Final Rule

Servicing of Single-Piece and Multi-Piece Rim Wheels

Nov 1982 NPRM

Feb 1984 Final Rule

Electrical Safety in Construction

Jan 1982 Draft proposal to ACCSH

Oct 1983 NPRM (revision)

July 1986 Final Rule

General Environmental Controls –TAGS

April 1984 NPRM

Sept 1986 Final Rule

Marine Terminals-Servicing Single Piece Rim Wheels

Aug 1986 NPRM

Sept 1987 Final Rule

Grain Handling Facilities

Feb 1980 RFI

Apr 1984 OSHA published a notice announcing the scheduling of a public hearing.

Dec 1987 Final Rule

Mar 1996 Technical amendment to Final Rule

Safety Testing of Certification of Certain Workplace Equipment and Materials

(Laboratory Accredited Revision)

Mar 1984 OSHA proposed to initiate a comprehensive overhaul of its regulatory procedures related to OSHA's requirements for safety testing or certification of certain workplace equipment and materials.

Aug 1984 Informal hearings held

Apr 1988 Final Rule

Crane or Derrick Suspended Personnel Platforms

Dec 1971 CSA Crane and Derrick standard adopted

Dec 1973 ACCSH appointed an informal group to study issue

Feb 1974 NPRM

Aug 1988 Final Rule

Concrete and Masonry Construction

Feb 1982 RFI and ANPR

Sept 1985 NPRM

Apr 1986 Notice of Informal Public Hearing

June 1988 Final Rule

Mechanical Power Presses (modified)

1982 OSHA has a contractor examine 1910.217 to recommend appropriate revisions to allow presence sensing device initiation (PSDI)

June 1983 Report distributed to individuals and organizations that are members of pertinent voluntary consensus standards organizations

Mar 1985 NPRM

Mar 1988 Final Rule

Powered Platforms

1971 ANSI standard adopted by OSHA

Nov 1982 Compliance Directive issued

Feb 1983 ANPR

Jan 1985 NPRM (amendment)

July 1989 Final Rule

Underground Construction

1971 ACCSH asked to study existing rules

Mar 1974 NPRM

1974 Proposal withdrawn

Aug 1983 New NPRM

June 1989 Final Rule

Hazardous Waste Operations

Oct 1986 The Superfund Amendments and Reauthorization Act of 1986 (SARA) mandates the Secretary of Labor to issue interim final worker protection for workers engaged in hazardous waste operations

Dec 1986 Interim final regulations issued

Aug 1987 NPRM

Mar 1989 Final Rule

Apr 1990 Final Rule; Corrections

Excavations

Oct 1982 Proposed revision to 1971 and 1972 standards submitted to Advisory Committee on Construction Safety and Health (ACCSH).

Apr 1987 NPRM

Oct 1989 Final Rule

Control of Hazardous Energy Sources (Lockout/Tagout)

1977 RFI

May 1979 ETS Petition

Sept 1979 Petition denied

June 1980 ANPR

Apr 1988 NPRMM

Sept 1989 Final Rule

Stairways and Ladders

1971 OSHA adopts Construction Safety Act standard

Nov 1986 NPRM

Nov 1990 Final Rule

Concrete and Masonry Lift-Slab

Sept 1988 NPRM

Oct 1990 Final Rule

Electrical Safety Work Practices

Nov 1987 NPRM

Aug 1990 Final Rule

Welding, Cutting and Brazing

1971 OSHA adopts existing standard for Welding, Cutting and Brazing

Apr 1990 Final Rule (reorganization)

Chemical Process Safety

July 1990 NPRM

Feb 1992 Final Rule

Confined Spaces

July 1975 ANPR

Oct 1979 New ANPR

Mar 19080 ANPR (Construction)

June 1989 NPRM

July 1989 Comment period for NPRM extended

Jan 1993 Final Rule

Fall Protection

1971 OSHA adopts several regulations related to fall protection

Dec 1986 NPRM

Aug 1994 Final Rule

Electrical Power Generation

<

Jan 1989 NPRM

Jan 1994 Final Rule

Retention of DOT Markings, Placards and Labels

Nov 1990 Congressional mandate

Sept 1993 NPM

July 1994 Final Rule

Personal Protective Equipment

1971 Established Federal and consensus standards adopted

Aug 1989 NPRM

Apr 1994 Final Rule

Logging Operations

1971 OSHA adopts ANSI standard

June 1976 NIOSH publishes criteria document, Recommendations For An Occupational Standard For Logging From Felling To First Haul.

May 1989 NPRM

Oct 1994 Final Rule

Scaffolds

1971 OSHA adopts 1969 Construction Safety Act scaffolds standard

Dec 1972 OSHA amends standard

Dec 1986 NPRM

Aug 1996 Final Rule

PPE for Shipyards

Nov 1988 NPRM

July 1994 OSHA reopens record to incorporate general industry docket

May 1996 Final Rule

Longshoring and Marine Terminals

June 1994 NPRM

July 1997 Final Rule

Powered Industrial Truck Operator Training

1971 OSHA adopts ANSI Safety Standard

Mar 1988 Petition

Mar 1995 NPRM

Jan 1996 NPRM (2) expands scope

Dec 1998 Final Rule

Confined Spaces (Amended)

Nov 1994 NPRM

Dec 1998 Amendment to Final Rule

Steel Erection

Jan 1986 NPRM (fall protection)

Jan 1988 Announced intention to regulate fall protection in steel erection separately from fall protection

1990 Petition

Petition denied

1991 Recommendation for negotiated rulemaking

Dec 1992 Notice of intent to establish negotiated rulemaking committee

May 1994 Steel Erection Negotiated Rulemaking Advisory Committee (SENRAC) established

June 1994 Negotiations begin

July 1997 SENRAC presents OSHA with consensus proposed standard

Aug 1998 NPRM

Dec 1999 OSHA consults with SENRAC on draft final rule

Jan 2001 Final Rule

Notes

RFI – Request for Information

ANPR – Advanced Notice of Proposed Rulemaking

NPRM – Notice of Proposed Rulemaking

ETS – Emergency Temporary Standard

ACGIH – American Council of Government Industrial Hygienists

STEL – Short-term Exposure Limit

Calculation of the number of years it took to issue a standard begins with a petition. In the case of no petition, start date is the RFI or ANPR.

APPENDIX H – SUBMITTED FOR THE RECORD, LETTER FROM CONGRESSMAN CHARLIE NORWOOD, CHAIRMAN, SUBCOMMITTEE ON WORKFORCE PROTECTIONS, TO THE HONORABLE ELAINE CHAO, SECRETARY OF LABOR, MAY 23, 2001

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EDUCATION AND THE WORKFORCE
SUBCOMMITTEE
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Charlie Norwood
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http://www.house.gov/norwood

May 23, 2001

The Honorable Elaine Chao
Secretary of Labor
United States Department of Labor
200 Constitution Avenue, N.W.
Washington, D.C. 20210

Dear Madame Secretary:

I write to seek your assistance in solving a problem that stems from the inappropriate use of the American Conference of Government Industrial Hygienists (ACGIH) process, and the group's Threshold Limit Values ("TLVs") (exposure standards). As you know, TLVs are incorporated by reference in numerous OSHA and MSHA standards, and used to trigger hazard communication ("HazCom") duties under OSHA's HazCom standard and MSHA's new "interim final" HazCom standard. Moreover, TLVs form the basis for enforcement actions under OSHA's general duty clause, and occasionally under broadly-worded OSHA and MSHA standards (e.g. posting of signs where "hazards" exist).

In the last few years ACGIH has adopted and proposed TLVs which are highly controversial because of their apparent lack of scientific basis. Although ACGIH claims to be a private group, DOL, MSHA, and OSHA employees are influential members of the ACGIH membership and committees. Thus, ACGIH TLV actions are often based on input, requests and/or participation by Department of Labor employees who serve on the ACGIH Board and/or the ACGIH TLV Committee and subcommittees. Most disturbing, the ACGIH acts on TLVs in secret, without criteria to govern the basis for TLVs, without public input, without judicial review and without accountability to taxpayers. Because these TLVs are incorporated by reference in OSHA and MSHA standards, this process amounts to secret rulemaking, outside the normal public notice and comment process.

A conflict of interest exists when Department of Labor personnel, charged with developing and enforcing governmental standards, enlist a private organization (in which these same personnel are influential members) to develop standards that are later relied on, used, or incorporated by reference by the agency. I also believe that it is inappropriate to use the ACGIH as a de facto advisory committee, without complying with the Federal Advisory Committee Act. We are further concerned that MSHA's new, "interim final" HazCom rule incorporates not only existing TLVs, but also any future TLV, thus making applicability of the rule dependent on unpredictable actions that the ACGIH, using its secret proceedings, may adopt in the future. (65 F.R. 59048, at59097, October 3, 2000)

In order to remedy this process, and bring fairness to the standards setting process, I ask that you take the following actions:

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(1) Revoke the TLV incorporation by reference in the "interim" MSHA HazCom Rule. The Secretary has authority to do so in the existing open rulemaking proceeding based on notice and comment procedures already in effect. The matter is pending before you now for decision in an open rulemaking docket on whether to make final the interim rule.

(2) Propose to revoke the OSHA HazCom Rule ACGIH incorporation by reference.

(3) Prohibit Department expenditures to support participation in any ACGIH activities by Department employees. If, in fact, ACGIH is a private organization as it claims, then it should be privately funded.

(4) Prohibit Department direct or indirect employees from serving on the ACGIH Board or TLV committees, to prevent conflicts of interest with their official duties.

(5) Prohibit enforcement based on ACGIH TLVs, either under the OSHA General Duty Clause or any other OHSA or MSHA standard that provides generic or generally worded health and safety mandates.

(6) Act to prevent indirect support of ACGIH through the unnecessary or excessive purchase of ACGIH TLV books.

(7) Prohibit the use of state grant funds to support ACGIH activities, memberships or the purchase of TLV books.

(8) Prohibit the indirect support of employee travel to ACGIH meetings through the scheduling of concurrent Department meetings.

(9) Require Department employees engaged in ACGIH or activities to conduct such activities on personal time, rather than Department time, and without the use of Department equipment, telephones or facilities.

Sincerely,

Charlie Norwood, M.C.

APPENDIX I – SUBMITTED FOR THE RECORD, LETTER FROM RICHARD STRANO, EXECUTIVE DIRECTOR, AMERICAN CONFERENCE OF GOVERNMENTAL INDUSTRIAL HYGIENISTS, TO THE HONORABLE ELAINE CHAO, SECRETARY OF LABOR, JUNE 13, 2001

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June 13, 2001

The Honorable Elaine Chao
Secretary of Labor
United States Department of Labor
200 Constitution Avenue, NW
Washington, D.C. 20210

Dear Madam Secretary:

On May 23, 2001, Congressman Charlie Norwood wrote to you concerning what he describes as the inappropriate use of the ACGIH® (American Conference of Governmental Industrial Hygienists) processes and the group's TLVs® (Threshold Limit Values).

Mr. Norwood's letter contains a number of factually incorrect and/or misleading statements. However, before addressing these issues, you should know that ACGIH is a private, not-for-profit, professional organization that has been in existence since 1938. ACGIH's 4200 members are scientists, toxicologists, epidemiologists, physicians, and industrial hygienists who are concerned with issues involving workplace health and safety. Our members are employed by academic institutions, major corporations, labor organizations, and federal, state and local agencies.

ACGIH receives no government funding. Government employees participate in ACGIH activities in the same way that government employees participate in the activities of other professional organizations such as the American Medical Association, the American Bar Association, and the American Dental Association.

ACGIH does not write standards. ACGIH publishes exposure guidelines in which ACGIH affirmatively states that: "(The TLVs) are not developed for use as legal standards and ACGIH does not advocate their use as such. However, it is recognized that in certain circumstances individuals or organizations may wish to make use of these recommendations or guidelines as a supplement to their occupational safety and health program. ACGIH will not oppose their use in this manner, if the use of TLVs and BEIs in these instances will contribute to the overall improvement in worker protection. However, the user must recognize the constraints and limitations subject to their proper use and bear the responsibility for such use."

ACGIH also states in this publication of exposure guidelines, "It is not appropriate for individuals or organizations to impose on the TLVs or the BEIs their concepts of what the TLVs or BEIs should be or how they should be applied or to transfer regulatory standards requirements to the TLVs or BEIs."

In developing TLVs, ACGIH convenes a committee of outstanding scientists called the Chemical Substances – TLV committee. A majority of the members of this Committee are employees of academic institutions. Other members of the Committee are employed by major chemical manufacturers, organizations of those manufacturers, and governmental agencies. The Committee appoints subcommittees. Each subcommittee, with the assistance of the ACGIH professional Staff, compiles a comprehensive Documentation of the reported, peer reviewed, scientific literature relating to each substance under consideration. Interested parties, including manufacturers and users, are invited to submit data for consideration by the Subcommittees. After a review of all of the responsible data, the Subcommittees recommend a TLV which is the level of airborne concentrations of chemical substances and represent conditions under which it is believed nearly all workers may be repeatedly exposed day after day without adverse health effects.

As ACGIH states in its "Introduction to the Chemical Substances," "These limits are intended for use in the practice of industrial hygiene as guidelines or recommendations in the control of potential workplace health hazards and for no other use, e.g., in the evaluation or control of community air pollution nuisances; in estimating the toxic potential of continuous, uninterrupted exposures or other extended work periods; as proof or disproof of an existing disease or physical condition; or adoption or use by countries whose working conditions or cultures differ from those in the United States of America and where substances and processes differ. These limits *are not* fine lines between safe and dangerous concentrations, nor are they a relative index of toxicity. They *should not* be used by anyone untrained in the discipline of industrial hygiene."

The recommendations of the Subcommittees are reviewed by the full Committee, and if approved by the full Committee, are then sent to the ACGIH Board of Directors. If the recommendations are in turn ratified by the Board, the proposed TLV is published on a list called the NIC (Notice of Intended Change List), which is made available to all those interested in industrial health and safety issues throughout the world. While on the NIC List, the proposed TLV is not in effect, but is published in proposed form so that any and all interested parties can comment. The proposed TLV stays on the NIC list for approximately one year and sometimes longer. During the time that the proposed TLV is on the NIC list, the Subcommittees and the full Committee evaluate comments and additional information provided. The Subcommittees and full Committee then determine whether to recommend publication of a final TLV or to recommend further study.

As can be seen by the above, the process is an open process conducted by a dedicated group of highly qualified experts who volunteer their time and effort in order to promote health and safety in the workplace. ACGIH takes great pain to affirmatively state that the TLVs are guidelines, not standards, and are designed for use by qualified industrial hygienists.

With this background, let us now look at the specific allegations made by Congressman Norwood.

1. Mr. Norwood claims that the TLVs are "highly controversial because of their apparent lack of scientific basis." In fact, the TLVs are developed by some of our nation's outstanding experts as well as experts from other countries. And each TLV is accompanied by a published list of all the scientific studies used to determine the specific TLV. A library of these Documentations is kept at ACGIH headquarters and is available to anybody, whether or not a member of ACGIH, who wishes to obtain a

copy. A copy of a single, typical Documentation can be obtained for between $20 and $50, which represents ACGIH's cost for the Documentation.

2. It is alleged that ACGIH TLV actions, "are often based on input, requests and/or participation by Department of Labor employees who serve on the ACGIH Board and/or the ACGIH TLV Committee and Subcommittees." In fact, DOL employees who serve on the ACGIH Board and its committees act in the same way as DOL employees who may be active in other groups such as the American Bar Association, the American Medical Association, and the American Dental Association. These individuals volunteer their time in the interest of science and the professions they represent.

   From 1970 until the present time, on average, fewer than 10% of the members of the TLV Committee were employees of DOL or any other subdivision thereof. During the same time period, on average, fewer than 12% of the members of ACGIH Board were employees of DOL or any other subdivision thereof.

3. It is alleged that ACGIH, "Acts on the TLVs in secret, without criteria to govern the basis for TLVs, without public input, without judicial review and without accountability to the taxpayers." This is simply untrue. As set forth above, proposed TLVs are put out for public comment for about one year, and sometimes for a longer period, before they are adopted. In addition, the Subcommittees uniformly seek outside input during their processes of investigation and deliberation. Subcommittee proposals are reviewed by both a full Committee and by the Board of Directors in the form of a proposed TLV, and then again in final form. As a private organization, ACGIH's TLV guidelines are not subject to judicial review, and ACGIH is not accountable to taxpayers any more than are other organizations such as the American Medical Association, the American Dental Association, the American Bar Association and innumerable other private groups which promulgate guidelines or recommendations.

4. OSHA's ability to use the TLVs has already been considered by the Courts, and the United States Court of Appeals for the 11th Circuit has recognized that the TLVs are certainly something that OSHA can consider in the development of its own standards, although clearly OSHA is required to develop standards based on the requirements of the Occupational Safety and Health Act rather than the criteria of a private organization. (AFL-CIO v. OSHA 965 F.2d984 (11th Cir 1992)).

5. It is alleged that DOL personnel enlist ACGIH to develop standards. In fact, ACGIH does not develop standards and affirmatively states that its guidelines are not to be used as standards.

Finally, Mr. Norwood states that ACGIH is operating as a federal advisory committee without complying with the Federal Advisory Committee Act. It is ACGIH's position that it is not a federal advisory committee, and this issue is presently being litigated by both ACGIH and DOL as co-defendants in a matter now pending in the United States District Court in Macon, Georgia.

Madam Secretary, we believe that the recommendations made in Mr. Norwood's May 23, 2001 letter are based on allegations that are incorrect, and therefore these recommendations should not

be adopted. Again, we would like the opportunity to meet with you and provide further information. Thank you for your consideration.

Sincerely,

R. A. Strano

Richard A. Strano, CAE
Executive Director

RAS:bsr

APPENDIX J – SUBMITTED FOR THE RECORD, "RECENT LEGAL ACTIONS CHALLENGE ACGIH AND THREATEN THE PROFESSION," ACGIH TODAY, VOLUME 9, NO. 1, WINTER 2001

ACGIH Today

Winter 2001
Volume 9, No. 1

An Indispensable Resource for Industrial Hygienists and Related Professionals Worldwide

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Recent Legal Actions Challenge ACGIH and Threaten the Profession

ACGIH, which has never been sued during its 62-year history, was served with three separate, unrelated lawsuits during December 2000. Each of these complaints involve the Chemical Substance TLVs®. Two of the lawsuits put the future viability of ACGIH, and its work in promulgating practice guidelines, at risk. More importantly, the nature of these complaints calls into question the freedom of any party to undertake independent scientific research and publish results. This threatens the credibility of the occupational hygiene profession, and the ability of occupational hygienists to continue their occupational health work.

The ACGIH Board of Directors, along with other dedicated volunteers, some who are members of the CS-TLV Committee, and ACGIH Staff have concluded that a vigorous defense of ACGIH and its members is essential if they are to continue to progress in the cause of worker health and safety. Board Chair, Scott E. Merkle, CIH, states, "The nature of the allegations brought in these actions brings a real threat to the ability of professional practitioners to fully protect workers based upon sound and thorough science. These allegations are unfounded and are without basis. Nonetheless, any adverse judgment in these cases could very well dampen, if not silence, the dissemination of the results of credible research by all scientists in all fields of endeavor. At stake is the right of any organization or group to express scientific opinions based on their reasoned evaluation and judgment. These cases threaten our right to free speech as granted in the First Amendment to our Constitution." Merkle continued, "After careful consideration and with the advice of experienced legal counsel, we have concluded that a vigorous and thorough defense of ACGIH and the IH profession is necessary. There is no alternative. We stand by ACGIH and the significant contributions it has made for over half a century. We stand by our TLV Committee. We stand by our policies, procedures, and processes. We stand by our recommended Threshold Limit Values, and we stand by the fairness and the thoroughness of the system used in their development and dissemination."

The bases for the allegations of the three lawsuits vary to the extent that a separate legal defense has been mounted for each one. The substances involved are Sodium Sesquicarbonate (Trona), Synthetic Vitreous Fibers (specifically Refractory Ceramic Fibers (RCF)), and Vinyl Chloride.

In the Trona case, the plaintiffs (Anchor Glass Container Corp.; FMC Corporation; The General Chemical Group, Inc.; OCI Chemical Corporation, Solvay Minerals, and the Wyoming Mining Association) argue that ACGIH is a Federal Advisory Committee, and should, therefore, be subject to the rules and procedures mandated in the Federal Advisory Committee Act, which was passed by Congress in 1972. Clearly, ACGIH is not a Federal Advisory Committee, and the plaintiffs have developed this strategy in an effort to squelch the dissemination of credible, scientific evidence on Trona. Other defendants in this case are the United States Department of Labor and the Department of Health and Human Services. This action is brought in Federal District Court in Macon, Georgia.

In the second case, the plaintiffs (the Refractory Ceramic Fibers Coalition; Thermal Ceramics, Inc; Unifrax Corporation; and Vesuvius U.S.A. Corporation) allege that the research undertaken by ACGIH members is flawed, and that the conclusions that have been approved at

(*see* Legal Actions *on page 3*)

Court Ruling Favors ACGIH

TLV Publication Expedited

See page 3 for details

Legal Actions

(continued from page 1)

several levels, and ultimately ratified by the Board of Directors, are wrong. The plaintiffs seek to have an ACGIH TLV that is higher than ACGIH believes is warranted based on the science. Moreover, the plaintiffs seek to restrain ACGIH from publishing the TLV for RCF that was recommended by the CS-TLV Committee and ratified by the Board of Directors. The Complaint, filed in Federal District Court in Atlanta, Georgia, seeks substantial monetary damages. It alleges an inappropriate relationship, if not a conspiracy, between ACGIH and the Federal government on the recommended TLVs.

The third lawsuit is brought by the family of a worker who was exposed to Vinyl Chloride over a period of time. Along with ACGIH, defendants include over 20 chemical and other manufacturing companies, and other not-for-profit groups such as the Society of the Plastics Industry. The plaintiff alleges that ACGIH and others conspired to withhold evidence regarding Vinyl Chloride. There is no truth to this allegation. This action is brought in the 23rd Judicial District Court of Brazoria County, Texas.

According to ACGIH General Counsel, Steven John Fellman of Galland, Kharasch, Greenberg, Fellman & Swirsky, P.C. in Washington, D.C., "ACGIH has acted within all legal requirements in developing and publishing TLVs. It has every right and responsibility to defend its position. Beyond my commitment to continue a thorough and reasoned defense of ACGIH, its members, and the industrial hygiene profession, my concerns extend to similar not-for-profit, voluntary, membership organizations in other fields of endeavor which disseminate recommendations and practice guidelines intended to protect people from injury and death."

Mr. Fellman and his associates are working primarily on the RCF case. Additional legal counsel has been retained in Macon and Atlanta, Georgia, and in Texas for our defense.

ACGIH Executive Director, Richard Strano, CAE, noted, "Since December these unwarranted actions have consumed a great deal of precious time an effort, both among our key, dedicated volunteers and our Staff. The Trona ca and the RCF case are precedent-setting ones, and require our full and concerte attention. I am confident that the extenc efforts of our Board of Directors, Comm tee and other ACGIH members, Staff, ar legal counsel, will result in a full exoner tion of ACGIH and the TLVs, and the value they both bring to society througl out the world. To extend any less effort would be a disservice to the industrial hygiene profession, and to all other professional groups who work to dissem nate practice guidelines for the improvec health and safety of people everywhere."

The paperwork filed in these legal proceedings is extensive and voluminou: A summary of each of the lawsuits appears below. ◆

Case Summaries; Court Ruling Favors ACGIH

ANCHOR GLASS CONTAINER CORP., et.al. vs. ACGIH, USDOL, and USDHHS

This action is brought by the producers and users of trona and seeks to prohibit ACGIH from publishing a trona TLV and from holding meetings to discuss trona. The Complaint argues that ACGIH is a quasi-governmental, standard-setting organization. The Department of Labor (OSHA) and the Department of Health and Human Services (NIOSH) are included because of their alleged reliance upon, and use of TLVs®, and because employees of OSHA, MSHA, and NIOSH are members of ACGIH.

The Plaintiffs argue that ACGIH serves as an advisory committee to DOL and HHS, but has never complied with the requirements of the Federal Advisory Committee Act (FACA), and therefore, cannot be permitted to adopt a trona TLV, and DOL and HHS cannot use or rely on a TLV for trona. They argue that publication of the trona TLV will mislead employees and consumers about safe levels of trona exposure and that they will be irreparably damaged by such publication. They seek monetary damages from ACGIH.

CARLIN DAVID STAPLES, et.al. vs. DOW CHEMICAL COMPANY, et.al.

Mr. Staples is a 38-year-old father of six, seriously ill with brain cancer. Mr. Staples and his six children bring the suit against Dow, et.al. ACGIH was not named in the initial action but was added as a defendant in a subsequent Amended Petition. Mr. Staples was exposed to vinyl chloride monomer from December 1982 until October 1997.

ACGIH is included as a defendant under a conspiracy theory for fraudulently concealing evidence and for spoilage of evidence. The Plaintiffs seek punitive damages and compensatory damages.

REFRACTORY CERAMIC FIBERS COALITION, et.al vs. ACGIH

The plaintiffs allege that ACGIH is a standard-setting organization and that the TLV for RCF is unreasonable and unjustified. RCFC argues that its own Recommended Exposure Guideline (REG) is base on the principle that it is prudent to reduc RCF levels to the maximum feasible extent and is set at the lowest level that appears feasible. It also notes conflicts of interest due to the involvement in the TLV process of federal employees and employees of labor unions. RCFC asks the Court to enjoin ACGIH from studying RCF and from publishing its TLV, and it seeks the assessment of damages.

On January 12, 2001, the United States District Court in Atlanta held a hearing on RCFC's request for a Temporary Restraining Order enjoining ACGIH from publishing the RCF TLV. After viewing the legal briefs filed by both parties and listening to counsel for both parties, the Court denied RCFC's request, finding that it does not appear that RCFC is likely to win. ACGIH is free to publish the TLV for RCF. The case will now proceed to a hearing on the merits. ◆

APPENDIX K – SUBMITTED FOR THE RECORD, "ACGIH CONTINUES TO DEFEND AGAINST TLV LAWSUITS," ACGIH TODAY, VOLUME 9, NO. 3, SUMMER 2001

Summer 2001
Volume 9, No. 3

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ACGIH® Continues to Defend Against TLV® Lawsuits

ACGIH® continues to vigorously defend itself against three separate and unrelated lawsuits, all of which were filed during December 2000. The Chemical Substances TLVs® are the subject of all three of the suits. Working with ACGIH general counsel in Washington, D.C., and with additional law firms in Texas and in Atlanta and Macon, Georgia, ACGIH has no choice but to defend itself against these unwarranted attacks on the credibility of its TLVs. Because the TLVs are internationally recognized and used throughout the world, the successful conclusion of these cases is essential to the continuing efforts to protect workers everywhere.

To date, ACGIH has prevailed in quashing the attempt of one of the plaintiffs to impose a temporary restraining order that would have precluded publication of the 2001 TLVs® and BEIs®. Subsequently, the Annual Report of the TLV Committee was distributed with the Winter issue of *Today!*, and the 2001 TLVs® and BEIs® were shipped to members and customers last month.

An updated summary of the three cases follows:

ANCHOR GLASS CONTAINER CORP., et. al. vs. ACGIH, U.S. DOL, and U.S. DHHS

This action is brought by the producers and users of trona. It seeks to prohibit ACGIH from publishing a trona TLV, and from holding meetings to discuss trona. The Complaint argues that ACGIH is a quasi-governmental, standard-setting organization. The Department of Labor (OSHA), and the Department of Health and Human Services (NIOSH) are included because of their alleged reliance upon, and use of TLVs, and because employees of OSHA, MSHA, and NIOSH are members of ACGIH.

The Plaintiffs argue that ACGIH serves as an advisory committee to DOL and HHS, and therefore, cannot be permitted to adopt a trona TLV. Further, DOL and HHS cannot rely on a TLV for trona. They argue that publication of the trona TLV will mislead employees and consumers about safe levels of trona exposure, and that they will be irreparably damaged by such publication. They seek monetary damages from ACGIH.

Recently, the Federal Court in Macon overruled ACGIH's Motion to Dismiss. ACGIH had a partial victory in that the Court dismissed the Plaintiffs' "detrimental reliance" claim against us based on a lack of standing. The detrimental reliance claim was based on an argument that some of the Plaintiffs were supposedly encouraged by ACGIH to conduct a study on trona, but that ACGIH decided to ignore the results of that study. The Plaintiffs were seeking damages for the amount they expended on the study.

The Judge also dismissed the Plaintiffs' claims of "unconstitutional delegation and procedures" and "failure to follow substantive and procedural requirements." These claims dealt with the manner in which a government agency delegates its authority, and conducts its rulemaking process. The Judge dismissed these claims against ACGIH because they were claims attacking the way the government agency conducts its business, not ACGIH. Incidentally, the Judge also dismissed these claims against the government Defendants in this case.

see Lawsuit Updates *on page 2*

Board Recommends Amendment to Bylaws (see page 14)

Regular and Retired Regular Members

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Lawsuit Updates

continued from page 1

As for the remainder of the issues, the Judge denied our Motion to Dismiss on a number of other claims, including the Deceptive Trade Practices Act, which include a trona defamation claim.

We have now turned our efforts to completing the discovery process. Discovery must be completed by July 1. A trial date has been set for September 4 in Macon.

CARLIN DAVID STAPLES, et. al. vs. DOW CHEMICAL COMPANY, et. al.

Mr. Staples was a 38-year-old worker who had six children, and was seriously ill with brain cancer. ACGIH was not named in the initial action, but was added as a defendant in a subsequent Amended Petition. Mr. Staples was exposed to vinyl chloride monomer from December 1982 until October 1997.

ACGIH is included as a defendant, under a conspiracy theory, for fraudulently concealing evidence, and for spoilage of evidence. The Plaintiffs seek punitive damages and compensatory damages.

In January, ACGIH filed a Motion to Dismiss this case based on the fact that ACGIH is not a Texas Corporation, and does not do business in Texas; that ACGIH was added as a defendant subsequent to the Court's established deadline for such an Amended Petition; and that ACGIH engaged in no conspiracy to conceal or spoil evidence, or to do so at its own initiative. The Motion to Dismiss is pending.

REFRACTORY CERAMIC FIBERS COALITION, et. al. vs. ACGIH

The plaintiffs allege that ACGIH is a standard-setting organization, and that the TLV for RCF is unreasonable and unjustified.

On January 12, 2001, the United States District Court in Atlanta held a hearing on RCFC's request for a Temporary Restraining Order enjoining ACGIH from publishing the RCF TLV. After viewing the legal briefs filed by both parties, and listening to counsel for both parties, the Court denied RCFC's request, finding that it does not appear that RCFC is likely to win. ACGIH is free to publish the TLV for RCF.

Based on the January 12th ruling, which was very favorable to ACGIH, the parties have continued to discuss settlement of the litigation. ◆

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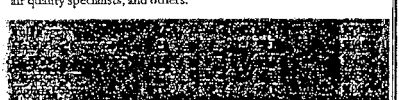

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APPENDIX L – SUBMITTED FOR THE RECORD, "ACGIH CHAIR SCOTT MERKLE SPEAKS TO OPENING SESSION ON LAWSUITS CHALLENGING ACGIH TLVS,"AIHCE CONFERENCE CONNECTION, JUNE 5, 2001

aih ce Conference Connection

Tuesday
June 5, 2001

New Orleans, Louisiana

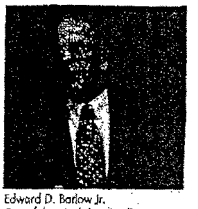
Leading Futurist Addresses AIHce on Ways to Prepare for Tomorrow

On Monday, Edward D. Barlow Jr., one of America's leading futurists, who helps individuals and organizations prepare for the ever-changing world of tomorrow, addressed the opening session of AIHce 2001 in New Orleans. Barlow highlighted the need for occupational health and safety professionals to secure essential information and knowledge; he noted that 80 percent of this exists outside of their own industry or fields of expertise. The need to work both "harder and smarter" is imperative, according to Barlow, because "the future is not in your rear-view mirror." Even more professional discipline will be needed, he advised, to stay in alignment with ongoing global changes.

Barlow tried to help conference attendees prepare for a far different and continually-evolving global marketplace by identifying the strategies and anticipatory thinking skills he sees as necessary to create a preferred future — both personally and professionally. He warned his audience to "anticipate these developments in advance," in order to "stay in alignment with change." Barlow also stressed the need for "reinventing yourself professionally every 12 to 18 months." He identified a number of helpful online resources to assist professionals in creating their own daily desktop to keep them informed of breaking developments both in the United States and abroad. Barlow's dynamic presentation highlighted both the need to expand organizational capacity and to increase professional literacy.

Included in his many straightforward suggestions were the following: collaborate with your competitors; recognize the critical need for training in emotional intelligence; enhance your ability to see market relationships; and find ways to meet customers' needs globally. Barlow counseled his audience that "the future is not bad — just different." He advised against whining, urging instead a focus on value-added products and services, understanding of the metric system and learning a second language, and finding ways to increase your own intellectual capacity by 20 percent a year.

His remarks opened AIHA's annual conference, the theme of which is "Embracing Change." Barlow has been on the speaking circuit since 1987 and has given over 1,500 presentations relating the influences of a changing world to various industries and organizations. The AIHce keynoter runs a consulting firm, Creating the Future Inc., in St. Joseph, Mich. He holds a master's degree in management from the University of Notre Dame, is a member of the graduate school faculty at the University of San Francisco and has held executive positions in business, health care and education.



Edward D. Barlow Jr.
One of America's leading Futurists

ACGIH Chair Scott Merkle Speaks to Opening Session on Lawsuits Challenging ACGIH TLVs®

The following is the text of a speech given by Scott E. Merkle, ACGIH chair, at the June 4 opening general session:

This morning, I stand before you to deliver what is the most important message in my professional career. As many of you may be aware, ACGIH is currently fighting three separate lawsuits, each questioning the development of Threshold Limit Values and our efforts to protect worker health.

Scott E. Merkle
ACGIH Chair

Descriptions of these cases are contained in the ACGIH newsletter that was distributed as you entered the hall this morning.

In my hand is the 2001 *TLV Book*. This represents 63 years of work and dedication. Will it be cast to the wind?

Consider for a moment the TLV documentation that describes the basis for each TLV in this book. The more than 2,500 pages of the TLV documentation represent decades of volunteer dedication. Will this be cast to the wind as well?

Our attorneys advise that I should not discuss the details of these lawsuits, or our defense of them. Let me just say that ACGIH stands by the process and procedures used in the development of the TLVs. We are right in our actions, both professionally and legally. But the task before us is monumental. Just 20 days ago, we delivered over 17,000 pages of our files and documented history to the plaintiff's attorney in one of the lawsuits. We are working to settle the issues where we can; and our defense will be strong and vigorous where we cannot.

These lawsuits are a threat to ACGIH's existence. But there is even more at stake than the survival of our organization. The use of the legal system in these cases rep

See MERKLE, page 7

MERKLE

Continued from page 1

resents a real and serious threat to our profession. These cases are a real and serious threat to worker health.

The TLVs and other voluntary exposure assessment guidelines are at the core of occupational hygiene practice. When we apply these guidance values in the assessment of worker exposure, we become part of the community of public health professionals. When we apply these values to control exposures, we are able to prevent the pain and suffering of occupational disease.

The role of voluntary guidelines is becoming more important to the practice of occupational hygiene than ever before. These lawsuits threaten the first amendment right of professional groups to develop recommendations and express opinions based on their evaluation of scientific information.

For over half a century, the ACGIH TLVs have become recognized around the world as premiere occupational exposure values. The TLVs are health-based values — health-based values that have gained acceptance as benchmarks in our profession because they are indifferent to the economic and public policy aspects of risk management.

But these cases would have ACGIH balance economic health against worker health. These cases would have us place the [illegible]ne right to make a profit ahead of [illegible]on's right to free speech. These [illegible]lance the TLVs.

[illegible]ect engage in public dia[illegible]th professionals to [illegible]ssing about the [illegible] guideline process. [illegible] include perspectives [illegible]vernment, labor and [illegible]alogue should explore ways [illegible]ove the process. But, let me [illegible] dialogue becomes debate in [illegible]room, we face the chance that the [illegible] will not be improved, but could be [illegible]oved.

In the fields of science, we seek the truth. In courts of law, the search is for justice. In fields of science, we focus on progress. In courts of law, the focus is on process.

In my heart, I believe we will overcome these challenges. But I cannot stand before you now and guarantee that justice will not be blind to the truth.

I, on behalf of ACGIH, would like to thank all those who have offered support. This help is doubly meaningful, for it not only provides support to sustain our efforts, but it also provides a statement that what ACGIH does and what its TLV committees do is important, and is worth trying to save.

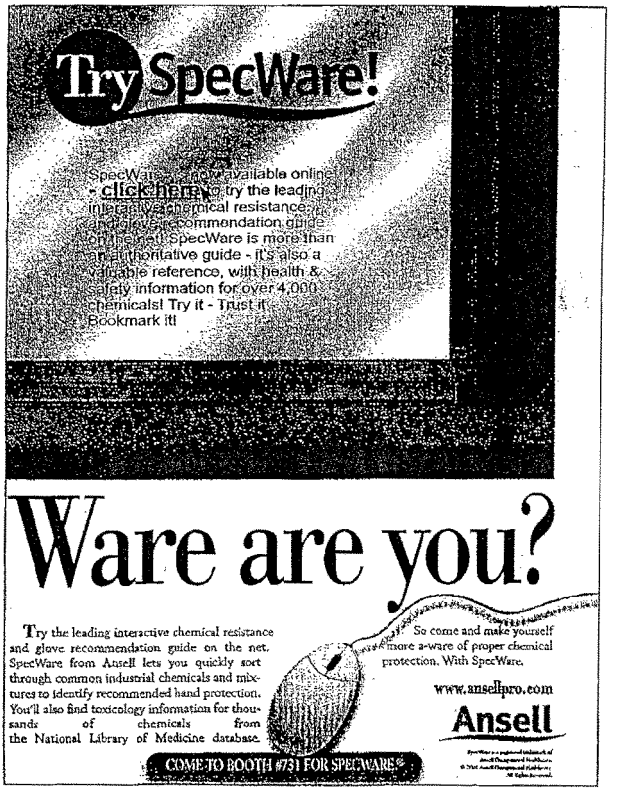
I urge you all to think carefully about what these lawsuits mean. I encourage you to become informed and become involved. If you didn't get a copy of the ACGIH newsletter this morning, I invite you to visit the ACGIH booth in the exhibit hall this week. Find out more information about these issues and how you might help.

With your help, we can prevail. With your help, we can save the TLVs. We can preserve the voluntary exposure guideline process and its vital role in protecting worker health.

ACGIH is an organization that traces its heritage to the very beginnings of our profession in this country. I now implore you — join with us in the effort to overcome this challenge, a challenge that could forever close the pages of this *TLV Book* and render impossible the writing of additional pages.

Thank you for your attention.

Thousands of attendees attended nearly 100 professional development courses on Saturday and Sunday. Topics included microbiology, fire protection engineering, management and indoor air quality.



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HEARING ON THE ROLE OF CONSENSUS STANDARD-SETTING ORGANIZATIONS WITH OSHA

Thursday, November 1, 2001

U.S. House of Representatives

Subcommittee on Workforce Protections

Committee on Education and the Workforce

Washington, D.C.

The Subcommittee met, pursuant to notice, at 10:33 a.m., in Room 2175, Rayburn House Office Building, Hon. Charlie Norwood, Chairman of the Subcommittee, presiding.

Present: Representatives Norwood, Isakson, Keller, Owens, and Solis.

Staff present: Victoria Lipnic, Workforce Policy Counsel; Travis McCoy, Legislative Assistant; Molly Salmi, Professional Staff Member; Jo-Marie St. Martin, General Counsel; Patrick Lyden, Professional Staff Member; Scott Galupo, Communications Specialist; Deborah Samantar, Committee Clerk/Internship Coordinator; Peter Rutledge, Minority Senior Legislative Associate/Labor; Maria Cuprill, Minority Legislative Associate/Labor; and Brian Compagnone, Minority Staff Assistant/Labor.

Chairman Norwood. The Subcommittee on Workforce Protections of the Committee on Education and the Workforce will come to order.

We're meeting today to hear testimony on the role of consensus standard-setting organizations involved with OSHA. Under Committee rule 12 (b), Opening Statements are

limited to the Chairman and the Ranking Minority Member on the Subcommittee. Therefore, if other Members have statements, they will be included in the hearing record. With that, I ask unanimous consent for the hearing record to remain open 14 days to allow Members' statements and other extraneous material referenced during the hearing to be submitted in the official hearing record. Without objection, so ordered.

OPENING STATEMENT OF CHAIRMAN CHARLIE NORWOOD, SUBCOMMITTEE ON WORKFORCE PROTECTIONS, COMMITTEE ON EDUCATION AND THE WORKFORCE

We are here today to pick up where we left off earlier this year and to continue our discussion about ways to better the OSHA regulatory process. At our last hearing, we heard a lot about the OSHA rulemaking process in general. There were a number of suggestions made for reform. Today, we will focus more specifically on the role of consensus standard-setting organizations with OSHA.

I know that consensus standard-setting organizations can play many roles with OSHA, not simply confined to rulemaking. They can also work with OSHA in partnerships to improve the quality of OSHA's work, and to share ideas and expertise with OSHA staff about advancing safety and health in the workplace.

Improving safety and health in the workplace is why we are here today. I know some may think this is a rather conventional topic for an OSHA hearing, given the highly unconventional times we have been living in since September 11th. However, given the experiences of all of us on Capitol Hill recently, particularly those of us who are still shut out of the Longworth Building, or those working in post offices, in fact, there may be no better time to hold a hearing related to occupational safety and health. It seems to me that when we are faced with new threats to workplaces every day, examining ways to continuously improve OSHA is a worthwhile effort.

Let me take a moment to welcome our witnesses. We appreciate their willingness to take time out of their busy schedules to testify before the Subcommittee. I especially want to acknowledge our witness from ACGIH. Because of our first hearing and my correspondence with the Secretary of Labor regarding ACGIH, I committed that ACGIH would be given the opportunity to testify. I am pleased that they were able to make it today.

Let me add that some may think I am interested in putting ACGIH out of business. To the contrary, I am not interested in putting ACGIH or anyone else out of business. I certainly don't want to be in a position of discouraging private groups from working on threshold limit values for chemicals or standards that make improvements to our knowledge of safety and health.

I do, however, believe that Congress has an obligation to pay attention to what OSHA does with information provided by private standard-setting organizations. If OSHA is in any way relying on private standards, then it seems to me that OSHA needs to ensure the integrity of the process used by the private group. If it cannot do so, then OSHA should not make use of that information. I certainly hope, and fully expect, that we will hear from someone from OSHA on this subject very, very soon.

It strikes me there are three reasons why we ought to look at the work of private consensus standard-setting organizations and the role they can play with OSHA. First, we've got a rulemaking process that is too slow, oftentimes for very good reasons, highly politicized, and really seems to satisfy no one.

Second, we've got a number of OSHA standards, such as the air contaminants standards that are out of date, and most would agree need to be updated.

Third, we've got a number of private, voluntary consensus standard-setting organizations that may have much to offer, and that do good work, but cannot meet all the requirements we expect in an OSHA rulemaking in terms of transparency, due process, creation of a public record, and ability of the regulated community to comment. In short, if we want to see OSHA improve the standards process, even to make updates to standards currently on the books, we can't quite get there from where we are today. But we can go forward.

I'd like us to figure out where we can go from here. I look forward very much to the discussions today, and the suggestions from all of our witnesses.

WRITTEN OPENING STATEMENT OF CHAIRMAN CHARLIE NORWOOD, SUBCOMMITTEE ON WORKFORCE PROTECTIONS, COMMITTEE ON EDUCATION AND THE WORKFORCE – SEE APPENDIX A

Chairman Norwood. Now want to yield to the distinguished Ranking Member, Mr. Owens, for whatever Opening Statement he wishes to make.

OPENING STATEMENT OF RANKING MEMBER MAJOR OWENS, SUBCOMMITTEE ON WORKFORCE PROTECTIONS, COMMITTEE ON EDUCATION AND THE WORKFORCE

Thank you, Mr. Chairman, for yielding to me. I want to thank this morning's witnesses also for their time and effort to be here with us. I look forward to your testimony.

This is the second hearing we've had relating to OSHA rulemaking. Let me be explicit about what my interest is in this hearing. Last year, the National Advisory Committee on

Occupational Safety and Health issued a report and recommendations related to OSHA's rulemaking process. As stated in the NACOSH report, in 1971 OSHA adopted tables covering most of the substances specifically regulated by OSHA. These exposure limits were adopted from existing lists of federal and consensus standards, many of which were first published by ACGIH. Those values are now 30 years old. The 2000 ACGIH list contains different, and usually lower, values for many of the substances on the list, as well as a substantial number of additions. However, changing the permissible exposure limit for any substance on the list requires extensive rulemaking.

Since 1971, OSHA has completed rulemaking for only 28 toxic substances. In 1988, OSHA attempted to overcome this limitation by undertaking a generic rulemaking for more than 300 substances. However, the 11th circuit court of appeals vacated that standard on the grounds that OSHA had not properly made the required determinations of significant risk, or feasibility for each individual chemical. Meanwhile, OSHA can only enforce the old values, notwithstanding 30 years of evidence that they may be harmful.

I am not particularly concerned about how a consensus standard organization functions. Nor do I think we need debate whether or not a specific standard has consensus status. Notwithstanding the fact that a standard was issued by a consensus standard organization, if there is a controversy regarding the standard, then for my purposes, it is not a consensus standard.

Even with these qualifications, I believe that there are voluntary standards that are both more protective than the current OSHA standard and that enjoy consensus status. NACOSH has specifically recommended that the Congress authorize the Secretary of Labor to adopt the updated consensus standard without going through the full rulemaking process. If the concern is that this represents too much delegation to the Secretary, then perhaps the Congress can act directly to update the standards, as we did with the needlestick legislation last year.

As I said at the last hearing, I do not think that this Congress is going to be able to improve OSHA's standard-making process, but, where voluntary standards are both broadly accepted by business and more protective of workers, then there should be a means by which the OSHA standard can be conformed to the consensus standard.

Finally, I commend the Chairman for affording the American Council of Government Hygienists an opportunity to testify. I continue to strongly feel that the June 14th hearing was inappropriate at best. It was wrong for this Subcommittee to be used to take sides in pending litigation, and it is especially wrong when only one party to that litigation was permitted to participate in the hearing. While affording ACGIH an opportunity to participate now does not wholly rectify the previous wrong, it does mitigate it somewhat, and I commend the Chairman for that action today.

Again, I thank today's witnesses for being here, and I yield back the balance of my time.

Chairman Norwood. Thank you, Mr. Owens. And now I would like to introduce our panel of witnesses:

Mr. Patrick Breysse from the American Conference of Governmental Industrial Hygienists. Mr. Travis Nichols on behalf of the American Bakers Association. Mr. David Karmol from the American National Standards Institute. Mr. John Biechman from the National Fire Protection Association. Mr. Henry Lick on behalf of the American Industrial Hygiene Association.

Welcome, all. Thank you for your time and willingness to come. As with most of our oversight hearings, it's a learning process for us all to try to determine how we can improve what the government does.

Before the witnesses begin their testimony, I would like to remind the Members that we ask questions after the entire panel has testified. And I suspect that we're going to get interrupted during that time with votes, for which we will recess briefly. In addition, Committee rules impose a five-minute limit, ladies and gentlemen, on all questions, as you know.

There is a timer light set out before each of you there. When the yellow light comes on, we will ask that you begin to wind down your testimony. We note many of you have extensive testimony all of which will go into the record. So because you're only going to be given five minutes we'll ask you to summarize your testimony.

Mr. Breysse, you may begin now, sir.

STATEMENT OF PATRICK BREYSSE, VICE CHAIR- ELECT, AMERICAN CONFERENCE OF GOVERNMENTAL INDUSTRIAL HYGIENISTS, JOHNS HOPKINS UNIVERSITY, BALTIMORE, MD

My name is Patrick Breysse. I'm appearing today on behalf of the American Conference of Governmental Industrial Hygienists, ACGIH. I'm an industrial hygienist, and I'm also a Professor at the Johns Hopkins University Bloomberg School of Public Health. I currently serve as the Vice Chair-elect of the ACGIH, and in January 2002 I will rotate to the Chairmanship.

I'd like to thank the Committee for this opportunity to appear with you today. I know this Committee is concerned about OSHA, about the OSHA standard setting activities, the amount of time it takes OSHA to set a standard, the content of the standards, and the amount of litigation generated by the standards.

In prior testimony before the Committee, it has been stated that OSHA uses ACGIH to set standards, to avoid the requirements of the OSHA statutes and the Administrative Procedures Act. I would like to take issue with that today.

At the outset, I would like to set the record straight that ACGIH is an independent, scientific, guideline-setting organization. We were established in 1938, many years before

OSHA was created. ACGIH is not a tool of OSHA. ACGIH does not set standards. We do not recommend standards. We publish guidelines for use by practicing professional industrial hygienists as one of many factors, as one of many tools an industrial hygienist may use in evaluating whether specific hazards exist in one workplace or another. These guidelines are referred to as threshold limit values, TLVs, or biological exposure indices, BEIs.

As an industrial hygienist, part of my job is to advise employers and employees about how to maintain a healthy and safe workplace. I can't be an expert on every single substance and every single hazard that might be present in the workplace. I must look to some centralized body of knowledge, hopefully created by my peers, to help me in developing my recommendations. In recognition of this need, ACGIH was created.

The threshold limit values are guidelines that industrial hygienists like myself will use to help them in their professional practice. These guidelines were never meant to be used as standards. Each TLV is a representation that a committee of the ACGIH experts have reviewed the scientific literature on a substance, made a determination that the existing scientific data supports conclusions that an average worker can be exposed to a certain level of a substance without adverse health effects, and that this average worker can be exposed day in and day out for an entire working lifetime.

Because of the conservative nature of the TLV guideline-setting process, ACGIH does not claim that exposures above the levels are necessarily dangerous, but that there isn't enough data for which we feel comfortable saying that higher levels would be sufficiently protective.

The TLVs are published for use by industrial hygienists, and along with each TLV an extensive documentation laying out the rationale for a specific TLV, and the literature that was relied upon to set the specific TLV is published. ACGIH strongly recommends that the industrial hygienists who use TLVs also have the companion documentation to use. One goes along with the other. It's not possible to use number or value, which we publish in a booklet every year, without understanding the scientific rationale that goes behind it. This is a fundamental tenet of industrial hygiene practice.

With my statement, I've provided the Committee with copies of two documentations. These two documentations will serve as examples of the type of TLVs and the documentations that we produce. You will note that this publication emphasizes repeatedly that TLVs are guidelines that industrial hygienists use, and are not meant to be used as standards. That's a point I can't make often enough.

This Committee has been told that ACGIH acts in secret. We don't believe this is true. Before a TLV is published in final form, we publish in our booklet that the substance is under study. Once a subject comes under study, a subcommittee of the full TLV committee assigns a person to review the literature, and makes a draft recommendation for a threshold limit value, and a proposed documentation. This draft documentation and the value is reviewed by the full subcommittee, where, if they agree with it, they can pass it on to the full committee, or if they don't agree with it, they will modify it, and debate it further.

Once the substance is approved at the subcommittee level, it gets approved and debated at the full committee level. Ratified by the board of directors, it becomes a threshold limit value, and we publish it under the notice of intended change. So it's a preliminary value, or a draft value at that point.

Once we publish the draft value, that's an alert to all affected parties of the number we're considering, and the research that we relied upon to set that number. Parties are free to comment at that point, and substances will stay in the notice of intended change for roughly a year, or in some cases, much longer than a single year. All the comments will be reviewed, and if germane to the threshold limit value, and appropriate for changing the value, they will be changed.

Once the threshold limit value is removed from the notice of intended change, the full committee votes on it, and it becomes the final threshold limit value at that point, and the board of directors ratifies it.

WRITTEN STATEMENT OF PATRICK BREYSSE, VICE CHAIR-ELECT, AMERICAN CONFERENCE OF GOVERNMENTAL INDUSTRIAL HYGIENISTS, JOHNS HOPKINS UNIVERSITY, BALTIMORE, MD
SEE APPENDIX B

Chairman Norwood. Thank you, Mr. Breysse. I encourage all Members to read your testimony. I found it very interesting reading, and I hope everybody does look at it.

Mr. Travis Nichols, you are recognized for five minutes.

STATEMENT OF TRAVIS NICHOLS, DIRECTOR OF SAFETY, BAKERY CHEF, INC., LOUISVILLE, KY ON BEHALF OF THE AMERICAN BAKERS ASSOCIATION

Good morning, Mr. Chairman, distinguished Members of the Subcommittee. Thank you for the invitation to address this hearing today. With everything going on in the world right now, it's comforting to know that the business of our government continues forward.

I am a health and safety leader for a company called Bakery Chef, Incorporated, based in Louisville, Kentucky. Our company is a moderately sized bakery company that has five bakeries located through the United States, and we employ roughly 700 employees. We make a variety of products, many of which you've probably sampled yourself; biscuits, breads, hotcakes, materials of this nature.

My responsibility at our company is the management for all safety and health programs and initiatives, including regulatory accountability and Workers' Compensation. I began my

career with the company out on the production floor as a baker, and was encouraged to continue forward, working with our company in health and safety matters, and actually helped develop our health and safety department.

My company fully supports creating a safe work environment for our employees. They encourage these activities. They even paid for my tuition to become a nurse so I could better help our health initiatives with our company. In my role as a health and safety professional for our company, I work with both our operations personnel and leadership to maintain a safe work environment.

Today I am testifying on behalf of the American Bakers Association. The ABA is a trade association that represents the nation's wholesale baking industry. Its membership consists of more than 300 wholesale bakeries and allied service firms. These companies represent approximately 80 percent of the nation's baked goods. The members of the ABA collectively employ tens of thousands of employees nationwide in the production, sales, and distribution of baked goods.

In the past few years, the baking industry has become very concerned about one of the so-called consensus organizations, the American Conference of Governmental Industrial Hygienists. ACGIH creates TLVs that are frequently used by OSHA as the foundation for their exposure limits, and that are also used by OSHA in what is known as general duty clause violations. In addition to federal OSHA, 23 state OSHA plans rely heavily on these TLVs that ACGIH develops. These state and federal OSHA plans need to have the confidence in the procedures and the end results of the consensus standards that they are relying on.

As the wholesale baking industry has found out, ACGIH has issued several TLVs that have questionable scientific bases. Making matters worse is that every aspect of the development of these TLVs is done in secret, with no public input. During the recent development of a TLV for flour dust, ABA, the American Bakers Association, was unable to get copies of proceeding minutes, the list of committee members, their professional qualifications, summaries of the scientific analysis, nothing. Our written statement covers the number of attempts that we made to open the discussion on the flour dust TLV.

ABA was joined by the North American Millers Association and Canadian National Millers Association to conduct an analysis of ACGIH's justification for this flour dust TLV. Sandler Occupational Medicine Associates, SOMA, conducted this analysis, and found that the TLV that they had created for flour dust was based on very limited, indefinite, and unconfirmed information that is not substantiated. Quite simply, the scientific evidence did not provide a basis for the control of exposure at specific thresholds, particularly to the exposure to flour dust for purposes of preventing or limiting flour allergen sensitization and other work-related effects.

ACGIH cloaks its TLV standards in legal disclaimers that note that their work products are not intended for use in enforcement. Let me tell you from personal experience, these TLVs are being used quite readily for enforcement purposes. In early 2000, when we first learned of the TLV for flour dust, we were greatly shocked, because it was 30 times lower than OSHA's nuisance dust level that had been established. It was also far lower than any of the SOMA

standards for materials that we would commonly think are more serious in nature, such as copper dust.

Our company formed an in-house team, and we worked with Kentucky OSHA, who we've had a great relationship with, to study this. In looking at the SOMA critique, we found that the science just isn't there. This is a fatally flawed threshold limit value. OSHA investigated us for exposures to flour dust, and found that under the OSHA standards, we were more than 50 times in exposures to our people as what was required by OSHA.

When we were, in turn, investigated under this new TLV, it was found that, through some questionable testing, that we did not meet the requirements for this new TLV. The difference between the old standard and the new standard is significant, and the science, quite simply, isn't there. Personnel working in the department, making biscuits, who would normally wear hairnets, earplugs, safety glasses, and are not required under OSHA's standard for exposure to wear respiratory protection, under this new TLV would be required to wear respiratory protection very similar to that you've probably seen here on Capitol Hill recently in dealing with hazardous materials. This is an extreme leap for making biscuits.

Our largest request and it's in our written documentation is that the process is opened up and democratic and allows us to have a seat at the table in forming a true consensus standard.

Chairman Norwood. Thank you very much, Mr. Nichols. I encourage everyone to read your testimony. I think we have about six or seven minutes left before the next vote. There will be just one vote, so we'll try to reconvene ten minutes after it. We'll be back as fast as we can. We're in recess.

[Recess.]

Chairman Norwood. The Committee will come to order. I apologize, gentlemen, for our disruption. Hopefully, we won't be disrupted now for an hour or so.

Mr. Karmol, I think it is your turn to be recognized for five minutes.

STATEMENT OF DAVID KARMOL, DIRECTOR OF PUBLIC POLICY AND GOVERNMENT AFFAIRS, AMERICAN NATIONAL STANDARDS INSTITUTE, WASHINGTON, D.C.

Thank you, Mr. Chairman and Members of the Committee, for the invitation to testify today. I am David Karmol, Director of Public Policy and Government Affairs of the American National Standards Institute. This hearing is of great interest to us, as ANSI and many ANSI-accredited developers of voluntary consensus standards work closely with OSHA, as they do with many other federal agencies. I'll summarize my written statement filed with the Committee, and ask that the full statement be made part of the record.

The voluntary standardization system in the United States is the most effective and efficient in the world. For nearly 100 years, with the active support and participation of both the private sector and the U.S. government, ANSI has coordinated the voluntary standardization system in the United States. We accredit standards-developing organizations, and designate American national standards that provide dimensions, ratings, terminology and symbols, procedures, test methods, performance, and safety requirements. There are today approximately 13,000 such American national standards, produced by over 200 ANSI accredited developers, including two on this panel today, NFPA and AIHA.

ANSI is also the United States representative to the International Organization for Standardization, and through the U.S. national committee, the International Electrotechnical Commission. Last month the Chairman of our ANSI Board of Directors, Oliver Smoot, was elected President-elect of ISO for 2002. Chairman Smoot and ANSI President Mark Hurwitz extend their greetings and their appreciation for your interest.

As the only accreditor of U.S. standards-developing organizations, ANSI ensures the integrity of the standards development process, and determines whether standards meet the criteria to be designated American national standards. To be accredited, a standards-development process must adhere to ANSI's principles of openness, balance, public review, and due process, which include the right to appeal. ANSI principles also require a complete record of evidence that representatives of all materially affected interest categories have reached a consensus on a proposed standard. ANSI regularly audits its accredited standards developers, to ensure that they are adhering to their procedures and to current ANSI requirements.

Now, ANSI recognizes there are many ways to develop standards, and that in some instances, other methods are appropriate for the respective user community. For the record, let me say that ANSI has no objection to organizations that develop standards outside the so-called formal process used within the ANSI community. ANSI believes it is up to standards users to decide where, and under what process, they want particular standards developed.

While the term, “public-private partnership” has been in vogue in recent years, it has been a reality for ANSI since our founding in 1918. We are a 501(C)(3) organization, but our membership includes federal agencies, and representatives of many of those agencies are members of our Board of Directors. These include the Department of Defense, NASA, the Environmental Protection Agency, the National Institute for Standards and Technology, the

Consumer Products Safety Commission, and OSHA.

A series of laws enacted by the Congress require government agencies to use appropriate voluntary consensus standards. These are: The Consumer Product Safety Improvement Act of 1990, the National Technology Transfer and Advancement Act of '95, the Health Insurance Portability and Accountability Act of 1995, the Telecommunications Reform Act of 1996, and the FDA Modernization Act of 1997.

These laws, as well as OMB Circular A-119, which has been issued and reissued by every administration since 1978, all are intended to achieve savings for the agencies, better coordination with the private sector, and regulations for procurement activity and international trade. ANSI has a positive, productive relationship with OSHA. We've had a series of memorandums of understanding with OSHA since the late 1970s that recognize that it is in the national interest to work together cooperatively on standardization matters. An OSHA representative serves on the ANSI board of directors, and OSHA employees are valued participants in standards-developing organizations.

We'd like to bring to the Committee's attention a serious problem that may require congressional action to resolve. OSHA regulations contain hundreds of outdated standards. In some cases the standards referenced have been out of date for 30 years or more. OSHA cannot update these regulations without going through a full public review process that the agency does not have the resources to accomplish. This is a nonpartisan issue. Assistant Secretaries of Labor for OSHA from both political parties have tried to resolve the problem, without success. We've discussed the issue with Assistant Secretary Henshaw. He understands the problem, and we're ready to work with him and the Committee to resolve this problem.

In conclusion, ANSI shares the Committee's desire to ensure that the Federal Government, most certainly including OSHA, relies upon the use of voluntary consensus standards that have been developed in an open, balanced process that provide protections against arbitrary or capricious actions, and against unfair dominance by an interest group. Thank you.

WRITTEN STATEMENT OF DAVID KARMOL, DIRECTOR OF PUBLIC POLICY AND GOVERNMENT AFFAIRS, AMERICAN NATIONAL STANDARDS INSTITUTE, WASHINGTON, D.C. – SEE APPENDIX D

Chairman Norwood. Thank you, Mr. Karmol. Just so you know, this Committee understands the problem, too, and we're in the process of trying to think through it. That's part of what these hearings are all about. So we appreciate any help your organization offers this Committee in the days to come.

Mr. Biechman, you are recognized for five minutes.

STATEMENT OF JOHN BIECHMAN, VICE PRESIDENT FOR GOVERNMENT AFFAIRS, NATIONAL FIRE PROTECTION ASSOCIATION, ARLINGTON, VA

Thank you, Mr. Chairman and Members of the Committee, for allowing me to testify this morning. My name is John Biechman. I'm Vice President for Government Affairs at the National Fire Protection Association.

NFPA is a 105-year-old not-for-profit codes and standards development organization headquartered in Quincy, Massachusetts. Its mission is to reduce the worldwide burden of fire and other hazards on the quality of life. NFPA publishes over 300 codes and standards. The American National Standards Institute accredits all of NFPA's codes and standards, and they meet the requirements for voluntary consensus standards of the Technology Transfer Act of 1995.

NFPA develops and renews its codes and standards through a voluntary consensus process. Over 5,000 volunteers participate in more than 200 technical standards committees. The technical committee members represent a balanced cross-section of industry, labor, and allied interests. They are selected based on their technical expertise and ability to fully participate in the work of the committee. The NFPA process is open, balanced, ensures due process, and provides for an appeals process.

OSHA staff has participated in several of NFPA's technical committees, including our commercial maritime-related committees, our flammable liquids, finishing processes, and pyrotechnic committees. Since the 1975 code cycle, OSHA has participated in NFPA's national electrical code correlating committee, and NFPA's standard 70E, the electrical safety requirements for employee workplaces. OSHA has been involved in that. The standard was specifically developed for an OSHA rulemaking, and with OSHA participation.

Because NFPA is accredited by ANSI, our codes and standards must be updated at least every five years. Oftentimes, however, NFPA standards are revised on a more frequent basis to reflect new technology or findings. Several federal agencies and departments reference NFPA standards. A list of the NFPA codes and standards to be revised or reaffirmed is published in the Federal Register, through the National Institute of Standards and Technology, NIST, at the outset of each review cycle. This affords the opportunity for those interested in NFPA codes and standards to participate in the process.

To address NFPA's specific experience with OSHA, the original 1970 OSH act allowed the Department of Labor to jump start rulemaking to improve worker safety, by adopting consensus safety standards through an expedited regulatory process known as the 6(a) process. Approximately 50 NFPA standards were adopted in the mid 1970s, and most are still codified as baseline OSHA safety standards. Many of the referenced NFPA standards date back to the 1960s. Most have been superseded by state of the art successor standards adopted by NFPA, and are applied in the workplace today, but OSHA has not adopted them.

One reason it is difficult to update OSHA safety standards is that the 6(b) process that succeeded the 6(a) expedited process often takes several years at rulemaking, and only a few rules are considered each year. The problem is further exacerbated because OSHA inspectors are required to issue de minimus violations when an employer complies with newer additions of a consensus standard, rather than the obsolete standard referenced in the code of federal regulations. Recognizing the problem with this approach, OSHA inspectors can waive fines, but the de minimus violation remains.

One possible solution to this problem would be for OSHA to recognize contemporary editions of consensus standards in the C.F.R. by title, number, and edition date as acceptable for OSHA compliance, as long as the level of protection as determined by OSHA is at least as effective as the original consensus standard cited. In this way, an original standard adopted by OSHA in the 1970s under the 6(a) process would be maintained as the minimum, but employers would be free to use a later addition without penalty. The original standard would continue to be referenced in the C.F.R., and a notation would be added to reference later additions.

NFPA has worked well with OSHA, and encourages OSHA to continue to work within the voluntary consensus standards development process. Furthermore, we hope that OSHA, when participating in the voluntary consensus process, will take into consideration the thoughts and suggestions of technical committees, because they are truly balanced, and voluntary consensus committees that represent state of the art technology, and best work practices found within the industry today.

Mr. Chairman, I want to thank you for giving us the opportunity to testify this morning.

WRITTEN STATEMENT OF JOHN BIECHMAN, VICE PRESIDENT FOR GOVERNMENT AFFAIRS, NATIONAL FIRE PROTECTION ASSOCIATION, ARLINGTON, VA – SEE APPENDIX E

Chairman Norwood. Thank you very much.

Mr. Lick, you may now begin your testimony.

STATEMENT OF HENRY LICK, PRESIDENT, SAFETY AND HEALTH SOLUTIONS, LTD, GROSSE ILE, MI, ON BEHALF OF AMERICAN INDUSTRIAL HYGIENE ASSOCIATION

Chairman Norwood and Members of the Subcommittee, my name is Hank Lick, and I've been invited here to provide testimony on the role of consensus standard-setting-organizations with OSHA. I appreciate the opportunity to provide input on this important health and safety

issue.

At the present time, I am President of Health and Safety Solutions, a health and safety consulting company that I formed this year. Previous to that, I was at the Ford Motor Company for 32 years, and retired as manager of occupational environmental health sciences. I have also been active as a member and chair of several industry and governmental advisory committees, and recently completed six years on the National Advisory Committee on Occupational Safety and Health, NACOSH. At this time I am privileged to be serving as President of the American Industrial Hygiene Association.

Before I begin, Mr. Chairman, I'd like to take this opportunity to thank you on behalf of millions of Americans who desire a safe and healthy workplace, for your involvement in addressing this particular issue. I applaud your efforts, and I also would like to ask that my written testimony be inserted into the record.

For several years, I have been concerned with the degree of difficulty OSHA has promulgating health and safety standards. Since consensus standards were first adopted after the passage of the OSH Act, a relatively small number of standards have been promulgated. Further standards, such as the permissible exposure limits have not been successfully updated. The average time to develop and promulgate a standard is 10 years. During my service on NACOSH, I provided advice to OSHA on the development of standards, and in 1998, I requested NACOSH conduct a study to determine the reasons why the OSHA standard-setting process is so difficult.

NACOSH sought information from various stakeholders. After hearing from the stakeholders, NACOSH concluded that the standard-setting process was not working as intended. There were many recommendations included in the NACOSH report, and I have included a summary attached to my testimony. In fairness, many external and legal barriers have made the process more difficult. Several layers of review are now present that were not foreseen in the OSH Act. However, NACOSH stated that, “OSHA and the National Institute of Occupational Health and Safety have not developed management systems to address potential changes in the regulatory environment.” Further, NACOSH concludes, “OSHA and NIOSH do not synergistically act in setting standards.”

Also, OSHA has not supported its internal and advisory resources effectively. In my opinion, this is due to a weakness in strategic and tactical planning. OSHA and NIOSH should not shoulder all the blame for the standard-setting process not working. Consensus standard-setting organizations and professional associations should be more consistent and uniform in their support. These entities, together with OSHA and NIOSH, must form stronger alliances to resolve differences in scientific opinion early in the standard-setting process.

As the world's largest association of occupational and environmental health professionals, AIHA members are well aware that exposure limits and standards are a primary tool in disease prevention. AIHA's latest position in permissible exposure limits is also attached to my testimony for your review. But AIHA has not limited itself simply to adapting statements on this problem. Earlier this year, we formed a task force composed of labor, industry, and professional association representatives to see if an agreeable solution on this issue could be found. While it's

early, I'm confident that this is a first step in finding a solution. I'm also convinced that leadership of an organization such as AIHA will bring the parties together. Our relationship with OSHA and NIOSH, labor, and industry is excellent, and I offer the assistance of AIHA as you move forward.

Since the NACOSH report, though, several events have occurred to point out the need to immediately address the standard-setting process, including the use of the Congressional Review Act on the OSHA ergonomic standard, and the lawsuits against ACGIH. These events have not changed my opinion that the standard-setting process is essentially broken. However, they do point out that we need to resolve this issue. The broken standard setting process impacts business, and distract OSHA from its primary mission of protecting worker health and safety. The ACGIH TLV process is the only viable worker exposure limit-setting process we now have. OSHA PELs, though, are essentially 1968 ACGIH TLVs, and therefore, for the most part, are outdated and irrelevant. Some say that the ACGIH process is flawed, but if ACGIH is no longer involved in standard setting, then someone else needs to step up to the process.

It has been 32 years since the passage of the OSH Act. Businesses that weren't even imagined at that time now dominate commerce. Many hazards that were present at that time have been controlled, but new hazards have replaced them. The global economy is dynamic, but our standard-setting process is not. Congress needs to amend the OSH Act to incorporate today's realities. Businesses must support a consensus standard setting process with their best talent and financial resources, and health and safety professionals and their associations must work together, and with consensus standard-setting organizations.

In closing, I'd like to applaud your efforts hoping that we will be able to find a better way to improve the health and safety of American workers. AIHA stands ready to assist you in Congress in every possible way in this goal. I'd be happy to answer any questions that you might have, and I thank you very much for your time.

WRITTEN STATEMENT OF HENRY LICK, PRESIDENT, SAFETY AND HEALTH SOLUTIONS, LTD, GROSSE ILE, MI, ON BEHALF OF AMERICAN INDUSTRIAL HYGIENE ASSOCIATION – SEE
APPENDIX F

Chairman Norwood. Thank you, Mr. Lick, for your testimony. And indeed, gentlemen thank you for your testimony. I'll remind us all that the question and answer period is limited to five minutes per Member. However, we will have more than one round. I'll recognize myself for the first five minutes. I'm going to direct this question to the whole panel generally.

It seems to me that we have somewhat of a consensus on this panel that it's extremely difficult to get any kind of agreement about the science behind standards, even within the consensus standard-setting organizations. I wonder if any of you, or all of you agrees with that? Anybody?

Mr. Lick. I'd like to answer that.

Chairman Norwood. Yes.

Mr. Lick. There are different constituencies that people represent, and different areas of experience. The health standards field is so broad; it's hard for anyone to know everything about a particular subject. Just take, for instance, the ergonomic standard. You may be good at doing things in the industrial environment, but when it comes to offices, you fall down. So it's hard for everyone to know everything.

Typically, unless you have an extremely large group, which presents another problem, it's hard to get in all the information that you need to have. And in many cases, people that have the information don't share it.

Chairman Norwood. Anybody else have a thought about the difficulty of the science, and obtaining a consensus even within your own groups? Do any of you think this is a problem?

Mr. Breysse?

Mr. Breysse. Yes. I'd like to share our perspective, since ACGIH does not consider itself to be a consensus standard-setting group in the manner that you've heard others speak about today.

We are an independent group of scientists, if you will, who look at the literature. We recognize that, in many cases, there's tremendous uncertainty with respect to what should be safe, what studies should be given more weight, what studies should be given less weight. However, we are able to reach agreement within our own committees about what level is most protective. And the way we are able to do that is because we adopt a relatively conservative approach. Since we don't advertise our standards as being consensus standards by any means, we're able to reach some agreement among our own committee members about just how low we really think levels should be, and what the most protective level we feel comfortable about is. And when we adopt that philosophy, we're able to reach some agreement within our own committee.

However, we recognize that when we publish these numbers out in the broader scientific community where people have to look at aspects associated with both technical and economic feasibility, that that creates some difficulty for them. However, we do not consider those issues within our own group. And therefore, I think we eliminate some of the complexity that other groups have to deal with.

Chairman Norwood. It interests me that, in your testimony, you stated over and over again that your standards are not developed for use as legal standards. I am convinced you believe that, and you mean that. However is any of your TLV standards, through no fault of your own, used as legal standards?

Mr. Lick. We recognize that, through no fault of our own, in fact against our own recommendation that countries around the world use them, and they creep into the regulatory arena in certain aspects of OSHA regulations.

However, we feel very strongly, as health and safety professionals, that numerical guidelines for safe levels of exposure are just one tool in the arsenal of a health and safety professional that allows you to make decisions about what's appropriate for any workplace or not.

For example, we heard this morning that adopting a TLV would result in increased respiratory protection. We don't recommend anything about respiratory protection. In a mature health and safety program, decisions have to be made about how to protect somebody with respect to respiratory protection, or with respect to other engineering controls, in a broader context of a medical monitoring or a medical surveillance program. And in that context, a TLV is just one piece of information. They become codified as standards, in the sense that if you're above this level, you're overexposed, if you're below this level, you're safe. We really think this misrepresents what we feel these numbers stand for.

Chairman Norwood. Since you don't feel you're putting out consensus standards your group doesn't necessarily concern itself with issues of transparency and due process for the regulated community; is that correct?

Mr. Lick. We concern ourselves with transparency to the extent that we operate within our own policies and procedures. Now, we're more than willing to discuss the understanding more broadly, but we don't think it's an issue of transparency. We don't consider these things, in the broader context
with respect to your question, because we're not a consensus standard-setting group.

Chairman Norwood. Since you aren't producing a consensus standard, you work on different guidelines than those who are. Would you agree that, whether you like it or wish it, OSHA accepts your standards as consensus standards by reference? Would you agree, through no fault of your own, that OSHA uses your non-consensus standards that have some problems with due process for those that are regulated?

Mr. Lick. I would agree that OSHA references the TLVs in a number of places. However, I'm not so certain that they are used in the formal standard.

Chairman Norwood. When they reference it, doesn't it become a regulation that has the teeth of law and therefore it is a legal standard from their point of view, but maybe not from yours?

Mr. Lick. If OSHA references a TLV in the hazard communication standard, it just says you have to list the TLV on the material safety data sheet. Does that make it a standard? I don't think so.

Chairman Norwood. Well, what does it do for OSHA? What do they make it?

Mr. Lick. You know, I'm not comfortable commenting on exactly how OSHA utilizes this information. I think I'd rather stick more closely to how we feel our information should be used.

Chairman Norwood. All right. My time is up. But I'm coming back to ask Mr. Nichols that same question.

I recognize Mr. Owens.

Mr. Owens. In follow-up on the Chairman's question, Mr. Breysse, you have an organization with unique expertise, that's respected not only in this country, but also throughout the world, you said.

Mr. Breysse. Yes.

Mr. Owens. Do you receive fees when organizations and governments adopt your standards?

Mr. Breysse. No, we do not.

Mr. Owens. Or use them as references?

Mr. Breysse. No, we do not.

Mr. Owens. So there's no reason for you to ever be conflicted about what you're doing, in terms of the ultimate use of your information?

Mr. Breysse. That's correct.

Mr. Owens. Thank you. Mr. Nichols, in several instances in your testimony, you say that an OSHA hygienist inspected your facility, or did exposure monitoring at your workplace. I want to be absolutely clear on this, and I'm confused. Was that individual a federal employee, or an employee of the state of Kentucky?

Mr. Nichols. Mr. Owens, that was an employee of the state OSHA.

Mr. Owens. The state of Kentucky?

Mr. Nichols. That is correct, sir.

Mr. Owens. Has federal OSHA ever sought to impose the flour TLV in your company?

Mr. Nichols. No, they haven't, sir, but that becomes part of the issue. Kentucky OSHA, after having the opportunity to review the rationale that ACGIH had presented to create the TLV, and after reviewing the Sandler analysis, withdrew their citation because the science wasn't there. That still doesn't mean these situations will not take place for other states.

Mr. Owens. Are you aware of any situation where federal OSHA has cited anyone for failure to comply with the flour TLV?

Mr. Nichols. Federal? No, sir.

Mr. Owens. You don't know of any instances?

Mr. Nichols. There's the potential for that to happen, though.

Mr. Owens. I know you stated this in your prepared statement, but once again, for the record, isn't it in fact true, the Kentucky citation based on the flour TLV was dismissed?

Mr. Nichols. That is correct, sir.

Mr. Owens. It was dismissed.

Mr. Nichols. It was.

Mr. Owens. So the kind of gas mask photo that you showed was unnecessary. That was never required, right?

Mr. Nichols. It would have been required under their citation. It was withdrawn once they had an opportunity to see the science.

Mr. Owens. It's a science fiction that you chose to use. They never went that far.

Mr. Nichols. No. That would have been the required abatement had they not just recently withdrawn it.

Mr. Owens. Mr. Lick, you state that AIHA has formed a task force to find a solution to the problem of updating. How much time do you think this task force will need to complete its work?

Mr. Lick. That's really hard to say. It depends upon the good will of everyone. Also, the issue that was holding us back was the lawsuits against ACGIH. I see it continuing. This is encouraging, but we've also tried this several times before. If there is genuine interest on the part of Congress and OSHA to resolve this, then we can go further.

The issues of what is a consensus standard certainly have to be resolved, and I might say that not only did industry object to using the ACGIH TLVs at one point in time, but the labor community did also. So industry may, at times, view them as too strict, and labor may view them as not strict enough. So there has to be a meeting of the minds where people understand that they can't have everything.

So if you can get to yes on that point, then I think it's a fairly simple task to do. But as I've said, we've been down that road several times before. It's a new effort to try to do that.

Mr. Owens. Our society becomes ever more complex, and we tend to always be way behind in terms of the methods we use to react. In New York at ground zero, an article was written recently that showed that you have a cocktail of pollutants that the workers are being subjected to, or the people who live adjacent to that area. And the comments by the government agencies and authorities are very confusing and mixed up. And it seems that you have a situation there which nobody is on top of, or really knows how to deal with.

In the Anthrax situation, it's pretty clear that nobody really knows how to deal with that. Several of you are industrial hygienists, and you all are interested in this area of expertise. Is there a role here for the industrial hygienist, and for the kind of thing we're talking about that's a gap that needs to be filled, and a role that you can play?

Mr. Lick. With both the situations you reference, between the World Trade Center, and also the anthrax situation, it really is looking at the things in a total systems approach, and it's more of emergency preparedness. Now, the TLVs as far as World Trade Center goes, those folks at ground zero when the buildings came down were exposed to a massive amount of dust. So the TLVs really would have no application there.

Mr. Owens. I'm talking about the workers, who are working there every day now, to clean up the mess.

Mr. Lick. Now we're into a different kind of situation for the workers. The first week or so, we were trying to recover people, and get people back in their residences and people back in their offices. So the plan that you would have at that point in time would be a recovery plan, which would be a lot different. As to the level of emergency planning, I think, that you've seen New York respond pretty well. And I also think that NIOSH and EPA and OSHA responded pretty well.

Mr. Owens. Is there a role for you?

Mr. Lick. The role is in the emergency planning process. You have to have a plan before you get here. I mean, you can't say that smallpox is eradicated, when there's still potential for smallpox out there. So it's the issue of the surveillance system. By the way, the surveillance system in the TLV or the PEL process doesn't exist the way it should to feed data back.

Mr. Owens. Okay. I don't want to get into smallpox. Anthrax has shown up in the workplace. Those two postmen died.

Mr. Lick. It's a question of practicing as a system.

Mr. Owens. Mr. Breysse, would you care to comment?

Mr. Breysse. Yes. The examples you and Hank Lick pointed out, illustrate the complexity of providing adequate health and safety in not only traditional workplaces, but in these unique settings such as we see today with bioterrorism and the World Trade Center collapse. I've been up in New York doing air monitoring on workers up there, and I could say that the health and safety community has to learn how to do a better job at responding to those disasters, looking at, in a rapid way, what the levels of exposures are. And in this situation, the TLVs are obviously relevant, as are the PELs, but they're just one piece of information. People are exposed to multiple things at the same time. Looking at one level, and comparing it to another TLV, I think defeats the whole purpose of being up there.

So we have to look as a profession at how we can respond to these things better, how we can collect the information we need in a more rapid manner, how we can provide the appropriate worker protection in a timely manner, with the associated training that goes along with it. We don't want to have the situation now where people are choking and coughing, and they're complaining about respiratory disease from having worked up there for a couple months, and inhaled high levels of dust in some cases. But not just dust. There are gases and vapors, possibly bioaerosols, as well as dust. So it's very complicated.

Mr. Owens. The world has run off and left us, and much of this discussion is sort of obsolete. We're so far behind; it's criminal, almost.

Mr. Lick. Yes, sir.

Mr. Owens. Thank you.

Chairman Norwood. Thank you, Mr. Owens. I'd now like to recognize Mr. Isakson, from the great state of Georgia, for five minutes.

Mr. Isakson. Thank you, Mr. Chairman.

Mr. Karmol, this may sound like a dumb question, but I wanted to ask you. When ANSI, goes through its disciplines and develops a standard in telecommunications, or health, or the petroleum industry, or whatever, would you define that generally as a minimum standard, an acceptable standard, or a high threshold standard?

Mr. Karmol. Mr. Isakson, first of all let me start by saying that ANSI itself does not develop standards. We accredit the organizations that do.

But in particular with respect to what you asked for example, it might be IEEE that would develop that kind of a standard. It's really up to the standards-developing organization to designate the scope of the standard, and determine whether it's a minimum, or a range. It's up to the developer, and it's up to the consensus process.

What we ensure is that the process involves all materially affected parties, that they reach a consensus, that it's transparent, that records are kept, and that there's the right to appeal if that is not done. So it is up to the user. And that's really one of the strengths of the American system.

We don't determine from above how the standards should be put together. The users and those who have to work with the standards determine it.

Mr. Isakson. So it's fair to say, then, that the agencies that you accredit develop standards that will sometimes be a minimum, sometimes acceptable, and sometimes high. Because of the consensus process it may be the standard itself that's being set, and what it deals with. Isn't that correct?

Mr. Karmol. I think that's fair to say. And I might ask Mr. Beichman if he'd want to comment.

Mr. Isakson. That's fine. I'm leading up to another question I want to ask Mr. Beichman.

I'm sorry that I missed some of your testimony. Could you elaborate on any enforcement problem for a company that may have a higher standard for fire protection, for example, than might be the standard required by OSHA? Are there difficulties?

Mr. Biechman. Congressman, there are difficulties if the OSHA standards are old, or based on a consensus standard that had been developed 30 years ago. In my testimony I indicated there's a manual called FIM, and that's Field Inspection Manual. Inspectors are really required to issue a citation. They can waive the fee or the fine involved, but the citation remains. And that's the difficulty of an employer or a company upgrading, if you will, to current standards, but being in violation of the existing OSHA standard.

Mr. Isakson. That's exactly the reason I asked the question. It's an unintended consequence of the delay in the process caused by an old standard, which at the time was acceptable but actually ends up being in conflict with a new standard that's set due to newer science, newer discoveries, or new industry liability.

Which brings me to my last question, Mr. Chairman, for Mr. Nichols with the bakery industry. Would I be correct in saying that most of the standards set by American industry are set expeditiously and scientifically, but also motivated because of the liability concern they have for their employees and their company? Is that a fair statement?

Mr. Nichols. The standards set by OSHA?

Mr. Isakson. No, the standards set by your particular company, or your particular industry. Flowers is a big bakery in Georgia. They are constantly changing their standards within their plants, I'm sure, out of an interest for the health of the employees, but also to limit the liability they have as an employer. Is that a fair statement?

Mr. Nichols. Exactly, sir. And it makes good business sense to have a safe work environment.

Mr. Isakson. So it's also possible that an antiquated rule or a standard adopted with the best of intentions actually could be inconsistent with a more responsible treatment for a particular problem, contamination, process, or use. Is that a fair statement?

Mr. Nichols. I think the key is, in developing new standards, even consensus standards, there has to be involvement by the industry. I believe the problem we're running into is that we are being held accountable for consensus standards that are not really consensus standards. They have not been developed, and the science and the thought process in developing those haven't been well thought out.

Mr. Isakson. Thank you, Mr. Chairman.

Chairman Norwood. We'll have a second round of questions if that agrees with you, Mr. Owens.

Mr. Breysse, is what Mr. Nichols just said true?

Mr. Breysse. No, I think I would take issue with that. I think it's fair to say that different groups of people could look at the same body of science and come up with different conclusions.

Chairman Norwood. But you don't disagree with what he said, in that they aren't consensus standards?

Mr. Breysse. I guess I need to be clearer about what exactly I'm agreeing to.

Chairman Norwood. Well, basically he said that the standards that he has to live by are not consensus standards, and therefore, in their opinion, they're not often well thought out.

Mr. Breysse. Well, I guess I would take issue with the, "not well thought out" part.

Chairman Norwood. I thought you would.

Mr. Breysse. We feel that our TLVs are extremely well thought out. We recognize that other people would have a different interpretation of the science. And in fact, we have, in our committee, significant representatives from private industry, who are there to represent the perspective of private industry. And many of those companies have their own internal health and safety guidelines. Frequently these are large companies often in conflict with our own TLVs, and they seem to manage to do business in this country just fine.

Chairman Norwood. "Representatives of large companies" meaning what companies? Mobil? Exxon?

Mr. Breysse. Exxon. I could tell you exactly. We have Dow, Dupont, Exxon, Mobil, and Merck.

Chairman Norwood. Now, which one of those large companies knows anything about flour?

Mr. Breysse. Oh. Well, I'm speaking more broadly about the TLV process in general, rather than specific in the context of the flour question.

Chairman Norwood. Let me, for the record, set something straight. Mr. Nichols, my understanding is that your problem was with Kentucky OSHA. However, all state OSHA's have to be approved by federal OSHA, and generally my experience is that they work hand in hand.

Mr. Breysse, I don't want you to misunderstand where I'm coming from. I don't really care what your organization does. That is your business. You are a private company. You fund yourself with dues, and you fund yourself with the sale of a book. Now, if you don't do a good job, your book sales will fall, and that's your business. That is not my business. So please understand that.

In your testimony, you referred to the disclaimer listed in the ACGIH TLV booklet, which makes the statement that, "TLVs are not developed for use as legal standards, and ACGIH does not advocate their use as such." What gets Congress involved in this is that you go on to say that you won't oppose their use in this particular kind of manner.

Now here is the rub. When you put out a non-consensus TLV standard, and it is accepted by reference as if gospel by OSHA, then the weight of the Federal and state governments is brought down on people who don't necessarily agree with that science, which is none of my business as long as OSHA doesn't accept you by reference.

However, unless you have a great deal of transparency in your organization, and have due process for the regulated community, it appears to me that there are Americans on both sides of these issues, some of which aren't being treated fairly if they have no open, transparent process. And OSHA has that responsibility. There is no question OSHA has that responsibility.

Here is the complaint. Not so much with you. You do whatever you have to do. It is none of my business. But when OSHA turns it into law without any transparency or any due process, Congress either has to tell OSHA they can't accept a non-consensus standard by reference, or be somehow or another involved. If OSHA is going to do that, you have to be more transparent and have due process and I don't want to tell you what to do. That is your particular business.

You stated in your testimony that, in your, "search for the truth for what a TLV really is, comments are invited from interested parties when the TLV is being set." What is meant by "interested parties"?

Mr. Breysse. When we recommend a new TLV, we publish that value on what we call the notice of intended change list. At that point, anybody who feels they're impacted by that, or have anything to say with respect to whether they think that is on target or off target, is free to submit information to the TLV committee that will be reviewed by the subcommittee. We don't define "interested party" ourselves. We leave it to the health and safety community to decide who's impacted and submit comments.

Chairman Norwood. What is the "health and safety community"? What does that mean?

Mr. Breysse. Well, we are fundamentally a health and safety organization and members of the industrial hygiene community are the people who are most likely to receive our booklet, to receive our publications, to visit our web page, to go to meetings where ACGIH has a booth. And so our primary means of outreach with respect to what we're doing is through the occupational health and safety professional community.

Chairman Norwood. So if someone wants to come and comment to your organization, they can do that?

Mr. Breysse. Absolutely.

Chairman Norwood. They can come and make verbal comments, so that they know their comments are being heard?

Mr. Breysse. We discourage verbal comments. Number one, because there's no formal record of that. Number two, because they take a long period of time. Written comments usually are more organized and more thoughtful, and can be reviewed by a larger number of people.

Chairman Norwood. Are they?

Mr. Breysse. Yes.

Chairman Norwood. Are you sure?

Mr. Breysse. Yes, I am, sir. In some cases we do. When we think there's enough information, perhaps a one on one conversation is appropriate. We will schedule a larger symposium early in the TLV setting process, to which affected parties can come and present data, when they feel there's enough new data to be presented. And we will publish it in our association journal and it becomes part of the peer-reviewed literature, so it is easier for us to reference when we document our TLVs.

Chairman Norwood. My time is up.

Mr. Owens, you're recognized.

Mr. Owens. I have no further questions.

Chairman Norwood. Well, I'd like to continue, with your permission. There are a few other things I'd like to ask.

In your testimony, Mr. Breysse, you note that "ACGIH members amended the bylaws a year ago to permit industrial hygienists working for industry to have a full voting active membership in the association, on the same status of industrial hygienists working for academic institutions, or for federal, state, and local governmental agencies." I have two questions about that. What prompted that change? Why did you guys decide to do that?

Mr. Breysse. First of all, there's obviously been an evolution over the years of how we've proceeded. We've gone from being, in our early years, very close to government. We evolved through our middle years to being very close to industry, where there was a lot of informal contact. However, in the early 1980s, we underwent a tremendous amount of criticism about being too close to private industry.

Chairman Norwood. Right.

Mr. Breysse. At that point we reevaluated our practice. We've always had contacts with industry-affected members, but as a result, we had a variety of industry-sponsored members who were serving as consultants to the committee. These people participated in the debates about the TLVs. However, they couldn't vote on whether they thought the number was appropriate or not. And in our attempts to become more transparent and more balanced, we thought it was appropriate, if we were going to rely on these people, to open our membership so that these individuals could become voting members. They can serve on the committees with the full status, that myself as a university member, or as a government person could serve.

So fundamentally it came down to a question of balance, and we felt it was appropriate to allow these people, if they're participating, to also vote.

Chairman Norwood. Let me take a minute to ask some fast questions.

What I've heard you say today, that we can all agree on, is ACGIH is not a consensus standard-setting organization. You've said that over and over in your testimony. Does the ACGIH TLVs development subcommittee meet in closed, not publicly announced sessions? Is the subcommittee composed of members whose names are kept secret from the public?

Mr. Breysse. The members of the full committee are known and open to the public. The internal subcommittee membership, however, is not.

Chairman Norwood. Once the developmental subcommittees adopt a TLV, would you agree that the ACGIH board members rarely, if ever, read or analyze the underlying scientific literature, and instead rely on the committee's recommendation? Isn't that correct?

Mr. Breysse. The role of the board of directors is to ratify what the full committee proposes. And in that context, in some cases, we spend a lot of time on the science if it's very complicated. A good example is we have a recent hand-arm activity level TLV, where we spend a lot of time reviewing it.

In other cases, the science doesn't engender as much debate, and the full board of directors focuses on the process. We look at when the notice of intended change was promulgated, what kind of comments were delivered, were they of a controversial nature or not. And if things proceeded relatively smoothly in those cases, a TLV will be adopted, ratified by the board of directors in a rather expedient way, without a lot of time spent going over the science.

Chairman Norwood. So the board is not required to review the scientific literature before they vote on a TLV?

Mr. Breysse. They don't do an independent review of the scientific literature.

Chairman Norwood. Is it the practice of your organization for one subcommittee member to be charged with developing a particular TLV and its documentation? One person?

Mr. Breysse. For the first draft, that's true.

Chairman Norwood. Do any conflicts of interest occur? For example, the author of the diesel exhaust TLV and documentation was Thomas Toome. Toome was a DOL employee charged with writing the last Administration's DOL MSHA diesel standard, and worked on both things simultaneously, using the two processes to support each other.

Referring to an earlier question Mr. Owens asked about potential conflict, the answer was, well, you don't get paid to do this. But are there other ways to have conflicts in these situations?

Mr. Breysse. Yes, you're absolutely right. I didn't mean to imply that because we don't get paid, there aren't any conflicts. In fact, the conflict of interest policy of ACGIH is something we spent a great deal of time on over the last year. And we have, through the development and implementation of that process identified a number of conflicts that we think are inappropriate.

Without getting into any specifics, one of those conflicts was the one you just mentioned, and under the auspices of the board of directors, working with the chemical substances TLV committee, we are reassigning the authorship of documents to individuals who have no readily apparent conflict, such as the one you mentioned.

Chairman Norwood. Are you perhaps willing to identify the TLVs that have been proposed or finalized in the last 10 years, where federal employees were the primary authors?

Mr. Breysse. No, I don't believe we are.

Chairman Norwood. Would you be?

Mr. Breysse. I'd have to speak to my counsel before I answer that question.

Chairman Norwood. Why don't you consider that a request. We would like to have your answer.

Mr. Breysse. Okay.

Chairman Norwood. Why is it that the ACGIH keeps the primary authors of the TLVs, and their documentation secret?

Mr. Breysse. Well, you know, it's not as sinister as sounds.

Chairman Norwood. Well, I don't mean to make it sound sinister, and I hope you don't take it that way. I'm just curious. Why couldn't people who are affected have this information? It's not your fault, but OSHA takes TLVs and turns them into a law, so the people that are affected should know this information.

Mr. Breysse. Right. But put yourself in the position of us for a minute. We take the intellectual capital of our volunteers and we translate it into what we think is a tremendous service to society. We're a modest organization. We operate on a budget substantially less than $4 million a year, yet we feel we produce a great good. And we're able to do that because we're harvesting the intellectual capital of our volunteers.

We want to make their job as efficient as possible, and as easy as possible. The one thing we don't want is any one person to feel they are responsible for a single TLV. A person could draft the first one, but at that point it becomes a committee product. We want the committee responsible for it, not that person. We don't want them burdened with a lot of individual communications. We don't want them to be held responsible 10 years from now if "the number is 10 and not 1", because in reality, all they're doing is creating the first draft. They're not creating the product. It's a committee product.

Chairman Norwood. But it's always of interest to those that are being affected with lack of due process, to know who started the thing. That naturally would be of concern to people that are affected by the bottom line, or the outcome of the TLV, as OSHA turns it into a federal law.

Mr. Breysse. I think a fair question to ask is, maybe not who wrote it first, but how it is identified it, and why was it picked on? You may notice if you look in our TLV booklet, there's over a hundred substances on the notice on the under study list, and there's about 40 on the notice of intent to change.

We've been working on developing and standardizing our policies and procedures in an attempt to become more transparent to groups like the gentleman on my left is associated with. We've now formalized a process through which we can explain to people, why we are picking on flour dust, or why we are picking on this other chemical. And it's not just because somebody sits there and says, "Jeez, I think this is a bad chemical, let me write a doc on it," or because I work for a company, or a regulatory agency that really would like to tackle this, but can't, so "let me write a document on it." That's not how we operate.

Chairman Norwood. Well, knowing your organization and how all of this works, would you agree that governments should not adopt TLVs?

Mr. Breysse. We're reluctant to make recommendations about policy. In fact, this is the first time that I am aware of anybody from ACGIH testifying in front of Congress about any of these matters at all. So I'm just going to defer that question, and say we don't want to get into that debate. We think it's the role of this committee and the role of the health and safety community to look at how we regulate the workplace, but it's not the role of ACGIH, and we just don't want

to be involved.

Chairman Norwood. I don't blame you. I truly don't blame you. And frankly I'm in sympathy with you on that.

I'm going to ask you two other quick questions, just because it's going to help us know how to deal with OSHA that takes your non-consensus standards and turns them into law. Will ACGIH open all of its TLV development meetings to permit attendance and participation to all interested parties? Would you be willing to do that?

Mr. Breysse. No, I don't believe we would be willing.

Chairman Norwood. Would you adopt a new process that includes scientific peer review by non-ACGIH independent science? Would you be willing to consider that?

Mr. Breysse. Well, I guess in answer to your previous question, I don't want to say that we're not willing to consider anything. Clearly, we've been challenged over the last year, and due to that challenge, we're reevaluating everything we do. So I'm happy to say we're willing to consider all these things.

Do I really think we're going to open things up? No. Do I think it's conceivable that we might have some external peer review? It's possible. And quite frankly at the last board meeting we actually initiated some debate on what the merits of that would be.

Chairman Norwood. Mr. Owens?

Mr. Owens. I have one closing comment, Mr. Chairman.

Chairman Norwood. Yes.

Mr. Owens. I'd like to note that ACGIH is a private, non-government organization that taxpayers do not fund. And I would also like to note that you, Mr. Chairman, have repeatedly implied that OSHA holds employers liable for ACGIH TLVs; TLVs that OSHA has never formally adopted. I want the record to reflect that that is just not true. They do not hold employers liable.

Chairman Norwood. Mr. Nichols, how do you feel about that?

Mr. Nichols. One of my concerns, Mr. Chairman, reflected by the question Mr. Owens asked earlier, is the fact that our incident involved the state OSHA, that does a great job working with us and, I think, did the correct thing in the end. But the problem is that there is a history of federal OSHA adopting these TLVs as the exposure limits that would then be enforced by our state agencies. That's why a lot of our requests have been for leadership from federal OSHA on this issue.

We out in the field are being held accountable to these TLVs as if they were law. And these are not consensus standards for the industry. Had we not contested the citation, the picture that I showed with the young man wearing a full facemask respirator would have been the reality in our baking facility. I wish it was science fiction, but it's not.

Chairman Norwood. Let me ask one last question, so each of you may have an opportunity to comment. What would any of you do or recommend to update the permissible exposure limits found in the air contaminants standard?

Mr. Lick. This is not new with ACGIH, but goes back ages. ACGIH has made a significant contribution over the years. So what I would do is take the ACGIH list as it is now and put it into an ANSI process.

There's more than just OSHA at stake. I think Congressman Isakson mentioned the issue of litigation. You run across these things in litigation. Let me say that OSHA, to a large business, is kind of irrelevant. It's really how you're preparing yourself, how you treat your employees, what your litigation responsibility is, and everything else. Asbestos is the biggest example of this with all the companies going bankrupt.

So I would take the ACGIH process, or the list as it is right now, and roll it into an ANSI process. I think from what I know, the majority of my board of directors would probably agree, although I don't think we've had a vote on that. A consensus-setting process would be much better, in the long run, for the country to get the input of everybody. It just would be a better way to go. But having said all that, some of my colleagues in industry are very forthright in turning data over, others are not.

In my testimony, I talked about people that participate in the ANSI process. Before OSHA, you would get the guys like myself that participated in the ANSI process. After OSHA, you got someone that was further down on the food chain. You know, an up and coming person, but not with the years of experience. So if you change the process, industry has to step up. Industry has to step up and put its best people into the process, and also financially support it. As a chair of an ANSI committee in the past, I had to go and recruit people from all aspects, to get them involved.

So there is the issue of the best people participating, because you need the people with the longest, or the grayest hair to participate in this process. You can't have the young kids, because they haven't seen enough. And when there's a meeting that's in California, industry can't say, “Well, that's in California, you can't go, because we're in Detroit. And you go to the next meeting when it's in the Midwest.”

So industry has to step up. And in my experience, that's been so-so. This gets back to the question that Mr. Owens asked before. Where are we going to go with this process? People have to get serious. Perhaps the asbestos litigation and some of the other stuff will make people serious. But that's where we've got to go. We have to have a real serious process.

I think ANSI is the best game in town, and that's where we need to go. The OSH Act itself has to be changed, because you have to have this process where it's going to freely move. You can't have regulations that have standards that are 30 years old, whether it's NFPA or whatever, if you're doing business in a large company, or even in a small company.

I can speak to small companies, since there's a vast regulatory burden on small companies. It's hard enough knowing what's in the Federal Register to begin with. Even then you find out it's outdated. There are some health and safety, environmental, and fire people who know what's in there. But do they practice good in the profession? I don't know. But certainly, the process has to be so where it's current.

And then the professional organizations have to do their part in making sure that you have the education process, and people are aware of it. And then you have to have outreach to small business, because half the time small business has a hard time understanding what is meant; even ANSI standards. In many cases, people in the business write the standards for us, not for the people who run a small business. I used to say when I was in NACOSH, you tell me a standard.

I say this about ergonomics. My brother runs two tire stores in Cleveland. Can he understand what this standard is all about, and can he comply? That's where we fall down, because we put these standards together, and it's nice to say that they don't have an economic impact. But if we're truly going to make an impact on health and safety in this country, we've got to have a standard-setting process that small business can embrace, and large business can embrace and support.

Chairman Norwood. Preparing for this hearing I read there had been a recommendation that perhaps some of these standards should be written so somebody like me can understand them! And the consensus was, "Oh, no, we can't do that, because if we do then it leaves them open to interpretation." But my concern is always for the mom and pops. I think big business in this country does a very good job, for selfish reasons. It's the mom and pops that suffer if you're not careful with these standards.

I have to vote.

I agree with you, we don't need standards that are 30 years old. That just doesn't make sense. And I can't get anybody to make sense out of it, except perhaps if you're afraid of the legal profession. Surely out of all of the different standards that all of you set, there would be consensus for change on a great number of them. My concern is with those that there isn't a consensus on, and those that cause some of the fights in your committee meetings when trying to determine what a TLV is. Those are the ones that OSHA is going to have to go through a regular rulemaking process on, because I am a big believer in due process and in transparency. But surely there are a number of standards that we as a nation could agree on to move and improve, that wouldn't take all of OSHA's resources. And that's part of what this hearing is really about.

The other part of what this hearing is really about is that OSHA does indeed accept standards by reference that haven't met consensus, and I'm going to stop that one way or the

other. I'll tell you one of the ways I'm going to stop it. At the next hearing, and it's going to be very soon, we'll have OSHA sitting right at that table and they're going to have to explain some things. People like you have to play a role in this process. You have to help us, as government, to develop this. I look forward to hearing from, and working with all of you.

Obviously we didn't get to all the questions today, and if you'd be kind enough, we'll mail you some additional questions. Please respond at your leisure in writing, because we really are trying to discover the way to do the right thing. But we're not going to let non-consensus science destroy people. I'm going to be very involved in keeping that from happening.

Mr. Nichols, I happen to know a lot of what you've been through, but Mr. Breysse, I also know a lot of what others in my backyard have been through under the same circumstances. So I'm very interested in transparency and due process, and stating publicly that OSHA has no business accepting your standards that are non-consensus by reference. You ought to say that to them, because I think that's what's gotten you in a bit of a mess.

Ladies and gentlemen thank you very much for your time, and I look forward to working with all of you in the future.

Whereupon, at 12:30 p.m., the Subcommittee was adjourned.

APPENDIX A - WRITTEN OPENING STATEMENT OF CHAIRMAN CHARLIE NORWOOD, SUBCOMMITTEE ON WORKFORCE PROTECTIONS, COMMITTEE ON EDUCATION AND THE WORKFORCE

Subcommittee on Workforce Protections Hearing on

"The Role of Consensus Standard Setting Organizations"

Chairman Norwood – Opening Statement

We are here today to pick up where we left off earlier this year and to continue our discussion about ways to better the OSHA regulatory process. At our last hearing we heard a lot about the OSHA rulemaking process in general. There were a number of suggestions made for reform. Today, we will focus more specifically on the Role of Consensus Standard Setting Organizations with OSHA.

I know that consensus standard setting organizations can play many roles with OSHA – not simply confined to rulemaking. They can also work with OSHA in partnerships to improve the quality of OSHA's work, and to share ideas and expertise with OSHA staff about advancing safety and health in the workplace.

Improving safety and health in the workplace is why we are here today. I know some may think this is a rather conventional topic for an OSHA hearing -- given the highly unconventional times we have been living in since September 11th. However, given the experiences of all of us on Captiol Hill recently, particularly those of us who are still shut out of the Longworth Building, or those working in Post Offices, in fact, there may be no better time to hold a hearing related to occupational safety and health. It seems to me that when we are faced with new threats to workplaces everyday, examining ways to continuously improve OSHA is a worthwhile effort.

Let me take a moment to welcome our witnesses. We appreciate their willingness to take time out of their busy schedules to testify before the Subcommittee. I especially want to acknowledge our witness from ACGIH. Because of our first hearing and my correspondence with the Secretary of Labor regarding ACGIH, I committed that ACGIH would be given the opportunity to testify. I am pleased they were able to make it today.

Let me add that some may think I am interested in putting ACGIH out of business. To the contrary, I am not interested in putting ACGIH or anyone else out of business. I certainly don't want to be in a position of discouraging private groups from working on threshold limit values for chemicals or standards which make improvements to our knowledge of safety and health.

I do, however, believe that Congress has an obligation to pay attention to what OSHA does with information provided by private standard setting organizations. If OSHA is in any way relying on private standards then it seems to me that OSHA

needs to ensure the integrity of the process used by the private group. If it cannot do so, then OSHA should not make use of that information.

I certainly hope -- and fully expect --that we will hear from someone from OSHA on this subject soon.

It strikes me there are three reasons why we ought to look at the work of private consensus standard setting organizations and the role they can play with OSHA. First, we've got a rulemaking process that is slow – often times for very good reason, highly politicized, and seems to satisfy no one.

Second, we've got a number of OSHA standards, -- the air contaminants standard is one of them – that are out of date – and that, most would agree, need to be updated.

Third, we've got a number of private, voluntary consensus standard setting organizations who may have much to offer, and who do good work, but who cannot meet all the requirements we expect in an OSHA rulemaking in terms of transparency, due process, creation of a public record and ability of the regulated community to comment. In short, if we want to see OSHA improve the standards process – even to make updates to standards currently on the books -- we can't quite get there from there from where we are today.

But we can go forward. I'd like us to figure out where we can go from here. I look forward to the discussion today and the suggestions from all of our witnesses.

APPENDIX B - WRITTEN STATEMENT OF PATRICK BREYSSE, VICE CHAIR-ELECT, AMERICAN CONFERENCE OF GOVERNMENTAL INDUSTRIAL HYGIENISTS, JOHNS HOPKINS UNIVERSITY, BALTIMORE, MD

Statement of
Patrick N. Breysse, Ph.D., CIH
Before Subcommittee on Workforce Protection,
Committee on Education and the Workforce,
United States House of Representatives

November 1, 2001

My name is Patrick N. Breysse, and I am a Professor at the Bloomberg School of Public Health at the Johns Hopkins University in Baltimore, Maryland. I hold a Ph.D. from the Johns Hopkins University School of Public Health. I also serve as Vice Chair-Elect of ACGIH Worldwide (the American Conference of Governmental Industrial Hygienists, Inc.) and as a member of the ACGIH Board of Directors. I am the Board of Directors' liaison to the ACGIH Chemical Substance TLV (Threshold Limit Values) Committee.

I am submitting this statement on behalf of ACGIH in response to the statement made by Mr. Henry Chajet before this Subcommittee at its June 14, 2001 hearing on OSHA Rulemaking. On behalf of ACGIH, I thank the Subcommittee for the opportunity to present this statement.

Mr. Chajet's statement contained certain conclusions that are not correct and certain facts that are incomplete. In order to set the stage for my discussion, there are some basic facts that should be understood:

1. ACGIH does not set standards.

2. ACGIH does not make submissions to government agencies.

3. ACGIH does not participate in or submit comments in government rulemaking proceedings.

4. ACGIH does not engage in lobbying and does not normally submit statements to Congressional Committees. This is the first Congressional Hearing in which ACGIH has participated. This statement is being submitted only to respond to the incorrect and misleading statements about ACGIH.

5. ACGIH does not serve as a vehicle for government employees to avoid notice and comment rulemaking responsibilities.

6. ACGIH is not a quasi-government agency or a federal public advisory committee.

7. ACGIH does not act "in secret" as alleged by Mr. Chajet.

8. ACGIH is not a de facto "Federal Advisory Committee (FAC)."

What is ACGIH, What Does It Do, and How Does It Do It?

ACGIH is a not-for-profit, scientific professional society with approximately 4,200 individual members. ACGIH members include occupational health and safety scientists who work for universities, private industry, for federal, state and local governments, and for others. As a scientific organization, ACGIH regularly publishes educational materials relating to worker health and safety issues. It holds educational events related to worker health and safety issues. It also provides industrial hygienists in at least 62 countries throughout the world, with a central resource for scientific information on issues related to occupational safety and health. This information assists the industrial hygienist in making independent assessments of diverse issues in the environment within which they practice their profession.

ACGIH's most well known publication is its TLVs and BEIs book, which is published annually. I am submitting the 2001 version of this book with this statement for the record. It is this publication which is the center of the controversy created by Mr. Chajet.

TLVs (Threshold Limit Values) and BEIs (Biological Exposure Indices) are developed as guidelines by ACGIH to assist industrial hygienists in the control of health hazards. ACGIH annually publishes a Policy Statement on the uses of TLVs and BEIs. This Statement, approved by the ACGIH Board of Directors on March 1, 1988, is contained on the inside of the front cover of every copy of the TLVs and BEIs book. It states:

> "POLICY STATEMENT ON THE USE OF THE TLV'S AND BEI'S
>
> The Threshold Limit Values (TLVs) and Biological Exposure Indices (BEIs) are developed as guidelines to assist in the control of health hazards. These recommendations or guidelines are intended for use in the practice of industrial hygiene, to be interpreted and applied only by a person trained in this discipline. They are not developed for use as legal standards and ACGIH does not advocate their use as such. However, it is recognized that in certain circumstances individuals or organizations may

> wish to make use of these recommendations or guidelines as a supplement to their occupational safety and health program. ACGIH will not oppose their use in this manner, if the use of TLVs and BEIs in these instances will contribute to the overall improvement in worker protection. However the user must recognize the constraint and limitations subject to their proper use and bear the responsibility for such use.
>
> The Introduction to the TLV/BEI book and the TLV/BEI Documentation provide the philosophical and practical basis for the uses and limitations of the TLVs and BEIs. To extend those uses of the TLVs and BEIs to include other applications, such as use without the judgment of an industrial hygienist, application to a different population, development of new exposure/recovery time models, or new effect end points, stretches the reliability and even viability of the data-base for the TLV or BEI as evidenced by the individual Documentations. It is not appropriate for individuals or organizations to impose on the TLVs or the BEIs their concepts of what the TLVs or BEIs should be or how they should be applied or to transfer regulatory standards requirements to the TLVs or BEIs."

On the same page, ACGIH goes even further and in a special blocked paragraph with a title "Special Note To User" it is stated:

> "The values listed in this book are intended for use in the practice of industrial hygiene as guidelines or recommendations to assist in the control of potential workplace health hazards and for no other use. These values are not fine lines between the safe and dangerous conditions and should not be used by anyone untrained in the discipline of industrial hygiene. It is imperative that the user of this book read the Introduction to each section and be familiar with the Documentation of the TLVs and BEIs before applying the recommendations contained herein. ACGIH disclaims liability with respect to the use of the TLVs and BEIs."

The "Policy Statement" and "Special Note to User" listed above make it abundantly clear that ACGIH is not publishing the TLVs or BEIs as standards and that it is completely inappropriate for individuals or organizations to transfer regulatory standards requirements to the TLVs or BEIs. Thus the claim by Mr. Chajet or others that the TLVs or BEIs are standards published by ACGIH, is completely erroneous.

ACGIH has made it abundantly clear that it publishes TLVs and BEIs as guidelines

to assist the industrial hygienist in making workplace assessments of occupational exposures. As an example, if you are an industrial hygienist employed by a manufacturing company and you know that workers in the companys' plants are regularly exposed to a certain chemical, you can refer to the TLV/BEI Book and use the information provided as a reference point for making your individual decision as to what to recommend to the company. If you follow the specific instructions within the TLV/BEI Book you will obtain a copy of the Documentation for the substance involved and review that Documentation before making any recommendations. You can then use the information provided as one part of the equation in making a determination of what is appropriate for a specific workplace situation.

I have used the word "Documentation" in connection with the TLVs and the BEIs and I would like to explain exactly what I mean. For every TLV and BEI, ACGIH publishes a comprehensive scientific summary explaining the rationale for its action in establishing the TLV or BEI. The Documentation also contains a comprehensive list of the scientific literature relied upon in developing the TLVs or BEIs and an analysis of the major studies relied upon.

Again, I emphasize that the TLVs and the BEIs are not developed for use in rulemaking proceedings or in standard setting activities. ACGIH does not submit the TLVs or the BEIs to any government agencies that are responsible for rulemakings or to any private organizations that are setting standards. The TLVs and the BEIs are guidelines designed to assist industrial hygienists in the control of workplace hazards.

A second important concept to be understood is that the TLVs and the BEIs are not intended to show how dangerous a substance may be at various levels of exposure and should not be considered fine lines between hazardous and safe. These guidelines, in general terms, provide the opinion of ACGIH that nearly all workers may be repeatedly exposed to certain substances day after day without adverse health effects. The TLV represents a judgement, based on the available scientific literature or experience, that exposure at a certain level to a particular substance does not pose an unreasonable risk, and that the scientific literature and experience does not permit the same conclusion at a higher level of exposure.

Mr. Chajet claims that the problem with the TLVs are that they are not supported by proper science and that they are prepared in secret. Neither of these allegations is true. As I will explain below, the TLVs are supported by the best peer reviewed science available. Further, the TLV process is an open process and not a secret process.

What is the Value of the TLVs/BEIs?

ACGIH is proud to say the TLVs/BEIs are recognized on a worldwide basis as one of, if not the best, compilations of occupational exposure guidelines and worker health and safety information. Even though ACGIH has repeatedly represented that these guidelines are not designed to be used as standards, thirteen countries use the

TLVs as standards, and they are uniformly referenced in scientific literature in the development of worker safety and occupational health standards in many countries throughout the world. Scientists on a worldwide basis, in at least 62 countries, recognize the validity and excellence of ACGIH's science. But let me try to put that in perspective.

In his testimony before this Subcommittee, Mr. Chajet indicates that one of his qualifications that enables him to make such a judgment regarding ACGIH science and procedures is that he has served as an Associate Professor at the Johns Hopkins University School of Public Health. This is a very prestigious and very high ranking academic credential and would carry some weight - - if it were true. In order to be an Associate Professor at Johns Hopkins, you have to be appointed to the faculty in accord with established procedures for tenure-track professors. By contrast, Johns Hopkins also has "Faculty Associates". These are people invited to teach a specific course or lecture on a specific subject as a type of "Adjunct" lecturer. These people need not have the qualifications necessary to become an Associate Professor. They are not on a tenure track. And they are certainly not entitled to represent that they are Associate Professors. Mr. Chajet served as a "Faculty Associate" not an Associate Professor at Johns Hopkins. Attached to this Statement is a letter from the Assistant Dean of the Johns Hopkins University Bloomberg School of Hygiene and Public Health setting forth the fact that Mr. Chajet should not use the title of Associate Professor when describing his former relationship with the Johns Hopkins University.

Now, let us look in detail at the procedure that ACGIH follows in adopting a TLV.

ACGIH TLVs are established through a committee structure designed to involve independent scientists of multiple disciplines, input from all interested parties both within and outside ACGIH, and provide two levels of review. Further, after a proposed TLV has been prepared and the appropriate Documentation developed and made available to the public, the proposed TLV is put on the public "Notice of Intended Changes" (NIC) list for approximately one year or more. During that time, any interested party has the opportunity to submit additional information to the TLV Committee. All of the information submitted is carefully reviewed. At the end of a period of approximately one year, the TLV may be published in the original form proposed, published in a revised form with an additional NIC notice, maintained on the NIC list for an additional period of time in order to permit more information to be developed, or be withdrawn. It is difficult to understand how anyone can claim that the process is a "secret" process when a notice of any new TLV or any change in existing TLV is published to the world for comment approximately one year before it is considered for a final vote necessary in order to become effective.

The ACGIH TLV Committee has about 30 members who represent 4 major disciplines: Industrial Hygiene, Occupational Medicine, Occupational Epidemiology, and Toxicology. Members of ACGIH interested in joining the Committee are asked to complete a short application form and provide a resume or curriculum vitae. In evaluating any application for membership, the membership

Subcommittee of the TLV Committee looks at the following criteria: disciplinary training and education, professional background, and past relevant experience. As a whole, it is expected that a majority of the Committee will have industrial hygiene expertise, with a majority of those having practical experience. The remainder of the Committee will be comprised of persons who have expertise in one or more of the following: occupational medicine, epidemiology, toxicology or other related specialties (e.g., statistics, chemistry, etc.). A preference will be given for individuals with ten or more years of professional experience and with advanced degrees in their fields of expertise. Individual members of the Committee must demonstrate writing capabilities and communications skills through publications, presentations or other activities. It is expected that the membership of the Committee will reflect the demographics of the industrial hygiene and occupational health workforce. Persons with multi-disciplinary backgrounds and experience are encouraged to apply.

Members of the TLV Committee are expected to volunteer annually approximately four weeks of their time to the work of the Committee. This four weeks includes time spent attending four meetings each year; time spent in preparing and reviewing TLV Documentations; and time spent in participating in Administrative Subcommittee activities. Senior members of the TLV Committee are also expected to provide guidance and mentorship to the new members. Each member of the TLV Committee (with the exception of the Chair and the Vice-Chair) is affiliated with one of the Chemical Substances Subcommittees. There are expectations that each member of a Chemical Substance Subcommittee will prepare at least two TLV Documentations annually; at least one of which should be for a new substance. In addition to Chemical Substance Subcommittee activities, each member of the TLV Committee is expected to actively participate on at least one other Administrative Subcommittee.

I wish to emphasize that the makeup of these Committees are not composed primarily of federal government employees out to write regulations without following the Administrative Procedures Act. The TLV Chemical Substances Committee is chaired by Lisa M. Brosseau, ScD, CIH of the University of Minnesota. The Vice-Chair is Laura E. Fleming, M.D., Ph.D., M.Ph. University of Miami. I am submitting a list of the current TLV Committee members with this Statement. The majority of the members of the Committee are affiliated with academic institutions. Although government employees from, for example, the Department of Labor and the National Institutes of Health certainly play an important role as Committee members, an equally important role is played by Committee members from such well known companies as Dow Chemical Company, Exxon Mobil, DuPont, and Merck & Co. Since 1970, the committee has consisted, on average, of 73% members from affiliations other than the federal government.

The TLV Committee determines priorities based on an evaluation of what substances are commonly found in the workplace, what substances pose the greatest potential dangers, and what substances are produced to a great extent in the United

States. Once a substance is identified as a substance that would be an appropriate subject for a TLV, the matter is put before the Committee leadership. With their approval, the appropriate Subcommittee will add the substance to its list of materials under study. The Subcommittee will take up the substance as soon as there is available manpower - - a member of the Subcommittee will conduct a review of the literature and develop an initial draft of the Documentation. The initial author of the documentation is selected based on his or her special knowledge with reference to the substance involved. With the assistance of the ACGIH scientific staff and possibly paid outside consultants, the Subcommittee member assigned to the project collects information, assembles the information, evaluates the information, and then prepares a recommendation for consideration by the TLV Subcommittee.

The proposed recommendation is accompanied by a comprehensive Documentation. The matter is reviewed by the Subcommittee and individual Subcommittee members comment on the proposed TLV level and the Documentation. The Subcommittee discusses the information available, the most appropriate scientific interpretation of the information, and whether or not the information is directly applicable to the workplace. Scientists from various disciplines provide their expertise. The initial preparer of the document may be asked to further review or redraft the recommendation and the Documentation, which is then submitted to the subcommittee for additional review, discussion and recommendation. Once the Subcommittee reaches a decision, the initial Documentation and recommendation are prepared in a form for submission to the full TLV Committee. Again, each member of the TLV Committee gets copy of the proposal TLV together with the Documentation. The full Committee may accept the recommendation or recommend that the Subcommittee again review its findings.

If the full Committee recommends that the Subcommittee proposed TLV be approved, the matter is forwarded to the ACGIH Board of Directors. If the recommendation is ratified by the ACGIH Board of Directors, it is then posted on the Notice of Intended Change List for approximately one year. During that time period, comments are invited from all interested parties, including producers, users, etc. of the substance. It is important to note that the Subcommittee developing a TLV for any substance welcomes producers and users of that substance to submit occupational health and industrial hygiene data and comments. ACGIH regularly publishes information about what substances are being considered for possible TLVs by the TLV Committee. The TLV Subcommittees considering specific substances are composed of volunteers and have only a limited amount of time to meet. Therefore, except in unusual circumstances, interested parties are requested to submit information to the Subcommittees and the full Committee in writing. The Subcommittees are interested in reviewing any and all relevant scientific studies that have been conducted in accord with recognized scientific protocols. The Subcommittees generally will not consider data that has not been obtained and prepared in accord with accepted scientific methodologies. It is not uncommon for the TLV Committee or the Subcommittees to get requests from interested parties to make an oral presentation. However, such requests are generally denied as the

committee has found that such oral presentations are much less persuasive than sound scientific studies and can take up limited meeting time necessary for thorough discussions. The Committee has invited researchers to discuss their findings with them, however, from time to time.

In Mr. Chajet's testimony, he expresses concern that the TLVs had once been submitted to the entire ACGIH membership for ratification whereas now the report of the TLV Committee is submitted to the Board of Directors for ratification. He implies that the decision by the Board is in some way less democratic and more autocratic then the decision by the entire membership. In fact, few ACGIH members attend the annual Business Meeting of the Association. Typically, approximately 65 out of 4,200 members have attended that meeting. When the TLVs were presented for a vote at the Annual Meeting, each member was provided with the recommendation of the TLV Committee and the members could vote Yes or No. In all instances, the members voted to approve the recommendation of the Committee. Although members certainly could have reviewed the Documentations if they had chosen to do so, very few did review such Documentations. The ACGIH Board was concerned that this perfunctory review by the membership served no actual purpose. The Board felt it would be more responsible to provide a level of review by the Board of Directors. Prior to voting, each member of the Board has specific information with regard to the proposed TLVs and electronic copies of the proposed Documentations. In addition, a member of the Board of Directors serves as a liaison with the TLV Committee and can report to the Board with regard to the deliberations at the Committee and Subcommittee levels. With regard to the allegations that there are no written recommendations at the Subcommittee and Committee levels, these allegations again are untrue. The Committee and the Subcommittees do make written recommendations. Recently, steps have been taken to insure that these written recommendations and Committee and Subcommittee minutes are more uniform in content and detail.

Although ACGIH has long had a conflict of interest policy, that policy was based on the concept of members of Committees, Subcommittees, and the Board of Directors voluntarily disclosing conflicts of interest or biases when such existed. In September 2000, ACGIH adopted a more structured conflict of interest policy. This policy is modeled after the policy followed by the National Academy of Sciences. Members of the Board and the TLV Committee and Subcommittees are required to disclose all conflicts of interest and sign a written form on an annual basis acknowledging that they have read the ACGIH policy on conflicts of interest and biases and that they have agreed to fully comply with that policy.

As an industrial hygienist who often consults with industry, I am well aware of issues involving the practicality of applying a set of guidelines such as the TLVs. Other major issues that must be considered by industry include cost and technical feasibility. Reducing workplace exposure levels is not something that can be typically accomplished instantaneously. Reduction involves the expenditure of funds and an evaluation of numerous possible control options with varying degrees of technical feasibility. As a result, implementation of control options in a

workplace with multiple chemical and physical hazards requires careful consideration of costs and benefits as well as engineering feasibility.

These are complex issues that create pressures that government agencies such as OSHA and MSHA must deal with in a regulatory arena. When Congress drafted the Occupational Safety and Heath Act, Congress included within the confines of the statue requirements related to economic efficiency and the availability of reasonable control technologies. By contrast, ACGIH TLVs and BEIs have no such limitations. ACGIH TLVs and BEIs are designed solely on the basis of worker health and safety issues. Individual industries are free to use these guidelines within their own specific health and safety programs with due consideration to aspects of cost and feasibility. ACGIH TLVs and BEIs state that if a worker is exposed to a certain substance at a level of "X" amount or less, the worker does not have a unreasonable risk of injury. This level is determined without consideration of the cost of achieving that level of exposure. The level is determined regardless of whether technology exists to reduce exposure to that level. Because the ACGIH does not consider factors such as economic and technological feasibility, the TLVs and BEIs do not meet the criteria placed on most government agencies that set standards. Therefore, ACGIH does not recommend the TLVs and the BEIs be used as legal standards. ACGIH specifically says in its Policy Statement that these guidelines are developed for the use by industrial hygienists in their normal workplace activities.

Should federal government scientists be allowed to participate in ACGIH activities? Absolutely! Government lawyers participate in the American Bar Association activities. ABA Committees, including government representatives, routinely publish papers analyzing court decisions and agency regulations. Government physicians who are members of the American Medical Association, routinely participate on AMA Committees that publish information with regard to the public health. Governmental industrial hygienists are no different from government lawyers and government doctors. They should be allowed to participate in the activities of a scientific society such as ACGIH as long as participation in such activities does not violate the conflict of interest policies established by the various agencies for which they work and/or the ACGIH Conflict of Interest Policy.

One final point, as a scientist with over 25 years of experience in conducting research, I strongly disagree with Mr. Chajet's allegation that there is a lack of scientific justification for certain of ACGIH's TLVs. I am submitting with this Statement copies of the ACGIH TLVs for Benzene and Formaldehyde. I ask that the Committee review these Documentations which are typical of the Documentation for substances covered by a TLV or BEI. I am sure that you will find that the science supporting these Documentations meets the highest standards and provides an ample basis for supporting the position taken. I submit the Benzene TLV because this TLV is an example of how the TLVs are addressed as new scientific evidence becomes available. The TLV for Benzene was 100 PPM in 1945. It was lowered to 50 PPM in 1946, to 35 PPM in 1949, to 25 PPM in 1957, to 10 PPM in 1963, and thereafter to 0.5 PPM in 1997. Unfortunately, in some cases ACGIH is presented with concerns about a substance for which there is little

scientific data. In these cases the TLV committee may make a conservative judgement about a TLV. This is not a question of scientific justification but rather a safety judgement on the part of ACGIH about what is prudent in the face of scientific uncertainty.

Finally, Mr. Chajet accuses ACGIH of risking its reputation by failing to solve structural problems. ACGIH, as any scientific organization, encourages discussion, encourages expressions of new and varying ideas, encourages expressions of opposite viewpoints. Within its various Committees, ACGIH has followed these precepts and as a result, there are instances where discussions with regard to many issues are heated and adversarial. These types of discussions only result in a better review and an end product that more accurately reflects the state of the art. To encourage these types of discussions and avoid even the appearances of impropriety, the ACGIH members amended the Bylaws a year ago to permit industrial hygienists working for industry to have a full voting active membership in the Association on the same status of industrial hygienists working for academic institutions or federal, state or local governmental agencies. The ACGIH Board of Directors recently adopted a more comprehensive conflict of interest and bias policy as I described above. ACGIH has an extensive website which includes scientific literature available to persons throughout the world through the use of the world wide web. The data we rely on is open and available to all. Our process is open. ACGIH publishes notification of the substances that are under investigation by the TLV Committee so that all interested parties are aware of the substances under consideration. ACGIH publishes proposed TLVs and BEIs a year before the TLVs or BEIs become effective so that all interested parties have ample opportunity to comment and submit data. We encourage input from any and all parties. We never publish a TLV or BEI without a full and comprehensive Documentation. We tell the world that TLVs and BEIs are only guidelines and should not be used as standards.

As Mr. Chajet has stated in his testimony: "The ACGIH name and the TLV trademark are recognized and respected around the world, based on a 50 year history of advancing the heath protection of the workforce." There is no reason that this Committee should deny a government employee the right to participate in ACGIH activities if that employee follows the rules and regulations of his or her respective agency.

ACGIH thanks you for this opportunity to present this Statement. If you have any further questions with regard to ACGIH, please contact me and I will be glad to provide answers to your inquiries.

APPENDIX C - WRITTEN STATEMENT OF TRAVIS NICHOLS, DIRECTOR OF SAFETY, BAKERY CHEF, INC., LOUISVILLE, KY, ON BEHALF OF THE AMERICAN BAKERS ASSOCIATION

Statement of
THE AMERICAN BAKERS ASSOCIATION
Before The
House Subcommittee on Worker Protections

November 1, 2001

"The Role of Consensus Standard Setting Organizations with OSHA"

I. INTRODUCTION AND SUMMARY

The American Bakers Association (ABA) thanks the House Subcommittee on Workforce Protections, and especially Chairman Charles Norwood, for holding this critically important hearing on the role of consensus standard setting organizations and the Occupational Safety and Health Administration (OSHA).

By way of background, the American Bakers Association ("ABA") is the trade association that represents the nation's wholesale baking industry. Its membership consists of more than 300 wholesale bakery and allied services firms. These firms comprise companies of all sizes, ranging from family-owned enterprises to companies affiliated with Fortune 500 corporations. Together, these companies produce approximately 80 percent of the nation's baked goods. The members of the ABA collectively employ tens of thousands of employees nationwide in their production, sales and distribution operations. The ABA, therefore, serves as the principal voice of the American wholesale bakery industry.

The ABA and its member companies long have devoted substantial efforts to enhance workplace safety and health programs in the industry in general, and to share expertise for the benefit of injury and illness prevention activities at individual facilities. Towards these ends, ABA's Safety Committee – comprised of corporate safety directors at ABA-member companies of various sizes – has routinely focused on the impact of OSHA compliance obligations on company operations, as well as other pro-active measures that reduce illnesses and injuries in bakery production and distribution activities. As a result, many wholesale baking operations have improved their safety and health performance in recent years. For a number of industry facilities, these improvements have been reflected in the rates of injuries and illnesses that are recorded on OSHA logs, as well as their workers compensation cost experience, which reflect both the frequency and severity of compensable work-related injuries and illnesses. The ABA, through the active participation of its Safety Committee, also has participated in numerous consensus standard setting proceedings over the years - including but limited to the American National Standards Institute, the National Fire Protection Association, and the Baking Industry Sanitation Standards Committee. The comments that follow largely are based on the observations and experience of the corporate safety directors who

are active members of the ABA's Safety Committee.

My name is Travis Nichols and I am the Health & Safety Leader for Bakery Chef, Inc. based in Louisville, Kentucky. I am pleased to be testifying on behalf of the American Bakers Association. Bakery Chef Inc. is a moderately sized company comprised of 5 bakery facilities spread across the United States. In total, the company employs around 700 employees. Our facilities make a variety of high quality bakery goods including biscuits, hotcakes, muffins, waffles, breads and rolls, which are used throughout the country by several food service companies.

My responsibilities at Bakery Chef include the management of all company safety and health programs and initiatives, including regulatory accountability and workers compensation. I began my career with the company over 10 years ago, working as a production employee in one of our Louisville facilities. The company strongly encourages the involvement of all employees in the operation of the business. The empowerment which the company provided me encouraged me to become an active participant in our company's health and safety initiatives. Eventually, I was able to actually help design the structure of our company's Health, Safety and Environmental Department and create the position I now hold with the company. During this entire process, the company has been completely supportive in my development and role. The company even paid my tuition to nursing school so that I could become a better health resource for all our employees.

In my role as Health & Safety Leader, I work very closely with both facility leadership and production employees to help ensure our company is a safe place to work for all. As a nurse, safety professional and former production worker, I consider myself an advocate for our employees and their families in the ongoing business of maintaining a safe work environment. Bakery Chef is strongly committed to providing a safe and healthy workplace to our highly trained and valued employees. Our company's philosophy is identified with the acronym SQP that stands for Safety, Quality, Productivity and People. Safety is our company's first priority in all decisions, from the boardroom all the way to the production floor. This front line commitment to Safety at all levels of our organization has helped us maintain superior performance when it comes to preventing the occurrence of significant injuries and illnesses in our facilities. On average, our OSHA Recordable Injury and Illness Rate has been almost half that of the rest of the baking industry for the past four years according to the Bureau of Labor Statistics.

In the past several years, the wholesale baking industry has become acutely concerned about one so-called consensus organization – the American Conference of Governmental Industrial Hygienists (ACGIH). ACGIH develops Threshold Limit Values (TLVs) on a variety of potentially harmful substances in the workplace. While ACGIH's TLVs are technically considered to be exposure guidelines and not have the weight of law, they are frequently used by OSHA as a foundation for Permissible Exposure Limits (PELs) and could be used by OSHA for so-called "general duty clause", Section 5(a)(1) violations.

In addition, the 23 states that have adopted their own safety and health programs in lieu of the federal OSHA program rely heavily upon the TLVs that ACGIH develops. These states have a charter obligation to provide safety and health protection equal to or greater than the federal program. These states need to have confidence in the procedures and end results of the consensus standard setting organizations upon which they rely for guidance in developing their own standards and enforcement proceedings. In the case of ACGIH, the experience of the ABA has found them woefully lacking.

ACGIH THRESHOLD LIMIT VALUE ON FLOUR DUST.

In September 1999, the ACGIH began the process of developing for the first time a threshold limit value for flour dust. The laudable goal of the proposed ACGIH TLV for flour dust was to eliminate flour dust as a possible sensitizing agent that could contribute to asthmatic conditions in baking industry employees.

ACGIH announced that it was looking at establishing a level of .5 milligrams per cubic meter (mg/m^3) of inhalable dust. By way of comparison, the current ACGIH TLV for grain dust is 4 mg/m^3 and the OSHA PEL for grain dust is 10 mg/m^3 as an 8 hour Time Weighted Average (TWA). This is the standard as it applies to grain silos, grain mills and related industries. OSHA's current PEL for nuisance dust, which flour dust is considered, is 15 mg/m^3.

ABA and its Safety Committee was obviously concerned that there might be new evidence showing that employees in the baking industry were being exposed to conditions that could lead to serious adverse health conditions. ABA attempted to contact ACGIH for a better understanding of the science supporting their proposal and what opportunities there were to open a dialogue to discuss this important issue. ABA was informed that ACGIH does not provide affected industries with an opportunity to discuss TLVs under consideration or have a voice in their development. At best, ACGIH will occasionally allow a representative of an industry to address their organization.

Particularly disturbing is that all attempts to find out any information - even a list of members of the Chemical Substances Committee - were ignored. Repeated phone calls, emails and correspondence were not acknowledged during the entire time that the ACGIH imposed "decision clock" was ticking. It became very clear that the ABA and the North American Millers Association (NAMA) were going to have to take serious steps to be heard in the process.

In the spring of 2000, our organizations and the Canadian National Millers Association contracted with Sandler Occupational Medicine Associates (SOMA) to conduct a literature review of the documentation ACGIH was relying upon to determine whether to issue a TLV. In addition, we asked SOMA to determine if there was additional research material that could be helpful in determining whether a health risk existed.

The findings of the SOMA review were clear and startling: the scientific evidence does not support the ACGIH TLV. In fact, the SOMA study concludes:

> "Research in this area as reported by many independent studies has found that sensitization to flour dust does not account for a majority of reported symptoms in flour workers. This is based on the absence of evidence of flour sensitization in most symptomatic workers. Research findings support the conclusion that symptoms in flour workers are primarily *non-allergic* and that flour dust primarily acts as a *non-specific irritant* rather than as a sensitizer or allergy- causing substance." (Emphasis added.)
>
> "Published data pertaining to exposure thresholds for flour-related effects, including sensitization and irritant effects are very limited. Furthermore, the data that serve as the basis for the TLV-TWA for flour sensitization *were not intended to be definitive for identifying exposure thresholds and do not provide confirmation* of the appropriateness of the TLV-TWA."(Emphasis added.)
>
> "In conclusion, the TLV-TWA provided in the ACGIH document is based upon *very limited, indefinite and unconfirmed information and is not substantiated* by the accumulated scientific evidence regarding flour dust exposure. From a scientific and occupational medical perspective it is surprising that a TLV-TWA would be developed based upon such limited data. *The scientific evidence does not provide a basis for control of exposure at specific thresholds*, particularly exposure to flour dust for purposes of preventing or limiting flour allergen sensitization and other work-related effects. The ... accumulated research does not provide scientifically-based, appropriately-derived support in the areas relevant to exposure threshold determination as provided in the ACGIH document." (Emphasis added.)

On September 1, 2000, the ABA, NAMA and CNMA submitted the SOMA study to the ACGIH Chemical Substances/Threshold Limit Value Committee for their review with a request that the ACGIH should withdraw the proposed TLV on flour dust. Later that month, ACGIH issued the final TLV on flour dust. Calls from our organizations were ignored. Not until almost six months later did we receive a summary dismissal of our request that the TLV be withdrawn. In fact, the February 21, 2001, response failed to address the very serious issues raised in our letter and in the SOMA study. It merely stated that "ACGIH received no substantive comments on the proposal during the year it was on the NIC. ACGIH believes that

the *Documentation* for the flour dust TLV and the research cited therein adequately support the TLV."

To further illustrate how out of touch the ACGIH is with our concerns about the lack of scientific evidence, our organizations received a letter date June 14, 2001 stating that they "have carefully reviewed the critique of the Documentation ..." and that "Review and evaluation of these reports has, in the Committee's opinion, strengthened the support for the TLV-TWA of .5 mg/m^3 as inhalable dust". It is inconceivable that even a cursory review of the SOMA study would lead to such conclusions.

Beginning in May 2001, the ABA repeated its request that the TLV be withdrawn and extended an invitation to the ACGIH to send representatives of the Chemical Substances/Threshold Limit Value Committee to a September meeting with the ABA Safety Committee to discuss this issue further. Despite three separate letters and over a dozen phone calls and emails, these requests went unanswered. Three days prior to the September meeting, a representative from the ACGIH education department responded that they would be unable to meet with the safety and health professionals of the wholesale baking industry to discuss this serious issue. Apparently, they were more concerned about getting a publication on the market instead of getting their TLVs right. Just this week, we have learned that ACGIH as a policy does not attend such meetings and that a meeting between a representative of ACGIH and our industry might be possible. This leads one to ask whether they are a true consensus organization or just another safety manual supply company.

All of this is not intended to air our dirty laundry as it were, but merely to point out that a so-called "consensus organization" is conducting its scientific evaluations and decision making completely in private, with no outside input or oversight, and thus no confidence in the final work product. It is no wonder that ACGIH has found itself battling numerous lawsuits and may continue to face legal action. Their work product - at least in the case of flour dust - is unsubstantiated, unreliable, and completely secretive.

BASIS FOR REGULATION AND ENFORCEMENT.

As I stated earlier, OSHA and the state OSHA plans rely upon the ACGIH TLVs as a basis for regulations and enforcement activities. It is for these reasons that ACGIH's processes should be open and responsive to the public and should instill the highest level of confidence by both regulators and the regulated community.

I would like to share with you how the TLV issued by ACGIH has manifested itself with our company. During the later part of 2000, our company was conducting a regularly self-administered industrial hygiene study to maintain our awareness of employee exposures to substances in their work environment. The primary exposures we experience and monitor in our facility are our employee's contact with biscuit and hotcake mixes and the associated ingredients we use to make these products.

During the exposure monitoring, the industrial hygienist we hired to conduct the study informed us of ACGIH's newly proposed exposure standard to flour dust, which is a primary ingredient of the baking process. We were greatly concerned with the new exposure level proposed by ACGIH as it presented a significant change from what had previously been administered by OSHA, the industry, or any other consensus standard setting organization -- including ACGIH. The new exposure standard recommended by ACGIH was 30 times lower than what was regulated by OSHA for total dust exposure and twice the exposure limit enforced by OSHA for exposure to substances that would be commonly considered a more substantial respiratory hazard, such as copper dust. The new exposure recommendation presented by ACGIH was also based on an exposure monitoring methodology different from the total dust or respirable dust monitoring commonly used in the management and enforcement of respiratory exposures. The validity of this monitoring methodology is a subject of great debate within the industrial hygiene community.

Our company reacted to this news by immediately forming an in-house team to further examine the issue and ensure our company was taking all the prudent steps necessary to ensure our employees' ongoing safety. One of the first parties we turned to for consultation on this matter was the Kentucky Occupational Safety and Health Administration. We have had a good working relationship with Kentucky OSHA for years. The Division of Education and Training at Kentucky OSHA is extraordinarily helpful to employers throughout the state. They are a constant source for free training, regulatory information and guidance to safety and health professionals in our state.

We contacted Kentucky OSHA several times and sent them a formal letter requesting guidance on the flour dust exposure issue. We maintained communication with Kentucky OSHA regularly as we awaited their guidance on the issue. As our team further investigated the proposed exposure limit being considered by ACGIH we became more concerned with the science behind the proposed TLV. Even a rudimentary review of what little information we could retrieve from ACGIH raised questions due to some of the contradictory studies referenced by ACGIH in the establishment of their new TLV. Furthermore, it appeared that ACGIH had made their decision largely on the results of one or two foreign studies with questionable findings. We wondered why we could not find references to studies conducted in the U.S. by well-respected American authorities on the subject in ACGIH's decision.

At the beginning of 2001, Kentucky OSHA received two complaint calls regarding our facility, which is totally uncharacteristic with our history. During the inspections that resulted from these calls, no safety violations were identified by the compliance officers. One complaint listed by Kentucky OSHA on one of the inspections dealt with flour exposure in an area where biscuits are manufactured and dust exposures are far below OSHA requirements for respiratory protection. A few weeks later, an OSHA Industrial Hygienist appeared at our company to conduct exposure monitoring of the personnel in the identified department.

The results of the initial exposure monitoring conducted by OSHA revealed the personnel in the department identified on the complaint had a average exposure level over 50 times lower than the exposure limit for organic respirable dust required by OSHA for respiratory protection.

The OSHA Industrial Hygienist returned the following week to conduct exposure monitoring of the personnel in the department using the ACGIH recommended exposure limit and sampling methodology. The Kentucky OSHA industrial hygienist admitted that she was not aware of the newly recommended flour dust TLV during her previous inspection and went on to admit that she had not yet been trained in the new sampling methodology used by ACGIH in administering the new exposure recommendation. Despite this, she went ahead and conducted exposure monitoring. The results of the second round of monitoring using the ACGIH exposure recommendations revealed levels of exposure that exceeded the newly recommended TLV.

Based on the assertion that we had violated the new ACGIH TLV for flour dust exposure, Kentucky OSHA cited our company with a serious violation of the General Duty Clause and Respiratory Protection Standards. Kentucky OSHA adopted the ACGIH TLV as a consensus standard on the belief that it was developed by a reputable resource in cooperation with the wholesale baking industry. As you can imagine, this came as a great shock to the ABA and those industry safety professionals that have serious reservations regarding this new TLV. The citation presented by Kentucky OSHA required that our company take immediate steps to abate our employee's exposure to flour dust above the ACGIH TLV. This would result in our personnel making biscuits, who previously had not been required to wear respiratory protection under OSHA exposure standards, to start wearing full face mask respirators like those worn by the Hazardous Materials workers responding to the recent Anthrax threats around the country. This would present an extraordinary leap in hazard management for bakery facilities of any size. It is likely that few employers in the baking industry could ever meet the excessive engineering and respiratory requirements that would be required under this flawed TLV.

Kentucky OSHA formally dropped their citation in this matter last week following our contest of the citation. It appears that this is due to the fact that its review of the scientific foundation of the TLV and the SOMA critique conducted for the wholesale baking industry came to the same conclusion of the industry - that it is based on bad science. The ACGIH TLV simply is not a "consensus" standard for our industry. Our industry manages employee safety based on sound science and facts, which have been thoroughly peer reviewed in an open and democratic manner with our government. Kentucky OSHA should not have been put in the position of explaining why they cited a company based on an ACGIH TLV it unwittingly thought to be valid. It should have confidence, without going thorough a review of the recommendation with the industry or other experts directly involved with the issue, that the TLV is valid, supported and proper.

The Subcommittee also should be aware that the ABA has received inquiries just in the last week from its members in Michigan and California indicating that both of those state OSHA plans are looking into the TLV for flour dust in possible enforcement proceedings. In addition, our counterparts in Canada also are feeling the effects of the new TLV. We have learned from the Canadian National Millers Association and the Baking Association of Canada that the federal safety and health administration and many of the provinces simply adopt or use as reference the ACGIH TLVs. Currently, there are a number of inspections and potential enforcement proceedings underway in Canada, all based on a TLV that is fatally flawed, in terms of both the science on which it is purportedly based, and the process that led to its adoption.

One final point to bring to the Subcommittee's attention is that on many occasions, the ACGIH's TLVs are used in workers compensation proceedings. Each state sets its own standards as to what type of evidence can be admitted into a determination of work-related injury or illness. Many states again rely upon the TLVs with the belief that they are above question. As we have spelled out, in the case of the flour dust TLV, the evidence and process is clearly in question. Clearly, for a state workers compensation board to rely upon consensus standards in making important determinations involving compensation for work related injury or illness, they must be based on a solid foundation.

RECOMMENDATIONS.

Clearly OSHA and the state OSHA plans need to be extremely careful regarding the type of information upon which they rely upon for regulations and enforcement. While one can argue specific points about NFPA or ANSI standards, at least the affected parties have ample opportunity to find out the details of the substance, and also how the standard-setting process works. In all cases, those directly impacted have a seat at the table. They also have charter requirements that all issues raised during public comments need to be resolved by the issuing Committee. This is the only way to ensure an outcome in which everyone can have confidence.

In the case of ANSI, ABA works closely with its industry partners, the equipment manufacturers of the Bakery Equipment Manufacturers Association and the educational arm at the American Institute of Baking to review the voluntary consensus standard pertaining to bakery equipment, Z-50. As an industry utilizing ovens and flour silos with potential explosion hazards, we work closely with the NFPA on its consensus standards. Again, everyone has a seat at the table and a voice in the development process. Local, state and federal agencies that look to these organizations for assistance and guidance all have the confidence in the procedures and work product of these organizations.

We strongly urge Congress to insist that OSHA utilize only data and consensus standards that meet minimum requirements for openness and participation. In addition, we urge Congress to add further confidence in the regulatory process by requiring OSHA to utilize scientific data and economic impact analysis that has

been independently peer-reviewed.

We also urge Congress in the strongest way possible to insist that OSHA avoid using ACGIH's TLVs as the basis for regulations and enforcement proceedings. OSHA also should instruct the state OSHA plans that - given recent controversies involving ACGIH standards, that states also should refrain from utilizing the TLVs. While we are loath to have the federal government impact the states' ability to conduct workers compensation programs as they see fit, it would be helpful to have some communication to state workers compensation administrators that the ACGIH TLV process and product have come under question. Until such time that ACGIH conducts itself in an open and fair manner that ensures confidence in its work product, it should not be the basis for any local, state or federal regulatory or enforcement proceeding.

Finally, while OSHA should continue to encourage its employees to participate in consensus standard setting organizations that meet basic open meetings and disclosure requirements, it should require them to push those organizations such as ACGIH that do not into changing their policies, or - alternatively - such agencies should withdraw the participation of their employees. Only then will the public be served in a way in which it can be confident of the results.

Our greatest fear is that government agencies will continue down this dangerous path of unwittingly adopting recommendations of so-called "consensus" organizations without first thoroughly examining the background of each issue. My hope is that we can count on our government to ensure democracy in the rules and standard setting process, due to the broad impact of those guidelines in multiple settings..

Thank you again for the opportunity to address this important issue.

APPENDIX D - WRITTEN STATEMENT OF DAVID KARMOL, DIRECTOR OF PUBLIC POLICY AND GOVERNMENT AFFAIRS, AMERICAN NATIONAL STANDARDS INSTITUTE, WASHINGTON, D.C.

Statement of David L. Karmol
Director of Public Policy and Government Affairs
American National Standards Institute (ANSI)
Before the
Subcommittee on Workforce Protection
Of the
House Committee on Education and the Workforce

November 1, 2001

"The Role of Consensus Standards-Setting Organizations with OSHA"

Thank you Mr. Chairman and members of the Committee for inviting me here today to testify on "The Role of Consensus Standards-Setting Organizations with OSHA." I am David Karmol, Director of Public Policy and Government Affairs of the American National Standards Institute. The topic of this hearing is of great interest to us, as ANSI and many of the developers of voluntary consensus standards accredited by ANSI work very closely with the Occupational Safety and Health Administration (OSHA).

A few of the ANSI members who have expressed strong interest in this issue include the American Industrial Hygiene Association (AIHA), the American Society of Mechanical Engineers International (ASME), the American Society of Safety Engineers (ASSE), ASTM (formerly the American Society for Testing & Materials), the National Fire Protection Association (NFPA), and the National Safety Council (NSC).

ANSI's Role

The voluntary standardization system in the United States is the most effective and efficient in the world. For almost 100 years, this system has been administered and coordinated by the private sector through ANSI, with the cooperation of federal, state and local governments. ANSI does not write standards; it serves as a catalyst for standards development by its diverse membership. The Institute is a unique partnership of industry; professional, technical, trade, labor, academic and organizations; and some 30 government agencies. These members of the ANSI federation actually develop standards or otherwise participate in their development, contributing their time and expertise in order to make the system work.

ANSI accredits various standards developers to develop American National Standards. These standards developers primarily are national trade, technical, professional, consumer, labor and certification organizations. Thousands of individuals from companies, organizations (such as labor, consumer and industrial groups), academia and government agencies voluntarily participate and contribute

their knowledge, talent and efforts to the standards development process.

ANSI determines whether standards developed by ANSI-accredited standards developers meet the necessary criteria to be approved as American National Standards. ANSI's approval of these standards is intended to verify that the principles of openness and due process have been followed and that a consensus of all interested parties has been reached. In addition, ANSI considers any evidence that the proposed American National Standard is contrary to the public interest, contains unfair provisions or is unsuitable for national use.

The voluntary consensus standards development process has proven its effectiveness across a diverse set of industries and in federal, state and local government processes. These industries include telecommunications, safety and health, information technology, petroleum, banking and household appliances. There are now approximately 13,000 ANSI-approved American National Standards that provide dimensions, ratings, terminology and symbols, test methods, interoperability criteria, and performance and safety requirements. These efforts continue today and are being applied to new critical areas such as the environment and healthcare.

ANSI also is the United States representative to the two major, non-treaty international standards organizations: The International Organization for Standardization (ISO) and, through the United States National Committee, the International Electrotechnical Commission (IEC). In the conformity assessment area, ANSI accredits organizations that certify that products meet certain standards. In addition, through a joint program, ANSI and the Registrar Accreditation Board (RAB) accredit organizations that register quality systems conforming to the ISO 9000 and ISO 14000 series of standards.

In fulfilling its roles and responsibilities, ANSI continues to pursue its mission to "[e]nhance both the global competitiveness of U.S. business and the U.S. quality of life by promoting and facilitating voluntary consensus standards and conformity assessment systems and safeguarding their integrity." In summary, ANSI ensures the integrity of the U.S. voluntary consensus standardization system by serving as (1) an open, national forum for standards-related policy issues, (2) the only accreditor of standards developers, ISO Technical Advisory Groups (TAGs) and an accreditor of product certifiers, and (3) a primary source of information and education on standards and conformity assessment issues.

ANSI Processes and Procedures

As the only accreditor of U.S. standards developing organizations, ANSI ensures the integrity of the voluntary consensus standards development process and determines whether standards meet the necessary criteria to be approved as American National Standards. The goal of the ANSI process is to obtain a document that a balanced consensus of materially affected interest groups believes is an appropriate standard. Due process is critical when it comes to determining if

that consensus has been fairly achieved. Accordingly, the ANSI Procedures require that a draft proposed standard be appropriately circulated (both to the consensus body and the public at large) and that an attempt is made to resolve all negative comments. There must be an appeals process. If a balanced consensus body then votes on and approves the proposed document after reviewing all unresolved negative comments and any substantive changes to the text, consensus has been achieved and due process has been satisfied. This basic formula has been the hallmark of the ANSI process for decades, and it has earned widespread respect and acceptance.

If a standard is developed according to ANSI requirements, there should be sufficient evidence that the standard has a substantive reasonable basis for its existence and that it meets the needs of producers, users and other interest groups. If a vote on a standard was or is somehow perceived as having been subtlety manipulated, any person or entity who is materially affected by or otherwise interested in the standard — whether a voting member of the consensus body or a public commentator — can appeal the decision. The grounds for an appeal to ANSI include issues such as lack of balance on the consensus body, dominance by any person or entity, inadequate response to a negative comment (again whether from a voting member of the committee or a public commentator), and improper restraint of trade concerns. The appeals process, and the requirement that all consensus bodies seek to have representatives from a balanced group of interested parties, assures that no one interest can manipulate the process unfairly. The ANSI system is designed so that contrary evidence proffered by opponents of the standard must be properly addressed and responded to or else the standard will fail to achieve ultimate approval

In addition, proper procedures are of little value if they are not followed in practice. As a result, in addition to the review ANSI undertakes when a standard is submitted to it for approval as an American National Standard, the Institute also has implemented a mandatory standards developer audit program. The program is designed both to verify an accredited developer's compliance with current ANSI requirements and to provide guidance on more efficient or effective ways to address various aspects of the standards development process.

While all American National Standards must be developed in accordance with these basic hallmarks of the ANSI process, accredited developers may satisfy these requirements in innovative ways and rely extensively on electronic communications. If there is a ready consensus by the interested parties on a proposed standard, the standard can meet the procedural requirements for, and be approved as, an American National Standard in 4-6 months.

ANSI recognizes that there are many ways to develop standards, and that in many instances other methods and the resulting standards are entirely appropriate for the targeted user community. For the record, let me say that ANSI has no objection whatsoever to the existence of organizations that develop standards outside the so-called "formal" process used within the ANSI community. ANSI has never had—

nor has it ever sought—exclusivity in promulgating a standards development process.

ANSI believes that it is up to the users (in this case, OSHA) to decide where and under what process they want particular standards developed. In many instances, that will be within the formal standards setting process.

The Public-Private Partnership

While the term "public-private partnership" has been in vogue in Washington in recent years, it has been a reality for ANSI since our founding. In fact, ANSI was founded in 1918 by a group of private sector organizations and government agencies that recognized the need to have a forum in which they could address common concerns. As a private sector organization with many government members, ANSI has a strong tradition of working cooperatively with government as well as industry, organizations and consumer interests.

ANSI is a private sector organization in which many government representatives active at all levels, from our Board of Directors to the committees that promulgate, maintain and implement the procedures pursuant to which standards developers are accredited and American National Standards are developed and approved. Government representatives participate in ANSI delegations addressing international standardization issues, thereby strengthening the U.S. voice in international standardization negotiations.

When Congress enacted the National Technology Transfer and Advancement Act of 1995 (NTTAA), it specifically and strongly encouraged the participation of the U.S. government in the development of voluntary consensus standards. It was the clear intent of Congress that federal employees play an active role in the development of standards that will be used in regulation, procurement, and trade. This action by the Congress confirmed a basic principle of the U.S. standardization—that standards setting is a partnership process in which government and the private sector are equal partners. The importance of the private-public partnership was reaffirmed in a series of laws enacted by Congress in recent years, including these:

- Consumer Product Safety Improvement Act of 1990
- The National Technology Transfer and Advancement Act of 1995 (P.L. 104-113)
- Health Insurance Portability and Accountability Act of 1995
- Telecommunications Reform Act of 1996
- FDA Modernization Act of 1997

Each of these laws reinforced the principle that the Federal government should rely heavily upon private sector standards, and that the government should participate actively in the development of those standards.

The U.S. is an example to the rest of the world on how the public and private sectors can work cooperatively. Using voluntary standards allows the government to achieve economies of scale and have access to the most modern technologies and a wide range of technical experts. If federal participation in standards development were curtailed, over time these benefits might be lost to the federal government—costs would go up and antiquated technologies would remain in use. While the private sector would suffer the loss of the expertise of often uniquely knowledgeable government experts, the government would lose the benefit of critical, timely access to private sector expertise.

Absent the practical benefits of technical dialogues among those who are directly affected, government regulations and procurements would become increasingly arbitrary and the private sector would have to contend increasingly with regulatory and procurement decisions based upon outdated or purely theoretical information.

Our economy cannot afford for the U.S. Government to be shut out of the voluntary standards development process.

ANSI and OSHA

ANSI has a positive, productive relationship with OSHA. We have had a Memorandum of Understanding with OSHA since 1978 that recognizes that it is our national interest to work together cooperatively on standardization matters. The MoU has been updated periodically by succeeding administrations of both political parties. An OSHA representative serves on the ANSI Board of Directors and on our policy committees; others from OSHA participate in our Government Member Council and other ANSI activities. And, very importantly, OSHA representatives participate in the standards development activities of ANSI-accredited standards developing organizations.

We believe that both the Federal government and the private sector benefit from OSHA's participation in the development of voluntary consensus standards, which are sometimes incorporated by reference into OSHA regulations. The "give-and-take" that occurs at all levels within ANSI's open, neutral forum affords both industry and regulator to gain a more realistic understanding of each other's objectives and requirements. As a result, OSHA is able to reference in regulations the private sector standards that they have had a voice in developing, with consideration having been given to the effect of those standards upon industry, consumers and other affected interests. We believe that this results in more rulemaking] by OSHA than might otherwise be the case. Industry also benefits because they obtain a better understanding of the regulators' requirements and have an opportunity to provide technical input before issues move into the formal rulemaking process. This process also gives industry an opportunity to anticipate

regulatory actions and incorporate them in their planning efforts.

The U.S. Government relies heavily on voluntary standards, including occupational safety and health standards. Whether we are speaking of regulation, procurement, or trade and competitiveness, private sector standards are important to accomplishing public policy. In the area of procurement, for example, agencies such as the Defense Department and General Services Administration are most concerned about quality, price, and appropriateness of products. They can and do choose freely among standards, using standards that have been developed by ANSI-accredited developers or by others, depending on their needs.

Regulators are among the strongest supporters of standards developed by ANSI-accredited developers. The principles of ANSI's process—openness, balance, due process, public review and consensus—assure that all stakeholders have an opportunity to participate in the development of the standard and that no one interest group has dominated the process.

As a matter of law and policy, and with the strong support of Congress, regulators rely heavily upon voluntary consensus standards when promulgating regulations for health, safety, and protection of the environment. Thanks in large measure to the successful implementation of the National Technology Transfer and Advancement Act (NTTAA), government agencies such as OSHA have continued to participate in the private sector standards development process and to rely upon the resulting standards as an alternative to regulatory rule-making

A Serious Problem Involving OSHA's Use of Consensus Standards

We would like to bring to this Committee's attention a serious problem that may require Congressional action to resolve.

OSHA regulations contain within them references to hundreds of outdated standards. In some cases, the standards referenced have been out of date for thirty years or more, yet they are still part of current OSHA regulations. We understand that OSHA's enabling legislation prevents the agency from adopting new versions of standards without subjecting them to a full public review process, and that the agency does not have the resources to accomplish this. As a result, industry and workers sometimes must use 30-year-old standards to be legally in compliance with OSHA requirements; if they use updated, current standards, they are in jeopardy of violating of OSHA regulations and being subjected to fines and other serious legal penalties.

OSHA and the private sector are equally concerned about this situation. I would like to assure this Committee that this is a nonpartisan issue. Assistant Secretaries of Labor for OSHA from both political parties have tried to resolve this problem, without success.

While there is no simple solution in sight, we believe that we must find a way to

resolve this so that industry and the workforce can rely upon current processes and technology and still be in compliance with OSHA legal requirements.

We have brought this matter to the attention of John Henshaw, the new Assistant Secretary of Labor for Occupational Safety and Health, and have been assured that he shares our desire to find a solution to this long-standing problem. We are eager to accept his invitation to work with him on this issue. We appreciate the opportunity that the Committee has given us to bring attention to this issue.

The National Standards Strategy

In its capacity as "umbrella organization" for U.S. voluntary consensus standardization, ANSI provides a lively forum in which diverse interests freely discuss and debate issues of importance to them. One of the most important issues addressed by ANSI for the past two years is that of developing a National Standards Strategy. The close partnership that exists between the U.S. Government and private sector in the area of standardization is nowhere more evident than in the development of the National Standards Strategy.

The initiative for developing a National Standards Strategy originated with a challenge by the Director of the National Institute of Standards and Technology to the ANSI Board of Directors. That was an excellent example of government challenging the private sector to assume leadership of a national strategic effort. When ANSI responded by launching the National Standards Strategy initiative with the full support of the private sector, the Federal Government played an active role as an equal partner in the development of the Strategy. Representatives of OSHA, the Consumer Product Safety Commission, Defense Department, Environmental Protection Agency, Food and Drug Administration, National Aeronautics and Space Administration, National Institute of Standards and Technology, and Office of the U.S. Trade Representative took an active part in the discussions and helped shape all parts of the Strategy. Thus, procurement, regulatory, and trade agencies were active participants in development of the National Standards Strategy.

The importance of this partnership principle in standardization is so important, in fact, that the first tactic in the National Standards Strategy developed by a broad spectrum of ANSI's many constituent groups, including the government is, "Build on the trend to use voluntary consensus standards through existing public/private partnerships."

In addition, the Strategy recognized the importance of adherence to the following principles of standards development. The overarching principles of the Strategy are quoted below:

> "U.S. interests strongly agree on the principles necessary for the development of national or international standards to meet societal and market needs." With that testament to fundamental unity of vision, the document sets forth the

principles that underlie the U.S. National Standards Strategy:

"In successful standards processes:

Decisions are reached through consensus among those affected.

Participation is open to all affected interests.

Balance is maintained among competing interests.

The process is transparent--information on the process and progress is directly available.

Due process assures that all views will be considered and that appeals are possible.

The process is flexible, allowing the use of different methodologies to meet the needs of different technology and product sectors.

The process is timely; purely administrative matters do not slow down the work.

Standards activities are coherent, avoiding overlap or conflict.

"Successful standards processes yield the right results:

Standards are relevant, meeting agreed criteria and satisfying real needs by providing added value.

Standards are responsive to the real world; they use available, current technology and do not unnecessarily invalidate existing products or processes.

> Standards are performance-based, specifying essential characteristics rather than detailed designs."

With this statement of principles, the Strategy reaffirms the principles that underlie the existing U.S. system of voluntary consensus standardization. The Strategy then goes on to recognize and emphasize the fundamental element that gives the American approach to standardization its strength and uniqueness: its sectoral focus. We believe that this sectoral focus, as much as any other factor, distinguishes U.S. standardization practice and policy from that of much of the world.

For nearly a century, the U.S. consensus standardization system has been effective in developing standards that meet industry's needs and adequately address public interest concerns. Thanks in large measure to the successful implementation of the National Technology Transfer and Advancement Act (NTTAA), government agencies have continued to participate in the private sector standards development process and to rely upon the resulting standards as an alternative to regulatory rule-making.

Conclusion

ANSI shares this Committee's desire to ensure that the federal government—most certainly including OSHA—relies upon the use of voluntary consensus standards that have been developed in open, balanced processes that provide protections against arbitrary or capricious actions, and against unfair dominance by any interest group. This is a top priority for all of us, and we look forward to working closely with you and your staff on this issue.

We also want to work with you to resolve the ongoing problem of OSHA's reliance upon outdated standards in its regulations.

Thank you for this opportunity to testify. I would be happy to answer any questions that you might have.

APPENDIX E - WRITTEN STATEMENT OF JOHN BIECHMAN, VICE PRESIDENT FOR GOVERNMENT AFFAIRS, NATIONAL FIRE PROTECTION ASSOCIATION, ARLINGTON, VA

Testimony Before the Subcommittee on the Workforce Protection
Committee on Education and the Workforce
US House of Representatives

"The Role of Consensus Standard Setting Organizations with OSHA."

By
John Biechman
Vice President for Government Affairs
National Fire Protection Association

November 1, 2000

Chairman Norwood and Committee Members, thank you for allowing me the opportunity to testify before you today on "the role of consensus standard setting organizations and OSHA." My name is John Biechman, I am Vice President for Government Affairs at the National Fire Protection Association (NFPA).

NFPA is a 105-year-old, not-for profit, codes and standards development organization, headquartered in Quincy, Massachusetts. Its mission is to reduce the worldwide burden of fire and other hazards on the quality of life by providing and advocating scientifically-based consensus code and standards, research, training, and education. NFPA has over 75,000 members and publishes over 300 codes and standards. All of NFPA's codes and standards are accredited by the American National Standards Institute (ANSI) and meet the requirements for voluntary consensus standards of the Technology Transfer Act of 1995 (PL 104-113).

NFPA develops and renews its codes and standards through a voluntary consensus process established by NFPA's board of directors and regulated by the NFPA Standards Council. Over 5000 volunteers participate in more than 200 technical standards committee. Technical committee members represent a balanced cross-section of industry, labor, and allied interests. They are selected based on their technical expertise and ability to fully participate in the work of the committee. The NFPA process is one that is open, balanced, ensures due process and provides for an appeals process. OSHA staff has participated in several of NFPA's technical committees, including: our commercial maritime related committees, our flammable liquids, finishing processes, and pyrotechnics committees. Since the 1975 code cycle, OSHA has participated in NFPA's National Electrical Code ® Correlating Committee and NFPA's Standard 70E – "*Electrical Safety Requirements for Employee Workplaces*." The standard was specifically developed for an OSHA rulemaking, with OSHA participation. NFPA 70E is the most comprehensive electrical safety document available today, and has been adopted, in part, by the agency.

Additionally, it is important to note that NFPA members and staff have participated in several OSHA activities, including advisory committees and the OSHA Training Institute, sharing technical knowledge and expertise.

Because NFPA is accredited by ANSI, our codes and standards must be updated at least every 5 years. Often times, however, NFPA's standards are revised on a more frequent basis to reflect new technology or findings.

Several federal departments and agencies reference NFPA's standards. A list of the NFPA code and standards to be revised or reaffirmed is published in the Federal Register through an agreement with the National Institute of Standards and Technology (NIST) at the outset of each review cycle. This affords the opportunity for those interested in NFPA codes and standards to participate in the process.

To address NFPA's specific experience with the Occupational Safety and Health Administration (OSHA), the original 1970 OSHA Act allowed the Department of Labor to "jump start" rulemaking to improve worker safety by adopting consensus safety standards through an expedited regulatory process known as the 6(a) process. Approximately 50 NFPA standards were adopted in the mid 1970's and most are still codified as base line OSHA safety standards. Many of the referenced NFPA standards date back to the 1960's and some as far back as the 1950's. Most have been superceded by state-of-the-art successor standards adopted by NFPA and applied in the work place today, but have not been adopted by OSHA.

The problem is that when designing buildings or manufacturing processes, or installing electrical wiring and safety systems, employers use today's safety standards not yesterdays. Unfortunately, OSHA has not been able to easily update its regulations to today's standards.

The reason it is difficult to update these OSHA safety standards is that the 6(b) process that succeeded the 6(a) expedited process often takes several years at rulemaking and only a few rules are considered each year. There is also concern by some that replacing outdated safety systems would require employers to purchase new equipment and concern expressed by others that change might reduce safety. The problem is further exacerbated because OSHA inspectors are required to issue de-minimus violations when an employer complies with newer editions of a consensus standard rather than the obsolete standard referenced in the Code of Federal Regulations (CFR). Recognizing the problem with this approach, OSHA inspectors can waive fines but the de-minimus violation remains on the books.

A possible solution to this problem would be for OSHA to recognize contemporary editions of consensus standards in the CFR by title, number and edition date as acceptable for OSHA compliance (or any earlier edition that was current when the facility was built) as long as the level of protection, as determined by OSHA, is at least as effective as the original consensus standard cited. In this way, an original standard adopted by OSHA in the 1970's under the 6(a) process would be maintained as the minimum but employers would be free to use a later edition

without penalty. The original standard would continue to be referenced in the CFR and a notation would be added to reference later editions.

In summary, NFPA has worked well with OSHA for nearly three decades, and we look forward to continuing that relationship. NFPA would encourage OSHA to continue to work within the voluntary consensus standards development process; open communication between OSHA staff and standards development organizations is beneficial for the government and the standards development organizations. Working together could make it possible to resolve differences before standards are finalized. Furthermore, we hope that OSHA, when participating in the voluntary standards consensus process, will take into consideration the thoughts and suggestions of technical committees because they are truly balanced, voluntary consensus committees that represent state-of-the-art technology and best work practices found within industry today.

Again, Mr. Chairman, thank you for the opportunity to testify before the committee today.

APPENDIX F - WRITTEN STATEMENT OF HENRY LICK, PRESIDENT, SAFETY AND HEALTH SOLUTIONS, LTD, GROSSE ILE, MI, ON BEHALF OF AMERICAN INDUSTRIAL HYGIENE ASSOCIATION

TESTIMONY

The Role of Consensus Standard Setting Organizations

UNITED STATES HOUSE OF REPRESENTATIVES
HOUSE EDUCATION AND THE WORKFORCE COMMITTEE
SUBCOMMITTEE ON WORKFORCE PROTECTIONS
HONORABLE CHARLES NORWOOD, CHAIRMAN

November 1, 2001

Submitted by:
Henry B. Lick
Ph.D., CIH, CSP, ROH

CHAIRMAN NORWOOD AND MEMBERS OF THE SUB-COMMITTEE:

My name is Hank Lick and I have been invited here today to provide testimony on "The Role of Consensus Standard Setting Organizations". I appreciate the opportunity to provide input on this important health and safety issue. At the present time, I am President of Safety and Health Solutions, an occupational and environmental health and safety consulting company that I formed earlier this year upon my retirement from the Ford Motor Company. I was employed at Ford for thirty-two years and retired as Manager of Occupational and Environmental Health Sciences.

I have also been active as a member and/or chair of several industry and governmental advisory committees during my forty years as an occupational health and safety professional. I recently completed six years of service as a member of the National Advisory Committee on Occupational Safety and Health (NACOSH). I also have the privilege of serving as the current President of the American Industrial Hygiene Association (AIHA), the world's largest association of occupational and environmental health professionals. I have been a member of AIHA for 32 years and have earned certifications as a Certified Industrial Hygienist (CIH), a Certified Safety Professional, and a Registered Occupational Hygienist in Canada.

Before I begin Mr. Chairman, I would like to take this opportunity to thank you on behalf of the millions of Americans, both employees and employers who desire a healthy and safe workplace, for your involvement in addressing the role of consensus standard setting. Your leadership is critical in improving this country's record of workplace-related injury and illness that affects workers and their families and impacts

our communities. I applaud your efforts. I would also like to ask that my entire written testimony be inserted into the record.

For the past several years, I have been concerned with the degree of difficulty and the excessive time needed for the Occupational Safety and Health Administration (OSHA) to promulgate health and safety standards. Since consensus standards were first adopted in the first two years after the passage of the Occupational Safety and Health Act, a relatively small number of standards have been promulgated. Further, standards such as the Permissible Exposure Limits have not been successfully updated. The average time, depending how the time of standard introduction is measured, to develop and promulgate a standard, is ten years. The first ANPR for the Confined Space Entry Standard was 1975 and the final rule was promulgated in 1993. The request for information on the Lock Out Standard was in 1977 and the final rule was 1989.

During the six years I served on NACOSH, I provided advice to OSHA on the development of standards or rules on Recordkeeping, Ergonomics, and Safety and Health Programs. In 1998, after fours years of no progress in these areas, I requested NACOSH conduct a study to determine the reasons why the OSHA standard setting process is so difficult.

To identify the root causes, NACOSH sought information from panels of various stakeholders involved in the standard setting process and from individuals and organizations that had participated in previous standard setting at OSHA or other governmental agencies. After hearing from the panels, NACOSH concluded that the standards process was not working as intended in the OSH Act. I was pleased to be one of the principle authors of this report. Some of the major recommendations in the report were:

- Develop constituencies earlier in the process
- Develop standards based on national hazard trends
- Develop a regulatory handbook to be used as a reference aid for OSHA personnel
- Monitor and participate in the consensus standard making process
- Assist Advisory Committees

There were many more recommendations included in the NACOSH report. A summary of these recommendations is attached as Document 1.

In fairness, many external legislative barriers and court interpretations have made the process more difficult. Several layers of review are now present that were not foreseen in the OSH Act. However, NACOSH stated that OSHA and the National Institute for Occupational Safety and Health (NIOSH) have not developed management systems to

address potential changes in the regulatory environment. Further, NACOSH concluded that OSHA and NIOSH do not act synergistically in the standards setting process.

Several other federal agencies have been more successful in setting standards. This is due partially to their success in gaining public support for their regulatory agenda. This success has translated into more resources to apply to standard setting. In addition to not gaining public support, OSHA has not managed and supported its internal and advisory resources effectively. This is due, in my opinion, to weaknesses in strategic and tactical planning and the subsequent failure to meet project goals in a timely manner.

NACOSH concluded that OSHA must use the tested management techniques that are available today and aggressively pursue new technology. OSHA and NIOSH must adapt to today's realities.

OSHA and NIOSH should not shoulder all of the blame for the standards process not working. Consensus Standard Setting Organizations and Professional Associations should be more consistent and uniform in their support. These entities, together with OSHA and NIOSH must form stronger alliances and resolve scientific opinion differences early in the standard setting process. NACOSH realized that this is a difficult challenge because of competing crossovers in professional areas of expertise and natural constituencies.

I believe it is also important, at this time, to update you on some efforts to address this issue taking place within the professional associations. As stated earlier, I am currently the president of the American Industrial Hygiene Association. As the world's largest association of occupational and environmental health professionals, AIHA members are well aware that exposure limits and standards are a primary tool in disease prevention. AIHA has adopted a position statement and white paper on permissible exposure limits (PELS) and the latest version of this position statement and white paper is attached to my testimony (Document 2) for your review.

But AIHA has not limited itself to simply adopting statements on the problem. Earlier this year, AIHA began the process of forming a task force composed of labor, industry and professional association representatives to see if an agreeable solution on this issue could be found. While early in its efforts, I am confident that this is one of the first steps in finding a solution. I am also convinced that it will require the leadership of an association like AIHA to bring the parties together. AIHA has no political agenda and is highly regarded as a credible and un-biased organization. Our relationship with OSHA, NIOSH, labor and industry is excellent. I offer you the assistance of AIHA as you move forward.

Several things, however, have happened since the NACOSH report was issued that require us to immediately address the standard setting process; a new administration, the use of the Congressional Review Act on the OSHA Ergonomics Standard, and the lawsuits against the American Conference of Governmental Industrial Hygienists Threshold Limits process. These events have not changed my opinion that the standards setting process is essentially broken. However, they do point out we are in a

crisis mode and we need to quickly resolve this issue.

The broken standard setting process is impacting business and is distracting OSHA from its primary mission of protecting worker health and safety. The ACGIH TLV process is now the only viable worker exposure limit setting process. The OSHA PELs are essentially the 1968 ACGIH TLVs and they are, for the most part, outdated and irrelevant. Some say the ACGIH process is flawed, but if ACGIH is no longer involved in the standard setting process, some other standard setting body needs to step up and see that the exposure limit setting process continues.

It has been thirty-two years since the passage of the Occupational Safety and Health Act. Businesses that were not even imagined now dominate commerce. Hazards that were present at that time have been controlled and new hazards have replaced them. However, old hazards still exist and must continue to be addressed. The global economy is dynamic, but our standard setting process is not. Congress needs to amend the OSH Act to incorporate today's realities; businesses must support the consensus standard setting process with their best talent and with financial resources; and health and safety professionals and their associations must work together and with consensus standard setting organizations.

In closing, I applaud your efforts and sincerely hope that we can be successful in finding ways to improve the health and safety of America's workers. I, as well as the organization I represent, the AIHA, stand ready to assist you and Congress in every possible way.

Again, I appreciate the opportunity to appear here today and relay some of my experience and knowledge. At this time I would be more than happy to answer any questions you may have.

Thank you.

DOCUMENT 1

NACOSH

RECOMMENDATIONS TO IMPROVE STANDARD DEVELOPMENT PROCESS

GENERAL ---- OSHA needs to do a better job of managing itself and demonstrating this to the public and congress. It needs to learn how to use constituents and the public concern.

Develop constituencies early in the conceptual phase and later in the writing phase by more effect outreach efforts to trade and professional

associations.

Develop a campaign to improve public and Congressional perception of OSHA.

Develop standards based on national hazard trends and issues consistent with the priority and strategic planning processes.

Develop a standards process room (War Room) with wall charts illustrating every phase of the standard development process.

Develop a regulatory handbook to be used as a reference and training aid for OSHA Staff involved in the standard setting process and for others such as compliance officers to better understand their role in the process.

Improve integration of the OSHA and NIOSH strategic plans in the process.

Develop a tactical plan that includes gap analyses, timing milestones, comprehensive outreach, and compliance staff training, once a commitment to development of a standard is made.

Improve internal organization and management of OSHA standards develop resources.

Monitor and participate in the consensus standard making process.

Work to develop consensus interpretations of the terms of hazard, material impairment, significant risk, economic feasibility, and technical feasibility.

ADVISORY COMMITTEES ---- Advisory Committees are an effective tool, particularly when contentious issues are involved.

Establish a department that can expand and contract as needs dictate to support , coordinate, and communicate the activities of Advisory Committees.

Develop an operations guide for Advisory Committee members.

Assist Advisory Committees in developing operational plans with specific goals, objectives and timing milestones.

Assure membership of Advisory Committees reflect health and safety professionals that are representative of the regulated community.

Assure administrative and report writing support is readily available to Advisory Committees.

Assure adequate an adequate budget to fully support committee operational plans.

CONSENSUS STANDARD SETTING AND PROFESSIONAL ORGANIZATIONS ----- Consensus Standard Setting and Professional Organizations can play a significant role in diffusing the "sound science" or "no science" argument. OSHA must cultivate these organizations as trusted partners and allies.

Re-establish the Office of Professional Association Liaison.

Draw Consensus Standard Setting and Professional organizations into the OSHA and NIOSH strategic and tactical planning processes.

Partner with Consensus Standard Setting and Professional organizations in developing outreach and communication strategies.

Maintain a continuous dialogue with Consensus Standard Setting and Professional organizations.

Support workshops, seminars, and conferences organized by Consensus Standard Setting and Professional organizations in areas related to OSHA and NIOSH strategic initiatives.

Encourage Professional organizations to use and strengthen the Inner-Society Forum as a platform to discuss contentious issues and to develop broadly supported priorities.

Develop mechanisms for Professional organizations and major companies to submit data relative to standards proposed or under development.

Develop speakers bureaus from Consensus Standard Setting and Professional organizations to support positions to the public and Congress.

Encourage Professional organizations to become health and safety advocates in addition advancing their professional agendas.

CONGRESS

Congress needs to reopen the Occupational Safety and Health Act to address standard setting activities such as Permissible Exposure Levels to quickly reflect advances in technology and research and occupational Epidemiology developments.

DOCUMENT 2

AMERICAN INDUSTRIAL HYGIENE ASSOCIATION

POSITION STATEMENT ON PERMISSIBLE EXPOSURE LIMITS (PELs)

It is the position of the American Industrial Hygiene Association that:

1. Exposure limits such as OSHA's PELs are a primary tool in disease prevention when used by industrial hygienists as part of a comprehensive occupational safety and health program.

2. OSHA should seek whatever resources or legislative changes are needed to allow the updating of all existing PELs to current science and to set such new PELs as are necessary to protect worker health. In the meantime OSHA should select chemicals for PELs based on scientific principles and specific criteria developed with all stakeholders.

3. For compliance purposes OSHA has defined PELs as values not to be exceeded. However, when designing exposure monitoring programs employers must assign a statistical interpretation to the PEL. Therefore, OSHA should provide guidance regarding suitable statistical interpretations so that the employers can design effective performance-based exposure monitoring programs that are consistent with OSHA's expectations.

4. OSHA should develop a peer-reviewed guideline for the derivation of PELs. AIHA believes that PELs must be based on the best scientific information available and must include a well-documented critical evaluation of the supporting information. AIHA also believes that appropriate uncertainty factors must be applied to compensate for the inherent uncertainties in the existing data and extrapolation to human populations.

5. Employers have the responsibility to assess the risks to the health of their workers and adequately control worker exposures to hazardous substances or agents for which there are no PELs. Employees must be fully consulted in the development of these risk assessments and informed of the results.

6. PELs should be consistent across occupational populations and should be accepted by other federal agencies when the goal is protecting occupational health.

Adopted by Board of Directors: January 2, 1998

AMERICAN INDUSTRIAL HYGIENE ASSOCIATION WHITE PAPER ON PERMISSIBLE EXPOSURE LIMITS (PELs)

The focus of this white paper is on the regulatory permissible exposure limits (PELs) for airborne chemicals as promulgated by the Occupational Safety and Health

Administration (OSHA). However, recognizing that OSHA has not been able to set up-to-date PELs for every chemical of concern in the workplace, these comments go further to suggest what employers and industrial hygienists may do to fill the need.

1. Exposure limits such as OSHA's PELs are a primary tool in disease prevention when used by industrial hygienists as part of a comprehensive occupational safety and health program.

The concept of the use of exposure limits as a means of protecting worker health has evolved from the industrial hygiene community's 50 years of experienceo in developing and using such limits. Maximum Allowable Concentrations (MACs), Threshold Limit Values (TLVs), Workplace Environmental Exposure Levels (WEELs), Recommended Exposure Limits (RELs), and industry-developed Occupational Exposure Limits (OELs) have been essential tools of the practicing industrial hygienist. While the goals, where stated, may differ5 (e.g., to limit occupational cancer to 1 case in 1000 exposed workers over a working lifetime or to protect "nearly all workers"), these exposure limits are all designed to reduce the occurrence of worker illness or impairment resulting from exposure to chemicals. The use of exposure limits to prevent occupationally-related illness has been an effective tool used by industrial hygienists for more than five decades. AIHA recognizes the controversies that are often involved in the setting of these limits both in the regulatory and voluntary arenas. In developing PELs the major concerns include scientific soundness, feasibility, timeliness, documentation, and opportunity for involvement of affected parties in the decision-making process. We believe that when these considerations are a part of the limit-setting process and when the limits are applied as part of a comprehensive occupational safely and health program they are a primary tool in disease prevention.

2. OSHA should seek whatever resources or legislative changes are needed to allow the updating of all existing PELs to current science and to set such new PELs as are necessary to protect worker health. In the meantime OSHA should select chemicals for PELs based on scientific principles and specific criteria developed with all stakeholders.

It is a disservice to worker health that the majority of OSHA PELs are based on recommendations that were made almost 30 years ago (i.e., 1968 Threshold Limit Values of the American Conference of Governmental Industrial Hygienists). AIHA supports the concept that OSHA should review and update the PELs on a regular (three-to five-year) cycle based on National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Limits

(RELs), the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs), AIHA Workplace Environmental Exposure Levels (WEELs), and other appropriate national and international standards that are based on good science. All of the limits noted above are developed by technical-professional associations (AIHA and ACGIH) or a government agency (NIOSH), and they undergo extensive technical reviews and follow a formal process for development, review, and approval of individual limits. While the procedures and rationales may differ, all of

these limits provide a scientifically sound starting point and foundation for prompt and continuing upgrading of the OSHA PELs. By starting with such a foundation, the past record (new PELs for only about two dozen substances in more than

25 years) can be markedly improved and worker health protection will be enhanced by promptly considering new information.

Without a regular review and update process, many more PELs will become out of date. Researchers and other professionals are constantly developing new information regarding toxicity at the molecular, organ, and whole body levels. This information must be incorporated into the PEL update process. To make this periodic update faster and more efficient, OSHA should make maximum use of work done by the professional groups previously identified as well as those within the international community that have developed science-based values.

By itself, this approach may not pass challenges in the courts unless the burden-of-proof requirements for adopting PEL updates are more flexible than those in the present OSHAct. This is suggested by the decision by the 11th Circuit Court that vacated the 428 PELs adopted in January 1989. One suggested approach is to continue to require OSHA to follow fully the

Administrative Procedures Act (to ensure adequate review and comment), but to establish legislatively a "not arbitrary or capricious" criterion rather than a "substantial evidence on the record" criterion regarding adoption of PELs by the Agency. There may be other legislative approaches that will provide a balance between adequate technical/scientific review and the requirements defined by legislation in the courts. A balance must be struck between the opportunity for the regulated community to review and input to a standard-setting process and the need to reduce the time period for regulatory action. The present criteria clearly need modification when one considers OSHA's limited accomplishments in this area since 1970.

Given the difficulty OSHA has demonstrated in setting PEL standards it is necessary to consider prioritizing chemicals for update considerations. This discussion assumes that it is unlikely that OSHA would attempt to review, and possibly change, all exposure limits simultaneously. It also assumes that OSHA is unlikely to group chemicals into certain classes and regulate all chemicals in a certain class at the same time.

Paustenbach; articulates the concerns of the stakeholders in the PEL update. His two points regarding the setting of priorities in the updating of PELs should be considered.

> "The prospect of a "list" of chemicals seems to bother everyone. To some extent, there is a general mistrust of any process wherein a certain chemical is targeted for regulation while another is not. One way to prevent this from being the focus of attack would be to drop the list entirely. Instead, the Agency might present a generic formula for different toxicological effects for calculating "preliminary" PELs for various classes of chemicals (e.g. carcinogens, irritants, and

> CNS depressants). Then when consensus is reached on the formulae, the information on the various chemicals need only be put in to the "master equations", which would yield a comprehensive list of PELs for hundreds of chemicals."

and

> "The lack of transparency in OSHA's process for selecting the initial chemicals reinforced the perception that some special interest groups were more effective than others in preventing their chemicals from >getting listed.= This issue needs to be hit >head on= by the agency. There seems no better way than to share publicly the data and analyses that supported the Agency's proposal. OSHA should then encourage technical comments on this information. After having assembled up-to-date information that is "more or less" accepted by the stakeholders, the Agency should then publish several different algorithms for establishing a priority list."

In summary, the process of choosing chemicals must be as objective as possible, based on sound scientific principles and specific criteria. The stakeholders must be given an opportunity to participate in every phase of this process. A weight of evidence process for judging the overall body of toxicological and epidemiologic data must be developed which clearly states procedures for evaluation of individual study data.

3. For compliance purposes OSHA has defined PELs as values not to be exceeded. However, when designing exposure monitoring programs employers must assign a statistical interpretation to the PEL. Therefore, OSHA should provide guidance regarding suitable statistical interpretations. Employers can thus design effective performance-based exposure monitoring programs that are consistent with OSHA's expectations.

OSHA has provided some guidance regarding the statistical interpretation of various PELs. In the preamble to the 1987 benzene standard OSHA acknowledged that exposures derive from continuous distributions where there is some finite probability of a random overexposure, even in a controlled work environment. OSHA stated in both the benzene preamble and the preamble to the 1978 lead PEL that the long-term average exposure should be "well below" the PEL. The 1992 formaldehyde standard included a non-mandatory appendix that suggested that statistical tests could be used as part of an exposure sampling strategy:

> "...a properly designed sampling strategy showing that all employees are exposed below the PELs, at least with a 95 percent certainty, is compelling evidence that the exposure limits are being achieved..."

This appendix was derived from the NIOSH 1977 Occupational Exposure Sampling

Strategy manual, in which NIOSH stated:

> "In statistical terms, the employer should try to attain 95% confidence that no more than 5% of employee days are over the standard."

Along similar lines the AIHA Exposure Assessment Strategies Committee (EASC) recommends that the exposure profile - or distribution of exposures - of a Similar Exposure Group (and by extension, the exposure profile of each member of the exposure group) be controlled to the point that the 95th percentile exposure is less than the PEL. Compelling evidence that the exposure profile is controlled can be developed by statistically analyzing the data and determining if the 95% upper confidence limit for the 95th percentile is less than the PEL. If a substance is strictly a chronic disease agent, the EASC suggests that it is reasonable to focus attention on the long-term average exposure or mean of the exposure profile. In the absence of specific guidance, it is reasonable to set a Long-term Average Occupational Exposure Limit (LTA OEL) at one third or less of the single shift PEL. Several statistical tests are available for determining if the true mean is less than the LTA OEL.

In summary, the EASC recommends that, as a general principle, exposures be controlled so that the 95th percentile is less than the PEL. This is applicable to both short-term exposure limits and full-shift TWA exposure limits. As a general principle, the long-term exposure to chronic disease agents should be evaluated against a LTA OEL. If exposures are assessed

(and when necessary, work practices evaluated and controls modified or introduced) using a exposure monitoring program designed using the EASC guidance there will nearly always be some finite probability of a random over-exposure (e.g., short-term exposure within a shift or full-shift TWA, depending upon the type of PEL). If exposures are monitored and controlled according to the EASC guidance this probability should be no more than 5%, and preferably less.

Based upon the guidance in the preambles to the benzene and lead PELs and Appendix B of the formaldehyde PEL, it could be argued that such an exposure monitoring program would be considered appropriate for monitoring exposures to these substances. However, OSHA provides no similar guidance for assigning a statistical interpretation to the Z-table PELs or for the other single substance 6(b) standards. Furthermore, the sampling strategy specified by OSHA in each of the 6(b) standards will not reliably detect poorly controlled work environments .

AIHA recommends that OSHA clearly state both the immediate and long-range goals for chronic disease agent PELs. For example, the long-range goal might be to reduce the long-term mean exposure, as averaged over, say, one or several years of exposure, to below one half or one third of the single shift PEL. The immediate goal might be to limit the probability of exceeding the PEL to 5% or less. AIHA also recommends that OSHA clearly state the goal for controlling short-term exposures when there is a short-term exposure limit or ceiling standard. For example, the goal might be to limit within-shift exposure variation so that the probability of exceeding a short-term exposure limit

or ceiling standard is no more than 5% or 1%, respectively.

Industrial hygienists could then design performance-based exposure monitoring and data analysis schemes that are both consistent with these goals - or statistical interpretations - and based upon state-of-the-art practices. Data collected, analyzed, and interpreted under such an exposure monitoring program would constitute "compelling evidence," as mentioned in formaldehyde standard, for demonstrating to OSHA that exposures are routinely controlled.

4. OSHA should adopt a peer-reviewed guideline for the derivation of PELs. AIHA believes that PELs must be based on the best scientific information available and must include a well-documented critical evaluation of the supporting information. Appropriate uncertainty factors also must be applied to compensate for the inherent uncertainties in the existing data and extrapolation to human populations.

A peer-reviewed guideline for the derivation of PELs is needed to provide consistency in this process. Such a guideline could also be used by the private sector to derive occupational exposure limits for agents that do not have legal or consensus standards. The guideline should address data collection and evaluation, identification of the critical endpoint, methodology or model selection in deriving the limit, and documentation requirements. Criteria for the selection of an 8-hr. TWA, STEL, and Ceiling Limit should be clearly established. Likewise, criteria for the designation of a skin notation should also be delineated. Since alternative work schedules have become more commonplace, they should be addressed in the PEL guidance. The body of knowledge concerning risk assessment and management will continue to grow as a result of strong research efforts in this area. Therefore, the methods used in establishing PELs must be part of a dynamic process, inclusive of innovative improvements as they are verified and peer-reviewed. There is a particular need to incorporate means whereby inherent uncertainties in the risk assessment process can be addressed.

PELs should be based on the best available data concerning relevant toxicity and exposure potential. Information sources can include on-line databases, standard texts, and solicitation of potentially important unpublished data from sources such as manufacturers and users. Every effort should be made to obtain original references for all data since review articles and other secondary references frequently contain errors or significant omissions of relevant information. Furthermore, it is often difficult to evaluate the technical merits of data cited in secondary references. Unpublished, confidential company reports should not be used unless a publicly available summary can be provided which contains sufficient detail as to the methods used, results observed, and conclusions drawn, so as to permit a critical review of the adequacy of the report.

Data to be collected include physicochemical properties, toxicity, toxicokinetics, toxicodynamics, nuisance properties (e.g., odor), and exposure and population parameters. Available toxicity data vary widely in nature and quality from agent to agent. Therefore, all available data should be reviewed and its quality and value as a

basis for setting a PEL determined. Several aspects of study design and reporting must be considered when assessing the quality of toxicity data; guidance is available from many sources.

Summaries of those studies determined to be adequate and appropriate for use in setting PELs should be included in the PEL documentation. Those data deemed valuable from studies judged inadequate will also be included with appropriate discussion of study inadequacies and data limitations; these data may be considered supporting in nature but should not be the basis of the PEL. The toxicity data documented for each PEL should include a summary of pertinent human and animal data, genotoxicity data, summaries of cancer hazard and reproductive hazard evaluations where available, and a summary of pertinent metabolism/toxicokinetic data. Some chemicals may cause effects in animals at inordinately high doses, under unusual exposure conditions, or under other unique circumstances. The relevance of such information should be considered. If available data on human experience establish results different from those obtained in animals, the human data should take precedence. Human experience should be emphasized to the extent credible data are available.

The goal of the toxicity data review is the delineation of all adverse effects relevant to the setting of a PEL. The rationale for a PEL may be derived from epidemiology data or human experience. When human data are lacking, the PEL will be derived from animal data. The basis for the PEL should generally be the adverse effect and associated NOAEL/LOAEL occurring first on the dose-response curve; this is referred to as the critical effect. The NOAEL is defined as the exposure level at which there are no statistically or biologically significant increases in frequency or severity of adverse effects between the exposed population and its appropriate control. Effects may be produced at his level, but they are not considered to be adverse. The LOAEL is the lowest exposure level in a study or group of studies that produces statistically or biologically significant increases in frequency or severity of adverse effects between the exposed population and its appropriate control. The manner by which other adverse effects are prevented by protecting against the effect chosen as the rationale for the PEL should be indicated in the documentation.

A risk assessment methodology to characterize the dose-response curve and derive the PEL should be selected based on the nature of the effect and quality of data. Several quantitative risk assessment methods exist that can be applied to low dose risk estimation of carcinogenicity; these include linear, mechanistic, tolerance distribution, time-to-tumor and biologically motivated models . An uncertainty factor approach would be appropriate for nongenotoxic effects where exposure thresholds can be demonstrated. Limitations of the traditional uncertainty factor method in PEL setting include lack of risk comparisons, limited consideration of the slope of the dose-response curve, and use of NOELs that are dependent on test sample size and therefore, may not be highly certain. In order to address some of these limitations, different models could be considered to develop the dose-response curve. For example, the Benchmark Dose approach, which is a statistical confidence limit on a dose corresponding to a specific increase in the response rate over the background rate, may address these shortcomings in some instances. This method utilizes the entire dose-

response curve, does not require that a NOAEL be identified, and allows estimation of risk at multiple exposure levels.

Comparative toxicokinetic data should be utilized when available to help address uncertainty related to interspecies extrapolation. Generally, if credible human data exist, minimal uncertainty factors should be applied as compared to situations where only animal data are available. The seriousness and reversibility of the critical effect should also be considered in developing an appropriate uncertainty factor. For example, a lower factor may be used where the PEL is based on avoidance of localized, reversible, sensory irritation whereas higher factors should be applied where the critical effect is systemic in nature. Default assumptions should only be used in the absence of adequate data and should be scientifically defensible. Supporting documentation for the risk assessment and PEL derivation should include a discussion of uncertainties identified and means by which they are addressed. Identified uncertainties should drive future research projects.

5. Employers have a responsibility to assess the risks to the health of their workers and adequately control worker exposures to hazardous substances or agents for which there are no PELs. Employees must be fully consulted in the development of these risk assessments and informed of the results.

AIHA recognizes that even a streamlined and simplified PEL rule-making process will be a relatively slow process that will never be able to generate exposure limits for all of the substances that are likely to present a health risk to employees. Furthermore, there may be other workplace hazards, such as biologic agents or physical hazards, for which Permissible Exposure Limits may not be applicable. As a result, there will be many substances or agents present in the workplace which do not have regulated exposure limits. In the absence of these limits, employers still have a responsibility to control exposure to protect against material impairment to health or diminished functional capacity.

To ensure workers are adequately protected, it is the AIHA's position that employers formally document an assessment of risks created by any work and the means for controlling these risks. This involves evaluating the hazards of the substances or agents (their anticipated health effects, likely target organs, and the synergistic effects which may occur from combined or sequential exposures to other substances), the likely routes of exposure (inhalation, dermal, ingestion, or subcutaneous), the nature of the extent to which work groups could be exposed (the duration, frequency, and intensity of exposure), and the effectiveness of controls. These risk assessments must be developed in consultation with and the involvement of affected employees. They should be reviewed regularly and whenever there is a significant change in the health information or in the work.

In some instances there may be sufficient information available from manufacturers, suppliers, the literature in occupational medicine, industrial toxicology or other disciplines to set a self-imposed working standard. In these situations employers should develop recommended exposure limits using the best scientific information as was previously described and to conduct exposure monitoring to confirm compliance

with these limits. These proprietary exposure limits and useful information about effective controls should be provided to other users of these substances, perhaps on the Material Safety Data Sheet or in product literature.

Responsible product stewardship suggests that employers should observe OELs for the non-PEL substances present in their workplaces that may present a risk to their employees as a result of exposure. These limits could be based on RELs, TLVs, or WEELs or on the recommendations of the supplier or manufacturer of the substance. OELs should, ideally, be risk-based exposure values derived from human experience or toxicologic studies. Where such data are not available, structure activity relationships (SAR) may be used as a last resort. AIHA recommends that such risk-based exposure limits, together with explicit operational precautionary and control statements, be included as part of an enhanced hazard communication program that has as its core an "Operational Material Safety Data Sheet (MSDS). " Operational MSDSs provide the prescribed procedures, the results to be recorded and the criteria for defining adjectives such as "use a suitable respirator" or "employ good local ventilation." In practice, however, the burden of these requirements would fall on the producers of non-PEL substances (generally larger companies) since they would be the first employer to have such substances in their workplace and are presently required to furnish an MSDS to their customers. Adoption of these recommendations would be economically efficient since it would internalize the cost of providing the health protection data needed by the multiple users of non-PEL substances on the relatively few suppliers or importers of substances.

For some substances medical examinations and appropriate tests would be a critical element of worker protection. Employers need to establish programs to perform appropriate medical tests when needed.

The principles obligating employers to perform workplace risk assessments have been the framework of worker health legislation in many countries, particularly within the European Union. These requirements would logically be a part of any comprehensive health and safety program standard issued by OSHA . The AIHA recommends this approach be adopted to supplement programs for updating Permissible Exposure Limits.

6. PELs should he consistent across occupational populations and should be accepted by other federal agencies when the goal is protecting occupational health.

PELs are derived for use by occupational health professionals to protect the health of workers in their environments. To accomplish this certain assumptions are made. The population at risk is assumed to be healthy and ranging in age from 16 to 72 years. Exposures are usually periodic averaging forty hours per week. There may be susceptible or hypersensitive individuals for which the PEL will not prevent adverse effects.

PELs, TLVs and WEELs at times have been inappropriately applied in other public health situations (e.g., control of air pollution exposures for the general public). Vast

differences in general population exposure conditions and protection goals rule out the application of occupational limits to the control of environmental exposures for the general public. Most often the goal of public health is the elimination of all risk to a population of all ages and varying degrees of health which may be involuntarily and continuously exposed to an agent. In the occupational environment susceptible individuals can be protected by use of additional exposure controls with the guidance of an occupational health professional. These options are not usually available within a community. It is therefore inappropriate and scientifically unjustifiable to use these limits in non-occupational applications.

AIHA believes that PELs must be consistent across occupational populations including, for example, manufacturing operations and office environments. PELs are health-based levels, which must take into account the common finding that a single chemical can have varying adverse effects at different exposures or doses. For example, a chemical may be a potential systemic chronic health hazard at one dose level and also be a transient sensory irritant at a different exposure or dose level. AIHA believes that the development of a single PEL must take into account all known adverse effects associated with that chemical. PELs must be set to protect against the lowest documented effect level based on sound science, thereby also affording protection against effects occurring at higher dose levels. AIHA is opposed to the establishment of multiple "tiered" PELs intended to be applied in different occupational settings. To ensure consistency across the occupational work force, PELs must be derived to protect against adverse effects across both gender populations. PELs set to protect against teratogenicity would need to be used and enforced regardless of a worker's gender.

PELs should be set without regard to control feasibility in an industry or workplace. It is true that workplace exposures may vary between industries, but it is also true that an agent's adverse health effects remain constant. Since the ultimate goal of a PEL is to control adverse effects, it is inconsistent to derive limits for varying industries based on control technology. In instances where engineering control is not feasible, enforcement directives should allow compliance via additional alternate control strategies (e.g., administrative controls or respirators as a last choice). Because these control strategies, especially the use of respirators, are often less effective than engineering controls, they should be used under the direction of occupational health professionals.

To further ensure consistency, OSHA PELs should be accepted by other federal agencies when the goal is protecting occupational health. The ultimate goals of most other agencies are to protect the public health, which sets them apart from an occupational environment. OSHA's primary goal is occupational safety and health and as such is in the best position to understand, evaluate and promulgate appropriate occupational exposure standards.

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