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EXAMINING THE USE OF NON-CONSENSUS STANDARDS IN WORKPLACE HEALTH AND SAFETY

HEARING

BEFORE THE

SUBCOMMITTEE ON WORKFORCE PROTECTIONS

OF THE

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

ONE HUNDRED NINTH CONGRESS

SECOND SESSION

April 27, 2006

Serial No. 109–36

Printed for the use of the Committee on Education and the Workforce

Available via the World Wide Web: http://www.access.gpo.gov/congress/house
or
Committee address: http://edworkforce.house.gov

U.S. GOVERNMENT PRINTING OFFICE

27–980 PDF WASHINGTON : 2006

For sale by the Superintendent of Documents, U.S. Government Printing Office
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EXAMINING THE USE OF NON–CONSENSUS STANDARDS IN WORKPLACE HEALTH AND SAFETY

Thursday, April 27, 2006
U.S. House of Representatives
Subcommittee on Workforce Protections
Committee on Education and the Workforce
Washington, DC

The subcommittee met, pursuant to call, at 10:35 a.m., in room 2175, Rayburn House Office Building, Hon. Charlie Norwood [chairman of the subcommittee] presiding.

Present: Representatives Norwood, Biggert, Kline, Owens, Kucinich, and Woolsey.

Staff present: Byron Campbell, Legislative Assistant; Steve Forde, Communications Director; Rob Gregg, Legislative Assistant; Richard Hoar, Professional Staff Member; Kimberly Ketchel, Deputy Press Secretary; Molly McLaughlin Salmi, Deputy Director of Workforce Policy; Deborah L. Emerson Samantar, Committee Clerk/Intern Coordinator; Loren Sweatt, Professional Staff Member; Jody Calemine, Labor Counsel; Michele Evermore, Legislative Associate/Labor; Tylease Fitzgerald, Legislative Assistant/Labor; Peter Galvin, Senior Legislative Associate; Rachel Racusen, Press Assistant; Marsha Renwanz, Legislative Associate/Labor; and Mark Zuckerman, Minority Staff Director.

Chairman NORWOOD [presiding]. A quorum being present, the Subcommittee on Workforce Protections will now come to order.

First, I would like to start by noting that today is "take our daughters and sons to work" day. And I would like to welcome any students that may be with us today, and note that this can be an important day to demonstrate the importance of education and for exposing children to the many future career opportunities that will be available to them in this country's workplace.

We are meeting here today to hear testimony on examining the use of non-consensus standards in workplace health and safety. If you would, we have some definitions up, and as I continue, I hope you can see those. They are a little small, but I hope you can read them.

Under committee rule 12(b), opening statements are limited to the chairman and the ranking minority member of the subcommittee. Therefore, if other members have statements, they may be included in the hearing record.

With that, I ask unanimous consent for the hearing record to remain open for 14 days to allow member statements and other extraneous material referenced during the hearing to be submitted in the official hearing record. Without objection, so ordered.

Today we are going to take a look at an issue that has been the focus of previous oversight by this subcommittee. It is an issue of great interest and, frankly, of great concern to me: the ongoing practice by the Department of Labor, whereby DOL incorporates by reference non-consensus standards set by outside standard-setting organizations in the hazard communication rule.

Do we have anybody here from DOL? That is real unfortunate. They will be here next time at the panel, I promise you.

Some of you may recall that the subcommittee held hearings on this very topic in 2002. I am curious to see if any improvements have been made since 2002 or if the people are still facing the problems we heard about in 2002.

At the outset, I would like to note that there are several lawsuits challenging DOL's so-called "incorporation" practice. One such case involves the American Conference of Government Industrial Hygienists, which was invited, but declined to testify at today's hearing.

Regardless of the pending lawsuits, I am interested in hearing how the incorporation-by-reference practice impacts the regulated community and its overall role in health and safety regulations at the Department of Labor.

Before we go any further, let me please draw your attention to the monitors on my right and left, which display the definition of a national consensus standard under the OSH Act. According to the statute, that is what Congress likes, the term "national consensus standard" means any occupational safety and health standard or modification thereof which, one, has been adopted and promulgated by a nationally recognized standards-producing organization under procedures whereby it can be determined by the secretary that persons interested and affected by the scope or provision of the standard have reached substantial agreement on its adoption. That is No. 1 on a consensus standard.

No. 2, it was formulated in a manner which afforded for diverse views to be considered; and three, has been designated as such a standard by the secretary, after consultation with other appropriate Federal agencies.

You will note that there is no corresponding definition in the OSH Act of a non-consensus standard. The OSH Act simply does not recognize any outside standard that is not consistent with the principles outlined right here. That is a very important distinction that is basically at the center of this debate.

Critics of the incorporation-by-reference practice, several of whom are witnesses today, maintain that the heart of the problem exists in standard setting bodies that do not allow for stakeholder input. By comparison, if DOL were to promulgate standards within the hazard communication rule, a myriad of Federal regulations would apply to the promulgation of these regulations.

To begin with, DOL would have to provide the regulated community with public notice by way of the Federal Register, so says Con-

gress. A notice and comment rulemaking would be required, so says Congress.

DOL would also be required to defend the adoption of any standard as legal, assure the standard's technical feasibility, and evaluate the standard's impact on small business, so says Congress. In some cases, a negotiated rulemaking could be entered into between DOL, the affected industry, and the relevant worker representatives. However, none of these important processes are required when DOL incorporates a non-consensus standard by reference. This chairman believes that is illegal and we are going to find out at the end of the day whether it is or is not.

Now, I want to be clear. My goal here is to ensure transparency in the rulemaking process. The employees, their representatives, and the regulated industries have a right to provide input into the regulatory process, so says Congress.

I also believe that government employees should have access to professional development. There is nothing wrong with that. However, I strongly believe that the system governing the relationship between a government employee and his or her association with a non-consensus standard-setting organization must be fundamentally fair and ethically acceptable. We will get into that during this hearing.

I look forward to hearing from our witnesses today about how that might be possible, to achieve that, and exploring other ideas to strengthen the regulatory process regarding health and safety standards.

It is now my pleasure to yield to the ranking member, my friend Mr. Owens, for whatever opening statement he wishes to make.

[The prepared statement of Mr. Norwood follows:]

Prepared Statement of Hon. Charlie Norwood, Chairman, Subcommittee on Workforce Protections, Committee on Education and the Workforce

Today we are going to take a look at an issue that has been the focus of previous oversight by this Subcommittee. It is an issue of great interest and, frankly of continued concern to me—the ongoing practice by the Department of Labor, whereby DOL incorporates, by reference, non-consensus standards set by outside standard-setting organizations in the hazard communication rule.

Some of you may recall that the Subcommittee held hearings on this very topic in 2002. I am curious to see if any improvements have been made or if the people are still facing the problems we heard about in 2002.

At the outset, I would like to note that there are several lawsuits challenging DOL's so-called "incorporation" practice. One such case involves the American Conference of Government Industrial Hygienists (ACGIH), which was invited—but declined—to testify at today's hearing.

Regardless of the pending lawsuits, I am interested in hearing how the incorporation by reference practice impacts the regulated community, and its overall roll in health and safety regulations at the Department of Labor.

Before we go any further, let me please draw your attention to the monitors on my right and left, which display the definition of a national consensus standard under the OSH Act. According to the statute:

"The term national consensus standard means any occupational safety and health standard or modification thereof which (1) has been adopted and promulgated by a nationally recognized standards-producing organization under procedures whereby it can be determined by the Secretary that persons interested and affected by the scope or provision of the standard have reached substantial agreement on its adoption, (2) was formulated in a manner which afforded for diverse views to be considered, and (3) has been designated as such a standard by the Secretary, after consultation with other appropriate Federal agencies."

You will also note that there is no corresponding definition of a non-consensus standard, because the OSH Act does recognize any outside standard that is not con-

sistent with the principles outlined above. That is a very important distinction that is at the center of this debate.

Critics of the incorporation by reference practice, several of whom are witnesses today, maintain that the heart of the problem exists in standard setting bodies that do not allow for stakeholder input. By comparison, if DOL were to promulgate standards within the hazard communication rule, a myriad of federal regulations would apply to the promulgation of those regulations.

To begin with, DOL would have to provide the regulated community with public notice by way of the Federal Register. A notice and comment rulemaking would be required.

DOL would also be required to defend the adoption of any standard as legal, assure the standard's technical feasibility, and evaluate the standard's impact on small business. In some cases, a negotiated rulemaking could be entered into between DOL, the affected industry, and relevant worker representatives.

However, none of these important processes are required when DOL incorporates a non-consensus standard by reference.

Now I want to be clear; my goal here is to ensure transparency in the rulemaking process. The employees, their representatives, and the regulated industries have a right to provide input in the regulatory process.

I also believe that government employees should have access to professional development. However, I strongly believe that the system governing the relationship between a government employee and his/her association with a non-consensus standard setting organization is fundamentally fair and ethically acceptable.

I look forward to hearing from our witnesses today about how that might be possible, and exploring other ideas to strengthen the regulatory process regarding health and safety standards.

Mr. OWENS. Thank you, Mr. Chairman.

Tomorrow is Workers Memorial Day. On April 28, we honor the thousands of American workers killed on the job each year in such grievous incidents as scaffolding collapses, unprotected falls, explosions, machinery upheavals, and ditch collapses.

Between 5,000 and 6,000 Americans die each year as a result of such serious workplace hazards and safety lapses. From New York to California, we join surviving family members, coworkers, friends and community residents in mourning their untimely deaths. Most importantly, we seek accountability to prevent such wrongful workplace deaths in the future.

This Workers Memorial Day is especially noteworthy given the way the year started. It began with a massive explosion at the Sago underground coal mine in Upshur County, West Virginia, that trapped 13 miners. Cable News Network provided round-the-clock coverage of delayed rescue attempts and anxious family members awaiting news of their loved ones.

We all know how that initial story ended, with 12 mineworkers found dead and the sole survivor near death due to severe oxygen deprivation. The story of repeated and severe safety violations at Sago mine and dereliction of duty at the Federal Mine Safety and Health Administration continues to unfold as the Federal and state investigations continue.

In addition to the 12 coal mineworkers killed at Sago, 14 other coal miners have been killed on the job this year. They have been killed in mine fires, roof collapses, machinery failures, and like scenarios. These deaths occurred at mines other than Sago in West Virginia and elsewhere in Pennsylvania, Kentucky, Alabama, Maryland and Utah.

In the first 4 months of 2006, 26 coal miners have been killed on the job, which is more than the number killed in all of 2005 all together. Coal miner fatalities are soaring and it is our responsi-

bility, as members sitting on the congressional subcommittee with jurisdiction over MSHA, to address this serious crisis.

Mr. Chairman, today's hearing does not focus or even touch upon the crisis of mineworker deaths. Neither does it address ways to address pressing worker safety issues under the jurisdiction of the Occupational Safety and Health Administration. Two such OSHA issues are unavoidable, given the front-page attention they are getting in newspapers across the country. They are also the responsibility of this subcommittee, given our jurisdiction over OSHA.

First, there is the ever-rising death toll of those first responders who went to Ground Zero in New York for rescue and recovery work after the terrorist attacks of 9/11. Earlier this month, a New Jersey medical examiner cited "Ground Zero" as the cause of death of a detective involved in 9/11 recovery work. According to the autopsy report of 34-year-old Detective James Zagroda, there was no other explanation for the presence of innumerable foreign body granulomas, such as fiberglass, in his lungs than his work sifting for human remains and evidence in the Ground Zero rubble.

Congressional oversight is called for here because OSHA declined at that time to enforce worksite safety standards at Ground Zero. Although the OSHA Web site declares that no lives were lost in the Ground Zero cleanup, deaths like Detective Zagroda's that are directly attributable to Ground Zero toxins now begin to keep turning up. OSHA's failure to require the use of appropriate personal protective equipment at Ground Zero merits immediate congressional investigation.

I request unanimous consent that an article about Detective Zagroda's death be inserted in the record.

Chairman NORWOOD. So ordered.

[The information referred to follows:]

[From the Chief Leader Editorial, April 21, 2006]

Need WTC Delayed Death Bill

A New Jersey Medical Examiner's finding that a Detective who was involved in the recovery efforts at the World Trade Center site died because of the toxins he was exposed to has intensified the push of uniformed union leaders for a bill granting line-of-duty death benefits in such cases.

It should be increasingly clear that such treatment is warranted.

The autopsy by Dr. Gerard Breton of the Ocean County M.E.'s Office found "the presence of innumerable foreign body granulomas that are distributed throughout the lung tissue" of Det. James Zadroga. Fiberglass was among the substances discovered in his lungs.

There was no other explanation for finding those materials in the lungs of a 34-year-old man than his work sifting through the rubble at the Trade Center site looking for survivors, bodies, and evidence.

The ruling is the first conclusive finding that an emergency worker was killed as a direct cause of time spent at Ground Zero. There have been several other deaths, however—involving firefighters and Emergency Medical Service workers—where exposure to the deadly toxins at the site was almost certainly the cause.

Governor Pataki last year signed into law a bill that grants job-related disability pensions to those public employees who were unable to continue working because of illnesses they contracted—often years after exposure—from work related to the rescue and recovery efforts at the Trade Center and other sites where bodies or rubble were transported.

As the death toll begins to rise, the Legislature and the Governor must look to do something more for those whose work there winds up costing them their lives. Detective Zadroga's survivors, including his 4-year-old daughter, Tylerann, are entitled to eight years of disability pension payments, which are paid at three-quarters of his final salary. If his case was classified as a line-of-duty death by the NYPD,

the family would be entitled to the equivalent of his final year's pay until Tylerann was 19, and until 23 if she were a full-time student for that long.

This could get expensive for the city, since it is clear that some of these cases take years to manifest themselves. But it and the state—in other words, we, the public—owe that much to those who put themselves in harm's way, sometimes not realizing the extent of the danger because of pronouncements by both Federal and city officials that the air in the vicinity was of acceptable quality.

Those who pay with their lives should have their families properly compensated to honor their sacrifice.

Mr. OWENS. Second is OSHA's failure to enforce appropriate safety standards at recovery and reconstruction worksites in the Katrina-affected Gulf Coast area. Again, numerous reports have surfaced in the press of Gulf Coast workers afflicted with rashes, lesions, and respiratory distress. The respiratory symptoms are now so widespread among these workers that doctors and other medical experts commonly refer to them as a "Katrina cough."

In the aftermath of Hurricanes Katrina and Rita, OSHA's top political appointee announced the agency would not enforce workplace safety rules in the Gulf region. So for a considerable period of time, there was no enforcement of the OSHA rule on personal protective equipment, requiring employers to provide all workers with adequate masks, gloves and other appropriate safeguards.

Now, those unprotected workers exposed to Katrina toxins are suffering from asthma, respiratory distress and other illnesses. Again, this merits immediate congressional oversight.

Mr. Chairman, this morning's hearing flatly ignores the urgent need for such oversight of dangerously inadequate enforcement of U.S. safety laws at both MSHA and OSHA. Yet we are reminded of OSHA's inadequate safety enforcement in a new GAO report which documents OSHA's failure to conduct inspections of Federal worksites.

This GAO report further documents OSHA's failure to establish a national strategy for targeting worksites with higher rates of injury and illness for inspection. This subcommittee should call GAO to testify about these failures at OSHA, as well as recommended solutions.

I ask unanimous consent that an article about the new GAO report that appeared in yesterday's Washington Post be included in the record. The report is entitled "Death on the Job: The Toll of Neglect."

Chairman NORWOOD. So ordered.

[The information referred to follows:]

[From the Washington Post, April 26, 2006]

OSHA Comes Up Short on Workplace, Safety-Program Evaluations, Report Shows

By STEPHEN BARR

The Occupational Safety and Health Administration does not perform many safety inspections at federal workplaces and has not conducted any agency-wide evaluations of federal safety programs in the last six years, according to a recently released congressional report.

In addition, OSHA has not turned in a report on federal agency safety programs to the president since fiscal 2000, even though OSHA is required by a White House directive and regulations to review the programs each year, the report by the Government Accountability Office said.

"OSHA's oversight of federal agencies' safety programs is not as effective as it could be because the agency does not use its enforcement and compliance assistance resources in a strategic manner," the GAO report said.

Officials at OSHA acknowledged they have problems with their enforcement and compliance strategies "but noted that they have relatively few staff dedicated to federal agency oversight," the report said. The Labor Department, OSHA's parent agency, generally agreed with the findings, GAO said.

The GAO report was requested by Sens. Arlen Specter (R-Pa.) and Tom Harkin (D-Iowa), the chairman and ranking member of the Senate Appropriations subcommittee that oversees the Labor Department. "This GAO report assists in determining what further steps can be taken to ensure that workers have safe conditions and that violations are closely monitored," Scott Hoeflich, a spokesman for Specter, said.

During the past decade, more than 800 federal employees died from work-related accidents, with 47 deaths occurring in 2004, the most recent year that GAO could collect data from federal agency reports.

Although the size of the federal workforce has decreased by 6 percent in the past decade, GAO found that workers' compensation costs remained fairly constant, about $1.52 billion in 2004, compared with about $1.54 billion in fiscal 1995, after adjusting for inflation.

Claims involving traumatic injuries decreased slightly, to 74,322 in 2004 from 76,633 in 1995, GAO said. The injuries included sprains and strains of ligaments, muscles and tendons, sprains and strains of the back, bruises and cuts, GAO said.

A smaller number of employees filed claims involving non-traumatic injuries, such as hearing loss and carpal tunnel syndrome, GAO found. Those claims decreased to 5,903 in 2004 from 8,508 in 1995, GAO said.

Federal agencies are among the nation's largest employers. While many employees work in low-risk offices, large numbers are employed in hospitals, prisons, forests, parks and manufacturing.

For the report, GAO collected data from 57 agencies, representing about 80 percent of the federal workforce. The GAO survey found that eight agencies did not have procedures to ensure that an injured employee was seen promptly by a doctor, while 12 agencies did not have programs offering injured employees light-duty alternatives to help them return to work more quickly.

The report said 23 agencies did not have computer systems for collecting information about workplace hazards and whether they were corrected in a timely manner.

A new rule, which took effect last year, requires agencies to keep logs of workplace injuries and could be useful in helping OSHA target inspections in the future, GAO said.

OSHA officials told GAO that they also hope to rely on data being collected under a 2004 White House initiative. The "Safety and Health and Return to Employment" initiative seeks to reduce federal workers compensation claims and to get more injured federal employees back to work.

But GAO said some agency officials see the initiative as "a paper exercise," and GAO concluded "the impact of the initiative on agencies' safety programs is not clear."

At noon today, Robert M. Tobias, director of public sector executive education at American University, will be the guest on Federal Diary Live on washingtonpost.com and will take questions from federal employees. Stephen Barr may be reached at barrs@washpost.com.

Mr. OWENS. That said, I want to also call attention to the fact that Dr. Frank Mirer, a distinguished witness requested by members of the minority, is here with us this morning. As director of health and safety at the United Auto Workers International Union, Dr. Mirer will address the need for OSHA to set standards for certain hazardous chemicals now threatening worker health and safety. I welcome him to this hearing and look forward to hearing his very relevant testimony.

In closing, Mr. Chairman, I request that a summary of a new report by the AFL-CIO commemorating Worker Memorial Day be included in the record in its entirety. That report is entitled "Death on the Job: The Toll of Neglect, a National State-by-State Profile of Worker Safety and Health in the United States."

Chairman NORWOOD. So ordered.*

Mr. OWENS. Thank you.

[The prepared statement of Mr. Owens follows:]

Prepared Statement of Hon. Major R. Owens, Ranking Minority Member, Subcommittee on Workforce Protections, Committee on Education and the Workforce

Mr. Chairman, tomorrow is Workers Memorial Day. On April 28th, we honor the thousands of American workers killed on-the-job each year in such grievous incidents as scaffolding collapses, unprotected falls, explosions, machinery upheavals, and ditch collapses. Between 5000-6000 Americans die each year as a result of such serious workplace hazards and safety lapses. From New York to California, we join surviving family members, co-workers, friends and community residents in mourning their untimely deaths. Most importantly, we seek accountability to prevent such wrongful workplace deaths in the future.

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In addition to the 12 coal mineworkers killed at Sago, 14 other coal mineworkers have been killed on-the-job this year. They have been killed in mine fires, roof collapses, machinery failures, and like scenarios. These deaths occurred at mines other than Sago in West Virginia, and elsewhere in Pennsylvania, Kentucky, Alabama, Maryland and Utah. In the first 4 months of 2006, 26 coal mineworkers have been killed on the job, which is more than the total number killed in all of 2005. [Last year, a total of 22 coal miners were killed on the job.] Coal miner fatalities are soaring and it is our responsibility, as Members sitting on the Congressional Subcommittee with jurisdiction over MSHA, to address this crisis.

Mr. Chairman, today's hearing does not focus or even touch upon the crisis of mineworker deaths. Neither does it address ways to address pressing worker safety issues under the jurisdiction of the Occupational Safety and Health Administration (OSHA). Two such OSHA issues are unavoidable, given the front-page attention they are getting in newspapers across the country.

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Congressional oversight is called for here because OSHA declined to enforce worksite safety standards at Ground Zero. Although the OSHA website declares that "no lives were lost in the Ground Zero clean-up," deaths like Detective Zagroda's that are directly attributable to Ground Zero toxins keep mounting. OSHA's failure to require the use of appropriate personal protective equipment at Ground Zero merits immediate Congressional investigation. I request unanimous consent that an article about Detective Zagroda's death be inserted in the Record.

Second is OSHA's failure to enforce appropriate safety standards at recovery and reconstruction work-sites in the Katrina-affected gulf coast. Again, numerous reports have surfaced in the press of Gulf coast workers afflicted with rashes, lesions, and respiratory distress. The respiratory symptoms are now so widespread among these workers that doctors and other medical experts commonly refer to them as a "Katrina cough." In the aftermath of Hurricanes Katrina and Rita, OSHA's top political appointee announced the agency would not enforce workplace safety rules

*Submitted and placed in permanent archive file, *Death on the Job: The Toll of Neglect. A National and State-by-State Profile of Worker Safety and Health in the United States,* 15th Edition. April 2006, *http://www.aflcio.org/mediacenter/resources/reports.cfm.* (Submitted for the record by Rep. Owens)

in the Gulf region. So for a considerable period of time, there was no enforcement of the OSHA rule on personal protective equipment (PPE), requiring employers to provide all workers with adequate masks, gloves and other appropriate safeguards. Now, those unprotected workers exposed to Katrina toxins are suffering from asthma, respiratory distress and other illnesses. Again, this merits immediate Congressional oversight.

Mr. Chairman, this morning's hearing flatly ignores the urgent need for Congressional oversight of dangerously inadequate enforcement of U.S. safety laws at both MSHA and OSHA.

Yet we are reminded of OSHA's inadequate safety enforcement in a new GAO report which documents OSHA's failure to conduct inspections of federal worksites. This GAO report further documents OSHA's failure to establish a "national strategy for targeting worksites with high rates of injury and illness for inspection." This Subcommittee should call GAO to testify about these failures at OSHA and well as recommended solutions. I ask unanimous consent that an article about the new GAO report that appeared in yesterday's Washington Post be included in the Record.

That said, Dr. Frank Mirer, a distinguished witness requested by Members on this side of the aisle, is here with us this morning. As Director of Health and Safety at the United Auto Workers International Union (UAW), Dr. Mirer will address the need for OSHA to set standards for certain hazardous chemicals now threatening worker health and safety. I welcome him to this hearing and look forward to hearing his testimony.

In closing, Mr. Chairman, I request that a summary of a new report by the AFL-CIO commemorating Worker Memorial Day be included in the Record in its entirety.

Chairman NORWOOD. Before we begin, I would like to make note that the Labor Department has arrived. Steve Silbiger is here.

Mr. Silbiger, you better pay attention to this hearing and take a lot of notes. Is anybody else here from the Labor Department? If they are, please be recognized. I say to you, take notes. You are next.

We have a panel of distinguished witnesses today. Frankly, I am very eager to hear their testimony, but I would like to yield to my vice chairman, Judy Biggert, to introduce our first witness.

Mrs. BIGGERT. Thank you, Mr. Chairman.

It is my pleasure this morning to introduce Elizabeth Marcucci. Ms. Marcucci is the corporate safety director at Gonnella Baking Company, which has a number of facilities in the Chicago area, including one just outside my district in Aurora, and of course their bread is in all the stores in my area.

Ms. Marcucci holds a bachelor's degree from St. Joseph College in Indiana. She has been working for Gonnella Baking Company for the last 17 years. Over this period, she has saved the company millions of dollars in worker compensation costs and received various awards for her loss prevention measures.

In 2003, she won the National Safety Council's Distinguished Service to Safety Award, which is the highest honor bestowed on any individual by the council, in recognition for outstanding service in the field of safety.

She is a member of NCS and also the American Bakers Association, on whose behalf she is testifying today. She serves on the safety committee of that organization and the Greater Chicago Safety Council.

She is also a certified defensive driving instructor, a CPR first-aid instructor, and an 8-hour incident responder for hazardous material spills, and a 40-hour incident commander for hazardous materials. She keeps herself pretty busy.

So I appreciate her willingness to attend today's hearing and provide her insight into workplace safety.

I look forward to hearing your testimony.

I yield back. Thank you, Mr. Chairman.

Chairman NORWOOD. Ms. Marcucci, welcome. We are glad you are here. This is easy as pie. I am going to introduce everybody else, and then we will come back to you. You are a hazardous driving instructor? I have a staff member named "Crash" that might need some of your guidance. We will talk after this hearing is over with.

[Laughter.]

I would like to now recognize Mr. Jim Ruddell, who is the director of environment and safety for Franklin Industrial Minerals. He holds a master's degree in soil science and a bachelor's degree in forest science. Franklin Industrial Minerals has been in operation since 1910 and operates various types of mining facilities in Tennessee, Georgia, Alabama, Florida and Texas. Their operations produce over 5 million tons of minerals annually.

Mr. Ruddell, you are most welcome.

Next is Dr. Frank Mirer, who is the director of the health and safety department, International Union for the United Auto Workers. Dr. Mirer heads the technical coordination unit for safety policies for UAW. He represents the union before administrative agencies regarding occupational safety and health research. Dr. Mirer holds a Ph.D. in organic chemistry from Harvard University and is a certified industrial hygienist. This witness has been invited by the minority members of the subcommittee.

Anyway, we are very glad you are here.

[Laughter.]

Dr. MIRER. I was going to find out whether that——

Chairman NORWOOD. You don't want to hear the rest of it.

Dr. MIRER. I want to hear that.

[Laughter.]

Chairman NORWOOD. Mr. Henry Chajet is a partner at Patton Boggs. Mr. Chajet counsels and represents clients in environmental health and safety matters, focusing on crisis management, dispute resolution, trial and appellate litigation, standard setting, and liability prevention, and regulatory and congressional proceedings.

He defends investigations and enforcement actions by OSHA, MSHA, EPA, DOT, NTSB, NIOSH and other Federal and state agencies, as well as in related tort claims in criminal cases. Mr. Chajet represents plaintiff businesses who have sued the Department of Labor, claiming it is improperly relying on ACGIH in its standard-setting. He holds a degree from Case Western Reserve Law School and University.

I would like to remind all the members that we will be asking questions of the witnesses after their testimony. In addition, rule 2 imposes a 5-minute limit on all questions.

With that, can I call you Elizabeth?

Ms. MARCUCCI. That is fine.

Chairman NORWOOD. Elizabeth, you are up.

STATEMENT OF ELIZABETH MARCUCCI, SAFETY DIRECTOR, GONNELLA BAKING COMPANY

Ms. MARCUCCI. Good morning.

Thank you, Congresswoman Biggert, for your kind remarks.

Mr. Chairman, distinguished members of the subcommittee, thank you for the invitation to address this hearing. My name is Liz Marcucci, and I am the corporate safety director for Gonnella Baking Company in Chicago, Illinois. I also chair the American Bakers Association's safety committee and am testifying on behalf of the ABA.

ABA is the trade association that represents the nation's wholesale baking industry. Gonnella is a family owned bakery operation with three facilities in the greater Chicago land area, with approximately 350 employees. Our facilities make a variety of high-quality fresh and frozen bakery goods, including hand-crafted artisan breads and rolls. Gonnella is the proud hot-dog supplier of the world champion Chicago White Sox, Chicago Cubs and Chicago Bulls.

I started out as assistant safety director with Gonnella in 1984, and now my responsibilities include the management of all company safety and health programs, including regulatory accountability and workers compensation. In addition to ABA, I serve in several leadership capacities with the National Safety Council. The NSC honored me and the employees of Gonnella Baking Company with the distinguished service to safety award.

I am a safety advocate for all of our employees and their families. In a family business, this takes on added significance. Safety is our company's first priority in all decisions, from the president to our highly trained and valued employees. The baking industry is concerned with one so-called consensus organization, the American Conference of Governmental Industrial Hygienists, ACGIH. ACGIH's threshold limit values, TLVs, are used by OSHA for permissible exposure limits, PELs, and could be used by OSHA for so-called "general duty clause" violations.

In addition, the 23-state OSHA plans rely heavily upon the TLVs. These states need to have confidence in the procedures and results of the consensus standard-setting organizations upon which they rely. ABA learned that ACGIH issues TLVs of questionable scientific basis. Making matters worse in the development of a TLV, it is done with no public input.

During its development of a TLV on flour dust, ABA was unable to get any information on the development of the TLV. My written statement covers these issues in greater detail.

We were concerned because the TLV was 30 times lower than the OSHA nuisance limit and two times lower than the OSHA exposure limit for hazardous substances. The TLV relies on a controversial method different from the monitoring commonly used in the management and enforcement of respiratory exposures.

ABA contracted with Sandler Occupational Medicine Associates, SOMA, to conduct an analysis of ACGIH's justification for the TLV. They found that the TLV is based on "very limited, indefinite and unconfirmed information and is not substantiated." SOMA also found that "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 allergens sensitization and other work-related effects."

At the November 2001 subcommittee hearing, ABA articulated that TLVs come with some real consequences. ABA pointed out how a baking company in Kentucky was cited with a serious violation of the general duty clause and respiratory protection standards for failure to meet the TLV standard. The citation was withdrawn only when the company presented the SOMA study as a counterpoint to ACGIH's flawed analysis.

Kentucky OSHA in its review of the science came to the same conclusion as the baking industry, that the TLV is not based on sound science. During the citation investigation, it was revealed that Kentucky OSHA adopted the ACGIH TLV in the mistaken belief that it was developed in cooperation with the baking industry. This came as a great shock to the ABA. Kentucky OSHA should not have to explain why the cited company based on an ACGIH TLV unwittingly thought it to be valid.

The Kentucky OSHA citation should have required the immediate abatement of employees' exposure to flour dust above the ACGIH TLV with new ventilation systems and a full-face mask for respiratory protection. Few baking companies could meet the excessive engineering and respiratory requirements that would be required under this flawed TLV.

Unfortunately, the recent activities of California Occupational Safety and Health Standards Board tell a more disturbing story. At the end of 2004, with little notice and fanfare, California adopted a number of ACGIH's new TLVs, including flour dust as its own permissible exposure limits. Last year, ABA petitioned the California Occupational Safety and Health Standards Board, asking that the new TLV for flour dust be rescinded, submitting the SOMA study as supporting documentation.

In January, the board summarily rejected ABA's petition in language eerily similar to ACGIH's dismissal several years ago. Thankfully, however, California bakers have not been subjected to enforcement action.

OSHA needs to be extremely careful in what type of information it relies upon for regulations and enforcement. While one can argue with specifics about NFPA or ANSI standards, at least the affected parties have a seat at the table. These are true consensus organizations. This is the proper and transparent way to ensure an outcome in which everyone can have confidence.

We urge Congress to insist that OSHA utilize true consensus standards that meet minimum requirements for openness and participation. ABA also urges Congress to require OSHA to utilize scientific data and economic impact analysis that has been independently peer-reviewed. The OSH Act pertaining to the proper use of consensus standards should be enforced or strengthened to prohibit the use of ACGIH and similar unsubstantiated standards.

We urge Congress to insist that OSHA avoid using ACGIH's TLVs as the basis for regulations and enforcement proceedings. OSHA should instruct the state OSHA plans to also refrain from utilizing TLVs. OSHA should be more diligent in utilizing its review and approval authority over state-plan states to ensure that only true consensus standards be utilized.

Congress and OSHA should not just take ACGIH's word when it claims that "regulatory bodies should view TLVs as an expression of scientific opinion." Congress should clearly communicate to Federal and state regulatory agencies that ACGIH itself does not believe its standards "should be adopted as standards without an analysis of other factors necessary to make appropriate risk management decisions."

We applaud the chairman for his steadfast common sense leadership on this important issue. We encourage the subcommittee to aggressively move to correct these problems. Many companies are at risk of significant penalties and unnecessary abatement procedures based on ACGIH's scientific opinion, and not on facts.

Again, Mr. Chairman and members of the subcommittee, I greatly appreciate this opportunity to present the views of the baking industry, and would be happy to answer any questions.

[The prepared statement of Ms. Marcucci follows:]

Prepared Statement of Elizabeth Marcucci, Safety Director, Gonnella Baking Co., on Behalf of the American Bakers Association

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 Examining the Use of Non-Consensus Standards in Workplace Health and Safety. ABA greatly appreciates the opportunity to present its views again to the Subcommittee.

By way of background, the ABA is the trade association that represents the nation's wholesale baking industry. Its membership consists of more than 200 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 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 Liz Marcucci and I am the Corporate Safety Director for Gonnella Baking Company based in Chicago, Illinois. I am also Chair of the American Bakers Association Safety Committee. I am pleased to be testifying today on behalf of the ABA. Gonnella is a moderately sized family owned company operating 3 bakery facilities in the greater Chicago land area. Gonnella Baking Company employs approximately 350 employees. Our facilities make a variety of high quality bakery goods including handcrafted Artisan breads, bagels, rolls croissants and sweet goods. Many of these products are used throughout the country by retail and food service companies. Gonnella also is proud to be the hot dog bun supplier for the

World Champion Chicago White Sox, Chicago Cubs, Milwaukee Brewers and the Chicago Bulls.

My responsibilities at Gonnella include the management of all company safety and health programs and initiatives, including regulatory accountability and workers compensation. I like most of the family, started working with Gonnella when I was 15 years old. As with most family owned companies, I have done just about everything at least once from packaging bread to sweeping floors. I began my safety career with the company in 1984 as the Assistant Safety Director.

Since that time, with Gonnella's support and encouragement, I assumed leadership roles in not only the ABA but the National Safety Council as well. I serve on both the Food and Beverage Section and the Business & Industry Executive Committees for the National Safety Council. In 2001 the National Safety Council paid me and the employees at Gonnella a tremendous honor with the Distinguished Service to Safety Award.

In my role as Corporate Safety Director for Gonnella, I work very closely with both facility leadership and production employees to help ensure our company is a safe and healthy place to work for all. As a family business this takes on added significance and I consider myself an advocate for all of our employees and their families in the ongoing business of maintaining a safe work environment. Gonnella is strongly committed to providing a safe and healthy workplace to our highly trained and valued employees. Safety is our company's first priority in all decisions, from the President 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.

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. Of greater concern is the reliance by reference to the TLVs in OSHA's Hazard Communication Standard.

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.

II. ACGIH Threshold Limit Value on Floor Dust

In 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/m3) of inhalable dust. By way of comparison, the current ACGIH TLV for grain dust is 4 mg/m3 and the OSHA PEL for grain dust is 10 mg/m3 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, of which flour dust is considered, is 15 mg/m3.

ACGIH's newly proposed exposure standard to flour dust, which is a primary ingredient of the baking process, is 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.

ABA and its Safety Committee were obviously concerned that there might be new evidence showing that employees in the baking industry were being exposed to con-

ditions 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."

"Published data pertaining to exposure thresholds for flour-related effects, including sensitization and irritant effects are very limited. Furthermore, the data that serves 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."

"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."

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. After six months of wrangling with ACGIH, we received a summary dismissal of our request that the TLV be withdrawn. Ironically, ACGIH failed to address the very serious issues raised in our letter and in the SOMA study—they 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."

It was not until your leadership, Mr. Chairman, at the hearing in November of 2001 to investigate the reliance upon ACGIH's unsubstantiated reviews that ACGIH finally agreed to meet with the baking and milling industries. Only after you skillfully pointed out the fact that ACGIH itself recognizes that it is not a consensus organization and does not follow any of the elements of consensus organizations did they agree to at least meet. Unfortunately, the meeting was completely without merit and as the other witnesses have stated not much has changed.

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.

III. 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.

At the November 2001 hearing, Travis Nichol with Bakery Chef in Louisville, Kentucky articulated, these TLVs come with real consequences. Mr. Nichol, testifying on behalf of ABA, pointed out how his company was cited with a serious violation of the General Duty Clause and Respiratory Protection Standards for failure to meet the TLV standard. The citation was only withdrawn when his company presented the SOMA study as a counterpoint to ACGIH's flawed analysis and Kentucky OSHA in its review of the scientific foundation came to the same conclusion of the baking industry—that it is based on bad science.

During the citation investigation and follow up it was revealed that Kentucky OSHA had 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 originally presented by Kentucky OSHA would have required that the company take immediate steps to abate employees' exposure to flour dust above the ACGIH TLV. This would have resulted in employees, 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. 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.

It appears that this is due to the fact that 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.

Unfortunately, the recent activities by California's Occupational Safety and Health Standards Board tell a more disturbing story. At the end of 2004, with little notice and fanfare, California adopted a number of ACGIH's new TLVs, including flour dust, as it's own permissible exposure limits. Last year, ABA petitioned the California Occupational Safety and Health Standards Board asking for the new TLV for flour dust to be rescinded, submitting the SOMA study as supporting documentation for our request. In January, the Board summarily rejected ABA's petition in language eerily similar to ACGIH's dismissal several years ago. Thus far, however, California bakers have not been subjected to enforcement action.

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.

IV. 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, abatement methods 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 BEMA 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 have confidence in the procedures and work product of these organizations.

We strongly urge Congress to insist that OSHA utilize only data and true 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. At the very least, language in the Occupational Safety and Health Act pertaining to the proper use of consensus standards should be enforced or strengthened to prohibit the use of ACGIH and similar unsubstantiated standards.

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 numerous controversies involving ACGIH standards—states also should refrain from utilizing the TLVs. OSHA also should be more diligent in utilizing its review and approval authority over state plan states to ensure that only true consensus standards be utilized for enforcement and standard setting.

While we are loath to have the federal government impact the states' ability to conduct workers compensation programs as they see fit, ABA recommends that OSHA clearly communicate 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.

Congress and OSHA should not just take ACGIH at its word when it claims that its standards are for informational purposes and that "regulatory bodies should view TLVs and BEIs as an expression of scientific opinion." In addition to clearly communicating to federal and state regulatory agencies that ACGIH does not believe its standards, "should be adopted as standards without an analysis of other factors necessary to make appropriate risk management decisions", Congress should ensure that OSHA and states do not rely on "scientific opinion" as the basis for standards and enforcement..

We applaud the Chairman for his steadfast leadership and commonsense approach on this important issue. We encourage the Subcommittee to move aggressively to correct the problems in the Occupational Safety and Health Act pertaining to non-consensus standards. Many companies are at risk of significant penalties and abatement procedures based on ACGIH's "scientific opinion" and not on facts. Thank you again for the opportunity to address this important issue.

Chairman NORWOOD. Thank you very much, Liz.

I failed to mention prior to starting that you have a red, yellow, green light in front of you. I am going to be very generous for everybody today with time, but when that red comes on, begin to think about it might be time to close it down so we can get to the questions.

I would like to ask staff to put back up on the monitors the definition of "consensus standards" so our Labor Department people that are here can read them and write them down and memorize them.

With that, Mr. Ruddell, you are certainly recognized.

STATEMENT OF JAMES RUDDELL, DIRECTOR OF ENVIRONMENT AND SAFETY, FRANKLIN INDUSTRIAL MINERALS

Mr. RUDDELL. Mr. Chairman, members of the subcommittee, my name is Jim Ruddell. I am director of environment and safety for Franklin Industrial Minerals. We are a crushed limestone operation with over 400 employees, with operations in Georgia, Tennessee, Texas and Florida.

Thank you for the opportunity to appear before the subcommittee and testify on behalf of the National Sand, Stone and Gravel Association regarding ACGIH. Our concern is about the process by which it establishes threshold limit values or TLVs, that become de facto regulations by incorporation into regulatory standards developed by OSHA and MSHA.

NSSGA is the world's largest mining association by product volume. Its member companies represent more than 90 percent of the crushed stone and 70 percent of the sand and gravel produced annually in the U.S. Approximately 117,000 men and women work in the aggregate industry. During 2005, a total of 3.2 billion tons of crushed stone, sand and gravel valued at $17.4 billion were produced and sold in the United States.

There are two important points I would like to leave with you today. One is that while ACGIH has a history of providing high-quality and useful information concerning health effects on chemical substances, it is not a consensus standard organization. The process by which it develops guidance information, including the threshold limit values of chemical substances, does not involve the wider audience or operate in the sunshine like other recognized consensus standard organizations.

The second is the wide acceptance and incorporation by OSHA and MSHA of the ACGIH TLVs into the standards and regulations as if they were established by a consensus standard organization. In the case of the TLVs, whenever there is a new TLV adopted, it automatically changes the requirements under OSHA and MSHA. As a result, Federal standards are changed, bypassing the regulatory process where input can be provided.

An important consideration is that many ACGIH members work for regulatory agencies such as MSHA and OSHA, the very same ones that write the regulations. Even though ACGIH has in place a conflict of interest requirement that all members of the TLV committee must sign, it may not be possible to differentiate between work at ACGIH and work for their employer.

There are two recent examples of decision that affect the members of NSSGA. In one case, ACGIH published a notice of intent to change the existing TLV for calcium carbonate. ACGIH proposed reducing calcium carbonate by 90 percent based on a single German study of 32 individuals suggesting that the current level should be lowered because there is some evidence of nasal irritation. Calcium carbonate is an innocuous substance that is the main ingredient in Tums.

A second example involves crystal and silica. A proposed standard went through the TLV committee and was reduced by 50 percent. This reduction occurred while controversy continues about the quality of the scientific data supporting health effects and measurement methods of crystal and silica.

The salient issue is that these TLVs are incorporated by reference in the OSHA and MSHA hazard communication standards. This standard requires that every time there is a change in relevant information, we must revise our material safety data sheets. Further, we must retrain our employees. This also causes concern and anxiety of the general public who use these basic materials every day and view the MSDS as government-sanctioned public security warning systems.

NSSGA understands the legislation is being developed to encourage development and promulgation of voluntary consensus standards. NSSGA supports the use of voluntary consensus standards.

Mr. Chairman, that concludes my statement, and again thank you for the opportunity today.

[The prepared statement of Mr. Ruddell follows:]

Prepared Statement of James Ruddell, Director of Environment and Safety, Franklin Industrial Minerals, on Behalf of the National Stone, Sand and Gravel Association

Mr. Chairman and Members of the Subcommittee: Thank you for the opportunity to appear before the Subcommittee today to testify on behalf of the National Stone, Sand & Gravel Association regarding the American Conference of Governmental Industrial Hygienists (ACGIH) and our concern about the process by which it establishes Threshold Limit Values, or TLVs, that become de facto regulations by incorporation into regulatory standards developed by the Occupational Safety and Health Administration (OSHA) and the Mine Safety and Health Administration (MSHA).

Based near the nation's capital, NSSGA is the world's largest mining association by product volume. Its member companies represent more than 90 percent of the crushed stone and 70 percent of the sand and gravel produced annually in the U.S. and approximately 117,000 working men and women in the aggregates industry. During 2005, a total of about 3.2 billion tons of crushed stone, sand and gravel, valued at $17.4 billion, were produced and sold in the United States.

There are two important points I would like to leave with you today. One is that while the ACGIH has a rich history of providing high quality and useful information concerning the health effect of chemical substances, it is not a consensus standard organization. The process by which it develops guidance information, including the Threshold Limit Values of Chemical Substances, does not involve the wider audience or operate in the "sunshine" like those processes of other recognized consensus standard setting organizations or the Federal government.

The second and just as important point is the wide acceptance and incorporation by the Federal agencies OSHA and MSHA of the ACGIH TLVs into their standards and regulations as if they were established by a consensus standard organization. In the case of the TLVs, whenever there is a new TLV adopted, it automatically becomes a new standard under OSHA and MSHA. As a result, the Federal standards are changed and bypass the regulatory process where input can be provided or it can be challenged if necessary.

At its inception in 1938, the National Conference of Governmental Industrial Hygienists, which changed its name in 1946 to the American Conference of Governmental Industrial Hygienists, was one of only a few places where workplace exposure to hazardous substances was considered important. Initially, and until 2000, only members of the government and academic institutions could become members of the organization. In 2000, limited membership was extended to allow members from other organizations additional opportunities to serve on appointed committees and the board of directors.

An important consideration is that many governmental members work for regulatory agencies such as MSHA and OSHA, the very same ones that write regulations that incorporate the ACGIH TLVs. Even though the ACGIH has in place a conflict of interest requirement that all members of the TLV Committee must sign and agree to, it may not be possible to differentiate between work of ACGIH and work for their employer.

During the war-time industrial buildup, the ACGIH recognized a need to identify, understand and control worker exposures to hazardous substances encountered in the workplace. The Threshold Limit Values for Chemical Substances, the TLV Committee, was established in 1941. The first exposure limits, known as maximum allowable concentrations, were established in 1950. These workplace exposure limits

became known as the Threshold Limit Values (or TLVs) in 1951 and are still used today.

In most cases, the quality and volume of scientific information available did not compare with what we typically expect today. The process by which the ACGIH established these TLVs was through a committee of practicing professionals who met to consider any information available. The committee made recommendations to the ACGIH Board of Directors who approved the TLVs. The process included placing a given substance on the "Notice of Intended Changes" list for a period of two years to allow time to receive input and judiciously consider the information. In earlier times, information was actively sought from industry because they had the information available that could help to make a decision. That collaborative process, however, no longer seems to work effectively.

This model seemed to work quite well until the establishment of OSHA in 1970. OSHA was charged with the responsibility of regulating the workplace for protecting employee safety and health. When OSHA looked for a way to develop standards initially, they looked to consensus standards, such as the American National Standards Institute (ANSI), the American Society for Testing and Materials (ASTM) and the National Fire Protection Association (NFPA) in order to rapidly develop regulations for the protection of workers. At that time, there was no consensus organization setting exposure limits for workers. However, the ACGIH TLVs were in place and represented a considered list of hazardous substances where there was recognition of an exposure level that was believed to be safe for all workers. The 1971 TLVs were incorporated into the OSHA regulations as Permissible Exposure Limits (PELs) that must be met. In the case of the mining industry, the 1973 TLVs were incorporated for the same purpose. For the most part, these still are the requirements.

Today, the overall federal regulatory process is required to be more open-in the sunshine, so to speak-in order to allow for the input of all parties and consideration of data that is of high quality and scientifically valid in establishing a regulatory limit that everyone must meet. Hence, the recent Data Quality Act. Further, today's regulatory process requires the consideration of all available technical and economic feasibility data when setting permissible exposure limits for American workers.

The ACGIH, however, is not a consensus organization because its internal decision-making process excludes many of the parties that may be affected by the decisions that are made. The ACGIH recognizes this as evidenced in the disclaimer published in every edition of the TLV Booklet that says:

> * * * 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.

The ACGIH TLV process does not consider either technical or economic feasibility during its deliberations. While they accept input from interested parties, ACGIH is not required to act on the outside input received.

Perhaps this is a two-part issue. The ACGIH clearly states that its TLVs are not to be used as regulatory limits, but the regulatory agencies incorporate them by reference and they become a standard affecting all employers without the full open, regulatory process required today.

There are two recent examples of decisions that affect the members of the NSSGA.

In one case, calcium carbonate, the ACGIH published a notice of intent to change the existing TLV for calcium carbonate. It proposed reducing the calcium carbonate TLV by 90 percent based on a single German study of 32 individuals suggesting that the current level should be lowered because there was some evidence of nasal irritation. Calcium carbonate, the simple main ingredient in TUMS, is an innocuous substance that is used as filler in paints, plastics, paper coatings, pharmaceuticals and various food grade substances. Even the white powder used to keep chewing gum from sticking to the wrapper is pure calcium carbonate. The NSSGA in cooperation with the Portland Cement Association and Industrial Minerals Association-North America retained a well-known toxicologist specializing in inhalation toxicology to review and comment on the relevance of the German study. This report was submitted to the ACGIH TLV Committee for their consideration in setting a new TLV for this material. It is not known whether the report was influential, but when ACGIH published its 2006 TLV Booklet, the original Notice of Intended Change to reduce the TLV had been replaced with a new one announcing the intention to remove the existing TLV and its supporting documentation from the TLV booklet, suggesting that even the original TLV might be inappropriate. Of course, it will be at least another year, perhaps two, for the final decision to be made.

A second TLV for crystalline silica went through the TLV Committee and was significantly reduced for the second time since 2000. This reduction occurred while controversy continues about the quality of the scientific data supporting health effects and measurement methods of crystalline silica. Further, OSHA is in the midst of rulemaking on this particular substance where the issues of technical and economic feasibility must be considered.

The salient issue is that these TLVs have been incorporated by reference in the OSHA Hazard Communication Standard. The standard requires that every time there is a change in relevant information (for example, a reduction in the TLV or a change in carcinogen classification) every manufacturer of a listed substance must change the material safety data sheets (MSDS) they are required to produce under the Hazard Communication Standard to reflect this new information within three months. This also causes unwarranted concern and anxiety on the part of the general public who use these basic materials everyday and view the MSDS as a government-sanctioned public security warning system that gives them the needed sense of security that use of these products will not harm them or their families. Random setting and withdrawal of TLVs calls into question the standard setting process itself as well as the integrity of the underlying scientific standard setting body.

NSSGA understands that legislation to encourage development and promulgation of voluntary consensus standards by providing relief to standards development organizations is being developed. NSSGA support efforts to promote the use of voluntary consensus standards, which will encourage long-term growth and help maintain the competitiveness of U.S. enterprises around the world.

Mr. Chairman, that concludes my statement. Again, thank you for the opportunity to appear before the Subcommittee today. I am happy to respond to any questions.

Chairman NORWOOD. Thank you, Mr. Ruddell.

Dr. Mirer, you are recognized.

STATEMENT OF FRANKLIN E. MIRER, DIRECTOR, HEALTH AND SAFETY DEPARTMENT, UNITED AUTOMOBILE, AEROSPACE & AGRICULTURAL IMPLEMENT WORKERS OF AMERICA (UAW)

Dr. MIRER. Thank you, Dr. Norwood, Mr. Owens. I might point out I am a Brooklyn boy, born and bred. I hope to return there later in life.

My testimony today will focus on the need for OSHA to promulgate standards for a host of chemicals and what Congress can do to make this happen on the eve of Workers Memorial Day. We have copies of our poster over there. We hope you will look at it. We should be thinking about how we are going to protect workers.

Chronic illness arising from long-term chemical exposures at work accounts for 90 percent of the known work-related mortality. You can see the names of our known victims on the back of our poster, but most of the victims of chemical exposures are not aware of the chemical cause of their illness.

Reducing those known exposures is the most reliable and best opportunity to protect the lives and health of American workers. The fact is in the more than 3 decades OSHA has been in existence, OSHA has issued its new exposure limits for only 17 agents and groups of agents. These rules radically transformed the allowable exposures for those chemicals from the 1968 levels. Protected workers transformed industries, and largely avoided the high costs projected by industry doomsayers, and we have heard quite a bit of doom here already.

You have to think about what the consequences of OSHA not moving are, regardless of what you think about ACGIH, which are not in our view particularly protective levels or stringent levels. I only joined ACGIH after Henry sued them and drove them to the brink of bankruptcy. I figured I had to join them to support them.

Chairman NORWOOD. The taxpayers are buying enough from them. They won't go bankrupt.

Dr. MIRER. So let me talk about a real instance of what the consequences of not setting standards are. In November 2000, Dave Patterson, a machine operator at a brake systems plant in Mount Vernon, Ohio, began to get severely ill. In January, two additional members there, machinists J. J. Johnson and set-up man John Gooch were hospitalized for hypersensitivity pneumonitis, a serious disease that is like idiopathic extrinsic alveolitis. It can be fatal and lead to severe lung disorder.

One of these victims filed an OSHA complaint. On February 1, 2001, an OSHA inspector entered the factory, measured the exposures, issued no citation for metalworking fluids because the manufacturer, the employer, was found to be in compliance. Workers continued to get sick. NIOSH came in and you see the detail in my testimony. Several publications arose out of the incident, but I believe in my heart this problem went on for a whole year longer than it had to go on because of the lack of an OSHA standard.

That is one of a dozen, or more than a dozen outbreaks we know about, many in our plants from metalworking fluids. In our testimony, you read the long, sad story of how long we have worked on trying to get a new OSHA standard through this, including a consensus process where the majority of the industry representatives, not all of them, simply refused to recognize the scientific data supporting the need for the standard.

We had an 11-to-4 vote for OSHA to go forward on a standard, and yet OSHA and this administration withdrew it from their regulatory agenda, and then beat us in court over the need to go forward.

The most visible demonstration of the impact of OSHA's failure to move forward on new exposure standards was, in my view, the World Trade Center. OSHA measured according to their standards and polled those workers. There were no violations. There was nothing to worry about, and we can see what the consequences of that are in the daily newspapers in New York every day.

The chemical standards process has pretty much ground to a halt. We think the solution to this has to be broken legislatively, this particular impasse. First, OSHA should be required to meet as high a threshold to defend refusing a petition for a new standard, as it does to promulgate a new standard for chemical exposure.

Second, contrary to what has been suggested here, Congress should authorize OSHA one more time to adapt the threshold limit values list that we have now, to bring us into the 21st century. I am also suggesting an escape clause where those that find substantial reasons from affected parties should go into the OSHA 6(b) rulemaking process with a time certain for coming out of it at the end.

Just a word on consensus standards. Consensus standards are usually a negotiation between the equipment suppliers and the equipment users, where they address health and safety. They are usually a negotiation between the machine tool builders and the machine tool users for how to get a safety standard.

These are interest groups. They are not scientific groups and they don't have representation from the affected employees except

in very rare instances. So they are not the body to establish a scientific consensus or a scientific view.

In conclusion, the UAW appreciates the opportunity to testify. We look forward to moving to improve protections for American workers, not to try and erode those professional bodies that are attempting to give advice to employers on how to protect their workers.

Thank you very much.

[The prepared statement of Dr. Mirer follows:]

Prepared Statement of Franklin E. Mirer, Ph.D., CIH, Director, UAW Health and Safety Department, International Union, United Automobile, Aerospace & Agricultural Implement Workers of America (UAW)

My name is Frank Mirer and I am the Director of the Health and Safety Department of the United Automobile, Aerospace, and Agricultural Implement Workers of American (UAW), International Union. The UAW would like to thank you for the opportunity to testify on the use of nonconsensus standards in workplace health and safety. My testimony will focus on the need for OSHA to promulgate standards for a host of chemicals and what Congress can do to make this happen. On the eve of Workers Memorial Day, we should be thinking about protecting workers.

Chronic illness arising from long term chemical exposures at work accounts for 90% of known work-related mortality. Few of these victims are named on Workers Memorial Day, and many are not aware of the chemical cause of their illness. Reducing those known dangerous exposures is therefore the best opportunity to protect the lives and health of American workers. Recognizing the dangers of chemicals at work also would facilitate controlling those chemicals at home and in the community environment.

When OSHA was established in 1968, it inherited a group of chemical exposure limits, based on the science of the '60s and before. Those limits were set with substantial involvement of scientists affiliated with the chemical industries through the American Conference of Governmental Industrial Hygienists (ACGIH). Those limits were not intended to meet the criteria for protection mandated by the OSHA law. Nevertheless, this was a place to start in regulating chemical standards.

In the more than three decades that OSHA has been in existence, OSHA has issued standards for only 17 agents or groups of agents. These rules radically reduced allowable exposures from the 1968 levels, protected workers, transformed industries, and largely avoided high costs projected by industry doomsayers. Those costs incurred included wages of workers fabricating and maintaining control equipment, and cleaning the workplace, so these rules actually created jobs. OSHA should have issued rules for dozens more chemicals.

The effects of OSHA failing to set new standards can sometimes be seen in victims we can name. Here's a real story, documented in the scientific literature and the popular press.

In November 2000, Dave Patterson, a machine operator at a brake systems plant in Mt. Vernon, Ohio, initially reported breathing difficulties to his physician. In January 2001, machinist J.J. Johnson and set-up man John Gooch were hospitalized with hypersensitivity pneumonitis (HP), a serious disease that can lead to respiratory failure. Subsequently, additional HP cases developed as well as cases of bronchitis and occupational asthma (OA).

On February 5, 2001, an OSHA inspector responded to a complaint from one of the victims. The inspector issued no citation for MWF exposure because they found management in compliance. OSHA gave management a clean bill of health for metalworking fluids.

Workers continued to get sick. In June 2001, a National Institute for Occupational Safety and Health (NIOSH) Health Hazard Evaluation was called in by management and UAW Local 1939. By November 2001, 107 workers (out of 400) had been placed on restriction and 37 remained on medical leave. NIOSH identified 14 with occupational asthma, 12 with hypersensitivity pneumonitis, three with occupational bronchitis.

The UAW worked closely with TRW and NIOSH to protect our members. Ventilation was improved to bring exposure into compliance with UAW and NIOSH recommended limits. Eleven months after the first case, new cases stopped appearing, but some victims were still unable to return to work. Recent reports from our members and the press show that previous victims still suffer.

This was one of at least a dozen "outbreaks" of illness and disability from HP in machining plants which are in compliance with OSHA's exposure limits. These outbreaks were and are epidemics of acute severe illness on top of the endemic risks of asthma, other respiratory conditions, and most likely cancer.

Well before OSHA's 2001 inaction in Ohio, the problem was known to OSHA and to the industry. In 1993, the UAW petitioned OSHA for an emergency temporary standard for metalworking fluids based on research largely conducted jointly in the auto industry. OSHA denied that petition, but did convene an industry-labor-public health standards advisory committee. The automobile industry responded in 1995 and 1997 by convening symposia on the health effects and control measures for exposure to metalworking fluids. Both concluded that the effects were real and controls were feasible. The UAW negotiated exposure limits lower than OSHA with the auto industry employers, as well as other control measures. The year 1997 also saw the crafting of an American National Standards Institute (ANSI) standard on mist control for machine tools and a workshop was held to identify the cause and prevention of hypersensitivity pneumonitis. The following year (1998) NIOSH completed a "Criteria Document" on metal working fluids (a proposal to OSHA for a standard), concurring with the UAW recommended limit. The OSHA Standards Advisory Committee voted 11-4 that OSHA issue a comprehensive standard to drastically reduce the mist levels to which workers are exposed and to enact strict requirements for fluid management. OSHA responded to the SAC report by issuing voluntary guidelines, but left the new standard on the regulatory agenda.

So where was OSHA during the TRW outbreak? As workers were being hospitalized, an OSHA inspector was giving a "clean bill of health" to the plant, based on a 30+ year old standard that would allow a typical worker to inhale 1 pint of oil over the course of a working lifetime. And then, in October, 2001, OSHA deleted Metalworking Fluids (MWF) from the regulatory agenda, withdrawing the advanced notice of proposed rulemaking. OSHA acknowledged the respiratory illness from MWF exposure at prevailing and permitted exposure levels, but stated the asthma and hypersensitivity pneumonitis were "rarely fatal." The UAW petitioned the 3rd Circuit Court of Appeals to compel OSHA to restart the rulemaking. On March 24, 2004, that Court deferred to OSHA's decision NOT to act or start setting a standard.

Since 1970, scientific evidence and practical experience has identified workplace chemical causes of many instances of illness, disability and death among workers. Technical methods for estimating quantitative risks at various exposure levels—methods demanded by industry—demonstrate very large risks at very low exposures. Multiple studies have shown that widely distributed chemicals, like silica, are now known to cause cancer in humans. Lung cancer has been observed among workers exposed at levels permitted by the current OSHA standard and prevailing in American workplaces and at American construction sites. Organic dusts, like flour, are known to cause occupational asthma at exposure levels prevailing in American workplaces. A predictable fraction of asthma victims will die of that illness.

The most visible recent demonstration of the impact of OSHA's failure to move forward on new exposure standards was at the World Trade Center recovery site. The scientific literature and popular press recount the ongoing toll of disability and even death among recovery workers. Those accounts fail to connect the dots, that OSHA, and EPA, correctly reported that none of the measured exposures at the site violated outdated OSHA standards.

The standards process, when allowed to proceed according to law, drastically reduces permissible and actual exposures. The OSHA asbestos permissible exposure limit, revised several times, was cut to 1/50 of what it was in 1970, and even this limit leaves behind a substantial cancer risk. We still pay for the legacy of those old, high exposures.

Unfortunately, the chemical hazard standards process nearly ground to a halt in the last decade. The most recent rule protecting against cancer-causing chrome compounds was issued this year following a court order to regulate and a court decreed time limit to get it done. The mandated reduction is not sufficient, but it's something. The standard promulgated before chrome compounds, the methylene chloride standard, began with a UAW petition.

Without a doubt, these delays in the standard setting process have been aggravated by Congressionally imposed special reviews by "small" business

employers [but not employees of small business], OMB imposed regulatory reviews, and increasing demands for detailed economic analyses. These have injected procedural Botox into an agency already paralyzed by analysis. But the delays are also attributable to the failure of OSHA and the Administration to support prompt action in promulgating additional standards.

The legislative fix to this impasse has two parts. First, OSHA should be required to meet as high a threshold to defend refusing a petition for a new standard as it does to promulgate a new standard. Second, Congress should authorize OSHA to adopt the current Threshold Limit Values (TLV) list on a one time only basis. TLVs are developed by ACGIH, a group of scientists charged with investigating, recommending, and annually reviewing exposure limits for chemical substances. Generally, the TLV's are not as protective as permissible exposure limits set according to the OSHA law. Often the values allow a significant risk of material impairment to health, and don't push as far as would be economically feasible for the industry. In part, these shortcomings in protection arise from the nature of the ACGIH and its TLV committee, a set of volunteer organizations, with limited resources. ACGIH is not able to hold months of hearings, or hire specialized experts as OSHA might. But given OSHA's lack of action on setting new standards, the TLV's are a reasonable starting point in getting protection and future rulemaking. Congress should direct this action, not prevent this action. Where there is substantial objection to the limit for a particular agent, and a showing of material problems with compliance with that limit, OSHA should be compelled to place that agent in line for complete 6(b) rulemaking on a clear timetable.

The UAW was able to negotiate with auto industry employers to establish the TLV's as the internal occupational exposure guidelines, with updating as needed. A limited but significant number of TLV's really make a difference. They establish exposure levels lower than those which prevail or may prevail in the industry. For example, the TLV for carbon monoxide is ½ the OSHA permissible exposure limit, and this value can really drive improved ventilation in many industrial and service occupations.

In conclusion, the UAW appreciates the opportunity to testify before this Subcommittee. We look forward to continuing to work with Congress and OSHA to improve the safety and health of all American workers. Thank you.

Chairman NORWOOD. Thank you, Dr. Mirer.

Henry, you are up.

STATEMENT OF HENRY CHAJET, PARTNER, PATTON BOGGS, LLP

Mr. CHAJET. Thank you, Mr. Chairman.

Mr. Chairman and members of the committee, thank you for the opportunity to present testimony today on an issue of great importance to public policy in the United States and environmental and health and safety protections. We appreciate your leadership in this area and very much appreciate your help in making changes to solve a very significant problem.

In the beginning, Mr. Chairman, you asked had things changed much since you held a hearing here 4 years ago. My answer to that question is yes. They have gotten worse. We saw a number of years ago a promise by the Department of Labor and the Department of HHS and ACGIH to work on this issue and make it better. What we have seen is substantial deterioration of the process.

It is not just ACGIH either. It deals with other non-consensus standard groups. For example, the International Agency for Research on Cancer, which is IARC, which is based in Europe and to whom we have delegated the power of the United States government to make decisions.

That is what this is about. It is about the delegation or the illegal delegation of power to groups that are private or quasi-governmental, but they have no accountability to the citizens of our country or to you, the Members of Congress who pass these laws.

You have given authority to OSHA, to EPA, to MSHA, to NIOSH, and that authority has been taken from those agencies and given to these groups that we call non-consensus standard or-

ganizations. That is a very polite term. It is a very polite term for an insidious, growing problem of giving away the power of the United States and the rights of its people, us, to seek review and input. Because when we work at these organizations that are non-consensus, what that really means is they meet in secret.

What that really means is they don't tell us who the authors are of the product that they produce. They don't tell us what the conflicts of interest are or the bias, predetermined results. We don't even know the authors or the credentials of the people producing the material. It is that insidious growth of the giveaway of our rulemaking authority to these non-consensus groups that has brought us to where we are today.

This is not about whether X number of milligrams of a substance or Y number of milligrams of a substance causes a health problem. We can't answer that question here today on any particular substance. But I can tell you one thing: The ACGIH makes no dispute over the fact that they regulate based on nuisance. If it makes you sneeze, if it makes your eyes appear like allergies, they regulate to try to stop that.

And that is a worthy goal, but it is not what the OSH Act is all about. It is not what the EPA is all about. And because of that, we get these outrageous numbers by the bakers or other industries that they can't deal with these numbers, and they take away our competitiveness. This is a deceptive process. They take on the view that they are scientific, but in fact they produce junk science, and I use that term, Mr. Chairman, in a gratuitous way.

I am trying to give them credit for something, but it is very difficult when you get into any one of the TLVs we have examined, and we have examined six of them in the last 5 years. It is very difficult to see any science at all. For example, we have authors who have said in testimony the data does not support the TLV, authors, the people that actually wrote it. We have authors who have said, "I don't agree that we call that a human carcinogen," but there is the publication. We are stuck with it.

We have authors who have said, "Yes, I was the Federal employee in charge of that regulation, and I was also the ACGIH TLV author," with a direct conflict of interest. We know that the Federal Government is one of the largest funders of ACGIH and IARC. We don't know the extent of it. We know that there is $500,000 at least in publication purchases at ACGIH over the course of a couple of years.

We see the conflicts of interest of people that are testifying in tort claims. The expert on vibration TLVs was the ACGIH author. The vibration TLV was rejected by his own agency, NIOSH. We see these conflicts repeated. We see the lack of science repeated in the six that we have identified, and yet there is no direct remedy other than suing them and trying to peel the onion in that manner.

So we ask, Mr. Chairman, that you and the members of this committee and the Congress look at this problem, stop this illegal delegation of authority to these secret, non-consensus groups, and bring back the power to the agencies that you delegated this authority to.

Thank you very much.

[The prepared statement of Mr. Chajet follows:]

Prepared Statement of Henry Chajet, Esq., Patton Boggs, LLP

Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to testify regarding the important policy and legal impacts of non-consensus organizations (NCOs) that create and adopt government sanctioned safety, health and environmental standards. These NCOs make "findings," create "limits" designate "classifications," and establish "guidelines," that are used for federal agency standard setting.

The written testimony that I submitted for the record provides a summary and description, with documentary and testimonial evidence on an accompanying CD, of the secret, backdoor rulemaking conducted by one such NCO, the American Conference of Governmental Industrial Hygienists ("ACGIH"), and the junk science it has produced over the last ten years that is undermining the regulatory and legal system. Mr. Chairman, by using and supporting NCOs for standard setting, DOL, DOE, HHS, and EPA, are abrogating their duties through an insidious delegation of government authority that denies our fellow citizens the rights guaranteed by the Constitution and the protection of the laws enacted by the Congress.

For example, unless the Secretary of Labor acts immediately to stop OSHA, the agency will improperly interpret its Hazard Communication Rule issued in 1987, to automatically incorporate into law an invalid 2006 Threshold Limit Value?, or "TLV" limit, for silica, perhaps the most common mineral on earth and the basic component in glass, brick, concrete, stone, gravel and countless consumer and industrial products. The new TLV limit for silica is 1/4 the level deemed safe by valid OSHA and MSHA regulations and was created using secret authors with conflicts of interest and bias who ignored the scientific evidence that contradicts the TLV. The new TLV will have to be printed on material safety data sheets and become the basis of labels, warnings, and employee training. This will occur automatically, without any federal register notice or input from interested parties and without any of the protections of due process and appeal rights mandated by Congress. Later, some of my fellow members of the bar will call an expert witness to testify in product liability lawsuits, perhaps an ACGIH Committee member or the TLV author, who will describe the new silica TLV as the "standard of care" sanctioned by the United States government, and claim that exceeding the TLV level causes harm.

This is but one of many examples of how DOL, EPA, DOE and HHS continue to support, use, and rely on NCOs like the ACGIH. In contrast to NCOs, consensus organizations (e.g. ANSI), adopt standards according to strict procedures that are transparent, in open meetings, with a generous input and appeal process for all interested parties. The OSHA Act and other federal laws encourage agencies to use consensus standards, but unfortunately do not expressly prohibit their use of NCOs that, like ACGIH, adopt standards under a veil of secrecy. Unless you sue them, which I have done twice, it is impossible to discover the name of the author of a new limit, much less his or her credentials, bias and conflicts of interest, or the real reasons and basis for the limit. When you finally force NCOs like ACGIH to disclose their secrets, the results are shocking and demonstrate the real harm they cause: the encouragement and adoption of junk science by federal agency personnel that undermines the legal system in various ways, including:

One: NCOs produce standards like the silica TLV limit using closed, secret procedures, often tainted by hidden conflicts of interest and bias.

Two: NCOs like ACGIH do not use accepted scientific procedures such as outside, independent peer review and risk assessment, nor do they conduct independent research to support their standards. Yet, NCOs like ACGIH promote a false image of scientific integrity with the assistance of federal agency employees who participate in their standard setting and leadership.

Three: US and foreign NCOs, like ACGIH and the International Agency for Research on Cancer ("IARC"), not only are provided with government credibility through the participation of senior federal employees, but they are also supported with taxpayer dollars that include direct funding, publication purchases, meeting registration payments and expenses, and the extensive use of federal employee time and agency resources.

Four: To paraphrase one of the ACGIH's founders, NCOs like ACGIH provide a forum for agency employees to accomplish goals they could not otherwise accomplish in their official capacities.

Five: NCOs provide credibility for select university researchers and give them access to federal employees that can assist them in obtaining government grants and resources.

Six: Agencies misuse NCO standards to support rulemaking actions, to justify creating or lowering permissible exposure limits, or to impose regulatory requirements like air or medical monitoring or hazard communication. For instance, MSHA adopt-

ed a diesel exhaust standard in a rulemaking led by the agency official who secretly authored the corresponding diesel TLV. Similarly, MSHA issued a hazard communication rule that adopted the year 2000 TLV list, without disclosing that one its rulemaking leaders was the agency's secret official representative on the ACGIH TLV Committee. This year, DOE adopted all of the ACGIH's 2005 TLV limits as enforceable standards for its contractors.

ACGIH's clear conflicts of interest and bias on TLV limits are overwhelming. First, ACGIH has a marketing staff and sells TLV publications and meeting registrations for profit. OSHA, MSHA, and other federal officials that serve in ACGIH leadership roles make ACGIH purchasing and meeting registration decisions, help coordinate and plan ACGIH functions, and encourage agency personnel participation.

Through litigation, agency personnel in ACGIH leadership positions have been "caught" simultaneously developing agency rules and ACGIH TLV limits on the same issue (e.g., diesel exhaust), using ACGIH to support and promote agency regulatory action (e.g., global harmonization and control banding), and using agency research to support ACGIH standards that their agencies would not adopt (e.g., vibration ergonomics TLV) or that could not survive legal rulemaking because of faulty science.

TLV authors parlay their ACGIH roles into financial opportunities, including receiving federal research grants (e.g., TLV Committee Chairman), testifying as expert witnesses (e.g., vibration TLV author), and soliciting industry funding for their scientific research on pending TLV limits (e.g., copper).

Though ACGIH claims it has changed its ways, instituted a conflict and bias prevention procedure, and uses sound science to base its TLV limits, these claims are a marketing deception. ACGIH officials testified that ACGIH does not identify, record on a written form, and review conflicts and bias, as claimed on its web site. In fact, ACGIH officials have testified that ACGIH ignores conflicts when they are reported to the ACGIH and that they personally should have been removed from TLV authorship, but were not. ACGIH officials have acknowledged under oath that they described the scientific data as not supporting the copper TLV they published, that they disagree with the silica TLV carcinogen designation, and that they based a TLV for a solvent on an isolated finding of a single, unpublished rat study that a panel of experts for the National Toxicology Program found was unreliable and should not be used. The following are examples of recent forced disclosures regarding ACGIH TLV limits:

• The primary author of the silica and arsine TLV limits is a private consultant on these issues. He participated in a California silica rulemaking, without disclosing his secret TLV authorship or conflicts. He admitted that his silica TLV coauthor is an example of someone who "demonizes industry," and who had published an opinion that a reduced silica TLV should be adopted even before ACGIH reduced its TLV. The primary silica TLV author expressed his own disagreement with the ACGIH carcinogen classification for silica. He also admitted interpreting the scientific study upon which he based the new silica TLV limit in a manner inconsistent with the actual researcher who conducted the study, even though the study's research had complained to ACGIH about the misuse of the study.

• A senior MSHA employee authored the Diesel TLV even while he led the MSHA committee drafting the diesel rule and incorporated TLV materials in the rule. While DOL has announced new conflict prevention policies, no action has been taken to disclose and cure prior conflict-infected actions.

• In spite of the new DOL policy, MSHA continues to secretly pay an official to serve on the TLV Committee. That official admitted working on the MSHA Hazard Communication Rule that adopted the year 2000 TLV limits without disclosing her conflict to the public. In addition, MSHA approved her plaintiff's expert witness testimony, on a subject matter covered by the TLV Committee, while she was an MSHA employee and serving on the TLV committee as the MSHA representative.

• The TLV Committee Chair develops TLV limits for diesel particulate matter and beryllium, even while receiving millions of federal dollars to study these very substances. He admitted transferring the lead authorship for a TLV to avoid the appearance of a conflict, even though he remained involved in setting the TLV. He admitted being "gifted" valuable federal property—genetically altered animals for research by his organization (NYU) on pending TLV limits.

• The Copper TLV author did not recuse herself from developing that TLV even though she also sought private funding for copper research from industry. While she reported the conflict to ACGIH, she did not know why they did not remove her from the authorship and preferred that they would have done so.

• The author for the vibration TLV (an ergonomics TLV), served as an official NIOSH representative to the TLV Committee and has been a plaintiff's expert wit-

ness in 14 product liability cases claiming that hand tools are defective. He relies on his interpretation of the TLV he drafted, which NIOSH rejected, and which uses a single measurement for one minute to reflect a full day of vibration exposure, regardless of significantly lower measurements taken on the same day by him.

Given these and other conflicts and bias, it should be no surprise that these TLV limits are junk science. Moreover, there are no qualifications required to draft TLV limits. The author of the Copper TLV limit does not even have experience in industrial hygiene. Her TLV training amounted to a "power point presentation." The recent ACGIH Chairperson, who's also an OSHA regional administrator, described all of the types of medical and scientific expertise needed to create an exposure limit, admitted she did not have any of them, but contended that she required none of them to adopt TLV limits as the Chair of the ACGIH Board of Directors.

The TLV limits described above are arbitrary. The proposed Beryllium TLV limit changed by orders of magnitude several times in two years, without any new data or studies to justify the changes. One author admitted under oath that she simply gives "less priority" to studies that support higher exposure limits. The Copper TLV author admitted that because she missed the final committee meeting, she wrote, and ACGIH published, a different TLV than the committee voted to adopt. The Silica TLV likewise relies on incorrect literature and studies, including a discredited study involving defective lab equipment. The Silica TLV author even admits that in his opinion, silica is not a suspected human carcinogen, contrary to the ACGIH classification.

TLV authors do not search comprehensively for relevant scientific studies when writing a TLV. The Silica TLV author did not even read literature cited in his TLV documentation as support for his TLV. TLV authors don't review or consult other ACGIH publications, committees, or committee members, leading the Beryllium TLV to rely heavily on a blood test which another ACGIH committee deemed ineffective and infeasible. Similarly, one of OSHA's senior officials, Richard Fairfax, rejected the copper TLV as not supported by the evidence when he served as chairman of a TLV subcommittee and author of that TLV. The same TLV limit, based on the same invalid evidence, was proposed again by the current author, and published by ACGIH, without even knowing it had already been rejected by ACGIH itself due to the invalidity of its scientific basis.

ACGIH TLV authors do not consider, or even read, scientific comments submitted to ACGIH by industry and other interested parties. Thus, when the Silica TLV author misinterpreted a key study and the author of that study wrote and complained to ACGIH, the TLV author simply ignored the complaint. When the National Mining Association submitted comments to ACGIH on the proposed Copper TLV, they were not read by the TLV author. TLV limits also are not peer reviewed, even when specifically requested by TLV Committee members. The ACGIH TLV Chairman admitted that his request for the use of outside peer reviewers was rejected, and the Beryllium and Copper TLV author admitted that no scientific journal would publish her TLVs.

After being developed in secret by anonymous authors, TLVs are adopted with almost no further review within ACGIH. At one meeting in 2004, the ACGIH Board adopted 60 TLV recommendations at once, spending an average four to five minutes considering each. One former TLV Committee member wrote that "[t]here are just too many things to read in real life to let me spend time for a critical review."

Worse yet, the federal agencies financially support ACGIH, influence TLV limits, and improperly adopt and rely on them without any review of their scientific validity. One computer report shows over $500,000 in federal purchases of ACGIH products over a recent 3-year period. Another invoice shows over $54,000 in ACGIH purchases by just one OSHA regional office in one year.

A founder of ACGIH once said that an organization like ACGIH "can very often accomplish things which an organization of more official character is unable to do * * * * even though the same people are talking." Indeed, ACGIH's lawyers admitted that TLV limits are used by government as "de facto standards" when the proper rulemaking process becomes "bogged down." The Justice Department has admitted that federal agency employees serve on ACGIH TLV committees both in their "official" and un-official personal capacities, even though ACGIH deceptively advertises that its "volunteers" serve only in their personal capacity.

Conclusion

Mr. Chairman, ACGIH was once a legitimate creation of the federal government, managed and housed by the Public Health Service and NIOSH. It benefited the public by the adoption of TLV limits by its full membership, in an open, transparent and consensus process. Unfortunately, today the ACGIH is different. It has transformed into a rogue advisory committee; a hollow, secretive organization through which individuals with conflicts of interest change federal standards based on junk

science. This NCO backdoor rulemaking violates federal law and results in de facto standards which bear little resemblance to the latest scientific knowledge necessary to protect workers and the environment.

Mr. Chairman, I thank you for the opportunity to testify and for your efforts to focus sunshine on this issue and encourage sound science and accountability in government. As a result of this Subcommittee's hearings and a federal lawsuit five years ago, DOL, HHS and ACGIH promised reforms, after ACGIH withdrew its TLV limit for trona in a published apology that announced to the world there were no health effects to support the TLV limit. I regret to report, however, that the reforms never arrived, and instead the situation has deteriorated even further. I hope this hearing will spur meaningful change and I look forward to working with you to help restore the integrity of our regulatory system.

Chairman NORWOOD. Thank you for your testimony.

I think it is important to make it very clear that this chairman doesn't really care what the TLV is. I don't care what the PEL is. Whatever number is the correct scientific number, I am all for.

What I don't like that I see going on out there is that we are not following the law in determining that, and our great OSHA has been, and I have been at them for a number of years, trying to say to them, we need to produce new PELs in the 21st century. We really need to get some new threshold information and values in the 21st century, but we need to do it according to the law.

All advisory committees, standing or ad hoc, must have members representing management, labor, state agencies, as well as one or more designees of the secretary of HHS. Now, that is who should come together to determine what a TLV is. I don't think the way we are doing it now in secret is going to continue. I hope not. I am going to try to stop it.

And that is what this hearing is about, not that we don't need to improve our PELs greatly, because I know we do too. And I have tried on more than a few occasions actually to get some consensus out there and it is pretty hard to do and in the end it may well have to be Congress that once again demands we do it a certain way in order to get these PELs improved. But they have got to be proved in the sunlight where everybody gets some input.

Dr. Mirer said, well, now it is just two people coming together deciding and fighting back and forth about it, meaning I guess small business people who are concerned that these new standards are affecting their business fighting with whom. Well, the only people he can fight with about it are OSHA. You certainly can't fight anything with industrial hygienists who don't know what they have done. Nobody has any way of finding it out.

And also, Mr. Chajet, I want to ask you about this business that OSHA is not fighting employers' failure to comply with TLVs that are set by the governmental industrial hygienists, not specifically, not under the general duty clause. I am asking you, has this been your experience that OSHA takes TLVs from this secret organization and uses the general duty clause or not?

Mr. CHAJET. Mr. Chairman, we have seen examples of that. I think there is a much bigger problem and that is that OSHA forces employers to spend millions of dollars to change material safety data sheets every year when the ACGIH changes its list, and then they will cite you for having a material safety data sheet that doesn't have the TLV listed on there.

Chairman NORWOOD. What authority could you possibly tell me OSHA has to do that?

Mr. CHAJET. Mr. Chairman, they interpret their hazard communication rule that was adopted in 1987 to adopt a 2006 TLV developed by ACGIH, and how they interpret it that way, I can't explain. I think it is wrong. I think it is illegal. I think it is inappropriate, but yet that is what they do.

Chairman NORWOOD. They can't do it. It is not allowable for to use non-consensus standard-setting organizations. There is no where in the OSH Act that says that. It is very clear in the OSH Act that you have to use consensus standards. Tell me how they get away with breaking the law?

Mr. CHAJET. Mr. Chairman, I taught occupational safety and health law at Johns Hopkins graduate school of public health for more than 15 years. I have read that law thousands of times. I have to tell you, they have to give notice. They have to have public input. They have to have rulemaking and I don't understand how they can adopt the 2006 list or the 2005 list or the 2004 list every year over and over again without complying with the law.

They don't comply with the Federal Register Act, which says publish it in the Federal Register. They don't comply with the Federal Advisory Committee Act, which says when you are using a group like this that is advisory you have to comply with these procedures. They don't comply with any of it.

Dr. MIRER. Dr. Norwood, do you want an answer to this question, or his fabrications?

Chairman NORWOOD. You go ahead.

Dr. MIRER. OK. The communications standard which was adopted during the Reagan administration, I might add, has been in place for near 30 years now. It is a standard that requires the chemical supplier to disclose what they know about the hazards of a chemical. They are also entitled to argue against that, but they have to disclose what they know about the hazards of the chemicals.

Chairman NORWOOD. Disclose to who?

Dr. MIRER. To the person they are selling the chemical to, who in turn has to disclose it to their employees.

Chairman NORWOOD. Right. They have to have a written document that does that.

Dr. MIRER. So to help the employer help the chemical supplier, OSHA specified at that time the kinds of information that ought to be included in it, and that included the ACGIH TLV. What we are talking about——

Chairman NORWOOD. But OSHA doesn't have any authority to do that.

Dr. MIRER. Well, it is something that has been in place since 1987.

Chairman NORWOOD. That doesn't make it right at all. That is what we are talking about here now, what is right and what is wrong, not about whether we have had——

Dr. MIRER. That standard was litigated through the appeals courts many times. This issue never came up before, and it has been invented now, but that standard has been well reviewed judicially.

Chairman NORWOOD. Depending upon the definition of "consensus," again please. It is in the OSH Act.

Dr. MIRER. The consensus standard provisions there talk about the adoption of consensus standards during the initial period of OSHA. This is not adopting a consensus standard. It is requiring the employer, the chemical company to disclose what they know about the hazards of the chemical.

A review paper like a documentation for the TLVs or the TLV itself is information about the hazards of the chemical which only at their peril would any employer ignore, and only at their peril would any employer conceal that information.

Chairman NORWOOD. Which has what to do with the government hygienists?

Dr. MIRER. I am sorry?

Chairman NORWOOD. What does this have to do with the governmental hygienists, industrial hygienists? What has this got to do with that organization?

Dr. MIRER. The governmental industrial hygienists' documentation for the TLV and the TLV itself are very substantial, heavily reviewed for the compilation reviewed by OSHA.

Chairman NORWOOD. But they are used by OSHA and they are non-consensus.

Let me give Mr. Chajet an opportunity. You have impugned his reputation a little bit. Let me give him a minute to respond.

Mr. CHAJET. Thank you, Mr. Chairman.

Part of the problem is that my good friend Frank is thinking about the ACGIH the way it was 20 years ago, when it was an open process, when they were respected for good science, when they sought out his opinion, the opinion of industry professionals, the opinion of people that used the materials.

That has changed. That has changed because they closed the meetings, because they took the vote away from their membership. And yet this group still has that brand that made Frank and others think this is a great thing. But it is not.

Let me give you an example. The documentation that Frank is talking about that they put on the street and they asked people to believe is sound science, it is that documentation that when you peel the onion, you find out that it had one author and didn't get reviewed by anybody. The rest of the board didn't read it before they voted on it. They adopted 60 of them and they spent 4 1/2 to 5 minutes on each one in a half-day meeting.

This is the process. It is a secret author. And then when you ask the author, right, we have one documentation where the author said, "yes, I relied on this particular study that involved rats." Did you look at the human studies? "No." And then you ask the author, well, that particular study that involved rats, did you know that the national toxicology program said it was a bad study? He said, "yes, but I relied on it anyway."

And then you get a TLV. So Frank's image of what this process is about is different than the reality.

Chairman NORWOOD. We are not going to get consensus, I can tell. It is Mr. Owens time. You are recognized for whatever time you need.

Mr. OWENS. Mr. Chajet, would you say ACGIH is a racketeering enterprise or a communist conspiracy? Why do they do what they do? And what motivation would they have to do be a fraudulent organization, perpetrating misinformation?

Mr. CHAJET. Congressman, I wouldn't use those words, but they are an interesting concept. This organization is motivated by the motivations of its individual people. So you have one person, for example, who is working at the Mine Safety and Health Administration trying to get a regulation passed, and he is the author of the diesel regulation. And then he goes to ACGIH and he writes the diesel TLV. And then they use one to bootstrap the other. That is one motivation.

The other motivation is you have a ACGIH TLV author, and then he leaves the ACGIH and become a union expert witness on vibration, and he testifies and he makes thousands upon thousands of dollars to testify that if you violate this particular number, that tool will cause you harm. And then you know what happens in those court cases.

Mr. OWENS. So are you saying that there are some payoffs and kickbacks and some financial remuneration involved here? Either that, or somebody is trying to undermine the nation?

Mr. CHAJET. Congressman, there are direct conflicts of interest within that organization, and I have already provided background material to the committee which I would ask be introduced into the record, if that is possible.*

Mr. OWENS. Do you think the American Dental Association would fall in the same category?

Mr. CHAJET. I am sorry? I didn't hear you.

Mr. OWENS. Do you think the American Dental Association would fall in the same category?

Mr. CHAJET. I still didn't——

Mr. OWENS. The American Dental Association.

Chairman NORWOOD. My organization, the American Dental Association.

Mr. CHAJET. I think that is the best organization in America.

[Laughter.]

Mr. OWENS. Thank you. I want to change the subject a bit.

Mr. Ruddell, I understand from looking at the MSHA website that a mineworker was killed on the job just 5 days ago at Franklin Industrial Minerals' Anderson mine in Tennessee. You didn't mention that in your testimony.

Have you had any communications about this? As director of environmental safety for Franklin Industrial Minerals, what steps would you take to prevent similar work events at your mines?

Mr. RUDDELL. That situation is still under investigation, sir, and you are correct that we did recently have a fatality at one of our operations, and MSHA is thoroughly investigating it, along with us.

Mr. OWENS. In view of the fact that we are talking about Workers Memorial Day tomorrow, any steps you would take to prevent

*Submitted and placed in permanent archive file, testimony before the United States House of Representatives, Committee on Education and the Workforce, Subcommittee on Workforce Protections, Henry Chajet, ESQ., Patton Boggs LLP, Washington, DC (April 27, 2006).

similar kinds of things? You don't know anything about it at this point?

Mr. RUDDELL. No, I am familiar with it, but we are under investigation. I can get back to you on more details, but right now the investigation is ongoing and I don't have any specific answers for it, but I can get back to you.

Mr. OWENS. We obtained that information from an MSHA bulletin, a report from MSHA. Do you get that information as rapidly?

Mr. RUDDELL. I haven't seen it, so I really can't comment on it right now. But again, I would be happy to look at it and get back to you on it.

Mr. OWENS. Dr. Mirer, let's talk about relevant steps to protect workers in terms of the most important chemicals on the TLV list. Let's assume that there is a process going on out there that really wants to protect workers, that doesn't have some dark motives, is not a racketeering enterprise.

What should OSHA be doing to protect workers before these standards are set? We have chemicals coming on-line all the time, about 500 on the TLV list. Which are the most important for OSHA to move forward on?

Dr. MIRER. In the straightforward process that we actually started after the chairman's last hearing on this question, we attempted to set forward a consensus group that would make priorities for OSHA to move forward with rapid adoption. Part of the discussion there was what would happen where there were chemicals of substantial impact, like silica, like carbon monoxide, where the standards are clearly inadequate based on hundreds of studies of silica and many on carbon monoxide.

What would be the process after that? The process after that would be some trigger of OSHA doing rule 6(b) rulemaking, bound by a particular time. So you have a two-stage process. You make the priorities and you go forward.

In the interval, those situations which meet the definition of the general duty clause, that is to say, has the hazard been recognized generally in the employer's industry. In those situations, the employer has the obligation to abate the hazard, whether or not there is a TLV. The TLV is only part of the evidence to why there might be, and we could go forward with that.

For many of these situations, there are, as in the TRW situation, there are actual workers getting sick in the workplace. There are workers bringing these problems to the attention of the employer. There are unions and representatives of workers bringing these problems to the employer.

What we don't need is OSHA coming around and saying it is in compliance with the standard. As at the World Trade Center, we don't need OSHA coming around telling the employer they are in compliance with the standard and we have nothing to enforce. Even if we were enforcing, we would still have nothing to enforce in this situation. That is what we don't need.

We need to get OSHA out of that particular framework. If they are not moving forward with standards, I don't know what we are going to do or what we can accomplish.

Mr. OWENS. Just one final question to Mr. Ruddell. I happened to be watching the History Channel last night, and Marvels was

dealing with your industry, a fantastic, huge, magnificent industry. It makes a lot of money.

I just wondered, for both you and Ms. Marcucci, are we talking about high costs? Somebody has implied that the TLVs are just nuisances, that really they are not important. Sneezing is not a symptom of something more serious. These TLVs that we are talking about are being in the way.

Do they cause your industry, do they cost a great deal if you were to pay more attention to these TLVs and their impact on workers' health?

Ms. MARCUCCI. For the baking industry, it would cost approximately $500,000 to put in the equipment to lower the TLVs.

Mr. OWENS. A half-million for the whole nation?

Ms. MARCUCCI. I am sorry?

Mr. OWENS. A half-million for the bakeries across the whole nation?

Ms. MARCUCCI. For every bakery.

Mr. OWENS. Each bakery would have to pay $500,000?

Ms. MARCUCCI. We would have to put a half-million dollars worth of equipment into the baking facility or the equipment used to protect the employees. It would be dust collectors and face masks, et cetera, so approximately $500,000 to be utilized in the bake shop.

Mr. OWENS. This is for Pepperidge Farm or one of the big bakeries?

Ms. MARCUCCI. My small bakery would be approximately a half-million dollars for this equipment, to purchase it and to retrofit it to our existing equipment.

Mr. OWENS. That is your estimate? How many workers do you have?

Ms. MARCUCCI. We have 350.

Mr. OWENS. Oh, 350 workers.

Mr. Ruddell?

Mr. RUDDELL. Right now, I don't have exact numbers on what it would cost on some of the TLVs that have been proposed. We do have best available control technology for dust in our facilities. We actually sell dust as a product, so we try to recoup all of it, get all of it we can. So I am sorry. I can get back to you if you want, but I do not have a specific dollar figure for what it would cost us to comply with lower TLVs.

Mr. OWENS. Well, it pays to keep the dust out of the lungs of the workers, because you can sell it. Right?

Mr. RUDDELL. Well, what comes first is safety. For us to stay in business, the health and safety of our workers is No. 1. We do everything we can to protect our workers. We have standards set so that we know what targets we have to shoot for. We try to always be below those TLVs, whether they are set by AGCIH or whomever. But as far as a specific number, the biggest concern we have is the setting of the standards by inference, by reference, rather than going through the process. That is the main reason I am here.

Mr. OWENS. But generally, paying attention to the TLVs is good business.

Mr. RUDDELL. Yes.

Mr. OWENS. Thank you.

Mr. RUDDELL. We use them as a basis.

Mr. OWENS. Thank you.

Thank you, Mr. Chairman.

Chairman NORWOOD. Yes, sir.

Mr. Kline, you are recognized.

Mr. KLINE. Thank you, Mr. Chairman.

Thank you, lady and gentlemen for appearing before us today. It is some very fascinating testimony. I have to admit that I have learned an awful lot, that my level of knowledge and understanding was even lower than I thought when we started this, so it has been very helpful.

It is also interesting to have one witness accusing another of fabricating testimony. That is a little unusual for us, too, so it has been kind of an exciting day.

Mr. Chajet, let me come back to you, if I could. I have some notes here that, frankly, the staff has prepared, but they are interesting questions and I would like to pursue them if I could.

Your testimony suggests a pretty large expenditure of Federal dollars on ACGIH materials and conference. Do you have any idea how much? Can you kind of give us a sense for what is involved there?

Mr. CHAJET. Congressman, I will try to get those numbers. I have asked. I have sent requests. It is nearly impossible for me to get those numbers. We have two pieces of paper that I am happy to share with you. One is a printout and it came from ACGIH that looks like about $540,000 for books over the course of a couple of years. It is old.

I also have another piece of paper that is $54,000 purchase order for books from one local OSHA office in 1 year. Those are the only real pieces of evidence I have on how much they are spending. But I can tell you that the Federal agencies are supporting and giving credibility to these organizations, not just with resources and dollars and money, but with time.

The chairperson of the ACGIH for the last 2 years has been the OSHA regional administrator in Atlanta, Georgia. When you try to find out how that time is allocated and whether it is Federal payroll time or whether it is ACGIH time, they go to a meeting; 2 hours is ACGIH time and the next 6 hours it is OSHA business.

So I can't really give you an idea of the reality of it, but I can tell you I think it is the largest source of income of ACGIH and IARC.

Mr. KLINE. OK. So we are lacking documentation. The staff just gave me something here that is an order for supplies or services, but I can see that that trying to get to the bottom of that would be something this committee ought to involve itself in.

Lawsuits are always a matter of some interest, and I would say concern to me. Your testimony again references some lawsuits that have relied on these TLVs. Can you expand on that a little bit in the few minutes I have here?

Mr. CHAJET. Congressman, I don't know how many hundreds or thousands of lawsuits the TLVs have been introduced into. But I can tell you that one great example is the TLVs for vibration, which NIOSH rejected because they couldn't really member the dose.

The vibration changes all the time when you are putting your drill against hard wood or soft wood, and they can't really measure the effect either, but yet there is a TLV for it. The person that wrote that TLV, or claims to have written it, as the ACGIH committee member testified 14 times for plaintiffs.

How many times has that happened? I know that particular event has probably happened hundreds or maybe thousands of times.

Mr. KLINE. OK. Thank you.

I yield back, Mr. Chairman.

Chairman NORWOOD. Thank you.

Mr. OWENS. Mr. Chairman, I want to ask permission to submit additional questions to our witnesses in writing for the record.

Chairman NORWOOD. In writing? OK. Certainly, so ordered.

I have a couple of questions and I will be ready to summarize and close. Mr. Owens, do you wish to do the same? You will do yours in writing?

Mr. OWENS. Yes.

Chairman NORWOOD. Ladies and gentlemen, we will submit in writing and would greatly appreciate your prompt response, if you would. But I still have a couple of things I need to get off my back a little bit.

Liz, I know that there has been a lot of money spent by the American Bakers Association. I am of the studies that you have gone out and done in your organization. I don't know how much. Do you know how much the association has spent on trying to get good studies on actually what the peril ought to be in terms of flour?

Ms. MARCUCCI. Yes, Mr. Chairman. The first study cost us approximately $40,000, and we have just recently received a quote to update the program again for about half that cost.

Chairman NORWOOD. Now, my question is, do you think we could have gotten to an acceptable TLV with good science, that everybody could have agreed on? Because I agree with Mr. Ruddell, his answer to Mr. Owens, it is very important to pay attention to these threshold limit values, for your own sake and your own company's good. But why couldn't we come to some consensus on a TLV? Or was it done in private where you had absolutely no way of having any thoughts on the matter or any input?

Ms. MARCUCCI. As I mentioned in my testimony, Mr. Chairman, we were not given any of that information, and we were not given the opportunity to have open discussion about TLVs. Of course, we want TLVs in place to protect our employees, and we will use the resources necessary to protect our employees. But we request the opportunity to be able to have open dialog with ACGIH and other groups that are setting these standards.

Chairman NORWOOD. Well, if they were to set the standard, well, they did set the standard, do any of us know what science they used or what science they do as an association to determine the standard?

You get to go next. Yes, I am asking you. Where do they get their scientific material or do they produce any scientific material?

Ms. MARCUCCI. Mr. Chairman, I am not aware of where they get their material. We were not given any information. If you look at

my written statement that was handed in, it explains that we requested many times that information and were given nothing.

Chairman NORWOOD. So you are living with a threshold limit value of which somebody out there says this is good science, but Lord knows you can't know who?

Ms. MARCUCCI. Correct.

Chairman NORWOOD. Dr. Mirer?

Dr. MIRER. The documentation for the TLV, which is a review of all the science and an explanation for why they chose to set the standard where it is——

Chairman NORWOOD. Excuse me. May I interrupt? A review of—they review the literature? That is all they do?

Dr. MIRER. It is a review of the scientific—yes.

Chairman NORWOOD. All they do is look at other people's work?

Dr. MIRER. What do you mean "all they do"? They review the scientific literature. And then OSHA reviews the scientific literature.

Chairman NORWOOD. Do they do any science themselves? Do they actually study any of it themselves? Or do they look at a program done in Germany that nobody believes in anyway, but none of us can know they looked at it?

Dr. MIRER. Well, first of all, you do know they looked at it because they publish in advance with the notice of any changes——

Chairman NORWOOD. I don't know any of that.

Dr. MIRER. They publish the documentation for the TLV, which states each piece of information that they used to set the standard and the logic connecting to it. No, they do not themselves do the research. Neither does OSHA do any research itself to support the scientific literature that is there.

Second, they do accept, and I have written those comments myself, they do accept comments from anybody and they are reviewed in the TLV committee.

Chairman NORWOOD. Does anybody in here agree with that? That the government industrial hygienists accept anything from anybody?

Dr. MIRER. Yes.

Chairman NORWOOD. I am asking the other three.

Mr. CHAJET. Mr. Chairman, I can tell you that the author of the copper limit and ACGIH said under oath that she did not read the comments that were submitted. So whether you submit them or not doesn't matter. They don't read them.

Other authors have said, yes, we cite that literature, but we didn't read it. This is a very difficult process because you don't get to find that out until you sue them. People like Frank believe it is a scientific process, but it is not.

Chairman NORWOOD. Let me go back to Liz. She was not quite through, but I did want to give you a shot into that.

Liz, finish up.

Ms. MARCUCCI. Thank you, Mr. Chairman.

The purpose of the SOMA study was to check ACGIH's facts and science. SOMA totally dismissed ACGIH's science that this was based on, that the TLVs were based on.

Chairman NORWOOD. So take it a step further. We have a nonconsensus standard-setting organization that has supposedly nothing to do with the government, writing standards that the govern-

ment is accepting, and nobody can know anything about it, and this gets more complex because states see OSHA accepting it and what happens in the states?

Ms. MARCUCCI. From my presentation that I gave, we have had bakeries that have received OSHA violations by state-run plans for not following or not being within the ACGIH standards. So they were documenting the flour dust levels against ACGIH standards, which would not be correct.

Chairman NORWOOD. So standards around the nation, then, are dictating to companies around the Nation what their threshold limits ought to be, and it is done by people none of us know who don't work for the government, and the Labor Department is complicit in this illegal act.

Ms. MARCUCCI. Correct, Mr. Chairman.

Chairman NORWOOD. Did you get that?

Dr. MIRER. Can I correct one thing? We do know who writes them because the members of the TLV committee and consultants who participate in it are published in the book that they publish every year.

The scientific comments come into the secretariat and are distributed to the TLV committee members and they do not disclose who is working on any particular material, although the current rules require that the person working on the material have no interest in it, whether it is a conflict of interest or just an intellectual interest in the industry that they are working on. But they do know who wrote them.

Chairman NORWOOD. Do they not want us to know that they are being paid by the taxpayers during daylight? Do they not want us to know they work for OSHA?

Dr. MIRER. They disclose the employer of everybody who is working on it.

Chairman NORWOOD. So they don't mind us knowing they work for OSHA?

Dr. MIRER. They fully disclose who everybody is working for.

Chairman NORWOOD. So in daytime the taxpayers pay them at OSHA and at nighttime they go over to this organization and secretly write standards the rest of us have to live with, and then take them back over there and sit at the same desk and say, boy, this is a great standard. My buddy over there wrote it. I know it is the way to go.

And none of us get any input at all, which is against the OSH Act. I don't care what haz-com has to say in their regulation. That is not in the OSH Act. I care about the fact that OSH Act says consensus standards. And that is not what is happening.

And let me just conclude by saying there is a serious problem when these very same people who work for OSHA, the Labor Department, go over at night and write these standards that nobody gets any input to, and then the rest of us taxpayers get to pay them for it.

Now, we don't know how much is being paid yet. We do know there is a case in New England where $65,000 bought some of their books, but I am going to find out exactly how much the taxpayers are paying this non-government agency that is breaking the law. We are going to find it out, and they are going to stop.

Second, I agree with you that the PELs have to be updated. We couldn't get labor and business to decide on whether the table was round or square. Now, I tried very hard to get grownups to sit down and be reasonable about changing these PELs because you are right, they do need to be updated. I don't think there is anybody in this room who doesn't know that. Maybe Congress needs to act and do that if I can't get you all to sit down and work this out.

But the American governmental industrial hygienists are going to stop writing the laws of this land if it is the last thing I do on this earth. They better get ready because I am going to come after them, and I am going to keep coming after them, and you guys over at OSHA and the Labor Department that are letting this happen are next on that podium.

Under oath, we are going to find out why you are allowing this to happen. It is not tricking anybody, and it is absolutely against what Congress wants to happen. You are a Federal agency; supposedly you are supposed to enforce the law. Quit writing it. That is what you are trying to do and that is what you are letting happen.

Now, I hope you are writing it down, Steve, because we tried to fix this. Senator Enzi tried to fix this, and the Labor Department stopped it, and it is now war.

Thank you all for coming.

Excuse my tirade, but I do get enough after a while.

Your time has been greatly appreciated.

And this meeting is now adjourned.

[Whereupon, at 11:54 a.m., the subcommittee was adjourned.]

[Additional materials submitted for the record follow:]

Letter Submitted by the National Ready Mixed Concrete Association

May 5, 2006.

Hon. CHARLES W. NORWOOD,
Chairman, Subcommittee on Workforce Protections, Committee on Education and the Workforce, Rayburn House Office Building, Washington, DC.

DEAR CHAIRMAN NORWOOD: The National Ready Mixed Concrete Association (NRMCA) welcomes the opportunity to submit a statement about the important work that the House Workforce Protections Subcommittee is undertaking to deal with the issue of non-consensus health standards. NRMCA represents one thousand three hundred ready mixed concrete companies that employ seventy thousand men and women living and working in every congressional district in the United States and its territories.

Protecting employee health and safety is of paramount importance to NRMCA and its member companies. To achieve this objective, organizations must conduct work in an open environment, thereby ensuring that interested parties have an opportunity to voice comment and to provide expertise as the case may be. The current process in which the American Conference of Governmental Industrial Hygienists (ACGIH) sets threshold limit values (TLV) does not allow input from the public. The lack of public input into the ACGIH standards setting process combined with Occupational Safety and Health Administration (OSHA) personnel having input into the ACGIH process is cause for concern. Only by considering all relevant information contributed by all interested parties can the most protective measures for employee health be determined. NRMCA does not believe that the current process allows for such consideration to occur.

NRMCA asks that the Subcommittee on Workforce Protections delve into this matter more thoroughly to ascertain how the most appropriate and protective TLVs and PELs can be determined. NRMCA believes that deliberation of all relevant data

on the issue of employee health protection must occur to achieve the best work environment for employees in ready mixed concrete manufacturing.

Very truly yours,

THOMAS V. HARMAN, CSP,
Government Affairs, NRMCA.

Prepared Statement of the Independent Lubricant Manufacturers Association

The Independent Lubricant Manufacturers Association (ILMA) submits this statement for inclusion in the record of the Subcommittee on Workforce Protection's April 27, 2006 hearing, examining the use of non-consensus standards in workplace health and safety. The Association appreciates this opportunity to share its views on this matter with the Members of the Subcommittee.

Executive Summary

Protecting worker health and safety at the national level through regulation is a daunting task. Over the years, federal agencies have wisely looked to the private sector to help do the job properly. To assist federal agencies better leverage the energy and know-how of the private sector, Congress passed the "National Technology Transfer and Advancement Act of 1995" (NTTAA). Pursuant to the NTTAA, as supplemented by OMB Circular A-119, federal administrative agencies are directed to take into account privately developed consensus standards that relate to their regulatory activities. For a standard to be consensus, the development process must have the following attributes: (1) openness; (2) balance of interests; (3) due process; and, (4) an appeals process.

While the reliance on consensus standards typically enhances the regulatory efforts of federal agencies, the use of non-consensus standards can hinder, confuse and, in some cases, damage such efforts. The process that creates non-consensus standards often generates inferior and possibly defective information. Premising regulatory action on such inferior or defective information is not unlike building a house at a choice location using the finest materials, but neglecting to first lay a foundation. Without a solid foundation, a stylish new home is expensive in the short term, and ultimately useless in the long term.

The American Council of Government Industrial Hygienists (ACGIH) recently developed a Threshold Value Limit (TLV) for "Mineral Oil Used in Metal Working." This TLV is a non-consensus standard. Because it was developed in a closed, secretive process, ILMA asserts that it contains a number of conceptual and measurement defects.

Notwithstanding the presence of these defects, the Occupational Safety and Health Administration (OSHA) is poised to incorporate by reference the TLV once it becomes finalized by ACGIH. Once incorporated by reference, this TLV will instantly have legal status under OSHA regulations and may be the foundation of enforcement decisions made by OSHA and other administrative agencies. The defects in this TLV will undermine any subsequent regulatory action premised on the TLV.

The fact that OSHA has incorporated non-consensus standards into its regulatory programs for years is somewhat curious in and of itself, given that the Occupational Safety and Health Act has an express definition of "national consensus standard." 29 USC § 652 (3)(9). There is a gap between this definition in OSHA's enabling legislation and the Agency's practice of incorporating by reference non-consensus standards. This gap is further accentuated by OSHA's continued reliance on non-consensus standards despite Congress' mandate in the NTTAA.

Congressional action is needed to fill this gap. An efficient solution would be to require OSHA to rely only on "national consensus standards" as that term is already defined in the Occupational Safety and Health Act and is consistent with the NTTAA.

Introduction of ILMA

The Independent Lubricant Manufacturers Association (ILMA), established in 1948, is a national trade association of 135 manufacturing member companies. The overwhelming majority of these companies are "small businesses" as defined by the Small Business Administration. As a group, ILMA member companies blend, compound and sell over 25 percent of the United States' lubricant needs and over 75 percent of the metalworking fluids (MWF) utilized in the country.

Independent lubricant manufacturers by definition are neither owned nor controlled by companies that explore for or refine crude oil to produce lubricant base stocks. Base oils are purchased from refiners, who are also competitors in the sale

of finished products. Independent lubricant manufacturers succeed by manufacturing and marketing high-quality, often specialized, lubricants. Their success in this competitive market also is directly attributable to their tradition of providing excellent, individualized service to their customers.

ILMA believes that non-consensus standards should have little or no role in the development of workplace health and safety policies in the United States, and that immediate legislative action is needed to remedy the improper reliance that various federal agencies, especially OSHA, place on these non-consensus standards.

Given the closed nature of their development, non-consensus standards are substantially more susceptible to severe conceptual and measurement defects than consensus standards developed in an open, accountable and transparent process. Developing workplace health and safety policy in the shadow of these defects presents unacceptable threats to the health of American workers and creates costly burdens on businesses (large and small) across many industries.

ILMA's Current Nexus with Non-Consensus Standard Setting Organizations

ACGIH has enjoyed a long track record of doing a tremendous amount of good for the field of industrial hygiene and the protection of both the American workforce and workforces around the globe. Since the 1940s, ACGIH developed TLV recommendations for hundreds of chemicals and substances to which workers may be exposed in the workplace. For many years, ACGIH developed TLVs using an open, transparent development process based on sound scientific conclusions. All stakeholders in worker health and safety matters (those from government, academia and industry) had a seat at the table in developing TLVs. Unfortunately, this balance among stakeholders is no longer the case.

Presently, ACGIH promulgates TLVs by way of committees that operate in secret with anonymous authors for the TLVs. Though industrial hygiene professionals in the private sector are still permitted to be ACGIH members, they are categorically banned from serving on any TLV committees. ACGIH further dampens industry input by routinely refusing telephone and in-person meetings to discuss TLV development. In short, industry has gone from having a seat at the table to being systematically barred from the TLV development process. Though the opportunity to provide written comments exists, there is no "appeal" process to challenge, question or even engage in a professional discourse with the people responsible for developing and finalizing the TLVs.

ILMA believes that by closing the TLV development process, ACGIH has severely compromised the scientific value and legitimate utility of TLVs. Although ACGIH remains a private entity and has the right to conduct its membership, internal governance and TLV development procedures as it sees fit, a massive problem is created by the unwarranted credence that federal agencies, namely OSHA, give to ACGIH's TLV development process and how these agencies currently use newly-generated TLVs as a substitute for their own notice and comment rulemaking.

It is instructive for the Subcommittee to examine ACGIH's statement of position on its TLV development process at http://www.acgih.org/tlv/PosStmt.htm. ACGIH acknowledges that it does not evaluate the economic and technical feasibility of its recommendations or the availability of acceptable methods to determine compliance. ACGIH also points out that it does not follow a consensus process as the TLV "does not represent a consensus position that addresses all issues raised by all interested parties." While ACGIH makes these and other disclaimers about its TLV development process and the use of its TLVs, the group conveniently ignores that it knows how its TLVs are used. Moreover, ILMA suggests that the Subcommittee ask OSHA how much taxpayer money is spent each year on ACGIH publications, including the TLV handbook, and staff involvement in the organization.

There is a direct connection between the closed-process, secret development of ACGIH TLVs and affirmative worker health and safety regulatory responsibilities that American employers have under federal law. Under the Hazard Communication (HazCom) Standard, OSHA automatically adopts the latest version of ACGIH's TLV list every year and requires that manufacturers, including ILMA members, list the latest TLV limits on any Material Safety Data Sheet (MSDS) that they generate for use in the workplace. OSHA also uses new TLVs as the basis for, and to support, rulemaking actions that it initiates. OSHA can issue citations to employers under its "General Duty Clause" for violations of TLVs.

More important than the fact that the TLV development process and subsequent incorporation into U.S. worker health and safety regulations is patently unfair and fundamentally inconsistent with the premise of federal regulations (notice and the opportunity to comment and ultimately appeal), this non-consensus process generates defective decisions that have the potential to compromise the health and safety of the very workers the TLVs are designed to help as well as creating expansive

economic burdens on the business community, particularly the manufacturing sector. To illustrate, consider ACGIH's efforts to create a new TLV for mineral oil and mineral oil used in metalworking operations.

ACGIH's Proposed TLV for Mineral Oil—The Metalworking Fluid Industry's Perspective

On February 3, 2006, ACGIH released a draft version of a TLV recommendation for "Mineral Oil Used in Metal Working" and "Mineral Oil, Pure, Highly and Severely Refined." When used in metalworking situations, the draft TLV proposes a reduction from 5 mg/m3 to 0.2 mg/m3, time-weighted average (TWA). For "pure" mineral oil, the TLV remains at the current 5 mg/m3 TLV-TWA. In both cases ACGIH classifies highly and severely refined mineral oil as non-carcinogenic (A-4).

In other words, ACGIH is proposing to single-out mineral oil when used in metalworking operations and to reduce the TLV in those circumstances by a factor of 25.

As noted above, ILMA members manufacture more than 75 percent of all MWFs used in the United States. The scientists and industrial health and safety professionals that work for ILMA member companies likely account for the highest concentration of expertise on MWFs in the nation, if not the world. Because of ACGIH's closed and secretive TLV development process, ILMA's members had no role in developing the proposed mineral oil TLV.

From ILMA's preliminary assessment of the proposed TLV, there also appears to be a number of fundamental defects that are: (1) definitional; (2) conceptual, and (3) measurement/quantitative in nature. There is also a lack of context for the proposed TLV. These defects preclude the proposed TLV from presenting any positive value in the effort to protect worker heath and safety and will place an unconscionable economic and unnecessary regulatory burden on thousands of businesses, large and small.

Definitional Defects

MWFs are used in the processes of metal shaping, cutting and grinding. MWFs are also used to cool and lubricate in the metalworking environment. Though there are thousands of MWF products, most fall into four basic categories: (1) straight or neat oils; (2) soluble oils; (3) semi-synthetics; and, (4) synthetics.[1] Three of the four general categories of MWFs, straight, soluble and semi-synthetics all contain some quantity of mineral oil. Some have quite a bit of mineral oil (straight oil can have upwards of 90 percent), and some have very little mineral oil (semi-synthetics concentrates can have as little as 5 percent), especially after the concentrates are diluted before use.

Though the proposed TLV does not define "Mineral Oil Used in Metal Working," it notes that the proposed TLV of 0.2 mg/m3 is "recommended for occupational exposure to mineral oil aerosols in metal working operations where additives and metal or microbial contaminants are present." This statement appears to suggest that any MWF that contains some unspecified amount of mineral oil would be subject to the proposed TLV for mineral oil. Indeed, virtually all metalworking fluid products contain performance additives and, as a consequence of being used, contain very small pieces of the metal being "worked." Though ACGIH's stated goal is to reduce the alleged health impacts of mineral oil mist, the practical impact is to regulate thousands of metalworking products, some of which contain only a small fraction of highly refined mineral oil.

There is a major "disconnect" between ACGIH's stated purpose for proposing the new TLV (reduced occupational exposure to mineral oil mist) and the practical effect (setting a single TLV for a multitude of industrial products by way of an overly broad definition). The approach completely ignores not only the plurality of metalworking fluid products, but also the even larger plurality of industrial applications of metalworking fluid products. Furthermore, the practical effect of the definition

[1] Straight oils, used in today's MWFs typically consist of severely-solvent refined or severely-hydrotreated petroleum oil, or other oil of animal, vegetable or synthetic origin used singly, or in combination with performance additives. A movement toward exclusive industry use of severely refined base oil began in the 1960s and was complete by the mid-1980s, especially with the promulgation of the Hazard Communication Standard by the Occupational Safety and Health Administration.

Soluble oils contain severely-refined based oil, emulsifying agents and performance additives. The base oil content ranges from 30 percent to 85 percent, and these products, sold in concentrate, are then diluted with water at ratios ranging from 1:5 to 1:40.

Semisynthetics contain an even lower amount of severely refined base oil, maybe 5 percent to 30 percent (in the concentrate), and a higher fraction of emulsifiers and water (up to 50 percent of the concentrate). In concentrate, semisynthetics are translucent and are typically diluted with water at ratios ranging from 1:10 to 1:40.

Synthetics contain no mineral oil whatsoever.

(setting a TLV for most metalworking fluids regardless of mineral oil content) is in direct conflict with ACGIH's decision to limit TLV documentation to studies on straight mineral oil used in metalworking operations only, and to expressly exclude studies on the alleged heath effects of metalworking fluids. ACGIH, in other words, has proposed a de facto TLV for metalworking fluids while simultaneously and expressly excluding all studies of metalworking fluid.

ILMA believes that ACGIH's proposed definition of "Mineral Oil Used in Metal Working" simply could not be generated by an organization that relies on an open, consensus-based process for developing standards. The definitional inconsistencies between intended purpose and practical effect, not to mention the "Catch-22" documentation problem would just not make it through the brainstorming phase, let alone all the way to a proposed standard.

Conceptual Defects

The TLV distinguishes between "pure" mineral oils and mineral oils used in metal working operations. The proposed TLV for "pure" mineral oil 5 mg/m3 is twenty-five times higher than the proposed TLV for mineral oil used in metalworking, i.e., 0.2 mg/m3. ACGIH premises this distinction primarily on the presence of additives in metalworking fluids.[2] The existence of metals and microbial contaminants is also cited.

The proposed TLV also contains the following language:

A wide range of additives are used at concentrations ranging from a few parts per million to about 20% to modify the physical and/or chemical characteristics of mineral base oils in order to provide the performance requirements of specific applications. Additives are often proprietary materials and composition details will vary between individual suppliers.[3]

This distinction suggests that the alleged health effects of mineral oil in metalworking operations are due to constituents other than highly refined mineral oil—the additives, microbial contaminants and small pieces of metal commonly known as "fines" or "swarfs" generated by the metalworking process. ACGIH identifies neither additives nor microbial contaminants with any specificity, other than noting that these things "vary."

It stands to reason that if ACGIH's hypothesis is that constituents "in" or "added" to mineral oil when mineral oil is used in metalworking are the source of the alleged health effects, most of their attention should be focused on those constituents. Rather than dramatically lowering the TLV for mineral oil when used in metalworking, efforts should be undertaken to at least identify which constituents or combination of constituents (be they additives, microbial contamination or metal fines or swarfs) could be associated with any of the alleged occupational health effects. Once identified, suspect additives or microbial contamination phenomena should then be studied directly. This is an important point: by proposing to dramatically lower the TLV for mineral oils used in metalworking, ACGIH misses the significant opportunity to focus the resources of the organization on what might be truly causing the adverse health effects sometimes observed: microbial contamination.

This conceptual bungling is not merely a theoretical or academic problem. To the extent that an additive, a combination of additives or microbial contamination actually does present an occupational exposure risk, a TLV for mineral oil used in metalworking does nothing to protect against other occupational exposures to the same additives or combination of additives. More specifically, the same additives or contaminants could be found in synthetic metalworking fluids or metalworking fluids containing animal or vegetable oil—neither of which contain any mineral oil.

ILMA believes that these conceptual defects, just like the definitional defects would have been quickly rooted-out and corrected to the extent that ACGIH's TLV process was open and transparent rather than a closed, non-consensus process.

Measurement/Quantitative Defects

There are a number of critical measurement and quantitative interpretation errors in the proposed TLV that would not exist if the development process were open.

First, the test method contemplated to assure compliance with the new TLV does not just measure mineral oil; it measures "inhalable particulate mass." This test does not directly and specifically measure oil mist by itself, but rather a collection of general particulates, oil mist, and any organic compound that adheres to the sample and measuring equipment.

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[2] American Conference of Governmental Industrial Hygienists, Draft Total Limit Value Documentation, Mineral Oil (2006) at 1.

[3] Id. at 2.

Second, reliable measurements of total particulate at a level of 0.2 mg/m3 are not statistically feasible using standard measurement procedures. In other words, no generally available test procedure exists that would permit an industrial hygienist to even know whether a 0.2 mg/m3 is being achieved in any occupational setting. Conceptually, this is not unlike a state trooper using a radar device that can determine vehicle speed with an accuracy of +/− 5 miles per hour deciding to issue a speeding ticket for a motorist clocked at 66 mph in a 65 mph zone. The decision to set an exposure limit below what existing tests can tentatively measure would not pass muster in a true consensus standard setting process. Setting an exposure limit beyond what can be measured using state-of-the-art testing procedures is, in a word, silly.

Lack of Context for TLV Development

In addition to the manifold defects described above, ACGIH appears to have also largely ignored the fruits of an intensive discourse among the federal government, academia, industry and the courts regarding MWFs that has taken place over the past 13 years.

In 1993, the United Auto Workers (UAW), who is scheduled to testify at today's hearing, petitioned OSHA to regulate more stringently metalworking fluids and the components contained in the fluids (UAW sought to lower the Permissible Exposure Limit (PEL) for oil mist (mineral oil) from 5 mg/m3 to 0.5 mg/m3). The petition was unsuccessful, and UAW was also unsuccessful in asking the courts to force OSHA to take any regulatory action on MWFs. UAW v. Chao, 361 F.3d 249 (3rd Cir. 2004).

Concurrent with UAW's legal efforts, the federal government and industry continued to focus considerable attention on MWFs. Throughout the 1990s, industry, labor and the federal agencies partnered on a series of joint committees, seminars, meetings and workshops to discuss and develop better ways to understand the potential occupational risks associated with MWFs and voluntary strategies to address those potential risks. Notable efforts included:

- Multi-day symposiums in 1995 and 1997 on the metalworking environment, respiratory health and metalworking systems management jointly sponsored by NIOSH and American Automobile Manufacturers Association (AAMA). The events drew hundreds of people, including those from labor, government and other stakeholders;
- Organizational Resource Counselors (ORC), a human resource and health/safety consulting firm, convened a metalworking fluid task force in 1996 and published a comprehensive "Metal Removal Fluids Management Guide" in 1997 to be used by machine operators;
- ILMA formed the Metalworking Fluids Product Stewardship Group (MWFPSG) and joined ORC's efforts to issue a second edition of the Metal Removal Fluids Management Guide; and
- ACGIH held a two-day scientific symposium entitled "Health Effects of Mineral Oil Mist and Metalworking Fluids Symposium" in 2002, which was co-sponsored by ORC Worldwide, API, and the American Industrial Hygiene Association.

None of these above summarized efforts seem to have been incorporated into ACGIH's draft TLV for mineral oil used in metalworking, especially many of the peer-reviewed papers presented at the 2002 ACGIH symposium.

The Ripple Effect—The Challenges That The Work Force and Business Community Face When Federal Agencies Incorporate Defective Non-Consensus Standards into Their Regulations

In the event that the proposed TLV for mineral oil used in metalworking is finalized by ACGIH and subsequently adopted by OSHA, a chain reaction of needlessly costly events would take place.

First, all businesses that manufacture or use metalworking fluid that contains mineral oil as either a base or ingredient will be required to revise their MSDS information for those products. Costs associated this revision would be, on average, in the low six figures for each MWF manufacturer.

Second, businesses that use such metalworking fluids in their manufacturing operations (the customers of ILMA members) would be pressured to comply with the new dramatically lower TLV. One strategy would be to invest in costly new engineering controls in their facilities in an effort to try to meet the new impractical TLV. Such efforts would require expensive new machines or retrofitting existing machines, and the costly installation or retrofitting of ventilation systems. Prohibitive costs across the industry would be substantial and would likely exceed the capabilities of many smaller companies. Another option would be for customers to switch to synthetic or vegetable-based metalworking fluid products, which tend to be relatively more expensive than metalworking fluids that contain mineral oil. Though

some ILMA member companies that specialize in synthetic metalworking fluids would likely have some benefit, the change would cause palpable market disruption in the industry. The third option for many customers of ILMA members would be to move their manufacturing operations overseas.

In addition to these immediate steps, insurance rates could rise in anticipation of personal injury claims premised on the defective TLVs. Legal costs associated with such actions would burden these manufacturing businesses even further.

Putting a dollar figure on these events is difficult, especially given the intangible costs of industry's collective understanding of the confusing aspects of the TLV. Nevertheless, some of the estimates generated by the OSHA Metalworking Fluid Standards Advisory Committee process from 1997 through 1999 may prove instructive. During this process, the costs to retrofit existing automobile manufacturing facilities to achieve an exposure level for metalworking fluid of 0.5 mg/m3 were estimated to be about $1.9 billion for what was then the U.S. "Big Three," on top of the estimated $1 billion voluntarily spent on exposure reduction projects. Given that one estimate suggested that large automotive machining plants represented about 10% of the overall metalworking, it was estimated that the costs to achieve a level of 0.5 mg/m3 would be about $19 billion (in 1998 dollars). The costs to achieve a 0.2 mg/m3 TLV would be significantly higher.

The above-summarized defects are so serious as to render the proposed TLV effectively useless in any effort to improve occupational health and safety in the context of metalworking. Therefore, all monies spent and all actions undertaken by industry in response to this TLV being finalized and adopted by reference in OSHA's HazCom Standards will be money and time wasted. Further, because the focus is on mineral oil and not the additives or contaminants that might be truly causing the problem, dollars spent to retrofit existing machine tools with new engineering controls may still not yield a workplace setting fully protective of worker health and safety. The mistake will be measured in billions of dollars.

Possible Solutions to the Problem of the Federal Government's Improper Reliance on Non-Consensus Standards

In the scientific and research community, concepts and opinions (whatever the subject matter) that are not subject to challenge and peer-review by other scientists and researchers through an open, transparent process are generally accorded very little value. For these reasons, non-consensus standards, like TLVs now developed by ACGIH should be accorded very little value and should have minimal influence over industrial hygiene matters because they are patently non-consensus standards.

OSHA's tradition of annually adopting ACGIH's new TLV list has the practical effect of assigning an unwarranted and disproportionate importance to ACGIH's TLVs and sets into motion an absurd and needless "fire drill" for businesses impacted by the new TLVs and fosters an utterly false sense of security from the standpoint of occupational health and safety, because the TLVs are premised on the interpretation and evaluation of scientific data in a non-consensus setting.

If Congress enacted legislation (such as the provisions found in Senator Enzi's (R-WY) suite of OSHA reform bills, (S. 2066 to be specific)) that prohibits OSHA from adopting non-consensus standards, a number of very positive developments could take place.

First, in an effort to keep their TLV tradition alive, we suspect that ACGIH would voluntarily take efforts to reform the TLV development process so that it fit the notion of a "national consensus standard" as that term is defined in the Occupational Safety and Health Act (codified at 29 USC § 652 (3)(9)). OSHA would then also be able to rely on ACGIH's efforts in the manner contemplated by Congress in the NTTAA.

Second, by eliminating the monopoly that ACGIH has on developing occupational health and safety occupational exposure limits, other private organizations would have a legitimate opportunity to generate competing consensus standards. This competition would undoubtedly improve the integrity and quality of occupational health and safety data and the thoughtful application of the same in an effort to truly protect the American worker.

Third, and most importantly, the development of patently defective standards, such as the ACGIH TLV for mineral oil used in metalworking and other TLVs would no longer have artificially fertile ground in which to take root, and grow unchecked into flawed occupational exposure limits.

Conclusion

ILMA greatly appreciates the Subcommittee's continued interest in the topic of the use of non-consensus standards by federal agencies and respectfully urges that the Subcommittee take legislative action to assure that when federal agencies do

use standards generated by the private sector, the standards are developed in an open, consensus process.

We are, of course, happy to respond to any questions this statement may have raised.

Letter Submitted by David Felinski, Safety Director, the Association for Manufacturing Technology, Secretariat, ANSI B11 Series Reports

April 27, 2006.

Hon. CHARLIE NORWOOD,
Chairman, Subcommittee on Workforce Protections, Committee on Education and the Workforce, Rayburn House Office Building, Washington, DC.

After attending this morning's House of Representatives hearing (Subcommittee on Workforce Protection—non-voluntary consensus standards), I take strong exception to one of the comments Dr. Mirer (International UAW) made during his testimony. Although he was generally speaking about consensus standards, he specifically mentioned "machine tool standards" and made the following assertion that "they are not really consensus standards because it's just the users and the designers sitting around the table writing them."

I am the Safety Director for the Association for Manufacturing Technology (AMT). I am also the U.S. TAG Administrator to two separate ISO Technical Committees (in other words, I provide the U.S input into the ISO standards process in two separate committees), and I am the ANSI-accredited Secretariat and Standards Developing Organization (SDO) to over thirty American National (consensus) Standards and Technical Reports (ANSI B11 Series) on the subject of machine tool safety, ergonomics, risk assessment, control reliability, noise measurement, mist control and related topics. As Secretariat and Administrator, it is my role to ensure that we rigorously adhere to the ANSI (and ISO) developmental principles of Balance, Openness, Due Process, Consensus, and a mechanism for Appeals. I can assure you (and so can our ANSI auditor) that we maintain our accreditation precisely because we take those principles VERY seriously and adhere to them. Dr. Mirer's assertion is unfounded (certainly in our case, and I suspect it has little or no merit for the 203 other ANSI-accredited SDOs, but you should probably verify that with ANSI directly).

I am attaching a copy of our ANSI B11 Accredited Standards Committee roster; you will note that we have quite a variety of interest groups besides just "users" and "designers" including both OSHA and NIOSH. The International UAW used to be a Member of the B11 ASC until their representative retired a few years ago. We have been urging them to replace that person on the B11 ASC ever since (including my direct appeal to Dr. Mirer at the conclusion of today's hearing).

I should very much appreciate it if this "correction" to Dr. Mirer's unfortunate misstatement about the consensus standards process is entered into today's formal procedural record. Thank you.

Sincerely yours,

DAVID FELINSKI,
ANSI B11 Secretariat.

B11 ASC 2006

Company	Delegate	Alternate	Member Interest Category
AIAA—Aerospace Industries Association of America	Mr. Willard J. Wood, ARM Safety Administrator The Boeing Company PO Box 3707 MC 5C-04 Seattle, WA 98124-2207 Phone: 253-931-6491 Fax: 253-931-2747 Email: willard.j.wood@boeing.com	Mr. Lance E. Chandler Equipment Engineer The Boeing Company P.O. Box 3707 M/C: 50-51 Seattle, WA 98124-2207 Phone: 253-846-4018 Fax: 253-846-4149 Email: lance.e.chandler@boeing.com	Trade Association

B11 ASC 2006—Continued

Company	Delegate	Alternate	Member Interest Category
AEC—Aluminum Extruders Council Mr. Melvin Mitchell Safety Director MI Metals 301 Commerce Boulevard Oldsmar, FL 34677 Phone: 813-855-5695 x. 231 Fax: 813-855-6677 Email: mmitchell@mimetals.com	Mr. Doug Hart EHS Manager Pennex Aluminum Company 50 Community Street P.O. Box 100 Wellsville, PA 17365 Phone: 717-432-9647 x. 322 Fax: 717-432-4056 Email: dhart@pennexaluminum.com		Industrial/Commercial
AIAG—Automotive Industries Action Group	Mr. Ron Tillinger OH&S Program Manager AIAG 26200 Lahser Suite 200 Southfield, MI 48034 Phone: 248-358-9777 Fax: 248-358-3253 Email: rtillinger@aiag.org	Mr. Kent Lenzen OH&S Program Manager AIAG 26200 Lahser Suite 200 Southfield, MI 48034 Phone: 248-358-9777 Fax: 248-358-3253 Email: klenzen@aiag.org	Trade Association
ASSE—American Society of Safety Engineers	Mr. Bruce W. Main P.E. President Design Safety Engineering, Inc. PO Box 8109 Ann Arbor, MI 48107 Phone: 734-483-2033 Fax: 734-483-9897 Email: bruce@designsafe.com	Mr. George V. Karosas Senior Consultant 1100 West 31st Street La Grange Park, IL 60526 Phone: 708-352-9430 Fax: 708-352-9432 Email: gvkarosas@esi-il.com	Professional Society
AMT—The Association for Manufacturing Technology	Mr. Russell A. Bensman Staff Engineer The Minster Machine Company 240 W. 5th Street Minster, OH 45865-0120 Phone: 419-628-1765 Fax: 419-628-2222 Email: bensmanr@minster.com	Mr. Dan Soroka Director of Workholding Engineering Hardinge Inc. P.O. Box 1507 Elmira, NY 14902 Phone: 607-378-4423 Fax: 607-735-0650 Email: dsoroka@hardinge.com	Manufacturer Mr. Alan Metelsky Controls Engineering The Gleason Works 1000 University Ave. Rochester, NY 14692 PH: 585-784-6927 Fax: 585-241-4047 Email: ametelsky@gleason.com
The Boeing Company	Mr. Don R. Nelson Safety & Health Administrator The Boeing Company P.O. Box 3105 M/C: 031-AB10 Anaheim, CA 92803-3105 Phone: 714-762-3910 Fax: 714-762-0387 Email: don.r.nelson@boeing.com	Mr. Robert Eaker, PE, CSP Safety & Health Administrator The Boeing Company 2223 Field Avenue, N.E. Renton, WA 98059 Phone: 425-891-9517 Fax: 425-271-6723 Email: robert.j.eaker@boeing.com	User

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Company	Delegate	Alternate	Member Interest Category
CMI—Can Manufacturers Institute	Mr. Geoff Cullen Director of Government Relations Can Manufacturers Institute 1730 Rhode Island Avenue NW Site 1000 Washington, DC 20036 Phone: 202-232-4677 Fax: 202-232-5756 Email: gcullen@cancentral.com	Ms. Jenny Day Director Recycling Can Manufacturers Institute 1730 Rhode Island Avenue NW Site 1000 Washington, DC 20036 Phone: 202-232-4677 Fax: 202-232-5756 Email: jday@cancentral.com	Industrial/Commercial
DEERE & Co.	Mr. Gary D. Kopps Manager, Occupational Safety Deere & Company—Technical Center Occupational Safety Department One John Deere Place Moline, IL 61265-8098 Phone: 309-765-5155 Fax: 309-765-9860 Email: koppsgaryd@johndeere.com	Ms. Ellen Blanshan Occupational Safety Specialist Deere & Company—Technical Center One John Deere Place Moline, IL 61265-8098 Phone: 309-765-5691 Fax: 309-765-9860 Email: blanshanellen@johndeere.com	User
GM—General Motors	Mr. Michael Taubitz Global Regulatory Liaison General Motors Corporation PCC Central 2000 Centerpoint Pkwy. M/C/483-520-194 Pontiac, MI 48341-3147 Phone: 248-753-5771 Fax: 248-753-5831 Email: michael.taubitz@gm.com	Mr. Dallas Gatlin Mgr. Engineering Integration H&S General Motors Corporation PCC Central 2000 Centerpoint Pkwy. M/C 583-520-098 Pontiac, MI 48341-3147 Phone: 248-753-4761 Fax: 248-753-1004 Email: dallas.w.gatlin@gm.com	User
MBMA—Metal Building Manufacturers Association	Mr. Charles M. Stockinger Executive Director Metal Building Manufacturers Assn. 1300 Sumner Avenue Cleveland, OH 44115-2851 Phone: 216-241-7333 Fax: 216-241-0105 Email: mbma@mbma.com	Mr. Charles E. Praeger Metal Building Manufacturers Assn. 1300 Sumner Avenue Cleveland, OH 44115-2851 Phone: 216-241-7333 Fax: 216-241-0105 Email: mbma@mbma.com	Trade Association
MPIF—Metal Powder Industries Federation	Mr. Dennis R. Cloutier, CSP President Cloutier Consulting Services 6624 Parkland Avenue Cincinnati, OH 45233 Phone: 513-941-2917 Fax: 513-941-9727 Email: dennis@cloutierconsulting.com	Ms. Teresa F. Stillman Senior Mgr., Stand. and Tech. Services Metal Powder Industries Federation 105 College Road East Princeton, NJ 08540-6692 Phone: 609-452-7700 Fax: 609-987-8523 Email: tstillman@mpif.org	Trade Association

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Company	Delegate	Alternate	Member Interest Category
NIOSH—National Institute for Occupational Safety and Health	Mr. Richard S. Current, PE Research Engineer NIOSH Safety Research CDC 1095 Willowdale Road Morgantown, WV 26505-2888 Phone: 304-285-6084 Fax: 304-285-6047 Email: rcurrent@cdc.gov	Mr. James R. Harris Safety Engineer NIOSH 1095 Willowdale Road Morgantown, WV 26505-2888 Phone: 304-285-6120 Fax: 304-285-6047 Email: jharris@cdc.gov	Regulatory Agency
OSHA—Occupational Safety and Health Administration	Mr. Ken Stevanus Mechanical Engineer 200 Constitution Ave. NW Room N3609 Washington, DC 20210 Phone: 202-693-2260 Fax: 202-693-1663 Email:stevanus.ken@dol.gov	Mr. Robert Bell Mechanical Engineer 200 Constitution Avenue, NW Washington, DC 20210 Phone: 202-693-2053 Fax: 202-693-1663 Email: bell.rb@dol.gov	Regulatory Agency
PCI Property Casualty Insurers	Mr. John W. Russell Technology Director Liberty Mutual 2100 Walnut Hill Ln.,Ste. 100 Irving, TX 75002 Phone: 800-443-2692-x2880 Fax: 972-518-1923 Email: john.russell@libertymutual.com	Mr. Keith Lessner Vice President Property Casualty Insurers 2600 South River Road Des Plaines, IL 60018 Phone: 847-297-7800 Fax: 847-297-5064 Email: keith.lessner@pciaa.net	Insurance
PMMI—Packaging Machinery Manufacturers Institute	Mr. Charles F. Hayes Director of Technical Services PMMI P.O Box 678 Marshall, MI 49068 Phone: 269-781-6567 Fax: 269-781-6966 Email: cfhayes@voyager.net	Ms. Maria Ferrante Director of Workforce Development PMMI Suite 600 4350 N Fairfax Drive Arlington, VA 22203 Phone: 703-243-8555 Fax: 703-243-8555 Email: maria@pmmi.org	Manufacturer
PILZ—Pilz Automation Safety, LP	Ms. Roberta Nelson Shea General Manager Pilz Automation Safety, LP 7150 Commerce Boulevard Canton, MI 48187 Phone: 734-354-0272 Fax: 734-354-3355 Email: R.NelsonShea@pilzUSA.com	Mr. Lee Burk Training Manager Pilz Automation Safety, LP 7150 Commerce Boulevard Canton, MI 48187 Phone: 734-354-0272 Fax: 734-354-3355 Email: L.Burk@pilzUSA.com	Manufacturer
PMA—Precision Metalforming Association	Mr. William E. Gaskin President Precision Metalforming Association 6363 Oak Tree Boulevard Independence, OH 44131 Phone: 216-901-8800 x121 Fax: 216-901-9190 Email: wgaskin@pma.org	Ms. Christen A. Carmigiano Government Affairs Manager Precision Metalforming Association 6363 Oak Tree Boulevard Independence, OH 44131 Phone: 216-901-8800 Fax: 216-901-9190 Email: ccarmigiano@pma.org	Manufacturer

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Company	Delegate	Alternate	Member Interest Category
PSDMA—Presence Sensing Device Manufacturers Association	Mr. James V. Kirton Kirton Industrial Eq. LLC. 25 Skilton Rd. Watertown, CT Phone: 860-417-3097 Fax: 860-417-3097 Email: jimkirton@optonline.net	Mr. Michael S. Carlson Safety Products Marketing Manager Banner Engineering Corporation 9714 Tenth Avenue North Minneapolis, MN 55441 Phone: 763-593-3934 Fax: 763-544-3213 Email: mcarlson@bannerengineering.com	Distributor/Retailer
RIA—Robotic Industries Association	Mr. Jeff Fryman Director, Standards Development Robotic Industries Association PO Box 3724 Ann Arbor, MI 48106-0000 Phone: 734-994-6088 Fax: 734-994-3338 Email: jfryman@robotics.org	Ms. Roberta Nelson Shea General Manager Pilz Automation 7150 Commerce Blvd. Canton, MI 48187 Phone: 734-354-0272 x.208 Fax: 734-354-3355 Email: R.NelsonShea@pilzusa.com	Manufacturer
Rockwell—Rockwell Automation	Mr. Steven Dukich Senior Commercial Engineer Rockwell Automation 2 Executive Drive Chelmsford, MA 01824 Phone: 978-446-3214 Fax: 978-446-3322 Email: srdukich@ra.rockwell.com	Mr. Jay Tamblingson Manager, Application Engineering Rockwell Automation 1201 South Second Street Milwaukee, WI 53204 Phone: 414-382-4556 Email: jetamblingson@ra.rockwell.com	Manufacturer
STI—Scientific Technologies Incorporated	Mr. Frank Webster Vice President, Engineering Scientific Technologies, Inc. 6550 Dumbarton Circle Fremont, CA 94555 Phone: 510-608-3443 Fax: 510-608-7443 Email: fwebster@wbstr.com	Mr. Chris Soranno Machine and Process Safety Engineer STI Machine Service, Inc. 4501 Mackall Road South Euclid, OH 44121-4239 Phone: 216-224-5467 Fax: 440-794-7069 Email: chris—soranno@sti.com	Distributor/Retailer
SMACNA—Sheet Metal and Air Conditioning Contractors National Association	Mr. Michael McCullion Director of Safety and Health SMACNA, Inc. 4201 Lafayette Center Drive Chantilly, VA 20151-1209 Phone: 703-995-4027 Fax: 703-803-3732 Email: mmccullion@smacna.org	Mr. Roy Brown Safety Director SMARCA 1405 Lilac Drive North Suite 100 Minneapolis, MN 55422 Phone: 763-593-0941 Fax: 763-593-0944 Email: roy@smarca.com	Industrial/Commercial
TMA—Tooling and Manufacturing Association	Mr. Daniel Kiraly Director of Education Tooling & Manufacturing Association 1177 South Dee Road Park Ridge, IL 60068 Phone: 847-825-1120 x346 Fax: 847-825-0041 Email: dkiraly@tmanet.com		Manufacturer

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Company	Delegate	Alternate	Member Interest Category
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Prepared Statement of Andrew P. Morriss, Galen J. Roush Professor of Business Law & Regulation, Co-Director of Center for Business Law & Regulation, Case Western Reserve University School of Law, Senior Scholar, Mercatus Center at George Mason University*

Chairman McKeon and Members of the Committee, thank you for inviting me to submit testimony on the use of non-consensus standards in workplace safety and health regulation. I am a professor of law and an economist with over forty published articles and book chapters, largely on regulatory issues. I have recently researched the use of non-consensus standards in OSHA rulemaking for a forthcoming article in the Administrative Law Review (Spring 2006), with coauthor, Susan Dudley, Director of the Regulatory Studies Program at the Mercatus Center at George Mason University. I have attached a draft of that article, "Defining What to Regulate: Silica & the Problem of Regulatory Categorization," for the record.

Many current Occupational Safety and Health Administration standards are based on consensus standards developed by the American Conference of Governmental Industrial Hygienists (ACGIH). A historical review of how the ACGIH consensus standards became so influential is interesting and enlightening for the current debate.[1]

Initially organized in 1936 as the Temporary Conference of Official Industrial Hygienists, the ACGIH soon became the National Conference of Governmental Industrial Hygienists (NCGIH) and in 1946, adopted its current name. Its influence grew after World War II, in part because organized labor focused its efforts mainly on wages, rather than workplace issues like industrial diseases. The private sector lead improvements in workplace health after the war, and industry turned to the industrial hygienists' trade organization for standards. The ACGIH, which had expanded its membership criteria to offset the decline in government activity after the war, began to receive requests from firms for standards governing workplace exposure. The organization formed the Committee on Industrial Hygiene Codes, and it created a table of "maximum allowable concentrations" (MACs) as a first step toward a comprehensive industrial hygiene code in 1946. A separate Technical Standards Committee also considered the issues and took over the project. The organization also took advantage of increased interest in the subject during the war "to organize and develop industrial hygiene agencies where they had not previously existed. By the end of the war a network of units had been established in nearly every state and many large industrial cities."[2]

ACGIH then published its maximum allowable concentrations as "Threshold Limit Values." The organization insisted that the TLVs were merely guides and not "fine lines between safe and dangerous concentrations."[3] Despite regular repetition of such warnings, however, many states used TLVs as legal limits in state-level

*Affiliation given for identification purposes only.

[1] More detailed references to the source materials for the information provided in this testimony can be found in, "Defining What to Regulate: Silica & the Problem of Regulatory Categorization," by Andrew Morriss & Susan Dudley, forthcoming in the Administrative Law Review (spring 2006). Draft available at *http://papers.ssrn.com/sol3/papers.cfm?abstract—id=781684*.

[2] Jacqueline Karnell Corn, Protecting the Health of Workers: the American Conference of Governmental Industrial Hygienists, 1938-1988, at 43 (1989).

[3] See *Corn* at 60 (quoting the Committee on Threshold Limits).

workplace regulatory schemes, and they continue in widespread use around the world. The TLVs offered firms a focal point around which to structure their workplace safety campaigns, without requiring the firms to invest individually in the research necessary to set them. And firms could point to their compliance with "industry standards" if questions were raised about particular substances. The range of substances to which employees were exposed grew with the post-war explosion in the chemical industry, but there was no increase in dust exposures comparable to that introduced by the industrial revolution.

Between 1961 and 1970, it issued 220 TLVs, bringing the total to 500. ACGIH, and the TLV committees within ACGIH, had considerable autonomy. The organization rejected the consensus approach of the American Standards Association because its members asserted that experts should set the health standards without interference from outsiders and that ACGIH members' governmental employment freed them from conflicts of interest. But, public choice theory raises the question, what were ACGIH's and others' interests in the regulatory adoption of the TLVs?

First, the organization delivered professional status to its members, allowing them to both improve their status within firms and bureaucracies and to raise the profession as a whole. The ACGIH's role in setting standards adopted by state governments, and eventually the federal government, enhanced that status. Second, the adoptions gave the organization influence: Firms followed its recommendations, and government agencies adopted its TLVs. Strong evidence that the organization derived some benefit from their use can be found in the fact that the organization and its members tolerated such uses over long periods, uses that directly contradicted the TLVs stated purposes.[4]

Section 5(a) of the OSHAct mandates the Secretary of Labor to adopt, without dealing with title 5 of the Administrative Procedures Act, as soon as practicable, any of the consensus standards already established in federal regulations * * * Some argue that the Secretary had discussions (before adopting the standards). Others argue that the adoption was automatic because the big employers were already using these standards. *Corn*.

In addition, "There was some discussion in ACGIH about whether to adopt a consensus method, but ACGIH did not do so." *Corn* As one person described the situation:

Stokinger saw the legislation (OSHAct) required consensus standards from that point on (for the purpose of their being adopted as OSHA regulations.) So he looked around and appointed industry and union representatives on the TLV committee for the first time. I don't think this is appreciated. Stokinger was wrong, but he thought he could make the TLV committee (into) a consensus body if there were industry and union representatives. *Corn*

The ACGIH also played an important role for large firms, which, in turn, assumed key roles in creating and determining the TLVs. As one study noted, "It is easy to document the influence of industry, and of industry consultants in ACGIH,"[5] especially since unions generally did not participate in the TLV process and the ACGIH developed TLVs largely in response to industry requests.[6] Large firms thus obtained standardized TLVs around which state regulations, and eventually federal regulations, coalesced, helping prevent inconsistent standards. The process gave the firms influence over both the substances included and the levels set—influence they would

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[4] TLVs for about 400 substances were incorporated into OSHA consensus standards via their earlier use under the Walsh-Healey Act standards, although some were "based on inadequate documentation." See *Corn* at 91 (describing OSHA's congressional authority to bypass rulemaking procedures and establish "start-up" standards). ACGIH did not attempt to stop OSHA's inappropriate use of the TLVs. See *Corn* at 92 (clarifying that the TLVs were not meant to be standards). According to Corn, "ACGIH seemed to have mixed emotions about use of the TLVs. They wanted to contribute to the new federal effort to bring about a healthy and safe workplace, and they were proud of the TLVs. Very little discussion can be found about this issue." *Corn* at 92. In the one discussion recorded in the minutes, ACGIH seems to have been resigned to OSHA's inappropriate use of the TLVs. See *Corn* at 92 (elaborating that, although the ACGIH was displeased with the Labor Department for misusing the TLVs, it felt that if the Labor Department was going to use TLVs for that purpose it might as well use ACGIH's TLVs). The board responded to a question from the floor by saying: "There is nothing in my opinion, that ACGIH can do to prevent or stop anyone, any state or federal agency, from using our ACGIH TLVs in standards." *Corn* at 92-93. One participant recalled that, despite the language in the TLV publications warning against treating them as standards, the group "was rather tickled with themselves that the TLVs were being used that way." Interview with Leonard J. Goldwater, in *Corn* at 145. Goldwater also noted that the ACGIH "took no measures, whatsoever, to disassociate themselves from [OSHA's use of the TLVs] after it was made, after these things were adopted." *Corn* at 144. ACGIH standards were technically "not consensus standards, but the legislation establishing OSHA required that only consensus standards be adopted." *Salter*, at 42. As one informant [to the study] suggested:

[5] *Corn*. at 59. ACGIH and its members, however, deny that they are biased toward industry. Id. (explaining that many ACGIH members view the organization as an "industry watchdog").

[6] Liora Salter, Mandated Science: Science and the Scientists in the Making of Standards 47-48 (1988) (describing generally the informal process by which the ACGIH sets priorities and develops standards).

find much harder to exercise over government regulatory bodies. ACGIH thus played a larger part than the Baptists (to large firms "Bootleggers") in a "Bootleggers and Baptists" regulatory coalition.[7] It was a priestly caste in a theocracy.

Moreover, the eventual expansion of the federal role in occupational health and safety was foreseeable long before the creation of OSHA in 1970. The role of the ACGIH TLVs was also foreseeable. One ACGIH member and government agency employee described the use of TLVs by OSHA to a researcher as follows:

"I don't think it was accidental. There had been several attempts over the preceding years to promulgate an OSHAct * * * and it was just a question of time as to when there would be a national occupational health and safety program. The language of the OSHAct specifically provided for the Secretary of Labor to promulgate as interim or start-up standards, national consensus standards, that had already been promulgated under certain Acts including the Walsh-Healy Act. Now the people in the Bureau of Labor Standards who were responsible for promulgating those standards were the same people who were going to be responsible under OSHA for setting the interim standards. Many of these people were ACGIH members but that doesn't make it an ACGIH decision. These people knew what was coming down the road and that they would have a job to do. If you had that responsibility, what would you use?"[8]

The expansion of ACGIH's TLVs during the 1960s, and their "inappropriate" use in state, and eventually federal, regulations served not only the interests of the members, the organization, and the large firms, but also politicians. President Nixon supported initiatives like environmental legislation, at least in part for political advantage, but he also wanted to keep these initiatives carefully constrained to avoid incurring economic penalties or alienating his business supporters. Adopting the consensus standards, already in use at many large businesses, both satisfied his political need to appear to be doing something and minimized the economic effects and potential decline in support from business.

The passage of the OSH Act dramatically changed the institutional environment, and enhanced ACGIH's influence. The statute separated standard-setting and enforcement from the development of technical knowledge about workplace hazards, locating the former in OSHA and the latter in NIOSH.[9] It required the agencies to act quickly to create a base of federal standards.[10] OSHA had only two years to convert existing consensus standards into legally binding ones unless the agency found that doing so would not improve safety and health. This provision led to OSHA's wholesale adoption of things like the ACGIH TLVs as standards. Shortly after Congress established OSHA in 1971, the agency issued more than 4,000 general industry standards, based on national consensus standards of the American National Standards Institute and the National Fire Protection Association, as well as existing federal maritime safety standards. In just four months, OSHA took more than 400 pages of standards from a variety of prior programs and voluntary organizations and converted them into regulations. This had the effect of converting a set of largely discretionary industry guidelines into mandatory workplace design standards and, as noted below, changed the role of other agents in the market for health and safety.

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[7] The bootleggers and Baptists theory of regulation suggests that two different groups often work together to achieve political goals. See Bruce Yandle, Bootleggers and Baptists: The Education of a Regulatory Economist, AEI J. Gov't & Society 13 (May/June 1983), available at *http://www.mercatus.org/pdf/materials/560.pdf.* Like the bootleggers in the early twentieth-century South, who benefited from laws that banned the sale of liquor on Sundays, special interests need to justify their efforts to obtain special favors with public interest stories. The Baptists, who supported the Sunday ban on moral grounds, provided that public interest support. While the Baptists vocally endorsed the ban on Sunday sales, the bootleggers worked behind the scenes and quietly rewarded the politicians with a portion of their Sunday liquor sale profits. *Id.*

[8] *Salter* at 42.

[9] Under the OSH Act, when NIOSH recommends that OSHA promulgate a health standard, the Secretary of Labor must, within 60 days after receipt thereof, refer such recommendation to an advisory committee pursuant to this paragraph, or publish such as a proposed rule pursuant to paragraph (2), or publish in the Federal Register his determination not to do so, and his reasons therefor. The Secretary shall be required to request the recommendations of an advisory committee appointed under section 812(c) of this title if the rule to be promulgated is, in the discretion of the Secretary which shall be final, new in effect or application and has significant economic impact. 30 U.S.C. § 811(a)(1) (2000).

[10] This was supplemented by a general duty provision. The Act established a general duty on the part of employers to "furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees; and [to] comply with occupational safety and health standards promulgated under this chapter." 29 U.S.C. § 654(a)(1)-(2) (2000).

Some have criticized OSHA for not attempting to "sort through the existing standards to weed out those that were obviously silly and outdated."[11] Salter's study and Corn's institutional biography both suggest, however, that because ACGIH members in their capacity as bureaucrats were involved in the process the explanation may not lie in a lack of knowledge about whether particular provisions were "silly or outdated" but rather in a wholesale acceptance of a broader role for TLVs than had ever been officially acknowledged as a goal by ACGIH. Reinforcing this interpretation is the recollection of an ACGIH member, who described the situation to Professor Salter as follows:

At the time of OSHA's creation, there was a lot of soul searching at ACGIH. We wondered whether we should just fold up our tent and go home. There was a lot of encouragement in that direction coming from NIOSH. NIOSH felt that now it had legal responsibility for establishing criteria for standards, that ACGIH's TLV committee had done its job well, but that now we were in a new era and NIOSH superseded us. There were a lot of people at NIOSH who felt that way and weren't afraid to express it to the TLV committee and ACGIH itself. I was on the Board of Directors, but I think even more discussion was taking place in the TLV committees. It ended up with a wait and see attitude for a couple of years. By the mid1970s, there was a realization that the new system was not going to be responsive to current problems.[12]

Converting the TLVs into standards served the interests of the ACGIH by giving it a rationale for continuing its work and served the interests of OSHA in getting regulations on the book quickly.

Moreover, OSHA standards did not come into existence in a vacuum. Before OSHA, there were state and local regulatory efforts as well as vo luntary standards like the ACGIH TLVs. Large firms operating across jurisdictions benefited from nationalizing regulations, getting rid of conflicting local standards, and shifting the regulatory focus to Washington where they could afford to maintain lobbyists and lawyers. Indeed, the threat of conflicting state and local regulation remains a potent one. When the new Reagan Administration stopped work on a Carter Administration proposal for "right to know" rules, for exa mple, unions began lobbying for state and local versions. Worried about a patchwork of inconsistent rules, industries then sought federal rules that would preempt local standards. Adopting the ACGIH TLVs, with which they were already familiar, gave larger firms an advantage and forced their smaller competitors to incur additional costs.

The creation of NIOSH and OSHA led to "an enormous growth of professionals" in industrial hygiene: ACGIH membership boomed, and for the first time, a majority of ACGIH employees came from federal agencies. Membership soared from approximately 1,000 in 1968, to over 1,500 in 1973, to almost 2,500 in 1983.[13] An organization that began in 1938 primarily consisting of 76 employees, almost all state and local agency employees, grew to 3,720 members, with a substantial federal contingent, by 1988.[14]

In the case of crystalline silica, the subject of my research, knowledge of health effects grew after World War II largely through a combination of public and private investment. NIOSH and the International Agency for Research on Cancer (IARC) both pulled together a great deal of research on silica, but that research came from a mixture of private, nonprofit, and public sector funded researchers. Post-war problems with silica stem largely from OSHA's involvement. By ossifying the ACGIH standard, OSHA eliminated the flexibility of the ACGIH process without adding any compensating benefits (such as more comprehensive analysis) to the near universal acceptance of the TLV. OSHA's failure to respond to NIOSH and IARC since NIOSH first warned of the existing standard in 1974 is a textbook example of go vernment failure.

The regulatory history of silica shows not only that our understanding of health effects is constantly evolving, but that knowledge about hazards is endogenous—it arises in response to outside events, regulations, and interest groups. Accepting particular states of knowledge as definitive is thus a mistake, as is failing to consider the incentives for knowledge production created by regulatory measures.

Recognizing what Frederic Hayek called "the knowledge problem" is essential when it comes to understanding the appropriate role of organizations such as

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[11] Thomas O. McGarity & Sidney A. Shapiro, *Workers at Risk: the Failed Promise of the Occupational Safety and Health Administration* 37 (1993).

[12] *Salter* at 41.

[13] *Salter* at xi.

[14] *Salter* at x.

ACGIH, and occupational health issues generally.[15] First, before issuing new regulations, OSHA should clearly define what market failures, if any, impede efficient solutions to address health risks. Both employers and employees have incentives to protect health and safety in the workplace. Lack of information, particularly due to the lo ng latency period for many occupational diseases, may dampen these incentives. If the problem is a lack of information on risks and remedies, OSHA, and its research counterpart NIOSH, should focus on generating and dispersing better information. Although occupational health is not a field in which market forces are trusted, the serious problems with the current system cannot be solved without recognition of the important role played by the Hayekian knowledge problem.

The federal government can play two important roles in this information market place. It can be a supplier. Through entities like NIOSH, the government can sponsor and conduct research that will influence standards. It can be a consumer. Just as it did under the Walsh-Healey Act before OSHA's creation in 1970, the government can demand that its information suppliers meet standards the government believes are effective.

Further, any regulatory action must recognize the diversity in exposure and response across the varied workplaces. Heeding the lessons we've learned from the history of silica in the workplace, it is important to contrast the interest group incentives provided by a regulatory effort aimed at developing a uniform standard with those of a policy aimed at generating and disseminating information. The uniform standard provides incentives to interest groups to invest resources in influencing the standard to suit private goals (for example, gain advantage over competitors). In contrast, a focus on information provides incentives for interest groups to compete to develop and provide better information in support of their views of the risks and remedies.

The "market" for standards that existed before OSHA consisted of groups like the ACGIH, unions, trade associations, and others. NIOSH's entry into this market changed the dynamics, primarily because of the influence of NIOSH criteria documents in initiating OSHA standards. Encouraging the development of competing standards for occupational health would create market pressure for increasing knowledge about harms. Competitive standards have operated successfully in a number of areas, including organic food certification and kosher labeling, and have successfully improved quality in a number of areas.

In contrast to flexible standards that respond to different information, a uniform standard proves hard to adjust as new information becomes available, as is evidenced by the current OSHA exposure limit of 0.10 mg/m3. Knowledge is dynamic, and uniform standards necessarily lock in expectations based on the level of knowledge available at a given time. In particular, regulations that specify which remedies are acceptable or unacceptable discourage innovation into better solutions.

Economics teaches us that people respond to incentives and groups such as the ACGIH are no exception. A legitimate concern is that this could result in the "capture" of an organization by a set of interest groups. The best solution to this problem is to encourage competition among various organizations for evaluating health risks and developing standards. Competition would encourage exposure of inappropriate behavior, force organizations to justify their work product to win acceptance of their standards, and provide a marketplace of ideas about the most appropriate response. The problem we thus face is not that private organizations like ACGIH produce standards but that those standards sometimes become ossified through their adoption by government agencies, limiting the incentive to produce competing standards that could develop new solutions.

[Additional submission by the Mercatus Center of George Mason University placed in permanent archive file, *Defining What to Regulate: Silica & the Problem of Regulatory Categorization,* forthcoming, Administrative Law Review, spring 2006, Andrew P. Morris and Susan E. Dudley, draft, 26 April 2006.]

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[15] *See generally* Friedrich A. Hayek, *The Use of Knowledge in Society,* 35 Am. Econ. Rev. 519 (1945) (discussing problems with economic theory and the refinements needed to resolve those problems). Hayek's central point was that decentralized markets focus dispersed information—information that no one individual (not even a regulator) can obtain—and convey it efficiently to market participants.

Prepared Statement of the Precision Machined Products Association

Executive Summary

The protection of worker safety and health is an important national priority, and one with which the federal government is entrusted. This is not a new idea, Hippocrates said "In the first place, do no harm." That is a powerful charge and only requires seven words to make the point. What is new today, however, is that, as industrial processes grow more complex, and materials increase in number, the charge to "do no harm" requires a few more resources than one wise old man and seven words.

The OSH Act established as a foundation, the use of "National Consensus Standards" to assure that wisdom would be the cornerstone of their rulemaking and enforcement. The phrase "National Consensus Standards" provides us with a beacon of what was expected to be used as the basis of OSH regulatory activities. However today, "National Consensus Standards" are an illusion at best, they reflect neither national interests nor are they reflective of a true consensus, nor do they reflect a "standard" that would be constructed were a true "national consensus" of authorities empanelled to develop them.

The reliance of OSHA on non-consensus standards is bad governance, it's a bad example of how markets should work, its bad way to base policy, and it's bad science. Unless open consensus standards are used, there is no means to provide corrections—and those affected, those thought to be protected, the economy, the country and all of us will be impacted by the full weight of the law as directed by what ever the unknown biases, mistakes, omissions, and systemic errors the closed door process is subject to.

Hardly a description of "In the first place, do no harm."

PMPA—Making The Parts That Make Our World Safer

The Precision Machined Products Association is a not for profit 501(c)6 association representing the manufacturing companies of the NAICS 332721 Precision Machining Industrial Classification. Sales in our industry are reported to be $8.96 billion dollars for 2004 according to the US Census. Our industry consists of approximately 525 industry establishments and approximately 71,662 employees. Our association represents 500 member companies, approximately 350 of which are directly engaged in NAICS 332721. The balance of our members are suppliers to our industry. Our member companies are smaller enterprises, (median sales around $4 million annually) that apply their machining and manufacturing know how to produce precision components that not only make our world run—but also make our world safer. Automotive parts produced by our members range from simple fasteners that might anchor a seat belt to the floor through complex safety critical, anti-lock braking components and parts for airbags for occupant safety. Our members make parts used in plumbing, HVAC, fluid power, electrical and electronic applications as well as for aerospace technologies. Our members also produce a host of components for military armaments and the Department of Defense.

Many of our members are producing the ultimate in precision-machined parts—medical implants such as bone screws and other implantable products. The products that we make are generally metallic—steel, aluminum, brass and titanium, and include many others. Our members manufacture parts to very precise geometries and tolerances by machining, that is, by taking stock removal by cutting using tools on both mechanical automatic screw machines and also using Computer Numeric Controlled (CNC) machines.

In order to achieve the high precision and surface finishes needed by today's technologies, metalworking fluids are used to remove the heat from the work, help remove the chip from the cutting area, and to provide lubricity, control build up, and perform other functions. With metalworking fluids such an important part of our process, it is critical to our industry's sustainability that any regulations applied to our processes be the result of good science and a functional policy environment where the checks and balances exist to assure that the interests of all affected parties are given fair regard.

Our interest in the issue of non-consensus standards is driven by the fact that we will be the ones who have to bear the burden of bad policy and bad science implemented into law. Closed, smoke filled rooms have never been preferred to the fresh air and sunshine of open public processes, and the lack of an open dialogue and opportunity to participate in the processes that will determine the rules of the game for our manufacturing operations and our worker's safety is troubling, when we and other affected constituencies are not even given a seat at the table.

Congressional action is needed to assure that OSHA relies only on National Consensus Standards that are developed in an open, balanced public process such as

was directed by the National Technology Transfer and Advancement Act of 1995 (NTTAA); in fact the legislation that enables the Occupational Safety and Health Administration, 29 USC § 652(3)(9) also calls for true open national consensus. The current reliance on non-consensus standards excluding input from those affected seems contrary to the spirit of these congressional mandates.

PMPA Objects To The Use Of A Closed Non-Consensus Process For Determining TLV's For Regulatory Enforcement

American Council of Government Industrial Hygienists (ACGIH) does not employ an open consensus process where members from industry and other affected stakeholders may participate and share their intimate and practical knowledge on the subject. The closed TLV development process makes for bad science. Science functions best when the facts and data used to create one's findings are subjected to open scrutiny of other professionals. The exclusion of other knowledgeable professional industrial hygienists thereby makes the TLV's not subject to the self-correcting nature of scientific discourse.

This flaw in the process of creating TLV's thus condemns them as nonscientific, in the sense expressed by Mellett in 2004: "when a scientist, regardless of their field of expertise, publishes the results of their work, other scientists will subject their work to verification. Thus errors in science are detected very quickly. Indeed, you can argue that scientific progress is impossible without the search for error." The ACGIH closed-shop model of only insiders and not industry professionals participating in the development of TLV's thus removes a key component of scientific legitimacy, the public and open examination, verification, and correction of errors by other professionals. The ACGIH non-consensus methodology thus can be seen as not just being bad science—but rather "non-science" in that it lacks this key self-checking mechanism of the scientific community.

PMPA Objects To The ACGIH's Process Ignoring Prior Art And Knowledge in Their Process For Determining TLV's For Regulatory Enforcement

ACGIH has ignored prior art and knowledge in the area of metalworking fluids in its apparent determination to lower the TLV regardless of the facts. There is a history of and body of knowledge on the subject of metalworking TLV's in the public starting initially with the unsuccessful petition of OSHA by the United Auto Workers to more stringently regulate metal working fluids and their components in 1993. The UAW then sought to use the courts to advance their case for lowering limits on Metalworking fluids—UAW v. Chao, 361 F.3d 249 (3rd cir.2004). PMPA was part of a successful industry effort to stop this unwarranted regulation. As other testimony has shown, symposia, task forces, and other meetings have been convened on the subject of metalworking fluids. Despite the outcome of UAW v. Chao, the same TLV is now being proposed via a non-public non-consensus ACGIH route.

This ignoring of existing data and the court decision repudiates any claim that ACGIH might make for openness of its process or legitimacy of its dictates.

PMPA Objects To The ACGIH's Process For Determining TLV's For Regulatory Enforcement In Which Alleged Causative Agents Remain Unidentified, Resulting In An Overly Broad Regulatory Action On All Mineral Oil Containing Metalworking Fluids

The closed ACGIH process has resulted in a TLV standard for which the alleged causative agents remain unidentified. By not including industrial hygienists with industry expertise into their closed consensus process, our industry may soon be facing the task of managing a vague and undefined threat to our employee's safety—"mineral oils aerosols in metal working operations where additives and metal or microbial contaminants are present." This vague statement might be interpreted:

A. That the metal working fluid, by nature of having mineral oil content is the basis for the need for the lowered TLV;

B. That the additives might be the reason for the need for the lowering of the TLV;

C. That the metal contaminants might be the reason for the lowered TLV;

D. That microbial contaminants might be the basis for the recommendation for the lowered TLV.

This overly broad, nonspecific statement is bad science in that it does not establish which if any of the constituents named might actually be causative and justify the lowering of the TLV. Thus, the non-consensus process employed by the ACGIH has resulted in, if we may be permitted to use a metaphor, a regulatory approach that attempts to "ban cars rather than arrest drunk drivers." Overly broad, all-inclusive categories when no specific causative agent is identified makes for bad science, is bad policy, and it is sloppy governance.

PMPA Objects To The Potential Costs And Consequences Resulting From the ACGIH's Non-Consensus Process For Determining TLV's For Regulatory Enforcement

The potential costs and consequences of the ACGIH TLV proposal resulting from their non-consensus process are significant to our economy and our way of life. The costs to implement compliance in manufacturing to the proposed TLV have been estimated to be about $19 billion in 1998 dollars. Assuming that our GDP is $13 trillion, the cost of compliance with this rule would be one and a half tenths of a percent of US GDP. Our industry's total sales in 2004 were $8.96 billion dollars. As a result of a closed shop, non-public, non-consensus process, metalworking industries are likely to incur costs that are roughly double the total sales of the precision turned products industry's annual sales.

The non-public, non-open, non-consensus process employed by ACGIH has neither identified allegedly harmful causative agents, nor a mechanism for employee harm—just an overly broad categorical condemnation of metalworking fluids in general if they contain mineral oils. However, there is no denying that the costs to re-engineer our workplaces so that we can comply with the proposed TLV will close many of our shops and terminate the employment of many of our nation's most skilled workers. Does America want to take a family whose breadwinner operates two or three, million dollar pieces of precision machining equipment, who produces millions of dollars in sales revenue annually, earning up to $20 per hour plus benefits, producing more than up to 20 foreign workers, and force them out of work? Just because a group of uninvolved people, without input from anyone affected, thought that we would be better off with a standard that is close to the limit of our current technology's ability to determine conformance with?

Summary

The current closed, non-public, non-consensus process utilized by ACGIH lacks openness and any means of introducing daylight or any ability to correct or independently confirm the validity of its product Threshold Limit Values (TLV's) for regulating industry. By ignoring and excluding the input of all affected parties, the closed process employed by ACGIH is little more than bureaucratic bullying. This process may well have us on a fast track to waste—as it is conceivably a means of wasting almost one and a half tenths of a percent of U.S. GDP for no scientifically demonstrated benefits.

That OSHA can continue to adopt and enforce non-consensus standards using force of federal law is bad policy, and preventing outside professionals from participating in the process removes any self-correction that might actually give scientific credibility to that work. It is our hope that this Committee will help Congress get OSHA back on track to its foundational vision—open consensus standards and good science. Bureaucratic bullying and closed standards development should be phrases that best describe former Soviet governance, not American occupational safety and health rulemaking in the twenty first century.

[Additional materials submitted from the American Conference of Governmental Industrial Hygienists (ACGIH) follow:]

Prepared Statement of Robert D. Soule, EdD, CIH, CSP, PE, Chair, American Conference of Governmental Industrial Hygienists

The American Conference of Governmental Industrial Hygienists. (ACGIH®) submits this statement to correct testimony presented before this Subcommittee at its April 27, 2006 Hearing on the Use of Non-Consensus Workplace Health and Safety Standards. ACGIH thanks the Subcommittee for the opportunity to present this statement.

Certain testimony presented by Mr. Henry Chajet and Ms. Elizabeth Marcucci contains incorrect statements and unfounded conclusions regarding ACGIH. This Statement is presented to correct the record.

ACGIH is an independent, non-profit scientific organization that provides guidance to industrial hygienists on issues relating to health and safety in the workplace. ACGIH publishes Threshold Limit Values (TLV5®) and Biological Exposure Indices (BEIs®), which are based on scientific analysis of existing peer reviewed literature. The TLVs and BEIs are scientific opinions describing levels of workplace exposure that the typical worker can experience without adverse health effects. The TLVs and BEIs are guidelines to be used by industrial hygienists as one of many factors in evaluating the conditions in a specific workplace. They are health-based values. They are not standards and are not intended to be used as standards. TLVs

and BEIs are initially published on ACGIH's website in draft form as a Notice of Intended Changes (NIC). These NICs are available to all interested parties, who are given at least a full six months to provide comments. All comments are carefully reviewed before any final TLV or BEI is published.

ACGIH Does Not Set Standards

Five years ago, Dr. Patrick N. Breysse, as Vice Chair-Elect of ACGIH, submitted a written statement in response to Mr. Chajet's comments before this Subcommittee at an OSHA Rulemaking Hearing on June 14, 2001. (See Attachment A, Statement of Patrick N. Breysse). Dr. Breysse's statement was a clear and concise message to Congress that ACGIH's TLVs "are not developed for use in rulemaking proceedings or in standard setting activities." (Statement of Patrick N. Breysse, page 4) His statement contained several salient points that bear repeating as ACGIH again unfairly finds itself in the crosshairs of a Congressional hearing on the same issues that were raised in 2001.

The main evidence cited by Dr. Breysse to support the fact that the TLVs and BEIs are not standards and are not intended to be used as standards is the Policy Statement on the Uses of TLVs and BEIs and Special Note to User that are printed inside the front cover of the TL Vs® and BEIs® Book that ACGIH publishes and distributes annually. The Policy Statement explains that TLVs are "recommendations or guidelines intended for use in the practice of industrial hygiene" and are "not developed for use as legal standards and ACGIH does not advocate their use as such." On the same page, in a blocked paragraph titled "Special Note to User," ACGIH states that TLVs are "not fine lines between safe and dangerous concentrations and should not be used by anyone untrained in the discipline of industrial hygiene." Dr. Breysse demonstrated that ACGIH has taken all reasonable measures to inform users of the TLVs and BEIs, as well as the general public, that it does not set standards and that the TLVs and BEIs are not intended to be used as standards.

Five years later, ACGIH is again the target of harsh criticism and is wrongly being referred to as a standards setting entity by both Mr. Chajet and Ms. Marcucci, in testimony before this Subcommittee on April 27, 2006. It seems that Dr. Breysse's comprehensive statement from 2001 has received no proper consideration. Therefore, we now must reiterate our position that ACGIH is not a standards setting organization and that ACGIH does not intend that the TLVs or BEIs be used as standards.

At the Subcommittee Hearing on April 27, 2006, Charles Norwood, Chairman, Subcommittee on Workforce Protections, displayed the definition of a "national consensus standard," as defined in Section 3 of the OSH Act of 1970, on two television screens at either side of the hearing room:

The term "national consensus standard" means any occupational safety and health standard or modification thereof which (1), has been adopted and promulgated by a nationally recognized standards-producing organization under procedures whereby it can be determined by the Secretary that persons interested and affected by the scope or provisions of the standard have reached substantial agreement on its adoption, (2) was formulated in a manner which afforded an opportunity for diverse views to be considered and (3) has been designated as such a standard by the Secretary, after consultation with other appropriate Federal agencies. OSH Act of 1970, Sec. 3(9).

Along with remarks made throughout the hearing, Chairman Norwood's intentions were clear with this presentation: federal regulatory bodies, such as the Department of Labor ("DOL"), should adopt workplace health and safety standards based on a national consensus standard and through the rulemaking process described in Section 6 of the OSH Act. ACGIH does not take issue with this concept. However, since ACGIH is not an organization that establishes either national consensus standards or non-consensus standards, it should not be excoriated if the DOL, or any other federal agency for that matter, chooses to refer to a TLV or BEI in the course of the agency's activities.

Mr. Chajet testified that ACGIH adopts "standards under a veil of secrecy" and conducts "secret, backdoor rulemaking." This rhetoric obfuscates the simple truth: ACGIH is not a standard setting body. It is a private, nongovernmental scientific organization that publishes guidelines for industrial hygienists based on the review of existing published, peer-reviewed scientific literature. No ACGIH guideline is published in final form without at least allowing for a full six-month public comment period. ACGIH has repeatedly stated that regulatory bodies should view TLVs and BEIs as an expression of scientific opinion and not as workplace standards.

ACGIH Responded to the ABA's Comments on the Flour Dust TLV

The American Baker's Association (ABA), represented by Ms. Marcucci, Chair, ABA Safety Committee, presented testimony before the Subcommittee at its April 27, 2006 Hearing, criticizing the way that ACGIH establishes its scientific guidelines. Ms. Marcucci stated that ACGIH conducts "its scientific evaluations and decision making completely in private, with no outside input or oversight," resulting in "no confidence in the final work product." She bases this attack on allegations that the ABA was "ignored" in its attempts to contact ACGIH regarding the proposed flour dust TLV. Let us present the facts for the record.

The ABA was dissatisfied with ACGIH's proposed TLV for flour dust and contracted with Sandler Occupational Medicine Associates ("SOMA") to conduct its own review of the literature cited by ACGIH in the documentation supporting the TLV. After it was completed, the ABA submitted the SOMA review to ACGIH and requested that the proposed TLV on flour dust be withdrawn. Ms. Marcucci testified that the ABA received a summary dismissal, from ACGIH, of its request to withdraw the flour dust TLV. However, ACGIH's response to the SOMA study was not in the form of a summary dismissal but, rather, a comprehensive evaluation of the study and its reasons for not removing flour dust from the list of adopted TLVs. (See Attachment B, January 15, 2002 Letter from ACGIH to James A. Bair, Robb S. MacKie and Gordon Harrison)

On January 15, 2002, ACGIH submitted its evaluation of the SOMA study to the ABA, the North American Millers' Association and the Canadian National Millers Association. ACGIH clearly identified three specific issues—"Sensitization as an end-point", "Study criteria" and "Exposure threshold"—and carefully analyzed each in order to conclude that it was not persuaded to remove the flour dust TLV from its list of adopted values. However, the TLV Committee did incorporate certain materials from the SOMA study into the revised flour dust Documentation. Contrary to the testimony submitted by Ms. Marcucci, ACGIH has addressed the concerns and issues raised by the ABA regarding the flour dust TLV. This was not a process with no outside input. Outside input was, and is, encouraged and fully considered.

Conclusion

Workplace safety is an important concern of all Americans. Regulatory agencies in the U.S. and abroad are charged with establishing standards to protect workers from being exposed to dangerous substances in the workplace. Industrial hygienists are one of the groups of professionals with responsibilities for evaluating workplace conditions.

ACGIH investigates hazardous substances and conditions commonly found in the workplace by analyzing available peer reviewed literature. The evaluation is made by Committees of renowned scientists representing many disciplines. After evaluating the literature, the Committee publishes a comprehensive Documentation in draft form. The Documentation sets forth the level of workplace exposure that, based on the published peer reviewed guidelines, the Committee believes is a proposed safe level of exposure for the average worker. The draft Documentation including the proposed safe level of exposure (TLV or BEI) is then published for public comment. Comments are fully evaluated before a final TLV or BEI recommendation is made.

ACGIH does not engage in consensus or non-consensus standard making. The United States District Court for the Middle District of Georgia has rejected the unfounded claims raised by Mr. Chajet and ruled that ACGIH is not a federal agency; that ACGIH is not a Federal Advisory Committee; that ACGIH is not required to follow the Federal Administrative Procedures Act; and that ACGIH has a First Amendment right to publish its scientific opinion. (See Attachment C, Opinion of U.S. District Court on Motion to Dismiss, IBSA v. ACGIH, (Civ. Action No. 5:04 CV-394).) We think that this Subcommittee should recognize the excellent work that ACGIH has done to promote worker health and safety for more than 65 years.

ACGIH thanks the Subcommittee for this opportunity to correct the record in this matter.

Prepared Statement of Patrick N. Breysse, Ph.D., CIH, Professor, Bloomberg School of Public Health, Johns Hopkins University

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 (FAG)." 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 in the control of potential health hazards in the workplace. 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 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 BEls 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 evidence 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 BEls 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 BEls."

The "Policy Statement" and "Special Note to User" listed above make it abundantly clear that ACGIH is not publishing the TLVs® or BEIs as legal 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 trained 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/BEls 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 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 University, 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, include input from interested parties, and 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 proposed form, 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 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 approximately one year before it becomes an official recommendation of ACGIH effective.

The ACGIH TLV Committee has approximately 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 advance 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 contribute annually approximately four weeks of their time to the work of the Committee. This estimate 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 will also be 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) will be 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 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 a copy of the proposed 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. Each member of the Board has specific information with regard to the proposed TLVs and access to 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 minutes at the Subcommittee and Committee levels, these allegations again are untrue. The Committee and the Subcommittees do keep minutes.

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. Recently, in September 2000, ACGIH adopted a formal 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 legislation such as 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 BEls 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 BEls state that if a worker is exposed to a certain substance at a level of "X" amount or less, the worker does not have an unreasonable risk of injury. This level is determined regardless 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 BEls 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 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 this Documentation 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, and 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 almost 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 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.

SCHOOL OF HYGIENE AND PUBLIC HEALTH,
JOHNS HOPKINS UNIVERSITY,
Baltimore, MD, June 21, 2001.

Mr. Steven John Fellman,
Galland, Kharasch, Greenberg, Fellman and Swirsky, Washington, DC.

DEAR MR. FELLMAN: I would like to advise you that Mr. Henry Chajet held the part-time faculty title of "Associate" in the Department of Environmental Health Sciences of the Johns Hopkins Bloomberg School of Public Health (formerly the Johns Hopkins School of Hygiene and Public Health.) He held the title from January 1984 through June 2000. In that capacity, Mr. Chajet was co-instructor (with Mr. David Blum) of an 8-week course entitled "Occupational Safety and Health Law" that was taught annually.

Mr. Chajet has never held the title of "Associate Professor of Safety and Health Law" at the School of Public Health.

Please contact me with any questions.

Sincerely,

ROBIN FOX, M.S.,
Assistant Dean for Academic Affairs.

ACGIH WORLDWIDE,
1330 KEMPER MEADOW DRIVE,
Cincinnati, OH, January 15, 2002.

James A. Bair,
Vice President, North American Millers' Association, 1600 Maryland Avenue, SW, Washington, DC.

Robb S. MacKie, II,
Vice President, Government Relations, American Bakers Association, 1350 I Street, NW, Washington, DC.

DEAR JIM AND ROBB: ACGIH® has reviewed your request that it clarify its position on the use of Threshold Limit Values (TLVs®), prepare a substantive response to the SOMA Report, and put the TLV for Flour Dust back on the Notice of Intended Changes (NIC).

Enclosed is a new statement of position regarding the use of the TLVs. This statement clearly communicates ACGIH's position that TLVs are not to be used as standards by government agencies or other organizations. We are sending a copy of this statement to the Canadian authorities listed in Mr. Harrison's letter of January 4, 2002 addressed to ACGIH, and are posting this statement on the ACGIH website and publishing it in our newsletter, Today!. We have met with OSHA and provided that agency with a copy of this statement. We would be glad to send additional copies of this statement to state regulatory officials. If you have names and addresses of such persons that should get copies of the statement please provide them to us.

Also enclosed is the ACGIH analysis of the SOMA Report. This analysis was done by the TLV Committee and reviewed and approved by the ACGIH Board of Directors. Although neither the TLV Committee nor the Board of Directors believes that the SOMA Report provides a basis to put the Flour Dust TLV back on the NIC, ACGIH is always willing to look at new peer-reviewed literature. If any new peer-reviewed literature regarding Flour Dust is brought to ACGIH's attention, you can be sure that the TLV Committee will give full consideration to any new data, and then recommend whatever revisions it believes are appropriate to the TLV.

In conclusion, based upon the enclosed analysis, ACGIH has decided to retain the adopted TLV for Flour Dust and to not put it back on the NIC for 2002. It is our desire to maintain open lines of communication between ACGIH and the baking and milling industries. Should new peer-reviewed literature become available, please do not hesitate to bring it to our attention. The TLVs are not carved in stone. ACGIH is always willing to review and consider new peer-reviewed literature. Further, we would be glad to work with you to ensure the message on the appropriate use of the TLVs is communicated to the proper individuals and officials. Simply provide us with a list of names and addresses, and we will send them a copy of the ACGIH position statement on the use of TLVs.

Please do not hesitate to contact Steve Fellman or me if you have any questions.

Sincerely,

A. ANTHONY RIZZUTO,
Executive Director.

ACGIH WORLDWIDE,
1330 KEMPER MEADOW DRIVE,
Cincinnati, OH, January 15, 2002.

Gordon Harrison,
President, Canadian National Millers Association 90 Sparks Street, Ottawa, Ontario, Canada.

Paul Hetherington,
President and CEO, Baking Association of Canada, 7895 Tranmere Drive, Mississauga, Ontario, Canada.

DEAR GORDON AND PAUL: ACGIH® has reviewed your request that it clarify its position on the use of Threshold Limit Values (TLVs®), prepare a substantive response to the SOMA Report, and put the TLV for Flour Dust back on the Notice of Intended Changes (NIC).

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Please do not hesitate to contact Steve Fellman or me if you have any questions.

A. ANTHONY RIZZUTO,
Executive Director.

ACGIH WORLDWIDE,
1330 KEMPER MEADOW DRIVE,
Cincinnati, OH, January 15, 2002.

James A. Bair,
Vice President, North American Millers' Association, 1600 Maryland Avenue, SW, Washington, DC.

Robb S. MacKie, II,
Vice President, Government Relations, American Bakers Association, 1350 I Street, NW, Washington, DC.

Gordon Harrison,
President, Canadian National Millers Association 90 Sparks Street, Ottawa, Ontario, Canada.

DEAR SIRS: The TLV Committee expresses its thanks, again, for your comments on the Flour Dust TLV® Documentation. Your input is appreciated.

The Committee has reviewed the August 2000 report prepared by Sandler Occupational Medicine Associates, Inc. (SOMA) for the North American Millers' Association, American Bakers Association, and Canadian National Millers Association. Some of the materials reviewed by SOMA were not included in the initial TLV Documentation, because they were published after the Documentation was prepared. The Committee has incorporated these references into the Documentation, where appropriate. Thank you for calling these to our attention.

The Committee does not usually respond directly, or in detail, to the comments it receives, because its opinions are reflected solely in its written Documentation. Rather, the Committee reviews all such comments and makes changes to its written Documentation, as appropriate. In the case of the Flour Dust TLV Documentation, in addition to including new references, the TLV recommendation section was rewritten to further explain which studies and issues played a key role in the committee's decision to recommend a TLV of 0.5 mg/m3. You will note that the rewritten Documentation includes specific emphasis on the studies by Hartmann et al. (1985 and 1986), Awad el Karim et al. (1986), Musk et al. (1989), De Zotti et al. (1994), Cullinan et al. (1994 and 2001), Bohadana et al. (1994), Massin et al. (1995), Shamssain (1995), Gimenez et al. (1995), and Zuskin et al. (1998), as well as studies relied upon in the original Documentation.

The Committee has agreed, contrary to its usual practice, to respond to comments expressed in the report prepared by SOMA. Our responses are directed to the three specific issues raised in the SOMA report.

1. Sensitization As An End-Ppoint

The SOMA report argues that sensitization should not be the health end-point of concern, because there is a low correlation between respiratory symptoms and skin

or immunoassay tests. On the other hand, the SOMA report readily admits that bakers' asthma and respiratory sensitization are well-known health endpoints resulting from exposure to airborne Flour Dust. It also recognizes that respiratory symptoms may occur due to irritation effects of the dust. The report concludes that, if sensitization is of importance, it is likely to occur at airborne levels lower than levels at which respiratory symptoms due to irritation will occur.

The TLV Committee is not persuaded by the argument that a low correlation of skin or immunoassay tests with symptoms means that sensitization is a health endpoint that should be ignored. A preponderance of the data ranging from human case reports to epidemiologic studies points to this end-point as one of importance. The TLV Committee would be remiss in its mission to guide industrial hygienists if it were to conclude that sensitization is an unimportant health end-point, simply because the data are confounded by the effects of irritation and the relative non-specificity of current health outcome measures. Sensitization can result in debilitating disease that can lead, eventually, to an inability to work.

Furthermore, the SOMA report suggests that:

1. "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."

and

2. "The position of the ACGIH® document, that sensitization is the chief health outcome of concern, is, therefore, not supported by the scientific evidence."

TLVs are set based on the most significant health threat associated with exposure to a given chemical. For example, the TLV for benzene is set based on its carcinogenic potential, not its CNS effects. Deciding which health outcome is the most significant requires more than an analysis of what effect occurs most commonly. The medical consequences associated with the health outcome are also considered. In the case of Flour Dust, sensitization and the manifestation of allergic/asthma symptoms is a more significant outcome than simple irritation. As a result, the Committee believes this to be the most important health end-point of concern for this substance.

The SOMA report notes that there are flour additives that can cause allergy. The TLV Committee agrees and discusses this issue in its Documentation. However, it is clear that materials inherent to Flour Dust (proteins, enzymes, etc.) can be both sensitizing and irritating. Thus, the Committee has chosen to address Flour Dust as a single substance. It has indicated its interest in developing separate TLVs for some of the allergenic additives (such as alpha amylase), as well.

2. Study Criteria

We agree with the SOMA report that there are many shortcomings in the currently available literature. We agree that the data are limited and that there is no particular study, including that by Houba (1998), which points conclusively to a specific threshold of exposure below which sensitization will not occur. The TLV recommendation section in the Documentation was re-written to demonstrate that a number of studies, including those listed above, point to the recommended TLV.

The Committee does not make its decisions in the manner suggested by the SOMA report—by eliminating studies from its consideration when they do not meet the high standards described. Rather, the Committee evaluates each study carefully, taking into consideration both strengths and weaknesses. The Committee considers all of the literature together, and if it finds that there is a preponderance of evidence for a particular health effect, it makes its best effort to determine the level below which it is likely that that health effect will not occur. The Committee strives to select the health effect(s) of greatest significance to the long-term health of employees.

As noted above, the Committee welcomes comments on its written Documentation. However, the Committee suggests, respectfully, that to exclude or include certain studies solely on the basis of sets of criteria is unduly restrictive. Such an approach reflects a difference in opinion, rather than a matter of scientific understanding, and would result in the elimination of data that could be significant. The Documentation developed by the TLV Committee represents an opinion about data that are available in the peer-reviewed, published literature. Other parties are welcome to publish their own opinions about these data, which may differ from those of the Committee. We encourage SOMA to publish its report to make it available to the scientific community for broader inclusion in public discussions about Flour Dust health effects.

3. Exposure Threshold

The TLV Committee agrees with the SOMA report that a "threshold based upon sensitization is likely to be considerably lower than one based upon prevention of non-allergic (e.g. irritant) effects." Since the Committee is persuaded by its review

of the literature that sensitization is a key health end-point for this substance, it has sought to find a level for airborne Flour Dust below which nearly all workers are unlikely to develop sensitization. This level should provide assurance, as well, that exposures will not lead to respiratory symptoms resulting from respiratory tract irritation.

The TLV Committee has not relied solely on the Houba (1998) study for its recommendation of a TLV at 0.5 mg/m3. Rather, it has concluded from its review of a number of studies (listed above), and in particular those by Musk et al. (1989), Cullinan et al. (1994 and 2001), and Houba et al. (1996), listed in the TLV Recommendation section of the Documentation, that the TLV should be less than 1 mg/m3. The Committee has elected to recommend a level of 0.5 mg/m3.

Again, we thank the North American Millers' Association, American Bakers Association, and Canadian National Millers Association for their input on the TLV Documentation for Flour Dust. Changes were made to the Documentation to elucidate some of the issues raised and to include new references. We hope that this letter will serve to explain why the SOMA report did not persuade the Committee to remove this substance from its list of adopted values or to place this substance back on its list of substances and issues under study.

Sincerely,

LISA M. BROSSEAU, SCD,
Chair, TLV Chemical Substances Committee.

Statement of Position Regarding the TLVs® and BEIs®*

The American Conference of Governmental Industrial Hygienists (ACGIH®) is a private not-for-profit, nongovernmental corporation whose members are industrial hygienists and other occupational health and safety professionals dedicated to promoting health and safety within the workplace. ACGIH is a scientific association. ACGIH is not a standard setting body. As a scientific organization, it has established committees that review existing published, peer-reviewed scientific literature. ACGIH proposes guidelines known as Threshold Limit Values (TLVs®) and Biological Exposure Indices (BEIs®) for use by industrial hygienists in making decisions regarding safe levels of exposure to various chemical and physical agents found in the workplace. In using these guidelines, industrial hygienists are cautioned that the TLVs and BEIs are only one of multiple factors to be considered in evaluating specific workplace situations and conditions.

Each year ACGIH publishes its TLVs and BEIs in a book. In the introduction to the book, ACGIH specifically states that the TLVs and BEIs are guidelines to be used by professionals trained in the practice of industrial hygiene. The TLVs and BEIs are not designed to be used as standards. Nevertheless, ACGIH is aware that in certain instances the TLVs and the BEIs are used as standards by national governments, state governments, and local governments.

Governmental bodies establish public health standards based on statutory and legal frameworks that include definitions and criteria concerning the approach to be used in assessing and managing risk. In most instances, governmental bodies that set workplace health and safety standards are required to evaluate health effects, economic and technical feasibility, and the availability of acceptable methods to determine compliance with the proposed standard.

ACGIH TLVs and BEIs are solely health-based values. ACGIH TLVs and BEIs are established by committees that review existing published and peer-reviewed literature in various scientific disciplines (e.g., industrial hygiene, toxicology, occupational medicine, and epidemiology). Based on the available information, ACGIH formulates a conclusion on the level of exposure that the typical worker can experience without an unreasonable risk of disease or injury. The TLV and BEI are not quantitative estimates of risk at different exposure levels or by different routes of exposure.

Since ACGIH TLVs and BEIs are based solely on health factors, there is no consideration given to economic or technical feasibility. Regulatory agencies should not assume that it is economically or technically feasible for an industry or employer to meet TLVs or BEIs. Similarly, although there are usually valid methods to measure workplace exposures at TLVs and BEIs, there can be instances where such reli-

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*ACGIH is publishing this Statement in order to assist ACGIH members, government regulators, and industry groups in understanding the basis and limitations of the TLVs and BEIs when used in a regulatory context. This Statement was adopted by the ACGIH Board of Directors on January 11, 2002.

able test methods have not yet been validated. Obviously, such a situation can create major enforcement difficulties if a TLV or BEI was adopted as a standard.

ACGIH does not believe that TLVs and BEIs should be adopted as standards without an analysis of other factors necessary to make appropriate risk management decisions (e.g., control options, technical and economic factors, etc.). However, ACGIH does believe that regulatory bodies should certainly consider TLVs or BEIs as valuable input into the risk characterization process (hazard identification, dose-response relationships, and exposure assessment). Regulatory bodies should view TLVs and BEIs as an expression of scientific opinion.

ACGIH is proud of the scientists and the many members who volunteer their time to work on the TLV and BEI Committees. These experts develop written Documentation that include an expression of scientific opinion and a description of the basis, rationale, and limitations of the conclusions reached by ACGIH. The Documentation provides a comprehensive list and analysis of all the major published peer-reviewed studies that ACGIH relied upon in formulating its scientific opinion. Regulatory agencies dealing with hazards addressed by a TLV or BEI should obtain a copy of the full written Documentation for the TLV or BEI. Any use of a TLV or BEI in a regulatory context should include a careful evaluation of the information in the written Documentation and consideration of all other factors required by statute under the regulatory procedures of the governmental body involved.

- ACGIH is a not-for-profit scientific association.
- ACGIH proposes guidelines known as TLVs and BEIs for use by industrial hygienists in making decisions regarding safe levels of exposure to various hazards found in the workplace.
- ACGIH is not a standard setting body.
- Regulatory bodies should view TLVs and BEIs as an expression of scientific opinion.
- ACGIH TLVs and BEIs are based solely on health factors; there is no consideration given to economic or technical feasibility. Regulatory agencies should not assume that it is economically or technically feasible to meet established TLVs or BEIs.
- ACGIH believes that TLVs and BEIs should NOT be adopted as standards without an analysis of other factors necessary to make appropriate risk management decisions.
- TLVs and BEIs can provide valuable input into the risk characterization process. Regulatory agencies dealing with hazards addressed by a TLV or BEI should review the full written documentation for the numerical TLV or BEI.

[Additional court order submission from Mr. Owens follows:]

[Submitted and placed in permanent archive file, Court Order, *International Brominated Solvents Association v. American Conference of Governmental Hygienists, Inc.,* No. 5:04CV394 (D.M.D. Ga., 2005).]