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HAVE OSHA STANDARDS KEPT UP WITH WORKPLACE HAZARDS?

HEARING

BEFORE THE

SUBCOMMITTEE ON WORKFORCE PROTECTIONS

COMMITTEE ON

EDUCATION AND LABOR

U.S. HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

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C O N T E N T S

	Page
Hearing held on April 24, 2007	1
Statement of Members:	
Price, Hon. Tom, a Representative in Congress from the State of Georgia, prepared statement of	64
Journal of Occupational and Environmental Medicine study dated February 2006, "Evaluation of Flavorings-Related Lung Disease Risk at Six Microwave Popcorn Plants"	48
Wilson, Hon. Joe, ranking minority member, Subcommittee on Workforce Protections	3
Prepared statement of	4
Prepared statement of the Printing Industries of America, Inc. (PIA)	69
Prepared statement of the Tree Care Industry Association (TCIA)	71
Woolsey, Hon. Lynn C., Chairwoman, Subcommittee on Workforce Protections	1
Letter submitted by Adam M. Finkel, Sc.D., CIH	64
OSHA news release dated April 24, 2007, "U.S. Department of Labor's OSHA Announces Focus on Health Hazards of Microwave Popcorn Butter Flavorings Containing Diacetyl"	32
Statement of Witnesses:	
Fellner, Baruch, attorney, Gibson, Dunn & Crutcher	14
Prepared statement of	16
Foulke, Hon. Edwin, Assistant Secretary of Labor, Occupational Safety and Health Administration	5
Prepared statement of	7
Mirer, Frank, professor of environmental and occupational health sciences, Hunter School of Urban Public Health	18
Prepared statement of	20
Peoples, Eric, former employee of Glister-Mary Lee popcorn factory	9
Prepared statement of	10
"Popcorn-Worker Lung Caused by Corporate and Regulatory Negligence," published in the International Journal of Occupational Health, dated Jan.-Mar. 2007	34
Schneider, Scott, director of occupational safety and health, Laborers' Health and Safety Fund of North America	11
Prepared statement of	12

HAVE OSHA STANDARDS KEPT UP WITH WORKPLACE HAZARDS?

Tuesday, April 24, 2007
U.S. House of Representatives
Subcommittee on Workforce Protections
Committee on Education and Labor
Washington, DC

The subcommittee met, pursuant to call, at 1:37 p.m., in Room 2175, Rayburn House Office Building, Hon. Lynn Woolsey [chairwoman of the subcommittee] presiding.

Present: Representatives Woolsey, Payne, Bishop of New York, Hare, Wilson, Price, and Kline.

Staff present: Aaron Albright, Press Secretary; Tylease Alli, Hearing Clerk; Jordan Barab, Health/Safety Professional; Lynn Dondis, Senior Policy Advisor for Subcommittee on Workforce Protections; Michael Gaffin, Staff Assistant, Labor; Peter Galvin, Senior Labor Policy Advisor; Jeffrey Hancuff, Staff Assistant, Labor; Brian Kennedy, General Counsel; Joe Novotny, Chief Clerk; Megan O'Reilly, Labor Policy Advisor; Michele Varnhagen, Labor Policy Director; Mark Zuckerman, Staff Director; Robert Borden, General Counsel; Ed Gilroy, Director of Workforce Policy; Rob Gregg, Legislative Assistant; Victor Klatt, Staff Director; Jim Paretti, Workforce Policy Counsel; Molly McLaughlin Salmi, Deputy Director of Workforce Policy; Linda Stevens, Chief Clerk/Assistant to the General Counsel; and Loren Sweatt, Professional Staff Member.

Chairwoman WOOLSEY [presiding]. The hearing of the Workforce Protection Subcommittee on "Have OSHA Standards Kept Up With Workplace Hazards?" will come to order.

Pursuant to Committee Rule 12(a), any member may submit an opening statement in writing which will be made part of the permanent record.

I now recognize myself, followed by Ranking Member Joe Wilson, who is running over here as we speak, for an opening statement.

In 1970, the United States Congress passed the Occupational Safety and Health Act, OSHA, to provide every working man and woman in the nation a safe and healthful workplace. One of the most important roles that it gave the new agency was to develop safety and health standards.

The standards that OSHA has established have saved literally thousands of lives. For example, in 1978, when OSHA's cotton dust standard was adopted, there were 40,000 cases of brown lung disease annually. Twelve percent of all textile workers suffered from

this deadly disease. By the year 2000, and because of the OSHA standard, brown lung had virtually been eliminated. OSHA's 1978 standard on lead dramatically reduced lead poisoning. And the 1989 evacuation standard, designed to protect workers from trench collapse, has reduced deaths by more than 20 percent, while construction activity has actually increased by 20 percent.

OSHA has made an enormous difference in workers' lives, but sadly many workers are still at risk from unsafe conditions in their workplaces. The Bureau of Labor Statistics reported that in the year 2005 there were over 5,700 workers, or 16 workers a day, killed in the workplace.

In addition to terrible fatalities, there are millions more workers like Mr. Peoples, who is here to speak with us today as a witness, who suffer from injuries and illnesses based on their working conditions.

This is not a time to slow down on protecting worker safety. But yet that is what the administration has done. There are various areas where OSHA has failed to do its job, and over the coming months, this committee will look into those failures.

Today's hearing will focus on standard setting. And in this arena, the administration has the worst record on standard setting of any administration in the history of the law.

The administration began on a tragic note for American workers with the shameful repeal of OSHA's ergonomic standards. That was followed by the removal of dozens of rules from the regulatory agenda, including the standard to protect health care workers against tuberculosis.

I pray that we don't live to regret this when extremely drug-resistant T.B., which is killing two-thirds of those who get it in South Africa, arrives. If that reaches this nation in significant numbers, we don't have any standards. We don't know what to do about it in our workplace.

To date, this administration has issued only one significant health standard protecting workers against a cancer-causing chemical called chemical hexavalent chromium. And that standard was issued under court order; it was not done voluntarily.

One of the worst failures of this administration is its failure to issue a rule that requires employers to pay for employees' personal protection equipment. This rule was almost finished during the Clinton administration. Seven years later, OSHA has finally agreed to issue this standard, again under the threat of a court order.

Today we will hear the tragic story of Eric Peoples, who has popcorn lung disease and has lost much of his lung capacity. He faces, because of his exposure to a chemical, possibly a shorter life than others his age.

And that chemical is called diacetyl, and it is used in butter flavoring for popcorn. The industry and OSHA are well-aware that exposure to diacetyl has dire health consequences for workers, but OSHA has yet to initiate regulatory action.

In fact, the entire area of chemical regulation is a travesty. OSHA currently regulates only about 600 chemicals out of the tens of the thousands used in industry. Most Americans would be shocked to learn that these standards are based on science from the 1950s and the 1960s.

I am also concerned that OSHA is substituting voluntary programs for enforceable standards. We want to know what evidence OSHA has to argue that these voluntary programs are effective replacements for OSHA standards.

We owe it to our workers to protect their health and safety, which is what Cal-OSHA, my home state's program, is doing.

For example, in response to a union petition, Cal-OSHA is currently proceeding on the fast track to develop a standard for diacetyl and in conducting aggressive inspections of facilities that use this chemical in their operations. In addition, in contrast to federal OSHA, Cal-OSHA is also working on updating large numbers of its chemical standards.

The purpose of this hearing today is to begin to understand why OSHA is not even coming close to fulfilling its original mission and what we can do to correct it.

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

Mr. WILSON. Thank you, Madam Chairman. And indeed, I did sprint here.

And good afternoon. I would like to thank our witnesses for appearing before us today for what I know will be an interesting discussion about the work of the Occupational Safety and Health Administration.

This hearing is focused on the standard-setting process at OSHA. Some parties may be critical of the rulemaking process, the length of time required to create a regulation, and how difficult it is for OSHA to prioritize its regulatory agenda.

It is interesting, though, to look at the statistics. The Clinton administration promulgated 36 standards, three of them in the last month of the term. To date, the Bush administration has implemented 22 standards, with more than a year left in the term. So from the outset, the pace of regulatory rulemaking has not changed. The question may be of the priorities.

One area that OSHA has struggled with is an update of the permissible exposure limits, or PELs. Our late and dear colleague, Charlie Norwood, attempted to bring all parties together to work on an update of the PELs, but this process stagnated.

OSHA's attempt to update the PELs was turned back by the 11th Circuit Court of Appeals. It is important for us to find a way to achieve the goals of the OSHA act, and I am pleased that this is one area where the committee continues to focus its attention.

For a rule to become final, it must meet several legal tests. Some of these have been put in place by Congress and some by the court system. These tests are designed to improve the process by which workplaces are deemed safe from hazards.

I will be interested to hear from our witnesses if these procedures improve standard setting and any suggestions they may have to improve OSHA's standard setting in the future.

Again, I look forward to the witnesses' testimony. I, indeed, also look forward to working with Congresswoman Woolsey for promoting health and safety. And I thank you for being here today to appear before us.

[The prepared statement of Mr. Wilson follows:]

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

Thank you Madam Chair and good afternoon. I would like to thank our witnesses for appearing before us today for what I know will be an interesting discussion about the work of the Occupational Safety and Health Administration. This hearing is focused on the standard setting process at OSHA. Some parties may be critical of the rulemaking process, the length of time required to create a regulation, and how difficult it is for OSHA to prioritize its regulatory agenda. It is interesting, however, to look at the statistics. The Clinton Administration promulgated 36 standards, three of them in the last month of the term. To date, the Bush Administration has implemented 22 standards with more than a year left in the term. So, from the outset, the pace of regulatory rulemaking has not changed. The question may be the priorities.

One area that OSHA has struggled with is an update of the permissible exposure limits or PELs. Our former colleague Charlie Norwood attempted to bring all parties together to work on an update of the PELs, but this process stagnated. OSHA's attempt to update the PELs was turned back by the 11th Circuit Court of Appeals. It is important for us to find a way to achieve the goals of the OSH Act and I am pleased this is one area on which the Committee continues to focus its attention.

For a rule to become final it must meet several legal tests. Some of these have been put into place by Congress and some by the Court system. These tests are designed to improve the process by which workplaces are deemed safe from hazards. I will be interested to hear from our witnesses if these procedures improve standard setting and any suggestions they may have to improve OSHA's standard setting in the future.

Again I look forward to the witnesses' testimony and thank them for making the effort to appear before us today.

Chairwoman WOOLSEY. Without objection, all members will have 14 days to submit additional materials or questions for the hearing record.

I would like to introduce our very distinguished panel of witnesses who are here before us this afternoon.

And I welcome all of you witnesses. Thank you for being here.

For those of you who have testified before the committee in the past, you won't need me to explain this, but if you haven't, I need to explain our lighting system and the 5-minute rule.

Everyone, including members of Congress, are limited to 5 minutes for presenting or questioning. The green light is illuminated when you begin to speak. When you see the yellow light, it means you have 1 minute remaining. When you see the red light, it means your time has expired and you need to conclude your testimony. Don't think for a minute you have to stop mid-sentence or mid-thought. But it will let you know that you have used your 5 minutes.

And be certain that, as you testify, we want you to turn on your speaker so we can hear you, and talk directly into the microphone.

So our witnesses today are the honorable Edwin Foulke. He is the Assistant Secretary of Labor and the administrator of OSHA. Prior to his current position, he was a partner in the law firm of Jackson Lewis LLP, practicing in the area of labor relations. From 1990 to 1995, Mr. Foulke served on the Occupational Safety and Health Review Commission and was its chair from 1990 to 1994. He graduated from North Carolina State University and holds a J.D. from Loyola University and a master's of law from Georgetown.

Scott Schneider—Scott, for the last 9 years, has been the director of occupational safety and health for the Laborers' Health and Safety Fund of North America.

I am looking at what order we have you in here. Well, we are going to go down the order as you are, not as I am introducing you.

The Laborers' Union has over 800,000 members who are primarily construction workers. Mr. Schneider holds a master's degree in industrial hygiene from the University of Pittsburgh and a master's degree in zoology from the University of Michigan.

Eric Peoples—Eric was an oil mixer at the Glister-Mary Lee Popcorn Factory in Jasper, Missouri. He was born in Joplin. He was raised in Carthage, Missouri, and he currently resides in Carthage. He is a graduate of Carthage High School.

Baruch Fellner—Mr. Fellner is a partner at Gibson Dunn & Crutcher in Washington, D.C., practicing in the area of labor relations. He has also worked in the solicitor's office at the Department of Labor and in the Appellate Court branch at the National Labor Relations Board. Mr. Fellner received his B.A. from George Washington University and his law degree from Harvard Law School.

Franklin Mirer—Franklin Mirer is a professor of environmental and occupational health sciences at Hunter College in New York. For over 27 years, he was the director of the health and safety department at the United Auto Workers. Dr. Mirer received his bachelor's degree from Columbia and his master's and Ph.D. from Harvard University.

Welcome to all of you.

And we will begin with you, Mr. Assistant Secretary.

STATEMENT OF EDWIN FOULKE, ASSISTANT SECRETARY OF LABOR, OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

Mr. FOULKE. Thank you very much, Madam Chairwoman and members of the subcommittee.

Before I begin, I would request a brief moment to personally address Mr. Eric Peoples, sitting next to me, whose testimony here today brings in compelling terms how devastating an occupational illness or injury can be to the employees and to their families.

Mr. Peoples, I assure you that all of us at OSHA—and we have a number of the career staff here—are working hard to improve safety and health in our nation's workplaces.

Members of this subcommittee, thank you for the opportunity to appear here today to discuss the progress that the Occupational Safety and Health Administration is making to protect the nation's working men and women.

OSHA has a strong record of protecting the safety and health of our nation's workers, and I am pleased to have this opportunity to discuss the record with the subcommittee.

OSHA uses a variety of proven strategies to accomplish its mission of saving lives and reducing injuries and illnesses. This balanced approach includes strong, fair and effective enforcement, safety and health standards and guidance, training and education, and cooperative programs, compliance assistance and outreach.

I want to make it clear that while the agency offers technical assistance to employers to comply with OSHA standards and regulations, compliance is not voluntary. It is mandatory. In fact, since 2001, OSHA proposed more than $750 million in penalties for safety and health violations.

Furthermore, the record high number of 56 criminal referrals by this administration since 2001, the most of any administration, indicates the seriousness of the President's commitment to protecting employees and enforcing the law.

This commitment approach is achieving all-time low rates. For example, the overall workplace injury and illness rate, at 4.6 per 100 employees in 2005, is the lowest since the Bureau of Labor Statistics began publishing data in 1973. Since 2002, the injury and illness rate has fallen by more than 13 percent. More importantly, the overall fatality rate has fallen 7 percent, and fatality rates among Hispanics has declined by 18 percent since 2001.

Although this is unprecedented progress, we all acknowledge that there is still much more work left to do to accomplish the goals of having all working men and women return home safe and healthy at the end of every day.

Setting safety and health standards is a critical part of our balanced approach to protecting workers. Currently, OSHA is actively working on 21 projects which include four final rules, 10 proposed rules, two Regulatory Flexibility Act section 610 look-backs, and five other projects in early stages of development.

I am pleased to report that the Agency has devoted substantial resources to each of these regulatory projects, including the payment for personal protective equipment rule, which we expect to complete by November of this year.

With respect to silica, the Agency expects to issue a draft analysis on the health effects and the risk assessment as part of a scientific peer-review process. The peer-review process is necessary and appropriate in the case of silica, due to the extensive scientific literature and the complexity of the subject. Conducting such a peer review will ensure that appropriate regulatory decisions are based on firm scientific foundation.

Let me conclude by saying that employers and employees should have no doubt in their minds about OSHA's commitment to enforcing the standards and regulations promulgated under the Occupational Safety and Health Act.

The Agency's history of strong enforcement has demonstrated the serious consequences employers face when they neglect their responsibility of providing safe and healthful workplaces for their employees. In fact, OSHA conducted more than 38,000 federal inspections in 2006 and has exceeded its inspection goals in each of the last 7 years.

OSHA's aggressive enforcement record, coupled with the fact that more than one-quarter of all OSHA-related criminal referrals to the Department of Justice have occurred since 2001 illustrates the administration's strong commitment and desire to protect employees and rightfully enforce the law.

To complement these enforcement efforts, the Agency will continue to provide the regulating committee with much needed knowledge, tools and assistance to comply with the law.

Madam Chair, I would be happy to answer any questions that you or the committee may have. And I believe we have submitted a longer statement for the record.

[The statement of Mr. Foulke follows:]

Prepared Statement of Edwin G. Foulke, Jr., Assistant Secretary, Occupational Safety and Health Administration, U.S. Department of Labor

Madam Chairwoman and Members of the Subcommittee: Thank you for the opportunity to appear today to discuss the progress that the Occupational Safety and Health Administration (OSHA) is making to protect the Nation's working men and women. OSHA has a strong record of protecting the safety and health of our Nation's workers, and I am pleased to have the opportunity to discuss that record with the Subcommittee.

The Occupational Safety and Health Act (OSH Act) was enacted in 1970 to protect employees from hazards that may cause injury, illness, or death, and we take our obligations under this statute very seriously. We are proud of our record of results.

OSHA uses a variety of proven strategies to accomplish its mission of saving lives and reducing injuries and illnesses. This balanced approach includes: 1) strong, fair, and effective enforcement; 2) safety and health standards and guidance; 3) training and education; and 4) cooperative programs, compliance assistance and outreach. I want to make it clear, however, that, while we offer technical assistance to employers to comply with OSHA standards, compliance is not voluntary. There is no such term or practice as "voluntary compliance."

In fact, since 2001, as part of its strong enforcement program, OSHA proposed more than three-quarters of a billion dollars in penalties for safety and health violations and made 56 criminal referrals to the Department of Justice, which represents more than 25 percent of all criminal referrals in the history of the Agency.

OSHA's balanced strategy is achieving results, as evidenced by all-time low occupational injury, illness, and fatality rates. The overall workplace injury/illness rate, at 4.6 per 100 employees in 2005, is the lowest since BLS began publishing data in 1973. Since 2002, the injury/illness rate has fallen by more than 13%. Moreover, the overall fatality rate has fallen by 7 percent, and by 18 percent among Hispanics, since 2001. These numbers highlight the Administration's commitment and success in protecting the safety and health of the Nation's workforce.

A key component of OSHA's balanced approach is the development of protective safety and health standards and regulations. OSHA has set ambitious goals for its regulatory program as evidenced by its regulatory agenda published in the Federal Register last December. Let me assure you that the Agency is fully committed to achieving these goals.

As you are aware, rulemaking for safety and health standards is a complex process, which is governed by more than 30 years of Congressional, Judicial, and Executive Branch mandates. For example, as a result of judicial interpretations of the OSH Act, the Agency must study the feasibility and potential impacts of its standards in more depth than was the case early on in OSHA's history. In addition, the science impacting regulatory decisions has increased over the years in both volume and complexity.

OSHA has set ambitious goals under its current regulatory program. OSHA is actively working on 21 projects which include: four final rules, ten proposed rules, two Regulatory Flexibility Act Section 610 "lookbacks," and other projects in the early stages of development. The Agency has devoted substantial resources to each of these regulatory projects, and I am committed to doing everything in my power to achieve these goals.

OSHA's recent substantial progress on its regulatory program, in part, includes:

1. Amending the Respiratory Protection Standard
2. Completing the SBREFA process for Cranes & Derricks
3. Publishing an Advanced Notice of Proposed Rulemaking (ANPRM) to amend the Hazard Communication Standard for global harmonization of classifying and labeling chemicals
4. Publishing an ANPRM for the Standards Improvement Project
5. Holding stakeholder meetings on ionizing radiation
6. Publishing a final standard on Fire Protection in Shipyards
7. Publishing a final standard for Electrical Equipment Installations
8. Publishing a proposed standard on Explosives

In addition, OSHA is diligently working on a number of other regulatory agenda items, such as the Payment for Personal Protective Equipment (PPE) rule, which we expect to complete by November 2007. The Agency will soon be issuing an ANPRM on mechanical power presses, and final or proposed rules to update a number of standards based on recent consensus standards.

With respect to silica, the Agency expects to issue a draft analysis on the health effects and risk assessment as part of a scientific peer review process. The peer review process is necessary and appropriate in the case of silica due to the extensive scientific literature and complexity of the subject. Conducting such a peer review

will ensure that appropriate regulatory decisions are based on a firm scientific foundation.

OSHA has also received two petitions for Emergency Temporary Standards (ETS) to address important workplace health issues: pandemic flu preparedness and diacetyl in food flavorings.

Pandemic Flu:

The Occupational Safety and Health Act (OSH Act) Section 6(c)(1) states that an ETS is to be issued when "employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards" and OSHA can show "that the emergency temporary standard is necessary to protect employees from such danger." Currently, all available medical evidence indicates that no human influenza pandemic virus exists. Therefore OSHA cannot, at this time, meet the legal requirements of the OSH Act to issue an ETS on pandemic flu and OSHA has denied the ETS petition. This does not mean that OSHA is sitting back and waiting for a pandemic to strike before taking any action.

To the contrary, OSHA has taken measures to assist employers and workers to prepare for and respond to a pandemic influenza. OSHA has worked closely with the White House, the Department of Health and Human Services (HHS), and the Department of Homeland Security (DHS) and other Federal agencies to implement the President's National Strategy for Pandemic Influenza. As part of this effort, OSHA developed a guidance document entitled: Preparing Workplaces for an Influenza Pandemic, which helps employers and workers assess risk levels and provides guidance on how to plan now for a possible pandemic in the future. The Agency is also developing guidance specifically for the health care industry that includes recommendations for respiratory protection. Up-to-date information on pandemic flu preparedness is provided through www.OSHA.gov and www.pandemicflu.gov. Essentially, OSHA has already put in place the protections and policies that would be used should a pandemic strike.

Diacetyl:

In 2001, OSHA took immediate action when the hazard of butter flavorings containing diacetyl was brought to the Agency's attention by NIOSH's interim report on microwave popcorn manufacturing plants. The report's findings indicated that uncontrolled exposure to butter flavorings containing diacetyl was associated with the development of a severe obstructive lung disease called bronchiolitis obliterans.

OSHA promptly alerted its Regional Administrators and Area Directors to NIOSH's findings and instructed its field personnel to look into the issue when encountering individuals working around butter flavoring in popcorn manufacturing. OSHA's Region VII published a brochure on this topic and arranged for its distribution in the region. In 2004, OSHA issued a memorandum to senior field managers and encouraged them to contact employers in their regions who may have workers exposed to this potential hazard.

To further protect workers who may be exposed to this hazard, OSHA is finalizing a National Emphasis Program (NEP) for butter flavorings containing diacetyl in the manufacturing of microwave popcorn. The goal is to direct inspections to the facilities where workers may be at the greatest risk of exposure to this hazard. In addition, the NEP contains elements aimed at educating stakeholders about the hazard posed by butter flavorings containing diacetyl. Implementation of this NEP would allow OSHA to begin inspecting microwave popcorn manufacturing facilities by the end of May, and to inspect every such facility under Federal jurisdiction by the end of this year. This will be followed by a second NEP that focuses on establishments manufacturing food flavorings containing diacetyl.

OSHA is also developing guidance to alert employers and workers to the potential hazards associated with food flavorings containing diacetyl. The guidance will provide recommendations on how to control these hazards and to ensure that information about those hazards is effectively communicated to workers.

The Agency is currently reviewing the petition for an Emergency Temporary Standard and is engaged in site visits to microwave popcorn and flavor manufacturing facilities in order to fairly evaluate the merits of the petitioner's request.

Employers and workers should have no doubt about OSHA's commitment to enforcing the standards and regulations promulgated under by the OSH Act. The Agency's history of strong enforcement has demonstrated the serious consequences employers face when they neglect their responsibility of providing safe and healthful workplaces for their workers. In fact, OSHA conducted 38,579 Federal inspections in 2006 and has exceeded its inspection goals in each of the last 7 years. OSHA's aggressive inspection record, coupled with the fact that more than one-quarter of all criminal referrals to the Department of Justice in the Agency's history have oc-

curred since 2001, indicates the seriousness of the Administration's commitment to protecting workers and enforcing the law.

At the same time, the Agency is committed to providing the regulated community with the knowledge, tools, and assistance needed to comply with the law. By using all of OSHA's programs effectively, the Agency is able to save a significant number of lives each year. More workers return home safely each day because of the efforts of OSHA, its State Plan partners and all stakeholders who are committed to protecting employees from occupational hazards.

Madam Chairwoman, I would be happy to answer any questions.

Chairwoman WOOLSEY. Thank you, Mr. Secretary.

Mr. Peoples?

STATEMENT OF ERIC PEOPLES, FORMER EMPLOYEE OF GLISTER–MARY LEE POPCORN FACTORY

Mr. PEOPLES. My name is Eric Peoples. I was born in Joplin, Missouri, and raised in Carthage, Missouri, where I currently reside. I am 35 years old and have been married to Cassandra Peoples for 14 years. I have two children: Adrianna, age 13, and Brantley, age 11.

I have bronchiolitis obliterans. Bronchiolitis obliterans is a severe, progressive disease of the lung which has robbed me of my health, deprived my wife of a husband and my children of a daddy. A jury awarded me $20 million for my injuries.

I went to work at the Jasper popcorn plant in the fall of 1997 and left in March of 1999. I would give anything to know then what I know now.

At the time I was in perfect health, looking forward to a long and healthy life. The plant was run by local people and was one of the best jobs in the area. My co-workers were kind, honest people and treated me well the entire time that I worked there.

The plant manufactured microwave popcorn. The process combined oil, popcorn, butter flavor, salt, into microwaveable bags. I was promoted soon after I started and became a mixer.

The following facts are only known to me because they were discovered in my lawsuit in 2004. What the Jasper plant did not know was that the butter flavor that they were using had an increased quantity of diacetyl, a ketone that imparts a buttery taste. Many butter flavors contain about 3 percent diacetyl. This butter flavor contained 10 percent.

The company that supplied the butter flavor, Bush Boake Allen, a subsidiary of International Flavors and Fragrances, IFF, had extensive notice about hazards of butter flavor. They treated butter flavor as a hazardous material within their own plant.

Since at least 1994, their own workers were required to wear respiratory protection when working around the butter flavor. Despite wearing full-face respirators, many of the employees suffered severe eye injuries. Because of the damage and dangers of the product, the entire manufacturing process was enclosed so no one would be exposed to the vapors.

In addition, information had come to IFF about the respiratory effects of exposure to diacetyl. In 1986, two employees of a baking company had been diagnosed with bronchiolitis obliterans while mixing a butter flavoring for use in the cinnamon rolls.

IFF's trade organization, the Flavoring and Extract Manufacturers Association, or FEMA, supplied experts to the defendants in the case. The case was settled before trial.

In 1994, BASF Chemical Company, a supplier of diacetyl, sent IFF a material safety data sheet, MSDS, which disclosed rats that had inhaled the chemical diacetyl developed severe respiratory problems, including emphysema.

Additionally, another flavor company, Givaudan, had reported to FEMA that in 1996 flavoring chemicals were causing bronchiolitis obliterans in their plant. FEMA had a seminar in 1997 warning flavoring companies about this danger.

Despite all of this information, the buckets containing this product said the product was safe. The material safety data sheet said the product had no known health hazards, and that is what I believed.

Let me bring it home for you, if I can. I have a 20 percent lung capacity. I am currently on the inactive lung transplant registry. One case of pneumonia could cause me to need the transplant now.

The average rate of survival for someone with a lung transplant is about 5 years. Seventy-five percent of lung transplant patients are dead after 10 years.

One of the doctors who worked on the first case involving the two workers with bronchiolitis obliterans in 1990 said the flavoring industry was using workers as blue collar guinea pigs.

I played by the rules. I worked to support my family. The unregulated industry virtually destroyed my life. Don't let it destroy the lives of others. These chemicals that are used on food in large-scale production must be tested and proper instructions and labeling supplied with their sale.

Thank you.

[The statement of Mr. Peoples follows:]

Prepared Statement of Eric Peoples, Former Employee of Glister-Mary Lee Popcorn Factory

My name is Eric Peoples. I was born in Joplin, Missouri and raised in Carthage, Missouri where I presently reside. I am 35 years old and have been married to Cassandra Peoples for 14 years. I have two children, Adrianna, age 13 and Brantley, age 11. I have bronchiolitis obliterans. Bronchiolitis obliterans is a severe, progressive disease of the lung which has robbed me of my health, deprived my wife of a husband and my children of a Daddy. A jury awarded me $20 million dollars for my injuries.

I went to work at the Jasper Popcorn Company in the fall of 1997 and left in March, 1999. I would give anything to have known then what I know now. At that time I was in perfect health, looking forward to a long, healthy life. The plant was run by local people and was one of the best jobs in the area. My co-workers were kind, honest people and treated me well the entire time I worked there.

The plant manufactured microwave popcorn. The process combined popcorn, oil, butter flavor and salt into microwaveable bags. I was promoted soon after I started there and became a mixer.

The following facts are only known to me because they were discovered in my lawsuit in 2004. What the Jasper Plant did not know was that the butter flavor they were using had an increased quantity of diacetyl, a ketone that imparts a buttery taste. Many butter flavors contain about 3% diacetyl. This butter flavor contained 10%.

The company that supplied the butter flavor, Bush Boake Allen, a subsidiary of International Flavors & Fragrances (IFF) had extensive notice about the hazards of butter flavor. They treated butter flavor as a hazardous chemical within their own plant. Since at least 1994 their own workers were required to wear respiratory protection when working around the butter flavor. Despite wearing full-face respirators

many of their employees suffered severe eye injuries. Because of the dangers of the product the entire manufacturing process was enclosed so no one could be exposed to the vapors.

In addition, information had come to IFF about the respiratory effects of exposure to diacetyl. In 1986, two employees of a baking company had been diagnosed with bronchiolitis obliterans while mixing a butter flavoring for use on cinnamon rolls. IFF's trade organization, the Flavoring and Extract Manufacturers Association (FEMA), supplied experts to the defendants in the case. The case was settled before trial.

In 1994 BASF Chemical Company, a supplier of diacetyl sent IFF a Material Safety Data Sheet (MSDS) which disclosed rats that had inhaled the chemical diacetyl developed severe respiratory problems including emphysema. Additionally, another flavor company, Givaudan, had reported to FEMA in 1996 that flavoring chemicals were causing bronchiolitis obliterans in their plant. FEMA had a seminar in 1997 warning flavoring companies about this danger.

Despite all this information the buckets containing this product said the product was safe. The Material Safety Data Sheets said the product had "no known health hazards" and that's what I believed.

Let me bring it home to you if I can. I have a 24% lung capacity. I am currently on the inactive Lung Transplant registry. One case of pneumonia could cause me to need the transplant now. The average rate of survival for someone with a lung transplant is about five years. 75% of lung transplant patients are dead after 10 years.

One of the doctors who worked on the first case involving the two workers with bronchiolitis obliterans in 1990 said that the flavoring industry was using workers as "blue collar guinea pigs."

I played by the rules. I worked to support my family. This unregulated industry virtually destroyed my life. Don't let it destroy the lives of others. These chemicals that are used on food in large scale production must be tested and proper instructions and labeling supplied with their sale.

Chairwoman WOOLSEY. Thank you.

Mr. Schneider?

STATEMENT OF SCOTT SCHNEIDER, DIRECTOR OF OCCUPATIONAL SAFETY AND HEALTH, LABORERS' HEALTH AND SAFETY FUND OF NORTH AMERICA

Mr. SCHNEIDER. Thank you very much for the opportunity to testify today. I appreciate it. It is an important hearing.

The OSHA standard-setting process is broken. There are several reasons for this: first, an inadequate budget for setting standards; second, the layers of review that have been added over the years by Congress and the White House; and third, the lack of political will.

The silica standard is a good example. Silica causes a debilitating lung disease called silicosis. It is estimated that 3,600 to 7,300 people will get silicosis each year. Ten years ago, silica was declared a carcinogen, and OSHA and NIOSH held a national conference to eliminate silicosis.

The OSHA standard is so out of date it requires a measurement method that hasn't been used in industry since 1983 and OSHA itself has called obsolete. OSHA still has not committed to a date for publishing a proposed rule.

Setting standards for construction has been particularly problematic. Many standards are set for general industry that exclude construction with the promise to eventually extend coverage. Often this doesn't happen or only happens years later.

Hearing loss prevention is a worst-case example. In 1983, OSHA published a hearing conservation standard for general industry, promising to come out with one for construction later. Now, 24

years later, we still don't have coverage. OSHA has not even committed to publishing a proposal. In the meantime, thousands of construction workers continue to lose their hearing.

Other states, like California and Washington, are regulating some of these hazards. Why can't OSHA? This committee should demand a response from OSHA and a plan to move forward. Congress should consider a number of solutions to this problem, including, first, a standards board like the one used in California.

Second, setting time limits for OSHA to respond to petitions with the burden on them to explain any denials, and time limits for moving forward to a proposal and a final rule.

Third, rulemaking could be expedited if notices of proposed rulemaking could be published with less review since they do not represent a final standard.

And fourth, emergency temporary standards should be expanded for any hazards that present a high risk.

The current system is broken and needs a serious fix. And I appreciate this committee taking the first step by holding this hearing. And I will submit my full statement for the record.

Thank you very much.

[The statement of Mr. Schneider follows:]

Prepared Statement of Scott P. Schneider, MS, CIH, Director of Occupational Safety and Health, Laborers' Health and Safety Fund of North America

My name is Scott Schneider. I am the Director of Occupational Safety and Health for the Laborers' Health and Safety Fund of North America, a joint labor-management fund of the Laborers' International Union of North America (LIUNA) and its signatory contractors. The Laborers' Union represents about 800,000 mostly construction workers in the United States and Canada. I am a Certified Industrial Hygienist and a Fellow member of the American Industrial Hygiene Association. I have been working on occupational safety and health issues for the Labor movement for over 26 years. I am also a former member of the OSHA Advisory Committee for Construction Safety and Health (ACCSH).

The OSHA Act was passed with the promise to protect workers in America from death and serious injury and illness on the job. That promise has been broken.

My first introduction to OSHA rulemaking came in 1984 when I testified at an OSHA hearing on a proposed asbestos standard. My daughter was born during those hearings. It took OSHA 10 years to finalize that rule. Each year I would remind the folks at OSHA what grade my daughter was in at school until the final rule was issued when she was almost entering middle school. The delays in this instance were not in the process itself so much, the rule was published two years after the hearing, but from the litigation after because the published rule was not protective enough. Now, however, the delays occur much earlier, before the proposals are even published. It was an early lesson for me about the difficulty we face in gaining protection for workers.

When OSHA was created in 1970, OSHA standards were conceived as one leg of a three legged stool—standards, enforcement and outreach. While regulations cannot solve all problems, they are necessary to address market failures in order to keep the playing field level and set a minimum standard for all employers to meet. Many OSHA standards are outdated and the process for updating them or setting new ones is broken. There are three main reasons for this:

1) Lack of budget—only three percent of OSHA's budget—currently about $16 million—goes for standard setting. Currently the standards office is also responsible for developing guidance so the amount for new standards is even less.

2) Regulatory review—Over the years layers of review have been heaped on OSHA causing lengthy delays in the rulemaking process. New rules have to go through advisory committee review, paperwork review, small business review, OMB review, potential Congressional review and, new this past year, external scientific review.

3) Lack of political will—Many needed standards just never get put on the regulatory agenda or sit there for years because the administration is not interested in their promulgation.

About thirteen years ago OSHA began to use "negotiated rulemaking" to speed up the process and, hopefully, avoid litigation. They convened a panel of industry experts, both labor and management, to develop a draft consensus rule. Once published, because of the consensus, there should be less chance of litigation. But even when OSHA has used negotiated rulemaking, the publication of the proposed rule can often take years. The new Cranes and Derricks standard for construction was developed by a negotiated rulemaking team through monthly meetings over the course of one year. Consensus was difficult but was finally achieved. Yet, almost three years later the proposed rule has not been published. It is currently scheduled for publication in October, although these deadlines have a way of slipping.

Construction standards

OSHA has a bad habit of setting standards for general industry and exempting the construction industry from coverage, promising future rulemaking that may never come. Meanwhile construction is one of the most dangerous industries in the country with 100 construction workers dying on the job each month. In 1993, OSHA issued a standard to protect workers in confined spaces from the danger of asphyxiation. This standard was supposed to be adapted for construction. The calendar claims that a proposed rule would be issued by February 2007, but again that hasn't happened. After 14 years, we still don't have a proposed rule and workers keep dying in confined space fatalities.

In 1998, OSHA issued a general industry "lockout/tagout" standard to prevent injuries among workers doing maintenance on machinery. The development of a proposed standard for construction was dropped in September 2001 when OSHA summarily dropped over dozen proposed rules (including a proposal for comprehensive safety and health programs in construction and improving sanitation in construction) from its agenda, claiming it did not have the resources to pursue them all.

While standards need to be modified to meet the unique characteristics of the construction industry, that should not require a 10, 15 or 20 year delay. Such standards can and should be developed simultaneously with those for general industry. The nation's seven million construction workers do not deserve second class protection.

Silica and Hearing Loss in Construction

Silica is a common dust hazard in construction. Its dangers have been known for about three hundred years. Its cancer-causing properties have been well documented for over ten years. The risk estimates show very high risk of silicosis and cancer from exposures. Between 3,600 and 7,300 people are estimated to get silicosis each year. At the same time, numerous studies document successful and inexpensive control methods to reduce dust levels. The measurement methods required by OSHA for measuring silica levels are, by their own admission, "obsolete" and have not been used in voluntary standards since 1983. I'm not even sure how OSHA can enforce the current standard given the problems with measurement methods. The voluntary standard (TLV) for silica exposures was cut in half again last year for the second time in the past nine years. Yet OSHA's standard is mired in the past.

OSHA identified silica as a priority for its rulemaking efforts in 1994. Ten years ago OSHA and NIOSH held a National Conference to Eliminate Silicosis. Silica has been on the OSHA regulatory calendar for almost ten years. A draft standard has been developed and was reviewed by SBA in 2003. A peer review of the health effects data was to be completed this month. Yet there is still no date certain for a proposed rule to be published. While we wait for OSHA to move forward, construction workers and others continue to suffer and die from debilitating lung diseases and cancer as a result of this delay.

Hearing loss is an enormous problem in construction. In 1983, OSHA published a hearing conservation standard for general industry that triggers a comprehensive hearing protection program at less than half the allowable exposure limit for construction workers. Construction workers were excluded from that standard but OSHA promised to extend coverage in the future. Twenty-four years later OSHA's regulatory calendar now lists this as a "long-term action" and does not commit the agency to issuing a standard. Seven years ago last month at a national conference hosted by the Laborers' Health and Safety Fund on preventing hearing loss in construction, a previous OSHA assistant secretary claimed it would be a priority for his agency. That commitment has been lost. In the meantime thousands of construction workers have lost their hearing and their quality of life. Workers who have lost hearing may also be in danger of their lives on the job if they cannot hear warnings.

Some states have moved forward while OSHA delays. Washington State extended the hearing conservation standard to construction several years ago. New Jersey has instituted a ban on the dry cutting of masonry and California is expected soon to follow suit. Washington State has just published a tough new standard for crane safety, well before an OSHA rule is even proposed.

We urge the committee to press for a report on the status of these rulemakings, why OSHA has not moved more quickly to address these serious hazards and what their plan is to move forward on both these critical issues.

How can we fix this problem?

Congress should seriously consider a legislative fix to this problem. Here are several options to be considered:

1) Standards Board—California has had success with a Standards Board in promulgating many regulations, e.g. heat stress, safety and health programs, which OSHA has not even begun to consider. The Board has labor, management and academic members. One of LIUNA's Vice Presidents serves as a member of that Board.

2) Time Limits—Congress can set time limits for OSHA to consider and then issue proposals and final rules. In the past Congress has mandated that OSHA issue rules within a six-month period and the agency has done so (e.g. lead, hazardous waste). Congress should give OSHA a limited time, say four months, to consider any petition for new standards and require the agency to publish a response in the Federal Register as to its reasons for accepting or denying the petition. The burden should be on the agency to show why a standard should not be issued. Once committed to a rule making, the agency would be given additional deadlines to meet to ensure that rules are issued in a timely manner, say no more than three years. Congress would have to provide additional funding for OSHA dedicated to standard setting in order for it to meet these deadlines.

3) Expedited Rulemaking—Congress should streamline the rulemaking process. Once OSHA commits to developing a standard, a Notice of Proposed Rulemaking is published. These Notices of Proposed Rulemaking (NPR) undergo extensive review before they are published. Then they are reviewed by the public through a series of public hearings. The final rule is issued after a review of the record created through these public hearings. The NPR is not the final rule and should not be viewed as an end product. The vetting of NPRs is excessive and onerous. Congress should reduce the burden of proof needed for issuance of an NPR.

4) Emergency Temporary Standards (ETS)—Congress should review and expand the ability of OSHA to issue "emergency temporary standards." This section of the Act has been undermined by court decisions and is not used any more because of that. Congress could define risk criteria that once met would allow issuance of an ETS to speed up rulemaking for high risk hazards.

The current system is broken and blocked. We need a serious effort to solve this problem. Workers should not have to wait decades for needed protections. I hope Congress will take up this issue and craft a workable solution. This hearing is an important first step.

Chairwoman WOOLSEY. Thank you, Mr. Schneider.

Mr. Fellner?

STATEMENT OF BARUCH FELLNER, ATTORNEY, GIBSON, DUNN & CRUTCHER

Mr. FELLNER. Chairwoman Woolsey, members of the Workforce Protection Subcommittee, my name is Baruch Fellner. I am an attorney with the law firm of Gibson, Dunn & Crutcher.

Since OSHA's birth some 35 years ago, I have, as it were, worked both sides, having shaped OSHA's enforcement policies and priorities during its first decade and having questioned them thereafter.

I therefore hope to bring a broad, substantive and historical perspective to this committee's deliberations. To that end, I will reject the temptation of answering the question posed at today's hearing with a resounding yes, yes, that OSHA has moved with all deliberate speed in responding to workplace hazards.

That simple response is supported, indeed, by the fact that American workplaces, as you have heard, have become demon-

strably safer, as evidenced by the steady decline of reported workplace injuries, illnesses and fatalities.

A specific example of that process working involved an industry challenge to OSHA's most recent hexavalent chromium standard. I negotiated the settlement of that challenge on behalf of the electroplating industry.

It was beneficial to all parties. It was signed by the industry, OSHA, by Public Citizen and by the United Steelworkers.

Nevertheless, it is clear that, like any other agency dealing with complex scientific, technological and economic issues, OSHA's task is enormously difficult and time-consuming, and I would respectfully submit with good reason.

First, the OSHA statute requires the Agency to make detailed findings of significant risk of material impairment of employee health and to establish technological and economic feasibility before it can pursue regulation of a workplace hazard. These are not simple tasks. And to do them in a cursory fashion is to invite court rejection of OSHA standards.

Second, OSHA's regulations are on the frontiers of science. They rely on a variety of often conflicting retrospective, cross-sectional, prospective and, the gold standard, randomized control trial studies. Epidemiological and biostatistical analyses do not make OSHA's job any easier, and often intuition and anecdote that fuel public policy clash with evidence-based medicine.

And OSHA must do all of these things based upon what the statute describes as the best available evidence. Therefore, in the context of such cutting-edge science, OSHA's task of establishing permissible exposures limits is, indeed, a daunting one.

Third, nor can OSHA simply cut through all this complexity and recognize a few studies that seem to point in the direction of most protective standard it can promulgate. Even if the Agency could get away with such a truncated process, which I submit it cannot, it is simply not good public policy to ignore the enormous costs of OSHA regulations.

For example, by OSHA's own admission, the ergonomics regulation rejected by Congress under the Congressional Review Act would have cost American industry billions—that is billions—of dollars and made it the most expensive regulation in Department of Labor history and, some would suggest, in the history of the Republic.

In the context of a global economy and the outsourcing of American jobs, good public policy demands an appropriate balance between a standard-setting process that keeps up with workplace hazards and one that does not jeopardize the very existence of those workplaces.

Fourth, OSHA's regulatory actions are subject to the requirements of the Administrative Procedures Act. Since 1946, the APA and appellate review have been this Nation's insurance policy against arbitrary and capricious agency action.

And as this Congress well knows, it provides for notice and comment. It insists that all parties, not only those parties that are directly affected—and we were all moved by Mr. Peoples' statement—by substances themselves but also those parties that will be regulated by the very OSHA standards themselves.

We would submit that in a democracy this transparency, this notice and comment process, is more fundamental than any individual OSHA standard itself.

Fifth, and perhaps most importantly, the question before this committee frames the fundamental issue of OSHA priorities. What are the workplace hazards du jour, and should they galvanize OSHA's immediate attention? Can or should OSHA's priorities be micro-managed outside the Agency?

And in this regard, I think the ergonomics regulatory process is particularly instructive. It is a classic example of the doctrine of unintended consequences. The massive amounts of time and resources applied over 10 years to the ergonomics regulation clearly delayed and prevented the promulgation of other OSHA standards that would have been responsive to workplace hazards.

I welcome the opportunity to address these important questions as to the pace of OSHA standard setting. I respectfully submit that while the process appears glacial and cumbersome, it strikes an appropriate balance among the complex scientific, economic and public policy considerations.

I have submitted for the record a complete version of my comments, and I look forward to your questions.

[The statement of Mr. Fellner follows:]

Prepared Statement of Baruch A. Fellner, Gibson, Dunn & Crutcher, LLP

Summary of Testimony

This testimony will concentrate on the legal and public-policy constraints that prevent immediate promulgation of occupational safety and health standards. Among those constraints are requirements for notice and comment as well as court review of OSHA standards; the complexities of science and statistics on which such standards are based; the OSH Act statutory framework requiring findings of significant risk and feasibility to support OSHA standards; the staggering costs of such regulations; and the practical impact on available resources of competing regulatory priorities.

Chairman Woolsey, Members of the Workforce Protections Subcommittee, my name is Baruch Fellner, an attorney with the law firm of Gibson, Dunn & Crutcher, LLP. I very much appreciate your invitation to participate in this important hearing dealing with the question "Have OSHA standards kept up with workplace hazards?" I appear this afternoon in my personal capacity as a citizen and not on behalf of any clients. Indeed, since OSHA's birth over 35 years ago, I have worked both sides, having shaped OSHA's enforcement policies and priorities during its first decade and questioned them thereafter. I therefore hope to bring a broad substantive and historical perspective to this Committee's deliberations.

To that end, I will reject the temptation of answering the question posed at today's hearing with a resounding "yes"—that OSHA has moved with all deliberate speed in responding to workplace hazards. That simple response is supported by the fact that American workplaces have become demonstrably safer as evidenced by the steady decline of recorded workplace injuries, illnesses and fatalities—all while the economy has grown and jobs have increased at enormous rates over the past 35 years. Notwithstanding the pace of regulations, OSHA must be doing something right.

Instead of such a facile response, however, allow me to draw upon my experiences as a government attorney trying to get standards promulgated and then defending them, as well as a management attorney challenging such standards and finally as one who facilitates the settlement of such standards challenges in a manner that promotes the interests of all parties. For example, I represented the electroplating industry in its challenge to OSHA's most recent hexavalent chromium standard. We resolved our challenge to OSHA's standard in a settlement signed by the industry, OSHA, Public Citizen and the United Steelworkers. This agreement was recognized as a win for all parties and the vindication of a process that functioned properly to protect American workers.

Despite some evidence that the OSHA regulatory process is working, I would be the first to acknowledge that like any other agency dealing with complex scientific, technological and economic issues, OSHA's task is enormously difficult and time consuming. And, I would respectfully submit, with good reason.

First, the OSHA statute, as interpreted by decades of case law, requires the agency to make detailed findings of significant risk of material impairment of employee health before it can pursue regulation of a workplace hazard. See, e.g., Indus. Union Dep't, AFL-CIO v. Am. Petroleum Inst. ("Benzene"), 448 U.S. 607, 639 (1980) (holding that Secretary can regulate only if a "significant risk of a material health impairment" exists (emphases added)). In addition, OSHA must gather credible evidence with respect to the technological and economic feasibility of its regulations, and it must do so industry by industry. United Steelworkers v. Marshall, 647 F2d 1189 (D.C. Cir. 1980). Finally, it must perform what amounts to a cost benefit analysis. These are not simple tasks and to do them in a cursory fashion is to invite court rejection of OSHA standards.

Second, OSHA's regulations are on the frontier of science. They rely on a variety of retrospective, cross-sectional, prospective and randomized controlled trial studies. Epidemiological and biostatistical analyses do not make OSHA's job any easier. And often, intuition and anecdote that fuel public policy clash with evidence-based medicine. Therefore, in the context of such cutting edge science, OSHA's task of establishing permissible exposure limits is indeed a daunting one. See Cellular Phone Taskforce v. FCC, 205 F.3d 82, 90 (2d Cir. 2000). ("In the face of conflicting evidence at the frontiers of science, courts' deference to expert determinations should be at its greatest").

Third, nor can OSHA simply cut through all this complexity and recognize a few studies that seem to point in the direction of the most protective standard it can promulgate. Even if the agency could get away with such a truncated process, which it cannot as I will discuss in a moment, it is simply not good public policy to ignore the enormous costs of OSHA regulations. For example, by OSHA's own admission, the ergonomics regulation, rejected by Congress under the Congressional Review Act, would have cost American industry billions of dollars and made it the most expensive regulation in Department of Labor history, and some would suggest in the history of our Republic. In the context of a global economy and the outsourcing of American jobs, good public policy demands an appropriate balance between a standard setting process that keeps up with workplace hazards and one that does not jeopardize the existence of those workplaces.

Fourth, OSHA's regulatory actions are subject to the requirements of the Administrative Procedures Act ("APA"). 5 U.S.C. § 5 et seq. Since 1946, the APA and appellate review have been this nation's insurance policy against arbitrary and capricious agency action. The APA was passed during a period of expanding power for the federal government—and was the result of decades of careful deliberation on how to best provide Constitutional safeguards to govern agency action. The APA requires transparency in government through notice to stakeholders of proposed rulemaking, the opportunity for comment and informal hearings, the promulgation of final rules that deal with stakeholder concerns and the opportunity for appellate review. These activities take time, but in our democracy it is essential that all voices are heard and considered—particularly those that will be subjected to regulation—before difficult and controversial regulations are promulgated. That is the objective of the APA as reinforced by Section 6(b) of the OSH Act. That objective is more fundamental than any individual OSHA standard.

Fifth, and perhaps most importantly, the question before this Committee frames the fundamental issue of OSHA priorities: what are the workplace hazards du jour and should they galvanize OSHA's immediate attention? Can or should OSHA's priorities be micromanaged from outside the agency? In this regard, the ergonomics regulatory process is instructive. It is a classic example of the doctrine of unintended consequences. The massive amount of time and resources applied to the ergonomics regulation clearly delayed and prevented the promulgation of other OSHA standards that would have been responsive to workplace hazards.

Finally, the question of OSHA regulatory priorities is only part of a broader set of OSHA issues. What remains are more challenging, complex, and subtle issues about how to improve workplace safety—and let us be clear, this is the cause which unifies us all—not the question of how many standards OSHA has issued, or even whether all employers comply with these standards. Some of those questions to which I would invite this Committee's attention are:

- How best to get small businesses which rarely if ever have dedicated safety personnel to focus on safety in their workplaces, and assist them in navigating the complex minefield that OSHA's regulations have become.

• How should exposure levels be updated that seek control measures that would quickly over-burden employers and exacerbate the trend towards exporting jobs.

• Given that there will never be an OSHA inspector in every workplace, what is the best model to achieve employer compliance with OSHA regulations and good workplace safety practices?

• Is OSHA getting its "bang for its enforcement buck" by directing its inspectors to workplaces with the deadliest and most serious workplace hazards subject to regulations that are already on the books?

I welcome this opportunity to address the important question of the pace of OSHA standard setting. I respectfully submit that while the process appears glacial and cumbersome, it strikes an appropriate balance among the complex scientific, economic and public policy considerations. I look forward to your further questions.

Without regard to formal administrative requirements, OSHA may enact an emergency temporary standard to take immediate effect upon publication in the Federal Register if it is determined that (a) employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards, and (b) that such emergency standard is necessary to protect employees from such danger. See 29 U.S.C. § 655(6)(c)(1). This is a drastic measure intended only for the most dire and pressing of circumstances. See, e.g., Public Citizen Health Research Group v. Auchter, 702 F.2d 1150, 1155 (D.C. Cir. 1983) (noting that the power to enact emergency standards is "extraordinary," and "to be used only in limited situations * * * [in] response to exceptional circumstances.") (internal quotations and citations omitted).

Chairwoman WOOLSEY. Thank you, Mr. Fellner.

Mr. Mirer?

STATEMENT OF FRANK MIRER, PROFESSOR OF ENVIRONMENTAL AND OCCUPATIONAL HEALTH SCIENCES, HUNTER SCHOOL OF URBAN PUBLIC HEALTH

Mr. MIRER. I am Frank Mirer, now professor of environmental and occupational health at Hunter College of the City University of New York.

Previously, I spent 30 years in the trenches of OSHA standard setting, some with Mr. Fellner on the other side of the table. I was among the parties convened by the late Representative Norwood to talk about updating the PELs. And I, too, have negotiated settlements in post-standards litigation.

My academic project now is analyzing the regulatory process so that policy makers and Congress can implement standard setting and change the process based on sound science and objective data.

My key points today are that, first, new, updated 21st-century OSHA standards are necessary to protect workers, to keep from repeating the story that Mr. Peoples has told over again.

OSHA standard setting has ground to a halt in the current administration. For chemical exposures, there are many examples of OSHA standards which allow exposures so high that workers get sick, and many chemicals that aren't regulated at all.

It is true that many obstacles to new OSHA standards have been imposed by executive orders, Congress and the courts, but the fact is OSHA has the scientific backing and the resources to set many new standards if the staff were allowed to go forward with the process.

Now, it is clear that OSHA since 2001 has checked out of the standards business. Slow progress has ground to a halt. The personal protective equipment standard, which Mr. Foulke mentioned—the date was announced settling a lawsuit.

More than a year ago, a group of unions petitioned OSHA seeking an emergency standard to protect health care workers from pandemic flu and also other respiratory disease. This is essential to public health protection. It was denied.

A union petition to expand process safety management standard to workplaces with reactive chemicals that could explode was denied. A union petition for a standard on diacetyl is lying fallow.

The administration removed about two dozen items from the longstanding regulatory agenda, including metal working fluids that I will talk about later if there is time.

The standards reported by Mr. Foulke—some of them were takeaways, like the rules for respirators.

And most importantly, one of those changes was a change in the rules for recording workplace injuries which permits employers not to report and record injuries that they previously had to and is directly responsible for at least some, if not all, of the reduction in injury rates reported by Mr. Foulke and Mr. Fellner.

In fact, some of the other reductions were the implementation of the elements of the ergonomic standard that also caused that reduction.

Now, let me bring you something new. That is all old stuff. I am now teaching graduate students in industrial hygiene.

In my toxicology class, first we look at scientific data on health effects. Then we talk about exposure limits. And my students ask me why California limits occupational exposure to carbon monoxide—carbon monoxide, one of the oldest chemicals that we know about—to half of what OSHA allows, why a dry cleaning chemical, perchloroethylene, is limited to a quarter of what OSHA allows, or why a certain solvent found in inks California limits to one-fortieth of what OSHA allows.

One of these is a carcinogen. One causes reproductive abnormalities. Each of these was on OSHA's list for rulemaking. Each was removed by the administration.

In my longer testimony, I describe an experience at a machining plant in Ohio where workers suffered as bad similar adverse effects, respiratory effects.

In my testimony, we describe how an OSHA inspection in the middle of this outbreak found no problems because the plant was in compliance with the OSHA standard.

Our petition for a new standard was denied. Our court suit to try and get the standard moving again was unsuccessful. And so workers remain at risk for this.

I think what we need most importantly and most quickly from this committee is, at least for the meager remnants on OSHA's regulatory agenda, that the Congress get these things moving forward and, in particular, get the silica standard moving forward again. It has been too long. It causes illnesses just like you have heard about today.

Thank you very much.

[The statement of Mr. Mirer follows:]

Prepared Statement of Franklin E. Mirer, PhD, CIH, Professor, Environmental and Occupational Health Sciences, Urban Public Health Program, Hunter College School of Health Sciences, City University of New York

My name is Frank Mirer. I am Professor of Environmental and Occupational Health at Hunter College of the City University of New York. Previously, I served as Director of the Health and Safety Department of the United Automobile, Aerospace, and Agricultural Implement Workers of American (UAW), International Union. I thank you for the opportunity to testify just before Workers Memorial Day, the time we specially focus on protecting workers. My testimony will focus on the need for OSHA to promulgate new safety and health standards for a host of chemicals and other hazards.

I've had more than 30 years experience in the OSHA standards process. I first testified before OSHA on the standard for lead on May 13, 1977. Since then, the UAW took the lead on successfully pushing OSHA to set three key standards, and participated in more than a dozen other processes leading to OSHA rules. I also participated in the UAW's so far incomplete battle for a standard for metalworking fluids.

My academic project is analyzing the regulatory process, so that policy makers can both implement standard setting and change the process based on sound science and objective data.

The key points of my presentation today are:

1. OSHA standards are necessary to protect workers.
2. OSHA standard setting has ground to a halt in the current Administration.
3. For chemical exposures, there are many examples of OSHA standards which allow exposures so high that workers to get sick.
4. Many obstacles to new OSHA standards have been imposed by Executive Orders, the Congress and the Courts.
5. Despite this, OSHA has the scientific backing and resources to set these new standards, if the staff were allowed to set standards.

My recent review, and long experience, show that OSHA, since 2001, has checked out of the standards business. Slow progress in earlier years has ground to a halt and may even be moving stealthily backward. OSHA has staff and other resources to set standards, but that staff has not been permitted to operate. Since 2001, this Administration set one new chemical standard, for carcinogenic chromium, under court order. That standard actually permits employers to increase exposure levels under some circumstances. Unions were forced to sue to get improvements, and that litigation still pends. Regarding employers' responsibility to pay for required protective equipment like respirators and wire mesh gloves, Labor Secretary Elaine Chao finally committed to issuing a final rule in response to a union lawsuit and a court ordered deadline. That rule was promised by November 2007. The rulemaking record was completed in 1999.

More than a year ago, a group of unions petitioned OSHA seeking the emergency standard to protect health care workers, first responders and others whose jobs might put them at risk during a flu pandemic. The Administration denied that petition. This places the entire country at greater risk of retransmission of respiratory disease through the health care system.

A union petition to expand the Process Safety Management standard to workplaces with reactive chemicals that could explode or burn has been ignored. This expansion would be important to the communities near dangerous facilities exempt from the standard.

A union petition to protect food processing workers against the deadly vapors of an artificial flavor ingredient, diacetyl, has likewise been denied. These vapors cause a devastating and potentially fatal lung disease among workers making microwave popcorn, and may pose a hazard to workers and consumers down stream.

This Administration removed about two dozen items from a long standing regulatory agenda, including protection of health care workers against TB, and several very important chemical exposure limits, including metalworking fluids. Many of the initiatives left behind, like some rules for respirators, and recording workplace injuries, were takaways.

When the UAW sued OSHA for removing metalworking fluids from the regulatory agenda in 2001, in the face of continuing outbreaks of severe and disabling respiratory disease, the Administration defended the case saying resources were needed to set rules for silica and beryllium. But silica and beryllium are still hanging from then to now in the pre-rule stage, without even a date when a notice of a proposed rulemaking or a proposed standard might be issued.

Apologists for this record cite the new obstacles to standards which have been erected since 1970. I agree, it's time to reduce those obstacles. But the obstacles

don't fully explain the near complete halt. The first barrier to setting a new standard is getting the Labor Department to recognize that something needs to be done about a hazard. That's a political leadership decision. Once there's a decision to move forward, the task that causes the most delay is gathering business data to estimate costs. But, OSHA staff has figured out how to get that cost information. After that, the barriers, and sources of delay, are getting approval from the Office of Management and Budget to put a standard on the agenda, complete the small business (SBREFA) review to release a proposed standard, and to finally promulgate the final standard. But, OMB is not a free agent. The same President who appointed the Secretary of Labor and Assistant Secretary of Labor for OSHA also appointed the heads of OMB and the Small Business Administration.

For all that, OSHA has the resources to start and eventually bring to conclusion several meaningful standards each year. It may be a few years from starting down the pipeline to finishing, but OSHA has proven it can sustain its burden of proof in court when it tries to protect workers' health. It's time to hold the Administration accountable for its record. Not only has little or nothing been finished, but the pipeline is empty for any future President.

Chemical exposure limits are very important, and I want to address these at some length.

My students are graduate students in industrial hygiene. In my toxicology class, first we look at scientific data about health effects, then we talk about exposure limits. My students ask me why California limits occupational exposure to carbon monoxide to half what OSHA allows, or why a dry cleaning chemical (perchloroethylene) exposure in California is limited to ¼ of what OSHA allows, or why OSHA allows 40 times more exposure to a solvent (ethoxyethanol) sometimes found in inks. The dry cleaning chemical is a possible carcinogen, the ink solvent is a reproductive toxin. Health science supports the stricter limits, and implementation in California proves their practicality. Each of these substances was on OSHA's list for rulemaking, and each was removed by the Administration.

My professional organization, the American Industrial Hygiene Association, polled its members for the leading OSHA issue, the leading Legislative Issue and the leading professional issue for 2007-8. The answer in each category was the same: PEL's.

Chronic illness arising from long term chemical exposures at work accounts for the large majority 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 1970, it inherited hundreds chemical exposure limits, based on the science of the '60s and before. Those limits were set with substantial involvement of chemical industry scientists through the American Conference of Governmental Industrial Hygienists (ACGIH). Those limits were not intended to be as protective as rules mandated by the OSHA law. Nevertheless, these Threshold Limit Values were a starting line for limiting chemical exposures.

In the more than three decades of OSHA's existence, the agency has issued new permissible exposure limits for only 16 agents or groups of agents. Eight of these were set in the '70s, 3 in the '80's, 4 in the '90's, and only 1 in the 21st century Most of these rules were triggered by union or public interest petitions, and defended in court by these same groups. These rules radically reduced permissible exposures from the 1968 levels, protected workers, transformed industries, and largely avoided inflated high costs projected by industry doomsayers. Those costs which were actually incurred included wages of workers fabricating and maintaining control equipment, and cleaning the workplace, so these rules likely created jobs.

My conclusions, based on detailed review of scientific and regulatory history of the standards set and standards not set, are that OSHA could have, and should have issued rules for dozens of additional chemicals. I want to emphasize that OSHA staff could have met the legal tests for proof, and the procedural requirements of setting standards, with the resources now provided.

Yes, industry litigants have persuaded judges to increase OSHA's burden of proof to set a standard. Yes, regulatory legislation has imposed additional steps, delays and economic tests which stretch out the process by years. Yes, the Office of Management and Budget has been empowered by executive orders to slow the standard setting process and challenge OSHA's expert scientific and engineering conclusions. For all of that, OSHA has the resources and scientific and engineering support to start several standards each year, and to bring these rulemakings to successful conclusion within four years. That is, if the OSHA staff are permitted to do their work.

The effects of OSHA failing to set new exposure limits 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 in the year 2000? 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 that 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 to silica 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. OSHA and EPA may have measured the wrong chemicals at the wrong time, and have not taken mixtures into account, or special circumstances. Nonetheless, following OSHA standards allowed workers in large numbers to get sick, nobody disputes that anymore.

The stories of Popcorn Workers Lung, and respiratory illness from metalworking fluids, include the same plot elements: devastating illness from exposure levels permitted by OSHA or not limited at all, no action or ineffective action from OSHA.

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% 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. In the accompanying table, we see that OSHA's new rules have reduced allowable exposure by up to 1000-fold.

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 last year only after 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, and ended by settling a UAW lawsuit. Allowable exposure was reduced to 5% of what was previously allowed.

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 (botulinum toxin which paralyzes all muscles) into an agency already paralyzed by analysis. But the delays are also attributable to the failure of the OSHA political leadership and the Administration to support prompt action in promulgating additional standards.

The legislative fix to this impasse has at least three parts.

First, Congress has to hold the Administration's feet to the fire on the meager current regulatory calendar. In particular, OSHA must be directed to issue a proposed silica standard, hold hearings, and issue a final standard, each by a date certain.

Second, courts have severely limited the circumstances where OSHA can be compelled to move forward in standard setting. Meanwhile, management can sue OSHA whenever OSHA does make a new rule. OSHA should be required to meet a high threshold to defend refusing a petition for a new standard. The playing field should be leveled.

Third, 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 occupational health practitioners charged with investigating, recommending, and annually reviewing exposure limits for chemical substances. Generally, the TLV's do not limit exposure as much 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. 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.

In conclusion:

1. OSHA standards are necessary to protect workers.
2. OSHA standard setting has ground to a halt in the current Administration.
3. For chemical exposures, there are many examples of OSHA standards which allow workers to get sick.
4. Many obstacles to new OSHA standards have been imposed by Executive Orders, the Congress and the Courts.
5. OSHA has the scientific backing and resources to set these new standards, if the staff were allowed to start the process.

Annotated Chronology of OSHA PEL's Showing Extent of Exposure Limitation

Substance	1910	Date	Previous	Final	Reduction
Asbestos	1001	1971	12 f/cc	5 f/cc	2.4
13 Carcinogens	1003	1974	NA	NA	
Vinyl Chloride	1017	1975	500 ppm	1 ppm	500
Asbestos	1001	1976	5 f/cc	2 f/cc	2.5
Coke Oven Emissions	1029	1977	0.2 mg/M^3	0. 15 mg/M^3	1.3
Inorganic Arsenic	1018	1978	0.5 mg/M^3	0.01 mg/M^3	50
Lead	1025	1978	200 ug/M^3	50 ug/M^3	4
DBCP	1044	1978		0.001 mg/M^3	na
Acrylonitrile	1045	1978	20 ppm	2 ppm	10
Cotton Dust	1043	1978	1 mg/M^3	0.2 mg/M^3	5
Asbestos		1984	2 f/cc	0.2 f/cc	10
Ethylene Oxide	1047	1986	50 ppm	1 ppm	50
Benzene	1028	1987	10 ppm	1 ppm	10
Formaldehyde	1048	1988	3 ppm	0.75 ppm	4
Cadmium	1027	1992	0.2 mg/M^3	0.005 mg/M^3	40
Methylenedianiline	1050	1992		0.01 ppm	na
Lead In Construction	1926.62	1993	200 ug/M^3	50 ug/ M^3	4
Asbestos	1001	1994	0.2 f/cc	0.1 f/cc	2*
Asbestos in Construction	1926.1101	1994		0.1 f/cc	na
Butadiene	1051	1996	1000 ppm	1 ppm	1000
Methylene Chloride	1052	1998	500 ppm	25 ppm	20
Chromium (VI)	1026	2006	52 µg/M^3 c	5 µg/M^3	10.4**

* The four PEL's set for asbestos eventually mandated a 120-fold reduction from pre-OSHA PEL
** Pre-existing PEL was a ceiling limit in units of a different chemical form; actual permitted exposure under the new PEL could be higher than previous.

Chairwoman WOOLSEY. Thank you.

I think you heard the bells ringing. We have five votes, but we do have 5 minutes.

I am going to be here for the duration, so if there is anybody on the subcommittee that can't come back that would like to ask a question and use that 5 minutes, I am willing to yield.

Mr. Payne from New Jersey?

Mr. PAYNE. Thank you very much.

Let me just quickly ask a question to perhaps Mr. Foulke.

I have noticed a disturbing trend toward replacing standards with this voluntary alliance, mostly among industry members, instead of using OSHA standards. For example, instead of modifying the process safety management standard to include reactive hazards as the Chemical Safety Board recommended in 2002, OSHA established an alliance which was concluded last month.

The reactives issue is serious, having killed well over 100 workers in preventable explosions over the last couple of decades. In 2004, the Chemical Safety Board declared OSHA's response to be unacceptable.

So, Mr. Foulke, can you tell me what the reactives alliance accomplished aside from training a few dozen people and staffing

booths at numerous conferences? What was the actual accomplishment of this alliance?

Mr. FOULKE. The point of our alliance program is to tell industries and other organizations, such as labor organizations—to help them identify the safety and health hazards that directly impact on their particular industry and their particular workers.

And if you look at the alliances that we have worked with, a lot of them have been very successful in helping to produce guidance documents, best practices.

And I am not exactly sure with respect to this particular alliance—I know that the process safety management standard covered many of the recommendations that dealt with the reactive chemicals.

But what we were trying to do with—what we try to do with each one of our alliances is to outreach and to determine what are the most critical safety and health hazards that are facing that particular industry or that particular union's membership and then to address those by providing the best practices and guidelines and training——

Mr. PAYNE. All right. Let me just—because time is running, I am going got cut you off. But do you have any evidence that you think that it is more effective with the alliance than it would have been under OSHA? I mean, do you accomplish more safety, workers are in better shape?

Maybe a yes or no.

Mr. FOULKE. My answer would be yes. I think our alliance programs——

Mr. PAYNE. Okay. All right.

Mr. FOULKE [continuing]. Are very effective.

Mr. PAYNE. Then let me ask you another question, then. If that is yes, do you mean by less regulations no real—and actually, you concluded this. I mean, this particular alliance is over, so therefore I assume, then, that the problem is solved.

Mr. FOULKE. Well, what we did was we—in the particular alliances, when they are instituted, we may have developed the appropriate best practices—whatever we were focused in on, we would try to address those particular hazards.

The nice thing about the alliance program is that OSHA is able to outreach to so many more employers and thus cover so many more employees by quickly developing and working together to develop these guidance documents, these best practices, these training modules, all these different things that kind of—and that is why I said I think we have been very successful.

And I think the fact that the numbers I suggested on injury and illness rates going down show that the four-prong approach that OSHA utilizes is being effective.

Mr. PAYNE. Well, actually, I certainly disagree, and I think the word that you mentioned is "nice." I think that what OSHA is trying to be is nice. But when people are losing their lives in different work, you don't have to be nice. You have to have protections for the worker.

And I am not going to have time to ask, you know, Mr. Fellner a question, but I did take note that when he was saying that OSHA is moving with all deliberate speed, it reminded me of the

1954 Supreme Court decision that said that separate but equal is unconstitutional, that we should move with deliberate speed to integrate public schools in the United States. That was 50 years ago, and today public schools are more segregated than they were in 1954.

So when I hear "deliberate speed," I am glad that you reminded me of what I think is happening with OSHA.

I have to yield back the balance of my time.

Chairwoman WOOLSEY. Thank you.

Now we have to go vote. And as soon as the fifth vote is finished, we will be back up here. It will be at least 20 minutes.

[Recess.]

Chairwoman WOOLSEY. The hearing will come back to order.

Thank you for waiting for us. This is what our day is like, so, you know, back and forth, back and forth.

Mr. Bishop from New York will be the next to ask questions.

Mr. BISHOP. Thank you very much, Madam Chair, and thank you for holding this hearing. Thank you for indulging my schedule.

And thank you to the witnesses for your testimony.

Mr. Fellner, let me start with you. And I don't wish to be impolite, but I have to say I found your characterization of workplace hazards as the "hazards du jour" to be offensive.

And I don't mean this to be a flippant question, but would you be so cavalier in your description if you yourself were suffering from a workplace injury or a loved one were suffering from a workplace injury or hazard that had not been attended to over, let's say, a 14-year or 15-year period?

Mr. FELLNER. Congressman Bishop, the reference to "hazards du jour" is directly responsive to the question as framed by this committee; namely, is standard setting responsive to workplace hazards?

I submit to you with all respect, Congressman Bishop, that it cannot be responsive to workplace hazards in an orderly fashion when the issues that are gaining center stage are those that are in the press for 15 minutes or 30 minutes or the "hazards du jour."

Mr. BISHOP. All right.

Mr. FELLNER. There must be an orderly process.

Mr. BISHOP. If I may, can I infer from your answer that you would not place in that characterization "hazards du jour" the types of hazards that we have heard described here today, such as the hazard of working in confined spaces, one that I understand from Mr. Schneider's testimony has now not been addressed fully for 14 years? Would that have a hazard of somewhat greater duration than 1 day?

Mr. FELLNER. The answer specifically with respect to the standard that you have raised, the confined space standard—there is a confined space regulation. It is enforced by OSHA. It is enforced effectively by OSHA. It is not a hazard to which OSHA has not responded. It has responded.

There may be those——

Mr. BISHOP. If I may interrupt—I only have 5 minutes, so if I may interrupt.

Mr. FELLNER. I understand.

There may be those who suggest that it hasn't been responded to adequately.

Mr. BISHOP. I would like to ask Mr. Schneider to address your characterization of how OSHA has responded to that hazard.

Mr. SCHNEIDER. Well, unfortunately, that standard excludes the construction industry. And the construction industry has been working on a standard for confined spaces and has promised us one, but it hasn't been published yet. And 14 years later, construction workers are not afforded the same coverage, the same safety, as people that are not in construction.

Mr. BISHOP. I have one more question for you, Mr. Fellner. In your testimony, you suggest that good public policy demands an appropriate balance between a standard-setting process that keeps up with workplace hazards and one that does not jeopardize the existence of those workplaces, admittedly a difficult balance to arrive at and maintain.

Where would you place on that continuum the problem with diacetyl? Am I pronouncing it correctly? Where would you place that? Are we maintaining the appropriate balance? Are we not acting quickly enough? Are we acting too precipitously?

Mr. FELLNER. To the best of my knowledge, Congressman Bishop, there is no dose response curve with respect to diacetyl.

In the absence of a dose response curve on that particular substance, while there is some evidence of medical effects with respect to exposures to diacetyl at high levels, as the Supreme Court indicated in the benzene decision in 1980, that is insufficient to promulgate a standard at very, very low levels.

So the issues are complex. And even, I dare say, the State of California is having difficulties with those issues.

Mr. BISHOP. Let me go to Mr. Foulke.

Dr. Mirer, in his testimony, just asserts that OSHA standard setting has ground to a halt in the current administration. That is a characterization that is at odds with at least your written testimony. Would you comment, please, on Dr. Mirer's characterization?

Mr. FOULKE. Yes, Congressman Bishop. I would say that that characterization is incorrect. OSHA has been very involved in the standard making process. And just in 2006, 2007, we put out the hexavalent chromium standard. We have done an updated rule on fire protection in the shipyards.

We have done assigned protection factors for the respiratory protection, which allows employers to know what is the proper respiratory cartridges that they should use in their respirators for the particular—and we have also done electrical installation requirements, a final rule on that.

So we have been active just—and that has just been in 2006 and beginning of 2007. So to say that we are just—you know, and I have a list of other things that we have done, final activities that we have done, since 2001. So to say that the Bush administration has been inactive in moving on standards is incorrect.

Also, part of the whole standard-setting process, because of the different levels—and you have heard different people discuss the different things that have to be utilized as part of the standard-making process. Those things are ongoing, so we are working on

putting out—we put out requests for information on emergency preparedness.

I am trying to remember. We have done advance notice of proposed rulemaking where we asked the public for information. We conduct hearings. We put out notices of proposed rulemaking.

So all these activities are ongoing. To say that we haven't—you can look at all these—there is a series of things that we have been doing since 2001. And so I would say there is no way you can classify that we have been at a standstill.

Mr. BISHOP. Thank you.

May I ask Dr. Mirer to, sort of, substantiate why you have made the assertion that you have?

Mr. MIRER. Okay. The chrome standard was promulgated pursuant to a court order that required them to produce it by a date certain. The assigned protection factors which Mr. Foulke talked about is a takeaway. It allows employers to use less protective respirators than they previously were required to do.

The biggest takeaway was the change in record-keeping requirements which is responsible for at least part or maybe the majority of the reduction in injury rate that they are talking about as proof of their success.

Most of the other things they have pointed to are nickel-and-dime, modest changes. I think there is actually three or four rulemakings on record-keeping that came in this administration, each one of which was a takeaway.

Mr. BISHOP. Thank you very much.

My time is about to expire. Madam Chair, thank you.

Chairwoman WOOLSEY. Thank you, Mr. Bishop.

Ranking Member Wilson?

I want you folks to know that we have gone two on this side because you weren't in your seats quite yet, so we are going to go Mr. Wilson and then to Mr. Kline. And you each get 6 minutes because, guess what, we forgot to turn on the clock.

Mr. WILSON. Well, thank you, Madam Chairman, for your fairness.

And indeed, Mr. Peoples, I want to thank you for being here. I want to thank you for your courage. I understand the seriousness of your condition. I was on the board of the American Lung Association in South Carolina for 20 years, working to reduce the potential for respiratory injuries. And so again, I appreciate so much your being here today.

Additionally, I am really grateful to be here with Secretary Ed Foulke. Secretary Foulke and I worked together with the late Congressman, Governor Carroll Campbell of South Carolina. We know Secretary Foulke is one of the most prominent attorneys in South Carolina, one of the leading civic workers. In fact, Democrats and Republicans are very proud of the success of Secretary Foulke.

And so, I appreciate your being here today.

And in your testimony, Mr. Secretary, you indicated that the level of occupational injuries and illnesses was significantly reduced. In fact, the chart would indicate the lowest being recorded ever.

But at the same time, there has been an indication that OSHA is broken. Can you respond? Because it appears from the actual reports of injuries and illnesses that, indeed, success is abundant.

Mr. FOULKE. Yes, Congressman Wilson. And thank you for those nice comments about me.

No, as I indicated in my testimony, injury and illness rates since 2002 had fallen more than 13 percent. And more importantly, the overall fatality rate had dropped during that same time period by 7 percent, and 18 percent fatality rate reduction in Hispanics.

And I would say that it is because of the balanced approach that we have taken. And the numbers we indicated showed that the amount of enforcement that we have been taking—the fact that one-quarter of the criminal referrals have occurred since 2001 clearly indicates that we have a very strong enforcement.

But it is also important—there is a lot of employers out there that we are trying to outreach to through our compliance assistance programs, our alliances, our partnerships, our voluntary protection program.

All these programs were outreached into a greater and greater number of employers, and thus improving their health, and they are helping them to have a comprehensive safety and health program, at the same time allowing them to protect more and more workers throughout the country.

So the statistics show that the balanced approach that we have taken has been extremely effective.

Mr. WILSON. Well, I am very grateful for your success and that of OSHA.

Mr. Fellner, we have heard testimony today stating concern about the regulatory process in which OSHA must formulate regulations. Can you explain how the process evolved to where it is currently? Was it due to perceived failing by regulators to take into account scientific data?

Mr. FELLNER. Congressman Wilson, that is precisely correct. The standard-setting process, as I indicated in my testimony, is extraordinarily complex, first because the statute makes it so.

The statute talks about significant risk of material impairment. The seminal decision that dealt with significant risk of material impairment was the Benzene decision that issued in 1980.

And with the committee's permission, there is a salient paragraph which I think will inform the committee's deliberation that I would like to share with you.

In the Benzene decision, it says, "By empowering the Secretary to promulgate standards that are reasonably necessary or appropriate to provide safe or healthful employment and places of employment, the act implies that before promulgating any standard the Secretary must make a finding that workplaces in question are not safe. But safe is not the equivalent of risk-free. There are many activities that we engage in every day, such as driving a car or even breathing city air, that entail some risk of accident or material health impairment. Nevertheless, few people would consider these activities unsafe. Similarly, a workplace can hardly be considered unsafe unless it threatens the workers with a significant risk of harm."

That decision was not written by Justice Rehnquist or Justice Scalia; it was written by Justice Stevens. And that is the guiding lodestar by which OSHA must promulgate its safety and health standards, not in a risk-free society but rather where there is significant risks.

Since that decision, there have been multiple Court of Appeals decisions that have further made the process informed and complicated, particularly as our scientific environment becomes complicated.

And all of that is under the umbrella of the Administrative Procedures Act, which requires notice and comment to all. And it requires it to Mr. Peoples, and it requires it also to the industries that are regulated.

Chairwoman WOOLSEY. Thank you.

Mr. Kline?

Mr. KLINE. Thank you, Madam Chair.

And thank you to the witnesses for being here today. It is always fascinating to sit up here and listen to ourselves talk and realize how often we come down on different sides of an issue. I really would like to believe we are all trying to look for a way to be successful in reducing injury, illness and accident in the workplace. But, for example, the Chair opened with comments about the ergonomics regulations, and I would say I am extremely grateful that we were able to block those egregious ergonomics regulations. We just look at things differently.

I am very much impressed, Secretary Foulke, by this chart that shows ever-decreasing injury, illness rates and lost work days per employee. And that seems to me what we should be looking for, is we should be looking at results.

And so, one of the things that has been discussed are the so-called voluntary compliance issues, some of the things that OSHA has been using. I understood that to mean we are looking for ways to work with businesses, with employers, to make their workplace safer without having them be fearful of being slapped down, if you will, when OSHA comes.

Can you talk about that a little bit and how that is working?

Mr. FOULKE. Yes. Well, I first would correct the terminology, because that "voluntary compliance" has been bandied about by some people as indicating that OSHA somehow allows employers to voluntarily comply with safety and health standards. And that is flatout wrong; it is untrue.

All the standards that are written are mandatory standards. All employers are required to abide by those standards. And OSHA enforces those standards, as I indicated earlier about the number of the 38,000-plus inspections that we have done. We are enforcing them.

So what you are talking about, though, is compliance assistance. And that is where we have our different groups involving our outreach to employers and employees. This compliance assistance is not just solely for one group of the industry.

In fact, we outreach them to our different programs. Part of the ones, as I talked earlier, was to Mr. Bishop regarding the alliance program, where we bring in—normally, it is involving associations, some type of groups, sometimes labor unions, where we try to out-

reach and focus and help those people identify their significant problems and safety and health issues and work with them to come up with compliance assistance tools that can help them.

We also have what we call our consultation program, which is also part of our compliance assistance. The consultation is meant for small-and medium-size employers, where OSHA pays the states to have safety and health people come in and help small businesses develop comprehensive safety and health programs for their facilities, and thus helps them have a much more safe and healthy workplace for their employees.

Mr. KLINE. So this is not an OSHA inspection, per se. This is some assistance from your organization working with states to help businesses establish a safe working program. Is that correct?

Mr. FOULKE. That is correct. Under our consultation program and some of our compliance assistance programs like the voluntary protection program, we are trying to help the companies have comprehensive safety and health programs so that their worksites will be safer and healthier for their workers.

Mr. KLINE. Okay. Thank you very much.

I would like to move—I see my light is still green. That happens so rarely. I am excited here. Thank you, Madam Chair.

Personal protective equipment—we have had some testimony about that today. And there seems to be some confusion or difficulty.

Can you tell us, Mr. Secretary, what actions the Department has taken with respect to PPE and historically what challenges you face in trying to regulate in this area? We had some testimony from Mr. Fellner and others, but can you kind of clear that up for us?

Mr. FOULKE. Yes, Congressman. We are in the process of finalizing a rule for personal protective equipment. That will be finalized in November of this year.

Now, it is interesting to note that 95 percent of the—based on our analysis, we determined that currently 95 percent of the employers in the United States pay for their personal protective equipment.

So we have been moving on this standard as expeditiously as we can. We have held hearings on it the initial proposal. When we finished the proposal, we determined that the record needed to be opened up to determine information on tools of the trade. So we have been working on those things on the payment for PPE rule.

Now, we have already had in place, obviously, our personal protective equipment standards requiring employers to determine what hazards actually exist at their workplace and what personal protective equipment would be utilized to address that particular hazard.

So those rules have been in place. The question has been, who pays for it? And as I indicated, currently our information shows that 95 percent of the employers currently pay for PPE. We are finalizing the standard, and that standard will be out in November of this year.

Mr. KLINE. All right. Thank you, Mr. Secretary.

Thank you, Madam Chair.

Chairwoman WOOLSEY. Well, I yield myself 5 minutes.

I want to remind everybody who is here today that the title of the hearing is "Have OSHA Standards Kept Up With Workplace Hazards?", not "Has Compliance Worked for the Old Standards That Aren't Even Close to What We Need in This World of Ours?"

And then I would like to congratulate the subcommittee, because we have had some success. We had success before we even walked in here today. Today, OSHA put out a news release that announced that the National Emphasis Program will address popcorn lung. Well, guess what? We have been waiting how many years to get this even started, so we are glad that we have made an impact so far.

But, Mr. Foulke, I have—oh, and I would like to, by the way, with unanimous consent, enter into the record this press release from OSHA. Okay.

[The information follows:]

U.S. Department of Labor's OSHA Announces Focus on Health Hazards of Microwave Popcorn Butter Flavorings Containing Diacetyl

WASHINGTON.—The U.S. Department of Labor's Occupational Safety and Health Administration (OSHA) today announced that it is initiating a National Emphasis Program (NEP) to address the hazards and control measures associated with working in the microwave popcorn industry where butter flavorings containing diacetyl are used.

"We recognize that there are potential occupational health hazards associated with butter flavorings containing diacetyl," said Assistant Secretary of Labor for Occupational Safety and Health Edwin G. Foulke Jr. "Under this program, OSHA will target inspection resources to those workplaces where we anticipate the highest employee exposures to these hazards."

The NEP applies to all workplaces where butter flavored microwave popcorn is being manufactured.

In January, 2006, the National Institute for Occupational Safety and Health (NIOSH) released an investigative report on a microwave popcorn production facility. Several employees from this facility were diagnosed with bronchiolitis obliterans—a severe obstructive lung disease. Following a number of lung function tests and air sampling, NIOSH determined that inhalation exposure to butter flavoring chemicals is a risk for occupational lung disease. OSHA's National Emphasis Program will provide direction on inspection targeting and procedures, methods of controlling the hazard and compliance assistance.

The 24 states and two U.S. territories that operate their own OSHA programs are encouraged, but not required, to adopt a similar emphasis program.

Under the Occupational Safety and Health Act of 1970, employers are responsible for providing safe and healthful workplaces for their employees. OSHA's role is to assure the safety and health of America's working men and women by setting and enforcing standards; providing training, outreach and education; establishing partnerships; and encouraging continual process improvement in workplace safety and health. For more information, visit *www.osha.gov*.

Chairwoman WOOLSEY. So, Mr. Foulke, I have some questions for you, because this press release that appears in this announcement only addresses popcorn facilities. Well, we know that cases of bronchiolitis obliterans have been identified in food processing and in flavor plants that produce flavoring for a variety of food products, including candies and many other foods. Diacetyl is used in popcorn, it is used in candies, it is used in dog food, it is used in cheeses, et cetera, et cetera.

And this press release also—I will note that NIOSH issued an investigative report in January of 2006 implying that OSHA is acting somewhat rapidly. Well, actually, the first NIOSH report of

problems in popcorn facilities was published on April 26th, 2002, exactly 5 years ago.

So, Mr. Foulke, here is my question: With this release only applying to microwave popcorn plants, and given that diacetyl is in widespread use in the flavoring and food processing industry, and given that there is no safe level of exposure, wouldn't it make sense to expand this program to anywhere that food flavoring chemicals are in use?

In fact, isn't it true—this is going to be a two-part question—that none of the many cases found in California occurred in microwave popcorn plants?

Mr. FOULKE. Yes, Madam Chair, thank you.

And I would note, first of all, actually, NIOSH had an interim report back in 2001 on this particular issue. And OSHA, at that particular time, took immediate action to alert all administrators of this report and to identify, as part of our inspection process, those facilities where these particular symptoms or illnesses may be occurring.

We also developed and disseminated a brochure out of our Region 7 operations, which is where most of the popcorn manufacturers are located. And we also have been working on developing guidance.

So I would first point out the fact that OSHA, as soon as they knew there was a problem back in 2001, we got on it and started working on it.

Now, to answer your question with respect to diacetyl, I guess the question is, is diacetyl a hazard? And unfortunately, that is not an easy yes or no answer.

We believe that there is strong evidence that butter flavoring and certain other food flavorings present respiratory hazards to the exposed employees. But as you probably are aware, because it is obvious you have done a lot of research on this, flavorings are complex mixtures made up of a lot of a numerous variety of substances.

So, at this point in time, the question is—I don't believe that there has been—been found between any specific substance in flavoring—specific lung disease. Diacetyl is a substance of suspicion. Its role and the role of other flavoring compounds——

Chairwoman WOOLSEY. All right. I get your gist.

Mr. Peoples, would you like to respond to that?

Mr. PEOPLES. Being a blue-collar worker, as I was before my illness, I do speak, I believe, for the other blue-collar workers who, when we go to work, we truly believe that OSHA and NIOSH and the other government institutes have our best interests for our safety to work and support our families in mind.

For this to be brought up to them and for nothing to be done for—we are going on to 6 years now since I have been sick myself—that I have a hard time understanding why.

I do not understand the process. I have no knowledge of that whatsoever. But I still cannot figure out why it is taking so long for the proper testing, the proper regulations to be passed that companies have to abide by this. The allegiance, the voluntary allegiance, does not seem to be adequate enough.

I would like to refer the committee to the paper "Lung Disease Caused by Corporate Negligence," published in the International

Journal of Occupational Health, which we will supply to the committee and should be part of this record. That shows that my disease was caused by an industry-wide cover-up.

Chairwoman WOOLSEY. Without objection.

[The information follows:]

Popcorn-worker Lung Caused by Corporate and Regulatory Negligence:

An Avoidable Tragedy

DAVID EGILMAN, MD, MPH, CAROLINE MAILLOUX, CLAIRE VALENTIN

Diacetyl-containing butter flavor was identified as the cause of an outbreak of bronchiolitis obliterans (BO) and other lung diseases in popcorn-plant workers. Litigation documents show that the outbreak was both predictable and preventable. The industry trade organization was aware of BO cases in workers at butter-flavoring and popcorn-manufacturing plants but often failed to implement industrial hygiene improvements and actively hid pertinent warning information. Due to weaknesses in the organization and mandates of regulatory bodies, organizations such as NIOSH, OSHA, the FDA, particularly the "generally recognized as safe" (GRAS) system, and the EPA failed to detect and prevent the outbreak, which highlights the need for systemic changes in food-product regulation, including the need for corporations to act responsibly, for stronger regulations with active enforcement, for a restructuring of the GRAS system, and for criminal penalties against corporations and professionals who knowingly hide information relevant to worker protection. *Key words:* diacetyl; popcorn-worker lung; butter flavorings; bronchiolitis obliterans; corporate corruption; GRAS; occupational disease.

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In 2002, Kreiss et al. reported an outbreak of bronchiolitis obliterans (BO) and other lung diseases in popcorn-plant workers in Missouri.[1] The high levels of synthetic diacetyl combined with other elements of the butter flavoring were responsible for the outbreak of BO in the Jasper Popcorn Co., Givaudan Flavors, and other popcorn and flavoring plants.[2,3] It is possible that trace contaminants in synthetic diacetyl also contributed to the toxicity of this and other artificial butter flavors.

We reviewed an extensive number of documents produced during several lawsuits involving exposures to butter flavoring. The documents comprised a mix of internal correspondence, reports, programs, and presentations, as well as depositions of industry representatives and physicians. We also reviewed medical records of workers who died as a result of exposure to synthetic diacetyl. We obtained supplemental information from the internet and PubMed searches. Non-confidential documents are now available in a digital archive at <http://www.egilman.com/browse.php?display=list&dir=butter_flavoring/>.

We used an inductive process described as grounded theory to review the documents.[4] All documents underwent primary review by one author with selected reviews by the coauthors. We grouped material using a matrix by company and by theme. Themes included confidentiality agreements, warnings, regulation, medical information, and hygiene practices. Only the authors had a role in the mechanism of document review, presentation of results, or decision to submit the manuscript for publication, although some information could not be presented because several companies and/or their trade organization deemed it confidential.

While the medical cause of the BO outbreak among popcorn workers appears to have been the exposure to diacetyl, our evaluation of documents and depositions produced in litigation indicates that corporate malfeasance, confidentiality agreements, and inadequate governmental regulations contributed to the severity of the epidemic. Corporations failed to adequately test their products, while medical professionals and regulatory bodies failed to respond to the first cases of disease. Worker illnesses and the early knowledge about the dangers of diacetyl are chronicled below, as well as the link between the outbreak and changes in the butter-flavoring formulation that increased the concentration of diacetyl. The roles of the trade organization, Flavor and Extract Manufacturers Association (FEMA), and individual companies, including Tastemaker/Givaudan Flavors,* Sensient Flavors Inc., and Bush Boake Allen (BBA)/International Flavor & Fra-

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*Although the plant had several owners, upper management generally remained unchanged. In the late 1980s and early 1990s, the plant was affiliated with Mallinckrodt Flavors division (Fries & Fries). In 1992, the plant became a joint venture of Mallinckrodt and Hercules and operated as Tastemaker. In 1997, Roche purchased Tastemaker and the plant became part of Givaudan Flavors, a division of Roche. From 1988 to 1997, the plant was referred to as Tastemaker; from 1997 on, Givaudan.

grances (IFF)† are analyzed. Documents and depositions produced in litigation indicate that the flavoring companies, FEMA, and industry consultants were aware of the problem of BO among their workers but kept this information secret to protect their economic interests. Finally, the systemic regulatory failures, including the inadequacies of the "generally recognized as safe" (GRAS) system, poor worker compensation regulations, and the underhanded system of confidentiality agreements, as well as shortcomings of organizations such as NIOSH and OSHA, are discussed. Policy recommendations are offered.

THE FIRST DEATHS

There are several documented fatalities from BO and reports of countless other workers who have contracted the disease.[2,5] The first three deaths are presented here.

In the late 1980s, JI (index case) a 25-year-old food additive processor developed BO after working for approximately two years at the Cincinnati Tastemaker flavorings plant.[6] She had worked in the liquids-mixing area of the plant and had been exposed to many chemicals, including acetaldehyde and diacetyl.[7] Tastemaker did not provide respiratory protection, and the mixing vats were uncovered.[8] JI left the company in 1987 on disability leave, and died in 1992 at the age of 29. The case was referred to the Montgomery County, Ohio, Coroner's Office for investigation.[9] Suspecting occupational exposures, the coroner sent a letter to Tastemaker in November 1992 inquiring about the "circumstances" of her death and requesting information about chemical exposures as well as her work history.[10]

The second documented death from BO concerns DA, a 52-year-old white woman who had worked as a popcorn packager at the Gilster Mary Lee popcorn-packaging plant in Perryville, Missouri, from 1996 until 2003. A non-smoker, she suffered from a variety of breathing problems, including wheezing, paroxysmal nocturnal dyspnea, and shortness of breath, throughout her employment.[11] Doctors suspected that her symptoms were work-related.[12] Chest x-rays revealed that her lungs had a "ground glass" appearance.[12] The clinical diagnosis was pulmonary arterial hypertensive changes, chronic bronchitis, and bronchiolitis with bronchiectasis.[11] An open lung biopsy taken June 16, 2003, revealed mild nonspecific thickening of some alveolar septa and patchy aggregates of lymphocytes.[11] She died in 2003 from respiratory failure.

In May 2006, the third BO death was reported. LR had worked at Jasper Popcorn Co., Jasper, Missouri, for 18 months starting in 1995.[13] A lifelong non-smoker with no history of pulmonary complaints, LR began experiencing shortness of breath and a cough in late 1996.[13] In 2000, she visited the Mayo Clinic, where physicians diagnosed bronchiolitis obliterans linked to her exposure to chemicals at the popcorn plant.[13] In the last years of her life, she was confined to a wheelchair with oxygen, suffered from anxiety and depression, and was permanently and totally disabled.[13]

EARLY KNOWLEDGE OF BUTTER-FLAVORING TOXICITY

Allen Parmet, a local physician from Kansas City, recognized an occupational cause for the lung problems after examining a number of patients with similar respiratory symptoms who were exposed to butter flavorings at the Jasper plant. He reported and initiated the investigation into the occupational health hazards at the Jasper, Missouri, plant in 2000.[14] However, the Flavorings and Extract Manufacturer's Association (FEMA) and certain flavoring companies had known about the hazards years before; they had obtained information on the potential toxicity of diacetyl and the resulting BO disease in workers no later than 1986.

In 1976, The Research Institute for Fragrance Materials (RIFM) conducted diacetyl dermal toxicity tests on rabbits.[15] One animal died with evidence of systemic toxicity including dark lungs and a mottled liver. According to their web site, the RIFM database operates with the full cooperation of the Flavor and Extracts Manufacturing Association (FEMA); this indicates that the fragrance and flavor industries has been aware of the potential dangers of diacetyl since at least 1976.[16] However, there is no evidence that the RIFM followed up on this finding with further testing, no pathologic report was ever produced, and FEMA omitted the information on lung and liver toxicity from the toxicology summary on diacetyl that it supplied to NIOSH during the investigation of the Jasper plant.

In 1984–1985, two workers at International Bakers Services, Inc., a plant manufacturing cinnamon bun mix in South Bend, Indiana, developed BO.[17] Although NIOSH concluded that the cases were work-related, they could not identify a specific causal agent(s). At the time, NIOSH did identify diacetyl and many other specific exposures as potential causes and called for the use of a closed manufacturing process. NIOSH recommended:

> In the absence of a specific identified etiology for the two cases of severe obstructive lung disease, every attempt should be made to control airborne dust exposure in the mixing room [. . .] and employees should wear respiratory protective equipment whenever they are in the mixing room.[17]

In 1986, the two workers with BO from International Bakers Services filed lawsuits against Givaudan and 20 other flavoring manufacturers. Many of these manufacturers, including Givaudan, Polarome, and Citrus and Allied, were active FEMA members, and these compa-

†International Flavor & Fragrances completed the acquisition of Bush Boake Allen in 2000.

nies listed FEMA and RIFM personnel as defense witnesses in the case. Plaintiff's expert witnesses identified diacetyl among several other chemicals as the most likely causal agents.[18,19] The experts also identified about 40 chemicals that they felt should be tested for safety.[19] One expert spent ten days in deposition explaining the inadequacies of the manufacturing companies' warnings and testing program.[20] Susan Daum, an occupational physician who analyzed the cases, concluded her affidavit with the admonition:

> The fact that the defendants supplied chemicals to International Bakers Services, Inc. as ultimate users and consumers without having first tested these chemicals for inhalation or taken other appropriate measures to see that they were safe for use by humans is tantamount to using the Blenders at International Bakers Services, Inc., as blue collar guinea pigs. [18]

Finally, in 1993, BASF Germany performed an animal inhalation experiment to determine the LD_{50} for diacetyl.[21] BASF noted that dying animals had "dragging respiration, and gasping respiratory sounds."[21] Autopsy results of the lungs revealed "general congestion as well as focal hyperemia and moderate emphysema."[21] BASF also noted "focal atelectasis in all lobes of lung, bloody edema in the bronchi and intensified hydrothorax."[21]

Manufacturers are ethically and legally bound to possess expert knowledge about their products.‡ They should use this knowledge to both protect their own workers and warn their customers of any hazards associated with the use of their products. Butter-manufacturing companies should have been aware of the early warning signs of the dangers of diacetyl and should have passed this information onto their personnel and customers.[24,25]

CHANGES IN BUTTER-FLAVORING FORMULA

In 2002, Parmet and Von Essen reported on the epidemic of BO cases that appeared in workers at the Jasper popcorn-packaging facility in Missouri in the spring of 2000.[26] Although the diacetyl-containing butter flavor had been used for more than 50 years, this was the first epidemic caused by the flavoring reported in the published medical literature. Information produced by some of the manufacturers in tort litigation helps explain why the epidemic "suddenly" occurred in a plant that, until 1993, had operated without any apparent health problems. These documents reveal that the epidemic coincided with the introduction of a new butter flavoring that contained higher concentrations of diacetyl.

Jasper introduced Bush Boake Allen's (BBA's) new, "more concentrated" butter flavor in bulk in late 1992. This new flavoring contained two or more times the concentration of synthetic diacetyl than the butter flavors it replaced.[27] In addition, the previous flavors had much lower concentrations of synthetic and "natural butter flavorings" and some lacked the known toxins acetoin and acetaldehyde. All the cases of illness that occurred at the Jasper plant were exposed to this "more concentrated" flavoring in addition to other butter flavorings.[28,29]

Furthermore, in 1996, Jasper Popcorn Co. formulated and introduced a new "low fat" butter flavor.[30] This flavoring substituted butter flavor for soybean oil, further increasing the diacetyl concentration in the final flavoring.[29] Other popcorn manufacturers followed a similar process to create "low fat" popcorns.[29] Workers at the Jasper plant noted that the reformulated BBA butter flavoring had a noticeably "harsh" and "irritating" odor.[31]

The introduction of the new flavoring formulas was directly followed by an increase in the severity of the resulting cases. BO cases did not occur prior to 1993 at the Jasper plant, and workers suffered the most precipitous decline in lung function after the introduction of the high-concentration "low fat" flavoring in 1996.[28] The initial cases that occurred were limited to the most heavily exposed workers, i.e., "mixers" who blended the chemicals in uncovered vats. The second wave of disease, which occurred in 1996, coinciding with the introduction of the Jasper "low fat" flavoring, affected the majority of plant workers, including popcorn packers.[30] After Jasper complied with NIOSH's recommendations and introduced workplace controls, no new cases were noted.[32]

Recently, NIOSH researchers exposed rats for 24 hours to the flavorings in order to test their suspicion that the diacetyl-containing butter flavoring was the cause of disease.[33] The exposure "produced severe upper and lower airway changes in animals."[26] Hubbs et al. later reported that fully-formed BBA butter flavor caused more pathologic abnormalities in rats and was more toxic than pure synthetic diacetyl.[3,34,35] These studies provide further evidence that the increase of the diacetyl concentration in the butter flavoring most likely caused the popcorn-lung epidemic. In his 2002

‡In a 1941 internal document, the company Owens-Corning Fiberglass defined corporate responsibility, explaining, "From a humanitarian point of view, no company can afford to subject its employees to an unknown hazard. From a cold business point of view, no company can afford to jeopardize its own existence by subjecting itself to the liability of unknown hazards that may be encountered by those to whom it supplies the material."[22] Furthermore, the 1965 Restatement of Torts states, "One who, in the course of his business, profession or employment, or in any other transaction in which he has a pecuniary interest, supplies false information for the guidance of others in their business transactions, is subject to liability for pecuniary loss caused to them by their justifiable reliance upon the information, if he fails to exercise reasonable care or competence in obtaining or communicating the information."[23]

report, Parmet noted, in regard to a worker at the Jasper plant,

> There was significant improvement in his lung function and eye symptoms after exposure to this product ended and after corticosteroid therapy. These observations suggest that cessation of exposure is important for the treatment of this syndrome.[26]

INDUSTRY-WIDE KNOWLEDGE: "HIDING THE BALL"

Rather than warn workers and customers, the companies and their industry organization engaged in concerted action to hide information. The real history of the development of knowledge relating to the toxicity of diacetyl has come to light through the production of previously secret corporate documents and court testimony of corporate employees. The available history of each company is reviewed here, although some gaps in the information may still exist.

Cases of BO at Tastemaker/Givaudan Flavors

In 1992, following the death of the index case (JI) at Tastemaker, a second worker, JW, developed severe obstructive lung disease. A 1994 biopsy revealed that his condition had deteriorated and that he had developed chronic bronchiolitis.[36] JW worked in a different building than the index case, in a processing area where he was exposed to diacetyl but not acetaldehyde.[7] A third worker in the same processing area, CW, developed BO.[7]

After JI became ill, Tastemaker replaced her with MSM. MSM developed BO in 1993. Her private treating physician, concluded that "her symptoms are associated with her work environment."[37] Since MSM could no longer work, Tastemaker replaced her with RG. In 1996, the same physician, Dr. Baughman, determined that RG had developed BO "as a result of her exposure to chemical vapors" at work.[38] Although the plant provided RG with a respirator, she reported an acute overexposure to acetaldehyde in 1995.[39]

In 1998, Givaudan paid MSM and RG $8,750 each to settle complaints with the Ohio Bureau of Workers' Compensation that claimed that Givaudan had failed to follow specific safety requirements.[40,41]

Prior Knowledge at Tastemaker /Givaudan

In 1992, Tastemaker plant management began to investigate the outbreak of BO among workers.[42] Two years later, Tastemaker retained Dr. Stuart Brooks, the head of occupational medicine at the University of Cincinnati, to investigate BO cases among its manufacturing workers. By 1994, Brooks was aware of "five or six" cases of BO in workers at Tastemaker.[43] He submitted a special respiratory questionnaire and a final investigative protocol to Tastemaker in April 1995.[44] The proposed four-phase "Respiratory Health Inventory Program," with a $50,000 budget, was never implemented. Shortly thereafter, Tastemaker fired Brooks.[43]

In 1995, Tastemaker obtained a copy of the 1986 NIOSH Health Hazard Evaluation of the outbreak of BO at International Bakers Services, Inc., which had used a variety of flavorings, including diacetyl butter.[45] Although NIOSH never determined the specific cause of this outbreak, in 1995, Tastemaker toxicologist Nancy Higley determined that out of about 47 listed chemicals the International Baker and Tastemaker employees shared exposures to only three: acetaldehyde, benzaldehyde, and diacetyl.[45] Although Tastemaker was aware of NIOSH's interest in the issue and despite the fact that the Tastemaker plant is 5 miles from NIOSH's main offices in Cincinnati, Tastemaker (later Givaudan) never reported these cases to NIOSH or requested that NIOSH perform a free workplace hazard evaluation.[45]

Shortly after terminating Dr. Brooks, Tastemaker established a consulting agreement with James Lockey, MD, and the University of Cincinnati Division of Occupational and Environmental Medicine. Although NIOSH Fellows rotated through the occupational medicine clinic at the university, Lockey did not report the cases of BO to NIOSH at the time.[46] Tastemaker never shared Brooks' reports with Lockey, and, as part of their consulting agreements, both Brooks and Lockey had signed confidentiality agreements.[10,46]

Finally, as early as 1991, Givaudan had developed and marketed dicetyl-free substitute butter flavorings.[47] Yet, even after diacetyl came under suspicion, the companies continued to primarily sell dicetyl-containing butter flavorings.

Workplace Practices at Tastemaker/Givaudan

In 1992, Tastemaker instituted a three-year program to replace and repair its antiquated ventilation system and make some other improvements in plant ventilation.[42] Even after the improvements were implemented, Mr. Biscopink, vice president of operations at Tastemaker, noted that, "The large blend room was blending a butter flavor, which I understand is very dusty by nature. The room when observed was in horrible condition. [. . .] Just walking into the room it was difficult for me to breathe."[48] When John Hochstrasser, the Director of Environmental Health and Safety, sampled for dusts, he noted, "I used the same protective equipment that employees used in those operations. And from that, I could judge whether the powders were penetrating through the dust masks. And we found that they were. . . ."[42] Following this inspection, Tastemaker (later Givaudan) replaced the paper masks with full-face piece respirators, although they still failed to warn

their workers or their customers, the popcorn manufacturing plants, of the health risks associated with their product.

Between 1995 and 1997, the University of Cincinnati occupational health team conducted an epidemiologic study of current employees, which included a health history questionnaire and pulmonary function testing (PFT). Roy McKay, director of Occupational Pulmonary Services at University of Cincinnati, was on the team called to run the program. At his deposition, he expressed his frustration with the restrictions Tastemaker placed on his work:

> [I]t's hard to get a person to want to wear a respirator if they don't feel there's a need to wear the respirator. And I was not—I was limited into the type of language and wording I can use to describe the potential respiratory hazard that may exist. And that made it difficult with regard to worker training and reporting on deficiencies and things that we would find. **I was reminded never to say the word bronchiolitis obliterans to any of the workers, for example.**[49] [Emphasis added]

Although Tastemaker held a meeting with its employees to explain the PFT and respirator program, Tastemaker refused to allow McKay to provide information concerning exposure and risk to the affected workers. Tastemaker further requested that McKay not put his observations into writing.

In early 1997, Hochstrasser, the Director of Environmental Health and Safety at Tastmaker/Givaudan, became so frustrated with the company's inability to protect employees that he threatened to shut the plant down.[42] Shortly thereafter, Givaudan fired Hochstrasser.[50] In 1999, Hochstrasser filed a personal lawsuit against Givaudan alleging that he had been wrongfully discharged because of his "continuous insistence of fastidious observance of environmental and worker safety laws and regulations."[10] Hochstrasser claimed that management had impaired his efforts to protect worker health and that he had been given "advice from legal counsel" against discussing BO and other lung diseases of workers at Tastemaker.[51] Givaudan settled the suit, agreeing to pay Hochstrasser an annual annuity of $25,000 for 20 years.[42]

As a result of Givaudan's inadequate response, yet another plant worker developed bronchiolitis in 2005 from exposure at the Cincinnati plant.[52,53] OSHA recently completed an industrial hygiene inspection of that plant.[54] Despite the fact that Givaudan had made supplemental payments to some of its workers who had contracted BO to settle complaints that the illnesses had been caused by specific violation of Ohio safety rules, OSHA cited the plant for merely failing to disclose the availability of exposure records. The penalty was $0. There is no standard with which exposure levels of diacetyl could be compared so no other violation was cited.[54] As a result, OSHA failed to enforces the general-duty clause of the OSH act.

FEMA

The Flavor and Extract Manufacturers Association (FEMA) is a trade organization whose members include many of the butter-flavoring manufacturers. FEMA's purpose, according to its general counsel, is to "provide the members with assistance in safety assessment, provide the members with assistance in compliance with regulatory issues and to provide a forum for discussion of scientific and regulatory and safety issues that are important to the members."[55] FEMA has stated that as part of its mission it sought to keep the industry "to the extent possible, self-regulatory."[56] As the trade organization, FEMA could have played a powerful role in preventing the epidemic of lung disease by gathering and disseminating critical information regarding the dangers of diacetyl to its members. Unfortunately, FEMA's failure to provide adequate safety and regulatory oversight and to communicate important warning information to its members highlights the inadequacy of self-regulation.

According to one FEMA board member, FEMA relies heavily on its members to fully disclose all relevant information about health hazards:

> If there were questions about an ingredient or a product in the industry, the members would have shared the issues with each other and then either their own regulatory or toxicological staffs or the staffs working with the FEMA staff would evaluate the problem and the cause of the problem to determine what the cause was. And if there was a—a link, then appropriate action would be taken with respect to the ingredient either to—to change the way it was manufactured, to inform customers, or simply to suggest that in the plants, flavoring plants themselves, that better ventilation or working conditions be handled. . . . if we didn't get information, we obviously couldn't act on information.[57]

By 1996, Tastemaker (later Givaudan) had eight confirmed cases of BO and one death reported by the Ohio coroner, which they suspected was BO-related.[58] Dr. Lockey and personnel from Tastemaker met with FEMA's general counsel, John Hallagan, to inform him of the cases. Lockey informed FEMA,

> If we assume that the autopsy data is correct, you only see bronchiolitis obliterans one out of 40,000 times at autopsy. Clinically, we're seeing it 6 out of 300 times. So if you adjust the denominator to 40,000 that would be 800 per 40,000. I think the point I was making there is that the prevalence of this disease in this limited population is much higher than we expect.[58]

Conflicting reports exist regarding the number of cases of BO of which FEMA was aware. In 1997 and 1998, Hallagan called and visited members to ask whether they knew of any cases of BO.[55] Some members were already aware of the BASF study regarding the dangers of diacetyl but did not share this information with FEMA.[56] In 1997, in response to Tastemaker/ Givaudan's disclosure of BO cases, FEMA held an industry-wide meeting, "Respiratory Health and Safety in the Flavor Manufacturing Workplace," to inform members of workplace health issues. Although Givaudan disclosures had prompted the meeting, no one from Givaudan mentioned the cases of BO at the conference, and FEMA even agreed not to disclose Givaudan's identity, since the company was concerned about bad publicity.[10] By choosing to conceal Givaudan's identity, both the company and FEMA undermined the dissemination of important warning information. Furthermore, FEMA informed its members that it was aware of only one confirmed case of BO, misrepresenting the extent of industry knowledge on the dangers of diacetyl. Thus, while the 1997 conference could have been a powerful moment to share information about health hazards, it was a missed opportunity, and it falsely reassured the industry that the case of BO was an isolated event.

Sensient Flavors, Inc.

In response to their knowledge about the real and potential hazards of chemicals used in the plant, including diacetyl, Sensient, another butter-flavorings manufacturer, implemented a number of safety programs to protect its own employees. For example, by at least 1992, Sensient had begun medical evaluations and testing for respirator fittings for employees at its facility.[60] By at least 1997, Sensient had a written hazard-communication program.[61] This program included information about instructing employees on how to read and use Material Safety Data Sheets (MSDSs) and other safety warnings and precautions. The program outlined a system for ensuring that all products received into and used within the plant were labeled with appropriate warnings.

In 2004, Sensient actively concealed knowledge about irreversible obstructive lung disease by deleting detailed information about the harmful effects of diacetyl from proposed MSDSs. The environmental regulatory manager at Sensient Flavors in charge of MSDSs, Elizabeth O'Connor, created a report for diacetyl in May 2004 based on regulatory information from suppliers as well as agencies such as OSHA and FEMA. The original MSDS contained the following warning:

> Warning Summary: Dust may be irritating to skin, eyes, and respiratory passages. Vapor inhalation *may cause irreversible obstructive lung disease.* [Emphasis added][61]

Sensient's corporate counsel reviewed the proposed warning, and, after a series of meetings, they decided to delete the language about irreversible obstructive lung disease.[51] No doctor, toxicologist, or expert from NIOSH was consulted about the issue of irreversible lung disease.[61] Following legal consultation, the new MSDS sent to customers in October 2004 read:

> Warning Summary: Dust and/or vapors may be irritating to skin, eyes, and respiratory passages, *may cause air way injury or lung disease.* (Emphasis added][61]

Thus, even with knowledge from chemical suppliers and regulatory agencies about the harmful effects of diacetyl, Sensient removed accurate warnings about irreversible obstructive lung disease at the recommendation of Sensient lawyers.

Bush Boake Allen (BBA) and International Flavor & Fragrances (IFF)

Knowledge and industrial hygiene. Like Sensient, BBA (later IFF) received warning information from suppliers and was aware of the potential hazard related to diacetyl in its butter flavor. For instance, the 1991 MSDS IFF received from its supplier, Berjé International, clearly warned that workers needed a "positive pressure self-contained breathing apparatus" for respiratory protection when working with diacetyl.[62] IFF also obtained information about the respiratory hazards directly from its diacetyl suppliers, Gist Brocades. Gist Brocades' 1997 MSDS, received in 2001, included the BASF data and stated that inhalation was, "Harmful: possible risk of irreversible effects through inhalation."[63] However, IFF failed to pass this warning on to its customers.

In 1991, workers at BBA's butter-flavorings manufacturing areas developed severe eye and skin irritation.[64] In 1992, after researching these problems, BBA proposed air monitoring for diacetyl and acetoin and implemented a mandatory respirator program for its workers.[65] In the course of implementing the respirator program, BBA found that many of the diacetyl-exposed workers had abnormal lung function.[66] BBA never followed up on these findings, nor is there any evidence that they reported these abnormalities to the affected workers.

In 1995, BBA's safety committee performed a literature review on the toxicity of diacetyl in response to an outbreak of eye injuries in workers mixing butter flavor. They discovered the 1993 German BASF study on the toxicity of diacetyl in animals.[67] Beginning at least in 2001, BBA, now owned by IFF, instructed its workers to "start running cold water through all of the heating jackets," in order to cool the butter flavor to around room temperature (83–85 F) before adding the diacetyl.[68] Such instructions indicate that the company was aware of the dangers of diacetyl vapors at high tem-

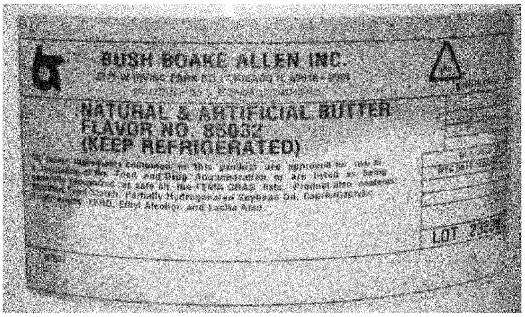

Figure 1—BBA label: example of an anti-warning. The label reads: Flavor ingredients contained in this product are approved for use in a regulation of the Food and Drug Administration or are listed as being generally recognized as safe on the FEMA GRAS lists. Product also contains: Acidified Food Starch, Partially Hydrogenated Soybean Oil, Capric/Caprylic Triglycerides, TBHQ, Ethyl Alcohol, and Lactic Acid.

peratures, although it did not pass this warning information on to its customers. The company then implemented a closed manufacturing process that minimized its own workers' exposures.[67] After the implementation of the closed manufacturing process and the temperature changes, BBA/IFF noted no further health problems and discarded the health information on diacetyl, again without warning customers.[67]

Anti-warnings: BBA misled customers. Not only did BBA fail to warn its customers of health risks, it misled customers with anti-warnings: language in or near warning statements that falsely reassures consumers.[69] Like Sensient, BBA used anti-warnings to minimize warnings about the adverse health effects of its butter flavor. A 1993 internal BBA memo noted, "our compounders feel they can be better protected by respirators that work effectively on the butter flavors [. . .] If we provide everyone with a mask, properly fit and train all Compounders, enforce proper storage of the masks, I think we will have a safer Compounding Department."[70] Yet, in the same year, BBA sent out MSDSs that told product users that respirators were "not normally required" and that there were "no known health hazards."[71] An internal memo in 1995 recommended that BBA "remove contradictory hazard statements from BBA produced MSDS."[72] However, BBA did not correct the butter-flavoring MSDSs.

Furthermore, the BBA label anti-warning (Figure 1) stated that "all flavor ingredients contained in this product are approved for use in a regulation of the Food and Drug Administration or are listed as being generally recognized as ***safe*** on the Flavor and Extract Manufacturers Association (FEMA) GRAS lists."[73] [Emphasis added] Since the GRAS evaluation process does not require any evaluation of potential worker hazard by the FDA, this statement creates the misimpression that ingredients have been tested and pose no risk to humans. In addition, the label listed only the harmless contents of the mixture, including food starch, soybean oil, capric acid, ethyl alcohol, and lactic acid, but failed to list the known toxic components such as diacetyl and acetaldehyde.[73] BBA claimed the use of these chemicals comprised a trade secret and could therefore be legally omitted from the MSDS listing requirement.[74] Thomas Bates, a BBA industrial hygienist, explained that diacetyl was never identified within any MSDS because of the trade-secret exemption but that all butter-flavoring companies knew that diacetyl was in butter flavor. He admitted that, in fact, it was "not a secret."[74] Finally, OSHA regulates acetaldehyde, so including it as an ingredient would have suggested that industrial hygiene evaluation of air levels and toxicity was required. In these ways, BBA omitted important information regarding occupational health risks and misled customers to believe in the safety of their products.

IFF attempts to warn customers. In 2004, IFF's insurance carrier refused coverage for bodily injuries related to "diacetyl containing butter flavors sold for use in popcorn."[75] Following this, in 2005, IFF, which had purchased BBA, became the first butter flavor manufacturer to create a new and improved MSDS to warn its customers.[76,77] In addition, IFF initiated a program to explain the changes in the MSDS and labels of their products to their customers.[78] Shortly thereafter, IFF stopped selling diacetyl containing butter flavorings to all customers except ConAgra.[78] IFF conditionally agreed to sell to ConAgra because of its "well known corporate citizenship including safety and health."[79] IFF modified its butter flavor MSDS to inform ConAgra of the respiratory risks of exposure and needed worker protection measures. It required that ConAgra acknowledge the receipt of the MSDS for butter flavors and sign a statement that indicated that its manufacturing facilities, including co-packers, were reading and following the MSDS information for the butter fla-

vors.[75] ConAgra believed those demands were unusual and not specific. When IFF refused to answer ConAgra's questions about the hazards of the butter flavor, ConAgra refused to comply with IFF's demands. IFF ceased sales and Givaudan replaced IFF as ConAgra's diacetyl butter-flavoring supplier.[79,80]

REGULATORY FAILURES: "DROPPING THE BALL"

EPA TSCA Reporting Requirement

Under Section 4 of the EPA's Toxic Substances Control Act, passed in 1976, manufacturers must keep records of significant adverse reactions related to health or the environment resulting from use of a chemical and must report any unpublished health and safety studies with respect to the chemical to the EPA. Under section 8e of the Act, manufacturers of chemicals or any person who "obtains information that reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment, must promptly report the information to EPA."[81] The flavorings industry did not comply with the TSCA requirements; only one company filed a section 8e report in 2004. As a federal regulatory body, the EPA must enforce its TSCA requirements in order to protect the public health.

Inadequacy of the GRAS System

Unbeknownst to consumers and occupational health professionals, regulation of some substances added to food has been abdicated to industry.[82] The 1958 Food Additives Amendment§ to the Federal Food, Drug, and Cosmetic Act exempted substances "generally recognized by experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures ... to be safe under the conditions of intended use" from food additive status.[83] Thus, as interpreted by the FDA, if a group of scientists hired by an industry organization determines that a substance is "safe," the FDA does not regulate the substance as a food additive and does not require agency review or approval before use.

The Food Additives Amendment instigated FEMA to establish an expert panel of scientists, which it claims has been "rigorously evaluating the safety of flavoring substances under conditions of intended use" for more than 40 years.[83] The FEMA expert panel notes, "Substances generally recognized as safe (GRAS) by the FEMA Expert Panel are not considered to be food additives, and are excluded from mandatory pre-market approval by the Food and Drug Administration."[83] Since the flavoring industry often refers to its food products as "generally recognized as safe (GRAS)," workers and customers often assume the products are safe when inhaled or when they otherwise come into contact with the mucous membranes or skin. However, the GRAS process does not evaluate substances for these risks.

Despite the fact that occupational exposures to GRAS chemicals have caused occupational diseases, OSHA does not regulate any substances added to food, including any evaluation of worker health problems. Furthermore, NIOSH does not routinely evaluate worker exposures to GRAS compounds. Under their mandates, both OSHA and NIOSH could regulate occupational hazards related to substances added to food, although the FDA is often assumed to have entirely reviewed the safety of all substances. As a result, regulation of the occupational hazards associated with GRAS substances falls through the cracks of bureaucratic overlap. It is evident from the diacetyl example that the GRAS system needs to be radically restructured and the oversight of each federal regulatory body must be more clearly delineated.

The Dangers of Industry Self-regulation

Key NIOSH staff, including Kay Kreiss and Richard Kanwal, recognized that butter flavorings labeled "GRAS" were widely used and that workplace controls in plants where workers used them were completely inadequate.[84] Kreiss knew the investigation into the hazard had to be expanded, but NIOSH management cut a deal with FEMA that stopped NIOSH investigations and allowed FEMA members to investigate themselves.[84] Kreiss recognized that this was folly and told the Baltimore Sun that, "We [NIOSH personnel] need to get into some of these plants because we don't have confidence that the flavoring industry has taken steps to actually prevent this disease, and we need to determine how widespread the exposure may be."[5]

Although the OSH act of 1971 gave NIOSH the right to inspect any plant, NIOSH chief spokesman Fred Blosser, removed the threat of use of this right, telling the *Baltimore Sun*, "You've got to ask if the expenditure of time, effort and money to go the forced-entry route to get into a plant is going to result in actions that benefit the workers. The answer is probably not."[5] Dr. Richard Lemen, a former 26-year career NIOSH employee, including service as its acting director, called this NIOSH position a "dangerous philosophy."[5] The threat of forced entry was often substantial enough to gain NIOSH entry and stimulate "voluntary" workplace improvements. Indeed, Lemen notes that, "without exerting its right of entry, NIOSH is reverting to the days before Congress created it and OSHA, when scientific study of worker health depended on the willingness of employers and workers died needlessly."[5]

§Public Law 85-929.72 Stat. 1784 (1958) codified at 21 USC Section 348 (1988).

In 2005, a case of BO at a flavorings manufacturing facility was reported to Cal/OSHA. Kreiss reported that, "We [NIOSH personnel] were told by staff members of the California Health department that [the trade association] made it clear that it did not want NIOSH involved in any of the California flavoring plants."[5] Both Kanwal and Kreiss felt it was wrong to hand the investigation over to the industry and felt the public health agency should handle the concern itself.

The industry hired Cecile Rose, MD, who did not feel that working for FEMA represented a conflict of interest. She told the *Sun* that her investigations had "found no major health problems, just 'mild abnormalities' in 16 workers."[5] However, a worker at a flavoring plant from 1988 to 2006, XX, may have a different view of the impact of self-regulation and physician conflicts on worker health.

XX participated in a National Jewish-sponsored respiratory screening program run by Dr. Rose beginning in 2004.[85] Dr. Rose found that he had abnormal lung function and referred him to his local physician, but did not inform him of the outbreak of BO at flavorings facilities. As a result, XX could not inform his physician of the potential risk of BO, and XX's physician, unaware of the bronchiolitis problem, did not consider this particular diagnosis. XX's physician was unable to determine the cause of his breathing problem, diagnosed his disease as asthma, and treated him with steroids. The physician referred him to an occupational health specialist, who reviewed multiple MSDSs from XX's worksite. He too was unable to determine whether any of these exposures had caused XX's disease. National Jewish documented XX's continued decline in lung function on an annual basis when it conducted screenings at this facility. In May 2006, his employer flew XX to National Jewish Hospital, where he was evaluated by Dr. Rose. About a month later, she told XX that his lung function had declined so far that he could no longer work at the plant. XX left work June 17, 2006. After leaving work he asked for and received his medical file from the flavorings company. The file contained a letter from Dr. Rose to the company indicating that she had diagnosed XX as having work-related BO.[85] Dr. Rose never informed NIOSH, OSHA, or state health authorities of this case. As the case illustrates, when federal bodies leave safety regulation and surveillance in the hands of the industry, they jeopardize worker safety and public health.

Material Safety Data Sheets (MSDSs)

OSHA requires suppliers to provide MSDSs to all facilities where their products are used. Since at least 1985, the Research Institute for Fragrance Materials (RIFM) along with FEMA has created a Flavor or Fragrance Ingredient Data Sheet (FFIDS), which flavoring companies have relied on to create their own MSDSs.[86] Although flavoring companies are highly competitive and refuse, in some cases, to disclose information they consider "trade secrets," the FFIDS allows companies to avoid competition regarding the relative safety of their products. This standardization of warnings allows companies to avoid competition regarding safety, including accusations by competitors that a product is more dangerous than another. Standardization of warning also allows companies to share health and safety information among themselves but hide it from their customers, workers, and government agencies (Appendix). For example, FEMA and its members never provided NIOSH with the 1993 BASF animal inhalation study in the popcorn-lung cases. They did not disclose the relative percentages of diacetyl and other toxic components of the butter flavorings, nor did they relate specific hygiene information about temperature and volatility. All this information was produced in tort litigation, and one of the authors (DE) forwarded it to NIOSH. Anti-trust action may be an underused regulatory intervention to penalize companies for concerted action that results in substandard warnings.

Furthermore, the 1997 FEMA conference included a lecture concerning misinformation that is often included in labels and MSDSs. The lecture included a list of potential problems with MSDSs, called "MSDS watch outs."[87]

Flavoring companies failed to implement the FEMA recommendations and their MSDSs contained (often identical) outdated information. None reported information from the NIOSH investigations from 1985 until 2004. Furthermore, the industries' MSDSs violated the "watch out" suggestions by recommending that users use an "approved respirator" and "adequate ventilation" without explaining the particular type of respirator or ventilation required for specific exposures. For instance, Givaudan's MSDS simply called for "adequate" ventilation, a term which Givaudan's industrial hygienist, Glenn Ingraham, called subjective.[88] No MSDS informed users of the workplace controls that manufacturers had implemented to eliminate exposures in their own plants, such as closed manufacturing processes, mandatory respirator programs, and cooling the mix below 85°F to reduce air levels prior to the addition of diacetyl. Unfortunately, it was only in 2004, in response to a twenty-million-dollar verdict for one of the popcorn-butter-flavor victims, that some flavoring manufacturers initiated improvements of their MSDSs and labels.[57] OSHA is now developing an enforcement initiative for compliance officers to review and evaluate the adequacy of MSDSs.[89] MSDS review should be accompanied by the threat of substantial financial penalization when companies fail to provide full disclosure and accurate information.

Workers' Compensation Laws

Strengthening state requirements for reporting occupational diseases is another promising avenue for control and prevention of diseases. In a 1990 report for the Centers for Disease Control and Prevention, Freund et al. state, "Although state reporting requirements for occupational disease may be disjointed systems that are currently plagued by underreporting and a lack of follow-up and control efforts, they exist because there is need for case identification of illnesses that require control and prevention."[90]

Currently, the Ohio Administrative Code, like other state codes, requires that physicians immediately report certain occupational diseases, including occupational asthma but not BO.[91] The private physician associated with the University of Cincinnati, Dr. Robert Baughman, who examined the three workers from the Tastemaker plant in 1992 and 1993, suspected that they all had BO. He was not required to report these under Ohio law. Tastemaker consultants Drs. Lockey and Brooks thought that several of the workers had occupational asthma, which should have been reported to health authorities.[58] Unfortunately, many physicians are uninformed of the regulations. Complete reporting and vigilant surveillance might have allowed the Ohio health department and NIOSH to discover the increased incidence of BO in workers and prevent future cases. Workers' compensation bureaus and state health departments should be required to refer all cases of occupational disease to NIOSH for possible investigation.

Furthermore, the Constitution of the State of Ohio states that workers can receive supplemental compensation for their disease if the employer failed "to comply with any specific requirement for the protection of the lives, health or safety of employees."[92] Except for the case of CW,¶ neither Tastemaker nor its subsequent owner Givaudan ever reported the confirmed cases to the Ohio Bureau of Workers' Compensation. In the future, the requirement that companies report occupational disease cases to compensation bureaus should be enforced and health authorities should use this information as a basis for investigation and control of workplace hazards. Currently, the State of Ohio tracks workers' compensation records to identify excessive lead exposures. Expanding the scope of the workers' compensation surveillance would allow the state to detect new and/or unusual clusters of occupational disease in the future. As Freund et al. (1990) recommended in their report to the Centers for Disease Control and Prevention, "uniform and streamlined requirements; coherent systems for data gathering, intervention, analysis, and dissemination; and innovative programs" are essential to effectively prevent occupational diseases.[90]

Confidentiality Agreements

The BO outbreak among popcorn workers also raises concerns related to the use of confidentiality agreements. As part of their consulting agreements with Tastemaker (later Givaudan), both Dr. Brooks and Dr. Lockey signed confidentiality agreements. The agreements were signed by Karen Duros, the company's general counsel, and read, "Copies of all written reports and correspondence regarding the project should be sent to me and marked 'privileged and confidential, prepared at the request of ***counsel*** with Givaudan.' "[10] [Emphasis added] Unlike consulting reports to Givaudan personnel, reports to legal counsel may not have to be disclosed during relevant litigation or at the request of government regulatory authorities, such as OHSA and NIOSH. Tobacco companies pioneered the ruse of labeling medical and other health information "prepared for legal counsel" to conceal important health and safety information.[95] Courts have declared that such documents are either not privileged or that in some cases the practice falls under the crime–fraud exception to legal privilege.[95]

Although Dr. Lockey wanted to publish his findings in 1995, he was unable to do so until 2002 since his confidentiality agreement prohibited publication.[58] In 2002, he submitted a copy of an abstract of his findings to the American Thoracic Society (ATS) and to Givaudan. In response, on June 24, 2002, Givaudan's lawyer sent Dr. Lockey a letter that outlined his confidentiality agreement and which stated,

> [As Tastemaker's new owner, Givaudan] has a right to request that you return all information in your possession relating in any way to the services you provided to Tastemaker. . . . In addition, Givaudan hereby requests that you do not disseminate any Tastemaker confidential information by way of public lecture, seminar, speaking engagement, or written publication unless you have received prior written permission from Givaudan to do so.[96]

By 1995, Dr. Lockey realized that the outbreak of BO was not limited to a single plant, and that workers throughout the flavoring industry needed to be protected.[58] In an effort to convince Givaudan to allow him to publish, Dr. Lockey told Givaudan that they had responded

¶To obtain worker compensation a worker must file a claim within two years after he recognizes the disease–work relationship. In 1999, Givaudan prepared a report of occupational injury for CW, the only African-American to develop BO, which they had him sign, and subsequently forwarded to the Ohio Bureau of Workers' Compensation. This form indicated that the BO diagnosis in CW had been made by company consultant physician James Lockey in 1995 and that CW had become aware of the occupational relationship long before the two-year statute of limitations. By signing the Givaudan prepared report, CW unknowingly relinquished his rights to medical coverage and compensation for financial loss due to his work injury.[94,95]

appropriately to the outbreak by hiring him and implementing workplace controls.[58] Givaudan then allowed his presentation to proceed; although, they requested that he stop publication of an ATS press release because the company did not want the information to receive publicity.[58] Dr. Lockey checked and assured them that the press had ignored the press release.

Lockey faced the same dilemma as Roy McKay when Givaudan prevented McKay from telling workers the full extent of the BO hazard as part of the respiratory program. McKay agonized over his predicament; he explained,

> I wasn't freely permitted to, in my opinion, fully describe the severity of the respiratory condition that could develop and at the—and since people that had a high interest in trying to figure out what was going on seemed to be extremely stressed there was a—it was kind of in this position all right, am I doing more good by staying here and being able to have the surveillance program and a strong respiratory protection program, try and keep that strong, or if they're dissatisfied with me then I leave, then what happens when I leave.[19]

Both Lockey and McKay faced a Hobson's choice: they could violate the confidentiality agreements and disclose vital information, or they could attempt to protect workers by continuing to collaborate with the company but keep the information secret. When a lawyer who represented injured workers at Jasper contacted him, Dr. Lockey explained his choice stating that sometimes in the interest of public health you have to keep things confidential.[96] Physicians and corporate consultants should not have to face this dilemma. Confidentiality agreements that prohibit disclosure of important information that may impact public health to state and federal authorities, such as NIOSH, OSHA, and the FDA, should be illegal. Criminal penalties should be applied to corporations and private physicians who fail to disclose this information, and Congress should grant immunity from litigation to physicians and others for violation of confidentiality agreements in these situations.

RECOMMENDATIONS FOR FIXING THE SYSTEM

Corporate responsibility, professional vigilance, and proper federal and state regulations could have prevented the epidemic of lung disease related to flavorings that has already led to three deaths and countless illnesses. To prevent future outbreaks of disease in workers and consumers, it is recommended that the federal government regulate all potential hazards from food and substances added to food, including those currently considered to be GRAS or "generally recognized as safe." The Delaney clause of the 1958 Food Additives Amendment, which bans the use of food additives that are known animal carcinogens, must be extended to GRAS substances. Furthermore, flavorings should be evaluated for possible allergenic and cardiac effects and for synergistic effects with other substances. The FDA should set minimum testing requirements, modeled after its drug testing program, for all substances added to food. The federal government should also vigilantly survey post-marketing data to detect abnormal disease occurrences.

Secondly, federal regulation must be extended to protect workers exposed to these substances from occupational health hazards. Federal regulatory bodies such as NIOSH and OSHA should have clearly delineated responsibilities that allow them to ensure that flavorings and other GRAS substances are tested for inhalational and occupational hazard. Since FEMA already has a list of chemicals that it believes are most likely to be hazardous to workers and consumers, the FDA, EPA, OSHA, and NIOSH should prioritize chemicals to be tested based on likelihood of exposure, likelihood and severity of adverse health effects, and extent of use. Based on this list, OSHA should require companies to perform these tests in addition to enforcing the general-duty standard for occupational safety.[97]

Thirdly, the federal government must evaluate tort reform in relation to public health disasters. Litigation remains one of the most importance means for determining how and why public health disasters, such at the BO epidemic, occur. No other process in the legal or regulatory system produces a similar kind or volume of information. Such information should be made publicly available to protect the public health. To paraphrase George Santayana, those who cannot decipher the past are condemned to repeat it.[98] A valuable model for the use of litigation discovery in public health education is the Legacy Tobacco Documents Library at the University of California, San Francisco, which houses 7 million documents related to advertising, manufacturing, marketing, sales, and scientific research of tobacco products. Since tort reform has limited public health litigation, the government must develop other vehicles, such as developing section 8e of TSCA, obligating companies to produce documents that may help prevent other public health disasters.

Finally, corporate responsibility must be enforced. Companies should be required to report occupational disease outbreaks to OSHA and NIOSH and state public health agencies; failure to do so should be criminalized. In addition, physicians and other health consultants should be given immunity from prosecution under confidentiality agreements when disclosing information to government authorities in the interest of public health. The popcorn-lung epidemic highlights the fact that in every instance, professionals, corporations, and federal authorities must prioritize health and safety over short-term profit in order to protect workers, customers, and the public.

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APPENDIX

Public versus Flavoring Industry Private Knowledge of Butter Flavoring Risk

Flavoring Industry Knowledge	Public Knowledge
1977—RIFM animal study shows lung changes in dead animals exposed to diacetyl breathing and gasping after exposure to diacetyl	
1985—RIFM report states that diacetyl is "harmful by inhalation"	
1985—Animal study provided to RIFM shows death, labored breathing and gasping after exposure to diacetyl	
1985—FEMA model MSDS states that inhalation capable of producing systemic toxicity[80]	
	1986—Two workers mixing "cinna-butter" containing diacetyl diagnosed with BO
1988 First case of BO at Tastemaker (later Givaudan) in a butter-flavoring manufacturing worker	
1988–2005—15 cases of BO and other severe lung disease, including one death, in Tastemaker/Givaudan Cincinnati plant	
1989—Animal study provided to RIFM shows shortness of breath in diacetyl-exposed animals	
1991—Eye and skin irritation in exposed workers in BBA butter-flavoring plant	
1991—BBA received Berje International MSDS, which clearly warned that workers needed a "positive pressure self-contained breathing apparatus" for respiratory protection when working with diacetyl.	
1991—Diacetyl monitoring in manufacturing area in BBA butter-flavoring plant	
1993—First Jasper case evaluated by FEMA consultant who subsequently ran industry meeting on respiratory hazards in flavoring industry in 1997	
1993— BASF study revealed severe lung damage caused by diacetyl in rats	
1993—Respirator program for diacetyl workers in BBA butter-flavoring plant	
1994—Closed system planned in butter room for safety concerns at BBA	
1997—IFF receives Gist Brocades MSDS, which includes BASF data	
	2000—Alan Parmet, astute local physician, reported severe lung disease in popcorn workers; arranged for NIOSH study
	2001—NIOSH identified butter flavoring as a possible cause of severe lung damage in popcorn workers
	2002—NIOSH conducted animal studies that revealed butter flavoring causes severe lung damage
	2004—Author (DE) provided 1993 BASF study to NIOSH
	2005—New case of lung disease at Givaudan related to occupational exposure
	2006—XX developed BO while in FEMA/National Jewish Hospital surveillance program

Mr. PEOPLES. I am sorry?

Chairwoman WOOLSEY. Without objection to your entering it into the record.

Mr. PEOPLES. Thank you.

I hope that OSHA will not be allied with the industries like the flavoring industries.

Chairwoman WOOLSEY. Thank you very much.

Mr. Price?

Mr. PRICE. Thank you, Madam Chair. I, too, thank you for holding this hearing, and I apologize for not being here earlier.

I want to thank all of the panelists for coming and taking time and being tolerant of our schedule.

I want to address a number of issues. First, the issue of butter flavoring.

And last year, the Journal of Occupational and Environmental Medicine published a study entitled, "Evaluation of Flavorings-Related Lung Disease Risk at Six Microwave Popcorn Plants." And I would like to submit that for inclusion in the record, Madam Chair.

Chairwoman WOOLSEY. Without objection.

[The information follows:]

JOEM • Volume 48, Number 2, February 2006 149

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Evaluation of Flavorings-Related Lung Disease Risk at Six Microwave Popcorn Plants

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Learning Objectives

- Explain how the concentration of diacetyl, an airborne butter-flavoring chemical, relates to the specific type of work performed by employees at plants producing microwave popcorn.
- Relate the level and duration of exposure to butter-flavoring chemicals such as diacetyl, as well as smoking history, to respiratory tract symptoms, airway dysfunction, and lung biopsy findings of bronchiolitis.
- Describe practical measures that may decrease exposure to butter-flavoring chemicals and forestall or prevent the development of respiratory tract disease.

Abstract

Objective: *After investigating fixed airways obstruction in butter flavoring-exposed workers at a microwave popcorn plant, we sought to further characterize lung disease risk from airborne butter-flavoring chemicals.* ***Methods:*** *We analyzed data from medical and environmental surveys at six microwave popcorn plants (including the index plant).* ***Results:*** *Respiratory symptom and airways obstruction prevalences were higher in oil and flavorings mixers with longer work histories and in packaging-area workers near nonisolated tanks of oil and flavorings. Workers were affected at five plants, one with mixing-area exposure to diacetyl (a butter-flavoring chemical with known respiratory toxicity potential) as low as 0.02 ppm.* ***Conclusions:*** *Microwave popcorn workers at many plants are at risk for flavoring-related lung disease. Peak exposures may be hazardous even when ventilation maintains low average exposures. Respiratory protection and engineering controls are necessary to protect workers.* (J Occup Environ Med. *2006;48:149–157*)

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The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the National Institute for Occupational Safety and Health.

The authors have no financial interest associated with this research.

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Since August 2000, National Institute for Occupational Safety and Health (NIOSH) staff have investigated the occurrence of fixed obstructive lung disease consistent with constrictive bronchiolitis obliterans in microwave popcorn workers exposed to airborne butter-flavoring chemicals. A NIOSH cross-sectional medical and environmental survey at plant A (the index plant) revealed an elevated prevalence of obstructive lung disease that was associated with cumulative exposure to diacetyl, the predominant butter-flavoring chemical in the air of the plant.[1,2] In experiments conducted at NIOSH, rats exposed to vapors from a butter flavoring used at this plant developed severe injury of their airway epithelium.[3] Rats developed similar airway damage (although less extensive) with inhalation of vapors of pure diacetyl.[4] These findings implicated butter-flavoring chemicals as a likely etiologic agent for obstructive lung disease in the workers at the index plant. Similar lung disease has also occurred in workers at flavoring-manufacturing plants.[5,6]

We performed medical and environmental surveys at five additional microwave popcorn plants to determine if other workers were at risk and to characterize exposures, controls, and work practices in different plants. In this article, we present our findings from cross-sectional evaluations at all six plants (including the index plant) and discuss the implications for prevention of lung disease and other health effects in workers exposed to butter flavorings.

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Materials and Methods

Selection of Plants

Under federal regulations (42 CFR 85),[7] NIOSH staff can conduct a workplace health hazard evaluation after receiving a request from company management, three current workers, or a labor union that represents the workers. Additionally, state health departments can request NIOSH technical assistance with a workplace evaluation. Of the six plant evaluations, two were requested by management, two by state health departments, and two by workers. Three of the plants, each with more than 100 workers, were owned by three of the five largest producers of microwave popcorn in the United States.

Medical Survey

At each facility, we invited all current workers to participate. After obtaining written informed consent from participants, NIOSH interviewers administered a questionnaire to collect information on symptoms, medical diagnoses, smoking history, work history, and work-related exposures. We used questions adapted from the American Thoracic Society standardized respiratory symptom questionnaire[8] to assess shortness of breath on exertion (when hurrying on level ground or walking up a slight hill, hereafter referred to as "SOB 1"; when walking with people your own age on level ground, hereafter referred to as "SOB 2"), chronic cough (usual cough on most days for 3 consecutive months or more during the year), and wheezing (apart from colds). A positive smoking history was defined as having smoked at least 20 packs of cigarettes in a lifetime or at least one cigarette a day for 1 year.

Using a dry rolling-seal spirometer interfaced to a computer, NIOSH technicians performed spirometry tests following American Thoracic Society guidelines[9] with results compared with spirometry reference values generated from the Third National Health and Nutrition Examination Survey (NHANES III).[10] We defined airways obstruction as a forced expiratory volume in the first second of exhalation (FEV_1) and an FEV_1/forced vital capacity (FVC) ratio that were both below the lower limit of normal. We administered a bronchodilator to differentiate reversible obstruction, defined as an increase in the FEV_1 of at least 12% and 200 mL, from fixed obstruction.

We aggregated the medical survey data from all six plants and used SAS software (SAS version 9.1, 2002–2003; SAS Institute, Inc., Cary, NC) for statistical analyses. We compared medical survey findings in ever-mixers (workers who reported having mixed oil and flavorings for at least 1 day) with findings in all other workers. We also compared findings in packaging-area workers (who had never worked as mixers) in two sets of plants—those with isolated heated tanks of oil and flavorings and those with nonisolated tanks—and compared findings in maintenance workers with those of workers who had never worked in maintenance, mixing, or packaging. χ^2 and Fisher exact tests were used to analyze categorical data, and Student t test was used to analyze continuous data. We considered P values of 0.05 or less to represent differences that were unlikely due to chance.

Some workers who reported undergoing medical evaluations by personal physicians due to respiratory symptoms that began after they started work in microwave popcorn production gave consent for us to review their medical records. We specifically looked for findings of fixed obstruction on spirometry, normal diffusing capacity, and evidence of air trapping on chest computed tomography (CT) scans, because the presence of these findings is consistent with bronchiolitis obliterans. We also reviewed available lung biopsy reports if biopsies had been performed.

Environmental Survey

We characterized the production process at each plant in terms of the number of production lines and number of heated tanks of flavorings and oil-flavoring mixtures, exposure controls (ie, general dilution and local exhaust ventilation, isolation of oil and flavoring-mixing processes), temperatures of the contents in heated tanks, and use of respirators by flavoring-exposed workers. As an indicator of exposure to butter-flavoring chemicals, we measured full-shift time-weighted average (TWA) air concentrations of diacetyl in several areas of each plant with sorbent tubes and gas chromatography according to NIOSH Method 2557.[11] At most plants, we also obtained personal exposure measurements for diacetyl with sampling equipment located on the worker. At one plant, we used a Gasmet DX-4010 Fourier Transform Infrared (FTIR) Gas Analyzer (Temet Instruments Oy, Helsinki, Finland) to measure real-time concentrations of diacetyl in a worker's breathing zone while he handled open containers of butter flavorings.

Results

General Production Process and Plant Characteristics

Plants varied widely in terms of plant size and number of workers, but the basic production process was similar. In each plant, one to three workers per work shift (ie, mixers) measured butter flavorings (liquids, pastes, and powders) in open containers such as 5-gallon buckets and poured the flavoring into heated soybean oil in large (eg, 500-gallon) heated mixing tanks, most of which had loose-fitting lids. Although visible plumes of vapors were often apparent when tank lids were opened, only one mixer at one plant reported consistent use of a respirator with organic vapor cartridges during mixing tasks. Mixers also added salt and coloring to the oil

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and flavoring mixture, which was then transferred by pipes to nearby packaging lines to be combined with kernel popcorn in microwaveable bags. Workers on the packaging lines operated the packaging machines and facilitated the placement of the finished product into cartons and boxes. In most plants, quality-control (QC) workers popped product in microwave ovens that were usually located in a separate QC laboratory. Other workers were located in warehouse and office areas. In separate areas of some plants, workers also packaged plain kernel popcorn in plastic bags without oil or flavorings.

The number of different butter flavorings used ranged from two in one of the smaller plants to more than 20 in the largest plant. Two small plants had one or two mixing tanks and one packaging line. One medium-sized plant had one mixing tank, three holding tanks for oil and flavorings, and three packaging lines. Three large plants had five or more tanks and seven or more packaging lines. In some plants, flavoring-mixing activities, and tanks were located in a separate room adjacent to the packaging area. In other plants, some or all tanks of heated oil and flavoring were located in the same room as, and in close proximity to, the packaging lines.

Diacetyl Exposures

Compared with the index plant, mean diacetyl air concentrations in the mixing areas at the other five plants were generally one to two orders of magnitude lower (Table 1). In four of these five other plants, the highest TWA diacetyl air concentration measured with area sampling in mixing areas was between 0.6 and 1.0 parts per million (ppm) compared with 98 ppm at the index plant. In plant F, the highest TWA diacetyl air concentration measured with area sampling in the mixing room was 2.7 ppm, just slightly above the lowest mixing-room TWA diacetyl air concentration in the index plant.

TABLE 1
Mixing-Area and Packaging-Area Diacetyl Air Concentrations at Six Microwave Popcorn Plants

	Diacetyl Air Concentration Mean (range; ppm)*			
	Mixing Area		Packaging Area	
Plant	Area	Personal	Area	Personal
A (index)	37.8 (1.3–97.9) (n = 12)		1.9 (0.3–6.8) (n = 22)	
B	0.6 (0.4–1.0) (n = 3)	0.6 (0.4–0.7) (n = 2)	0.7 (0.4–1.2) (n = 9)	0.5 (0.2–1.0) (n = 8)
C	0.4 (0.02–0.9) (n = 2)	0.03 (0.01–0.04) (n = 2)	0.03 (0.01–0.05) (n = 4)	0.02 (0.01–0.04) (n = 7)
D	0.2 (ND–0.6) (n = 3)	0.02 (ND–0.05) (n = 5)	0.004 (ND–0.03) (n = 13)	0.002 (ND–0.009) (n = 12)
E	0.6 (0.3–0.9) (n = 2)	0.4 (n = 1)	0.3 (0.2–0.4) (n = 2)	0.6 (0.3–1.2) (n = 3)
F	1.2 (0.5–2.7) (n = 6)	1.0 (0.2–2.0) (n = 7)	0.02 (LOQ–0.03) (n = 18	0.02 (LOQ–0.03) (n = 24)

* Parts per million parts air by volume.
ND indicates below limit of detection for the sampling method (0.001 ppm); 0.0005 used for calculation of mean; LOQ, below minimum quantifiable concentrations for the sampling method (approximately 0.01 ppm); 0.005 used for calculation of mean.

Of note, two of the three heated tanks in the mixing room of the index plant contained heated liquid flavorings only (ie, flavoring not yet mixed into soybean oil). None of the other plants used heated tanks to hold only butter flavoring. Plant D, the only plant that had both local exhaust ventilation of tanks and general dilution ventilation with outside air, had the lowest mixing area mean diacetyl air concentration. However, plants C and E, without either of these types of ventilation, had only slightly higher mean diacetyl air concentrations. In general, the mixing areas differed with regard to several characteristics simultaneously (eg, size of area, ventilation, number of tanks, tank temperatures, and numbers and types of butter flavorings used) such that the relative importance of any particular characteristic to measured diacetyl air concentrations could not be determined.

Real-time monitoring in a mixer's breathing zone at plant D revealed peak diacetyl air concentrations of over 80 ppm over several minutes while he poured liquid butter flavorings into tanks of heated oil (Fig. 1).

In five of the six plants, packaging areas had lower mean diacetyl air concentrations than mixing areas. Compared with the index plant, mean diacetyl air concentrations in the packaging areas of all other plants were much lower (Table 1). The lowest TWA diacetyl air concentration measured with area sampling in the packaging areas of plants B through F ranged from below the limit of detection (0.001 ppm) in plant D to 0.4 ppm in plant B. The highest TWA diacetyl air concentration measured with area sampling ranged from 0.03 ppm in plants D and F to 1.2 ppm in plant B (compared with 6.8 ppm in the index plant). Packaging area mean diacetyl air concentrations were much lower in plants where all tanks of heated oil and butter flavorings were in a room separate from the packaging area (range 0.004–0.03 ppm measured with area sampling in plants C, D, and F) compared with plants where some or all tanks were located adjacent to packaging lines (range 0.3–1.9 ppm measured with area sampling in plants A, B, and E). NIOSH air sampling at plant F occurred after the company had made recent ventilation changes to render air pressure negative in the mixing room relative to the packaging area. On a prelimi-

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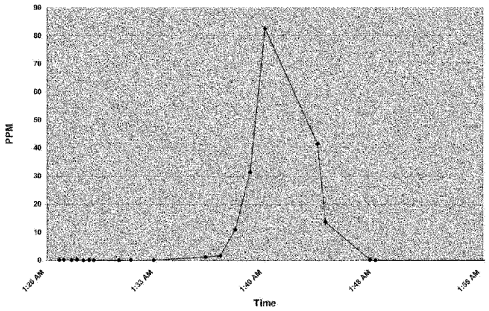

Fig. 1. Fourier Transform Infrared real-time diacetyl air concentrations at plant D. The diacetyl peak occurred when a mixer poured several 5-gallon containers of liquid butter flavoring into a heated tank of oil.

nary visit to this plant before the ventilation changes, NIOSH had determined that the mixing room had positive air pressure relative to the packaging area. This finding, and reports from several workers that the door to the mixing room was often left open, suggests that packaging area diacetyl air concentrations at plant F were probably higher in the past than those we measured. For an analysis of medical survey findings in packaging-area workers, we grouped plant F with plants A, B, and E ("nonisolated" or inadequately isolated tanks) and plant C with Plant D ("isolated tanks").

Survey Participation and Worker Characteristics

Of 708 current workers, 537 (76%) participated in our surveys (Table 2). The mean age of participants was 39 years. Slightly more than half of participants were male, and most were white. Sixty-three percent were current or former smokers.

Medical Records Review

In addition to the four known affected mixers and four known affected packaging-line workers among former workers of the index plant (plant A), medical records documented that an additional worker at plant A with past mixing experience,[12] mixers at plants B, D, and F (one at each plant), and three packaging-line workers at plant E had fixed airways obstruction, normal diffusing capacity, and evidence of air trapping on chest CT scans. The three largest plants (plants A, D, and F, each with over 100 workers) had mixers with these findings. Plant B (less than 10 workers) was one of two smaller facilities where a mixer also had these findings.[13] Of the lung biopsy reports we reviewed, two of three workers biopsied from plant A and three of six workers biopsied from plant E had findings consistent with constrictive bronchiolitis obliterans.

Medical Survey Findings in Mixers

Eighty-six workers across all six plants reported having mixed oil and butter flavorings for at least 1 day. Compared with workers with no history of work as mixers (ie, never-mixers), these ever-mixers had higher prevalences of all respiratory symptoms with statistically significant excesses for SOB 2, chronic cough, and wheezing (Table 3). The mean percent predicted FEV_1 was 89% in ever-mixers and 94% in never-mixers (statistically significant, $P = 0.02$). The prevalence of smoking was similar in the two groups (56% vs 64%). Stratifying by smoking status, ever-mixers had higher symptom prevalences and lower mean percent predicted FEV_1 than never-mixers, with several comparisons achieving statistical significance (Fig. 2). Mean percent predicted FEV_1 values were 91 (ever-mixers) and 93 (never-mixers) among ever-smokers and 87 (ever-mixers) and 96 (never-mixers) among never-smokers. Although the overall prevalence of airways obstruction was similar in ever- and never-mixers (approximately 11%), ever-mixers had a higher prevalence than never-mixers among never-smokers (15.8% vs 6.9%), although this difference was not statistically significant. Nine of 10 ever-mixers with obstruction had a bronchodilator administered; eight of the nine (89%) had fixed obstruction.

Of the 86 ever-mixers, 26 had worked as mixers for more than 12 months and 45 had worked as mixers for 12 months or less. (For 15, length of time as a mixer was unknown.) Compared with ever-mixers with 12 months or less of mixing experience, ever-mixers with more than 12 months of mixing experience had higher prevalences of all respiratory symptoms and airways obstruction; the difference for SOB 1 was statistically significant, whereas the differences for airways obstruction and SOB 2 were borderline significant (Table 4). The mean percent predicted FEV_1 was 82% in ever-mixers with more than 12 months of mixing experience and 95% in those with 12 months or less of mixing experience (statistically significant, $P = 0.004$). Both ever- and never-smokers with more than 12 months of mixing experience had higher prevalences of all respiratory symptoms and airways obstruction and a lower percent predicted FEV_1 than ever- and never-smokers with 12 months or less

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TABLE 2
Characteristics of Survey Participants at Six Microwave Popcorn Plants

Plant	Workers	Survey Participants n (%)	Age (years) Mean (range)	Male (%)	White (%)	Smokers Current (%)	Smokers Former (%)	Smokers Never (%)
A (index)	135	123 (91)	37 (18–67)	47	91	41	15	44
B	6	5 (83)	60 (53–76)	40	100	40	20	40
C	13	11 (85)	37 (23–62)	9	100	0	9	91
D	193	157 (81)	43 (18–71)	55	78	37	17	46
E	48	35 (73)	49 (25–64)	46	97	40	40	20
F	313	206 (66)	36 (18–67)	69	92	61	11	28
All plants	708	537 (76)	39 (18–76)	57	88	47	16	37

TABLE 3
Mean Percent Predicted Forced Expiratory Volume in One Second (FEV_1) and Prevalences of airways obstruction and Respiratory Symptoms in Workers Who Mixed Oil and Butter Flavoring Compared With Workers Who Never Performed This Task

	Ever-Mixers	Never-Mixers	*P* Value
Mean percent predicted FEV_1	89.4	94.2	0.02
Obstruction on spirometry, n (%)	10* (11.6)	47† (10.7)	0.8
Shortness of breath on exertion (SOB 1), n (%)	33 (39.3)	134 (30.7)	0.12
Shortness of breath on exertion (SOB 2), n (%)	15 (17.9)	43 (9.8)	0.03
Chronic cough, n (%)	21 (24.7)	55 (12.5)	0.003
Wheezing, n (%)	36 (42.4)	98 (22.2)	<0.0001

*Nine of 10 had a bronchodilator (BD) administered; eight of nine (89%) did not respond to BD.

†Forty of 47 had a BD administered; 31 of 40 (78%) did not respond to BD.

SOB 1 indicates shortness of breath when hurrying on level ground or walking up a slight hill; SOB 2, shortness of breath when walking with people your own age on level ground.

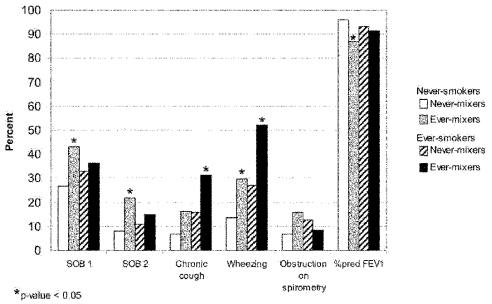

Fig. 2. Prevalences of respiratory symptoms and airways obstruction and mean percent predicted forced expiratory volume in 1 second in ever-mixers compared with never-mixers by smoking status. (Asterisk denotes $P < 0.05$ for comparison within smoking category.)

experience as mixers (Fig. 3). The differences for SOB 1 among never-smokers and in mean percent predicted FEV_1 among ever-smokers were statistically significant.

To determine if data from the index plant were responsible for the excess rates of obstruction and respiratory symptoms in the aggregate data, we repeated our analyses after excluding the data from the index plant. The prevalences of respiratory symptoms were still higher in ever-mixers compared with never-mixers; the excess for wheezing was statistically significant (38.3% vs 19.5%; $P = 0.001$) and for chronic cough was borderline significant (18.3% vs 10.3%; $P = 0.07$). Mean percent predicted FEV_1 was 90% in ever-mixers and 95% in never-mixers (statistically significant, $P = 0.02$). Mean percent predicted FEV_1 was 79.7% in ever-mixers with more than 12 months of mixing experience and 95% in those with 12 months or less of mixing experience (statistically significant, $P = 0.005$). Those with more time as mixers also had higher prevalences of all respiratory symptoms and airways obstruction but only the excess for SOB 1 was statistically significant (57.9% vs 22%; $P = 0.006$).

Medical Survey Findings in Packaging-Area Workers

Compared with packaging-area workers in plants with isolated tanks, packaging-area workers in plants with nonisolated or inadequately iso-

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TABLE 4
Mean Percent Predicted Forced Expiratory Volume in One Second (FEV_1) and Prevalences of Airways obstruction and Respiratory Symptoms in Workers Who Mixed Oil and Butter Flavoring for More Than 12 Months Compared With Workers Who Did This Task for 12 Months or Less Time

	Mixer >12 Mo	Mixer <12 Mo	*P* Value
	(*n* = 26)	(*n* = 45)	
Mean percent predicted FEV_1	82.1	95.0	0.004
Obstruction on spirometry, n (%)	5* (19.2)	2† (4.4)	0.09
Shortness of breath on exertion (SOB 1), n (%)	13 (54.2)	11 (24.4)	0.01
Shortness of breath on exertion (SOB 2), n (%)	6 (25.0)	3 (6.7)	0.06
Chronic cough, n (%)	7 (28.0)	8 (17.8)	0.32
Wheezing, n (%)	13 (52.0)	17 (37.8)	0.25

*Five of five had a bronchodilator (BD) administered; four of five (80%) did not respond to BD.

†Two of two had a BD administered; two of two (100%) did not respond to BD.

SOB 1 indicates shortness of breath when hurrying on level ground or walking up a slight hill; SOB 2, shortness of breath when walking with people your own age on level ground.

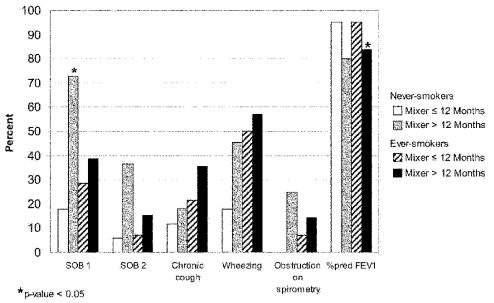

Fig. 3. Prevalences of respiratory symptoms and airways obstruction and mean percent predicted forced expiratory volume in 1 second in mixers with 12 or fewer months of mixing experience compared with mixers with more than 12 months mixing experience by smoking status.

lated tanks had higher prevalences of all respiratory symptoms and airways obstruction; the excess for wheezing was statistically significant ($P = 0.001$), and for airways obstruction, it was borderline significant ($P = 0.06$) (Table 5). Mean percent predicted FEV_1 was lower in packaging-area workers who worked near nonisolated tanks (93.7% vs 96.4%), but this difference was not statistically significant. Of 27 packaging-area workers with airways obstruction in plants with nonisolated or inadequately isolated tanks, 23 had a bronchodilator administered; 21 of 23 (91%) had fixed obstruction. The percentage of ever-smoker packaging-area workers was higher in plants with nonisolated or inadequately isolated tanks than in plants with isolated tanks (73% vs 45%). However, after stratifying by smoking status, both ever- and never-smoker packaging-area workers in plants with nonisolated or inadequately isolated tanks had higher prevalences of airways obstruction and most respiratory symptoms than ever- and never-smoker packaging-area workers in plants with isolated tanks (Fig. 4). The excesses for SOB 1 and wheezing among never-smokers were statistically significant.

After excluding data from the index plant from the analysis, packaging-area workers in plants with nonisolated or inadequately isolated tanks still had higher prevalences of airways obstruction (11.5% vs 5.5%; not statistically significant) and wheezing (25% vs 10.7%; statistically significant, $P = 0.01$), whereas the prevalences of other respiratory symptoms were similar in both groups.

Medical Survey Findings in Other Workers

Quality Control. For plants A, D, and F, Table 6 provides data on the number of bags popped by QC workers per day, diacetyl air concentrations in the QC laboratory, and spirometry results in QC workers. The other plants popped fewer bags and/or did not have workers that did QC work exclusively. Five of six QC workers tested (85%) had airways obstruction at plant A, which clearly had the highest QC laboratory mean diacetyl air concentration (0.6 ppm). No other plant had high rates of obstruction in QC workers.

Maintenance. Thirty-seven workers reported having worked in maintenance but never as a mixer or packaging-area worker. Compared with 138 workers with no history of work in maintenance, mixing, or in the packaging area, maintenance workers had higher prevalences of all respiratory symptoms with statistically significant excesses for SOB 2 (18.9% vs 5.8%; $P = 0.01$) and wheezing (32.4% vs 15.3%; $P = 0.02$) and a borderline significant excess for SOB 1 (37.8% vs 23.4%; $P = 0.08$). Mean percent predicted FEV_1 was lower in maintenance

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TABLE 5
Mean Percent Predicted Forced Expiratory Volume in One Second (FEV_1) and Prevalences of Obstruction and Respiratory Symptoms Among Packaging-Area Workers in Plants with Nonisolated or Inadequately Isolated Tanks of Heated Oil and Butter flavoring (Plants A, B, E, and F) Compared With Packaging-Area Workers in Plants With Isolated Tanks (Plants C and D)

	Packaging-Area Workers in Plants With Nonisolated Tanks (n = 195)	Packaging-Area Workers in Plants With Isolated Tanks (n = 75)	P Value
Mean percent predicted FEV_1	93.7	96.4	0.26
Obstruction on spirometry, n (%)	27* (14.0)	4† (5.5)	0.06
Shortness of breath on exertion (SOB 1), n (%)	68 (36.2)	20 (26.7)	0.14
Shortness of breath on exertion (SOB 2), n (%)	23 (12.2)	5 (6.7)	0.19
Chronic cough, n (%)	31 (16.2)	8 (10.8)	0.27
Wheezing, n (%)	57 (29.7)	8 (10.7)	0.001

*Twenty-three of 27 had a bronchodilator (BD) administered; 21 of 23 (91%) did not respond to BD.

†Four of four had a BD administered; two of four (50%) did not respond to BD.

SOB 1 indicates shortness of breath when hurrying on level ground or walking up a slight hill; SOB 2, shortness of breath when walking with people your own age on level ground.

workers (91.6% vs 94.3%), but this difference was not statistically significant and prevalence of airways obstruction was similar in both groups (8.1% vs 9.5%). After excluding data from the index plant from this analysis, maintenance workers still had excess wheezing that was statistically significant (34.5% vs 16%; $P = 0.02$). However, the prevalences of other respiratory symptoms were now similar in both groups, mean percent predicted FEV_1 was also similar (approximately 94%), and prevalence of airways obstruction was lower in maintenance workers (3.5% vs 8%).

Discussion

The investigation of severe fixed obstructive lung disease in workers of a microwave popcorn plant in 2000 identified inhalation exposure to butter-flavoring chemicals as the likely cause.[1,2] The results of animal studies showing severe airway epithelial injury after a 6-hour inhalation exposure to a butter flavoring used at this plant, and similar injury after a 6-hour inhalation exposure to pure diacetyl, provided additional support for this conclusion.[3,4]

Our analyses of aggregated data from medical and environmental surveys at the index plant and five additional microwave popcorn plants indicate an apparent widespread risk for occupational lung disease from exposure to butter-flavoring chemicals in this industry. In five of six plants, mixers and/or packaging-area workers with onset of respiratory symptoms after starting work had undergone medical evaluations that revealed fixed airways obstruction and other findings consistent with bronchiolitis obliterans. Our findings from medical surveys of current workers at these plants are consistent with the medical evaluations, indicating risk to mixers who combine butter flavorings with heated oil and to packaging-area workers who work near inadequately isolated tanks of heated oil and flavorings.

Our analyses highlight the high potential for lung disease in mixers of oil and butter flavorings. Mixers at four of six plants had medical findings consistent with bronchiolitis obliterans, and mixers with more than 12 months' mixing experience had the highest respiratory symptom and airways obstruction prevalences and the lowest mean percent predicted FEV_1 in our analyses of the data from surveys of current workers. At plant D, one of the four plants where a mixer had developed lung disease, the mean TWA diacetyl air concentration measured with area sampling in the mixing room was only 0.2 ppm compared with 37.8 ppm at the index plant. However, peak exposures measured at plant D during open handling of butter flavorings were much higher. These findings suggest that even when ventilation maintains low-average exposures, mixers are still at risk from

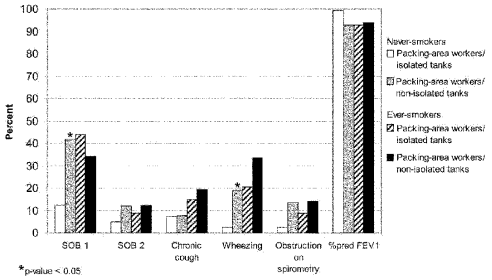

Fig. 4. Prevalences of respiratory symptoms and airways obstruction and mean percent predicted forced expiratory volume in 1 second in packaging-area workers in plants with isolated tanks compared with packaging-area workers in plants with nonisolated tanks by smoking status.

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TABLE 6.
Number of Bags of Microwave Popcorn Popped in Microwave Ovens per Quality Control (QC) Worker, QC Laboratory Diacetyl Air Concentrations, and Proportion of QC Workers With Airways Obstruction at Plants A, D, and F

Plant	Number of Bags Popped Per QC Worker	Diacetyl Air Concentration Mean (range; ppm)*	Proportion of QC Workers With Obstruction
A (index)	~100 per 8-hr work shift	0.6 (0.3–0.9)	5 of 6
D	~75 per 8-hr work shift	<0.001	0 of 3
F	~130 per 12-hr work shift†	0.02 (<0.01–0.03)	1 of 11

* Parts per million parts air by volume.
† At plant F, workers only performed this task 3 to 4 days per week for 1 of every 3 weeks.

brief, intense exposures associated with open handling of butter flavorings or opening lids to check on tanks of heated oil and flavorings.

Packaging-area workers near nonisolated tanks that contain heated oil and flavorings are likely at risk from higher average concentrations of flavoring chemicals in the air or from intermittent peak exposures when mixers add butter flavorings to tanks or lift tank lids to check on the contents. Of the three plants where tanks were isolated, plant C had the highest packaging area mean TWA diacetyl air concentration (0.03 ppm from area sampling). This was still an order of magnitude *lower* than the lowest mean TWA diacetyl air concentration in the packaging area at plants where tanks were not isolated (0.3 ppm from area sampling at plant E).

The high prevalence of airways obstruction in QC workers at plant A implies that this job can pose risk when many dozens of bags are popped daily without adequate control of exposures. In plants that performed QC popping of product, air concentrations of diacetyl in the QC laboratory were as low as, or lower than, the air concentrations in the packaging area in the same plant. However, the much higher temperatures that occur in microwave popping (compared with the temperatures in heated tanks) increase the volatilization of other chemicals. Because of this, QC workers' exposures may be substantially different from those of other production workers, and diacetyl air concentrations alone may not be a satisfactory predictor of risk for these workers. In addition, QC workers, like mixers, experience intermittent peak exposures that may increase their risk although their average exposures are much lower.

Because our analyses were conducted on data from cross-sectional medical surveys of current workers, it is possible that the prevalences of respiratory symptoms and airways obstruction in mixers and in packaging-area workers who worked near inadequately isolated tanks might have been higher if our survey had included former workers, some of whom may have left employment due to respiratory illness (a healthy worker effect). Given the fact that mixers comprised a small percentage of the workforce at all plants, including former workers might possibly have resulted in larger numbers of ever-mixers and led to additional findings of statistical significance in our analyses. During the initial cross-sectional survey at the index plant, we invited former workers to participate. However, despite our efforts to notify former workers about the planned survey through phone calls, mailed notifications, and media advertisements, many could not be located. Of an estimated 425 former workers who worked at plant A between 1992 and 2000, only 161 (approximately 38%) participated in our survey. Because of this low participation and the possibility that this was not a representative sample of former workers, we did not include this group in our analyses and did not attempt systematic surveys of former workers at other plants.

At this time, insufficient data exist on which to base workplace exposure standards or recommended exposure limits for butter flavorings. Because the risk for occupational lung disease may be partly due to short-term peak exposures, an exposure limit based on an 8-hour TWA may not be sufficient to protect workers. Moreover, because flavorings are complex mixtures of many chemicals, most of which have not been evaluated with respect to inhalation toxicity, focusing solely on diacetyl air concentrations may not be adequate to assess risk in different plants using a variety of different flavorings. Few flavoring chemicals have an Occupational Safety and Health Administration (OSHA)-permissible exposure limit (PEL) or a NIOSH-recommended exposure limit (REL).[14] The lowest mean TWA diacetyl air concentrations that we measured in mixing areas (0.02 ppm personal exposure and 0.2 ppm area air concentration) were at a plant with an affected mixer (plant D); therefore, it would seem prudent to maintain worker exposures to diacetyl below these levels.

Because entirely safe levels of occupational exposure to butter-flavoring chemicals are not known, it is important to limit worker exposures as much as possible. The most reliable way to do this will require microwave popcorn companies to re-engineer their production processes to closed systems that eliminate the need for workers to handle flavorings in open containers and to open the lids of heated tanks to check on their contents. Until this is accom-

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plished, all flavoring handling and mixing activities, and all tanks of heated oil and flavorings, should be isolated in a room under negative air pressure and with ventilation separate from the rest of the plant. In addition, all tanks should have local exhaust ventilation. Any worker entering the mixing room should wear, at all times, a NIOSH-approved air-purifying respirator with organic vapor cartridges and particulate filters or a more protective respirator (such as a supplied-air respirator). Respirator use must be part of a formal, written respiratory protection program that adheres to the requirements of the OSHA Respiratory Protection Standard (29 CFR 1910.134). Respirators should only be considered a short-term solution because they may allow intermittent exposures through improper use, improper fit, or respirator malfunction. Encapsulated powdered flavorings that release less flavoring-related vapors into the air may be a safer alternative to liquid and paste flavorings. However, workers may be at risk from any respirable dust generated during the handling of these powders, so workers should use respirators during open handling of powdered flavorings as well as during the handling of liquids and pastes. Because some flavoring chemicals, including diacetyl, are known irritants, skin and eye exposure should be limited with appropriate work clothes, gloves, and eye protection. Microwave ovens used by QC workers should have local exhaust ventilation, and bags of product should be allowed to cool before being opened. Because flavoring-related decreased lung function can occur before the onset of symptoms, relying solely on self-reporting of respiratory symptoms by workers as a way to identify early lung disease is insufficient to prevent clinically significant irreversible lung disease.[1] Therefore, regularly scheduled medical monitoring with spirometry for workers who enter the mixing room or perform QC popping of product in microwave ovens is essential for early detection of declines in lung function that may indicate flavoring-related lung disease.

Workers exposed to butter-flavoring chemicals in the manufacture of other food products besides microwave popcorn may also be at risk for occupational lung disease. Clinicians should consider this possibility if they are evaluating respiratory symptoms or impairment in patients with a history of work in food production or in flavoring-manufacturing plants. Diagnosis of lung disease that is possibly flavoring-related in such workers should prompt further evaluation of the affected worker's workplace and coworkers to identify ongoing risks, if any, so that disease in other workers can be prevented.

Acknowledgments

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Mr. PRICE. Thank you.

The study is interesting. In one point, it says that, "At this time insufficient data exists on which to base workplace exposure standards or recommended exposure limits for butter flavoring." However, the study concludes that these workers are at risk for flavoring-related disease and recommends respiratory protection and engineering controls to protect workers.

And I wonder, Mr. Foulke, if you might explain the special emphasis program with respect to the issue that was announced this morning, as the chair noted.

Mr. FOULKE. Yes. The National Emphasis Program that we will be implementing next month is an inspection program. It is part

of our enforcement operation. We have a number of National Emphasis Programs.

We also have Local Emphasis Programs on different subjects, on different topics. But this particular one is a National Emphasis Program involving butter flavors containing diacetyl in the popcorn industry—is our focus initially.

And what we are going to be doing is conducting inspections of all the popcorn manufacturing facilities, butter popcorn manufacturing facilities, under federal jurisdiction, because we have state plan states that are not under our jurisdiction like California. So we are going to be conducting inspections of all those facilities by the end of 2007.

And part of that inspection process will include reviewing the material safety data sheets to make sure that they have the proper information on there about that and other chemicals, to make sure that the hazard warnings are known to all those employees.

Mr. PRICE. So there is a process in place, and you are moving through that.

Mr. FOULKE. Yes. I could say what we are going to be doing is we are going to be inspecting all the facilities before the end of the year.

Mr. PRICE. Great. I appreciate that.

I want to change gears just a little bit. In my real life, I was an orthopedic surgeon, so I have some familiarity with ergonomic situations and the challenges there.

Mr. Fellner, we heard some testimony earlier that when the Department of Labor changed the recording of ergonomic injuries that this was the reason for the decrease in injury and illness rates. And I wondered if you might comment on that assertion.

Mr. FELLNER. Thank you, Congressman Price.

Indeed, that assertion is mistaken—assertion made by my friend Frank Mirer.

In point of fact, there was a column that was going to be added to the OSHA 300, the recordable injury form that OSHA requires employers to fill out. In its proposed standard, OSHA had suggested that there should be a separate column for musculoskeletal disorders.

In response to comments by me, amongst others, OSHA concluded that they could not define musculoskeletal disorders. And consequently, they decided not to issue that as a final rule.

However, what is very important to understand is that in so deciding, OSHA said however you employers used to define musculoskeletal disorders, continue to define it the same way, and continue to record it as you were recording it in the past.

Any suggestion that there was a diminution of recording musculoskeletal disorders as a result of that instruction by OSHA to the regulated community is simply false.

Mr. MIRER. Do I get to——

Mr. PRICE. I appreciate that.

Please, Dr. Mirer, yes.

Mr. MIRER. Under the old rules, if an employee was treatment-free for 30 days, the recurrence of a musculoskeletal disorder or any other injury was a new occurrence and was recordable. Now,

the employer does not have to record that, and most of these are recurrent illnesses.

If medical treatment is denied to the employee, it used to be recordable. It is not recordable now. And those are the two main ways in which they have done it.

The other point being, we talked about chemical exposures and the problems arising from those. If you retire and then die of asbestosis or silicosis or popcorn lung, you are not recordable, because the system particularly excludes these latent diseases that go on for a long time.

And there is quite a lot of scientific literature about the underrecording of occupational injuries and illnesses, at least half a dozen——

Mr. PRICE. I am running out of time, and I appreciate that, and I thank you.

And I think it brings up the point, however, that I think there are differences between exposures to elements and musculoskeletal inherent challenges in any workplace.

And I don't want to pick out certain companies, but UPS—in my area, I used to evaluate employees before they went on the job there. They go out of their way to make certain that their employees are doing things correctly and making certain that they are—because an employee who goes down is not productive for them, obviously.

So I think that there are differences between exposure to elements, which Mr. Peoples had, obviously, and exposure to inherent risk of certain jobs.

But I would commend the chairman for drawing attention once again to the title of this hearing, "Have OSHA Standards Kept Up With Workplace Hazards?"

And I would just make a comment, Madam Chair, if I may, that I am not certain that the government is nimble enough to keep up with the changing workplace and would suggest that we commend those institutions and those companies and workplaces that do, in fact, make certain that their employees are as safe as possible.

And I yield back the balance of my time.

Chairwoman WOOLSEY. Thank you, Mr. Price.

Mr. Hare from Illinois?

Mr. HARE. Thank you, Madam Chairman.

With all due respect, Mr. Secretary and Mr. Fellner, I don't share your rosy opinion of the job that OSHA has been doing. In 2005, we lost 5,071 people to workplace deaths. That same year, we had 50,000 to 60,000 workers die from occupational diseases.

And despite these alarming statistics, I find two pages of OSHA standards that have either been killed, delayed or thrown out by this administration—two pages of them. It is pretty hard to enforce a standard, from my perspective, when you throw them out.

So I don't share with you, Mr. Secretary, your boss's commitment to protecting our workers when you start throwing standards down the drain.

The other thing is I was interested in Mr. Fellner's comments when he talked about speed, and he mentioned it, and workplace du jour.

Let me say this. We had a hearing here earlier on the B.P. explosion where 15 people died and over 100 people were injured. It was 10 years, as I understand the testimony at that hearing, from the time OSHA had had an inspection there.

I don't think B.P. will be cited or OSHA will get a speeding violation for not going into that factory, into that plant, and looking at the problems there for a 10-year-period of time, Mr. Fellner.

With regard to Mr. Peoples, I wonder if his illness happens to be one of those illness du jours that you were referring to in your testimony.

The bottom line, it seems to me, here is, are we going to work and stand up for average working people?

You know, Mr. Peoples is sitting here today. It is fine to say that we feel very bad for him. The problem is that we take standards that we want to have on the books and protect people and we do little or nothing with them.

The chair and myself and a couple of other members of this committee have sent a letter to OSHA asking them to look into the Cintas Corporation, a company where a worker was killed. The Cintas people responded to us by basically telling us that the worker, in essence, was too stupid to know the job, and instead of putting the guards on, he was sucked into a dryer at 300 degrees for 30 minutes and killed. I think that is insulting to him and to his family.

It is my sincere hope, Mr. Secretary, that OSHA will take a look at this and will do whatever it can to make sure that Cintas starts complying. This is not what I would call a worker-friendly corporation.

I guess what I would like to know, from your perspective—you say that since you have become Secretary you have discovered it is difficult, and you thought it would be more difficult than the standards, et cetera, but it appears like there has been a lack of will from OSHA.

There has only been one, as I understand it, one major standard has been issued. So with all of these that have been cast aside, I am wondering, with only one standard that has been issued by OSHA, what has OSHA been doing?

Mr. FOULKE. Well, Congressman, I would say that we have been doing a great deal.

And as I indicated in my testimony and by my comments on some other questions, you know, we have done a number of final rules on—you know, you are trying to characterize what is a major rule or what is a non-major rule. I won't get into that debate, but clearly the hexavalent chromium was a major rule. The fire protection of shipyards—updated rule. Assigned protection factor, electrical installation requirements—all these are rules that we have been working on that are going to help employees with their safety and health.

So we are moving on things. We have done a whole series of things since 2001.

Mr. HARE. Mr. Secretary, isn't it very hard to cite a company when OSHA doesn't even go in and inspect to see if the workplace is safe?

I mean, there have been some companies that I understand that OSHA hasn't been into for 10 years to 15 years, so there has never been an inspection. I find it very difficult to understand how OSHA can protect the workplace and the workers in that workplace when there is no inspections.

And the second thing—and I appreciate the chart, you know, showing how things are doing just swell. But isn't it true that the Journal of Occupational and Environmental Medicine concluded that the substantial declines in the number of illnesses and injuries between 1992 and 2003 corresponded directly with the changes in OSHA record-keeping rules?

So are these charts that we are bantering about showing us how wonderful everything is, aren't these basically slanted figures, according to the Journal of Occupational and Environmental Medicine? Or is it, you know——

Mr. FOULKE. I am not exactly familiar with that specific—but I will state this, that if you look at the information that is provided there, and that is over a long period of time—and there was a break when the record-keeping changed. But even since that time period, even—and I won't get into a debate of if we have got apples to apples or oranges to oranges. But I would say from that period of time, from that change to the current, shows a continual decline in injury and illness rates and our fatality rates, so you know, we are making progress on it.

Are we there yet? No. And every talk, when I go out and I speak with people, every time, I tell them, "One fatality is one fatality too many." And I honestly believe that. So we are working on that.

But we are trending in the right direction, and, you know, we are moving as quickly—and we are working on the standards. So to say that we are not doing that, you know, I would disagree with your characterization of that.

Mr. HARE. Well, let me just ask you this, then, and finally—and I hope we will have a chance to ask another one. What is it going to take for OSHA to be able to go in a timely fashion? What do you need from us, in terms of Congress?

Is it the lack of inspectors, the lack of funds to hire additional inspectors? What is it going to take for OSHA to be able to go in, in a timely fashion, and do the best job that they can?

Listen, I understand accidents are going to happen. I am not suggesting for an instant that workers sometimes don't hit the wrong button, do something.

I am asking, what is it going to take so that we don't have to have a 10-year lapse between the time somebody may notify the company or OSHA that you have a problem and their coming in and doing an inspection?

Mr. FOULKE. Well, Congressman, I would say this. And I have been on both sides of the fence, so I feel like I can kind of come from a decent perspective here.

You know, I have looked at what OSHA targets. We have our site-specific targeting where we have identified 14,000 facilities that had the worst injury and illness rates. And those are the ones that were targeted. And part of that—and so we are going after the people that had the worst injury and illness record. So we are focusing in on this.

And we are going to also, as part of our enhanced enforcement programs, where we find employers that don't seem to respect the workers' rights to have a safe and healthy workplace, then we are expanding out on those inspections.

So clearly, we are focusing. And that kind of gets to some of the questions about what we are doing.

Chairwoman WOOLSEY. The gentleman's time has expired.

Mr. FOULKE. I am sorry.

Chairwoman WOOLSEY. He is going to get to ask another question.

Mr. FOULKE. I was just trying to answer his——

Chairwoman WOOLSEY. Finish your thought.

Mr. FOULKE. Well, I would just say that we are getting to that. Clearly, you don't want us to inspect employers that don't need to have great safety and health worksites. We have got to get to the people that don't have good worksites.

And I would say to you that OSHA has the best system of identifying those employers that need to be inspected, and we are going after them. And like I say, we did 38,000-plus inspections just in the federal sector.

Chairwoman WOOLSEY. Thank you.

We are going to have a couple more. I am going to ask another question. Mr. Hare wants to ask another question. Then we will wrap up, unless—Mr. Kline, do you have—okay. Thank you.

Mr. Foulke, my question to you is, how can OSHA change? What do we need to do to help OSHA change so that they can catch up with the California laws, Cal-OSHA? What is in the way of keeping up with California?

Mr. FOULKE. Well, you know, with respect to California, I would just have to say that we have different statutory and legal burdens to support our rulemaking effort that California does not have.

Chairwoman WOOLSEY. So you are saying we need to change our rulemaking statutory——

Mr. FOULKE. No.

Chairwoman WOOLSEY. I mean, is that holding us back?

Mr. FOULKE. It depends on what you would mean by holding you back. I would submit to you that if you look at the regulatory process that we have in place under the federal system, as opposed to California, we have things that the Congress has put in—Administrative Procedures Act. We have things in the OSHA Act that we have to follow. So those are just three of the things that the Congress has intended.

So we have this. And all those things were put on for specific reasons, that the Congress, in its wisdom, said, "You know, we have got to look at these things, because we can't rush into a standard, unless we have sound science." And I know that is what you want to have.

Chairwoman WOOLSEY. Okay. California is the size of a country, 37 million people. If they can do it, why can't the federal government?

Mr. FOULKE. Well, I guess it comes back to what I was just saying, that we have certain regulatory mandates that the Congress has required us to do under the act, under the Congressional Review Act—all those things.

Plus, on top of that, the court systems, as part of their review process on these things, have indicated that we have to do certain other things on feasibility and risk assessment.

Chairwoman WOOLSEY. Okay. I really want to leave a little bit of my time.

Mr. FOULKE. No, I am sorry. I apologize.

Chairwoman WOOLSEY. I mean, it sounds like we can—you know, we can't do it because we are us and they are them, and you know, there is something about learning from those that are successful.

Mr. Schneider and Mr. Mirer, I would like to ask you to each take a minute and just respond to whatever it is that you have heard today that you haven't been able to say anything about.

Mr. Schneider?

Mr. SCHNEIDER. Yes, I think the problem is—you know, I think there are these regulatory burdens to meet, et cetera, and they can be met. But the problem that is happening now is there is a huge lag in time before we even get to rulemaking, just the political will to decide that we are going to start a rulemaking and get it going.

Once it gets going, we can meet those burdens, but I think there really—you know, for example, on silica, we have waited, you know, years and years, and OSHA has not yet committed as to when they are going to publish a proposal. And just getting to that stage is, I think, where the delay is right now in this administration.

Chairwoman WOOLSEY. Okay. Thank you.

Mr. Mirer?

Mr. MIRER. I have been doing this 30 years. It is not that hard to do. There are barriers. They should be reduced. But it is not that hard to do if the OSHA staff are told to go ahead and do it: Get together the economic assessment. Put out the proposal. Hold the hearings. Move it through to the end. Take the litigation burden and get on with it.

They could do three or four standards, major standards, a year, or take a few years to get them through, but they could do it.

And then I ask why, if California could have half the exposure of carbon monoxide, a quarter of the exposure of the dry-cleaning chemicals, a fortieth of the exposure of the solvent chemicals—clearly, the economic impact is not there because the state is operating.

Why does not OSHA move forward with the process on these settled questions? We have got to get into the 21st century. We are not even done with the 20th in terms of scientific knowledge.

Chairwoman WOOLSEY. Okay. Thank you.

Mr. Hare?

Mr. HARE. I just have a question for Mr. Schneider and Mr. Mirer.

I asked the Secretary, and I don't think I got the answer, so maybe you could help me here. From your perspective, okay, from both of your perspectives, what can we as the Congress of the United States do, this institution do, to strengthen this Agency, to help it function better, to go in and be able to do the things that Congress has instructed this Agency to do?

It seems to me—I am not suggesting we throw money at a problem here, but I am wondering, from your end of it—and you talked about standards and only one. It is mind-boggling that there has only been one standard issued by OSHA.

But perhaps if you would spend the rest of my 5 minutes telling me, from your perspective, what can we do to help out here. Because I think that is what I am here to do, is to try to find out something we could do to make this Agency work better than it has.

Mr. SCHNEIDER. Thank you very much.

I think, really, what has worked in the past is Congress has said to the Agency, "You have 6 months to put out a standard on lead, or on hazardous waste," and the agency has had to comply with that.

And I think perhaps giving the agency some sort of legal time tables which they will be held to to put out regulations, and say, "You have 3 years to do this," give them enough time that they can comply with it, and perhaps the resources to meet those deadlines, I think that is the only way that we are going to sort of maybe bring them up.

And there are other things that could be done, but some of it is in my testimony.

Mr. MIRER. It is basically the same answer.

Number one, let's get what is left on the regulatory agenda done: silica, beryllium, some of these other materials that have been promised and nothing happened.

Second, increase the resources devoted to standard setting with a requirement that they actually produce something. There is $16 million a year, 80 people involved in this. They could be producing more than they are.

Finally, in a broader, longer-term change in the legislation, OSHA has to be required to respond to petitions for new protections with the same stringency that it is required to respond to an employer who wants to fight a standard. We have to move it forward.

And those three things, I think, would have a big effect.

The last thing is the PEL update project that has been talked about. That was Representative Norwood's, the late Representative's interest. We could get that done. You could get that done in a very short amount of time.

Chairwoman WOOLSEY. Thank you.

Well, thank you all for coming. We have heard today some really important information, but also information that I consider disturbing.

OSHA is failing to keep up with modern-day workforce hazards, and that, in turn, does not protect American workers. And this is totally unacceptable.

This coming Saturday is Workers Memorial Day, when we mourn workers in America and throughout the world, workers who have been hurt or killed on the job.

And in this country, although we have made a lot of progress since the passage of OSHA in 1970, we are still losing workers on the job. We are not where we need to be. And this administration

clearly does not have the health and safety of workers at the top of its priority list.

Unnecessary tragedies are still occurring, to Mr. Peoples and other victims of popcorn lung, to the miners who have lost their lives in Sago and in other mines, and to the millions of other workers who become sick, injured or killed every day.

As chair of this subcommittee, I pledge to make OSHA accountable. I pledge to explore legislative and other options to ensure that necessary and updated standards, as well as other measures to ensure health and safety, are put into place.

To that end, on Thursday Senator Kennedy and I will be introducing the Protecting America's Workers Act. This bill would expand coverage to include public employees and other workers, assess higher fines and penalties for employers who ignore the law, enhance whistleblower protections, and, in the area of standards, mandate the issuance of the standard for personal protective equipment.

Again, I thank you all for being here. You have been most marvelous and patient.

As previously ordered, members will have 14 days to submit additional materials for the hearing record. Any member who wishes to submit follow-up questions in writing to the witnesses should coordinate with majority staff within the requisite time.

Without objection, the hearing is adjourned.

[The prepared statement of Mr. Price of Georgia follows:]

Prepared Statement of Hon. Tom Price, a Representative in Congress From the State of Georgia

Throughout his career, Congressman Charlie Norwood championed the improvement of workplace conditions while crafting a reasonable balance between economic freedom and regulatory compliance for American businesses. As the former Chairman of the Workforce Protections Subcommittee, his record is one of great vision and profound impact. Congressman Norwood brought attention to issues like permissible exposure limits, non-consensus standards and worker protections. Before his passing in February, he introduced the Secret Ballot Protection Act, a piece of legislation aimed at preserving worker freedoms by ensuring access to the secret ballot in union organizing elections.

And despite the differences between Republicans and Democrats on workforce matters, Congressman Norwood always strived to bring the two sides together to tackle workplace safety standards. He understood that while OSHA, as a regulator, should labor to protect workers and advance conditions, the agency must also comply with the regulatory process outlined by Congress decades ago. Surely, there can be common ground in his approach.

As the Workforce Protections Subcommittee grapples with the question, "Have OSHA standards kept up with workplace hazards?," it would be wise to heed his example and remember his record. His work on permissible exposure limits and non-consensus standards holds valuable lessons for future debate. This subcommittee would be best served to honor the legacy of this great Georgian by recognizing his contributions.

[Letter submitted by Adam M. Finkel follows:]

May 8, 2007.

DEAR CHAIRWOMAN WOOLSEY: Although I was unable to attend your April 24 hearing "Have OSHA Standards Kept up with Workplace Hazards?" in person, I read all of the testimony with great interest, and viewed the Q&A portion on the Internet. I would like to provide some additional information on the issues involved, from the perspective of an expert in quantitative risk assessment and cost-benefit analysis, and that of a former Director of Health Standards Programs at OSHA (1995-2000) and a former Regional Administrator (Region VIII) for OSHA (2000-

2003). I am currently Professor of Environmental and Occupational Health at the UMDNJ School of Public Health, and a visiting professor of public affairs at the Woodrow Wilson School at Princeton University, although I have written these comments on my own time and am not representing the views of either of my academic institutions. In addition to my training and expertise in risk assessment, I have written numerous articles and books on issues of regulatory process, alternative regulatory design, agency priority-setting, and program evaluation; beginning later this year, I will also serve as executive director of the Penn Program on Regulation at the University of Pennsylvania Law School.

For the past 25 years, I have strongly supported the increased use of risk assessment and cost-benefit analysis in regulatory decision-making, so none of my comments on OSHA's disappointing performance should be mistaken for antipathy to the analytic burdens OSHA must meet. I simply believe, contrary to the views espoused by several of your witnesses (notably Assistant Secretary Ed Foulke and attorney Baruch Fellner) that two fundamental conclusions are indisputable in light of the scientific, economic, and historical facts:

• That the largest preventable health and safety risks remaining to be addressed in our society occur disproportionately in U.S. workplaces (as opposed to the ambient environment, consumer products, the transportation sector, etc.), and therefore, that failing to regulate means failing to extract benefits that far exceed their costs; and

• That although it is by no means easy for OSHA to promulgate cost-effective regulations that incorporate the best available scientific information, OSHA's appalling lack of progress is clearly due to a failure of will and/or talent—because under different leaders, OSHA's track record of producing health-protective but fair standards, meeting all the analytic and public-participation requirements, was far superior to what it is now.

I should emphasize that my concerns about OSHA's performance began before the 2001 Inauguration, although clearly output, morale, and other indices have declined steeply since that watershed. For example, I believe that some of the most productive ways for OSHA to help create safer and healthier workplaces involve meaningful partnerships with industry, sometimes in lieu of regulation, as long as the goal is to impel needed changes in behavior. Sometimes, traditional regulation would merely allow the relatively best workplaces to "backslide," while never reaching the worst performers; so in a national OSHA partnership with both the manufacturers and the installers of fiberglass insulation codified in 1999, the producers agreed to provide the needed resources, training, air monitoring, and PPE so that their customers could better protect their employees. I championed several such partnerships before leaving Health Standards in 2000, and tried to establish enforcement partnerships in Region VIII that required general contractors to improve health and safety performance among their subcontractors. But the very same ideas that President Bush's first head of OSHA dismissed as apparently too "intrusive" for industry (apparently preferring instead to emphasize "alliances," also known as "praise for continuing to do whatever you're doing") were met with benign neglect in the waning years of the Clinton administration, apparently for being insufficiently punitive to industry.

The way forward, I believe, lies in between these two doctrinaire positions. Indeed, the one sentence in Mr. Fellner's testimony I agree with completely is that "the massive amount of time and resources applied to the ergonomics regulation clearly delayed and prevented the promulgation of other OSHA standards." I supported the 2000 ergonomics regulation (although I had developed a rather different version of it before leaving my position in Health Standards), but I greatly regret having been instructed in 1998 to stop work on all the other standards under my purview, including some of the very ones (e.g., tuberculosis, chromium, Assigned Protection Factors, PEL update chemicals) that the current OSHA leadership later had the opportunity to "kill" or weaken substantially because they had never been finalized.

I will first provide some specific comments on Mr. Fellner's testimony, before concluding with a couple of other comments about issues raised at the hearing.

Concerns about Mr. Fellner's testimony:

1. In the second paragraph of his written testimony, Mr. Fellner concludes that based on the decline in recorded workplace fatalities and injuries, "OSHA must be doing something right." As much as I want to believe this, having devoted 11 years of my career to OSHA, we simply don't know how steep the real decline, if any, might be, and what portion of it (if any) is due to OSHA's presence rather than to inexorable trends. The fatality rate was falling before there was an OSHA, it fell twice as steeply in the 1980s as it has since then, and the number of workplace fatalities rose in two of the past three years. With regard to injuries, the amount of

under-reporting generates "noise" in the data that simply swamps any reliable "signal" of improvement (see, for example, Reference (1) below). More significantly, the statistics Mr. Fellner touts simply shed essentially no light on occupational illnesses (which scientists agree cause more than 90 percent of all of the premature deaths in the workplace), because the OSHA and Bureau of Labor Statistics recording systems are not designed to capture these sorts of fatalities. It has been 25 years since the last comprehensive survey of workplace exposures to hazardous substances, during which time Congress has funded dozens of large surveys of environmental hazards, dietary habits, etc. To the extent that OSHA is "doing something right," I am thus deeply concerned that this may not apply at all to the area of occupational health (as opposed to safety). The key measure of OSHA's activity in safety versus health is the number of inspections OSHA conducts in each area. OSHA claims (Ref. 2) that it conducted more than 6700 "health inspections" in FY06, or roughly 17 percent of its total inspections. But in response to a lawsuit I filed in 2005 under the Freedom of Information Act (see item #7 below), OSHA acknowledged that in only about 3 percent of the inspections in its history (roughly 70,000 inspections out of over 2 million conducted) were any chemical samples taken at all. It seems, therefore, that the vast majority of the so-called "health inspections" may in fact be safety inspections conducted by enforcement personnel with industrial hygiene credentials, and are only coded as "health inspections."

2. Throughout his testimony, Mr. Fellner exaggerates how hard it is for OSHA to promulgate standards. Perhaps it appears "daunting" to a non-scientist for an agency to have to synthesize and interpret toxicologic, epidemiologic, and engineering data, but that is exactly what risk assessors do routinely and well. Indeed, the quotation he offers from Cellular Phone Taskforce v. FCC makes clear that regulatory risk assessment is, if anything, even easier to conclude than risk assessment in other arenas, because when the evidence is at its most controversial, the "courts' deference to expert determinations should be [and is] at its greatest." And, despite the many requirements for OSHA to invite participation by stakeholders and respond substantively to their comments—all of which I support—when the will is there, the obstacle course can be completed cleanly and rather quickly. In one 18-month period of activity (late 1996 to early 1998)—OSHA promulgated three major final health standards—those for 1,3-butadiene, methylene chloride, and generic respiratory protection—and defended them in Congressional oversight hearings and court challenges, without a single provision being substantively weakened following any of this scrutiny.

3. In his third paragraph, Mr. Fellner refers to the recent hexavalent chromium standard as "a win for all parties and the vindication of a process that functioned properly to protect American workers." I have had no involvement in this rulemaking since leaving Health Standards in 2000, but I will point out that by OSHA's own calculations, the final standard leaves behind a lifetime excess cancer risk of between 10 and 45 cases per 1000 workers exposed under the legal limit. This risk is 10 to 45 times higher than the highest risk (1 per 1000) that the Supreme Court said (in its 1980 Benzene decision) could possibly be considered acceptably small, and 10,000 to 45,000 times higher than the 1-in-one-million standard Congress has called for in various EPA statutes. I would respectfully suggest that this regulation does not represent a "win" for chromium workers.

4. Mr. Fellner misses one of the main points of the Supreme Court's 1980 Benzene decision when he states that "OSHA [cannot] * * * recognize a few studies that seem to point in the direction of the most protective standard it can promulgate." The majority in Benzene made clear that OSHA has complete license to "use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection." The use of "conservative" assumptions has been endorsed by several National Academy of Sciences committees (see, e.g., Ref. 3) and was recently re-affirmed in a major EPA report, released by the Bush administration Ref. 4). It is crucial to note that in actual practice, OSHA's use of risk-assessment assumptions is markedly less "conservative" than that of EPA and other agencies (even though its resulting "acceptable" risk estimates are nevertheless much less stringent then those other agencies would allow). Still, an OSHA that recognized the gravity of its unfinished business could certainly make better use of Benzene and reduce the complexity of its assessments, if that was indeed contributing to the lack of output. I should also mention for completeness that if anything is exaggerated in cost-benefit analysis, it is the estimates of the costs of regulation—an ingrained bias that causes OSHA's (and other agencies') cost-benefit determinations to err on the side of under-regulation (see Refs. 5-7).

5. On the last page of his written testimony, Mr. Fellner makes reference to "hazards du jour." This strikes me as a thinly-veiled but bizarre insult to those inside

and outside the Agency who are concerned about the retreat from standard-setting. The Roman Empire (Pliny the Elder) knew about silicosis 2100 years ago, but OSHA's limit is still twice as high as the level NIOSH recommended more than 30 years ago. The beryllium PEL (2 micrograms per m3 of air, encountered every working day for a 45-year working lifetime) was developed in 1949, and it has been clear for more than a decade that the equivalent of one day's exposure at that level has caused a grave lung disease in some workers so exposed. Yes, OSHA is also failing to respond to new hazards, but these are not "fads."

6. In his next sentence, Mr. Fellner refers to outsiders trying to "micromanage" the agency. This choice of words is also disingenuous, unless you believe that "micromanaging" can apply to a request as fundamental as "do something rather than do nothing." Simply as a logical, not a partisan point of reference, it seems to me that this is akin to accusing those calling for a withdrawal of U.S. troops from Iraq of trying to "micromanage the war." In any event, the Supreme Court (ref. 8) recently expressed its clear view that when an agency (in this case, EPA) fails to decide whether it should even consider regulating an important hazard, "outsiders" may have a right to force it to perform this core task.

7. In his last bullet point, Mr. Fellner poses a laudable question: "Is OSHA * * * directing its inspectors to workplaces with the deadliest and most serious workplace hazards subject to regulations that are already on the books?" I believe that as important as this question is, no one can answer it properly at present, in large part because OSHA is actively thwarting such inquiries. I was forced to file suit against OSHA under FOIA in 2005, because I made a routine request for OSHA's air sampling data in order to ask this very question, among others (see Ref. 9). I had hoped to explore, for example, whether OSHA tends to increase its level of effort to inspect workplaces for particular substances, once it has found widespread violations of PELs for those substances—my experience as Director of Health Standards and as a Regional Administrator suggests that OSHA rarely seeks to make these sorts of connections, and may even turn its attention away from substances where widespread non-compliance has been detected. But OSHA has withheld these data from me, claiming (despite having released the data to others on many previous occasions) that it now believes there are "trade secrets" somewhere within the database—secrets that it has failed to mark as such and therefore cannot selectively redact. In some of its court filings in this pending litigation, OSHA has admitted that it has never analyzed (and has no plans to analyze) its own exposure data for beryllium, even though at least 11 of its own inspectors have been found to have blood abnormalities caused by beryllium exposure. The exposure histories of these inspectors would certainly provide one indication of where "the deadliest and most serious workplace hazards" could be found, but OSHA apparently has no interest in asking this question, or in allowing others to ask it.

Other Comments:

I also want to comment on the statement Rep. Wilson made at the hearing, to the effect that OSHA has issued "22 standards" since Inauguration Day 2001. OSHA's Office of Communications recently prepared a document entitled "OSHA Final Standards Published 1971 to Present" that indeed lists 22 actions after January 20, 2001. But by my count, 15 of the 22 items were either technical clarifications (4 items), approving state plans (2), plain language rewrites of existing standards (1), changes to whistleblower procedures (1), or substantive actions that served to deregulate rather than impose new requirements (7). Curiously, the OSHA document lists only 3 standards for calendar year 1997 (when I was HSP director)—but by the same expansive rules of what to list, we actually published 13 such actions in 1997 alone, and more than 70 during the first six years of the Clinton administration. I understand OSHA's frustration with "bean counting," but the proper response to those concerned with quantity over quality is to emphasize the significance of what was done, not to grossly exaggerate the output in one period while ignoring the same categories in previous periods.

Finally, I wish to make two points about the hazards of diacetyl. First, Mr. Fellner stated during questioning from Mr. Bishop that "there is no dose-response curve with respect to diacetyl," and that "in the absence of a dose-response curve, * * * as the Supreme Court indicated in the Benzene decision in 1980, that is insufficient to promulgate a standard at very low levels." I believe these statements are misleading at best, both as a scientific and legal matter. It would certainly be desirable to be able to know more about the shape of the dose-response function below the levels of diacetyl exposure that unambiguously can cause grave harm to those exposed—but it's certainly not true that there is no such function. It may be steeper at high doses than at low ones, and it may even have a threshold, but while we await such refinement there exists a wealth of information supporting the first-order assumption that (especially when extrapolating down by a factor of 100 or

less) a linear function makes biological sense (see, e.g., Ref. 10). I lack Mr. Fellner's extensive training in law, but I will observe that the Benzene court faulted OSHA for "avoiding the Secretary's threshold responsibility of establishing the need for more stringent standards" and avoiding its "obligation to find that a significant risk is present before it can characterize a place of employment as 'unsafe'"—it did not focus on the precise showing OSHA would have to make to support any particular exposure reduction once it had shown (through quantitative risk assessment) that some control was necessary to reduce a "significant" risk. In other words, OSHA does not have to know the precise shape of the diacetyl dose-response relationship if it wished to make the scientific and legal case (which I believe is, as they say, a "no-brainer") that uncontrolled exposure to diacetyl poses a significant risk of material impairment of health.

Secondly, Mr. Foulke's testimony indicated that in 2001, following release of a NIOSH report, "OSHA promptly alerted its Regional Administrators and Area Directors to NIOSH's findings and instructed its field personnel to look into the issue when encountering individuals working around butter flavoring in popcorn manufacturing." I was one of the 10 Regional Administrators at that time, and I remember receiving the NIOSH report. However, I also remember being frustrated to learn shortly thereafter that Region VII had established an alliance with the Popcorn Board, in which it received the names and addresses of relevant facilities, but only in that Region. I was dismayed that Region VII did not take the opportunity to ask the Board for the complete list of facilities nationwide, but was told (by my colleague and by the Assistant Secretary at the time) that if I wanted to know where the facilities were in our Region, I should "go get my own alliance." In effect, the OSHA leadership warned the field that lung disease might be found where diacetyl was used, but offered no assistance in helping us determine where the diacetyl was.

Conclusion:

Less than 10 years ago, I was proud to be part of an OSHA that was "keeping up with workplace hazards." During the period 1996-1998, we had roughly 12 doctoral-level staff in Health Standards, and we put out three major final rules, the tuberculosis proposal, completed cutting-edge risk assessments for six of the most important PEL update chemicals, established the fiberglass and other enforceable product-stewardship agreements, etc. Now only 2 or 3 health scientists with advanced degrees remain, and the output has plummeted, even though the scientific and procedural hurdles have not gotten any higher. For example, the methylene chloride rule has one of the most sophisticated biologically-based quantitative risk assessments ever conducted by any federal agency, and we re-wrote the entire analysis for this rule in under 2 years.

No one who has any expertise in regulatory science, economics, or process could possibly answer the question posed by this hearing ("Have OSHA Standards Kept up with Workplace Hazards?") in any way but "no." The solution is not to complain about the need to do good science, but simply to get back to doing good science, like OSHA used to do.

Thank you for the opportunity to submit my views for the record on these important public policy and scientific questions.

Sincerely,

ADAM M. FINKEL, SC.D., CIH.

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[Prepared statement of the Printing Industries of America, Inc. (PIA) follows:]

Prepared Statement of the Printing Industries of America, Inc. (PIA)

The Printing Industries of America, Inc. (PIA) is pleased to present this statement for the record before the House Committee on Education and Labor Subcommittee on Workforce Protections, and thanks Chairwoman Woolsey for holding a hearing to examine the important topic of workplace safety. PIA is the world's largest graphic arts trade association representing an industry with more than 1.2 million American employees. PIA's nearly 12,000 member companies are dedicated to the goal of providing safe work environments.

PIA would like to add to the dialogue on OSHA standards and workplace hazards by commenting on two specific aspects of workplace safety: the relationship of OSHA Standards to market-driven workplace safety technologies and employer-employee workplace safety education, particularly in the form of OSHA-Industry voluntary alliances.

OSHA Standards & Market-Driven Workplace Safety Technology

As we consider if and how OSHA Standards are keeping up with workplace hazards, PIA believes it is appropriate to consider the nature and structure of OSHA standards. Many of OSHA's standards are written in a static nature and quickly become outdated due to changes in technology and work practices. The process that OSHA has to observe in the development of new or in the revision of existing standards hampers the ability of OSHA to keep pace with changes in the workplace.

In addition to being quickly outdated, many of OSHA standards are cumbersome, laden with administrative burdens, and are inflexible. The combination of these factors has created a situation where safety can be jeopardized and is not advanced.

For example, since OSHA released its final version of the Lockout/Tagout Standard in 1989, tremendous progress has been made in safety systems of manufacturing equipment that have taken advantage more reliable circuitry, redundant systems, interlocks, guards, and light curtains. Ever since the standard was released, the printing industry has had ongoing discussions with OSHA regarding the application of the Lockout/Tagout Standard to routine procedures. These discussions have resulted in two letters of interpretations, but the effort to obtain these letters has taken years of effort. The letters focus on only one main alternative that can be followed for minor servicing and maintenance and do not recognize other alternatives brought about by advanced technologies.

One such alternative is the use of "light curtains" that form barriers in front of the point of operation and prevent a machine from operating if the light beam is broken by an object, like a hand or other body part. These light curtains are used to control the hazards of unexpected machine movement during the operation of a particular type of cutter, which is used to cut large press sheets into small ones. The light curtains also protect the worker from unexpected movement during the knife changing sequence. However, OSHA still requires that the equipment be completely de-energized during this particular service and maintenance procedure, and, most importantly, power to the cutter is required so that the blade can be positioned to allow for its removal and replacement. Turning off the power is not necessary, is cumbersome, and creates a disincentive for workers to follow standards, which could lead to unnecessary injuries.

Another positive example of workplace safety technology outpacing OSHA Standards is the state-of-the-art printing press that comes with automatic blanket washers that clean ink and other debris off blanket cylinders used to transfer printed images to paper. Workers previously washed industrial blankets by hand. The new technology is performed solely by machines, thereby reducing a worker's exposure to danger.

Neither of these worker safety initiatives was created by regulation or legislation, but by marketplace demand for safer processes and more competitive practices for American manufacturers. PIA believes that OSHA Standards should be written to allow for the new and improved market-driven safety technology in today's workplace that allow workers to do their jobs more efficiently and in an improved, safer manner.

Employer-Employee Workplace Safety Education

Employee education is a key part of workplace safety; it's outlined as a "responsibility" in the Act. Specifically, section (b) (2) of the original OSH Act states "that employers and employees have separate but dependent responsibility" to engage in safe work environments.

In recent years, there has been a joint effort by OSHA and industry to increase employee training on workplace safety.

In 2002, the OSHA—Graphic Arts Coalition Alliance on ergonomics was signed as one of the first voluntary is one example of industry helping OSHA conduct employee education on safety issues. The purpose of this Alliance, which was resigned in 2004 and again last summer, is to utilize the Printing Industries of America as a partner to:

• help identify and prevent workplace hazards specific to print process, like screen-printing or lithography,

• develop and disseminate case study illustrating the business value of safety and health,

• communicate workplace safety outreach through national PIA conferences and local meetings of printers, and to

• promote PIA member companies' participation in compliance assistance programs, Voluntary Protection Programs (VPP) and the Safety and Health Achievement Recognition Program (SHARP). Utilizing the trade association to promote these programs seems to work; Printing Industries of America member companies, such as RR Donnelley & Sons in Lynchburg, VA and Ploy Print, Inc. of Tucson, AZ, have received VPP and SHARP awards.

The Alliance also puts safety tools right in the hands of workers. For example, the Alliance's e-tool allows a worker in a screen printing facility to log on, select his or her printing specialty process to learn about common hazards and about what solutions OSHA and other workers in the same field recommend minimizing these hazards.

Alliances like this are important because OSHA can't educate all employers and employees by itself. PIA hopes that OSHA will consider alliances such as the one governing the graphic arts industry as an important tool in fulfilling the "responsibilities and rights" aspect of the OSH Act, and will continue utilizing such private-public partnerships to further the efforts of minimizing workplace hazards and improving overall worker safety.

Additionally, PIA would be remiss in not noting that just as OSHA can't educate all employers and employees by itself; neither can alliances such as the OSHA Graphic Arts Coalition Alliance be fully responsible for worker safety education. Employees must be equal partners in this venture and must take initiative to follow existing OSHA Standards to protect themselves from hazards.

In conclusion, PIA, on behalf of its nearly 12,000 member companies employing 1.2 million American employees, commends the Subcommittee for examining the topic of workplace safety. PIA looks forward to working with Congress and with OSHA to further initiatives that provide practical solutions to a shared goal of minimizing workplace hazards and improving overall workplace safety in the graphic arts industry.

Thank you for the opportunity to comment on this important topic.

[Prepared statement of the Tree Care Industry Association (TCIA) follows:]

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April 24, 2007

The Subcommittee on Workforce Protections
United States House of Representatives
2181 Rayburn House Office Building
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RE: Hearing on "Have OSHA Standards Kept up With Workplace Hazards?"

Dear Chair Woolsey, Ranking Member Wilson and Members of the Subcommittee:

On behalf of the Tree Care Industry Association (TCIA), we thank you for holding this important hearing and ask that you support an OSHA standard governing tree care operations. We petitioned OSHA for such a standard in May 2006 and anxiously await their action.

TCIA represents approximately 1,650 businesses engaged in commercial arboriculture (tree care) in the United States. Our members employ more than 100,000 people, and some estimates place the total number of people performing tree care work in the U.S. at 160,000.

Unfortunately, the industry is one of the most hazardous, with independent researchers Dr. John Ball and Shane Vosberg at South Dakota State University ranking it the fifth most dangerous in the U.S., based on the frequency of fatal accidents. TCIA takes improving safety for the tree care industry seriously. In fact, this is one of the five outcomes in the Association's long-term strategic vision. We were one of the first eleven industries in the nation to sign onto an OSHA Alliance, which we recently renewed. In addition, in 2006, TCIA launched the *Certified Treecare Safety Professional* (CTSP) program, the only safety credentialing program in the tree care industry, with the goal of creating a safety culture in each company. To realize the maximum safety benefit from these efforts, however, we also need clarity from OSHA through a standard specific to tree care work.

Unfortunately, no such standard currently exists. As a result, enforcement officers, as well as tree care companies and workers, lack clear guidance from OSHA on the specific safety measures needed to mitigate the risks unique to the industry. OSHA has attempted to "fill the void" by various methods, including applying regulations from other

industries, such as logging or construction, or relying on outdated or inapplicable consensus standards. This has led to confusion and inappropriate enforcement, with OSHA inspectors and unsophisticated employers running the risk of overlooking serious work site hazards that the inapplicable regulations and outdated standards do not cover.[1]

OSHA's Strategic Management Plan for fiscal 2003-08 lists tree care among seven industries targeted for significant reductions in illnesses and injuries. This task will be far more difficult if OSHA does not promulgate a tree care specific standard to follow or enforce. In short, the status quo is administratively inefficient and ineffective for OSHA and dangerous for arborists. It wastes OSHA's resources and leaves tree care workers and employers without clear federal guidance on the specific safety measures needed to mitigate the unique risks in our industry.

For the aforementioned reasons, we urge you to support TCIA's May 10, 2006 petition to OSHA, requesting the agency to promulgate a clear, industry-specific standard based on the existing consensus tree care safety standard that covers all arbor occupations: ANSI Z133.1. Developed through a consensus process by an accredited standards committee representing employers and employees, organized labor, equipment manufacturers, academia, etc., the Z133 Standard captures the collective wisdom and experience of the entire profession, translating that body of knowledge into standards of safe practice. An OSHA standard could be developed through the negotiated rulemaking process and be structured in a manner that allows reliance and the latest technologies via updates to Z133.

Again, we thank you for your commitment to health and safety and seek your action.

Sincerely,

Cynthia Mills, CAE, CMC
President & CEO

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[1] The risks to workers in our industry are unique, and there are numerous and substantial differences between arborists and other workers' industries in terms of hazards faced and practices used. Here are three examples: Methods that arborists employ when using truck-mounted cranes to drastically reduce hazards associated with tree removal are considered "non-conforming" by OSHA. Current OSHA fall protection standards fail to address the unique hazards and safe work practices of the arborist aloft in a tree or aerial lift. Finally, OSHA's Logging Standard, promulgated over 10 years ago to regulate an industry much smaller than ours, represents a very poor fit when regulating tree removal activities in our industry. Further, we were excluded from its promulgation, and yet must deal with its implications.

[Whereupon, at 3:59 p.m., the subcommittee was adjourned.]

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