

**SCIENTIFIC EVIDENCE IN THE
REGULATORY SYSTEM:
MANUFACTURING UNCERTAINTY
AND THE DEMISE OF THE FORMAL
REGULATORY SYSTEM**

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INTRODUCTION

Polluters and manufacturers of dangerous products have waged sophisticated campaigns to manufacture uncertainty about the scientific evidence used to support public health protection and victim compensation.¹ As a result, the Occupational Safety and Health Administration (OSHA) has virtually ceased issuing regulations that would limit potential exposure to causes of disease or other workplace hazards, even in the face of compelling scientific evidence. Unfortunately, following the U.S. Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,

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¹ A tobacco industry executive once said "doubt is our product." Brown & Williamson, Smoking and Health Proposal, Doc. No. 332506, at <http://tobaccodocuments.org/bw/332506.html> (last visited Dec. 31, 2004).

which requires federal judges to act as gatekeepers of expert testimony, courts have also become the targets of such campaigns.² Given the demise of OSHA's regulatory activities, litigation initiated by injured workers is likely to play an increasingly important role in eliminating or reducing workplace hazards, and therefore in preventing occupational illness and death. This article examines the responses of the legal and regulatory systems to workplace hazards, and explores the impact of litigation and regulation on the prevention of work-related disease in the United States.

I. POPCORN LUNG

In March 2004, Eric Peoples, a 32-year-old former employee of a microwave popcorn factory, sued International Flavors, the manufacturer of the butter flavoring used in his employer's plant, and was awarded \$20 million by a jury in Joplin, Missouri.³ Mr. Peoples, a nonsmoker, had developed bronchiolitis obliterans, a rare and devastating lung disease characterized by an obliteration of the pulmonary airways.⁴ Mr. Peoples is presently awaiting a lung transplant.⁵ Statistics suggest that, if a successful transplant is accomplished, Mr. Peoples can expect to live an additional ten years.⁶

Mr. Peoples is not alone in his diagnosis with this rare disease. Thirty cases of bronchiolitis obliterans have been documented

² 509 U.S. 579 (1993).

³ E & C Peoples v. Int'l Flavors, No. 01CV683025-07 (Mo. Cir. Ct. Mar. 15, 2004).

⁴ Bronchiolitis Obliterans is a "disease in which the bronchioles and occasionally some of the smaller bronchi are partly or completely obliterated by nodular masses which contain granulation and fibrotic tissue." TABER'S CYCLOPEDIA MEDICAL DICTIONARY 272 (17th ed. 1993).

⁵ Sara Shipley, *Study Showed Chemical was Toxic*, ST. LOUIS POST DISPATCH, Feb. 28, 2004, at C1. See also CBSNEWS.com, *Jury Gives Popcorn Worker \$20M* (Mar. 16, 2004), at <http://www.cbsnews.com/stories/2004/03/16/health/main606532.shtml>.

⁶ Connie Farrow, *Victim of Lung Disease is Awarded \$20 Million*, ST. LOUIS POST DISPATCH, Mar. 16, 2004, at A1.

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among workers employed at microwave popcorn factories.⁷ The lungs of eight workers from one plant were damaged severely enough to make them candidates for lung transplantation.⁸ Many of these workers are young nonsmokers.⁹

In early 2000, an occupational medicine physician in Kansas City, Missouri, contacted the Missouri Department of Health (MDOH) to report cases of bronchiolitis obliterans among workers at the popcorn plant in Joplin where Mr. Peoples was employed.¹⁰ In turn, officials from MDOH reported the outbreak to both the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH) to compel an investigation into the cause of the rare disease outbreak.¹¹ NIOSH scientists subsequently visited the factory and conducted medical evaluations of the workers.¹² In September 2001, NIOSH reported its preliminary results and distributed an information sheet to the factory's workers.¹³ The sheet contained the following statement: "There is a work-related cause of lung disease in this plant. We at NIOSH believe the problem is continuing even after the company made changes that we

⁷ NIOSH Report Examines Investigation of Popcorn Plant Workers and Lung Disease, Daily Labor Report (BNA) (Apr. 26, 2002), at <http://www.bna.com/products/labor/dlr.htm>; see also Shipley, *supra* note 5.

⁸ Shipley, *supra* note 5, at C1.

⁹ See Sara Shipley, *Snack Food: Is It Hurting Workers Who Make It?*, ST. LOUIS POST DISPATCH, Apr. 4, 2004, at A1; NAT'L INST. FOR OCCUPATIONAL SAFETY AND HEALTH, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, REPORT NO. DHHS 2004-110, NIOSH ALERT: PREVENTING LUNG DISEASE IN WORKERS WHO USE OR MAKE FLAVORINGS 3-4 (2003) [hereinafter NIOSH ALERT: PREVENTING LUNG DISEASE IN WORKERS WHO USE OR MAKE FLAVORINGS].

¹⁰ NAT'L INST. FOR OCCUPATIONAL SAFETY AND HEALTH, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, INTERIM REPORT NO. HETA #2000-0401, NIOSH INVESTIGATION OF GILSTER MARY LEE 4 (2001) [hereinafter NIOSH INVESTIGATION OF GILSTER MARY LEE].

¹¹ See Shipley, *supra* note 9, at A1.

¹² NIOSH INVESTIGATION OF GILSTER MARY LEE, *supra* note 10.

¹³ NAT'L INST. FOR OCCUPATIONAL SAFETY AND HEALTH, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, IMPORTANT WORKER HEALTH NOTICE ABOUT THE POPCORN PLANT IN JASPER, MISSOURI (2001).

recommended.”¹⁴

In 2001, NIOSH also conducted a study in which rats were exposed to airborne concentrations of butter flavoring for a single six-hour period.¹⁵ The NIOSH researchers reported lung damage among the rats exposed to vapors containing 285 to 371 parts per million (ppm) of diacetyl, the chemical that is the primary component of the butter flavoring.¹⁶ The study’s lead investigator, Dr. Ann Hubbs, reported that these findings were “the most dramatic case of cell death ever seen”¹⁷ in this type of experiment. In their 2002 report, the NIOSH researchers explained that the diacetyl levels to which they had exposed the rats were “not extraordinary when compared with levels measured in the workplace.”¹⁸

When NIOSH undertook its animal study, the agency did not know that BASF, the German chemical manufacturer, had conducted a similar study using pure diacetyl in 1993.¹⁹ That study, which was never reported to the U.S. government or published in scientific literature, found results very similar to those of NIOSH; one four-hour period of exposure to diacetyl resulted in an “abundance of symptoms indicative of respiratory tract

¹⁴ *Id.*

¹⁵ A.F. Hubbs et al., *Necrosis of Nasal and Airway Epithelium in Rats Inhaling Vapors of Artificial Butter Flavoring*, 185 TOXICOLOGY & APPLIED PHARMACOLOGY 128, 129 (2002).

¹⁶ NAT’L INST. FOR OCCUPATIONAL SAFETY AND HEALTH, U.S. DEP’T OF HEALTH AND HUMAN SERVICES, REPORT NO. HETA #2002-0408-2915, NIOSH HEALTH HAZARD EVALUATION REPORT: AGRILINK FOODS POPCORN PLANT 11 (2003).

¹⁷ Shipley, *supra* note 5, at C1.

¹⁸ Hubbs, *supra* note 15, at 128-35. The investigators reported that “[a] concentration of about 200 ppm was measured inside a vat that contained butter flavoring mixed with oil and salt.” *Id.* at 134. However, because the investigation occurred after local exhaust ventilation had been installed for the tanks, “previous concentrations were probably higher.” *Id.* Both the testimony about NIOSH’s investigation at the factory and the results of the animal experiments conducted by the agency’s scientists were presented to the jury in Mr. Peoples’ case.

¹⁹ Personal conversation with Kay Kriess, MD, National Institute for Occupational Safety and Health (Nov. 2, 2004).

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injury.”²⁰

According to American government scientists, there is little question that the Joplin workers developed bronchiolitis obliterans as a result of their work in the popcorn factory.²¹ The manufacturer of the butter flavoring, however, has refused to acknowledge a connection between the exposure of workers to the butter flavoring and the development of the lung condition. At a second trial involving one of the lung-damaged workers, the defendant’s toxicologist testified that there was insufficient evidence to conclude that the lung disease in the popcorn workers was caused by butter flavoring.²²

II. OSHA: RESPONSE OR RETREAT?

Outbreaks of work-related disease and death helped fuel the passage of the Occupational Safety and Health Act (OSH Act) in 1970.²³ In congressional hearings, workers and scientists described numerous outbreaks of work-related disease with regard to which no action was taken until a sufficiently large number of workers had died.²⁴ Tony Mazzocchi, a labor leader and forceful advocate for the OSH Act, called this “the body in the morgue approach.”²⁵ In order to prevent future work-related epidemics, Congress created OSHA and authorized the agency to develop standards

²⁰ BASF, INC., REPORT: STUDY ON THE ACUTE INHALATION TOXICITY LC50 OF DIACETYL FCC AS A VAPOR IN RATS 4-HOUR EXPOSURE, PROJECT NO. 1310247/927010 (1993) [hereinafter BASF REPORT].

²¹ Kay Kreiss et al., *Clinical Bronchiolitis Obliterans in Workers at a Microwave-Popcorn Plant*, 347 NEW ENG. J. MED. 330, 330-38 (2002).

²² *Testimony Ends in Second Trial on Claim that Popcorn Flavoring Caused Injury*, ASSOCIATED PRESS, Apr. 30, 2004.

²³ Occupational Safety & Health Act (OSHA), 29 U.S.C. 651 et seq. (1970).

²⁴ JOSEPH A. PAGE & MARY-WIN O’BRIEN, BITTER WAGES: RALPH NADER’S STUDY GROUP REPORT ON DISEASE AND INJURY ON THE JOB 165-66 (1973).

²⁵ Rafael Moure-Eraso, *Primary Prevention and Precaution in Hazard Identification in the NIEHS/NTP: Body in the Morgue Approach*, 117 PUB. HEALTH REP. 564, 564-73 (Nov.-Dec. 2002), available at http://www.publichealthreports.org/userfiles/117_6/117564.pdf.

based on the best scientific evidence available.²⁶ Congress afforded the agency a great deal of leeway in identifying hazards and setting protective exposure limits to enable the agency to act *before* large numbers of individuals became sick.²⁷

OSHA was first made aware of the risk of lung disease among popcorn workers in May 2000.²⁸ OSHA's Kansas City Area Office received a letter from the Missouri Department of Health (MDOH) that alerted the agency to a serious and potentially deadly health hazard confronting workers at the factory that employed Mr. Peoples.²⁹ The letter indicated that ten workers from one microwave popcorn-packaging facility had been diagnosed with bronchiolitis obliterans and that three of these workers were awaiting lung transplants.³⁰ Another twenty to thirty workers had less severe, but still notable respiratory symptoms. The MDOH reported that it planned to conduct an epidemiologic investigation of the disease cluster, but notified OSHA that obtaining medical releases and physician reports would take some time.³¹ Consequently, the MDOH asked OSHA to inspect the facility, noting that "[a]s a regulatory agency . . . [OSHA] can more promptly address this situation, and if there is an obvious hazard to workers, address it quickly."³²

A few days later, an OSHA inspector visited the microwave popcorn-packaging plant. According to the inspector's notes, the company had become "concerned that there might be some environmental problem at their facility so they had their insurance carrier Wausau come into their plant and conduct environmental sampling for total nuisance dust."³³ The records provided to OSHA

²⁶ Occupational Safety and Health Act of 1970 § 6(b)(5), 29 U.S.C. § 655 (2004) [hereinafter OSHA Act].

²⁷ *Id.*; See PAGE & O'BRIEN, *supra* note 24.

²⁸ Letter from Daryl W. Roberts, Director, Section for Environmental and Public Health, Missouri Department of Health, to Matt Gaines, Occupational Safety and Health Administration (May 19, 2000) (on file with authors).

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

³² *Id.*

³³ Nat'l Inst. for Occupational Safety and Health, Inspection Report, Report

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by the company indicated that the insurance carrier had taken the air samples four years earlier in 1996.³⁴ The OSHA inspector performed no additional dust sampling and offered his “professional opinion that it would be ludicrous to re-sample the area again.”³⁵

The inspector did, however, collect samples of respirable oil mist and send them to OSHA’s laboratory, only to have them discarded because the agency’s sampling method applied only to petroleum-based oils, not vegetable oil.³⁶ Having failed to collect usable exposure samples, the inspector, according to his own notes, “determined the company to be in compliance and closed out the case file since there were no other OSHA sampling protocols at his disposal to test further at the plant.”³⁷ Sixteen months later, in September 2001, an attorney representing several of the ill workers filed a complaint with OSHA and followed up with another complaint in December 2001.³⁸ In her letter to the agency, the attorney alleged that not enough had been done to improve ventilation in the plant, as evidenced by the fact that “one employee lost half of his lung capacity working in the plant after

ID 0728500, Inspection Number 303206387, *Health Narrative: CSHO Workplace Findings* (May 23, 2000) (on file with authors) [hereinafter CSHO Inspection Report]. The report was obtained through a Freedom of Information Act (FOIA) request. Portions of the inspector’s notes were redacted.

³⁴ Letter from Mike Freshwater, CIH, Senior Environmental Health Engineer, WAUSAU, to Jim Cook, Jasper Foods, Inc. (May 10, 1996) (on file with authors).

³⁵ See CSHO Inspection Report, *supra* note 33.

³⁶ *Id.* The document states:

The CSHO [compliance safety and health officer] got a telephone call from the lab indicating that they would be unable to analyze his oil mist samples. They said that the OSHA sampling method for oil mist pertained only to oil mist particulate off gassed from petroleum based oils and not vegetable food grade oils. They said they were unable to use the CSHO’s oil mist samples at all.

Id.

³⁷ *Id.*

³⁸ Letter from Amy R. Powell, Humphrey, Farrington, McClain & Edgar, P.C., to Rick Roberts, OSHA Kansas City Area Office (Dec. 19, 2001) (on file with authors).

the remedial measures” were taken.³⁹

Following the agency’s receipt of the attorney’s letters, a second OSHA inspector visited the plant on December 20, 2001 for only forty minutes.⁴⁰ According to the inspector’s notes, he did not conduct an inspection.⁴¹ OSHA subsequently sent a letter to the attorney who had filed the complaints denying the need for further investigation at the plant.⁴² OSHA explained:

[T]he hazard which you brought to our attention has been corrected and . . . Glister [sic] Mary Lee is complying with the recommendations of NIOSH The hazard does not fall within OSHA’s jurisdiction because there is [sic] no Permissible Exposure Limits for the food blend chemicals of concern that are used at the factory.⁴³

A. OSHA 101

In situations in which there is an obvious workplace hazard but no applicable OSHA standard, OSHA inspectors often cite to what is commonly referred to as “the general duty clause,” which outlines the obligation of employers to provide employees a place of employment that is free from recognized hazards that cause or

³⁹ *Id.* Ms. Powell complained: “Although NIOSH has been investigating the plant and certain measures have been taken to improve the ventilation . . . these measures were not enough” *Id.*

⁴⁰ Nat’l Inst. for Occupational Safety and Health, Inspection Report (OSHA-1), Report ID # 0728500, Inspection # 3043064083 (noting the inspector’s entry time at the facility as 16:00 hours, opening conference with the employer at 16:10 hours and closing conference at 16:50 hours) (on file with authors).

⁴¹ Nat’l Inst. for Occupational Safety and Health, Complaint/Inspection Case File Activity Diary, Kansas City Area Office, Complaint # 203783865, Inspection # 304306483 (including a handwritten note indicating “NIOSH was on site and conducting 18 month investigation for health hazard and ee [employee] exposures . . . closed complaint. No inspection & send “A” letter to comp [company]”) (on file with authors).

⁴² *See* Letter from Manuel Olmedo, OSHA Area Director, to Amy R. Powell, Humphrey, Farrington, McClain & Edgar, P.C. (Feb. 28, 2002) (on file with authors).

⁴³ *Id.*

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are likely to cause death or serious physical harm.⁴⁴ Although the OSH Act provides OSHA with the authority to cite companies for failing to comply with the general duty clause and courts have confirmed this authority in the context of judicial decisions,⁴⁵ in recent years agency officials have been reluctant to invoke the clause. In the case of the popcorn workers, OSHA's position is that hazards for which there is no applicable OSHA standard do "not fall within OSHA's jurisdiction."⁴⁶ With dozens of workers suffering from serious lung disease, the popcorn factory hazard would appear to be a logical candidate for an OSHA regulation.⁴⁷ To initiate the regulatory process, OSHA is required to make a determination that the proposed regulation would reduce or eliminate a "significant risk" for workers exposed to the hazard.⁴⁸

In the decision that established this requirement, the U.S. Supreme Court noted that the risk must be "quantified sufficiently to enable the Secretary [of Labor] to characterize it as significant in an understandable way."⁴⁹ In an effort to meet this mandate, OSHA has invested significant time and resources in preparing detailed quantitative risk assessments for its health standards.⁵⁰ Many of OSHA's health standards regulate the exposure of workers to carcinogens.⁵¹ Estimating the cancer risk associated

⁴⁴ OSHA Act § 5(a)(1), 29 U.S.C. § 654 (2004).

⁴⁵ See, e.g., *Int'l Union v. Gen. Dynamics Land Sys. Div.*, 815 F.2d 1570 (D.C. Cir. 1987).

⁴⁶ Letter from Manuel Olmedo to Amy R. Powell, *supra* note 42.

⁴⁷ See NIOSH ALERT: PREVENTING LUNG DISEASE IN WORKERS WHO USE OR MAKE FLAVORINGS, *supra* note 9.

⁴⁸ *Indus. Union Dep't, AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607, 639 (1980).

⁴⁹ *Id.* at 646.

⁵⁰ Testimony of Margaret Seminario before the House Committee on Employment and Education, Subcommittee on Workforce Protection on OSHA's Standard Setting Process (June 14, 2001) (on file with authors); NAT'L ADVISORY COMMITTEE ON OCCUPATIONAL SAFETY AND HEALTH, U.S. DEP'T OF LABOR, REPORT AND RECOMMENDATIONS RELATED TO OSHA'S STANDARDS DEVELOPMENT PROCESS (June 6, 2000) [hereinafter REPORT AND RECOMMENDATIONS RELATED TO OSHA'S STANDARDS DEVELOPMENT PROCESS].

⁵¹ OSHA has comprehensive health standards for the following 25

with exposure to various substances is difficult and often involves extrapolating from high to low doses, and from animals to humans. Recognizing this reality, the Supreme Court explained that it was not the Court's intention to place OSHA in a "mathematical straitjacket."⁵² Consequently, it permitted the agency significant flexibility in quantifying health risks.⁵³

Arguably, a risk assessment addressing workers' exposure to butter flavoring is less complex than one for a carcinogen because it relates to a disease with rapid onset and a clear range of disabling respiratory effects. An OSHA regulation to protect workers from adverse health effects related to exposure to butter flavoring could take one of at least two different approaches. One approach would be for OSHA to regulate popcorn manufacturing plants and prevent workers' exposure to all butter flavoring vapors until more is known about the cause or causes of the lung disease in popcorn workers. A regulation of this form would protect popcorn workers from exposure to all potentially hazardous chemicals, including diacetyl. In 1976, OSHA embraced this approach in developing a standard to protect workers from coke oven emissions by requiring reductions in exposure to coal tar pitch volatiles rather than attempting to identify the precise cancer-causing agent in the coke oven emissions.⁵⁴ Notably, if diacetyl is

substances that are designated by IARC as "known human" or "reasonably anticipated to be" carcinogens: asbestos; 3,3 dichlorobenzidine; chloromethyl methyl ether; ethyleneimine; bis(chloromethyl ether); aminodiphenyl; alpha-naphthylamine; N-nitrosodimethyl amine; beta-naphthylamine; 4-nitrobiphenyl; benzidine; 4-dimethylaminoazobenzene; 2-acetylaminofluorene; beta-propiolactone; coke-oven emissions; vinyl chloride; arsenic; benzene; acrylonitrile; formaldehyde; 4,4-methylenedianiline; cadmium; 1,3 butadiene; and methylene chloride. Other health standards issued by OSHA (i.e., cotton dust, lead, DBCP, and bloodborne pathogens) were designed primarily to protect workers from non-cancer health effects.

⁵² *Indus. Union Dep't, AFL-CIO*, 448 U.S. at 655.

⁵³ *See id.*

⁵⁴ Final Rule on Exposure to Coke Oven Emissions, 41 Fed. Reg. 46,742 (Oct. 22, 1976). At the time, there was considerable evidence that workers exposed to coke oven emissions and employed in certain tasks (i.e., "topside occupations") had an increased risk of lung cancer. What was unknown, however, was which specific component of the emission caused the cancer.

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the actual cause of the lung disease detected in popcorn workers, this approach would leave diacetyl-exposed workers in other industries unprotected.

Alternately, OSHA could issue a standard to regulate workers' exposure to diacetyl. There is powerful evidence to suggest that diacetyl has played a causal role in the development of bronchiolitis obliterans in workers at facilities other than microwave popcorn factories.⁵⁵ However, there have been no studies of workers exposed *only* to diacetyl, given that the chemical is only one (albeit often the primary) component of the flavoring mixtures to which the sick workers were exposed. Importantly, it is not uncommon for human evidence concerning the effects of environmental exposures to be limited or to contain uncertainties. In many industrial workplaces, there can be hundreds, if not thousands, of chemicals in the work environment. It is often impossible to identify the effects of any individual hazardous exposure. For obvious ethical reasons, additional information cannot be gathered using experiments that involve volunteer human subjects. Consequently, regulators generally look to animal evidence for additional information on the toxic effects of exposure. The BASF study demonstrated that laboratory animals exposed to pure diacetyl developed lung disease after short exposure.⁵⁶ In NIOSH's laboratory investigation, rats exposed to butter flavoring whose predominant component was diacetyl experienced a similar fate.⁵⁷ While diacetyl manufacturers are likely to claim (as they did in Mr. Peoples's suit) that there is legitimate scientific debate about the health effects of exposure to

OSHA suspected the excess cancer risk was related to workers' exposure to benzo(a)pyrene or other polycyclic aromatic hydrocarbons. In the absence of unequivocal evidence on the exact cancer-causing component, OSHA proposed a regulation to reduce coal tar pitch volatiles as the surrogate measure for coke oven emissions. *Id.*

⁵⁵ See NIOSH ALERT: PREVENTING LUNG DISEASE IN WORKERS WHO USE OR MAKE FLAVORINGS, *supra* note 9. There have been outbreaks of severe lung disease at several facilities in which diacetyl is an important component of the mixture of chemicals to which workers in the factory are exposed, including at least two factories which do not produce butter-flavored popcorn. *Id.*

⁵⁶ See BASF REPORT, *supra* note 20.

⁵⁷ See Hubbs, *supra* note 15.

this chemical, there is already a significant body of evidence suggesting that diacetyl exposure causes disease.⁵⁸ Further, there is *no* evidence that diacetyl is *not* the cause of bronchiolitis obliterans. Thus, a public health approach would support severely restricting airborne exposure to diacetyl unless and until it is shown to be safe.

Unfortunately, the likelihood of OSHA taking either of these regulatory paths is small. It appears to make little difference whether the White House is in Democratic or Republican hands. The fact remains that new workplace health standards are rare. In the last ten years, OSHA has issued standards for a total of two new chemicals.⁵⁹ Indeed, since its inception, OSHA has issued comprehensive standards for only thirty toxic materials.⁶⁰ Additionally, the agency enforces permissible exposure limits for only about 500 chemicals of the more than 12,000 chemicals characterized by the U.S. Environmental Protection Agency (EPA) as high volume chemicals.⁶¹ Of these 500 standards, all but a handful were borrowed in whole from the voluntary industry levels established prior to OSHA's creation in 1971.

With respect to chemicals such as those to which Mr. Peoples was exposed, the Flavor and Extract Manufacturers Association of

⁵⁸ NIOSH INVESTIGATION OF GILSTER MARY LEE, *supra* note 10, at 4; *Fixed Obstructive Lung Disease in Workers at a Microwave Popcorn Factory-Missouri 2000-2002*, 51 *Mortality and Morbidity Weekly Report* 345, 345-47 (Apr. 26, 2002); Kreiss et al., *supra* note 21.

⁵⁹ See Occupational Exposure to 1,3-Butadiene, 61 Fed. Reg. 56,746, 56,856 (Nov. 4, 1996) (to be codified at 29 CFR pts. 1910, 1915 and 1926); see also Occupational Exposure to Methylene Chloride, 62 Fed. Reg. 1494, 1619 (Jan. 10, 1997) (to be codified at 29 CFR pts. 1910, 1915 and 1926).

⁶⁰ REPORT AND RECOMMENDATIONS RELATED TO OSHA'S STANDARDS DEVELOPMENT PROCESS, *supra* note 50. This report included a list of OSHA Health Standards issued and the date each standard was originally published: asbestos (1972/1986); 13 carcinogens (1974); vinyl chloride (1974); coke oven emissions (1974); benzene (1978/1987); DBCP (1978); arsenic (1978); cotton dust (1978); acrylonitrile (1978); lead (1978); ethylene oxide (1984); formaldehyde (1987); chemical exposure in laboratories (1990); bloodborne pathogens (1991); 4,4' methylenedianiline (1992); cadmium (1992); 1,3 butadiene (1996); methylene chloride (1997). *Id.*

⁶¹ "High volume" means that more than 1 million pounds of the chemical is produced annually.

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the United States estimates that 1,037 flavoring ingredients pose potential respiratory hazards to workers.⁶² However, workplace exposure limits have been established for fewer than 5% of them.⁶³

B. OSHA's Response to the Popcorn Lung Outbreak

When faced with a hazard for which no standard has been set, OSHA has the authority to issue an emergency temporary standard or to invoke the "general duty clause."⁶⁴ OSHA selected neither of these options in approaching the prevention of lung disease among the popcorn workers. Despite significant "bodies in the morgue" evidence, OSHA maintains that "a cause-effect relationship between diacetyl and bronchiolitis obliterans has not been established, as food-processing workers with this lung disease were also exposed to other flavoring agents."⁶⁵

In lieu of industry regulation, OSHA elected to sign a "partnership agreement" in September 2002 with The Popcorn Board to "help foster a culture of prevention."⁶⁶ This move is part of a greater effort by OSHA to form alliances with corporations, trade associations, and other organizations to voluntarily develop and share information regarding worker health and safety. OSHA's Assistant Secretary reported in February 2004 that the agency had forty-six national alliances and 105 regional alliances.⁶⁷ There are

⁶² See NIOSH ALERT: PREVENTING LUNG DISEASE IN WORKERS WHO USE OR MAKE FLAVORINGS, *supra* note 9.

⁶³ *Id.*

⁶⁴ OSHA Act §§ 5(a)(1) & 6(c)(1), 29 U.S.C. §§ 654, 655 (2004).

⁶⁵ Occupational Safety and Health Administration, Safety/Health Topics, Chemical Sampling Information, Diacetyl, at http://www.osha.gov/dts/chemicalsampling/data/CH_231710.html (last visited Jan. 24, 2005).

⁶⁶ Occupational Safety and Health Administration, Cooperative Programs, Alliance, Regional Alliances and State Plans, Region VII, Agreement Establishing an Alliance between the Occupational Safety and Health Administration U.S. Department of Labor Region VII and The Popcorn Board (Sept. 22, 2002) [hereinafter Alliance Agreement], at <http://www.osha.gov/dcsp/alliances/regional/reg7/popcorn.html>.

⁶⁷ Testimony of John Henshaw, Assistant Secretary of Labor for Occupational Safety and Health, before the United States House of Representatives Committee on Appropriations (Feb. 26, 2004), *available at*

no specific requirements for forming an alliance with OSHA and, by design, the agreements lack an enforcement component.⁶⁸ According to OSHA's 2002 alliance agreement with The Popcorn Board, the two entities would work cooperatively to develop an internal document to be sent to OSHA field compliance officers.⁶⁹ Nearly two years later, the hazard bulletin that supposedly would help OSHA inspectors understand the butter flavor hazard and conduct effective inspections has not been issued.⁷⁰

Unfortunately, no other federal agency shares in OSHA's authority to address workplace hazards. Under the Toxic Substances Control Act (TSCA), chemical manufacturers are required to test their products to determine whether they pose a "significant risk of serious or widespread harm to human beings."⁷¹ If such a risk exists, the EPA can take action to prevent or reduce the risk. Diacetyl, the suspect hazard in butter flavoring, is a food additive and therefore is explicitly exempt from TSCA. Furthermore, relying on the TSCA to protect the public from

http://appropriations.house.gov/_files/JohnHenshawtestimony.pdf.

⁶⁸ Occupational Safety and Health Administration, Alliance: An OSHA Cooperative Program, at <http://www.osha.gov/desp/alliances/index.html> (last visited Jan. 24, 2005).

⁶⁹ See Alliance Agreement, *supra* note 66, which reads: "Representatives of The Popcorn Board will review and provide comment and input on a draft OSHA 'Hazard Information Bulletin' to be developed by OSHA for internal distribution to it's [sic] compliance officers in the field."

⁷⁰ Letter from Charles Adkins, OSHA Regional Administrator, to David Michaels, George Washington University (June 4, 2004) (on file with authors). The letter responded to a FOIA request and reported: "The Hazard Information Bulletin referenced in the Alliance is still under review at the OSHA National Office." *Id.*

⁷¹ 15 U.S.C. § 2603(f) (2005).

(f) Required actions:

Upon the receipt of any test data . . . or any other information available to the Administrator which indicates . . . that . . . a chemical substance or mixture presents or will present a significant risk of serious or widespread harm to human beings from cancer, gene mutations, or birth defects, the Administrator shall, within the 180-day period . . . initiate appropriate action

Id.

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chemical hazards is unlikely to be successful. Indeed, Congress's General Accounting Office (now known as the Government Accountability Office) reported that only four chemicals were restricted under TSCA in the period between 1976, when the Act became law, and 1994, when the study was carried out.⁷²

The Food and Drug Administration (FDA) is similarly limited in its ability to address potential workplace hazards. Although the FDA is charged with ensuring "the safety of the nation's domestically-produced and imported foods,"⁷³ because the FDA has concluded that diacetyl is "generally recognized as safe . . . as a direct food ingredient," the FDA has satisfied its statutory mandate.⁷⁴ That is, diacetyl is safe for humans to *consume*; however, the FDA makes no attempt to determine whether diacetyl is safe for workers to *inhale*.

Given the inability or unwillingness of the nation's regulatory apparatus to address workplace hazards, litigation by Mr. Peoples and similarly situated popcorn workers is a logical alternative. In fact, it may be the only means of compelling employers to protect their workers.

III. REAL AND MANUFACTURED SCIENTIFIC UNCERTAINTY IN THE REGULATORY PROCESS: AN INVITATION TO INACTION

There are few scientific challenges more complex than understanding the cause of disease in humans. Scientists cannot feed people toxic chemicals, for example, to see what doses cause cancer. Instead, investigators must harness the outcomes of "natural experiments" in which exposures have already occurred. In laboratories, by contrast, scientists design and control experiments on animals to determine the impact of toxic agents on

⁷² U.S. GEN. ACCOUNTING OFFICE, REPORT NUMBER GAO/T-RCED-94-212, TOXIC SUBSTANCES CONTROL ACT: EPA'S LIMITED PROGRESS IN REGULATING TOXIC CHEMICALS (1994).

⁷³ U.S. Food and Drug Admin., Overview of the Center for Food Safety and Applied Nutrition, at <http://www.cfsan.fda.gov/~lrd/cfsan4.html> (last visited Jan. 24, 2005).

⁷⁴ Listing of Specific Substances Affirmed as GRAS (Generally Recognized as Safe), 21 C.F.R. § 184.1278 (2005).

these subjects. Both epidemiologic and laboratory studies involve uncertainty and require scientists to extrapolate from study-specific evidence to make causal inferences and recommend protective measures.

Much of the public discussion (or controversy) surrounding public health and the environmental regulation of chemicals focuses on the acceptability of existing exposures. Policymakers recognize that uncertainty is inevitable in human risk assessment. However, as Christine Todd Whitman, former administrator of the EPA, points out, “the absence of certainty is not an excuse to do nothing.”⁷⁵ Generally, if a federal regulatory agency finds that exposures are contributing to or are likely to contribute to disease, polluters or others responsible for the exposure will be required to devote resources to ameliorating the problem. When the prospect of regulation is associated with substantial costs, a debate about the underlying science ensues, typically focusing on the question of scientific certainty.

Absolute certainty in the regulatory sciences is rare. Yet there is a growing trend in regulatory agencies that demands proof over precaution in the realm of public health and the environment. By way of example, the Nuclear Regulatory Commission (NRC) recently announced that it would permit the re-opening of the Davis-Besse nuclear reactor near Toledo, Ohio.⁷⁶ Two years earlier, the facility had come within a quarter-inch of a major radiation release, possibly the worst accident of this kind in U.S. history. A mixture of water and boric acid had eaten through six inches of carbon steel, leaving only a thin layer of stainless steel to contain the water in the Davis-Besse nuclear reactor’s vessel head.⁷⁷ When the facility was finally inspected, the last steel layer

⁷⁵ Christine Todd Whitman, Remarks on “Effective Policy Making: The Role of Good Science” at the National Academy of Science’s Symposium on Nutrient Over-Enrichment of Coastal Waters (Oct. 13, 2000), at http://www.usembassy.it/file2001_01/alia/a0010407.htm.

⁷⁶ Matthew L. Wald, *Nuclear Plant, Closed After Corrosion, Will Reopen*, N.Y. TIMES, Mar. 9, 2004, at A16.

⁷⁷ U.S. GEN. ACCOUNTING OFFICE, REPORT NO. GAO-04-415, NUCLEAR REGULATION: NRC NEEDS TO MORE AGGRESSIVELY AND COMPREHENSIVELY RESOLVE ISSUES RELATED TO THE DAVIS-BESSE NUCLEAR POWER PLANT’S

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was bulging, barely able to contain the highly-pressurized coolant.⁷⁸

Three months prior to NRC's inspection, NRC experts predicted cooling system breaches at the Ohio plant following the discovery of cracks in two similar nuclear reactors.⁷⁹ The agency asked the operators of all similar reactors to close voluntarily for inspection.⁸⁰ Davis-Besse's operator refused and NRC staff prepared an order demanding the closure and inspection of the reactor. The order was never issued, however, because the NRC supervisor demanded "absolute proof" that the vessel head was damaged before he would authorize a facility shutdown.⁸¹ Problematically, this proof could only be obtained through a post-shutdown inspection.

SHUTDOWN 1 (2004).

⁷⁸ See Memorandum from Hubert T. Bell, Inspector General, U.S. Nuclear Regulatory Commission, to Richard A. Meserve, Former Chairman, U.S. Nuclear Regulatory Commission, on "NRC's Regulation of Davis-Besse Regarding Damage to the Reactor Vessel Head (Case No. 02-03S)" 17 (Dec. 30, 2002) ("The remaining thickness of the RPV head in the wastage area was found to be approximately 3/8 inch . . ."), available at www.nrc.gov/reading-rm/doc-collections/insp-gen/2003/02-03s.pdf; Memorandum from Hubert T. Bell, Inspector General, U.S. Nuclear Regulatory Commission, to Nils J. Diaz, Chairman, U.S. Nuclear Regulatory Commission, on "NRC's Oversight of Davis-Besse Boric Acid Leakage and Corrosion during the April 2000 Refueling Outage (Case No. 03-02s)" 6 (Oct. 17, 2003); 16 N.R.C. INSPECTOR GENERAL SEMIANNUAL REP. NO. 2 (Oct. 1, 2003 – Mar. 31, 2004) ("This was the only material preventing a breach of the reactor coolant pressure boundary . . ."), available at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1415/v16n2/>.

⁷⁹ Memorandum from Hubert T. Bell to Richard A. Meserve, *supra* note 78, at 6.

⁸⁰ U.S. GENERAL ACCOUNTING OFFICE, REPORT NO. GAO-04-415, NUCLEAR REGULATION: NRC NEEDS TO MORE AGGRESSIVELY AND COMPREHENSIVELY RESOLVE ISSUES RELATED TO THE DAVIS-BESSE NUCLEAR POWER PLANT'S SHUTDOWN 2 (2004).

⁸¹ *Id.* at 34.

IV. "DOUBT IS OUR PRODUCT"⁸²

The production and use of scientific data in public policy has become an adversarial endeavor with unfortunate results both for science and society. An entire industry has emerged to lend support to the generic assertion, made with great frequency by opponents of regulation, that science is uncertain and that regulation cannot proceed until more conclusive data are collected. This industry specializes in magnifying and manufacturing uncertainty about the science supporting public health regulation. The tobacco industry has perfected the strategy. For nearly fifty years, tobacco companies hired scientists to disprove that smokers were at a greater risk of dying of lung cancer, heart disease, and other tobacco-related illnesses than were nonsmokers.⁸³ The industry also hired scientists to refute evidence that environmental tobacco smoke increased disease risk in nonsmokers.⁸⁴ In each case, the scientific community eventually reached the consensus that tobacco smoke caused the studied medical conditions.⁸⁵ In

⁸² Brown & Williamson, *supra* note 1.

⁸³ The tobacco industry's strategy for casting doubt on the adverse health effects of their product has been documented by numerous researchers including RICHARD KLUGER, *ASHES TO ASHES: AMERICA'S HUNDRED-YEAR CIGARETTE WAR, THE PUBLIC HEALTH, AND THE UNABASHED TRIUMPH OF PHILIP MORRIS* (1996); STANTON A. GLANTZ, JOHN SLADE, ET AL., *CIGARETTE PAPERS* (1996); DAVID KESSLER, *A QUESTION OF INTENT: A GREAT AMERICAN BATTLE WITH A DEADLY INDUSTRY* (2001).

⁸⁴ KLUGER, *supra* note 83; GLANTZ, *supra* note 83; KESSLER, *supra* note 83.

⁸⁵ OFFICE ON SMOKING AND HEALTH, U.S. DEPARTMENT OF HEALTH, EDUCATION AND WELFARE, NO. 1103, *SMOKING AND HEALTH: REPORT OF THE ADVISORY COMMITTEE TO THE SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE* (1964), available at http://www.cdc.gov/tobacco/sgr/sgr_1964/1964%20SGR%20Intro.pdf; Office on Smoking and Health, U.S. Department of Health, Education and Welfare, DHEW Publication No. 79-50066, *Smoking and Health: A Report of the Surgeon General* (1979), at <http://www.cdc.gov/tobacco/sgr/>; National Research Council, *Environmental Tobacco Smoke: Measuring Exposures and Assessing Health Effects* (1986); OFFICE OF HEALTH AND ENVIRONMENTAL ASSESSMENT, U.S. ENVIRONMENTAL PROTECTION AGENCY, REPORT NO. EPA/600/6-90/006F, *RESPIRATORY HEALTH EFFECTS OF PASSIVE SMOKING: LUNG CANCER AND OTHER DISORDERS* (1992);

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spite of overwhelming scientific evidence and the smoking-related deaths of millions of people, the tobacco industry waged a campaign that successfully delayed regulation and victim compensation for decades.

Among other tools used by the tobacco industry to manufacture scientific uncertainty was the journal *Tobacco and Health Research*, a publication aimed at physicians and scientists. The journal's criteria for selecting articles are telling: "the most important type of story is that which casts doubt on the cause and effect theory of disease and smoking."⁸⁶ The journal's public relations firm, Hill and Knowlton, advised that headlines "should strongly call out the point—Controversy! Contradiction! Other Factors! Unknowns!"⁸⁷ The same message was communicated to the public. One tobacco industry executive explained: "*Doubt is our product* since it is the best means of competing with the 'body of fact' that exists in the minds of the general public. It is also the means of establishing a controversy."⁸⁸

The manufacture of doubt has become so commonplace that it now is unusual for the science behind an environmental regulation to remain unchallenged. The National Toxicology Program, for example, biannually issues a list of substances that can cause cancer.⁸⁹ Before a new substance can be designated a carcinogen, it must be subjected to a public process involving several independent scientific reviews. During this process, industry-employed scientists have challenged the designation of various substances as "cancer-causing" and have disputed the evidence underlying the assignment of this designation to alcoholic

Richard Doll et al., *Mortality in relation to smoking: 50 years' observations on male British doctors*, 328 BRIT. MED. J. 1519, 1519 (2004).

⁸⁶ Memorandum from Carl Thompson, Vice President, Hill & Knowlton, Inc., to William Kloepfer, Jr., Vice President, The Tobacco Institute, Inc. (Oct. 18, 1968), *available at* http://tobaccodocuments.org/ti/TIMN0071488-1491.html#footnote_4.

⁸⁷ *Id.*

⁸⁸ Brown & Williamson, *supra* note 1.

⁸⁹ NATIONAL TOXICOLOGY PROGRAM, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, TENTH REPORT ON CARCINOGENS (2002), *available at* <http://ehp.niehs.nih.gov/roc/toc10.html>.

beverages,⁹⁰ beryllium,⁹¹ crystalline silica,⁹² ethylene oxide,⁹³ nickel compounds,⁹⁴ and certain wood dusts.⁹⁵ In each of these cases, the examined substance had already been categorized by the International Agency for Research on Cancer as “carcinogenic to humans.”⁹⁶

Debates regarding the validity of science persist, even in the face of powerful evidence. Within the scientific community, for example, there is strong consensus that broad-spectrum ultraviolet

⁹⁰ See William Waddell, Public comment as reported in the Report of Carcinogens Subcommittee Meeting, National Toxicology Program Board of Scientific Counselors (Dec. 2-3, 1998), *available at* <http://ntp.niehs.nih.gov>.

⁹¹ H. Daniel Roth, Public comment as reported in the Report of Carcinogens Subcommittee Meeting, National Toxicology Program Board of Scientific Counselors (Jan. 20-21, 2000), *available at* <http://ntp.niehs.nih.gov>; Dimitrios Trichopoulos, Public comment as reported in the Report of Carcinogens Subcommittee Meeting, National Toxicology Program Board of Scientific Counselors (Jan. 20-21, 2000), *available at* <http://ntp.niehs.nih.gov>.

⁹² Robert Glenn, Public comment as reported in the Report of Carcinogens Subcommittee Meeting, National Toxicology Program Board of Scientific Counselors (Dec. 2-3, 1998), *available at* <http://ntp.niehs.nih.gov>; William Moll, Public comment as reported in the Report of Carcinogens Subcommittee Meeting, National Toxicology Program Board of Scientific Counselors (Dec. 2-3, 1998), *available at* <http://ntp.niehs.nih.gov>.

⁹³ Julian Preston, Public comment as reported in the Report of Carcinogens Subcommittee Meeting, National Toxicology Program Board of Scientific Counselors (Dec. 2-3, 1998), *available at* <http://ntp.niehs.nih.gov>; M. Jane Teta, Public comment as reported in the Report of Carcinogens Subcommittee Meeting, National Toxicology Program Board of Scientific Counselors (Dec. 2-3, 1998), *available at* <http://ntp.niehs.nih.gov>; Sara Schotland, Public comment as reported in the Report of Carcinogens Subcommittee Meeting, National Toxicology Program Board of Scientific Counselors (Dec. 2-3, 1998), *available at* <http://ntp.niehs.nih.gov>.

⁹⁴ Adriana Oller, Public comment as reported in the Report of Carcinogens Subcommittee Meeting, National Toxicology Program Board of Scientific Counselors (Dec. 2-3, 1998), *available at* <http://ntp.niehs.nih.gov>.

⁹⁵ William Blot, Public comment as reported in the Report of Carcinogens Subcommittee Meeting, National Toxicology Program Board of Scientific Counselors (Dec. 13-15, 2000), *available at* <http://ntp.niehs.nih.gov>.

⁹⁶ International Agency for Research on Cancer, Overall Evaluations of Carcinogenicity to Humans, *available at* <http://monographs.iarc.fr/monoeval/crthgr01.html> (last visited Jan. 26, 2003).

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(UV) radiation from sunlight and tanning lamps causes skin cancer. Regardless, the trade association that represents tanning salons has continued to question the scientific evidence that supports UV radiation's designation as a carcinogen.⁹⁷

Similarly, opponents of OSHA regulation have disputed many of the health standards proposed by the agency.⁹⁸ For example, when OSHA first proposed to regulate exposure to cotton dust, the cause of a serious lung disease among textile workers, the textile industry asserted a number of claims in order to halt or delay regulation.⁹⁹ The industry argued that the lung disease, known as byssinosis, was not a true clinical entity and that additional research was required to identify the exact portion of the cotton plant that caused the respiratory problem.¹⁰⁰ OSHA considered all

⁹⁷ Stephen Ross, Public comment, as reported in the Report of Carcinogens Subcommittee Meeting, National Toxicology Program Board of Scientific Counselors (December 13-15, 2000), *available at* <http://ntp.niehs.nih.gov/ntp.htdocs/Liason/121300.pdf>.

⁹⁸ Section 6(f) of the Occupational Safety and Health Act of 1970 allows "any person who may be adversely affected by a standard . . . [to] file a petition challenging the validity of such standard with the United States court of appeals" OSHA Act § (6)(f), 29 U.S.C. 655 (2005). *See* Color Pigments Mfrs. Ass'n, Inc. v. OSHA, 16 F.3d 1157 (11th Cir. 1994) (discussing OSHA's cadmium standard); Am. Dental Ass'n v. Secretary of Labor, 984 F.2d 823 (7th Cir. 1993) (discussing OSHA's bloodborne pathogens standard); Am. Petroleum Inst. v. OSHA, 581 F.2d 493 (5th Cir. 1978) (discussing OSHA's benzene standard); Iron & Steel Inst. v. OSHA, 577 F.2d 825 (3d Cir. 1978) (discussing OSHA's coke oven emissions standard); Am. Soc'y for the Plastics Indus. v. OSHA, 509 F.2d 1301 (2d Cir. 1975) (discussing OSHA's vinyl chloride standard); Synthetic Organic Chem. Mfrs. Ass'n v. Brennan, 503 F.2d 1155 (3d Cir. 1974) (discussing OSHA's 14 carcinogens); United Auto Workers v. Pendergrass, 878 F.2d 389 (D.C. Cir. 1989) (discussing OSHA's formaldehyde standard); United Steelworkers of Am. v. Marshall, 647 F.2d 1189 (D.C. Cir. 1980) (discussing OSHA's lead standard); AFL-CIO v. Marshall, 617 F.2d 636 (D.C. Cir. 1979) (discussing OSHA's cotton dust standard); Indus. Union Dep't v. Hodgson, 499 F.2d 467 (D.C. Cir. 1974) (discussing OSHA's asbestos standard).

⁹⁹ Proposed Health Standard on Cotton Dust, 41 Fed. Reg. 56,498 (Dec. 28, 1976).

¹⁰⁰ *See* Statement of M.C. Battigelli, M.D., before the Public Hearing Concerning the Proposed Change in the OSHA Cotton Dust Standard (Apr. 1, 1977) (on file with authors); *see also* Statement of W.K.C. Morgan, M.D., West

of the available scientific evidence and proceeded with its regulation. Today, byssinosis has been virtually eliminated in the United States—an unqualified public health success.¹⁰¹

Unfortunately, the strategy of creating uncertainty regarding the risks associated with pharmaceutical use, chemical exposure, and the use of hazardous products, has been remarkably successful. By raising the cry of “junk science” and questioning the validity or strength of scientific evidence, polluters and manufacturers of dangerous products have been able to delay, often for decades, regulations and other measures designed to protect the health and safety of individuals and communities. This strategy, which has been readily employed by the textile industry and tobacco manufacturers, has been embraced by many industries facing new regulation. Through the promotion of the “junk science” movement, polluters and manufacturers have sought to influence public opinion by ridiculing scientists whose research presents an economic threat, irrespective of the quality of the scientists’ research. Further, industries facing regulation frequently challenge the scientific studies (and even scientific methods) used in the regulatory and legal arenas as fundamentally flawed, contradictory, or incomplete. Thus, they assert, it would be unfair or premature to regulate the exposure in question or to compensate the worker or community resident who may have been made sick by the exposure.

V. DOUBT, SCIENCE AND THE COURTS

The influence of “junk science” arguments on the judiciary is

Virginia University School of Medicine, before the Public Hearing Concerning the Proposed Change in the OSHA Cotton Dust Standard (on file with authors); Statement of Jack W. Whitworth, M.D., American Textile Manufacturers Institute, Inc., before the Public Hearing Concerning the Proposed Change in the OSHA Cotton Dust Standard (on file with authors).

¹⁰¹ See NAT’L INST. FOR OCCUPATIONAL SAFETY AND HEALTH, U.S. DEP’T OF HEALTH AND HUMAN SERVICES, PUBLICATION NO. 2003-111, THE WORK-RELATED LUNG DISEASE SURVEILLANCE REPORT (2002); see also Regulatory Review of OSHA’s Cotton Dust Standard, 65 Fed. Reg. 76667-01 (2000) (noting that the prevalence of byssinosis among cotton textile workers declined from 20% in the 1970’s to 0.68% in 2000).

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clear. In recent years, courts have come to worship scientific certainty. Since the Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, federal judges have had an obligation to serve as scientific gatekeepers, allowing into evidence only expert testimony that meets specific standards for relevance and reliability.¹⁰² In fact, a recent study found that courts are now asking doctors who testify as experts to meet standards that exceed those that the doctors use to diagnose and treat their own patients.¹⁰³

The influence of the *Daubert* decision is evident in the litigation regarding the harmful effects of Parlodel, a drug prescribed in the early 1990s to stop postpartum lactation.¹⁰⁴ Until it was withdrawn from the market, a number of young women who had been prescribed Parlodel experienced severe circulatory system episodes, such as heart attacks and strokes, shortly after taking the drug.¹⁰⁵ On the basis of case reports and animal studies, in 1985, the FDA requested that the drug's manufacturer include warnings about hypertension, seizure, and stroke on the drug's label.¹⁰⁶ Evidence continued to accumulate and the FDA's concern became so great that, in 1994, it requested that Parlodel's manufacturer stop selling the drug to lactating women.¹⁰⁷ However, when several women sued the drug's manufacturer, claiming that Parlodel was responsible for their illnesses, their cases were thrown out of court for lack of scientific certainty.¹⁰⁸ Similarly, judges in several jurisdictions refused to allow jurors to consider the testimony of scientists or physicians who opined that

¹⁰² *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

¹⁰³ Jerome P. Kassirer & Joe S. Cecil, *Inconsistency in Evidentiary Standards for Medical Testimony: Disorder in the Courts*, 288 JAMA 1382, 1382-87 (2002).

¹⁰⁴ Margaret A. Berger, *What Has a Decade of Daubert Wrought?* AM. J. OF PUB. HEALTH (forthcoming 2005).

¹⁰⁵ See Kassirer & Cecil, *supra* note 103.

¹⁰⁶ Opportunity for a Hearing on a Proposal to Withdraw Approval of the Indication, 59 Fed. Reg. 43347-01, 43347-43348 (Aug 23, 1994).

¹⁰⁷ *Id.* at 43347.

¹⁰⁸ See *Siharath v. Sandoz Pharm. Corp.*, 131 F. Supp. 2d 1347 (N.D. Ga. 2000); *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194 (11th Cir. 2002).

Parlodel could cause circulatory disorders.¹⁰⁹

Applying the *Daubert* rule, these judges demanded a level of certainty that was virtually impossible to provide. Some experts have suggested that the Supreme Court's *Daubert* decision or, more appropriately, some judges' interpretation of *Daubert*, encourages an anti-scientific method for evaluating scientific evidence.¹¹⁰ In contrast to the weight-of-the-evidence approach employed by scientists, this method requires that each piece of scientific data be evaluated independently for relevance and reliability—an approach University of Texas law professor Thomas O. McGarity refers to as “corpuscular.”¹¹¹

Opponents of workplace safety and environmental regulation are seeking to institutionalize this anti-scientific approach in federal agencies. The U.S. Chamber of Commerce, for example, advocates the application of the “*Daubert* criteria” to regulatory proceedings.¹¹² However, this corpuscular approach is problematic when applied to the determination of causation in individual tort cases, and it is both counterproductive and dangerous when applied to the scientific evidence that forms the basis of public health regulations. Since its inception, OSHA has used a weight-of-the-evidence approach to demonstrate the necessity of protective action and to craft health standards that have ultimately proved successful in reducing hazardous exposures. OSHA's early health standards were not based on perfect scientific information; nonetheless, the weight of the evidence was sufficient to support

¹⁰⁹ See Kassirer & Cecil, *supra* note 103, at 1387.

¹¹⁰ Carl Cranor, *Scientific Inference in the Laboratory and the Law*, AM. J. OF PUB. HEALTH (forthcoming 2005); Sheldon Krinsky, *The “Weight-of-Scientific-Evidence” in Policy & Law*, AM. J. OF PUB. HEALTH (forthcoming 2005); Ronald Melnick, *A Daubert Motion: A Legal Strategy to Exclude Essential Scientific Evidence in Toxic Tort Litigation* AM. J. OF PUB. HEALTH (forthcoming 2005).

¹¹¹ Thomas O. McGarity, *Science In The Regulatory Process: On the Prospect of Daubertizing Judicial Review of Risk Assessment*, 66 LAW & CONTEMP. PROBS. 155 (2003).

¹¹² U.S. Chamber of Commerce, *Scientific Information in Federal Rulemaking*, available at http://www.uschamber.com/issues/index/regulatory/scientific_rulemaking.htm (last visited Jan. 28, 2005).

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the issuance of protective regulations that have saved lives.¹¹³

Given OSHA's reluctance to issue new occupational health standards, litigation pursued by injured workers is likely to play an increasingly important role in eliminating or reducing workplace hazards, and in preventing occupational illness and death. Despite the above evidentiary limitations, litigation remains a viable and valuable avenue for workers seeking to hold employers accountable for their failure to ensure workplace health and safety.

While the damage has already been done to Mr. Peoples's lungs and to the lungs of other popcorn workers, the \$20 million verdict in Mr. Peoples's case is likely to compel manufacturers and employers to ensure that workers are provided adequate protection. Perhaps it will even encourage the food industry to develop a way to make butter-flavored microwave popcorn without endangering the lives of workers.

¹¹³ David Michaels & Celeste Monforton, *Manufacturing Uncertainty: Contested Science and the Protection of the Public's Health and Environment*. AM. J. OF PUB. HEALTH (forthcoming 2005).