

THE POPCORN LUNG CASE STUDY: A RECIPE FOR REGULATION?

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I.

INTRODUCTION

Highway 71 runs straight down from the Canadian border to a place just seventy-five miles north of the Gulf of Mexico, and almost exactly in the middle of that road, almost exactly in the middle of the country, and at the heart of this story, sits the small town of Jasper, Missouri. Home to just over one thousand people, Jasper is also the location of a factory owned by the Gilster-Mary Lee Corporation. Its product is microwaveable popcorn.

In the late 1990s, workers at the factory began getting unusually sick. After about a year and a half on the job, some of them developed what they thought was asthma, or a very bad cold, or maybe influenza. Eventually, Dr. Allen Parmet diagnosed one after another of them with a rare and irreversible disease: bronchiolitis obliterans. Though questions of causation can rarely be answered with absolute certainty, many scientists believe that the chemical which gives popcorn its buttery flavor—diacetyl—is the reason for the workers' illness.

This paper is intended to provide an overview of what has happened over the past decade in response to a condition now commonly known as "popcorn lung." The case study will proceed in chronological order, outlining the symptoms of the disease, the science surrounding diacetyl, and attempts to regulate the chemical through administrative action, litigation, and legislation. Next, the article will analyze the various regulatory vectors to arrive at three core conclusions: (1) the media may wield the greatest ability to compel regulation, (2) "regulation by litigation" has both direct and indirect force, and (3) tort reform may be necessary in light of the civil justice system's imperfect response to even minor toxic tort situations. No tale of toxic harms has ever had a happy ending, but perhaps the story of popcorn lung can teach us something about the regulation of toxins that will help us deal more effectively with similar public health crises in the future.

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II.

AN INTRODUCTION TO BRONCHIOLITIS OBLITERANS:

“TAKE FOUR BULLDOZERS AND PUT THEM ON YOUR CHEST. THEN PUT AN ELEPHANT ON TOP OF THOSE BULLDOZERS.”

Bronchiolitis obliterans, first described in 1835, is the medical name for a disease which results in “functional obstruction of bronchioles.”¹ Normally, when air enters the lungs, it passes first through the bronchi, then into smaller branches called bronchioles, and finally into circular sacs called alveoli where oxygen and carbon dioxide are exchanged. Less than one millimeter in diameter, the bronchioles do not have supporting cartilage rings, making them more susceptible to collapse than the bronchi.² Their inflammation, known as bronchiolitis, can manifest itself in a variety of symptoms.³ In the case of bronchiolitis obliterans, “the clinical consequence of this injury and inflammation is irreversible airway obstruction.”⁴

A variety of conditions have been identified as probable causes of bronchiolitis obliterans, and many of them give rise to different versions of the disease. Development of bronchiolitis obliterans has been associated with toxic fume inhalation, mineral dust exposure, viral infection, bone marrow transplant, heart and lung transplantation, and several other conditions.⁵ Occupational exposure to “irritant gases,” such as oxides of nitrogen, chlorine, phosgene, ozone, hydrogen sulfide, sulfur dioxide, and various dusts, has also been associated with the symptoms of bronchiolitis.⁶

In its early stages, the disease appears “unremarkable”: patients typically present with a nonproductive cough or shortness of breath.⁷ As a result, bronchiolitis obliterans is often misdiagnosed. One study that examined nine cases of bronchiolitis obliterans in patients who worked at the Jasper, Missouri, popcorn plant found that not a single one was diagnosed with bronchiolitis obliterans upon first visiting a doctor.⁸ Common diagnoses included pneumonia, asthma, emphysema, bronchitis, chronic obstructive pulmonary disease (COPD), hay fever, and sinusitis.⁹ Although the condition stabilizes once the irritant is removed, the damage

1. 1 MURRAY & NADEL'S TEXTBOOK OF RESPIRATORY MEDICINE 1297 (Robert J. Mason, V. Courtney Broaddus, John F. Murray & Jay A. Nadel eds., 4th ed. 2005) [hereinafter MURRAY & NADEL'S].

2. *Id.* at 1295.

3. *Id.* at 1296.

4. E. Neil Schachter, *Popcorn Worker's Lung*, 347 NEW ENG. J. MED. 360, 360 (2002).

5. MURRAY & NADEL'S, *supra* note 1, at 1297–1300.

6. Schachter, *supra* note 4, at 360.

7. MURRAY & NADEL'S, *supra* note 1, at 1297.

8. M. Akpinar-Elci, W. D. Travis, D. A. Lynch & K. Kreiss, *Bronchiolitis Obliterans Syndrome in Popcorn Production Plant Workers*, 24 EUR. RESPIRATORY J. 298, 300 (2004).

9. *Id.*

caused by bronchiolitis obliterans is permanent.¹⁰ Corticosteroids may be useful in treating patients who are diagnosed early,¹¹ but after the disease advances beyond its early stages, the only treatment is a lung transplant.¹² With a global shortage of organ donors, obtaining such a transplant is extremely difficult.¹³

The various legal, regulatory, and media responses to popcorn lung can best be understood only after examining the physical and emotional trauma associated with the disease. Eric Peoples had worked in the mixing room of the Jasper popcorn plant for approximately ten months when he developed a fever and chills.¹⁴ He was diagnosed first with pneumonia, then asthma, and finally bronchiolitis obliterans.¹⁵ Just twenty-seven years old, his lung capacity was reduced to eighteen percent of normal.¹⁶ He told a Congressional committee that the disease “has robbed me of my health, deprived my wife of a husband, and my children of a daddy.”¹⁷ He needs a double-lung transplant,¹⁸ but he told Congress that even if he gets one, the average recipient lives for only five years after the surgery.¹⁹

10. Dr. Cecile Rose, a pulmonologist and expert on bronchiolitis obliterans, stated in a Q&A with a reporter from the *Wall Street Journal*, “If [patients are] removed from exposure . . . the lung function usually stabilizes. It does not continue to deteriorate. But it does not respond to medical treatment and typically does not improve.” Jacob Goldstein, *Health Blog Q&A: Microwave Popcorn and Lung Disease*, WALL ST. J. ONLINE, Sept. 5, 2007, <http://blogs.wsj.com/health/2007/09/05/health-blog-qa-microwave-popcorn-and-lung-disease> (interview with Dr. Rose).

11. MURRAY & NADEL’S, *supra* note 1, at 1300.

12. Andrew Schneider, *Popcorn Supplier to Drop Toxic Chemical; Consumer’s Lung Disease May Be Linked to Flavoring*, SEATTLE POST-INTELLIGENCER, Sept. 5, 2007, at A1 (“The rare lung disease that Rose diagnosed in her patient—bronchiolitis obliterans—can cause death in severe cases. Lung transplants are the only hope that patients have.” Further, “In manufacturing plants, [diacetyl has] been linked to bronchiolitis obliterans—irreversible obstructive lung diseases—for which lung transplants are often the only way to survive.”). See also MURRAY & NADEL’S, *supra* note 1, at 1300.

13. David L. Kaserman, *Fifty Years of Organ Transplants: The Successes and the Failures*, 23 ISSUES L. & MED. 45, 49–53 (2007–2008). In 2003, doctors performed 1085 lung transplants, but the waiting list for lungs totaled 3970. *Id.* at 49, 52. The waiting list for a lung transplant has increased every year since at least 1988. *Id.* at 52. As a result, “The annual death toll [as a direct consequence of organ shortage] has now reached over 6,000 patients, which is over twice the number of lives lost in the tragic 9/11 attacks.” *Id.* at 53.

14. Stephen Labaton, *OSHA Leaves Worker Safety Largely in Hands of Industry*, N.Y. TIMES, Apr. 25, 2007, at A1.

15. *Id.*

16. *Id.*

17. *Have OSHA Standards Kept up with Workplace Hazards?: Hearing Before the Subcomm. on Workforce Protections of the H. Comm. on Education and Labor*, 110th Cong. (2007) [hereinafter Statement of Eric Peoples] (statement of Eric Peoples, former employee, Gilster-Mary Lee popcorn factory), available at <http://www.access.gpo.gov/congress/house/house06ch110.html>. See also YouTube.com, OSHA Hearing: Eric Peoples’ Testimony, <http://www.youtube.com/watch?v=xT1FYXFgLF4> (last visited Mar. 8, 2009) (video recording of Mr. Peoples’s statement before the House Subcommittee).

18. Labaton, *supra* note 14.

19. Statement of Eric Peoples, *supra* note 17, at 10.

For workers afflicted with popcorn lung, perhaps the cruelest symptom is a severely reduced ability to breathe. Gerald Morgan worked with Eric Peoples at the Jasper plant. He now requires breathing assistance twenty-four hours per day.²⁰ "I've got oxygen tubes stuffed up my nose all the time," he told the *Kansas City Star*. "You don't get enough oxygen to do anything. I hardly leave my house anymore."²¹ Keith Campbell became ill after two years of working at a microwave popcorn factory in Marion, Ohio. When he was just forty-four, doctors told him that he had the lung capacity of an eighty-year-old.²² Barbara Materna, chief of the occupational health branch in the California Department of Health Services, summarized the disease and its ramifications: "The airways to the lung have been eaten up. . . . [Those with the disease] can't work anymore, and they can't walk a short distance without severe shortness of breath."²³

The condition of those who suffer from bronchiolitis obliterans is sometimes tragic. Irma Ortiz was supposed to wear a disposable face mask while mixing flavors at work, but eventually could not keep the mask on because her nose would run and she coughed continuously.²⁴ Once called a roadrunner for her speed in the workplace, she cannot finish a sentence without "panting phrases as if she were hiking a steep hill."²⁵ A life-long non-smoker, "she does not like to be in public because long, body-shaking coughing fits could overcome her at any time."²⁶ Hal Woods, who worked in Jasper, had to keep plastic bags tied around his hands and filled with "a Vaseline-like jelly to keep his skin from falling off."²⁷ According to his stepson, "Two- and three-inch chunks of skin were just peeling off."²⁸ Gerald Morgan described his breathing troubles to a reporter from the *Kansas City Star*: "Take four bulldozers and put them on your chest. Then put an elephant on top of those bulldozers."²⁹ With such quotidian characters and such gruesome facts, it is little wonder that this story would eventually find its way onto the nationally televised morning talk shows and the covers of major newspapers. It was only a matter of time.

20. Steve Rock, *Popcorn Plant Lawsuits Winding Down*, KAN. CITY STAR, Nov. 24, 2005, at B1.

21. *Id.*

22. Labaton, *supra* note 14.

23. Jesse McKinley, *Flavoring-Factory Illnesses Raise Inquiries*, N.Y. TIMES, May 6, 2007, § 1 (Late Edition), at 33.

24. Sonya Geis, *Flavoring Suspected in Illness; Calif. Considers Banning Chemical Used in Microwave Popcorn*, WASH. POST, May 7, 2007, at A03.

25. *Id.*

26. *Id.*

27. Stephanie Armour, *Special Report: Is Butter Flavoring Ruining Popcorn Workers' Lungs?*, USA TODAY, June 20, 2002, at A01 (telling the story of popcorn lung from 1999 through mid-2002).

28. *Id.*

29. Rock, *supra* note 20.

III.

DIACETYL AND THE PROBLEM OF CAUSATION:

“THE MOST DRAMATIC CASE OF CELL DEATH EVER SEEN.”

It did not take long for the scientific community to conclude that the cluster of bronchiolitis obliterans found in Jasper, Missouri, was caused by something in the factory of the Gilster-Mary Lee Corporation. Dr. Allen Parmet, who treated some of the Jasper workers, asked the Missouri Department of Health to investigate the factory in early 2000, just one year after Eric Peoples’s diagnosis.³⁰ By March 2002, the *Journal of Occupational and Environmental Medicine* published a letter to the editor that Dr. Parmet co-authored. The letter concludes:

The relative risk of a few former employees out of a total of approximately 400 is much higher than would be expected for the occurrence of bronchiolitis obliterans in the general population, which has been estimated to be between 1:40,000 and 1:100,000. The effect seems to be seen only in the current and former employees of a popcorn packaging facility and not in the general population of the surrounding county. . . . We believe these cases represent a new and potentially lethal occupational pulmonary disease, Popcorn Packers’ Workers’ Lung.³¹

Stating that the cause of the disease was occupational was relatively easy; determining what within the factory specifically caused the workers’ illness, however, would prove more difficult.

The problem lay in the fact that popcorn production plants and other facilities that use diacetyl are polluted by dozens of chemical compounds whose effects on the respiratory system are largely unknown. One study published in the *New England Journal of Medicine* indicated that “more than 100 volatile organic compounds” were found in air samples from the mixing room of the Jasper plant.³² None of them was known to cause bronchiolitis obliterans.³³ Partly because diacetyl was the predominant

30. Sara Shipley, *Snack Food: Is It Hurting Workers Who Make It?*, ST. LOUIS POST-DISPATCH, Apr. 4, 2004, at A1.

31. A. J. Parmet & Susanna Von Essen, Letter to the Editor, *Rapidly Progressive, Fixed Airway Obstructive Disease in Popcorn Workers: A New Occupational Pulmonary Illness?*, 44 J. OCCUPATIONAL & ENVTL. MED. 216 (2002).

32. Kathleen Kreiss, Ahmed Gomaa, Greg Kullman, Kathleen Fedan, Eduardo J. Simoes & Paul L. Enright, *Clinical Bronchiolitis Obliterans in Workers at a Microwave-Popcorn Plant*, 347 NEW ENG. J. MED. 330, 330 (2002). Kreiss conducted this study in her capacity as chief of the field studies branch at the National Institute for Occupational Safety and Health (NIOSH) Division of Respiratory Disease Studies in Morgantown, West Virginia.

33. *Id.* at 330–31.

compound found in the air samples,³⁴ and partly because a new butter flavoring that contained diacetyl was introduced to the plant in 1993,³⁵ scientists turned towards diacetyl in the hopes of finding a link to bronchiolitis obliterans.³⁶

Diacetyl is a naturally occurring substance found in beer, butter, cheese, coffee, fruit, and other foods.³⁷ Formally known as 2,3-butanedione, diacetyl is a ketone, appears as a yellow vapor, and has a “pungent odor.”³⁸ It is commonly used to flavor foods³⁹ and is listed as “generally recognized as safe” by the U.S. Food and Drug Administration (FDA).⁴⁰ Most manufacturers of popcorn used diacetyl to mimic the flavor of butter,⁴¹ and according to the testimony of Eric Peoples, the Jasper plant used more than three times the amount of diacetyl found in most butter flavors.⁴²

Concerns about the safety of diacetyl are neither new nor limited solely to the context of popcorn plants. According to Dr. David Egilman, an associate professor at Brown University specializing in community health and an expert for litigants harmed in popcorn manufacturing plants, diacetyl has been suspected of causing illnesses since the mid-1970s.⁴³ “There’s lots of cases where this chemical is the only consistent factor,” he told a reporter.⁴⁴ And since diacetyl is used so widely as an artificial flavor, concern is not limited to the popcorn industry.⁴⁵ In fact, the

34. *Id.* at 331.

35. *Jasper County Jury Awards \$15M to Former Popcorn Plant Maintenance Man and His Wife*, MO. LAWYERS WEEKLY, Apr. 18, 2005.

36. Schachter, *supra* note 4, at 360.

37. Labaton, *supra* note 14; OCCUPATIONAL SAFETY & HEALTH ADMIN., U.S. DEP’T OF LABOR, DIACETYL (2006), <http://www.osha.gov/dts/sltc/methods/partial/t-pv2118/t-v2118.html>.

38. William Atkins, *Artificial Butter Flavorings Produced in Popcorn Factories Linked with Lung Cancer*, ITWIRE, May 8, 2007, <http://www.itwire.com/content/view/11913/1066/>.

39. Labaton, *supra* note 14.

40. 21 C.F.R. § 184.1278 (2008). Diacetyl obtained “generally recognized as safe” (GRAS) status in 1983, and despite requests that the FDA revoke it, *see infra* text accompanying notes 201, 236, the chemical retains its GRAS classification as of April 2008. *Id.*

41. *Four Popcorn Makers to Drop Toxic Chemical*, MSNBC.COM, Sept. 5, 2007, <http://www.msnbc.msn.com/id/20605135/>.

42. Statement of Eric Peoples, *supra* note 17, at 9 (stating that many butter flavors contain “about 3% diacetyl,” whereas the Jasper plant’s “butter flavor contained 10%”).

43. McKinley, *supra* note 23.

44. *Id.*

45. *See* DAVID MICHAELS, CHRISSY MORGAN & CELESTE MONFORTON, PROJECT ON SCIENTIFIC KNOWLEDGE AND PUBLIC POLICY (SKAPP), A CASE OF REGULATORY FAILURE: POPCORN WORKERS LUNG, http://defendingscience.org/case_studies/A-Case-of-Regulatory-Failure-Popcorn-Workers-Lung.cfm [hereinafter SKAPP Case Study] (last visited Mar. 8, 2009). The Project on Scientific Knowledge and Public Policy is an organization that “examines the nature of science and how it is used and misused in government decision-making and legal proceedings.” DefendingScience.org, About Us, <http://defendingscience.org/About-Us.cfm> (last visited Mar. 8, 2009). Prior funding for the

California Department of Health Services reported a case of bronchiolitis obliterans in a worker who was mixing flavors to be used in dog food.⁴⁶ Despite the chemical's heavy use as an artificial flavor, Dr. Parmet stated as recently as April 2006 that much about diacetyl remains unknown: "There must be a safe level. We don't know what it is."⁴⁷

Various scientific studies suggest that diacetyl is the cause of bronchiolitis obliterans, but none state this conclusively. The leading study of the Jasper employees' respiratory ailments found that workers in the mixing room faced, on average, levels of diacetyl that were 800 times greater than those encountered by a minimally exposed group of people who worked outside the production area.⁴⁸ The study also found that "[t]he prevalence of airway obstruction increased with increasing cumulative exposure to diacetyl."⁴⁹ Nonetheless, the authors concluded only that "diacetyl *may be* a cause of respiratory disease *or a marker* of the causative exposures in this population,"⁵⁰ and that "the butter flavoring is *a biologically plausible cause* of the respiratory effects."⁵¹ While the data was strong enough to "support the conclusion that an agent in butter flavoring caused occupational bronchiolitis obliterans," the authors noted that "many questions remain about the specific agents involved and about safe and unsafe levels of exposure."⁵²

More recent studies arrived at similar conclusions. Scientists in the Netherlands examined a group of workers employed by a diacetyl production plant in Europe between 1960 and 2003.⁵³ Three out of 175 workers (and at least 4 out of 206) suffered from bronchiolitis obliterans, confirming the researchers' hypothesis that they would find a cluster of cases of bronchiolitis obliterans linked to the diacetyl plant.⁵⁴ Nonetheless, it was impossible to conclude that diacetyl, and not one of the several other chemicals involved in its production, was the cause of the disease.

Project derived in part from a trust established pursuant to a court order in the Silicone Gel Breast Implant Products Liability litigation. *Id.*

46. SKAPP Case Study, *supra* note 45.

47. JoplinIndependent.com, How Safe Is Handling Buttered Popcorn? (2006), http://www.joplinindependent.com/display_article.php/mariwinn1145826205.

48. Kreiss, Goma, Kullman, Fedan, Simoes & Enright, *supra* note 32, at 331.

49. *Id.* at 333.

50. *Id.* at 336 (emphasis added).

51. *Id.* at 337 (emphasis added).

52. *Id.*

53. Frits G. B. G. J. van Rooy, Jos M. Rooyackers, Mathias Prokop, Remko Houba, Lidwien A. M. Smit & Dick J. J. Heederik, *Bronchiolitis Obliterans Syndrome in Chemical Workers Producing Diacetyl for Food Flavorings*, 176 AM. J. RESPIRATORY & CRITICAL CARE MED. 498, 498 (2007).

54. *Id.* at 498, 502. It is likely that the statistics cited above under-represent the number of workers with bronchiolitis obliterans because the study did not investigate the lung function of the ten individuals who were deceased at the time of the study. *Id.* at 503. All of the workers at the European plant were exposed to similar levels of diacetyl as their counterparts in Jasper, Missouri. *Id.*

The authors echoed the Kreiss study: “[D]iacetyl may either be a cause of respiratory disease or a marker of another causative exposure. . . . [O]ur study suggests a causal role of diacetyl. However, we cannot rule out a possible contribution of acetoin or even acetaldehyde, either as causative or contributing agents.”⁵⁵

In light of the equivocation in her previous study, Dr. Kreiss’s response is worth noting here. Writing explicitly in her personal capacity—and not as a National Institute for Occupational Safety and Health (NIOSH)⁵⁶ representative—Kreiss provided a warning and a conclusion: “[A]ny uncertainty regarding cause impedes preventative action. For the association between diacetyl and fixed obstructive lung disease, many criteria for causal inference have been fulfilled.”⁵⁷ She added that since the van Rooy study “limits the candidates for new regulation to diacetyl and acetoin,” and since diacetyl “is the more reactive, volatile, and concentrated . . . its control makes good sense.”⁵⁸

Animal tests support the conclusion that exposure to diacetyl may be harmful to the lungs. In 1993, German chemical manufacturer BASF conducted a study in which it exposed rats to diacetyl for a single four-hour period.⁵⁹ The results, which were never published, revealed an “abundance of symptoms indicative for respiratory tract injury.”⁶⁰ Eight years after the BASF study, NIOSH conducted a similar test, exposing rats to diacetyl vapors for a single six-hour period.⁶¹ After subjecting the animals to levels of diacetyl that were “not extraordinary when compared with levels measured in the workplace,”⁶² lead researcher Dr. Ann Hubbs reported that the findings represented “the most dramatic case of cell

55. *Id.*

56. NIOSH is a federal agency charged with conducting research and issuing recommendations relating to worker safety and illness. *About NIOSH*, <http://www.cdc.gov/niosh/about.html> (last visited Mar. 8, 2009). It is under the umbrella of the Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services. *Id.*

57. Kathleen Kreiss, *Occupational Bronchiolitis Obliterans Masquerading as COPD*, 176 AM. J. RESPIRATORY & CRITICAL CARE MED. 427, 428 (2007).

58. *Id.*

59. BASF, STUDY ON THE ACUTE INHALATION TOXICITY OF DIACETYL FCC AS A VAPOR IN RATS: 4-HOUR EXPOSURE 1 (1993), *available at* http://www.defendingscience.org/case_studies/upload/BASF-Study.pdf.

60. *Id.*

61. For a brief description, see David Michaels & Celeste Monforton, *Scientific Evidence in the Regulatory System: Manufacturing Uncertainty and the Demise of the Formal Regulatory System*, 13 J.L. & POL’Y 17, 20 (2005).

62. A. F. Hubbs, L. A. Battelli, W. T. Goldsmith, D. W. Porter, D. Frazer, S. Friend, D. Schwegler-Berry, R. R. Mercer, J. S. Reynolds, A. Grote, V. Castranova, G. Kullman, J. S. Fedan, J. Dowdy & W. G. Jones, *Necrosis of Nasal and Airway Epithelium in Rats Inhaling Vapors of Artificial Butter Flavoring*, 185 TOXICOLOGY & APPLIED PHARMACOLOGY 128, 134 (2002).

death ever seen” in experiments of this nature.⁶³ Another study exposed guinea pigs to diacetyl and revealed adverse effects to respiratory tissue and structure.⁶⁴

IV.

CALLS FOR REGULATION:

“THE SCIENCE IS MURKY.”

As dozens of workers fell sick with respiratory conditions and scientists scrambled to conduct studies, a chorus of interest groups and individuals implored the government to regulate diacetyl. Although a handful of government entities could potentially regulate diacetyl, the Occupational Safety and Health Administration (OSHA) is the federal agency directly responsible for responding to workplace harms and safety risks. Created in 1970 by the Occupational Health and Safety Act,⁶⁵ OSHA has the authority to establish and enforce standards relating to health and safety in the workplace. When acting in the areas of “toxic materials or harmful physical agents,” OSHA

shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.⁶⁶

The agency nevertheless retains broad discretion to set standards.⁶⁷ OSHA is also authorized to inspect and investigate workplaces,⁶⁸ and must do so in response to citizen petitions if the Secretary “determines there are reasonable grounds” to believe “that a violation of a safety or health standard exists that threatens physical harm, or that an imminent danger exists.”⁶⁹ Under the “general duty clause,”⁷⁰ employers are required to not only comply with all rules promulgated by OSHA, but also to provide workplaces that are “free from recognized hazards that are causing or are

63. Sara Shipley, *Study Showed Chemical Was Toxic*, ST. LOUIS POST-DISPATCH, Feb. 29, 2004, at C1.

64. See Letter from David Michaels, Professor, George Washington Univ. Sch. of Pub. Health, to Elaine L. Chao, U.S. Sec’y of Labor (July 26, 2006), *available at* <http://defendingscience.org/upload/Scientists%20Letter%20to%20OSHA%20on%20Diacetyl07262006.pdf>.

65. 84 Stat. 1590 (1970) (codified as amended 29 U.S.C. § 655).

66. 29 U.S.C. § 655 (b)(5)(2008).

67. § 655(b) (“The Secretary may by rule promulgate . . . any . . . standard, (1) Whenever the Secretary . . . determines that a rule should be promulgated in order to serve the objectives of this chapter.”).

68. § 657.

69. § 657 (f)(1).

70. § 654.

likely to cause death or serious physical harm.”⁷¹ To assist OSHA, NIOSH conducts research with the ultimate goal of developing “recommended occupational safety and health standards.”⁷²

With this regulatory framework as a backdrop, it was inevitable that OSHA and NIOSH would quickly become involved in the events taking place in southwestern Missouri. After discovering the Jasper cluster of bronchiolitis obliterans cases, Dr. Parmet notified the Missouri Department of Health (MDOH), which contacted OSHA, the Centers for Disease Control (CDC), and NIOSH.⁷³ In a letter dated May 19, 2000, MDOH requested that OSHA visit Jasper and inspect the Gilster-Mary Lee factory: “As a regulatory agency, we believe that you can more promptly address this situation, and if there is an obvious hazard to workers, address it quickly.”⁷⁴ Four months later, OSHA sent an inspector to the plant. He noted that the plant’s insurance carrier had sampled the air for dust four years earlier,⁷⁵ and thus it was his “professional opinion that it would be ludicrous to re-sample the area again.”⁷⁶ Oil samples that the inspector took were discarded by the OSHA lab because they were not obtained using the proper method for collecting vegetable oils.⁷⁷ The inspector “determined the company to be in compliance [sic] and closed out the casefile [sic].”⁷⁸

By contrast, NIOSH researchers quickly descended on Jasper, Missouri, to thoroughly investigate the plant and the health of the people who worked within it. The agency’s findings, eventually published in the *New England Journal of Medicine*, revealed that many of the factory workers suffered from respiratory ailments and implicated diacetyl as a cause.⁷⁹ In December 2000, NIOSH issued interim recommendations prescribing that workers wear respirators until engineering controls could be put in place to eradicate workers’ exposure to the artificial butter flavoring.⁸⁰ The agency worked closely with the factory to implement

71. § 654 (a)(1).

72. § 671 (c)(1).

73. Michaels & Monforton, *supra* note 61, at 19; Shipley, *Snack Food*, *supra* note 30.

74. Letter from Daryl W. Roberts, Dir., Section for Env'tl. Pub. Health, MDOH, to Matt Gaines, OSHA (May 19, 2000), *available at* http://defendingscience.org/case_studies/upload/Roberts-Letter.pdf.

75. *See* Michaels & Monforton, *supra* note 61, at 22–23 n.34 (citing Letter from Mike Freshwater, CIH, Senior Env'tl. Health Eng'r, WAUSAU, to Jim Cook, Jasper Foods, Inc. (May 10, 1996)).

76. OCCUPATIONAL SAFETY & HEALTH ADMIN., INSPECTION NO. 303206387, INSPECTION REPORT 4 (2000), *available at* http://defendingscience.org/case_studies/upload/OSHA-Inspection-Report-2000.pdf.

77. *See id.*; Michaels & Monforton, *supra* note 61, at 23.

78. OCCUPATIONAL SAFETY & HEALTH ADMIN., INSPECTION NO. 303206387, *supra* note 76, at 4.

79. Kreiss, Gomaa, Kullman, Fedan, Simoes & Enright, *supra* note 32, at 336. *See supra* text accompanying notes 48–52.

80. SKAPP Case Study, *supra* note 45.

control mechanisms relating to diacetyl and impose physical changes to the structure of the plant.⁸¹ Nine months later, NIOSH distributed a warning to the workers: “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 recommended.”⁸²

The responses of OSHA and NIOSH continued along divergent paths for the next several years. An attorney from the Missouri firm of Humphrey, Farrington, McClain & Edgar, P.C.⁸³ had filed an OSHA complaint via the internet in September 2001 and contacted OSHA by letter in December 2001.⁸⁴ Stating that “one employee lost half of his lung capacity working in the plant *after* the remedial measures that NIOSH suggested were taken to improve the ventilation,” the attorney requested that an OSHA investigator visit the plant once again.⁸⁵ Just one day later, a second OSHA inspector arrived at the Jasper plant. He stayed for forty minutes and declined to conduct an inspection.⁸⁶ Perhaps this should come as no surprise: under George W. Bush, OSHA largely eschewed regulation in favor of a “voluntary compliance strategy,” partnering with big business.⁸⁷ Apparently, voluntary compliance did not call for aggressive inspections.

OSHA explained its short visit in a letter sent to the attorneys. For two reasons, it concluded that “no further investigation is warranted.”⁸⁸ First, OSHA claimed that “the hazard . . . has been corrected” and “Glister [sic] Mary Lee is complying with the recommendations of NIOSH.”⁸⁹ Second, the agency reasoned that “[t]he hazard does not fall within OSHA’s jurisdiction because there is no Permissible Exposure Limits for the food blend chemicals of concern that are used at the factory.”⁹⁰ This is somewhat circular logic, since OSHA is the regulatory body charged with setting Permissible Exposure Limits (PELs). In other words, OSHA maintained that since OSHA itself had never previously regulated diacetyl, OSHA could not now take any regulatory action.

81. *Id.*

82. Michaels & Monforton, *supra* note 61, at 19–20.

83. By the time of publication, the firm had changed its name to Humphrey, Farrington & McClain, P.C. See <http://www.hfmlegal.com/> (last visited Mar. 8, 2009).

84. Letter from Amy Powell, Humphrey, Farrington, McClain & Edgar, P.C., to Rick Roberts, Kansas City Area Office, OSHA (Dec. 19, 2001) (italics in original), *available at* http://defendingscience.org/case_studies/upload/Powell-Complaint-to-OSHA.pdf.

85. *Id.*

86. Michaels & Monforton, *supra* note 61, at 24.

87. Labaton, *supra* note 14.

88. See Letter from Manuel Olmedo, Area Dir., Kansas City Area Office, OSHA, to Humphrey, Farrington, McClain & Edgar, P.C. (Feb. 28, 2002), *available at* http://defendingscience.org/case_studies/upload/OSHA_2002_Olmedo_Letter_about_Gilster_Mary_Lee.pdf.

89. *Id.*

90. *Id.*

Meanwhile, NIOSH continued its efforts to study the effects of diacetyl. It measured exposure to butter flavoring vapors at ten microwave popcorn facilities across the country, conducted experiments on laboratory animals, and announced a concentration of diacetyl in air that it considered dangerous.⁹¹ In December 2003, the agency issued an alert to 4000 businesses that might use or make butter flavoring, providing an overview of the problem and offering a detailed list of recommendations.⁹² To this day, NIOSH is still studying respiratory conditions at flavoring factories as well as the link between diacetyl and bronchiolitis obliterans.⁹³

Aside from the academic and site-specific contributions of NIOSH, no federal agency took immediate action to regulate the use of diacetyl. OSHA did not move to set a Permissible Exposure Limit for diacetyl, nor did the agency undertake any real effort to assist workers whose health had been endangered or compromised due to their employment in flavoring factories, including popcorn plants.⁹⁴ Instead, OSHA teamed up with industry, signing a "partnership agreement" in September 2002 with the Popcorn Board, the trade association that represents popcorn manufacturers.⁹⁵ This "alliance" was supposed to enhance communication between OSHA and the manufacturers and permit the Popcorn Board to review and help draft a "Hazard Information Bulletin" that OSHA would distribute to its compliance officers in the field.⁹⁶ No bulletin was ever issued, and the partnership was terminated in March 2003.⁹⁷

There are several things that OSHA could have done if it were seeking to actively regulate diacetyl and protect workers. As Dr. David Michaels⁹⁸ and Dr. Celeste Monforton⁹⁹ explain in their article *Scientific Evidence in*

91. See SKAPP Case Study, *supra* note 45.

92. NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH, NIOSH ALERT: PREVENTING LUNG DISEASE IN WORKERS WHO USE OR MAKE FLAVORING (2003), <http://www.cdc.gov/niosh/docs/2004-110/>.

93. NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH, NIOSH SAFETY & HEALTH TOPIC: FLAVORINGS-RELATED LUNG DISEASE, <http://www.cdc.gov/niosh/topics/flavorings/> (last visited Mar. 8, 2009) ("NIOSH is continuing to evaluate new information pertaining to the risk of bronchiolitis obliterans from occupational exposures to flavorings, in order to determine appropriate further steps to help safeguard workers' health.").

94. See Letter from Manuel Olmedo, *supra* note 88; Labaton, *supra* note 14; Michaels & Monforton, *supra* note 61, at 29.

95. Michaels & Monforton, *supra* note 61, at 29.

96. See SKAPP Case Study, *supra* note 45.

97. *Id.*

98. Dr. Michaels served as Assistant Secretary of Environment, Safety, and Health in the Department of Energy in the Clinton administration and is Professor and Associate Chairman of the Department of Environmental and Occupational Health at the George Washington University School of Public Health and Health Services, as well as the Director of SKAPP. Michaels & Monforton, *supra* note 61, at 17; Project on Scientific Knowledge and Public Policy, Biography of David Michaels, <http://www.defendingscience.org/David-Michaels-bio.cfm> (last visited Mar. 8, 2009).

99. Dr. Celeste Monforton worked in OSHA and in the Mine Safety and Health Administration under President Clinton. Now at the George Washington University

the Regulatory System: Manufacturing Uncertainty and the Demise of the Formal Regulatory System, OSHA could have invoked the general duty clause, citing companies for their failure to “provide employees a place of employment that is free from recognized hazards that cause or are likely to cause death or serious physical harm.”¹⁰⁰ OSHA could also have initiated the process of regulating diacetyl based on a determination that regulation would “reduce or eliminate a ‘significant risk’” for workers.¹⁰¹ Michaels and Monforton suggest that OSHA could have promulgated a regulation provisionally prohibiting popcorn plants’ exposure of workers to all butter flavoring vapors or, alternatively, issued a standard to limit levels of diacetyl alone in all workplaces.¹⁰²

Instead, OSHA adopted a policy of non-regulation. Led by Edwin G. Foulke, Jr., who describes himself as a man who “firmly believes in limited government,” the agency charged with overseeing worker safety had imposed, as of April 2007, just one major safety rule, by the *New York Times*’ count, since George W. Bush took office.¹⁰³ By contrast, during the presidency of George H. W. Bush, OSHA issued eleven significant regulations to improve workplace safety.¹⁰⁴ Foulke’s “voluntary compliance strategy” has led OSHA to take a laissez-faire approach to diacetyl, even as the “body in the morgue” evidence continues to pile up.¹⁰⁵ Asked whether he thought that diacetyl causes bronchiolitis obliterans, Foulke told the *Times* that “the science is murky.”¹⁰⁶

V.

REGULATION BY LITIGATION:

“I’D RATHER HAVE MY HEALTH BACK.”

In the face of regulatory paralysis and scientific uncertainty came trial lawyers. Barred by workers’ compensation statutes¹⁰⁷ from suing popcorn production companies like the Gilster-Mary Lee Corporation, enterprising attorneys initiated lawsuits against the chemical companies that sold

School of Public Health and Health Services, she works as a lecturer and researcher and also conducts research for SKAPP. Project on Scientific Knowledge and Public Policy, SKAPP Staff, <http://www.defendingscience.org/SKAPP-Staff.cfm> (last visited Mar. 8, 2009).

100. Michaels & Monforton, *supra* note 61, at 24–25.

101. *Id.* at 25 (quoting Indus. Union Dep’t, *AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607, 639 (1980)).

102. *Id.* at 26–27.

103. Labaton, *supra* note 14. The *New York Times* noted that the single major safety rule was promulgated pursuant to a federal court order. *Id.*

104. *Id.*

105. *See id.*

106. *Id.*

107. The relevant statutory scheme in Missouri is MO. REV. STAT. §§ 287.010–.811 (2007).

diacetyl-rich butter flavoring.¹⁰⁸ A subsidiary of International Flavors and Fragrances, Inc. (IFF) Bush Boake Allen, Inc., sold butter flavoring to the Jasper, Missouri, popcorn plant.¹⁰⁹ With headquarters in New York and annual sales of more than two billion dollars, IFF claims to be the world's largest flavor and fragrance company.¹¹⁰ Among other claims to fame, the company has produced fragrances for Estée Lauder, Calvin Klein, Ralph Lauren, Emporio Armani, and many more.¹¹¹ But a Jasper County jury smelled a rat when attorneys for IFF insisted that their butter flavoring is safe when handled properly.¹¹² After a two-week trial¹¹³ and just over three hours of deliberation, they awarded Eric and Cassandra Peoples a verdict of twenty million dollars.¹¹⁴

The Peoples case represented just the first in a series of dominoes that would fall in the litigation against IFF. After a wave of publicity surrounding the Peoples verdict, Jasper County Circuit Judge William Crawford instituted a gag order for the popcorn workers' cases that he oversaw.¹¹⁵ But jury after jury found for the plaintiffs. Verdicts from four of the first eight cases to reach trial totaled \$52.7 million.¹¹⁶ Of the other four cases that went to trial before November 2005, three were settled for undisclosed amounts. The single judgment for IFF was overturned due to juror misconduct, and the parties eventually settled.¹¹⁷ All of these cases were initiated and resolved between 2004 and 2005.

Somewhat ironically, the litigation in Jasper proceeded according to a plan that neither side had hoped for at the outset. The plaintiffs had filed a single class action lawsuit, but two months before trial, the court determined that they had not properly sought class certification.¹¹⁸ After

108. On October 4, 2001, the *New York Times* reported that sixteen current and former employees had filed claims for workers' compensation with Gilster and had brought a putative class action against the chemical manufacturer. Based on an interview with an attorney for the plaintiffs, the *Times* reported that "Gilster-Mary Lee has denied liability and until recently also denied benefits," suggesting that the company *stopped* denying benefits. Philip J. Hilts, *Artificial Butter Suspected in Lung Disease*, N.Y. TIMES, Oct. 4, 2001, at A20.

109. Statement of Eric Peoples, *supra* note 17, at 9.

110. Int'l Flavors & Fragrances, Inc., Fact Sheet, <http://www.iff.com/internet.nsf/FactSheet!OpenForm> (last visited Mar. 8, 2009).

111. *Id.*

112. *See Popcorn Lung Victim Wins Suit; Jury Slaps Makers of Flavoring with \$20 Million Penalty*, CHI. TRIB., Mar. 16, 2004, at 10.

113. Labaton, *supra* note 14.

114. *Popcorn Lung Victim Wins Suit*, *supra* note 112.

115. *Jasper County Jury Awards \$15M*, *supra* note 35.

116. *19 More Plaintiffs Settle with Butter Flavoring Manufacturer*, MO. LAWYERS WEEKLY, Nov. 14, 2005.

117. *Id.*

118. *See Int'l Flavors & Fragrances, Inc. v. Valley Forge Ins. Co.*, 738 N.W.2d 159, 161 (Wis. Ct. App. 2007) (describing the litigation in Jasper in the course of resolving an insurance dispute between IFF and its insurers).

severing the claims of each worker, the court assigned a docket number to each case.¹¹⁹ Ignoring IFF's insistence that it had yet to conclude discovery, the court denied the defendant's request for a continuance and retained the initial trial schedule for the Peoples case.¹²⁰ Two months later, Eric and Cassandra Peoples walked out of the Jasper County courthouse with a twenty million dollar verdict.¹²¹

At trial, arguments for the plaintiffs were relatively straightforward. They summoned two doctors to the stand who drew connections between the plaintiffs' lung conditions and their workplace.¹²² The plaintiffs maintained that IFF "failed to give instructions on safe use of the products"¹²³ and failed to warn the Jasper plant that the flavoring was hazardous.¹²⁴ They insisted that their illnesses were caused by exposure to chemicals in the butter flavoring.¹²⁵ Their final expert was an economist, whose role was likely to provide the jury with an objective measure of the plaintiffs' economic harm, and therefore translate physical and psychological pain into pecuniary gain.¹²⁶ And it is likely that they were able to introduce evidence alluded to by Dr. Parmet in his speech at Missouri Southern State University: while IFF required its own employees to wear full respirators while handling the flavoring, the company distributed its product with a label indicating that it was "irritating."¹²⁷ After 2004, new labels on the product read "lethal."¹²⁸

There can be little doubt that the plaintiffs' attorneys played on the emotional strings of the jurors. During the trial, the Peoples's attorney, Ken McClain, stated, "'Eric feels like he's in prison.'"¹²⁹ Referring to all popcorn plaintiffs, McClain has said, "'The only thing this group of people ever did wrong was go to work.'"¹³⁰ By focusing on the plaintiffs' injuries and the defendants' questionable conduct, attorneys for the plaintiffs were able to construct a narrative that made jurors more willing to find a link between diacetyl and bronchiolitis obliterans. Indeed, proving causation would seem to be the most difficult aspect of plaintiffs' case: under tort law, a plaintiff must demonstrate that the defendant was both the "factual cause" and the "proximate cause" of the injuries. In court, plaintiffs had

119. *See id.*

120. *See id.*

121. Rock, *supra* note 20.

122. *See 19 More Plaintiffs Settle*, *supra* note 116 (listing expert witnesses called in the case).

123. Rock, *supra* note 20.

124. *\$20 Million Awarded in Popcorn Lawsuit*, MSNBC.COM, Mar. 15, 2004, <http://www.msnbc.msn.com/id/4536217/>.

125. *Id.*

126. *See 19 More Plaintiffs Settle*, *supra* note 116.

127. *See JoplinIndependent.com*, *supra* note 47.

128. *See id.*

129. *Popcorn Lung Victim Wins Suit*, *supra* note 112.

130. Shipley, *Study Showed Chemical Was Toxic*, *supra* note 63.

the burden of showing that their lung problems would not have developed absent exposure to diacetyl¹³¹ and that their disease was a foreseeable risk that rendered defendants' conduct negligent.¹³² Although they bore the burdens of production and persuasion, the plaintiffs only needed to prove causation under the usual "more likely than not" preponderance standard applied in civil cases.

There is no public record of Eric Peoples's testimony at trial, but in his testimony before Congress, he summarized the case against IFF. Wearing oxygen tubes in his nose,¹³³ Peoples stated that Bush Boake Allen, a subsidiary of IFF responsible for supplying the flavoring, knew of the hazards of the flavoring and treated it accordingly at its own plant: workers near the butter flavoring frequently suffered severe injuries, even though they were required to wear full-face respirators, and the company eventually enclosed the entire manufacturing process so that the vapors could not reach anyone.¹³⁴ Peoples also testified that IFF knew about the BASF study as early as 1994 and that BASF had provided IFF with a Material Safety Data Sheet (MSDS) describing the severe respiratory problems observed in rats exposed to diacetyl.¹³⁵ Nonetheless, IFF's own MSDS, which was visible to workers, claimed that the product posed "no known health hazards."¹³⁶ Peoples suggested that the entire flavoring industry was aware of cases of bronchiolitis obliterans, and was exploiting workers as "blue collar guinea pigs."¹³⁷

Counsel for IFF was forced to make more technical arguments in the Peoples case. Their list of experts included an industrial hygienist, a toxicologist, and a pulmonologist.¹³⁸ IFF argued that diacetyl was not the cause of Peoples's disease, and that even if it were, his illness was due to Gilster-Mary Lee's mishandling of the chemical.¹³⁹ The company claimed that information sent to plant directors in Jasper warned that the flavoring should be mixed in a well-ventilated area and advised workers to wear respirators while heating it.¹⁴⁰ "We know beyond a shadow of doubt that if you use basic hygiene practices, you don't have a problem in this plant," stated the IFF attorney in his closing arguments.¹⁴¹ In another Jasper

131. See RESTATEMENT (THIRD) OF TORTS (Draft) § 26. See also *id.* § 28 (describing the burden on the plaintiff).

132. See *id.* § 29.

133. See YouTube.com, OSHA Hearing: Eric Peoples' Testimony, *supra* note 17.

134. Statement of Eric Peoples, *supra* note 17.

135. *Id.*

136. *Id.*

137. *Id.* Peoples stated that he was quoting a doctor who had treated workers with bronchiolitis obliterans in 1990.

138. See *19 More Plaintiffs Settle*, *supra* note 116 (listing expert witnesses called in the case).

139. Labaton, *supra* note 14.

140. *\$20 Million Awarded in Popcorn Lawsuit*, *supra* note 124.

141. *Id.*

worker's case, IFF contested whether diacetyl caused the plaintiff's bronchiolitis obliterans and maintained that the maintenance worker plaintiff, Richard Brand, began showing symptoms of lung disease before the butter flavoring was introduced to the Jasper plant in May 1993.¹⁴² Juries found IFF's arguments unpersuasive in both cases.¹⁴³

In the wake of so many verdicts against it, IFF pursued an aggressive settlement policy. By November 2005, the company had settled with fifty-four of the Jasper popcorn plant workers.¹⁴⁴ And although IFF appealed each of the initial verdicts,¹⁴⁵ the company ultimately settled every case that the court had severed from the original class action,¹⁴⁶ including the Peoples case.¹⁴⁷ One commentator suggests that IFF has paid over one hundred million dollars to resolve the diacetyl cases,¹⁴⁸ and that figure may not include undisclosed settlements. Whatever the sum, it is not enough to satisfy all plaintiffs; as Gerald Morgan told a local reporter, "I'd rather have my health back."¹⁴⁹

The litigation surrounding diacetyl has not been confined to the Jasper plaintiffs and IFF. Humphrey, Farrington & McClain, P.C., which successfully represented many of the Jasper workers, has tried or settled over 100 cases involving diacetyl and other chemical flavorings and had over 500 more diacetyl cases pending across Illinois, Indiana, Iowa, Maryland, Missouri, and Ohio as of April 2007.¹⁵⁰ In addition, workers recently filed a case in California against the Flavor and Extract Manufacturers Association (FEMA), charging that it "actively concealed adverse toxicity data regarding diacetyl and other flavoring chemicals, as well as several cases of bronchiolitis obliterans in flavorings workers."¹⁵¹ And a federal court in Missouri remanded a case that had been improperly removed from state court involving *eleven* defendants.¹⁵² Still, it appears that by the end of 2007, no case involving occupational bronchiolitis obliterans had proceeded to trial aside from those in Jasper, Missouri.¹⁵³

142. *Jasper County Jury Awards \$15M*, *supra* note 35.

143. *See 19 More Plaintiffs Settle*, *supra* note 116 (listing the amounts that juries awarded the Peoples and Brand plaintiffs).

144. Rock, *supra* note 20.

145. *Id.*

146. *See* Int'l Flavors & Fragrances, Annual Report (Form 10-K), at 10 (Feb. 22, 2007), *available at* <http://www.secinfo.com/dsvrn.u1Zy.htm>.

147. Labaton, *supra* note 14.

148. SKAPP Case Study, *supra* note 45.

149. Rock, *supra* note 20.

150. Labaton, *supra* note 14.

151. *See Workers' Suit Claims Flavor Industry Hid Diacetyl Dangers from OSHA*, *INSIDE OSHA*, Nov. 12, 2007.

152. *Bowling v. Kerry, Inc.*, 406 F. Supp. 2d 1057, 1059 (E.D. Mo. 2005) (denying the defendants' efforts to remove the case to federal court based on a claim of diversity jurisdiction).

153. *See* Int'l Flavors & Fragrances, *supra* note 146, at 10–11 (listing two additional cases brought against IFF by workers from the Jasper plant as well as fifteen other cases

Nor have plaintiffs limited their legal theories to negligence, strict products liability, and loss of consortium. In a series of claims rejected by the U.S. District Court for the Northern District of Iowa, plaintiffs alleged that companies involved in the sale of diacetyl-based flavoring were engaged in civil conspiracy and fraudulent concealment.¹⁵⁴ One complaint charged that three companies¹⁵⁵ agreed to “affirmatively conceal known hazards of [their] butter flavorings by providing anti-warnings stating that their butter flavorings were safe.”¹⁵⁶ The court permitted plaintiffs’ claims for negligence and loss of consortium to proceed but granted defendants’ motion to dismiss the other claims, finding that plaintiffs failed to plead fraud with the particularity required by Federal Rule of Civil Procedure 9(b).¹⁵⁷ Shortly thereafter, IFF settled with the plaintiffs.¹⁵⁸ The court subsequently rejected the remaining defendants’ summary judgment motion relating to the surviving causes of action.¹⁵⁹

A recent case provides an interesting look at IFF’s post-Jasper strategy. John Weimer, Jr. worked at the Snappy Popcorn Company’s microwave popcorn factory in Breda, Iowa, which used butter flavoring supplied by IFF.¹⁶⁰ Faced with another lawsuit from Humphrey, Farrington & McClain, the flavoring conglomerate moved to bifurcate the trial into a liability phase and a punitive damages phase. Only if the jury found IFF liable, awarded compensatory damages, and determined that punitive damages were appropriate would the trial proceed to a second phase for calculation of punitive damages. IFF argued that without bifurcation, the company would suffer prejudice upon the jury hearing evidence of IFF’s finances.¹⁶¹ The court disagreed, placing faith in jurors to follow instructions relating to compensatory and punitive awards and finding no clear prejudice to IFF.¹⁶² Not surprisingly, the case settled one week before trial.¹⁶³

brought against IFF by workers from other flavoring plants around the country, none of which had gone to trial as of the end of 2007).

154. See *Kuiper v. Int’l Flavors & Fragrances, Inc.*, 240 F.R.D. 438, 440 (N.D. Iowa 2007); *Remmes v. Int’l Flavors & Fragrances, Inc.*, 453 F. Supp. 2d 1058, 1060 (N.D. Iowa 2006).

155. The companies are IFF, Givaudan Flavors Corp., and Sensient Flavors, Inc. *Kuiper*, 240 F.R.D. at 442–43, 445 (citing complaint). The complaint also accused defendants Flavors of North America, Inc., the Flavor and Extract Manufacturers Association of the United States (FEMA), and the Roberts Group, L.L.C. of involvement in fraudulent concealment and civil conspiracy. *Id.* at 443–44.

156. *Id.* at 442–43, 445 (quoting complaint).

157. *Kuiper*, 240 F.R.D. at 448; *Remmes*, 453 F. Supp. 2d at 1072.

158. *Kuiper v. Givaudan, Inc.*, No. C06-4009-MWB, 2007 U.S. Dist. LEXIS 79313, *3 n.1 (N.D. Iowa Oct. 25, 2007).

159. *Id.* at *5.

160. *Weimer v. Int’l Flavors & Fragrances, Inc.*, No. C05-4138-MWB, 2007 U.S. Dist. LEXIS 48669, *2 (N.D. Iowa July 3, 2007).

161. *Id.* at *3.

162. *Id.* at *7–8.

163. *Settlement Reached in ‘Popcorn Lung’ Lawsuit*, FOXNEWS.COM, July 10, 2007, <http://www.foxnews.com/story/0,2933,288854,00.html>.

A comparison between typical toxic harm litigation and the popcorn lung cases raises the important question of why IFF settled so many of these cases. Most scholars agree that tort law struggles to deal with the complexities of modern mass toxic harm litigation.¹⁶⁴ The legal system was created to regulate basic bilateral disputes, and despite procedural innovations relating to class actions and multidistrict litigation, the judicial system has simply not evolved to handle toxic torts well. Toxic harm cases often raise special challenges relating to latent disease, consolidation, differences across a plaintiff class, causation, choice of law, proliferation of claims, expert testimony, and judicial management.¹⁶⁵

To some extent, the popcorn lung litigation did not exhibit these typical difficulties. While diacetyl remains heavily used as a flavoring agent in factories across the country, it does not appear that as large a number of individuals have been affected as in other, more widespread toxic torts. According to IFF's most recent annual report, there have been just seventeen cases brought against the company following the Jasper litigation.¹⁶⁶ Those cases involve approximately 683 plaintiffs, of whom about 506 are workers.¹⁶⁷ The remaining plaintiffs are spouses or widows of workers or neighbors of a factory using diacetyl.¹⁶⁸ These numbers pale in comparison to the thousands of Vioxx cases that, until recently, filled dockets across the country.¹⁶⁹ It appears that of the individuals exposed to butter flavoring, relatively few suffer from bronchiolitis obliterans: only eight of the 135 workers at the Jasper plant were diagnosed with the disease.¹⁷⁰ Judicial management, therefore, was not a significant problem, nor did IFF face the prospect of crushing liability.

The typical difficulties in proving causation do not seem present in these cases. There are several possible explanations for this. First, although the science surrounding diacetyl is contested, bronchiolitis obliterans is somewhat of a "signature disease," almost analogous to mesothelioma in the asbestos context.¹⁷¹ Second, unlike many toxic effects, bronchiolitis obliterans cannot be caused by smoking cigarettes,¹⁷² which substantially restricts the ability of defendants to argue that

164. See, e.g., Robert L. Rabin, *Some Thoughts on the Efficacy of a Mass Toxics Administrative Compensation Scheme*, 52 MD. L. REV. 951, 951–55 (1993).

165. See generally JEAN MACCHIAROLI EGGEN, *TOXIC TORTS IN A NUTSHELL* 340–405 (3d ed. 2005) (chapter nine on mass toxic torts).

166. Int'l Flavors & Fragrances, *supra* note 146, at 10. IFF had been dismissed from one of the seventeen suits by the end of 2007. *Id.*

167. *Id.* at 10–11.

168. *Id.*

169. See, e.g., Heather Won Tesoriero, Sarah Rubenstein & Jamie Heller, *Merck's Tactics Largely Vindicated as It Reaches Big Vioxx Settlement*, WALL ST. J., Nov. 10, 2007, at A1.

170. Kreiss, Goma, Kullman, Fedan, Simoes & Enright, *supra* note 32, at 330.

171. *Id.* at 337; MURRAY & NADEL'S, *supra* note 1, at 1297–1300.

172. Armour, *supra* note 27, at A01.

something other than the chemical exposure caused the rare lung disease. Third, the latency period for respiratory ailments contracted by popcorn workers was relatively short,¹⁷³ making the causal connection easier to draw. Or maybe causation was simply not a problem for the jurors in Jasper: it is possible that the Jasper County juries were biased towards local, sympathetic plaintiffs.¹⁷⁴ The fact that the only documented popcorn lung cases that have gone to trial were held in the Jasper County courthouse makes extrapolation from those cases somewhat difficult. However, IFF has settled at least one case that would have been tried in an Iowa federal district court.¹⁷⁵ The company's reluctance to face a jury beyond Jasper, Missouri, might indicate that the law and the facts do not support its position in these cases.¹⁷⁶

The question of why IFF elected to settle so many of these claims has other possible answers as well. Once it was clear that IFF would not win on pre-trial motions and could not remove the cases to federal court in order to face presumably less hostile jury pools, the company may have decided to seek resolution of as many popcorn worker cases as possible in order to reduce the risk of large unfavorable jury awards and to contain its legal fees. It is also possible that IFF sought rapid resolution of these cases for an entirely different purpose: the company wanted to avoid the media.

VI.

THE IMPACT OF THE MEDIA:

"THE REAL TRAGEDY, JULIE, IS THAT THEY DON'T WARN ANYONE . . . THEIR FAILURE TO DO SO WILL BUY THEM LIABILITY NOT ONLY HERE, BUT ACROSS THE COUNTRY."

The role of the media in catalyzing a movement to further regulate diacetyl cannot be understated. A flurry of multi-million dollar verdicts not only put the town of Jasper, Missouri, on the map, but it also focused national attention on the disease that would quickly be dubbed "popcorn

173. See Akpınar-Elci, Travis, Lynch & Kreiss, *supra* note 8, at 299 (finding that the Jasper workers first fell ill after a median of 1.5 years of work in the plant).

174. Compare Neal Miller, *An Empirical Study of Forum Choices in Removal Cases under Diversity and Federal Question Jurisdiction*, 41 AM. U.L. REV. 369, 407-13 (1992) (finding that—whether real or imagined—attorneys fear bias of local juries against out-of-state defendants), with *id.* at 426 (noting that a report of the Federal Courts Study Committee found that although "there may be cases in which prejudice against an out-of-stater plays a role, the class of such cases is probably small").

175. *Kuiper v. Givaudan, Inc.*, No. C06-4009-MWB, 2007 U.S. Dist. LEXIS 79313, *3 n.1 (N.D. Iowa Oct. 25, 2007).

176. While parties settle cases for myriad reasons, the unwillingness of IFF's counsel to expose the company to liability imposed by a federal jury in Iowa weighs against the argument that jury bias favoring local parties was a major factor in the Jasper workers' cases.

lung.” The day after winning a twenty million dollar verdict, Eric Peoples and Kenneth McClain were introduced to a national audience via the morning talk shows. They appeared on CNN’s *American Morning*¹⁷⁷ and *The Early Show* on CBS, where they spoke for over five minutes. McClain had a strong message for IFF: “The real tragedy, Julie, is . . . that they don’t warn anyone. . . . [T]heir failure to do so will buy them liability not only here, but across the country.”¹⁷⁸

The phenomenon of popcorn lung was explored on the covers of national newspapers and small-town gazettes. The front page of *USA Today* warned of a plague in the heartland:

When the days turn humid in this farming town, the air becomes thick with the smell of butter from the Gilster-Mary Lee plant. . . . At night, when the building’s lights are ablaze, some residents say they’ve seen a yellowish cloud emanate from the building and fill the dark sky.¹⁷⁹

Meanwhile, a local Florida paper mixed poetry with journalism in describing one popcorn worker: “A coughing fit jerks Keith Campbell’s body tight, as if he’s being strangled by invisible demons. When the spasm passes, he leans his head back into his worn orange recliner and closes his eyes to let the dizziness pass.”¹⁸⁰ Stories about popcorn lung appeared in sources ranging from the *New York Times*¹⁸¹ and the *Washington Post*¹⁸² to personal blogs, one of which blazoned a sardonic headline: “Popcorn Delivers Buttery Goodness, Death.”¹⁸³

Popcorn lung was a story that the media liked to tell. A LexisNexis search of “all news” containing the words “popcorn,” “lung/lungs,” and “diacetyl,” before March 15, 2004—the day of the verdict in the Eric Peoples case—generated forty-two hits. From March 15, 2004, through December 1, 2008, there were 767 hits.¹⁸⁴ Writers profiled the popcorn workers, chronicled the litigation, and criticized OSHA’s unwillingness to

177. *American Morning: Ohio Mother Murder Case; Popcorn Worker Awarded \$20 Million in Lawsuit* (CNN television broadcast Mar. 16, 2004) (transcript available at <http://transcripts.cnn.com/TRANSCRIPTS/040316/ltm.04.html>).

178. *The Early Show: Popcorn Illness Nets \$20M* (CBS television broadcast Mar. 16, 2004) (video available at http://www.cbsnews.com/sections/_i_video/main500251.shtml?id=606539n).

179. Armour, *supra* note 27, at A01.

180. Sara Shipley, *Ohio Man’s Lungs Crippled by Vapors at Popcorn Plant, Doctors Say*, THE TRIBUNE (Port St. Lucie/Fort Pierce, Fla.), Apr. 10, 2004, at Domestic News.

181. See Labaton, *supra* note 14.

182. See Geis, *supra* note 24.

183. *Popcorn Delivers Buttery Goodness, Death*, CALAMITY NEWS, Sept. 4, 2007, <http://calamitynews.com/?p=1820>.

184. Nor were these hits clustered in a relatively brief period following March 15, 2004. LexisNexis’s “all news” database yields sixty-three hits between March 15, 2004, and March 15, 2005; just twenty-one of these hits are articles published between March 15, 2004 and March 31, 2004.

help. As the stories kept coming, awareness of a public health crisis steadily crescendoed, and with it, pressure in Washington started to escalate. Maybe the government would do something about diacetyl after all.

VII.

RENEWED CALLS TO REGULATE:

“THE PEOPLE ARE DYING RIGHT IN FRONT OF YOU. YOU CAN’T WAIT UNTIL YOU HAVE ALL THE EVIDENCE. YOU HAVE TO REGULATE IT.”

By the summer of 2006, labor interests and the scientific community converged to pressure the government to take action on behalf of all workers exposed to butter flavoring. On July 26, 2006, the United Food and Commercial Workers International Union (UFCW) and the International Brotherhood of Teamsters formally petitioned the U.S. Department of Labor to issue an Emergency Temporary Standard (ETS) for diacetyl.¹⁸⁵ They cited the Occupational Safety and Health Act: the “Secretary shall provide . . . for an emergency temporary standard . . . if [s]he determines (A) that employees are exposed to grave danger from exposure to substances or agents . . . and (B) that such emergency standard is necessary to protect employees from such danger.”¹⁸⁶ The unions proposed terms for an ETS and attached a letter signed by forty-two prominent scientists and former government officials¹⁸⁷ urging OSHA to take emergency action.¹⁸⁸

Over one year later,¹⁸⁹ OSHA notified the Teamsters that it would not be issuing an emergency standard. Relying heavily on what it claimed was scientific ambiguity, OSHA concluded that there was not enough evidence that an ETS was “necessary” and “would be technologically and economically feasible,” or that “current exposures constitute a grave

185. See Letter from Joseph T. Hansen, Int’l President, United Food and Commercial Workers Int’l Union, and James P. Hoffa, Gen. President, Int’l Bhd. of Teamsters, to Elaine L. Chao, Sec’y, U.S. Dep’t of Labor (July 26, 2006), *available at* <http://defendingscience.org/upload/Union%20Petition%20to%20CHAO%20on%20Diacetyl%20Signed.pdf>.

186. 29 U.S.C. § 655(c) (2000).

187. The signatories include a former director of OSHA and five former senior officials from OSHA, the EPA, and the Department of Health and Human Services. See *Unions Petition State for Standard to Protect Employees from Chemical Used on Popcorn*, WORKER’S COMPENSATION REPORT, Sept. 12, 2006.

188. See Letter from David Michaels to Elaine L. Chao, *supra* note 64.

189. OSHA’s response, written on September 25, 2007, was likely prompted by a series of events taking place in September. See *infra* text accompanying notes 214–250; Letter from Edwin G. Foulke, Jr., Assistant Sec’y of Labor for Occupational Safety and Health, to James Hoffa, Gen. President, Int’l Bhd. of Teamsters (Sept. 25, 2007), *available at* http://www.defendingscience.org/case_studies/upload/OSHA_Petition_Denial.pdf.

danger.”¹⁹⁰ OSHA emphasized that scientists still could not say conclusively whether diacetyl is the actual cause of bronchiolitis obliterans.¹⁹¹ Nonetheless, the agency stated that it intended to propose a permanent standard and was gathering data to begin the regulatory process. Until then, it would take various steps to inspect popcorn plants and flavoring factories using diacetyl and to disseminate accurate information to employers whose workers are exposed to diacetyl.¹⁹²

In his capacity as Director of the Project on Scientific Knowledge and Public Policy, Dr. David Michaels contacted the Environmental Protection Agency (EPA) and the FDA.¹⁹³ The EPA had previously announced that it was going to study the emission levels of diacetyl and other chemicals that are released when microwave popcorn bags are cooked and opened *by consumers*.¹⁹⁴ The study was completed in 2005, but had yet to be published.¹⁹⁵ As an explanation for the delay, the EPA had previously told Michaels that the primary investigator was “transferred to homeland security duties.”¹⁹⁶ Now, the EPA informed him that the study had to be sent to the popcorn industry “solely to ensure that no confidential business information is released” before its submission to a scientific journal.¹⁹⁷ Dr. Michaels was not the only party interested in the EPA study: the Associated Press had filed a Freedom of Information Act (FOIA) request for the study in late 2006.¹⁹⁸ That request was denied.¹⁹⁹ In response to Michaels’s request that the EPA undertake additional studies, the EPA responded, “Due to other more pressing research priorities, no other studies of microwave popcorn are planned at this time.”²⁰⁰

190. *See id.* at 2–4.

191. *Id.* at 4.

192. *Id.* These inspections are part of “National Emphasis Programs.” *See infra* text accompanying notes 246–254 (discussing the information OSHA eventually released). Again, it is important to recognize that a series of events in early September may have triggered such apparent eagerness to begin regulating diacetyl.

193. *See* Letter from David Michaels, Dir., Project on Scientific Knowledge and Pub. Policy, to Stephen L. Johnson, Adm’r, EPA (July 26, 2006), *available at* http://defendingscience.org/case_studies/upload/SKAPP_Letter_to_EPA_Administrator_Popcorn_Lung.pdf.

194. ENVTL. PROT. AGENCY, MICROWAVE POPCORN EMISSIONS RELEASED DURING COOKING AND BAG OPENING (2003), <http://oaspub.epa.gov/eims/eimsapi.dispdetail?deid=56572>.

195. Josh Funk, *Popcorn Makers Work to Remove Chemical*, WASHINGTONPOST.COM, Sept. 5, 2007, http://www.washingtonpost.com/wp-dyn/content/article/2007/09/05/AR2007090502014_pf.html.

196. *See* Letter from David Michaels to Stephen L. Johnson, *supra* note 193.

197. *See* Letter from Sally Gutierrez, Dir., Nat’l Risk Mgmt. Research Lab., EPA, to David Michaels, Dir., Project on Scientific Knowledge and Pub. Policy (Aug. 31, 2006), *available at* http://defendingscience.org/upload/EPA_Aug_2006_Response.pdf.

198. Funk, *supra* note 195.

199. *Id.*

200. Letter from Sally Gutierrez, *supra* note 197. The EPA ultimately published the study on November 1, 2007. *See* Jacky A. Rosati, Kenneth A. Krebs & Xiaoyu Liu,

The FDA was even less interested in acting on the possible risk posed by diacetyl. In response to a citizen petition filed by Dr. Michaels that urged the FDA to revoke diacetyl's status as "generally recognized as safe" (GRAS), the agency explained, "We have not reached a decision . . . because of the limited availability of resources and other agency priorities."²⁰¹ The agency could not be so trite when Chairwoman Rosa L. DeLauro of the House Appropriations Subcommittee on Agriculture, Rural Development, FDA, and Related Agencies formally requested that the FDA revoke diacetyl's GRAS status and remove the chemical from the market. In a two-page response, the FDA Commissioner stated that the agency lacked the evidence necessary to take action, but if it became clear "that the health of consumers is at risk through diacetyl exposure from food uses, it will take regulatory actions."²⁰²

Unhappy with the responses from federal agencies, proponents of diacetyl regulation shifted their focus to California. With the support of the forty-two scientists who demanded that OSHA take action, the United Food and Commercial Workers and the California Labor Federation petitioned the California Occupational Safety and Health Standards Board to issue an emergency temporary standard to regulate diacetyl.²⁰³ The petition was granted. As Acting Director of the California Division of Occupational Safety and Health (Cal/OSHA)²⁰⁴ Len Welsh explained, "In California, the situation is significantly different than in the rest of the nation, because we have already responded to this situation as an emergency"²⁰⁵ California's aggressive response to popcorn lung stemmed partly from the fact that, at that time, there were at least twenty-eight flavoring plants using diacetyl in California, and several cases of bronchiolitis obliterans had already been documented in the state by April

Emissions from Cooking Microwave Popcorn, 47 CRITICAL REVIEWS IN FOOD SCI. & NUTRITION 701 (2007), available at http://defendingscience.org/case_studies/upload/EPA_Diacetyl_Study.pdf.

201. See Letter from Laura M. Tarantino, Dir., Office of Food Additive Safety, Ctr. for Food Safety and Applied Nutrition, FDA, to David Michaels, Dir., Project on Scientific Knowledge and Pub. Policy (Mar. 6, 2007), available at http://www.defendingscience.org/case_studies/upload/FDA_Response_March_2007.pdf.

202. See Letter from Andrew C. von Eschenbach, Comm'r of Food & Drugs, to Rosa L. DeLauro, Chairwoman, House Appropriations Subcomm. on Agric., Rural Dev., FDA, & Related Agencies (June 12, 2007), available at http://www.defendingscience.org/upload/FDA_DeLauro_response.pdf.

203. *Unions Petition State for Standard*, *supra* note 187.

204. Despite the abbreviation, Cal/OSHA is a division of the California Department of Industrial Relations, not a local unit of OSHA. Cal. Div. of Occupational Safety & Health, <http://www.dir.ca.gov/dosh/>.

205. See Letter from Len Welsh, Acting Chief, Cal. Dep't of Indus. Relations, Div. Occupational Safety & Health, to Richard Alarcon, Cal. State Senator & Chair, Senate Labor & Indus. Relations (Sept. 11, 2006), available at http://defendingscience.org/upload/CalOSHA_response_to_Alarcon.pdf.

2006.²⁰⁶ Since granting the petition, Cal/OSHA has drafted a standard that would regulate exposure to flavorings containing diacetyl, acetoin, acetaldehyde, and benzaldehyde.²⁰⁷

Meanwhile, legislators at both the state and national levels joined the chorus agitating for regulation of diacetyl. California Assemblywoman Sally Lieber introduced a bill that would ban the use of diacetyl in California altogether.²⁰⁸ As to whether it made sense to act so drastically when the science was uncertain, Dr. Michaels told the press, “It’s not some carcinogen where you get cancer 30 years from now or something. The people are dying right in front of you. You can’t wait until you have all the evidence. You have to regulate it.”²⁰⁹ State Republicans disagreed. Just when the legislation was on the verge of passage, “suddenly and unexpectedly, the bill made a U-turn, thanks to a deft parliamentary maneuver by a Republican senator that left the majority Democrats outflanked and the legislation stalled until 2008.”²¹⁰

Emboldened by electoral victories in 2006, Democrats in the U.S. House of Representatives attempted to exert pressure on the Republican-controlled agencies. On April 14, 2007, they invited Eric Peoples to speak before a workforce protections subcommittee hearing provocatively entitled, “Have OSHA Standards Kept up with Workplace Hazards?”²¹¹ Just two months later, Representative Lynn C. Woolsey (D-CA) introduced a bill that would require OSHA to issue an emergency interim standard for diacetyl within ninety days of passage and a permanent standard within two years.²¹² “If OSHA will not act, then Congress must act,” she said.²¹³

206. McKinley, *supra* note 23.

207. The text of the proposed standard is available at http://www.defendingscience.org/upload/CA_Draft_Standard.pdf [hereinafter Cal/OSHA Draft Standard]. This standard requires employers to implement engineering and workplace controls, provide respiratory protection, provide medical evaluations for employees, add training programs relating to chemical exposure, and label diacetyl containers with a specific warning. It is conceivable that even if the statute is enacted, a court would find the state action preempted by the Occupational and Health Safety Act. *See, e.g., Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88 (1992).

208. Geis, *supra* note 24.

209. *Id.*

210. Shane Goldmacher, *Popcorn Chemical Bill Halted in Cliffhanger*, SACRAMENTO BEE, Sept. 18, 2007, at A4 (explaining Senator Runner’s call for a “‘reconsideration’ or revote,” which “erased the results of the previous vote and no other vote was taken”).

211. *Have OSHA Standards Kept up with Workplace Hazards?: Hearing Before the Subcomm. on Workforce Protections of the H. Comm. on Education and Labor*, *supra* note 17 (statement of Eric Peoples, former employee, Gilster-Mary Lee popcorn factory). *See also* YouTube.com, OSHA Hearing: Eric Peoples’ Testimony, *supra* note 17.

212. 153 CONG. REC. E1279 (extension of remarks, June 13, 2007) (statement of Rep. Woolsey).

213. *Id.*

VIII.

ANOTHER DIMENSION OF DISEASE:

"I AM POPCORN."

By September 2007, the debate over regulating diacetyl and butter flavoring was heating up, but what happened next would change the stakes entirely. On September 4, it was announced that Wayne Watson of Centennial, Colorado may have contracted bronchiolitis obliterans merely from consuming butter-flavored microwavable popcorn.²¹⁴ Lung specialist Dr. Cecile Rose treated Watson at the National Jewish Medical Research Center in July and wrote a letter to the FDA, CDC, EPA, and OSHA once she connected his lung condition with his snack.²¹⁵ Dr. Rose's letter was ominous: "We cannot be sure that this patient's exposure to butter-flavored microwave popcorn from daily heavy preparation has caused his lung disease. . . . However, we have no other plausible explanation."²¹⁶

According to Dr. Rose, the initial agency response to her letter was apathetic. The FDA asked her to submit the letter to its docket;²¹⁷ the CDC did not respond; the EPA informed her that her letter was categorized as an FYI submission; and OSHA sent Dr. Rose "a letter . . . saying this case report does not appear to be related to a workplace exposure."²¹⁸ However, once the public heard reports of Watson's case and learned that it was at least possible to get lung disease from microwaving popcorn, the agencies changed their tune: "We're taking [the doctor's] report very seriously," said a spokesperson for the CDC.²¹⁹ Similarly, after widespread press coverage of Watson's case, the FDA insisted that it was "carefully considering the safety and regulatory issues it raises."²²⁰

Popcorn consumers worldwide were concerned, but Watson remains the only known case of bronchiolitis obliterans related to popcorn consumption. By his own admission, the man's habits were extreme. Watson, a furniture salesman, claimed that he ate two to three bags of microwavable buttered popcorn a day for ten years. "I *am* popcorn," he

214. Heather Won Tesoriero, *Popcorn-Lung Man Revealed*, WALL ST. J. ONLINE, Sept. 6, 2007, <http://blogs.wsj.com/health/2007/09/06/>.

215. See David Michaels, *Popcorn Lung Coming to Your Kitchen? The FDA Doesn't Want to Know*, THE PUMP HANDLE, Sept. 4, 2007, <http://thepumphandle.wordpress.com/2007/09/04/popcorn-lung-coming-to-your-kitchen-the-fda-doesnt-want-to-know/#more-492>. This website, <http://thepumphandle.wordpress.com>, Dr. David Michaels's public health blog, was the first to break the news of Dr. Rose's Letter.

216. *Microwave Popcorn Scare; Lung Disease in Consumer May Be Linked to Butter-Flavored Snack*, CHI. TRIB. (RedEye Ed.), Sept. 6, 2007, at 14.

217. Goldstein, *supra* note 10.

218. *Id.*

219. *Popcorn Additive May Have Caused Serious Lung Ailment*, L.A. TIMES, Sept. 6, 2007, at C2 (alteration in original).

220. *Id.*

admitted. “It is my exclusive snack-food choice.”²²¹ Testing in Watson’s home revealed peak levels of diacetyl similar to those found in popcorn production plants.²²²

IX.

SELF-REGULATION:

“TO ELIMINATE EVEN THE PERCEPTION OF RISK FOR CONSUMERS . . . THE COMPANY HAS DECIDED TO ELIMINATE THE USE OF ADDED DIACETYL IN ITS MICROWAVE POPCORN PRODUCTS.”

One day after Dr. Rose’s letter hit the press, the popcorn industry announced that it would eliminate diacetyl from its popcorn. Three companies, ConAgra Foods, General Mills, and the American Pop Corn Company, together representing eighty percent of the microwave popcorn market, each proclaimed that they would be changing their recipes.²²³ It was unclear how quickly the companies would be able to replace diacetyl; they did not have an easy substitute ready.²²⁴ Several months before the announcement, a lawyer for the popcorn trade group told a reporter, “There is no single substance that can replace diacetyl because it is the single substance most responsible for the ‘buttery note.’”²²⁵ Nonetheless, ConAgra indicated that it would phase out the chemical within the next year, General Mills stated that it would act “soon,” and American Pop Corn announced that it would remove diacetyl entirely within ninety days.²²⁶

The timing of this announcement raises crucial questions of cause and effect. At first glance, it would seem that the companies were responding

221. Goldstein, *supra* note 10.

222. *Id.* Dr. Rose emphasized that Watson’s exposure is not comparable to the exposure of the workers. The level of diacetyl in Watson’s home only approached the levels of popcorn production plants for extremely short intervals of time (presumably upon microwaving popcorn).

223. *Popcorn Makers to Drop Chemical from Recipes; Butter Flavoring Tied to Lung Ailment*, WASH. POST, Sept. 6, 2007, at D03. Their products include Orville Redenbacher, Act II, Pop Secret, and Jolly Time. *Id.* According to a letter from ConAgra to the EPA, three billion bags of microwave popcorn are sold each year, representing one billion dollars in sales. Letter from Patricia Verduin, Senior Vice President Prod. Quality & Dev., ConAgra Foods, Inc., to Dr. Paul Gilman, Assistant Adm’r for the Office of Research and Dev., EPA (Nov. 29, 2004), *available at* http://www.defendingscience.org/upload/Letter_from_ConAgra_regarding_progress.pdf.

224. *See Popcorn Makers to Drop Chemical from Recipes*, *supra* note 223. One alternative to diacetyl is butter. This suggestion is raised by California Assemblywoman Sally Lieber. McKinley, *supra* note 23. Moreover, Jiffy Pop, ConAgra’s stovetop popcorn, uses natural butter. *Popcorn Makers to Drop Chemical from Recipes*, *supra* note 223.

225. McKinley, *supra* note 23.

226. Josh Funk, *Popcorn Producers Act on Fumes Report; Major Popcorn Makers Dropping Chemical Linked to Lung Ailment*, VIRGINIAN-PILOT (Norfolk, Va.), Sept. 6, 2007, at A7.

to the news from Centennial, Colorado. An article in *USA Today* highlighted this connection: "The decision [to eliminate diacetyl] comes a day after a doctor . . . said . . . that consumers, not just factory workers, may be in danger. . . ." ²²⁷ But the decision to remove diacetyl from microwavable popcorn was not made overnight. A Reuters article indicates that ConAgra made the decision to remove diacetyl only "after months of deliberations." ²²⁸ Moreover, American Pop Corn representatives told the press that the company had been "working on a new recipe . . . for several months." ²²⁹ In addition, Weaver Popcorn had announced its intentions to replace the butter flavoring a week *before* the news about Wayne Watson broke. ²³⁰

It was not that consumers might be at risk of a potentially lethal lung condition that motivated popcorn companies to modify their recipes; rather, it was the potentially costly impact of the media coverage. A letter from Doug Knudsen, President of ConAgra Foods Sales, demonstrates this point quite clearly. The letter begins, "Dear ConAgra Foods Customer: You may have seen reports *in the media* recently about *diacetyl*. . . ." ²³¹ It emphasizes that no "definitive study" has shown reason for consumers *qua* consumers to be concerned. ²³² "But to eliminate even the perception of risk for consumers, and to provide the safest possible environment for workers who handle large quantities of diacetyl, the company has decided to eliminate the use of added diacetyl in its microwave popcorn products." ²³³ The reference to "perception of risk" indicates that consumers may have been concerned and confused about the stories they heard on the news. The letter also makes clear that the company was acting first and foremost on behalf of its consumers, not its workers. ²³⁴ Mike Weaver, President of Weaver Popcorn Company, Inc., later made the point explicit: "[W]e know consumers are becoming increasingly concerned about this issue, so we've taken it out of our flavorings." ²³⁵

227. *ConAgra to Drop Popcorn Chemical Linked to Lung Ailment*, USA TODAY, Sept. 5, 2007, available at http://www.usatoday.com/money/industries/food/2007-09-05-popcorn-lung_N.htm.

228. Julie Steenhuysen, *FDA to Probe Popcorn Link in Man's Lung Disease*, REUTERS, Sept. 5, 2007, <http://www.reuters.com/article/domesticNews/idUSN0524254120070905>.

229. *Popcorn Makers to Drop Chemical from Recipes*, *supra* note 223.

230. *See ConAgra to Drop Popcorn Chemical*, *supra* note 227.

231. Letter from Doug Knudsen, President, ConAgra Foods Sales to ConAgra Foods Customer (Sept. 6, 2007) (first emphasis added), available at http://www.ingles-markets.com/food_safety/dacetyl.php.

232. *See id.*

233. *Id.*

234. Notice the sequence of clauses in the sentence cited above: "To eliminate . . . risk for consumers, and to provide . . . for workers" *Id.* (emphasis added). Contrast this letter with public comments made by a ConAgra spokeswoman: "We've made that decision based on the knowledge for the potential risk to our employees." *ConAgra to Drop Popcorn Chemical*, *supra* note 227.

235. Press Release, Pop Weaver, Pop Weaver Introduces First Microwave Popcorn

Removing diacetyl from microwavable popcorn was not about health; instead, it was about protecting the bottom line.

If it is the case that popcorn companies had been planning to remove diacetyl from their products for several months, the obvious question is why they delayed so long before making their announcements. One possibility is that the companies were waiting to see what would come of the House bill that would force OSHA to issue an emergency standard for diacetyl. It is also possible that they were waiting for the EPA study—which had not yet been published, but which they had reviewed—to be released. Maybe they were simply waiting to see if media interest in a rare disease that affected a relatively small number of workers would abate. Regardless, it is clear that the news from Colorado forced their hand: diacetyl had to go, if only to garner good press for the industry.

X.

WASHINGTON RESPONDS:

“WE CANNOT DELAY ACTION ON THIS MATTER.”

The fear that American consumers might be at risk for bronchiolitis obliterans catalyzed action not just by the popcorn industry, but also by Congress. On September 11, 2007, Representative DeLauro renewed her plea for the FDA to reconsider its designation of diacetyl as “generally recognized as safe.” In a letter to the Commissioner of the FDA, she wrote, “We cannot delay action on this matter. The FDA must pursue a comprehensive reexamination of diacetyl’s potential harm to any consumer who decides to have a bag of microwave popcorn. . . . I urge you to fully employ the FDA’s regulatory mandate to protect the public.”²³⁶

All signs indicated that the House would soon pass the legislation designed to force OSHA’s hand, and interested parties lobbied Congress on both sides. Unions, scientists, and even the flavoring industry supported H.R. 2693. The AFL-CIO put out a legislative alert, reminding representatives that even though diacetyl would be pulled from popcorn plants, action was necessary to regulate the flavoring agent wherever used.²³⁷ The Teamsters quoted a NIOSH study which found that diacetyl produced “astonishingly grotesque” effects in workers’ lungs, and opined

with Flavoring Containing No Diacetyl (Aug. 28, 2007), *available at* <http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=109&STORY=/www/story/08-28-2007/0004652723&EDATE=> [hereinafter Weaver Press Release].

236. Letter from Rosa L. DeLauro, Chairwoman, House Appropriations Subcomm. on Agric., Rural Dev., FDA & Related Agencies, to Andrew C. von Eschenbach, Comm’r, FDA (Sept. 11, 2007), *available at* http://www.defendingscience.org/case_studies/upload/DeLauro_FDA_letter2.pdf.

237. Letter from William Samuel, Dir., Dep’t of Legislation, AFL-CIO, to Representative (Sept. 24, 2007), *available at* http://www.defendingscience.org/case_studies/upload/AFLCIO_Dear_Representative.pdf.

that “it is unconscionable that these workers should have to wait any longer for a safety standard.”²³⁸ FEMA even supported the bill, finding that the legislation mirrored its own 2004 recommendations to manufacturers.²³⁹

Not surprisingly, OSHA and the White House made it clear that they opposed any legislative action. Edwin G. Foulke, Jr., the head of OSHA, wrote, somewhat ironically, that “the process the bill would require may result in missed opportunities to provide needed worker safety,” and that it “will not afford the best level of protection for workers.”²⁴⁰ His other concerns were far more persuasive: Foulke criticized the bill for bypassing the administrative process, for focusing on diacetyl alone, for relying on insufficient data, and for failing to give the agency enough time to analyze diacetyl use in industries beyond popcorn production.²⁴¹ This last point was echoed by the American Bakers Association, which opposed the bill in part because “NIOSH data does not accurately reflect the use of diacetyl in other sectors of the food industry, such as baking.”²⁴² OSHA’s concerns were substantially echoed by the White House in its own Statement of Administration Policy.²⁴³

Opponents of the Popcorn Workers Lung Disease Prevention Act united behind the position that the science remained murky. According to the administration’s letter, “more time is needed to gather sufficient evidence.”²⁴⁴ OSHA stated that “two years is too short a period of time to develop the information base and analysis necessary to adequately support the proposed and final rule, and to afford the public adequate time to comment on OSHA’s proposal.”²⁴⁵ Finally, the OSHA Fairness Coalition, composed of a broad range of industry groups, argued that “any need for this bill has been eliminated,” in part because some of the largest microwave popcorn manufacturers had announced their plans to stop using diacetyl.²⁴⁶

238. Letter from Frederick P. McLuckie, Legislative Dir., Gov’t Affairs Dep’t, Int’l Bhd. of Teamsters, to Representative (Sept. 24, 2007), *available at* http://www.defendingscience.org/case_studies/upload/Teamsters_Representative_Letter.pdf.

239. *See id.*

240. Letter from Edwin G. Foulke, Jr., Assistant Sec’y of Labor for Occupational Safety and Health, to George Miller, Chairman, Comm. on Educ. & Labor, U.S. House of Representatives (June 19, 2007), *available at* http://www.defendingscience.org/case_studies/upload/2693_Foulke_Letter.pdf.

241. *See id.*

242. Letter from Robb MacKie, President & CEO, Am. Bakers Assoc., to George Miller, Chairman, Comm. on Educ. & Labor, U.S. House of Representatives (June 19, 2007), *available at* http://www.defendingscience.org/case_studies/upload/American_Bakers_HR2693.pdf.

243. *See* OFFICE OF MGMT. & BUDGET, EXECUTIVE OFFICE OF THE PRESIDENT, STATEMENT OF ADMINISTRATION POLICY (Sept. 25, 2007), <http://www.whitehouse.gov/omb/legislative/sap/110-1/hr2693sap-r.pdf>.

244. *Id.*

245. Letter from Edwin G. Foulke, Jr., to George Miller, *supra* note 240.

246. Letter from OSHA Fairness Coal. to Members of the House of Representatives

Just two days before the House would vote on H.R. 2693, OSHA preempted the legislature. The agency announced that it would initiate the rulemaking process, issue a Safety and Health Information Bulletin (SHIB), and provide Hazard Communication Guidance.²⁴⁷ “I would characterize us as proactive,” said Jonathan Snare, the Acting Solicitor of the Labor Department.²⁴⁸ Those who had been waiting for OSHA action since the Jasper outbreak were less enthusiastic: “All of these things could have been done years ago. . . . And they wouldn’t do anything but for fear of legislation,” said Dr. Michaels.²⁴⁹ When the House passed H.R. 2693 just two days later, its accomplishment was almost immediately relegated to the status of a historical footnote.²⁵⁰

Since September 2007

OSHA immediately published the two documents that it had promised,²⁵¹ but whether it will promulgate a rule on diacetyl remains to be seen. On the same day that the House voted to force OSHA’s hand, the agency itself announced that it would be holding a stakeholders’ meeting in mid-October.²⁵² By then, it had already issued a Hazard Communication Guidance and a SHIB. The SHIB is intended to inform employers and employees about the possible effects of butter flavoring chemical exposure, recommend ways for employers to limit their employees’ exposures, and remind employers about relevant OSHA standards.²⁵³ The Hazard Communication Guidance is intended to provide

(Sept. 25, 2007), *available at* http://www.defendingscience.org/case_studies/upload/OSHA_Fairness_Coalition_HR2693_Reps.pdf.

247. Press Release, Occupational Safety & Health Admin., OSHA Announces Three Actions to Protect Workers Exposed to Butter Flavorings (Sept. 24, 2007), http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=NEWS_RELEASES&p_id=14489.

248. Cindy Skrzycki, *Popcorn Concerns Put Work Safety Back on Agenda*, WASH. POST, Oct. 9, 2007, at D1.

249. *Id.*

250. See Popcorn Workers Lung Disease Prevention Act, H.R. 2693, 110th Cong. (2007). Neither this bill nor any similar bill was ever considered in the Senate.

251. OCCUPATIONAL SAFETY & HEALTH ADMIN., RESPIRATORY DISEASE AMONG EMPLOYEES IN MICROWAVE POPCORN PROCESSING PLANTS (Sept. 24, 2007), <http://www.osha.gov/dts/shib/shib092107.html> [hereinafter SHIB]; OCCUPATIONAL SAFETY & HEALTH ADMIN., HAZARD COMMUNICATION GUIDANCE FOR DIACETYL AND FOOD FLAVORINGS CONTAINING DIACETYL, <http://www.osha.gov/dsg/guidance/diacetyl-guidance.html> (last visited Mar. 8, 2009) [hereinafter HAZARD COMMUNICATION GUIDANCE].

252. Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl: Announcement of Stakeholder Meeting, 72 Fed. Reg. 54,619 (Sept. 26, 2007) (to be codified at 29 C.F.R. pt. 1910). As of September 14, 2008, no further notices on the subject had been published in the Federal Register.

253. SHIB, *supra* note 251.

similar guidance to employers, manufacturers, and importers.²⁵⁴ The Hazard Communication Guidance explains OSHA's mandate that containers of diacetyl bear a label similar to one that reads: "DANGER: Can cause damage to respiratory tract and lungs if inhaled. Highly flammable. WARNING: Can cause eye, skin, nose, and throat irritation."²⁵⁵ Though this agency action has been disparaged as somewhat tardy, even critics would concede that the communication efforts are nonetheless extremely valuable.

Beyond the area of popcorn lung, Edwin Foulke's OSHA has continued its pattern of nonfeasance. In February 2008, combustible dust exploded at a Georgia sugar refinery, killing twelve workers and critically injuring eleven others.²⁵⁶ When OSHA insisted that it did not need to issue a combustible dust standard,²⁵⁷ Congress responded exactly as it had in the popcorn lung context. The House Committee on Education and Labor held hearings that served as a public thrashing of OSHA. In his opening remarks, Committee Chairman George Miller (D-CA) stated, "OSHA has utterly failed to fulfill its Congressional mandate. The agency is leaving the Congress with no other choice but to step in."²⁵⁸ On April 30, 2008, the House voted 247 to 165 to pass the Worker Protection Against Combustible Dust Explosions and Fires Act, which requires OSHA to produce an interim final rule regulating combustible dusts.²⁵⁹ The bill has been referred to the Senate Committee on Health, Education, Labor, and Pensions, where it remained as of December 2008,²⁶⁰ languishing in the face of a threatened veto from the White House.²⁶¹

254. See HAZARD COMMUNICATION GUIDANCE, *supra* note 251.

255. *Id.* It seems that this warning is not written in especially strong terms. Instead of "can" cause damage, a label which read "causes damage" might be more appropriate. Nevertheless, OSHA's recommendations on engineering controls designed to reduce the risk of exposure to diacetyl are helpful, see SHIB, *supra* note 251, and its warning is better than nothing.

256. Bob Deans, *Agency: Safeguards Would Have Saved Lives; Official Says Refinery Blast Preventable*, ATLANTA J.-CONST., Mar. 13, 2008, at 3D.

257. See Statement of Edwin G. Foulke, Assistant Sec'y, OSHA, before the H. Comm. on Education and Labor, 110th Cong. 22 (Mar. 12, 2008), available at <http://edlabor.house.gov/testimony/2008-03-12-EdwinFoulke.pdf> ("If employers follow the existing requirements established by these standards, employees will be protected from combustible dust hazards.").

258. *The Combustible Dust Explosion and Fire Prevention Act of 2008: Hearing on H.R. 5522 Before the H. Comm. on Education and Labor*, 110th Cong. 22 (2008) (opening statement of Chairman Miller), available at <http://edlabor.house.gov/statements/2008-03-12GMHearingStatement.pdf>.

259. Worker Protection Against Combustible Dust Explosions and Fires Act of 2008, H.R. 5522, 110th Cong. (2008); *House Passes Combustible Dust Bill As White House Threatens Veto*, INSIDE OSHA, May 12, 2008.

260. See Govtrack.us, H.R. 5522: Worker Protection Against Combustible Dust Explosions and Fires Act of 2008, <http://www.govtrack.us/congress/bill.xpd?bill=h110-5522> (last visited Mar. 8, 2009).

261. Julia Malone, *Bush Resists Dust-Buildup Legislation*, ATLANTA J.-CONST., Apr.

Meanwhile, popcorn companies eventually fulfilled their promises to produce microwavable popcorn without flavoring containing diacetyl. Pop Weaver was the first to do so, issuing a press release on August 28, 2007 in which the company boasted that it had overcome the “challenge” of finding a replacement for diacetyl.²⁶² General Mills followed suit in October, and American Pop Corn eliminated diacetyl from each of its recipes by January 1, 2008.²⁶³ On December 17, 2007, ConAgra announced that it had developed diacetyl-free recipes for Orville Redenbacher and Act II popcorn that would be on store shelves everywhere by January.²⁶⁴ None of the companies would reveal their revised recipes, and none disclosed whether some other chemical had replaced diacetyl.²⁶⁵ The popcorn producers likely reasoned that consumers had only one concern, so at least ConAgra advertised it all across the popcorn packaging: “No Added Diacetyl.”²⁶⁶ The chemical, once obscure, would become a household name.

XI.

CONCLUSION

Within eight years of the discovery of bronchiolitis obliterans in Jasper, Missouri, it is possible that the workplace health threat of popcorn lung has already been resolved. Before assessing the regulatory response to diacetyl, it is helpful to review the developments of the past few years. In 2004, the first jury to hear about the dangers of working at a popcorn factory that used diacetyl awarded Eric and Cassandra Peoples twenty million dollars. The media took great interest in Peoples and his illness, printing hundreds of stories on the topic. Meanwhile, juries consistently found for the plaintiff popcorn workers, prompting the largest producer of butter flavoring to settle dozens of cases. Calls to regulate the flavoring chemicals went unheeded until doctors discovered that it may be possible for consumers to contract bronchiolitis obliterans. Immediately following the news that one consumer had developed the disease, popcorn companies announced that they would remove flavoring containing diacetyl from their recipes. Finally, under pressure from Congress, OSHA initiated a rulemaking process targeting diacetyl.

30, 2008, at 4B; *House Passes Combustible Dust Bill*, *supra* note 259.

262. Weaver Press Release, *supra* note 235.

263. *See Chemical Removed from Popcorn; Four Biggest Makers Say It Will Take Several Months for Old Product to Leave Store Shelves*, GRAND RAPIDS PRESS (Mich.), Dec. 23, 2007, at A17.

264. Raquel Rutledge, *ConAgra Drops Popcorn Chemical; Flavoring Linked to Lung Disease*, MILWAUKEE J. SENTINEL, Dec. 18, 2007, at A1.

265. *Id.*

266. *Chemical Removed from Popcorn*, *supra* note 263.

Given the relatively small number of individuals who work with butter flavoring, it might appear surprising that the House would pass a bill specifically mandating its regulation and that a characteristically hands-off OSHA would begin the rulemaking process.²⁶⁷ Perhaps this was merely politics as usual: the case of popcorn lung provided an excellent opportunity for frustrated politicians to criticize the Bush administration. Indeed, Democrats were able to cast themselves as champions of the working class, and could point to their colleagues across the aisle as inefficient at best and industry-allied killers at worst.²⁶⁸ But this explanation is neither entirely satisfactory, nor is it complete.

It appears that the media played a significant, perhaps even decisive role in shaping the course of events. Even before the world learned that eating multiple bags of microwavable buttered popcorn per day may give consumers bronchiolitis obliterans, popcorn producers were already making plans to eliminate the use of diacetyl. At the same time, the country's biggest labor unions and many leading scientists were lobbying agencies and politicians to regulate diacetyl. The suggestion that the media may have played a substantial role in influencing litigation and regulation here is consistent with past experience. One account credits a *National Enquirer* story for an explosion in Bendectin litigation, and points to a correlation between press coverage and the number of lawsuits relating to breast implants.²⁶⁹ On the regulatory front, Cass Sunstein has stated that government too often focuses its attention on risks that are widely covered in the media; he refers to this effect as "a pathology of regulatory policy."²⁷⁰

But to say that the media catalyzed regulatory activity remains incomplete. Journalists have reasons for writing stories, and for popcorn lung, the articles were catalyzed by the successful litigation in Jasper. There were dozens of sick workers at the Gilster-Mary Lee factory (and around the country), but Eric Peoples, the first winner of a large jury award, became the face of popcorn lung. His story was routinely mentioned in the press, and he was the only bronchiolitis obliterans patient called to testify before Congress.

267. To a great degree, it would seem that the former sufficiently explains the latter. Faced with the possibility of being forced to issue a standard that it did not want to issue, OSHA initiated rulemaking largely in order to reassert its own control of the process, forestall formal rulemaking, and render the legislation moot before it reached the Senate.

268. See, e.g., Press Release, Office of Senator Edward Kennedy, Kennedy, Murray on the Urgent Need for Federal Regulation of Diacetyl Exposure (Sept. 7, 2007), available at http://kenedy.senate.gov/newsroom/press_release.cfm?id=8AA54210-3F0C-493C-A28C-D0E7AB1E4C7E ("It is shocking that the federal agencies charged with safeguarding American workers and consumers have failed to act, despite the growing evidence that this chemical is a serious threat.").

269. David E. Bernstein, *Review Essay: The Breast Implant Fiasco*, 87 CAL. L. REV. 457, 460, 471 (1999) (reviewing MARCIA ANGELL, SCIENCE ON TRIAL: THE CLASH OF MEDICAL EVIDENCE AND THE LAW IN THE BREAST IMPLANT CASE (1996)).

270. Cass R. Sunstein, *Which Risks First?*, 1997 U. CHI. LEGAL F. 101, 123 (1997).

To the extent that the problems presented by popcorn lung have been successfully resolved, that success may be largely attributable to litigation. One lesson to draw from the experience with diacetyl is that regulation by litigation has two forms, operating as both an ends and a means. What I will call “direct regulation by litigation” includes lawsuits, verdicts, and settlements that, by themselves, accomplish the purposes of regulatory action; “indirect regulation by litigation” involves other elements of industry reform that develop as an outgrowth of the legal activity. In Jasper, several dozen injured workers were successfully compensated through the litigation process (direct regulation by litigation). A combination of eight-figure verdicts and unusual facts drew the attention of the national media (and the bloggers), whose reports inspired widespread concern. Well before Wayne Watson’s case made the news, consumers wondered whether they could get sick from eating popcorn, and writers asked why OSHA was doing nothing to help the workers. This, in turn, inspired popcorn companies to remove diacetyl from their products, and motivated politicians to regulate diacetyl (indirect regulation by litigation). The litigation itself could only help a few individuals directly, but the consequences of just a small number of cases had an impact far beyond the courtroom.

The interaction between science and the various regulatory efforts is fascinating. If one focuses only on the litigation, it appears that the science did not matter nearly as much as it might have. As is often the case in toxic tort litigation, popcorn lung presented the legal system with questions of causation to which the scientific community lacked firm answers. Yet a series of juries was willing to conclude that IFF was legally responsible for the disease that the flavoring may have caused, and the manufacturer was willing to settle dozens of cases. Some might argue that this points to a flaw in our legal system: juries must decide cases that turn on empirical questions that scientists cannot answer with certainty. But justice cannot wait for scientific conclusions, which explains why legal standards for liability are not as strict as the requirements of scientific certainty.

If science did not play the pivotal role that it could have in the courtroom context, it may have played too significant a role in the regulatory arena. Time and again, regulators cited incomplete data as they resisted efforts to even initiate a process of standard setting. However, ambiguity is not an excuse for inaction; to say that diacetyl could not be regulated because the compound may not have been the direct cause of bronchiolitis obliterans misses the point. First, diacetyl could have been regulated on the grounds that the scientific community had at least tied it to a variety of respiratory and physical ailments. More importantly, butter flavoring in general, which had clear health effects on workers who inhaled it, could be regulated. Thus, the regulatory efforts of Cal/OSHA might be more appropriate than those enacted by the House of Representatives. Whereas the House bill would force OSHA to set a standard for diacetyl alone, the standard drafted by

Cal/OSHA targets four chemicals suspected of causing bronchiolitis obliterans.²⁷¹ In other words, the nexus between diacetyl and bronchiolitis obliterans is not a prerequisite to regulation of butter flavoring.

This comparison between regulation by litigation and regulation by executive agency reveals that the efficacy of each is closely tied to their respective required burdens of proof, either externally- or self-imposed. Juries were able to conclude that diacetyl caused bronchiolitis obliterans because the burden of proof in civil lawsuits is merely "more likely than not." To a jury operating under that standard, it is enough that the Kreiss study in the *New England Journal of Medicine* concluded that the Jasper workers "probably" had contracted their disease by inhaling butter flavoring.²⁷² But "probably" was not enough for Edwin Foulke, who emphasized a statement from NIOSH that "insufficient data exist" on which to base workplace exposure standards.²⁷³ In essence, OSHA imposed upon itself a "reasonable doubt" standard, refusing to regulate until it knew beyond all doubt that diacetyl caused bronchiolitis obliterans. Instead of erring on the side of caution vis-à-vis workers' health and safety, the agency erred on the side of caution vis-à-vis restricting the use of a chemical that was critical for the flavoring industry.

It is tempting to look over this case study and conclude that, despite delays, our various systems of regulation ultimately worked. Less than four years after the discovery of bronchiolitis obliterans in Jasper's popcorn workers, many workers had received compensation, manufacturers had withdrawn diacetyl from popcorn products, and OSHA had initiated a rulemaking process. But for people like Wayne Watson and Eric Peoples, the damage had been done. As Gerald Morgan put it, "I'd rather have my health back."²⁷⁴ When viewed from this perspective, one realizes that nearly all of the efforts at regulation can be described as reactive, operating ex post. If the government sets a rule for diacetyl after products containing the chemical have been pulled from the shelves, it would be equally ironic and irrelevant.²⁷⁵

Since preventative regulation is clearly preferable, the question becomes whether there is any way for governmental regulation to become more proactive and less reactive. Do people always have to get hurt before the regulators intervene? One obstacle to imposing regulations before individuals have been harmed is that the cost/benefit analysis

271. Compare H.R. 2693, *supra* note 250, with Cal/OSHA Draft Standard, *supra* note 207.

272. See Kreiss, Gomaa, Kullman, Fedan, Simoes & Enright, *supra* note 32.

273. Letter from Edwin G. Foulke, Jr., to George Miller, *supra* note 240.

274. Rock, *supra* note 20.

275. Despite this criticism, rulemaking on diacetyl remains worthwhile for two reasons. First, manufacturers continue to use diacetyl in areas other than popcorn production. Second, the voluntary removal of diacetyl from microwaveable popcorn by industry leaders does not prevent competitors from using diacetyl, nor does it foreclose industry leaders from using diacetyl in popcorn products in the future.

becomes skewed against regulating: the costs are easy to calculate, while the benefits are speculative. It becomes difficult to justify imposing real economic costs in order to save lives absent a quantifiable demonstration that lives are in fact at risk.

One response to this conundrum is to focus on information creation and distribution. This was the impetus behind OSHA's hazard communication standard,²⁷⁶ which imposes strenuous information disclosure requirements on manufacturers, importers, distributors, and employers. Designed to encourage a "downstream flow of information,"²⁷⁷ the hazard communication standard requires manufacturers, distributors, and importers to produce material safety data sheets (MSDS) regarding hazardous chemicals, which they must distribute to employers who, in turn, are required to pass the information along to employees.²⁷⁸ The standard also imposes requirements relating to product labels and warnings²⁷⁹ and employee training.²⁸⁰ These requirements are highly detailed²⁸¹ and frequently violated.²⁸²

The sheer quantity of violations of the hazard communication standard—even twenty years after the standard was implemented—suggests a systemic problem that must be addressed. Companies are violating OSHA's standards either because they do not understand them, or because the costs of violation are outweighed by the savings of avoiding data compilation and distribution.²⁸³ A logical response would be two-fold: increase efforts at educating the stakeholders about how to comply with the hazard communication standard and increase the costs of violation. In most circumstances not involving willful or repeat violations, violators can be fined a maximum of \$7000 per infraction.²⁸⁴ This may be an insufficient deterrent.

If IFF and Gilster-Mary Lee had followed OSHA's hazard communication standard, it is possible that workers would never have been

276. 29 C.F.R. § 1910.1200 (2008).

277. See DEP'T OF LABOR, OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, CHEMICAL HAZARD COMM'C'N, OSHA 3084 2 (1998), available at <http://www.osha.gov/Publications/osh3084.pdf>.

278. See *id.* at 2, 7; 29 C.F.R. § 1910.1200 (g) (2008).

279. § 1910.1200 (f).

280. § 1910.1200 (h).

281. See § 1910.1200 (spanning approximately 20 pages).

282. See *Target Top 4 OSHA Violations in '06 to Keep Employees Safe Next Year*, WORKER'S COMPENSATION MONITOR, Nov. 1, 2006 (citing 5586 violations of the hazard communications standards over a 12-month period, making the hazard communications standards the third-most frequently enforced OSHA standards).

283. One significant additional cost of compliance is the potential loss of sales due to disclosure of safety hazards.

284. OSHA can propose a penalty of anywhere from \$10 to \$7000, which can then be reduced up to 95% depending on the employer's good faith, history of other violations, and the size of the employer's business. If that reduction results in a penalty less than \$100, no fine is imposed. OSHA Office of Training & Educ., U.S. Dep't of Labor, OSH Act, OSHA Standards, Inspections, Citations and Penalties (1996), <http://www.osha.gov/doc/outreachtraining/htmlfiles/introscha.html>.

harm by diacetyl. As noted above, Eric Peoples testified before Congress that IFF had received a MSDS that included a description of a study in which rats exposed to diacetyl suffered severe respiratory problems.²⁸⁵ In addition, FEMA warned flavoring companies about a possible connection between flavoring chemicals and bronchiolitis obliterans.²⁸⁶ After IFF employees suffered severe injuries from their exposure to diacetyl, the company enclosed the manufacturing process to avoid employee exposure to fumes.²⁸⁷ Despite all of this, the MSDS that IFF distributed to the Gilster-Mary Lee factory stated that diacetyl posed “no known health hazards.”²⁸⁸ If IFF had warned downstream employers that exposure to diacetyl was hazardous, and if Gilster-Mary Lee responded by protecting popcorn factory workers from the chemical, it is possible that the popcorn lung phenomenon would never have afflicted Jasper workers.²⁸⁹

The relatively small scope of the diacetyl problem helps illuminate some of the issues posed by more widespread toxic situations. First, in the popcorn lung scenario, we find that litigation was *not* successful in resolving the claims of injured popcorn workers. It may seem that this claim contradicts the discussion above. To be clear, my argument above was based on a series of causal events: litigation led to large verdicts which led to media coverage which led to removal of a product from the market and so on. Here, my contention is that the litigation itself—standing alone—raises serious concerns about the viability of our civil procedure mechanism in the context of mass toxic torts. We find a system of civil procedure which continues to prioritize individualized justice over mass resolution of claims; we find a jury system which may be ill-equipped to grapple with scientific ambiguity; we find a punitive mechanism which makes the cost of a verdict so significant that defendants are effectively forced into settlements. Tort law, designed in part to promote deterrence, achieves that end, if at all, in a rough and imprecise manner.²⁹⁰ If the civil justice system struggled to deal with the relatively minor situation presented by popcorn lung, little wonder that it struggles so mightily under the weight of thousands of claims relating to more prolific toxic harms.²⁹¹

285. Statement of Eric Peoples, *supra* note 17.

286. *Id.*

287. *Id.*

288. *Id.*

289. See Richard H. Pildes & Cass R. Sunstein, *Reinventing the Regulatory State*, 62 U. CHI. L. REV. 1, 104 (1995) (noting that studies suggest that information disclosure “can be a helpful and cost-effective strategy” and citing empirical literature for the proposition that “workers do indeed respond to new information about risks, by quitting or demanding higher salaries”).

290. For an excellent discussion of the relationship between deterrence and punitive damage awards, see Cass R. Sunstein, Daniel Kahneman & David Schkade, *Assessing Punitive Damages (with Notes on Cognition and Valuation in Law)*, 107 YALE L.J. 2071 (1998).

291. See, e.g., Rabin, *supra* note 164, at 951–55.

In other words, claims that the tort system needs to be reformed as a result of its inability to deal well with the types of claims presented in asbestos, tobacco, and pharmaceutical products litigation are valid, but may give the tort system too much credit. The inability of plaintiffs to aggregate their claims in Jasper (and beyond), the jury's treatment of uncertain science, and the exorbitant punitive awards all suggest that the tort system may not deal well with even much smaller toxic harms. This case study, then, supports arguments for either substantial procedural changes to the modern tort system or a rejection of that system entirely and a movement towards an administrative/compensatory scheme.²⁹²

On the other hand, the successes of the popcorn lung litigation may teach us transferable lessons. One victory in the fight against popcorn lung was scored when the industry announced its intention to eliminate the use of diacetyl. In large part, this action was a response to consumer concern, which was cultivated and made possible by the media's attention to the illness and the related litigation. For better or worse, the media have an enormous role to play in regulating toxics. Still another victory in the regulation of diacetyl is found in the work of NIOSH and OSHA, which eventually acted to teach industry how to protect workers. Congress, too, deserves credit for forcing OSHA's hand. The wisdom of promulgating a rule on diacetyl remains open to debate, but criticism of OSHA for its failure to issue communications guidelines and a safety bulletin in a timely manner is well-founded. This case study provides those seeking regulation of toxic harms with a reminder that the balance of powers in Washington sometimes works: here, an active Congress was able to rouse an executive agency from its absolute hibernation.²⁹³

Given how unusual the facts of Wayne Watson's case are, it is unlikely that popcorn consumers will experience an epidemic of bronchiolitis obliterans. And now that NIOSH and OSHA have offered recommendations to manufacturers who use buttered flavoring, no workers who are joining the workforce should contract this terrible disease. Nonetheless, as doctors have become more aware of bronchiolitis obliterans, a significant number of workers who were previously diagnosed with a wide range of respiratory ailments may find that they actually have "popcorn lung." The systems of workers' compensation and civil litigation will likely deal with these claims in familiar ways.

But when the next outbreak happens, we should remember the Jasper plant for the lessons chronicled above. Effective litigation can have both direct and indirect regulatory force. An aggressive response by the media

292. *See generally id.*

293. This lesson was not lost on Congress, which recreated the type of legislative pressure it had cultivated in the effort to regulate diacetyl in order to catalyze OSHA to regulate combustible dust. *See Worker Protection Against Combustible Dust Explosions and Fires Act of 2008, supra* note 259.

may be able to remove potentially dangerous products from the market and potentially hazardous substances from the workplace. A vigorous response from government researchers and politicians should focus not on rulemaking and partisan bickering, but on immediate and constant distribution of accurate information to workers and industry. OSHA should consider new efforts to educate the relevant parties about the requirements of its hazard communication standard, and perhaps increase the cost of violations. Changes to the American tort system should be given renewed consideration in the context of toxic harms, no matter how small. A story that began in the small town of Jasper, Missouri, holds lessons for the entire country.