

Tests of lung function given to workers in the microwave popcorn factories showed rapid deterioration of breathing ability, ultimately linked to breathing the flavoring compound diacetyl.



### CASE STUDY 3

# The Poison that Smells Like Butter: Diacetyl and Popcorn Workers' Lung Disease

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

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

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

**“One of the doctors who worked on the first case involving the two workers with bronchiolitis obliterans in 1990 said that the flavoring industry was using workers as ‘blue collar guinea pigs.’ I played by the rules. I worked to support my family. This unregulated industry virtually destroyed my life. Don’t let it destroy the lives of others. These chemicals that are used on food in large scale production must be tested and proper instructions and labeling supplied with their sale.”**

— Statement of Eric Peoples to the House Committee on Education and Labor, 2007<sup>1</sup>

**F**IRST DESCRIBED IN 1835, *BRONCHIOLITIS obliterans* is a life-threatening and irreversible lung disease. It is a rare disease—most chest doctors see only a handful of cases in their careers. In individuals with *bronchiolitis obliterans*, the airways of the lungs are inflamed and scarred, resulting in severe shortness of breath and a dry cough.

Popcorn worker Gerald Morgan described living with *bronchiolitis obliterans* this way: “Take four

bulldozers and put them on your chest. Then put an elephant on top of those bulldozers.”<sup>2</sup>

Yet Eric Peoples’ disease started out, as many do, as “unremarkable.” Patients first present with a non-productive cough or shortness of breath, symptoms that may not be recognized as serious at the beginning. Only 10 months after working in the mixing room of the Jasper Popcorn Company, Eric Peoples developed symptoms that he thought were simply the result of a cold or the flu.<sup>3</sup> As he

*“Take four bulldozers and put them on your chest. Then put an elephant on top of those bulldozers.”*

described his illness at that time, “We tried to treat it with over-the-counter medications, and nothing seemed to work.”<sup>4</sup> Peoples’ doctors first diagnosed him with pneumonia. When his symptoms didn’t improve, he saw a specialist and was given a diagnosis of asthma.<sup>3</sup> When Peoples was hospitalized for continued breathing difficulties, further tests revealed *bronchiolitis obliterans*.<sup>3</sup> The 27-year-old was told that there was no cure and that he would need a double lung transplant to survive.<sup>3</sup>

Unlike many lung diseases, *bronchiolitis obliterans* is not caused by smoking. It’s a poorly understood and uncommon disease, linked to severe viral infections, some bad drug reactions, and, in a small number of prior cases, exposure to strongly irritating vapors or gases like ammonia, sulfur dioxide, and chlorine.<sup>5,6</sup> Because of the tragic stories of Eric Peoples and a handful of other workers, researchers have now added a food flavoring chemical, diacetyl, to the list of agents linked to this disease.

### The disease cluster

In early 2000, a lawyer, whose mother had fallen ill working at the same popcorn plant as Eric

Peoples, showed the medical records of several workers to Dr. Allen Parmet, a Kansas City physician who specializes in occupational hazards.<sup>3</sup> Immediately seeing a pattern, given the rarity of *bronchiolitis obliterans*, Dr. Parmet wrote to the Missouri Department of Health and Senior Services (MoDHSS) in May 2000, reporting eight cases of *bronchiolitis obliterans* among former workers of the Jasper Popcorn Company, a microwave popcorn manufacturer, now the Gilster-Mary Lee Corporation.<sup>7,8</sup> Dr. Parmet’s letter also stated that 20 to 30 former employees might have respiratory symptoms suggestive of subclinical bronchiolitis.<sup>7</sup> MoDHSS sought assistance from the National Institute for Occupational Safety and Health (NIOSH) as it proceeded with its investigation of the cases and also alerted the Occupational Safety and Health Administration (OSHA) on May 19, 2000 requesting that OSHA, “. . . inspect the facility for compliance with your regulations. 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.”<sup>7</sup>

### OSHA’s initial response

A few days later, on May 23, 2000, an OSHA inspector was sent to the Gilster-Mary Lee Corporation popcorn plant. In the inspection report, the inspector noted that company management had only recently become aware of the potential hazard in their facility when told by a workers’ compensation attorney that there were eight former employees with breathing problems.<sup>9</sup> Even though company management seemed to dismiss claims of work-related illness, they had asked their insurance carrier to sample the plant for dust.<sup>9</sup> The results were well below the allowable level set by OSHA.<sup>9</sup> Seeing these results, the OSHA inspector conducted no additional dust sampling, because it was his “professional opinion that it would be ludicrous to re-sample the area again.”<sup>9</sup> Samples of respirable oil mist were collected and sent to an OSHA lab in Salt Lake City.

Yet the lab did not test the samples, indicating that “OSHA’s sampling method for oil mist pertained only to oil mist particulate off gassed from petroleum based oils not vegetable food grade oils.”<sup>9</sup> The inspector “determined the company to be in compliance and closed out the case file since

## ABOUT THIS CASE STUDY

This case study tells the story of disabling and potentially fatal lung disease among workers exposed to butter flavoring chemicals. The case study follows the chronology of the story as it unfolded, revealing the response by federal and state agencies and the factors that influenced their actions, or lack thereof, to protect workers. This case points out the challenges of chemical-by-chemical regulation spanning multiple agency jurisdictions, and highlights the essential role played by occupational/environmental health specialists on the front lines of detecting and minimizing harm to workers.

there were no other OSHA sampling protocols at his disposal to test further at the plant.”<sup>9</sup> OSHA’s primary approach to protecting workers is enforcing specific standards. Where there is no standard, OSHA historically has taken only limited action despite its general duty to protect workers.

### **NIOSH investigates**

NIOSH has a different mission—it is charged with investigating hazards and making general recommendations for improving workplace health and safety, including recommendations to OSHA; it has no enforcement powers of its own. Working with MoDHSS, NIOSH investigators quickly determined that the eight sick employees worked primarily in just two production areas of the plant—they had worked either as mixers or as microwave-packaging workers. Based on the presence of eight affected workers, NIOSH and MoDHSS calculated a 5- to 11-fold excess of occupational lung disease compared to what would be expected based on national surveillance data.<sup>8</sup>

In November 2000, the government agencies broadened their investigation to include all current workers at the Jasper plant. They found that the workers had nearly three times the rates of chronic cough and shortness of breath that would be expected based on national data, and twice the rates of physician-diagnosed asthma, and chronic bronchitis.<sup>10</sup>

These early NIOSH and MoDHSS worksite investigations could not identify any known substance to explain the illnesses.<sup>8</sup> Yet because the risk of permanent lung damage was concentrated among mixers and packaging workers, NIOSH issued interim recommendations (with no legal force) in December 2000 that all workers wear respirators until further notice.<sup>8</sup>

As part of the November 2000 survey, NIOSH and MoDHSS also took samples of the worksite air. Samples detected respirable dusts and volatile organic compounds, which were primarily ketones, including diacetyl.<sup>11</sup> Mixing area employees’ exposures to diacetyl were 17 to 1,000 times greater than exposures of other employees at the plant, whereas the difference in exposure to respirable dusts was less than 10-fold between the least and most exposed groups.<sup>11</sup> This prompted health investigators to take a closer look at diacetyl.

### **Diacetyl: Generally recognized as safe?**

Diacetyl (also called 2,3-butanedione) occurs naturally in trace quantities in dairy products, fruit, and wine.<sup>12</sup> The microwave popcorn industry found that it made a good butter flavoring and increased the amount of diacetyl in its flavorings for a more intense butter taste.<sup>12</sup> The compound was first identified by the noted scientist Louis Pasteur in the 1860s in his research on the fermentation of beer and ale.<sup>12</sup> In the early 1900s, scientists realized they could inexpensively synthesize diacetyl from methyl ethyl ketone.<sup>12</sup> It is estimated that diacetyl is now added to more than 6,000 food products, including baked goods, beverages, candy, chips, and frozen dinners.<sup>12</sup> Neither OSHA nor NIOSH has required or recommended limits for diacetyl in workplace air that would ensure the safety of workers handling the chemical.<sup>13</sup>

As a chemical in food, diacetyl is regulated under the authority of the federal Food and Drug Administration (FDA). In general, food additives require premarket approval by FDA to ensure that they are safe for their intended use.<sup>14</sup> There’s an important loophole, though. Substances that are *generally recognized as safe* (GRAS) are not considered “food additives” and thus do not require premarket FDA approval.<sup>15</sup>

According to the FDA, a substance is determined to be to be GRAS if information about the substance is widely known and if there is consensus among qualified experts that available information indicates that the substance is safe under the conditions of its intended use. For substances used in food before 1958, a GRAS determination can be made through experience based on common use in food.<sup>14</sup>

Diacetyl has been considered GRAS since 1980, when an FDA review committee examined two toxicity studies—neither using humans and neither having any relevance to lung disease—and made the determination that: “There is no evidence . . . that demonstrates or suggests reasonable grounds to suspect a hazard to the public when [diacetyl is] used at levels that are now current or that might reasonably be expected in the future.”<sup>16</sup> The two studies that formed the basis of this determination were a test of mutagenic activity in cells cultured in the lab and an animal feeding study looking for

evidence of teratogenicity (effects on the fetus). Each study demonstrated no effect.

With hindsight, we can see a missed opportunity to prevent the cluster of lung disease cases in the microwave popcorn plants when, in 1994, the National Institute for Environmental Health Sciences' National Toxicology Program (NTP) nominated diacetyl for mechanistic, metabolism, and carcinogenicity studies based on ingestion.<sup>17</sup> With very limited funds available for this program, NTP

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*The more diacetyl a worker had breathed, the worse his/her lung function was.*

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can test only a few chemicals each year, and diacetyl was ultimately dropped from consideration in 1999. However, based on its initial testing, NTP acknowledged “the potent irritant properties of this chemical.”<sup>17</sup> Even if diacetyl had been subjected to a larger battery of tests, these might not have found evidence of lung toxicity, because as a food additive, the focus of NTP's additional testing focused on risks from ingestion, not from inhalation.<sup>17</sup>

Why were workers allowed to breathe very high concentrations of a toxic chemical? There were no workplace standards controlling its use, and no evidence that it would be harmful to workers. And, in the absence of any evidence that it was harmful, it was considered safe. Not until 2007, seven years after the Jasper, Missouri cluster was identified, did the NTP begin long-term animal testing, including respiratory toxicity testing, of diacetyl, based on a request by the United Food and Commercial Workers International Union (UFCW).<sup>17</sup>

**First links between respiratory illness and butter flavoring chemicals**

The NIOSH and MoDHHS survey of the Jasper popcorn factory in November 2000 found the diacetyl concentration in the air of the mixing tank room to average 18 parts per million (ppm). An intermediate concentration, 1.3 ppm, was documented in the packaging area, and lower but still detectable levels (averaging 0.02 ppm) were detected in other areas of the plant.<sup>8</sup> Short-term

“peak” concentrations in the popcorn production areas in general were as high as 98 ppm.<sup>11</sup>

This investigation also considered the health of workers, and it didn't just focus on the eight cases of the serious lung disease, *bronchiolitis obliterans*, but examined all the workers to see if there was evidence of a gradient of lung damage in the workforce generally. And there was: rates of symptoms of deep lung damage (such as chronic cough and wheeze) were found to track closely with where a worker spent most of his/her time working.<sup>10</sup> Measurements of breathing capacity across the workforce at Jasper showed the same thing—the more diacetyl a worker had breathed, the worse his/her lung function was.<sup>8,10</sup>

This was particularly strong evidence of diacetyl's danger. Not only was diacetyl linked directly to a handful of cases of disabling lung disease in the most heavily exposed, but it seemed also to have significant pulmonary health effects on those with lower levels of exposure. This meant that there could be thousands of “silent” cases of illness spread across industry, wherever diacetyl was being used.

**NIOSH moves forward**

In January 2001, NIOSH assisted Gilster-Mary Lee to improve ventilation, thus dramatically decreasing diacetyl concentrations in the mixing and packaging areas and reducing the risk of *bronchiolitis obliterans* in that plant.<sup>11</sup>

Eight months later, NIOSH issued its interim report on the investigations at the Gilster-Mary Lee plant. It provided evidence that the butter flavoring mixture containing diacetyl and other volatile organic compounds caused damage to the lungs of rats that was consistent with the way that *bronchiolitis obliterans* attacks human lungs.<sup>11</sup> NIOSH promptly shared its findings with workers at the plant in September 2001. The Institute's fact sheet began with the warning: “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.”<sup>18</sup>

In 2002, NIOSH published the first of several toxicological studies in which rats were exposed to airborne concentrations of butter flavoring similar to those found in factories.<sup>19</sup> There was substantial lung damage in the rats, described by the lead researcher, Dr. Ann Hubbs, as “the most

dramatic cases of cell death ever seen in some tissues.”<sup>20</sup> Subsequent toxicological studies published in 2006 exposed rats to pure diacetyl and found similar results.<sup>21</sup>

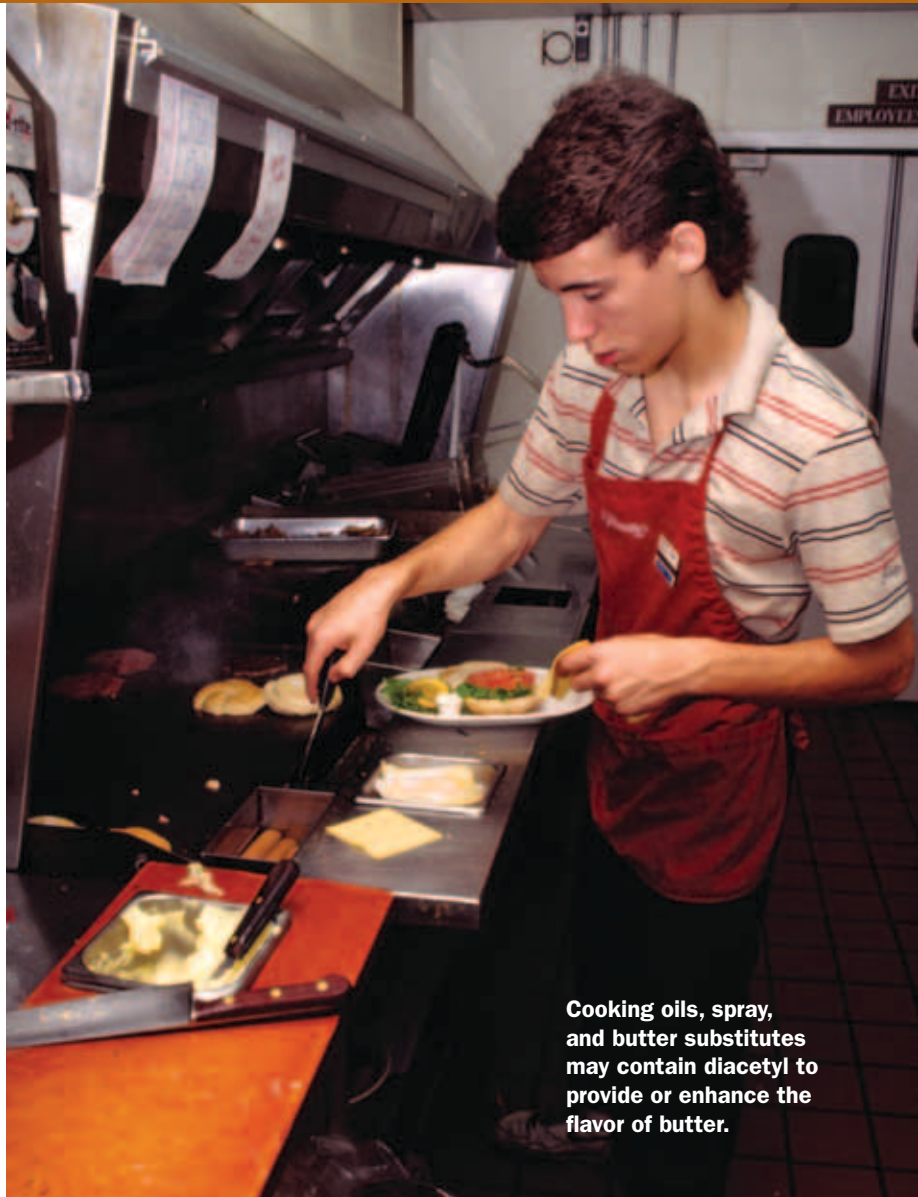
Unbeknownst to NIOSH researchers at the time, the German chemical manufacturer BASF had previously conducted an acute inhalation toxicology study, published as an internal report in 1993, that exposed rats to diacetyl for a single four-hour period. The results—which were never published in the scientific literature or reported to any government agency, but emerged during the legal trials of the cases brought by the Gilster-Mary Lee workers—found that in rats, “[exposures at the] mid and high concentrations resulted in an abundance of symptoms indicative for respiratory tract injury.”<sup>22,23</sup>

NIOSH also conducted similar medical and industrial hygiene evaluations in five other microwave popcorn plants. Results similar to those at the Gilster-Mary Lee plant were found: the prevalence of respiratory symptoms and the prevalence of airway obstruction were higher among workers in mixing operations and in packaging areas near tanks of oil and flavorings.<sup>24</sup> Among the important findings from these five plants was documentation of airway obstruction in a worker in the flavoring mixing area where the diacetyl concentrations were relatively low—less than 1.0 ppm. This suggested to NIOSH that the “safe” level in air must be well below this concentration.<sup>24</sup>

#### Where was OSHA?

It is often NIOSH that takes the lead to better characterize an occupational health problem and recommend solutions when a new and unknown workplace hazard emerges. Yet these solutions are simply recommendations. Only OSHA has the regulatory authority to enforce NIOSH’s recommendations. In contrast to NIOSH, whose scientists made successful efforts to identify hazards and to minimize new cases of respiratory illness among microwave popcorn manufacturing workers, OSHA watched and waited.

Sixteen months after the OSHA inspector had, in effect, closed out the case at the Gilster-Mary Lee facility, an attorney representing several of the sick workers filed a complaint with OSHA, and followed up with another complaint in December



**Cooking oils, spray, and butter substitutes may contain diacetyl to provide or enhance the flavor of butter.**

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2001. As detailed in a case study of popcorn workers’ lung produced by the Project on Scientific Knowledge and Public Policy, the attorney’s letter “alleged that not enough had been done to improve ventilation in the plant, as evidenced by the fact that ‘one employee lost half of his lung capacity working in the plant *after* the remedial measures that NIOSH suggested were taken’ (emphasis in original).”<sup>25</sup>

This prompted OSHA to send another inspector to visit the plant, but the inspector did not conduct an inspection. OSHA then sent a letter to the attorney who had filed the complaints, denying the need for further investigation at the plant. The letter explained: “[T]he hazard which you brought to our attention has been corrected and . . . Gilster [*sic*] Mary Lee is complying with the

recommendations of NIOSH. . . . The hazard does not fall within OSHA's jurisdiction because there is no Permissible Exposure Limits [*sic*] for the food blend chemicals of concern that are used at the factory."<sup>25</sup> But this reasoning is clearly flawed. The lack of a specific standard for diacetyl may limit OSHA's specific regulatory power, but not its authority to ensure that workplaces are safe.

The Occupational Health and Safety Act of 1970 created OSHA and gave it the authority to ensure that workplaces are free from "recognized

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hazards." Specific standards for individual chemicals are only one way to achieve this. When faced with a hazard for which no standard exists, OSHA has the authority to issue an emergency temporary standard or to invoke the "general duty clause" that requires employers to reduce or eliminate recognized hazards. Yet OSHA's legal advisors within the Department of Labor's Office of the Solicitor often prevent OSHA from taking such actions. The Bush administration's Department of Labor was not interested in having OSHA use its authority under the general duty clause to protect workers from diacetyl exposure. Further, OSHA also denied a petition for emergency temporary standards filed jointly by the United Food and Commercial Workers Union and the International Brotherhood of Teamsters.

In September 2002, OSHA entered into an alliance with the Popcorn Board, a trade group, to promote hazard communication and outreach efforts to at-risk workplaces.<sup>25</sup> Yet six months later, in March 2003, the alliance ended for reasons unknown, even though concern about exposures to diacetyl and other artificial butter flavoring compounds in the microwave popcorn manufacturing industry was peaking.<sup>25</sup> OSHA began inspecting facilities to control hazards associated

with diacetyl exposure only in 2006, six years after it was first alerted to the problem, five years after NIOSH first identified the likely risk factor contributing to the respiratory disease, and four years after strong incriminating evidence emerged from NIOSH's animal studies, showing that diacetyl was the most likely culprit.<sup>26</sup>

### Regulation by litigation

As one legal analyst has written about this juncture in the diacetyl story, "In the face of regulatory paralysis and scientific uncertainty came trial lawyers."<sup>27</sup> Workers can't usually sue their employers when their jobs make them sick—workers' compensation laws bar such direct suits. But lawsuits can be filed against the companies that produced the hazardous chemicals—in this case, the diacetyl-containing butter flavorings. Such actions are known as "third-party" suits.<sup>27</sup>

### Legal action against the manufacturer of diacetyl

International Flavors and Fragrances (IFF), Inc. acquired the original manufacturer of the butter flavoring used by Gilster-Mary Lee Corporation in 2000. A class action lawsuit was filed against IFF by the Gilster-Mary Lee workers and their spouses in September 2001 alleging that IFF and its corporate predecessor, Bush Boake Allen, Inc. had manufactured butter flavoring that caused their injuries.<sup>28</sup> A trial date was set for March 1, 2004.<sup>28</sup> After complex legal maneuvering separated individual injured worker's claims from the class action, a Missouri jury took just over three hours to deliver a verdict in favor of Eric and Cassandra Peoples. IFF was ordered to pay \$18 million to Eric Peoples and \$2 million to his wife.<sup>4</sup> During the trial, the plaintiffs argued that IFF had failed to warn Gilster-Mary Lee employees about the dangers of the butter flavorings or to provide adequate safety instructions.<sup>27</sup> IFF argued that diacetyl was not the cause of Peoples' disease, and that even if it was, harm was caused by his improper handling of the chemical.<sup>27</sup> As stated by IFF's attorney in closing arguments, information sent to microwave popcorn plant officials warned that the flavoring should be mixed in a well-ventilated area and that a respirator should be worn when heating it. "We know beyond a shadow of doubt that if you use basic hygiene practices, you don't

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**“Into the void left by regulatory paralysis and scientific uncertainty came trial lawyers.”**

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have a problem in this plant.”<sup>4</sup> Eric Peoples, however, noted that plaintiff’s attorneys had acquired during discovery detailed information that demonstrated IFF’s failure to warn Gilster-Mary Lee Corporation of the real harms of diacetyl:<sup>1</sup>

*The company that supplied the butter flavor, Bush Boake Allen...[acquired by IFF] had extensive notice about the hazards of butter flavor. They treated butter flavor as a hazardous chemical within their own plant. Since at least 1994 their own workers were required to wear respiratory protection when working around the butter flavor. Despite wearing full-face respirators, many of their employees suffered severe eye injuries. Because of the dangers of the product, the entire manufacturing process was enclosed so no one could be exposed to the vapors. In addition, information had come to IFF about the respiratory effects of exposure to diacetyl. In 1986, two employees of a baking company had been diagnosed with bronchiolitis obliterans while mixing a butter flavoring for use on cinnamon rolls.*

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

Between spring and summer 2005, IFF suffered many verdicts against it, and by November 2005 it had settled with 54 microwave popcorn plant workers.<sup>2</sup> All cases severed from the original class action were settled.<sup>27</sup> Today, hundreds of cases in several states are still pending. In August 2010, a jury in Chicago awarded another Jasper popcorn plant worker with *bronchiolitis obliterans* a \$30.4 million verdict.<sup>29</sup>

The early litigation results and rising consumer

concern about the safety of microwave popcorn probably played a role in the decision by leading microwave popcorn manufacturers to eliminate diacetyl from their products in 2007, as described below.<sup>30</sup>

**Successful regulation by litigation? Not so fast**

The diacetyl legal cases were rather quickly tried and settled compared to many other “toxic torts,” cases. In toxic tort cases, plaintiffs claiming harm bear the burden of proving causation by a preponderance of the evidence. The diacetyl plaintiffs thus had the burden of demonstrating that their lung problems would not have developed without their exposure to diacetyl, and that their disease should have been foreseen by their employer.<sup>27</sup>

Demonstrating that an industrial or environmental chemical exposure was the cause of a plaintiff’s disease is not an easy task. The legal requirement to demonstrate “factual” causation is inherently difficult because of scientific uncertainty: no matter how much we study the health effects of a chemical, uncertainties in our knowledge linger, given the complexities of the human body and limitations in the design of observational and even experimental studies.

Science by its very nature never operates in absolute certainties, but by the weight of the evidence. Despite this tenet of science, companies being sued in toxic torts often raise the specter of doubt by focusing on the limitations and uncertainties in the scientific evidence.<sup>31</sup> These uncertainties are magnified further in cases when the plaintiff’s disease has a long latency period (like cancer) or when the disease might also have been caused by some common exposure (like smoking).

In addition, in federal courts and in some state courts that follow the Supreme Court’s *Daubert* decision, judges have the authority to decide—often pretrial—whether expert evidence is sufficiently scientific to merit consideration in the case.<sup>3</sup> While judges have always maintained the authority to determine the admissibility of evidence, *Daubert* courts apply a more rigorous standard of evidence

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<sup>a</sup> *Daubert v. Merrell Dow Pharmaceuticals, Inc.* (1993) directed federal judges to serve as “gatekeepers” of expert testimony. In a subsequent 1997 decision in *General Electric v. Joiner*, the Supreme Court set a high bar for overturning trial judges’ decisions about admissibility of expert testimony: appellate judges were to uphold trial judges’ decisions unless they could find that the trial judge had abused his discretion. In 1999, the Supreme Court clarified in *Kumho Tire v. Carmichael* that it intended *Daubert* to apply to all expert testimony, not just evidence that relies on science. These three cases are known as the *Daubert Trilogy*. See Berger, MA. What has a decade of *Daubert* wrought? *American Journal of Public Health*. 2005;95:559–65.



and determine whether specific scientific expert testimony is both “relevant” and “reliable.” Because plaintiffs bear the burden of proof, defendants often file a *Daubert* motion first, calling into question the relevance and reliability of the plaintiff’s expert scientific testimony. These evidentiary standards are a giant hurdle for plaintiffs to surpass.<sup>32</sup> Judges have routinely misinterpreted scientific uncertainty to mean that specific evidence is “irrelevant” or “unreliable,” and have thus sup-

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*Science by its very nature never operates in absolute certainties, but by the weight of the evidence.*

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ported a defendant’s motion for summary judgment, by which cases are dismissed before ever being heard before a jury.<sup>33</sup>

As legal scholars have noted, the diacetyl cases did not exhibit the barriers typical of most toxic tort cases.<sup>27</sup> While scientific uncertainty linking health harms associated with diacetyl remains—as it does for nearly every exposure–disease association—*bronchiolitis obliterans* is a rare disease with only a few known causes. Rule out other known risks, such as organ transplantation and exposure to other toxic fumes, and you’re left with only one likely cause: diacetyl. And unlike many diseases, *bronchiolitis obliterans* has not been linked to smoking.

In addition, breathing diacetyl leads to severe, disabling lung disease without much of a time lag, and this simplifies the investigation of causal risk factors. Lastly, Eric Peoples’ case and the other initial Gilster–Mary Lee Corporation employees’ cases against IFF were filed in state courts not subject to evidentiary standards under the *Daubert* decision.

Thus, while our tort law system worked to provide a remedy for harms incurred by diacetyl–exposed workers, and may have ushered in a move towards eliminating this hazard in the absence of regulation by our federal and state governments, regulation by litigation is not a solution for the vast majority of toxic harms facing workers. Even though a successful toxic tort claim prevented future cases of disease, it can’t restore Eric Peoples’ lungs. Clearly,

the best solution is to identify and replace toxic chemicals before they enter the economy.

### **The hierarchy of industrial hygiene controls: when substitution isn’t safe**

NIOSH follows a well–established hierarchy of industrial hygiene controls when making recommendations to control workplace hazards. An employer is typically urged to start at the top of the list and try to control the hazard there, before moving down to a less effective strategy. The NIOSH hierarchy for diacetyl looks like this:<sup>13</sup>

1. Substitute a nonhazardous flavoring for the hazardous one.
2. Use engineering controls such as a closed production system, isolated mixing rooms, or very good local exhaust ventilation.
3. Make administrative changes to reduce exposures, such as enforcing procedures for safe handling, attention to maintenance, and rapid cleaning of spills.
4. Improve training and provide better information about the hazard and ways to avoid it.
5. Provide personal protective equipment such as respirators and gloves.
6. Monitor exposures and workers’ health.

The hierarchy of industrial hygiene controls for diacetyl, like those for most other industrial chemicals, puts substitution at the top because, if the chemical is eliminated, it can’t do any harm—there’s no need to worry about whether the ventilation system is being properly maintained, or whether each worker is using his/her respirator properly, for example.

But in its warning to popcorn manufacturers in 2003, NIOSH skipped substitution in its recommendations: “Engineering controls are the *primary* method for minimizing exposure associated with the use or manufacture of potentially hazardous flavoring.”<sup>13</sup> Why? NIOSH was likely worried that so little was known about the safety of flavorings that the manufacturers might choose a substitute chemical for which there was no evidence of risk, but which later turned out to be just as hazardous as diacetyl.

This is a serious systemic flaw in the way chemicals are regulated today. So few of the chemicals in commerce have been adequately tested that substi-

tution may be a risky proposition. The Government Accountability Office (GAO) has called the Environmental Protection Agency's (EPA's) meager record in assessing the toxicity of chemicals—among the tens of thousands in commerce—a “high risk” issue for public health.<sup>34</sup> Safe workplace exposure limits (either OSHA's Permissible Exposure Limits (PELs) or NIOSH's recommended Exposure Limits (RELs)) have been developed for fewer than 5 percent of the 1,037 flavoring ingredients that have the potential to be respiratory hazards based on their volatility and irritant properties.<sup>13</sup>

Despite this context, substitution is precisely what many microwave popcorn manufacturers did. In 2007, Pop Weaver and ConAgra, the two largest suppliers of microwave popcorn, announced that they were eliminating diacetyl from their products.<sup>30</sup> Two other suppliers, General Mills and American Pop Corn, subsequently followed the same course of action, each stating they were on the road to “eliminating” diacetyl from their recipes, or had already done so.<sup>35</sup>

But they didn't eliminate the hazard. The “new, safer, butter substitutes” in some cases are at least as toxic as diacetyl, and in other cases are essentially diacetyl by another name.<sup>36</sup> “Diacetyl trimmer” releases diacetyl in the presence of heat and water; and “butter starter distillates (starter mix)” contains high concentrations of diacetyl.<sup>36</sup>

“We've been very clear to flavor manufacturers, food companies and regulators that the so-called substitutes are diacetyl,” said John Hallagan, general counsel for the Flavor and Extract Manufacturers Association.<sup>36</sup> On December 23, 2009, NIOSH Director John Howard sent a letter to David Michaels, the new Assistant Secretary of Labor for OSHA, stating that research at NIOSH and the National Institute of Environmental Health Sciences addressing the respiratory toxicity of diacetyl substitutes demonstrates that the principal component of one such substitute, 2,3-pentanedione, has very similar animal toxicity to that of diacetyl. Moreover, another substitute, acetoin, lacks toxicity testing data and “accompanies diacetyl in many of the workplaces where *bronchiolitis obliterans* occurs in workers who make or use flavorings.”<sup>37</sup>

While substitution is the preferred approach to protect not only workers but also the broader



**Bronchiolitis obliterans—a lung disease as frightening as it sounds—was diagnosed in a cinema employee who routinely popped dozens of bags of microwave popcorn to fill a dispenser like this.**

public from chemical hazards, it's dangerous to pick substitutes without a thorough overhaul of our system to manage the safety of chemicals in commerce. Even limited evidence of hazard from a chemical should stimulate the search for safer alternatives. Designed correctly, chemical regulations can stimulate scientific research and technological innovation. But at present, the United States has a disjointed collection of overlapping jurisdictions for chemicals, and a system that tends to treat hazards as "safe until proven hazardous"—just the opposite of what is needed to protect workers and the public. Tragically, the doctor quoted by Eric Peoples was right when he said that workers are our nation's "blue collar guinea pigs."<sup>1</sup>

### What is the true scope of diacetyl's impact?

From the public health perspective, Eric Peoples and the other Gilster–Mary Lee workers made sick by diacetyl are sentinels: their experience raised the alert about this chemical. But a much larger group of people have been affected by it.

### More workers affected

Nobody knows how many workers are exposed to artificial butter flavorings, because there is no way to identify facilities that use these chemicals. In 2004 and 2006, Dr. Phil Harber, an occupational physician at the University of California at

severe airway obstruction—a broad category of serious lung disease that includes *bronchiolitis obliterans*.<sup>39</sup> Eight workers in this study were confirmed as having either *bronchiolitis obliterans* or fixed obstructive lung disease.<sup>39</sup>

When these two sentinel cases of *bronchiolitis obliterans* were found in California, the California Department of Health Services' Hazard Evaluation System and Information Services (HESIS) wanted to rapidly warn other workers about the risk of diacetyl, but had no way of finding out which workplaces used butter flavorings.<sup>40</sup> California's experience is emblematic of this problem nationally: there are no federal laws requiring firms to disclose the volume of chemicals that they produce or the customers to whom they sell them.<sup>b</sup> In California, attempts to request that chemical manufacturers and importers voluntarily disclose their client lists have been ineffective. For example, of the 96 manufacturers and importers that HESIS contacted requesting client lists for seven chemicals that pose chronic health hazards, only six companies complied with the request.<sup>40</sup> Of 127 manufacturing facilities in California using flavorings, only 16 voluntarily disclosed that they used diacetyl.<sup>41</sup> California attempted to pass a law to rectify this problem, but the bill was vetoed by the Governor in 2007.<sup>40</sup> The lack of an infrastructure to support health officials in meeting their responsibility to identify and warn workers who are at risk, and identify early-stage cases of disease, is a significant gap in efforts to protect worker safety and health.

### The first cases among the public

When the cases of *bronchiolitis obliterans* at the Jasper popcorn plant hit the national news media, one of the first questions journalists asked was: is there a risk to people who buy and eat microwave popcorn? In 2003, EPA's Indoor Air Quality Research program began a study to characterize compounds released when microwave popcorn was popped and opened. The study was completed in late 2005.<sup>42</sup> The Agency circulated its report to the popcorn industry to assure company officials that no confidential business information was

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Los Angeles, diagnosed the first two cases of *bronchiolitis obliterans* in California. The two worked at separate flavoring manufacturing facilities, and both handled diacetyl.<sup>38</sup> These cases triggered an investigation by the California Department of Health Services of medical surveillance data from 15 flavor manufacturing companies in California. The study found evidence of increased risk of

<sup>b</sup> Massachusetts and New Jersey have the only state laws that require high volume users of toxic chemicals (facilities that use 10,000 pounds per year and employ at least 10 employees) to report their use to state agencies. Supply chain information is not included in these laws.



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**Workers have a right to a safe and healthy workplace. But that won't happen as long as chemicals like diacetyl are untested and unregulated.**

disclosed or would be released to the public.<sup>43</sup> Yet EPA never publicly released its results. Despite a petition and a Freedom of Information Act request to get EPA to release its findings to the public, EPA refused to do so, saying that this might prevent the scientists involved in the study from getting their work published in the peer-reviewed literature.<sup>42,43</sup> The EPA scientists' research was published in November 2007. Their work revealed that diacetyl was one of the predominant emissions and that 80 percent of the total chemical emissions occur when the microwave popcorn bag is first opened after popping.<sup>44</sup> Yet the research fell short of determining what, if anything, these results mean for consumer risk.

Nevertheless, risks to consumers did come to light. Two months before EPA's scientists published their research, Dr. Cecile Rose, the director of occupational disease clinical programs at National Jewish Medical and Research Center in Denver, evaluated a 53-year-old Colorado man for decreasing lung function.<sup>45</sup> The man had eaten microwave popcorn twice a day for more than 10 years.<sup>45</sup> As Dr. Rose told the *New York Times*, "When he broke open the bags, after the steam came

out, he would often inhale the fragrance because he liked it so much."<sup>45</sup> Dr. Rose later measured diacetyl levels in the man's home that were similar to levels found in the microwave popcorn plants.<sup>45</sup> Since 2007, cases of lung disease possibly linked to butter flavoring exposure in microwave popcorn have been identified, including a Blockbuster Video employee who, every Friday and Saturday, popped 30 bags of microwave popcorn in a small back room of the store and emptied them into a larger popcorn machine for patrons to scoop out and enjoy with their movies. A lung biopsy confirmed a diagnosis of *bronchiolitis obliterans*.<sup>36</sup>

### **Hope for greater protections through regulatory action**

With intensifying public pressure, thanks in part to a significant number of media stories about the cases of popcorn workers' lung, as well as public health scientists calling upon FDA, EPA, and OSHA to act, more protective policies are being pursued by some, but not all, agencies.<sup>25</sup>

**FDA:** Despite petitions to the FDA by the Project on Scientific Knowledge and Public Policy on September 6, 2006 and by US Congressional

Representative Rosa DeLauro of Connecticut on September 11, 2007 requesting that FDA revoke diacetyl's GRAS status, diacetyl is still on the GRAS list as of this writing. In January 2010, the Project on Scientific Knowledge and Public Policy received a letter from Mitchell Cheeseman, Acting Director of the FDA's Office of Food Additive Safety, stating that the petition is still under active review, and that this review is incorporating all existing scientific evidence and is considering the issue of inhalation.<sup>46</sup>

**EPA:** Despite publishing its research in 2007 confirming emissions of diacetyl from opening a bag of microwave popcorn after cooking, EPA has not acted on this evidence or explained what its findings mean for consumer health.

**Cal OSHA:** Prompted by the cases of *bronchiolitis obliterans* among workers in California exposed to butter flavoring ingredients and inaction by OSHA on the issue, California pushed forward regulatory options to prevent harm to workers who are exposed to diacetyl. On August 18, 2006, the Division of Occupational Safety and Health at the California Department of Health Services received a letter from 23 California legislators requesting adoption of an emergency standard and then a permanent standard covering exposure to diacetyl. A similar letter was sent to the Occupational Safety and Health Standards Board by the California Labor Federation and the California affiliate of the United Food and Commercial Workers International Union.

In November 2009, a proposed diacetyl standard was issued for public comment. The first diacetyl standard in the country was passed by a 6-1 vote by the California Occupational Safety and Health Standards Board on September 16, 2010. The adopted standard affects flavoring and food manufacturing facilities that use diacetyl and food flavorings that contain 1 percent or greater concentration of diacetyl. This "process-oriented standard" does not mandate a PEL, but rather a series of industrial hygiene controls, hazard communication, and medical surveillance procedures that affect exposure levels not only of diacetyl, but of other butter flavoring ingredients as well. Thus the standard has the capacity to reduce exposures

not only to diacetyl, but also to hundreds of chemicals that are found with diacetyl in various butter flavoring mixtures.

**OSHA:** OSHA has faced pressure by Congress to use its regulatory authority to protect workers from diacetyl. On June 13, 2007, Congresswoman Lynn Woolsey introduced a bill entitled "Popcorn Workers' Lung Disease Prevention Act." The bill would require OSHA to (1) issue an interim standard within 90 days to regulate worker exposure to diacetyl; (2) issue a final standard within two years that provides no less protection than the recommendation in NIOSH's December 2003 Alert; and (3) require NIOSH to study and report to OSHA on the safety of food flavorings that may be used as substitutes for diacetyl.<sup>47</sup>

The bill was passed on September 26, 2007. Yet days before, OSHA preempted the legislation by announcing that it would initiate a rule-making process for diacetyl, issue a Safety and Health Information Bulletin, and provide Hazard Communication Guidance. Both of these products simply provide basic information about a hazard. The former is intended for the public and OSHA's internal staff; the latter is intended for employers.

OSHA has issued its Safety and Health Information Bulletin and Hazard Communication Guidance, but has yet to promulgate a rule. On January 21, 2009, OSHA issued an Advanced Notice of Proposed Rulemaking in the federal register. On November 25, 2009, Senator Sherrod Brown wrote to Secretary of Labor Solis urging her to expedite the final rule-making process, taking place 10 years after the dangers of diacetyl were first publicly documented.<sup>48</sup>

On a factsheet about diacetyl on its website, OSHA still maintains (as of this writing) that "a cause-effect relationship between diacetyl and *bronchiolitis obliterans* is difficult to assess because of mean diacetyl exposure levels ranging over four orders of magnitude for workplaces with affected individuals. In addition, food-processing and flavor-manufacturing employees with this lung disease were exposed to other volatile agents."<sup>49</sup> According to OSHA's spring 2010 regulatory agenda, its next step is to conduct a scientific peer review of its draft risk assessment of diacetyl.<sup>50</sup>

## LESSONS LEARNED

**T**he story that unfolded in a small popcorn plant in Jasper, Missouri, provides important lessons for the entire country.

First, when physicians are trained in occupational health and effective state occupational health surveillance systems are in place, workers' lives are protected. If it were not for astute physicians such as Dr. Alan Parmet and Dr. Phil Harbor, who diagnosed the first cases of occupation-induced illness among workers exposed to butter flavoring chemicals and who initiated effective health hazard investigations by their state health departments and NIOSH, even more workers' illnesses would have gone unnoticed and additional cases would undoubtedly have occurred. We are extremely fortunate that the popcorn lung story unfolded in the time and places it did, as the chance of a rapid response in other cities and states across the United States might not have been as likely, given lack of capacity and resources.

The Institute of Medicine has declared that there is a "critical shortage" of specialty-trained occupational and environmental physicians in communities, in academic medical centers, and in public health and related agencies.<sup>51</sup> According to a survey of medical school graduates, only 1.4 percent have taken an occupational medicine elective, and among the half of medical schools that require teaching of occupational medicine, the mean required curriculum time over the four years was four hours.<sup>52-53</sup> Similarly, according to a survey by the Council of State and Territorial Epidemiologists, 34 of 50 US states have minimal to no surveillance or epidemiology capacity in occupational health.<sup>54</sup> The

occupational medical and epidemiologic response seen in this case study is a model for the type of public health infrastructure needed across the United States.

A second key lesson revealed by this story is that protecting workers from future diacetyl/butter flavorings disasters requires a new system of ensuring adequate safety and health information regarding all chemicals in commerce and a more coordinated federal chemicals management infrastructure. While the Department of Labor's failure to respond by having OSHA use its regulatory authority to protect workers using butter flavorings is indefensible, we must ask a much larger and more fundamental question. Why is our chemicals management system in the United States—a system that spans jurisdictional boundaries across EPA, FDA, OSHA, and other agencies—dependent on first destroying the lives of workers like Eric Peoples, our "blue collar guinea pigs"? Why was diacetyl determined to be "generally recognized as safe" based on minimal testing, and why was no thought given to the impacts on workers or the general public exposed by routes other than ingestion? And while substituting a safer butter flavoring for diacetyl is the most protective strategy to prevent occupational illnesses, why is there no system to foster research that produces and identifies safer chemicals?

No tale of toxic harms has a happy ending. But the story of popcorn workers' lung teaches us of the need for effective occupational health and chemical regulatory systems to prevent workers from falling ill simply by showing up for work and doing the job asked of them.

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CASE STUDY 3 — **TIMELINE**

DATE	EVENT
<b>1980</b>	FDA issues a GRAS designation for diacetyl based on a test of mutagenic activity in cells cultured in the lab and an animal feeding study examining evidence of teratogenicity. No inhalation studies were conducted.
<b>February 1993</b>	Researchers for the German company BASF publish an internal report of the inhalation toxicity of diacetyl in rats. The rats underwent a single four-hour exposure to diacetyl vapors. Animals exposed at medium and high concentrations showed an abundance of symptoms indicative of respiratory tract injury.
<b>1994</b>	NTP nominates diacetyl for comprehensive mechanistic, metabolism, and carcinogenicity studies based on ingestion exposure.
<b>1999</b>	NTP drops diacetyl from its comprehensive testing list, though initial testing found the chemical to have potent irritant properties.
<b>May 2000</b>	Dr. Parmet notifies the MoDHHS to report multiple cases of <i>bronchiolitis obliterans</i> among workers of a Jasper, Missouri, popcorn plant. Dr. Parmet's letter also suggests that dozens of former workers also show symptoms of subclinical <i>bronchiolitis obliterans</i> .
<b>May 2000</b>	MoDHHS notifies OSHA of Dr. Parmet's letter and asks OSHA to inspect the Jasper, Missouri, popcorn plant.
<b>May 2000</b>	OSHA inspector visits the plant, but oil mist samples cannot be analyzed by OSHA's laboratory.
<b>August–November 2000</b>	NIOSH investigates a Missouri microwave popcorn facility; findings indicate that workers exposed to flavorings at the microwave popcorn plant are at risk for developing obstructive lung disease.
<b>December 2000</b>	NIOSH issues interim recommendations to the Jasper microwave popcorn plant for all workers to wear respirators to control exposure to the artificial butter flavoring compounds pending the implementation of engineering controls.
<b>August 2001</b>	NIOSH issues its Interim Report about its Jasper popcorn plant investigation.
<b>September 2001</b>	NIOSH investigators return to the Jasper factory they studied to distribute materials describing investigation results, ongoing activities, and precautions to be taken by workers.
<b>September 2001</b>	A class action lawsuit is filed against IFF by Jasper plant workers and their spouses.
<b>September and December 2001</b>	Attorney representing sick workers files complaints with OSHA, noting that workers' health continued to decline after the Jasper plant took measures recommended by NIOSH.
<b>February 2002</b>	OSHA replies to complaint filed by attorney, stating that the hazard has been corrected based on the plant's compliance with NIOSH's exposure control recommendations and that OSHA does not have jurisdiction over the food chemicals concerned because there is no Permissible Exposure Limit (PEL).
<b>April 2002 and August 2002</b>	Articles in <i>Morbidity and Mortality Weekly Report</i> (April 26, 2002) and in the <i>New England Journal of Medicine</i> (August 2002) are published describing MoDHHS's and NIOSH's investigations. The articles reveal that the rates of airway obstructive symptoms were higher among workers who worked in the production area of the plant versus other areas. The papers also reported that the more a worker was exposed to diacetyl, the worse her/his lung function was.
<b>2002–2003</b>	NIOSH scientists conducting toxicity experiments find significant adverse respiratory effects from exposure to diacetyl vapors. One of the lead researchers reveals that the substantial lung damage observed in the rats tested represented "the most dramatic cases of cell death ever seen in some tissues."

DATE	EVENT
September 2002– March 2003	OSHA begins alliance with the Popcorn Board to promote hazard communication to at-risk workplaces. The alliance ends six months later without issuing and circulating any hazard information.
Spring–Summer 2003	EPA's Indoor Air Quality Research Update reports that a project to characterize compounds emitted through popping and opening microwave popcorn is expected to be completed in December 2003.
December 2003	A NIOSH Alert is issued suggesting safeguards and asking employers to caution workers. The alert recommends: "engineering controls are the primary method for minimizing exposure associated with the use or manufacture of potentially hazardous flavoring."
March 2004	A Missouri jury delivers a verdict in favor of Eric and Cassandra Peoples for \$20 million—the first of many trials of Jasper popcorn plant workers.
August 2006	A group of California legislators, UFCW, and the California Labor Federation petition Cal OSHA to adopt an emergency temporary standard for diacetyl in California.
September 2006 & May 2007	The Project on Scientific Knowledge and Public Policy and Congresswoman Rosa DeLauro write to FDA Commissioner Andrew von Eschenbach requesting that the agency re-examine diacetyl to revoke its GRAS status.
June 2007	FDA Commissioner Andrew von Eschenbach responds to DeLauro's request, stating that "the agency does not have evidence that would cause it to take immediate action with respect to diacetyl" and that "FDA continues to monitor the scientific literature for studies conducted to define and clarify the dangers associated with exposure to diacetyl vapors."
June 2007	Congresswoman Lynn Woolsey introduces a bill that would force OSHA to set an interim standard for diacetyl exposure within six months and a final rule in two years.
August 2007	Manufacturer Pop Weaver announces that it has eliminated diacetyl from its microwave popcorn.
September 2007	Dr. Cecile Rose, chief occupational and environmental medicine physician at National Jewish Medical and Research Center, diagnoses a case of <i>bronchiolitis obliterans</i> in a man who did not have occupational exposure to diacetyl but was a regular, heavy consumer of microwave popcorn.
November 2007	EPA scientists publish their research in <i>Critical Reviews in Food Science and Nutrition</i> finding that diacetyl was a predominant compound emitted from cooking microwave popcorn and that more than 80 percent of the total chemical emissions occur when the bag is first opened after cooking.
September 2007– December 2007	ConAgra, Pop Weaver, General Mills, and American Pop Corn announce that they are eliminating diacetyl from their products or have already done so.
September 2007	The US House of Representatives passes the Popcorn Workers Lung Disease Prevention Act, which requires OSHA to set a standard to protect workers from diacetyl.
January 2009	OSHA issues a Advanced Notice of Proposed Rulemaking for a diacetyl standard.
November 2009	Senator Sherrod Brown writes Secretary of Labor Solis to expedite diacetyl rulemaking.
November 2009	Proposed Cal OSHA standard for diacetyl is issued for public comment.
December 2009	FDA's Acting Director of the Office of Food Additive Safety states that petitions from the Project on Scientific Knowledge and Public Policy and Congresswoman DeLauro about diacetyl's GRAS status are still under review.
December 2009	NIOSH Director John Howard sends letter to David Michaels, Assistant Secretary of Labor for OSHA stating that the new substitutes for diacetyl demonstrate animal toxicity very similar to that of diacetyl.



## Acknowledgments

This case study draws on several others that have come before it, notably: (1) David Michaels, Chrissy Morgan, and Celeste Monforton’s “A Case of Regulatory Failure—Popcorn Workers Lung” along with continued analysis and links to historical and recent material posted by staff of the Project on Scientific Knowledge and Public Policy website ([www.defendingscience.org](http://www.defendingscience.org)) and the blog, The Pump Handle (<http://scienceblogs.com/thepumphandle>); as well as (2) Andrew Dulberg’s “The Popcorn Lung Case Study: A Recipe for Regulation” that was published in the New York University Review of Law and Social Change (2009). We are deeply grateful for the investigative journalism of Andrew Schneider, whose writings brought the subject of hazards to workers using diacetyl and butter flavorings to the attention of millions and who continues to educate us about recent developments. We also extend our gratitude to Dr. Robert Harrison and Celeste Monforton for reviewing this case study and to Gale Bateson as well as Dr. Robert Harrison, who spoke with us at length about California’s experience in its efforts to protect workers from exposure to diacetyl and other butter flavoring chemicals.

## References

1. Statement of Eric Peoples. *Have OSHA Standards Kept up with Workplace Hazards? Hearing Before the Subcommittee on Workforce Protections of the House Committee on Education and Labor, 110th Congress, 2007*. Available at: [http://www.defendingscience.org/case\\_studies/upload/Eric\\_Peoples\\_Testimony\\_April07.pdf](http://www.defendingscience.org/case_studies/upload/Eric_Peoples_Testimony_April07.pdf). Accessed: February 27, 2010.
2. Rock S. Popcorn plant lawsuits winding down. *The Kansas City Star*. November 25, 2005.
3. Labaton S. OSHA leaves worker safety largely in hands of industry. *The New York Times*. April 25, 2007. Available at: <http://www.nytimes.com/2007/04/25/washington/25osha.html>. Accessed: February 27, 2010.
4. Farrow C. Popcorn worker awarded \$20 million in lawsuit over lung damage from butter flavoring. *The Associated Press*. March 16, 2004.
5. Kullman G, Boylstein R, Jones W, et al. Characterization of respiratory exposures at a microwave popcorn plant with cases of bronchiolitis obliterans. *J Occup Environ Hyg*. 2005;2(3):169-78.
6. Sharples LD, McNeil K, Stewart S, et al. Risk factors for bronchiolitis obliterans: a systematic review of recent publications. *J Heart Lung Transplant*. 2002;21(2):271-81.
7. Roberts D. Letter to Occupational Safety and Health Administration. May 19, 2000. Available at: [http://defendingscience.org/case\\_studies/upload/Roberts-Letter.pdf](http://defendingscience.org/case_studies/upload/Roberts-Letter.pdf). Accessed: February 27, 2010.
8. Simoes E, Phillips P, Maley R, et al. Fixed obstructive lung disease in workers at a microwave popcorn factory—Missouri, 2000-2002. *MMWR*. 2002;51(16):345-347.
9. Occupational Health and Safety Administration. *Inspection Report, May 23, 2000*. September 26, 2000. Available at: [www.defendingscience.org](http://www.defendingscience.org). Accessed: February 25, 2010.
10. Kreiss K, Gomaa A, Kullman G, et al. Clinical bronchiolitis obliterans in workers at a microwave-popcorn plant. *N Engl J Med*. 2002;347(5):330-8.
11. Gormaa A, Kullman G, Fedan K, et al. *NIOSH investigation of Glistar Mary Lee—Technical Assistance to Missouri Department of Health. Interim Report*. Report No: HETA#2000-0401. Missouri Department of Health, Office of Epidemiology. August 21, 2001. Available at: <http://www.cdc.gov/niosh/hhe/reports/pdfs/2000-0401-2991.pdf> (Appendix C). Accessed: February 27, 2010.
12. Schneider A. Additive found in more than 6,000 products its not new - Pasteur identified diacetyl in 1860s. *Seattle Post-Intelligencer*. December 21, 2007. Available at: [http://www.seattlepi.com/national/344349\\_history21.html](http://www.seattlepi.com/national/344349_history21.html). Accessed: September 27, 2010.
13. National Institute for Occupational Safety and Health. *NIOSH Alert: Preventing Lung Disease in Workers Who Use or Make Flavorings*. Report No: 2004-110. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. 2003. Available at: <http://www.cdc.gov/niosh/docs/2004-110>. Accessed: February 27, 2010.
14. U.S. Food and Drug Administration. *History of the GRAS List and SCOGS Reviews*. Available at: <http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASubstancesSCOGSDatabase/ucm084142.htm>. Accessed: February 15, 2010.
15. Gaynor P, Cianci S. How U.S. FDA’s GRAS notification program works. *Food Safety Magazine*. December 2005/January 2006.
16. U.S. Food and Drug Administration. *Database of Select Committee on GRAS Substances (SCOGS) Reviews: Diacetyl*. Available at: <http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=scogsListing&id=103>. Accessed: February 15, 2010.
17. National Toxicology Program. *NTP Research Concept: Artificial Butter Flavoring and Certain Components, Diacetyl and Acetoin*. Available at: [http://ntp.niehs.nih.gov/files/Artificial\\_butter\\_flavoring\\_concept\\_for\\_BSC.pdf](http://ntp.niehs.nih.gov/files/Artificial_butter_flavoring_concept_for_BSC.pdf). Accessed: February 16, 2010.
18. National Institute for Occupational Safety and Health. *Important Worker Health Notice about the Popcorn Plant in Jasper, Missouri*. September 9, 2001. Available at: [http://defendingscience.org/case\\_studies/upload/NIOSH-Worker-Notice.pdf](http://defendingscience.org/case_studies/upload/NIOSH-Worker-Notice.pdf). Accessed: March 21, 2010.
19. Hubbs AF, Battelli LA, Goldsmith WT, et al. Necrosis of nasal and airway epithelium in rats inhaling vapors of artificial butter flavoring. *Toxicol Appl Pharmacol*. 2002;185(2):128-35.
20. Shipley S. Microwave popcorn—study showed chemical was toxic. *St. Louis Post-Dispatch*. February 28, 2004. Available at: <http://www.mindfully.org/Pesticide/2004/Microwave-Popcorn-Toxic28feb04.htm>. Accessed: March 21, 2010.
21. Hubbs A, Battelli L, Mercer R, et al. Inhalation toxicity of the flavoring agent, diacetyl (2,3-butanedione), in the upper respiratory tract of rats. *Toxicol Sci*. 2004; 78:438-439.

22. BASF. *Study on the Acute Inhalation Toxicity LC50 of Diacetyl FCC as a Vapor in Rats 4-hour Exposure*. BASF, Department of Toxicology. 1993. Available at: [http://defendingscience.org/case\\_studies/upload/BASF-Study.pdf](http://defendingscience.org/case_studies/upload/BASF-Study.pdf). Accessed: March 21, 2010.
23. Michaels D. Popcorn lung: OSHA gives up. In: *Doubt Is Their Product: How Industry's Assault on Science Threatens Your Health*. New York, NY: Oxford University Press, Inc. 2008. 110-123.
24. Kanwal R, Kullman G, Piacitelli C, et al. Evaluation of flavorings-related lung disease risk at six microwave popcorn plants. *J Occup Environ Med*. 2006;48(2):149-57.
25. The Project on Scientific Knowledge and Public Policy. *A Case of Regulatory Failure: Popcorn Workers Lung*. Available at: [http://defendingscience.org/case\\_studies/A-Case-of-Regulatory-Failure-Popcorn-Workers-Lung.cfm](http://defendingscience.org/case_studies/A-Case-of-Regulatory-Failure-Popcorn-Workers-Lung.cfm). Accessed: February 16, 2010.
26. Finkel A. *Personal Communication*. August 20, 2009.
27. Dulberg AS. The popcorn lung case study: a recipe for regulation? *Rev Law Soc Change*. 2009;33(1):87-126.
28. *Int'l. Flavors & Fragrances, Inc. v. Valley Forge Ins. Co.*, 2007 WI App 187, 304 Wis. 2d 732, 738 N.W.2d 159.
29. Lehr J. Illinois worker wins \$30 million verdict in diacetyl popcorn chemical lawsuit. *The Joplin Globe*. August 16, 2010. Available at: <http://www.joplinglobe.com/local/x369041172/Illinois-worker-wins-30-million-verdict-in-diacetyl-popcorn-chemical-lawsuit>. Accessed: August 31, 2010.
30. Schneider A. Popcorn supplier to drop toxic chemical. Consumer's lung disease may be linked to flavoring. *Seattle Post-Intelligencer*. September 5, 2007. Available at: [http://www.seattlepi.com/food/330230\\_popcorn05.html](http://www.seattlepi.com/food/330230_popcorn05.html). Accessed: February 27, 2010.
31. Michaels D. *Doubt is Their Product: How Industry's Assault on Science Threatens Your Health*. New York: Oxford University Press. 2008.
32. Berger MA. What has a decade of Daubert wrought? *Am J Public Health*. 2005;95 Suppl 1:S59-65.
33. The Project on Scientific Knowledge and Public Policy. *Daubert: The Most Influential Supreme Court Ruling You've Never Heard of*. Tellus Institute. June 2003. Available at: <http://www.defendingscience.org/upload/Daubert-The-Most-Influential-Supreme-Court-Decision-You-ve-Never-Heard-Of-2003.pdf>. Accessed: February 27, 2010.
34. U.S. Government Accountability Office. *High-Risk Series: An Update*. Report No:GAO-09-271. U.S. Government Accountability Office. January 2009. Available at: <http://www.gao.gov/products/GAO-09-271>. Accessed: February 27, 2010.
35. Associated Press. Popcorn firms removing flavoring chemical. Additive linked to lung ailments in factory workers. *The Boston Globe*. December 18, 2007. Available at: [http://www.boston.com/business/globe/articles/2007/12/18/popcorn\\_firms\\_removing\\_flavoring\\_chemical](http://www.boston.com/business/globe/articles/2007/12/18/popcorn_firms_removing_flavoring_chemical). Accessed: February 27, 2010.
36. Schneider A. Just when you thought it was safe to make popcorn. *AOL News.com*. December 10, 2009. Available at: <http://www.aolnews.com/nation/article/just-when-you-thought-it-was-safe-to-make-popcorn/19273632>. Accessed: February 27, 2010.
37. Howard J. Letter to David Michaels, Assistant Secretary of Labor for Occupational Safety and Health. December 23, 2009. Available at: <http://thepumphandle.wordpress.com/2010/01/05/perils-of-butter-flavorings-diacetyl-substitutes>. Accessed: February 25, 2010.
38. Associated Press. California struggles with its own diacetyl problem. *AP Features*. October 23, 2007. Available at: [http://www.thefreelibrary.com/\\_/print/PrintArticle.aspx?id=1611403697](http://www.thefreelibrary.com/_/print/PrintArticle.aspx?id=1611403697). Accessed: February 27, 2010.
39. Centers for Disease Control and Prevention. Fixed obstructive lung disease among workers in the flavor-manufacturing industry—California, 2004-2007. *MMWR*. 2007;56(16):389-393.
40. Gail Bateson. Executive Director, Work Safe. *Personal Communication*. March 4, 2009.
41. von Euw M. *The Search for Diacetyl among Flavoring Manufacturers in California*. Summer internship final presentation. 2010.
42. Funk J. Popcorn markers work to remove chemical. *Washington Post*. September 5, 2007.
43. Michaels D. What do Pop Weaver and the EPA know about diacetyl? *The Pump Handle*. August 30, 2007. Available at: <http://thepumphandle.wordpress.com/2007/08/30/what-do-pop-weaver-and-the-epa-know-about-diacetyl>. Accessed: February 5, 2010.
44. Rosati JA, Krebs KA, Liu X. Emissions from cooking microwave popcorn. *Crit Rev Food Sci Nutr*. 2007;47(8):701-9.
45. Harris G. Doctor links a man's illness to a microwave popcorn habit. *The New York Times*. September 5, 2007. 2007. Available at: <http://www.nytimes.com/2007/09/05/us/05popcorn.html>. Accessed: February 27, 2010.
46. Cheeseman MA. A letter to Drs. Monforton and Wood. 2010. available at: [http://defendingscience.org/case\\_studies/upload/FDA-response-to-petition-Jan-28-2010.pdf](http://defendingscience.org/case_studies/upload/FDA-response-to-petition-Jan-28-2010.pdf).
47. 110th Congress 2007-2008. *H.R. 2963: Popcorn Workers Lung Disease Prevention Act*. 2007. Available at: <http://www.govtrack.us/congress/bill.xpd?bill=h110-2693>. Accessed: March 31, 2010.
48. Brown S. A letter to the Honorable Hilda L. Solis. November 25, 2009. Available at: [http://defendingscience.org/case\\_studies/upload/SherrodBrown\\_Diacetyl\\_11\\_25\\_09.pdf](http://defendingscience.org/case_studies/upload/SherrodBrown_Diacetyl_11_25_09.pdf). Accessed: March 10, 2010.
49. Occupational Safety and Health Administration. *Chemical Sampling Information; Diacetyl*. Available at: [http://www.osha.gov/dts/chemicalsampling/data/CH\\_231710.html](http://www.osha.gov/dts/chemicalsampling/data/CH_231710.html). Accessed: February 16, 2010.
50. Regulatory Info.gov. *RIN Data; DOL/OSHA; RIN:1218-AC33; Occupational exposure to diacetyl and food flavorings containing diacetyl*. Spring 2010. Available at: <http://www.defendingscience.org/upload/OSHARegAgendaApril-2010-Diacetyl.pdf>. Accessed: April 26, 2010.
51. Institute of Medicine. *Addressing the Physician Shortage in Occupational and Environmental Medicine: Report of a Study*. National Academy of Sciences. 1991.
52. Levy BS. The teaching of occupational health in United States medical schools: five-year follow-up of an initial survey. *Am J Public Health*. 1985;75(1):79-80.
53. Association of American Medical Colleges. *Student graduation questionnaire*. Washington, DC. 1987
54. Council of State and Territorial Epidemiologists. *2009 Epidemiology Capacity Assessment*. 2009. Available at: <http://www.cste.org/dnn/Portals/0/2009EpidemiologyCapacityAssessmentReport.pdf>. Accessed: March 15, 2010.