**WISCONSIN COURT OF APPEALS**
**DISTRICT 1**
**APPEAL NO. 2022AP001014**

NICKEY MONCEL,

Plaintiff-Respondent,

PATRICIA MONCEL,

Plaintiff,

v.

FLAVOR DEVELOPMENT CORP.,

Defendant-Appellant,

SENTRIX INGREDIENTS, LLC,

Defendant.

On Appeal from the Circuit Court for Milwaukee County
Circuit Court Case Number 2017CV006330
The Honorable William Sosnay Presiding

# RESPONDENT'S BRIEF

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## STATEMENT ON ORAL ARGUMENT AND PUBLICATION

Respondent Nickey Moncel does not believe that oral argument is needed. This case presents a straightforward review of the evidence supporting the jury's verdict, which requires only application of familiar legal principles to a well-established record.

For the same reasons, Respondent believes that publication is unwarranted. The standards for reviewing a jury's verdict are commonly known. Likewise, to the extent that Appellant contests the admission of expert testimony, the standards for doing so are comprehensively set forth in: (1) the Wisconsin Supreme Court's decision in *Seifert*, and (2) nearly 30 years of federal cases applying *Daubert*.

## INTRODUCTION

This appeal arises from a jury's verdict for plaintiff Nickey Moncel ("Moncel") for damages following his exposure to a toxic chemical called diacetyl. Moncel worked at a coffee shop where he flavored coffee beans with flavorings from Flavor Development Corp. ("Flavor"). While doing so he inhaled diacetyl fumes created by the flavorings, with no exhaust fan or respirator, daily. This continued for four years, from 2008 to 2012.

Diacetyl is widely known to cause obstructive lung disease, particularly its most severe form – bronchiolitis obliterans. More than 50 peer-reviewed studies confirm this fact. The National Institute for Occupational Safety & Health (NIOSH) warned of the dangers posed by diacetyl in 2003, five years before Moncel's first exposure, recommending that manufacturers remove diacetyl from their products. Most did, but Flavor did not. Diacetyl is so hazardous that the company selling diacetyl to Flavor as a raw ingredient made Flavor promise, in writing, to warn its customers of the danger. Yet Flavor broke that promise, giving no warning to Moncel or his employer. And so Moncel developed bronchiolitis obliterans. The disease has ruined Moncel's ability to enjoy retirement with his family.

To recover for his injuries, Moncel sued Flavor in the Circuit Court of Milwaukee County. The case was tried before a jury, the Honorable

William Sosnay presiding. After seven days of trial, the jury returned its verdict for Moncel and against Flavor. Flavor then filed post-trial motions, which were all denied. This appeal follows.

## ARGUMENT

Flavor attacks the jury's verdict based on the sufficiency of the evidence.[1] The standard of review is strict. "Appellate courts in Wisconsin will sustain a jury verdict if there is any credible evidence to support it." *Morden v. Continental AG*, 2000 WI 51, ¶ 38, 235 Wis. 2d 325, 351, 611 N.W.2d 659, 672. The verdict is given "great deference," and courts "indulge in every presumption" in support of it. *Anderson v. Combustion Eng'g, Inc.*, 2002 WI App 143, ¶4, 256 Wis. 2d 389, 393, 647 N.W.2d 460, 462 (internal quotations omitted). Moreover, where (as here) a circuit court approves the jury's verdict, the standard of review is "even more stringent." *Morden*, 2000 WI 51, ¶ 40. The circuit court's approval entitles the jury's determination to "special deference," and "this court will not overturn the jury's verdict unless 'there is such a complete failure of proof that the verdict must be based on speculation.'" *Id.* (quoting *Coryell v. Conn*, 88 Wis. 2d 310, 315, 276 N.W.2d 723 (1979)).

[1] "A motion to change a jury's special verdict answer challenges the sufficiency of the evidence to sustain the answer." *Danner v. Auto-Owners Ins.*, 2001 WI 90, ¶ 72, 245 Wis. 2d 49, 82, 629 N.W.2d 159, 176 (citing Wis. Stat. § 805.14(5)(c)).

When applying these requirements, "appellate courts search the record for credible evidence that sustains the jury's verdict, not for evidence to support a verdict that the jury could have reached but did not." *Id.*, 2000 WI 51, ¶ 39. And, of course, the Court considers "the evidence in a light most favorable to the jury's determination" and "accept[s] the particular inference[s] reached by the jury." *Id.* Flavor's brief, which alternates between downplaying and outright ignoring Moncel's evidence, fails to meet this burden. Moncel offered substantial credible evidence on every element of his claim, including liability and causation. The jury had a right to credit that evidence and return its verdict in his favor.

## I. THE EVIDENCE SUPPORTS THE JURY'S FINDING THAT FLAVOR'S DIACETYL CAUSED MONCEL'S INJURIES

Flavor first challenges the evidence supporting the jury's causation finding. To establish causation, a plaintiff need only show "that the defendant's negligence was a substantial factor" in bringing about the claimed harm. *Ehlinger v. Sipes*, 155 Wis. 2d 1, 12, 454 N.W.2d 754, 758 (1990). "[S]ubstantial factor," in turn, means "that the defendant's conduct has such an effect in producing the harm as to lead the trier of fact, as a reasonable person, to regard it as a cause, using that word in the popular sense." *Id.* (internal quotation omitted). This

simply requires the presentation of "probable facts from which negligence and causal relations may be reasonably inferred." *Id.* at 13 (cleaned up).

The causation evidence at trial was compelling. To maintain consistency with Flavor's brief, we summarize that evidence in terms of "general causation" and "specific causation."[2]

### A. Evidence of General Causation – Diacetyl Can Cause Obstructive Lung Disease, Including Bronchiolitis Obliterans, at the Levels Moncel Inhaled.

"General causation examines whether the substance . . . had *the capacity* to cause the harm alleged." *C.W. ex rel. Wood v. Textron, Inc.*, 807 F.3d 827, 831 (7th Cir. 2015) (emphasis in original) (internal quotations omitted); *see also* Michael D. Green et al., *Reference Guide on Epidemiology, in* Reference Manual on Scientific Evidence 392 (Fed. Jud. Ctr., 2d ed. 2000) ("General causation is concerned with whether an agent increases the incidence of disease in a group and not whether the agent caused any given individual's disease."). Flavor concedes that "[d]iacetyl is capable of causing health problems in humans," as well it

[2] No Wisconsin case has explicitly broken the causation analysis into general and specific causation, and no party is advocating for such an explicit change to Wisconsin law. The distinction arises commonly, however, in toxic tort and product liability cases elsewhere, and we engage with that distinction here simply to mirror Flavor's brief and to show that Favor's arguments still fail.

should. *Flavor Brief* at 12. The dangers posed by diacetyl are extensively documented and beyond reasonable challenge.

The first big cluster of diacetyl cases arose at a microwave popcorn plant in Jasper, Missouri. (1/26/22AM:T.24). A local doctor noticed a series of bronchiolitis obliterans cases among the workers and notified the Missouri Department of Health. (1/26/22AM:T.25). That agency, in turn, brought in NIOSH researchers to conduct an in-depth investigation. (*Id.*). The NIOSH researchers concluded that diacetyl was causing the bronchiolitis obliterans, and published their findings in the New England Journal of Medicine. (1/26/22AM:T.25-26). This prompted over 50 more studies, both by NIOSH and others, all concluding that inhaling diacetyl causes obstructive lung disease, including bronchiolitis obliterans. (1/26/22AM:T.26, 31-32). Based on these studies, the causation link between diacetyl and obstructive lung disease is now a "medical consensus." (*Id.*).

Flavor tried to avoid this medical consensus at trial by claiming Moncel was exposed to only "very miniscule amounts" of diacetyl at his work. (1/24/22:T.59). But the evidence showed otherwise. To start, all agreed that the relevant Flavor products contained levels of diacetyl ranging from .5% to 3%, depending on the flavor. (1/27/22:T.76, 78). Flavor's President and Operations Manager each admitted that these

amounts were hazardous if inhaled. (1/27/22:T.18, 78, 80). In fact, the amounts were so hazardous that the company selling diacetyl to Flavor made Flavor promise, in writing, 12 times, to warn its customers of the danger.[3] (ECF.662, 654, 670, 659, 648, 665, 650, 634, 651, 635, 636, 671*)*. Flavor also acknowledged that its diacetyl-containing products "should not be used within a confined space or at an elevated temperature without proper ventilation or a NIOSH organic vapor respiration." (*Id.)*. But because Flavor never warned Moncel or his employer of the dangers, that's exactly what happened.

Moncel worked in a small building that was "pretty cramped." (1/25/22AM:T.33). The temperature was elevated because Moncel had to roast the coffee beans before flavoring them. (1/25/22PM:T.14). The area where Moncel handled the flavors had no exhaust fans, and he was provided no respirator. (1/25/22PM:T.15; ECF.760 - Ex. 180D:14). And this exposure wasn't "for a limited time," as Flavor claims. *Flavor Brief* at 13. It happened for years. Moncel was the primary person who handled the flavorings from 2008 to 2015.[4] (1/25/22AM:T.35). He handled the flavorings throughout the day, every day he worked. (*Id*.).

[3] Flavor purchased raw diacetyl from a company called O'Laughlin. (ECF.760 - Ex. 180A:175). Flavor then used this raw diacetyl as an ingredient in its flavors. (1/27/22:T16).
[4] Flavor stopped using diacetyl in 2012. (1/27/22:T.37). Moncel therefore was exposed to Flavor's diacetyl from 2008 to 2012.

He started as a part-time worker, but moved to full-time, working close to 7 hours a day, 7 days a week. (1/25/22AM:T.36).

The concentration of Flavor's diacetyl was high in the air surrounding Moncel's workspace. The flavors created a strong odor, and there was never any doubt that Moncel was breathing them in. (1/25/22PM:T.17). When Moncel would go home at night, he would "still smell and taste the flavor in [his] nose and mouth." (*Id.*). Each night he dropped his clothes outside because they smelled like flavoring. (1/25/22PM:T.18). The flavors were left open overnight, so Moncel could still smell them when he returned to work each morning. (1/25/22PM:T.19).

All of this created a dangerous accumulation of diacetyl fumes. When a bucket containing diacetyl is stirred, as Moncel did at work, "[v]ery significant, very large amounts" of diacetyl collect "in the head space" above it. (1/26/22AM:T.42). This diacetyl in the head space is "in the parts-per-million," which is "a very significant exposure." (*Id.*). That's important because even "a relatively small amount of Diacetyl flavorings can result in dangerous exposures to workers." (1/26/22AM:T.40). The amount present in Flavor's products (1-3% diacetyl) is "far in excess" of these amounts, and "would be extremely dangerous." (1/26/22AM:T.38-39).

Flavor's own expert, Dr. Brent Kerger, reaffirmed the level of Moncel's diacetyl exposure. NIOSH has established a recommended exposure limit (REL) for diacetyl in the amount of "five parts per billion as an eight-hour average and 25 parts per billion as a fifteen-minute average." (1/28/22:T.71-72). But Dr. Kerger testified that he believed Moncel "was exposed during the flavoring process to 99 parts per billion and 248 parts per billion" of diacetyl. (1/28/22:T.71). Thus, even under Dr. Kerger's conservative estimate, Moncel was exposed to 20-50 times more diacetyl than the NIOSH REL.[5] (1/28/22PM:T.72). These diacetyl levels were "extremely dangerous," and a "very serious problem." (1/26/22AM:T.38-40). From these facts, the jury reasonably concluded that: (1) diacetyl is a dangerous chemical capable of causing severe obstructive lung disease when inhaled, including bronchiolitis obliterans; and (2) Moncel was exposed to enough diacetyl to produce that effect.

[5] As noted, Dr. Harrison placed Moncel's exposure at a much higher level, in the "parts per million." (1/26/22AM:T.42). A single part per million is the same thing as 1000 parts per billion. Dr. Harrison's numbers more closely track levels known to exist in coffee plants: "NIOSH has gone in and measured the levels of Diacetyl in the air in coffee roasting plants where workers are also adding flavors to coffee and [found] exposures far in excess or far above this five-part-per-billion or thirty-five-part-per-billion level." (1/26/22AM:T.40).

### B. Evidence of Specific Causation – Flavor's Diacetyl Caused Moncel's Bronchiolitis Obliterans.

Unlike general causation, which examines whether a substance can cause the harm alleged, specific causation "examines whether the substance did, *in fact*, cause the harm alleged." *Wood*, 807 F.3d at 831 (emphasis in original). To show specific causation, Moncel presented the testimony of two medical doctors: Dr. Charles Pue and Dr. Rose Franco.

Dr. Pue is board-certified in pulmonology and critical care. (1/26/22PM:T.75). He began treating diacetyl patients in the early 2000s, when 150 workers at a factory in Ohio contracted diacetyl-induced obstructive lung disease. (1/26/22PM:T.76-77). As his expertise grew, other doctors increasingly referred diacetyl cases to him. (1/26/22PM:T.77). He has examined many hundreds of patients exposed to diacetyl. (1/26/22PM:T.79-80). This experience has shown him that diacetyl-induced obstructive lung disease is not limited to workers in large factories using "millions of pounds of diacetyl." *Flavor Brief* at 13 n.3. Workers at "mom and pop" shops are just as affected. (1/26/22PM:T.84-85). And even diacetyl concentrations lower than those in Flavor's products are hazardous and can damage the lungs if inhaled. (1/26/22PM:T.83-84).

Dr. Pue applied his experience treating diacetyl victims when evaluating Moncel. He followed the same procedure on Moncel as he does for every patient. (1/26/22PM:T.83-85). He took a comprehensive history, and performed a physical examination, blood work, and pulmonary function tests. (1/26/22PM:T.87-88). He also drew upon his extensive knowledge of the scientific literature about obstructive lung disease caused by diacetyl inhalation. (1/26/22PM:T.77-78).

During Dr. Pue's evaluation, he considered and ruled out every other possible cause of Moncel's symptoms: (1) smoking (1/26/22PM:T.97-99); (2) smoke from roasting or organic coffee matter (1/26/22PM:T.106-07); (3) excessive dust exposure (1/26/22PM:T.107); (4) allergy-induced or bronchial asthma (1/26/22PM:T.108); (5) childhood asthma (1/26/22PM:T.110); (6) chronic obstructive pulmonary disease (1/26/22PM:T.110-11); (7) heart problems (1/26/22PM:T.111); (8) gastroesophageal reflux (1/26/22PM:T.111-12); and (9) obesity (1/26/22PM:T.112-13). After ruling out these possibilities, Dr. Pue was left with the fact that Moncel worked with diacetyl almost daily, for four years, standing directly over buckets of diacetyl-laced flavorings and inhaling diacetyl fumes. (1/26/22PM:T.93). And the onset of Moncel's disease dovetailed with that of the hundreds of other diacetyl victims Dr. Pue has treated over the years. (1/26/22PM:T.92-93). These facts left

"absolutely no doubt in [his] mind" that Moncel contracted bronchiolitis obliterans by inhaling Flavor's diacetyl. (1/26/22PM:T.118).

Dr. Rose Franco is triple board-certified, including in pulmonology. (1/26/22PM:T.5). She has practiced as a pulmonologist for over 20 years. (1/26/22PM:T.8). She began treating Moncel when he came to her office in 2016 with shortness of breath. (1/26/22PM:T.9-10). She performed a full evaluation, reviewed the relevant scientific literature, and conducted her own differential diagnosis. (1/26/22PM:T.8-9, 15-16). She too concluded that Moncel suffered from severe obstructive lung disease caused by Flavor's diacetyl. (1/26/22PM:T.24). Because of a negative CAT scan, she called this condition "occupationally induced asthma" instead of bronchiolitis obliterans.[6] (1/26/22PM:T.19, 23). But the variation in labeling doesn't matter clinically – both are obstructive lung diseases, so it's "six one, half dozen the other." (1/26/22PM:T.109). Both Dr. Pue and Dr. Franco agreed that Moncel's obstructive lung disease was caused by diacetyl.

Crediting this testimony in the light most favorable to the verdict, as we must, the jury reasonably concluded that Moncel suffered injury

[6] Dr. Pue explained that even a high-resolution CAT scan "can't see the bronchioles because they're microscopic." (1/26/22PM:T.104). And "only one-fourth of patients with biopsy proven bronchiolitis obliterans have an abnormal CT so that's not a reason to exclude bronchiolitis obliterans." (1/26/22PM:T.109).

in the form of bronchiolitis obliterans, and that Flavor's diacetyl was at least a "substantial factor" in causing that injury. Even under Flavor's own theory of the case, Moncel was exposed to more than enough diacetyl to cause his disease. And the doctors ruled out all other possible causes. The record provides no basis for overturning the jury's causation finding.

## II. THE CIRCUIT COURT PROPERLY EXERCISED ITS BROAD DISCRETION IN ADMITTING THE TESTIMONY OF DRS. HARRISON, PUE, AND FRANCO

Flavor all but concedes that the above evidence, if properly admitted, is enough to support the jury's finding on causation. Flavor therefore shifts its attack to arguing that the Circuit Court erred in admitting the testimony of Moncel's three expert medical doctors: Dr. Robert Harrison, Dr. Charles Pue, and Dr. Rose Franco. The standard of review for that claim has two parts. First, the Court "decides whether the circuit court applied the proper legal standard under Wis. Stat. § 907.02(1) . . . ." *Seifert v. Balink*, 2017 WI 2, ¶ 89, 372 Wis. 2d 525, 568, 888 N.W.2d 816, 838.[7] Then, "[o]nce satisfied that the circuit court applied the appropriate legal framework," the Court moves on to determine whether the circuit court "properly exercised its discretion" in

[7] Wis. Stat. § 907.02(1) governs the admission of expert testimony. That section, in turn, adopts the standard of *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). *Seifert*, 2017 WI 2, ¶ 6.

admitting the evidence. *Id.*, ¶ 90. Here, the Circuit Court explicitly applied the correct standard under Section 907.02(1) and *Daubert*, and then properly exercised its discretion in concluding that the expert doctors' testimony was both reliable and admissible.

### A. The Circuit Court Applied the Proper Legal Standard.

Under *Daubert*, "rejecting expert testimony is 'the exception rather than the rule.'" *Id.*, ¶ 54 n.11 (quoting Fed. Rule Evid., Advisory Committee Note (2000)). "[C]ases are legion that, correctly, under *Daubert*, call for the liberal admission of expert testimony." *Johnson v. Mead Johnson & Co.*, 754 F.3d 557, 562 (8th Cir. 2014).[8] Indeed, the very purpose of *Daubert* was to "liberalize the rules governing the admission of expert testimony," making the rule "one of admissibility rather than exclusion." *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686 (8th Cir. 2001) (internal quotations omitted). And as the Wisconsin Supreme Court has cautioned, "exclusion is rarely justified in cases involving medical experts." *Seifert*, 2017 WI 2, ¶ 85.

The *Daubert* standard allows admission of expert testimony so long as it is sufficiently reliable. *Id.*, ¶ 56. To guide this reliability

[8] Because Wis. Stat. § 907.02(1) mirrors Fed. R. Evid. 702 and *Daubert*, the Wisconsin courts look to both federal and state cases in other jurisdictions that interpret *Daubert* and its progeny. *Seifert*, 2017 WI 2, ¶ 55.

analysis, both *Daubert* and *Seifert* provide a non-exhaustive list of factors to consider:

> "(1) whether the methodology can and has been tested; (2) whether the technique has been subjected to peer review and publication; (3) the known or potential rate of error of the methodology; and (4) whether the technique has been generally accepted in the scientific community."

*Id.*, ¶ 62 (quoting *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 152 (3d Cir. 1999)). That's the *exact* standard the Circuit Court applied here. (App. 71-72). Because the Circuit Court correctly applied the law under *Daubert* and *Seifert*, its decision to admit the testimony of Drs. Harrison, Pue, and Franco is given broad deference and reviewed solely for an erroneous exercise of discretion. *Seifert*, 2017 WI 2, ¶ 93 n.50; *accord Beaudette v. Louisville Ladder, Inc.*, 462 F.3d 22, 25 (1st Cir. 2006) ("We review a district court's decision to admit or exclude expert testimony for abuse of discretion, giving broad deference to the determination made by the district court as to the reliability and relevance of expert testimony.").

Flavor tries to escape this deference by claiming the Circuit Court applied a different (and incorrect) legal standard. *Flavor Brief* at 36. The record shows that's not true. As discussed, the Circuit Court carefully articulated the proper standard under *Daubert* and *Seifert*. Then, in the comment cited by Flavor, it simply observed that the

amendments to Section 907.02(1) had not caused the "huge se[a] change" in Wisconsin law that some had feared. (App. 73). After making that comment, the Circuit Court reiterated that if the expert testimony "will assist the jury, then the dispute is more about cross examination." (*Id.*). Which is exactly the law: both *Daubert* and *Seifert* emphasize that "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof" are the presumptive methods of contesting expert testimony, not exclusion. *Daubert*, 509 U.S. at 596; *Seifert*, 2017 WI 2, ¶ 86.[9] The Circuit Court committed no error in saying the same thing.

### B. The Circuit Court Properly Exercised Its Discretion in Admitting the Testimony of Dr. Harrison.

Dr. Harrison is board-certified in occupational medicine and internal medicine. (1/26/22AM:T.18).[10] He testified about general causation – whether diacetyl can cause lung disease. Applying the widely-used "Bradford Hill" considerations, Dr. Harrison concluded that

[9] *See also Robinson v. GEICO Gen. Ins. Co.*, 447 F.3d 1096, 1100 (8th Cir. 2006) (*Daubert* is "satisfied where expert testimony advances the trier of fact's understanding to any degree.") (quoting Charles Alan Wright & Victor James Gold, Federal Practice and Procedure: Evidence § 6265 (1997)); *Wood v. Minn. Mining & Mfg. Co.*, 112 F.3d 306, 309 (8th Cir. 1997) (Under *Daubert*, "[t]he exclusion of an expert's opinion is proper only if it is so fundamentally unsupported that it can offer no assistance to the jury.") (cleaned up).

[10] Dr. Harrison's credentials and experience are summarized at 1/26/22AM:T.17-24. Flavor does not contest his qualifications to testify as an expert.

diacetyl is capable of causing obstructive lung disease, and in particular the bronchiolitis obliterans suffered by Moncel. (1/26/22AM:T.35-36).

### 1. Dr. Harrison's Bradford Hill Analysis Is a Proper and Reliable Methodology.

"The Bradford Hill methodology refers to a set of criteria that are well accepted in the medical field for making causal judgments." *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1235 n.4 (9th Cir. 2017). It is widely-recognized as reliable under *Daubert*. *In re Roundup Liab. Litig.*, 390 F. Supp. 3d 1102, 1130 (N.D. 2018) ("To the extent the *Daubert* question is whether consideration of the Bradford Hill factors is a reliable method for determining causation as a general matter, the answer is yes.").

A Bradford Hill analysis looks at nine considerations, all of which support a finding of general causation here:

a. *Consistency of the observed association*. This factor "means that more than one study shows the same thing." (1/26/22AM:T.34). Dr. Harrison cited more than 50 studies showing the "vast medical and scientific literature that states diacetyl causes occupational lung disease." (ECF.519 at 32).[11] As he summarized, "that's very persuasive

[11] Plaintiff provided Dr. Harrison's Expert Report and deposition to the Circuit Court as part of the *Daubert* briefing. (ECF.522). Although Flavor ignores these materials, they are part of the record on which the Circuit Court made its *Daubert* decision.

when there's consistency every time a researcher goes out and looks at lung disease and correlates it with exposure." (1/26/22AM:T.34).

b. *Strength of the association*. The strength factor "has to do with how statistically powerful are those studies." (*Id*.). Almost all the studies of workers exposed to diacetyl find a statistically significant increased risk of lung disease. (ECF.522 at 13; 1/26/22AM:T.34). In one of the most significant studies, for example, diacetyl-exposed "workers had 3.3 times the expected rate of airway obstruction; those who had never smoked had 10.8 times the expected rate." (Report at 13).

c. *Specificity of the association*. Specificity "refers to a single cause associated with a single effect." (ECF.522 at 18-19). It is measured by assessing "the improvement in lung disease after implementation of control measures for diacetyl exposure." (ECF.522 at 19). In eight serial cross-sectional medical and industrial hygiene surveys from 2000 to 2003, "marked improvement in respiratory symptoms and lung function" occurred after reduction of diacetyl exposure. (*Id*.). That result "lend[s] support for the specific relationship between diacetyl and lung disease." (*Id*.).

d. *Temporality of the association*. "[A] causal interpretation is strengthened when exposure is known to precede development of the

disease." (ECF.522 at 20). The studies cited by Dr. Harrison satisfy this criterion. (*Id.*).

e. *Biological gradient (dose-response relationship).* For diacetyl, "there is clear-cut evidence for dose-response as seen in the initial study of diacetyl-exposed workers performed by Kreiss et al (2002)." (ECF.522 at 20-21). This study, along with other NIOSH studies, established such a clear dose-response relationship that NIOSH used it to formulate its REL for diacetyl. (ECF.522 at 21-22).

f. *Biological plausibility*. Many animal studies show the mechanism of airway damage like that experienced by workers. (ECF.522 at 22). "Diacetyl is a very reactive molecule," and it causes damage by interacting with the cells in the lining of the lungs to cause "an electrical imbalance of the membranes." (01/26/22AM:T.35-36).

g. *Coherence*. Other lines of evidence confirm "that diacetyl causes significant inflammatory markers (neutrophilic airway inflammation) consistent with the clinical findings of bronchiolitis obliterans and other lung diseases (Akpinar-Elci 2006)." (ECF.522 at 23).

h. *Human experimental evidence*. Exposing humans to diacetyl in a laboratory would be unethical. (01/26/22AM:T.36). But "both laboratory data and diacetyl air sampling data from microwave popcorn,

food flavoring and coffee roasting companies demonstrate the high risk of lung disease in these settings." (ECF.522 at 23).

For all these reasons, Dr. Harrison concluded: "The medical consensus regarding Diacetyl exposure is that it causes lung disease." (01/26/22AM:T.31). Dr. Harrison expressed this opinion to a reasonable degree of medical certainty, stressing there's "not a shadow of a doubt" that diacetyl causes obstructive lung disease, including bronchiolitis obliterans. (*Id.*).

Flavor never contested Dr. Harrison's application of the Bradford Hill factors, either in its *Daubert* motion or at trial. Indeed, Flavor's own President admitted that diacetyl is hazardous, even at the percentages his company sold to Midwest Roasters. (1/27/22:T.18). Flavor's expert agreed that "Diacetyl is capable of causing lung disease." (1/28/22AM:T.75). And even in its brief now, Flavor concedes general causation -- "[d]iacetyl is capable of causing health problems in humans." *Flavor Brief* at 12. Under these facts, the issue of admitting Dr. Harrison's testimony wasn't even close. Dr. Harrison: (1) drew upon his undisputed qualifications; to (2) present a careful (and largely uncontested) analysis; (3) using the Bradford Hill methodology that is widely-accepted as reliable under *Daubert*; (4) supported by more than 50 studies; that (5) showed diacetyl causes obstructive lung disease,

including bronchiolitis obliterans. The Circuit Court properly exercised its discretion in allowing him to do so.

### 2. Moncel Was Exposed to Diacetyl in an Amount Sufficient to Cause Obstructive Lung Disease.

Flavor centers its argument against Dr. Harrison on the notion that he could testify only after establishing Moncel's exact "level of exposure" to diacetyl. *Flavor Brief* at 37. But that's not the law. Courts recognize that:

> "[o]nly rarely are humans exposed to chemicals in a manner that permits a quantitative determination of adverse outcomes . . . . Human exposure occurs most frequently in occupational settings where workers are exposed to industrial chemicals like lead or asbestos; however, even under these circumstances, it is usually difficult, if not impossible, to quantify the amount of exposure."

*Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 264 (4th Cir. 1999) (quoting Fed. Jud. Ctr., *Reference Manual on Scientific Evidence* 187 (1994)). Thus, "while precise information concerning the exposure necessary to cause specific harm to humans and exact details pertaining to the plaintiff's exposure are beneficial, such evidence is not always available, or necessary, to demonstrate that a substance is toxic to humans given substantial exposure and need not invariably provide the basis for an expert's opinion on causation." *Id.*; *accord Heller*, 167 F.3d at 157 ("even absent hard evidence of the level of exposure to the

chemical in question, a medical expert could offer an opinion that the chemical caused plaintiff's illness.").

For these reasons, a plaintiff is not required "to produce a mathematically precise table equating levels of exposure with levels of harm." *Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 928 (8th Cir. 2001) (cleaned up). Rather, any need for exposure evidence is limited to that "from which a reasonable person could conclude that [the plaintiff's] exposure probably caused [his] injuries." *Id.* (internal quotations omitted).[12] Such inquiry here looks to the "totality of the circumstances surrounding the work of [Moncel] and the products [he] generally used." *Zielinski v. A.P. Green Indus. Inc.*, 2003 WI App 85, ¶ 18, 263 Wis. 2d. 294, 308, 661 N.W.2d 491, 497.

There's no dispute about the products Moncel used. Moncel worked with Flavor products containing diacetyl levels ranging from .5% to 3%, depending on the particular flavor. (1/27/22:T.76, 78). Both Flavor's President and its Operations Manager admitted that's a dangerous amount if inhaled. (01/27/22:T.18, 78). And the Material Safety Data Sheets (MSDSs) for the diacetyl in Flavor's products

[12] *Accord Garrido v. Team Auto Sales, Inc.*, 913 N.W.2d 95, 103 (S.D. 2018); *Nonnon v. City of New York*, 932 N.Y.S.2d 428, 436-37 (N.Y. App. Div. 2011); *King v. Burlington N. Santa Fe Ry. Co.*, 762 N.W.2d 24, 41 (Neb. 2009); *Alder v. Bayer Corp.*, 61 P.3d 1068, 1086 (Utah 2002).

confirmed that "[c]hronic exposure may cause lung damage," and diacetyl "has been linked to bronchiolitis obliterans, a disease characterized by inflammation and scarring in the smallest airways of the lungs." (ECF. 658*)*. These facts by themselves are enough to allow the inference that Moncel's exposure was enough to cause obstructive lung disease. *Howell v. Centric Grp., LLC*, No. 09-cv-02299-MSK-CBS, 2011 WL 4499372, at *5 (D. Colo. Sept. 27, 2011) ("the MSDS alone might be sufficient to raise an issue of fact regarding general causation"); *see also Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 808-09 (3d Cir. 1997) (warning labels "relevant in forming an expert opinion of causation.").

Nor is there any dispute about Moncel's working conditions. Flavor's President agreed that its diacetyl "should not be used within a confined space or at an elevated temperature without proper ventilation or a NIOSH organic vapor respiration." (ECF.662*)*. But that's how Moncel worked every day. His small building was "pretty cramped" (1/25/22AM:T33). The roasting beans inside elevated the temperature. (1/25/22PM:T.14). The flavoring area had no exhaust fans (1/25/22PM:T.15). Moncel had no respirator (ECF.760 - Ex. 180D:14). The diacetyl-laced flavors created such a strong odor that, when Moncel went home at night, he would "still smell and taste the flavor in [his]

nose and mouth." (1/25/22PM:T.17).[13] And this exposure continued for four years, with Moncel working up to 7 hours a day, 7 days a week. (1/25/22:AM:T.35-36).

All this evidence bolsters a finding that Moncel was exposed to a dangerous concentration of diacetyl. The 50+ studies Dr. Harrison cited confirm that "[v]ery significant, very large amounts" of diacetyl fumes will accumulate in the "head space" above a stirred bucket, such as Moncel used. (1/26/22AM:T.42). Dr. Harrison continued: "So if you take Diacetyl at less than one percent in a liquid and you measure how much Diacetyl is coming off of that into the head space, it's in the parts-per-million, which is, as I mentioned earlier, a very significant exposure." (*Id.*).[14] That's important because even "a relatively small amount of Diacetyl flavorings can result in dangerous exposures to workers." (1/26/22AM:T.40). The amount present in Flavor's products (1-3% diacetyl) is "far in excess" of the amounts in these studies, and "would be extremely dangerous." (1/26/22AM:T.38-39). At a minimum, Dr.

[13] *Cf. Clark v. Keller Transp., Inc.*, No. 1:13-CV-279-SWS, 2015 WL 11108911, at *3 n.4 (D. Wyo. Jan. 13, 2015) ("exposure can be shown through mere detection of the odor.").

[14] Flavor argues that Dr. Harrison should have considered what it calls "background diacetyl" caused by "grinding unflavored coffee beans." *Flavor Brief* at 39-40. But Dr. Harrison explained that no scientific body has found any correlation to lung disease arising from simply roasting or grinding coffee beans. (1/26/22AM:T.40-41). Cases of lung disease are found only in studies with workers flavoring beans. (*Id.*).

Harrison's testimony would allow a reasonable person to conclude that Moncel's diacetyl exposure "exceeded safe levels," and therefore "probably caused [his] injuries." *Bonner*, 259 F.3d at 928, 931; *see also Bednar v. Bassett Furniture Mfg. Co.*, 147 F.3d 737, 740 (8th Cir. 1998) (evidence "provided a sufficient basis from which a trier of fact could infer that the baby's exposure to gaseous formaldehyde exceeded safe levels."). His testimony was therefore helpful to the jury and admissible.

### 3. Flavor Admits That Moncel's Diacetyl Exposure Was 20-50 Times the Recommended Limit.

Flavor's argument fails for yet another reason: the company's own expert admitted that Moncel was exposed to 20-50 times more diacetyl than the recommended limit. As discussed, NIOSH has established a recommended exposure limit (REL) for diacetyl in the amount of "five parts per billion as an eight-hour average and 25 parts per billion as a fifteen-minute average." (1/28/22:T.71-72). Flavor's expert, however, testified that he believed "Moncel was exposed during the flavoring process to 99 parts per billion and 248 parts per billion" of diacetyl. (1/28/22:T.71). Thus, there's no dispute that Moncel was exposed to 20-50 times more diacetyl than the NIOSH REL.[15] (1/28/22PM:T.72). These

[15] As discussed, Dr. Harrison placed Moncel's exposure at a much higher level, in "parts per million." (1/26/22AM:T.42). A single part per million is the same thing as 1000 parts per billion. Dr. Harrison specified that this exposure would be "far in excess or far above" the NIOSH recommended limit. (1/26/22AM:T.40).

facts are still more evidence that Moncel's diacetyl exposure "exceeded safe levels" and "probably caused [his] injuries." *Bonner*, 259 F.3d at 928, 931.

Flavor asks the Court to ignore its expert's admissions because NIOSH's REL is a "government regulatory standard[]." *Flavor Brief* at 38-39. First, that's not factually correct. The Occupational Safety and Health Act of 1970 created two separate agencies: NIOSH and OSHA. OSHA is a regulatory agency. NIOSH, on the other hand, is "OSHA's research arm." *Indus. Union Dep't, AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607, 618-19 (1980).[16] NIOSH conducts its research "on the basis of the best available evidence," to recommend "exposure levels that are safe for various periods of employment." 29 U.S.C. §§ 655(b)(5), 669(a)(3). NIOSH doesn't set regulatory standards, OSHA does.[17]

Dr. Harrison described how NIOSH led the way in researching the dangers posed by diacetyl. (1/26/22AM:T.25). NIOSH researchers

[16] *See also Principi v. Survivair, Inc.*, No. 6:04-cv-476-Orl-JGG, 2005 WL 5960351, at *1 n.1 (M.D. Fla. Nov. 22, 2005) ("NIOSH is the federal agency responsible for conducting research and making recommendations for the prevention of work-related injury and illness. NIOSH is part of the Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services. OSHA is part of the Department of Labor.").

[17] Flavor concedes that NIOSH "is a non-regulatory arm of the CDC," and its REL is not a regulatory standard. *Flavor Brief* at 39 n.11.

authored the pivotal diacetyl study that appeared in the New England Journal of Medicine in 2002, and continued to publish more peer-reviewed diacetyl studies after that. (*Id.*; ECF.522 at 39-41). And NIOSH relied on those peer-reviewed studies when it set the REL for diacetyl:

> Using cross-sectional pulmonary function data from diacetyl exposed workers, NIOSH conducted analyses to determine the exposure-response relationship and identify risk of pulmonary function decrease at various levels of diacetyl exposure. NIOSH found that a relationship exists between diacetyl exposures and lower pulmonary function.
>
> Utilizing this quantitative risk analysis, NIOSH recommends that exposure to diacetyl be kept below a concentration of 5 parts per billion (ppb) as a time-weighted average (TWA) during a 40-hour work week. NIOSH has determined that workers exposed to diacetyl at this concentration should have no more than a 1 in 1000 chance of suffering reduced lung function associated with diacetyl exposure and less chance for developing bronchiolitis obliterans. To further protect against effects of short-term exposures, NIOSH recommends a short-term exposure limit (STEL) for diacetyl of 25 ppb for a 15-minute period.

(ECF.522 at 21-22) (quoting NIOSH, *Criteria for a Recommended Standard: Occupational Exposure to Diacetyl and 2,3-Pentanedione* (2016)). Thus, contrary to Flavor's claim, NIOSH "based its REL on scientific data" showing "the diacetyl exposure level capable of causing human lung disease." *Flavor Brief* at 38. And, as Dr. Harrison confirmed, the exposure levels produced by the amount of diacetyl in

Flavor's products were "far in excess" of NIOSH's REL, making the products "extremely dangerous." (1/26/22AM:T.38-39).

Flavor is also wrong on the law. Contrary to Flavor's assertion, courts look to NIOSH standards – and even OSHA standards – when deciding causation. *See, e.g.*, *Curtis v. M&S Petroleum, Inc.*, 174 F.3d 661, 667 (5th Cir. 1999) (allowing general causation expert to rely on OSHA standards for benzene); Bednar, 147 F.3d at 739 (allowing general causation expert to rely on NIOSH standards for formaldehyde); *Bettisworth v. BNSF Ry. Co.*, No. 8:17-CV-491, 2020 WL 3498139, at *9 (D. Neb. June 29, 2020) (allowing expert to testify on exposure levels based on NIOSH standards for elemental carbon); *In re FEMA Trailer Formaldehyde Prods. Liab. Litig.*, No. 09-3251, 2010 WL 1935878, at *1 (E.D. La. May 11, 2010) (NIOSH standards for formaldehyde are "one measuring stick" for occupational exposure levels).[18] The NIOSH REL is the gold standard for evaluating diacetyl exposure, and is based on

[18] *See also Sarkees v. E.I. Dupont De Nemours & Co.*, 15 F.4th 584, 593 (2d Cir. 2021) (approving expert's causation opinion because she "carefully considered available data, including the series of NIOSH reports"); *Bell v. Mine Safety Appliances*, No. 1:13-cv-01075, 2016 WL 3063970, at *2 (W.D. Ark. Feb. 11, 2016) (expert's opinion properly based on NIOSH protection factors); *Stults v. Int'l Flavors & Fragrances, Inc.*, No. C 11-4077-MWB, 2014 WL 12603223, at *6 (N.D. Iowa July 18, 2014) ("NIOSH reports are relevant to the question of whether diacetyl causes lung disease."); *In re W.R. Grace & Co.*, 355 B.R. 462, 490 (Bankr. D. Del. 2006) (considering exposure levels based on OSHA standards for asbestos); *Seaboard Sys. R.R., Inc. v. Page*, 485 So. 2d 326, 327-28 (Ala. 1986) (NIOSH standards admissible and authoritative).

dozens of peer-reviewed studies. The REL doesn't suddenly become unreliable or bad science just because the researchers who authored it work for the government.

#### 4. This Case Presents Undisputed Evidence of Exposure That Was Not Present in *Thiele* or *Downs*.

Ignoring the above case law, Flavor relies almost exclusively on two cases where Dr. Harrison was not allowed to testify: *Thiele v. DSM Food Specialties USA, Inc.*, No. C18-4081-LTS, 2022 WL 94938 (N.D. Iowa Jan. 10, 2022), and *Downs v DSM Specialties USA, Inc.*, No. 1:18-cv-00033, 2021 WL 6133743 (S.D. Iowa Oct. 28, 2021). *Flavor Brief* at 38-41. Those cases, however, are outliers. Through the hundreds of cases in which Dr. Harrison has been disclosed as an expert, he's been excluded fewer than five times. (1/26/22AM:T.46). Almost every expert who testifies regularly has random decisions like this – it just shows that different trial judges exercise their discretion differently. For example, another judge in the Northern District of Iowa allowed Dr. Harrison to give virtually the same opinions that the *Thiele* court found objectionable. *Herbst v. Givaudan Flavors Corp.*, No. C 17-4008-MWB, 2018 WL 6310271, at *3 (N.D. Iowa Dec. 3, 2018). Plaintiff respectfully submits that both *Thiele* and *Downs* reached the wrong result. This Court need not become embroiled in that quarrel, however, because the

record here contains undisputed evidence of Moncel's exposure that fully addresses the concerns raised in *Thiele* and *Downs*.

The *Thiele* court began by acknowledging the Eighth Circuit's approval of using NIOSH standards as "evidence of the threshold limit of safe exposure" for a chemical. *Thiele*, 2022 WL 94938, at *5 (citing *Bednar*, 147 F.3d at 739). And although the court questioned whether the NIOSH REL for diacetyl was the proper measure for the threshold of harm, it expressly declined to rule on that issue. *Id.* at *9. Instead, the court based its decision strictly on a "fail[ure] to identify any level of diacetyl to which Thiele was actually exposed." *Id.* Whether the *Thiele* court was correct on that point or not, no similar issue is presented here. All the facts necessary to establish Moncel's actual exposure were undisputed:

- The relevant Flavor products contained diacetyl levels between .5% and 3% (as admitted both by Flavor's Operations Manager and its expert) (1/27/22:T.78; 1/28/22:T.41-42);
- These levels of diacetyl are hazardous and capable of causing lung disease if inhaled (as admitted by Flavor's President and Operations Manager) (1/27/22:T.18, 78);

- Flavor's products caused Moncel to inhale diacetyl in the amount of 99 parts per billion as an eight-hour average, and 248 parts per billion as a fifteen-minute average (as admitted by Flavor's expert), (1/28/22:T.71); and
- Those levels exceeded the recommended exposure level by 20-50 times (as admitted by Flavor's expert), (1/28/22:T.72).

This is exactly the information found lacking in *Thiele*, and at a minimum Dr. Harrison properly testified based on these undisputed exposure levels.

*Downs* is distinguished for the same reasons. There too the issue was how the plaintiffs could "show they were exposed to toxic levels of diacetyl" at the Iowa plant where they worked. *Downs*, 2021 WL 6133743, at *6.[19] Because that data was unavailable, Dr. Harrison tried to analogize to levels found in air sampling data taken from "another ConAgra plant in Marion, Ohio." *Id*. The *Downs* court found this approach unacceptable because Dr. Harrison could not describe "specific similarities or dissimilarities" in the design and operations of the two plants, such as their "types of general and local ventilation systems" and

[19] The *Downs* court in dicta included a footnote calling the NIOSH REL into question as a "regulatory standard." *Downs*, 2021 WL 6133743, at *6 n.8. But the court did not address the controlling Eighth Circuit case law allowing general causation experts to rely on NIOSH standards. *Bednar*, 147 F.3d at 739.

number of "air exchanges." *Id*. at *7. Again, that issue just doesn't exist here, where the relevant exposure data is known, undisputed, and enough to cause Moncel's bronchiolitis obliterans.[20]

### C. The Circuit Court Properly Exercised Its Discretion in Admitting the Testimony of Dr. Pue.

Dr. Charles Pue is board-certified in pulmonology and critical care. (1/26/22PM:T.75).[21] He testified on specific causation – whether diacetyl in fact caused Moncel's bronchiolitis obliterans. Drawing on: (1) his experience in treating patients exposed to diacetyl, and (2) his differential diagnosis of Moncel, Dr. Pue concluded that Flavor's diacetyl caused Moncel's disease.

#### 1. Dr. Pue Relied on His Extensive Experience in Treating Patients Exposed to Diacetyl.

Medical doctors are given wide latitude to testify based on their experience. *Seifert*, 2017 WI 2, ¶ 85 ("*Daubert*'s role of ensuring that the courtroom door remains closed to junk science is not served by excluding medical expert testimony that is supported by extensive relevant

[20] Flavor faults Dr. Harrison for referring to "generic lung disease" when Moncel suffered from bronchiolitis obliterans. *Flavor Brief* at 37. Dr. Harrison testified, however, that diacetyl "causes a spectrum of different lung diseases." (1/26/22AM:T.75). All of these involve damage to the airway lining creating scar tissue – the difference is just one of degree. (*Id*.; 1/26/22PM:T.82). Obliterans refers to the most severe form of the disease, where the scarring becomes so large that it completely closes off an airway. (1/26/22PM:T.82).

[21] Dr. Pue's credentials and experience are set forth in ECF.646. Flavor does not contest his qualifications to testify as an expert.

medical experience. Such exclusion is rarely justified in cases involving medical experts."). This latitude arises from the very nature of the practice of medicine:

> The classic medical school texts explain that medicine is scientific but not entirely a science. Medicine is not a science but a learned profession, deeply rooted in a number of sciences and charged with the obligation to apply them for man's benefit. Much of medical decision-making relies on judgment and is difficult to quantify or even to assess qualitatively. In medicine, knowledge is often uncertain, the human body is complex, and etiology is often uncertain. Furthermore, practical and ethical concerns prevent studies calculated to establish statistical proof. Physicians must use their knowledge and experience as a basis for weighing known factors along with inevitable uncertainties to mak[e] a sound judgment.

*Id.*, ¶ 79 (internal quotations omitted). For these reasons, the reliability analysis for a medical opinion "'focus[es] upon personal knowledge or experience.'" *Id.*, ¶ 78 (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999)).

Dr. Pue's experience in treating diacetyl patients is unquestioned. He began treating diacetyl patients in the early 2000s, when 150 workers at a factory in Ohio contracted diacetyl-induced obstructive lung disease. (1/26/22PM:T.76-77). As his expertise grew, other doctors increasingly referred diacetyl cases to him. (1/26/22PM:T.77). He has examined many hundreds of patients exposed to diacetyl. (1/26/22PM:T.79). This experience has shown him that diacetyl-induced obstructive lung disease

is not limited to workers in large factories: workers at "mom and pop" shops like Moncel's employer are just as affected. (1/26/22PM:T.84-85). And even diacetyl concentrations lower than those in Flavor's products are hazardous and can damage the lungs if inhaled. (1/26/22PM:T.83-84).

Dr. Pue applied this experience when evaluating Moncel. He treated Moncel the same as he does every patient. (1/26/22PM:T.83-84). He took a comprehensive history, and performed a physical examination, blood work, and pulmonary function tests. (1/26/22PM:T.87-88). He then used all this information to "make a sound judgment" about the cause of Moncel's disease, just as clinicians do every day. That judgment is reliable and admissible under *Daubert* and *Seifert*.

**2. Dr. Pue Performed a Proper Differential Diagnosis.**

Dr. Pue's procedure in evaluating Moncel is called a "differential diagnosis." This is "something that all physicians use whenever you're evaluating any patient." (1/26/22PM:T.78). Dr. Pue's differential diagnosis involved first "thinking about what could they have, what's causing the problem," and then systematically "crossing things off the list" as they are ruled out. (*Id.*). As he described it, "the list starts off

really large in the beginning and you whittle it down until you figure out what's most likely to be causing their problem." (*Id.*).

In weighing the possible causes of Moncel's bronchiolitis obliterans, Dr. Pue considered and ruled out: (1) smoking (1/26/22PM:T.97-99); (2) smoke from roasting or organic coffee matter (1/26/22PM:T.106-07); (3) excessive dust exposure (1/26/22PM:T.107); (4) allergy-induced or bronchial asthma (1/26/22PM:T.108); (5) childhood asthma (1/26/22PM:T.110); (6) chronic obstructive pulmonary disease (1/26/22PM:T.110-11); (7) heart problems (1/26/22PM:T.111); (8) gastroesophageal reflux (1/26/22PM:T.111-12); and (9) obesity (1/26/22PM:T.112-13). After eliminating these possibilities, Dr. Pue was left with Moncel's daily diacetyl exposure, standing over buckets of diacetyl-laced flavoring and inhaling diacetyl fumes for four years. (1/26/22PM:T.93). And the onset of Moncel's disease matched that of the hundreds of other diacetyl victims Dr. Pue has treated over the years. (1/26/22PM:T.92-93). These facts left "absolutely no doubt" in his mind that Moncel contracted bronchiolitis obliterans by inhaling Flavor's diacetyl. (1/26/22PM:T.105, 117-18).

Differential diagnoses like this are "presumptively admissible" under *Daubert*. *Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 989

(8th Cir. 2001).[22] To qualify for this presumption, a differential diagnosis should include: (1) "physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests," and (2) "determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely." *Westberry*, 178 F.3d at 262 (internal quotations omitted). That's exactly what Dr. Pue did here.

Flavor argues that Dr. Pue failed to "rule in" diacetyl as a possible cause of Moncel's disease. *Flavor Brief* at 44-46. A medical expert, however, need not:

> always cite published studies on general causation in order to reliably conclude that a particular object caused a particular illness. The first several victims of a new toxic tort should not be barred from having their day in court simply because the medical literature, which will eventually show the connection between the victims' condition and the toxic substance, has not yet been completed. If a properly qualified medical expert performs a reliable differential diagnosis through which, to a reasonable degree of medical certainty, all other possible causes of the victims' condition can be

[22] *Accord Bitler v. A.O. Smith Corp.*, 400 F.3d 1227, 1237 (10th Cir. 2005) ("[D]ifferential diagnosis is a common method of analysis, and federal courts have regularly found it reliable under *Daubert*."); *Clausen v. M/V New Carissa*, 339 F.3d 1049, 1058 (9th Cir. 2003) ("[A] reliable differential diagnosis passes muster under *Daubert*."); *Mattis v. Carlon Elec. Prods.*, 295 F.3d 856, 861 (8th Cir. 2002) ("A medical opinion based upon a proper differential diagnosis is sufficiently reliable to satisfy *Daubert*."); *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 758 (3d Cir. 1994) ("[D]ifferential diagnosis generally is a technique that has widespread acceptance in the medical community, has been subject to peer review, and does not frequently lead to incorrect results.").

> eliminated, leaving only the toxic substance as the cause, a causation opinion based on that differential diagnosis should be admitted.

*Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1209 (8th Cir. 2000) (internal citations omitted).[23] In other words, a reliable differential diagnosis alone provides a valid foundation for a causation opinion, even when no epidemiological studies, peer-reviewed published studies, animal studies, or laboratory data are offered in support. *Westberry*, 178 F.3d at 262.

In any event, the record confirms that Dr. Pue *did* rule in diacetyl as a possible cause. Dr. Pue has studied diacetyl and its effects on the lungs for years. He detailed exactly how diacetyl causes lung damage.[24] He is familiar with and relied on the many studies linking diacetyl and obstructive lung disease, starting with the 2002 study in the New England Journal of Medicine. (1/26/22PM:T.78-79). He relied on "all the pulmonary textbooks," on-line literature, governmental evaluations, and NIOSH studies. (1/26/22PM:T.82-83). He reviewed the MSDSs for

[23] *Accord Hollander v. Sandoz Pharms. Corp.*, 289 F.3d 1193, 1211-12 (10th Cir. 2002); *Hardyman v. Norfolk & W. Ry. Co.*, 243 F.3d 255, 265-66 (6th Cir. 2001); *Heller*, 167 F.3d at 155.

[24] Diacetyl is an alpha-diketone that's very toxic to the lining of the lungs. (1/26/22PM:T.80). Because diacetyl is soluble in water, and the airway's liquid is water, diacetyl dissolves when inhaled and creates scar tissue. (1/26/22PM:T.81). This especially affects the smaller airways (bronchioles), and obliterans occurs when an airway becomes so scarred that it completely closes off. (1/26/22PM:T.81-82).

diacetyl, which confirm that it causes bronchiolitis obliterans. (1/26/22PM:T.89). And, as discussed, he has treated hundreds of other patients who became ill after inhaling diacetyl. (1/26/22PM:T.79-80). All this was sufficient foundation for Dr. Pue to rule in diacetyl as a possible cause of Moncel's disease. *Best v. Lowe's Home Ctrs., Inc.*, 563 F.3d 171, 181 (6th Cir. 2009) (expert "did not arbitrarily 'rule in' Aqua EZ as a potential cause, but instead concluded from the MSDS sheet and his own knowledge of medicine and chemistry that the chemical it contains can cause damage to the nasal and sinus mucosa upon inhalation.").

Flavor also challenges the timing of Moncel's disease, claiming that diacetyl exposure should produce an immediate onset of symptoms. *Flavor's Brief* at 47. That statement is simply the testimony of Flavor's expert, Dr. Kerger, and conflicts with the literature and Dr. Pue's clinical experience. Dr. Pue testified that with diacetyl exposure in the workplace, "[i]t's almost never an instantaneous exposure and symptoms start afterwards." (1/26/22PM:T.92). Immediate onset is "not the norm," and occurs only in "very, very high exposures." (*Id.*). The normal onset is "a cumulative effect" and takes place gradually, just as it did for Moncel. (1/26/22PM:T.93). Dr. Kerger may disagree (although he's not a medical doctor and has never treated a diacetyl patient), but that in no way changes the *Daubert* analysis or renders Dr. Pue's opinions

inadmissible.[25] The jury had a right to resolve any "battle of the experts," and it did so in Moncel's favor. *In re Dealer Mgmt. Sys. Antitrust Litig.*, 581 F. Supp. 3d 1029, 1075 (N.D. Ill. 2022) ("Defendants' criticisms raise 'battle of the experts' issues that should be resolved through cross-examination, not *Daubert* motions.").

Finally, Flavor argues that "Dr. Pue has no reliable basis for differentiating Dr. Franco's asthma diagnosis." *Flavor Brief* at 46. True, Dr. Franco labeled Moncel's disease as "occupationally-induced asthma," rather than bronchiolitis obliterans. (1/26/22PM:T.19). But this is a distinction without a difference: Dr. Franco fully agrees that Flavor's diacetyl caused Moncel's illness, she just applies a different name to the disease. (1/26/22PM:T.24). The reason for this slight variation is that Moncel had a single negative CT scan, and Dr. Franco believes a positive scan is needed to diagnose bronchiolitis obliterans. (1/26/22PM:T.23). Dr. Pue disagrees: "only one-fourth of patients with biopsy proven bronchiolitis obliterans have an abnormal CT so that's not a reason to exclude bronchiolitis obliterans." (1/26/22PM:T.109). In any event, such "quibbling over labels" doesn't matter clinically: whatever Moncel's

[25] *In re EQT Corp. Sec. Litig.*, No. 2:19-cv-00754-RJC, 2022 WL 3293518, at *20 (W.D. Pa. Aug. 11, 2022) ("That the experts disagree does not mean that one must be excluded under *Daubert*."); *McCreless v. Glob. Upholstery Co.*, 500 F. Supp. 2d 1350, 1353 n.2 (N.D. Ala. 2007) ("Two experts can disagree and yet both be allowed to testify").

condition is called, "we're both saying he's got occupationally-induced lung disease." (*Id*.).

### D. The Circuit Court Properly Exercised Its Discretion in Admitting the Testimony of Dr. Franco.

Dr. Rose Franco is a triple board-certified pulmonologist who treated Moncel for his injuries. (1/26/22PM:T.7-8). Like Dr. Pue, she testified on specific causation, confirming that Flavor's diacetyl caused Moncel's obstructive lung disease. (1/26/22PM:T.14-15). Dr. Franco based this opinion on: (1) her experience as a pulmonologist practicing for more than 20 years (1/26/22PM:T.5, 8); (2) the differential diagnosis she performed on Moncel (1/26/22PM:T.8-9); and (3) her review of the scientific literature relating to diacetyl. (1/26/22PM:T.15-16). Again, "exclusion is rarely justified in cases involving medical experts," particular when a doctor bases her opinions "on methods reasonably relied on by clinical physicians." *Seifert*, 2017 WI 2, ¶¶ 81 n.39, 85. Dr. Franco used her "knowledge and experience" to "make a sound judgment," and that judgment was both reliable and admissible. *Id*., ¶ 79.

Flavor concedes "Dr. Franco's qualifications" and "the medical foundation" for her diagnosis – it just argues that she was wrong to attribute Moncel's disease to the company's diacetyl. *Flavor Brief* at 42.

But Flavor's arguments are simply a summary of its cross-examination, not reasons for excluding Dr. Franco's testimony.[26] For example, Flavor complains that Dr. Franco "obtain[ed] information solely from [Moncel]" relating to his diacetyl exposure. *Id.* That's called taking a patient history, and doctors do it all the time.[27] Dr. Franco treated Moncel the same way she treated all her other patients, and she had no duty to independently confirm everything he told her while seeking treatment.

Flavor also misstates the record when attacking Dr. Franco. Flavor claims, for instance, that Dr. Franco agreed she cannot "separate the coffee dust in the air" from "diacetyl in flavorings" as the cause of Moncel's lung disease. *Id.* at 43. What she actually said, however, was that she couldn't "state it was specifically the diacetyl in the flavoring *alone* that caused" Moncel's disease. (1/26/22PM:T.40) (emphasis supplied). Similarly, Flavor claims that Dr. Franco agreed Moncel's disease could have been caused by "dust from unflavored coffee beans," but then failed to rule out that possibility. *Flavor Brief* at 43. But her

[26] *Seifert*, 2017 WI 2, ¶ 86 (proper means of attacking medical testimony is "'[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof'") (quoting *Daubert*, 509 U.S. at 597).

[27] *Brown v. NCL (Bahamas) Ltd.*, 190 F. Supp. 3d 1136, 1144 (S.D. Fla. 2016) ("the opinions of treating physicians on injury causation—based on medical knowledge, physical examination, and patient histories—are routinely admitted in federal courts."); *Etherton v. Owners Ins. Co.*, 35 F. Supp. 3d 1360, 1372 (D. Colo. 2014) (same).

real testimony was that "other organic compounds could possibly be causing his asthma *as well*." (1/26/22PM:T.39) (emphasis supplied). These differences are crucial: tortfeasors "may be held liable even though another cause is also a substantial factor in contributing to the result." *Ehlinger*, 155 Wis. 2d 1, 13. This is because "[t]here may be more than one substantial causative factor in any given case," and "[t]he defendant's negligent conduct need not be the sole or primary factor in causing the plaintiff's harm." *Id*. (internal citations omitted). Dr. Franco's acknowledgment that other factors might have aggravated Moncel's diacetyl-induced lung disease in no way renders her testimony inadmissible. Nor does it absolve Flavor of its responsibility for exposing Moncel to a known harmful chemical.

Finally, Flavor is wrong in arguing for exclusion of Dr. Franco's opinions based on an alleged lack of "underlying authority." *Flavor Brief* at 43. First, Dr. Franco's experience as a doctor is enough to allow her testimony; there's no further requirement that she cite medical literature or published studies. *Seifert*, 2017 WI 2, ¶ 84 (requiring "familiarity with accepted medical literature or published standards" for reliability "is an erroneous statement of the law."). Second, Dr. Franco *did* cite such studies. She performed her own research "to make sure [she was] on sound footing with what [she was] saying."

(1/26/22PM:T.16). In doing this research, she reviewed "scientific literature on lung disease that concludes that diacetyl causes obstructive lung disease." (1/26/22PM:T.15). And that scientific literature confirmed what she'd already "seen in [her] own research and . . . studies as a pulmonologist." (1/26/22PM:T.15-16). Dr. Franco's diligent efforts went beyond the ordinary, and certainly exceeded the level required to testify. Again, Flavor's experts may disagree with her conclusions, but the jury had a right to resolve any conflicts in Moncel's favor. *Bonner*, 259 F.3d at 930 ("Although it is common that medical experts often disagree on diagnosis and causation, questions of conflicting evidence must be left for the jury's determination.").

## III. THE EVIDENCE SUPPORTS THE JURY'S LIABILITY FINDINGS

Flavor next challenges the evidence supporting the jury's liability findings of design defect and failure to warn. "Wisconsin cases have discussed three categories of product defects – manufacturing defects, design defects, and defects based on a failure to adequately warn." *Godoy ex rel. Gramling v. E.I. du Pont de Nemours & Co.*, 2009 WI 78, ¶ 29, 319 Wis. 2d 91, 111, 768 N.W.2d 674, 683. Moncel submitted theories based on design defect and failure to warn, and the jury found in his favor on both counts. Those findings are well-supported by the evidence.

### A. Flavor Sold Defectively Designed Products Containing Dangerous Amounts of Diacetyl.

Under Wisconsin law, "[a] product is defective in design if the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the manufacturer and the omission of the alternative design renders the product not reasonably safe." Wis. Stat. § 895.047(1)(a). The jury applied this law and found Flavor's products defective because the flavorings all contained dangerous amounts of diacetyl.

There's no serious dispute that diacetyl is dangerous and causes obstructive lung disease. NIOSH began studying the dangers of diacetyl-containing flavorings in 2000, which led to its 2002 article in the New England Journal of Medicine documenting such hazards. (1/26/22AM:T.25-26). NIOSH continued studying diacetyl, and again warned of the dangers of diacetyl-containing flavorings in 2003. (1/26/22AM:T.26). After NIOSH performed still more studies, the scientific community reached a consensus that diacetyl is a dangerous and highly toxic chemical. (1/26/22AM:T.31-32). More than 50 studies confirm the danger posed by diacetyl. (*Id.*). Diacetyl is so dangerous that NIOSH measures its recommended exposure limits in parts per

*billion*, 1000 times stricter than the limits used for most chemicals. (1/26/22AM:T.37-38).

There's also no doubt that a reasonable alternative design existed for Flavor's flavoring products without diacetyl. We know this because Flavor removed diacetyl from all of its products in 2012. (1/27/22:T.37). Flavor's consulting designer and flavor chemist, David Straus, testified that Flavor did so because "[e]veryone in the industry was starting to move out of it," and "[t]here were other chemicals that you can use if you have a brain and the flavors. You don't have to use that stuff . . . ." (ECF.760 - Ex. 180B:84-85). Flavor could have adopted this alternative design without diacetyl into its flavorings at any time before 2012; it just chose not to.

Finally, Flavor's failure to remove diacetyl from its products made them not reasonably safe. NIOSH has established recommended exposure limits for diacetyl exposure in the workplace. (1/26/22AM:T.38). Exceeding these limits, especially at the level Flavor did, is extremely dangerous. (1/26/22AM:T.38-39) (objection omitted); *see also* (1/27/22:T.78) (all diacetyl levels used by Flavor hazardous if inhaled). And the best way to avoid this danger is to remove diacetyl from the product, which should have been done no later than 2003. (1/26/22AM:T.30-31). From this evidence, the jury had a right to

conclude that Flavor's products were defectively designed by 2003, well before Moncel's exposure.

Flavor largely ignores this evidence, simply claiming that "not a single witness" testified that its flavors "containing diacetyl posed a risk to humans." *Flavor Brief* at 50. As discussed throughout, that's not true. In fact, *Flavor's own President* admitted the danger. (1/27/22:T.18) (diacetyl hazardous even at the percentages in the flavorings sold to Moncel's employer). Flavor's Operations Manager confirmed that admission. (1/27/22:T.80). And Flavor's expert agreed that the company's products exposed Moncel to diacetyl at levels 20-50 times the recommended limits. (1/28/22:T.71-72). From this evidence, the jury reasonably concluded that the diacetyl in Flavor's products posed a risk of harm that made those products not reasonably safe.

### B. Flavor Failed to Warn of the Danger Posed by Diacetyl in Its Products.

Flavor also challenges the jury's finding on failure to warn. Diacetyl is so hazardous that Flavor's supplier of raw diacetyl made the company promise, in writing, 12 times, to warn its customers of the danger. (ECF.662, 654, 670, 659, 648, 665, 650, 634, 651, 635, 636, 671). But the jury found that Flavor broke that promise and never warned Moncel or his employer.

Moncel produced abundant evidence to support the jury's finding of no warning, starting with his own testimony. Moncel opened the boxes shipped by Flavor as part of his job, and therefore knew exactly what they contained. (1/25/22PM:T.8). He confirmed that those boxes never contained any warnings about diacetyl. (1/25/22PM:T.9-10). Moncel's testimony, standing by itself, is sufficient for the jury's finding that Flavor failed to warn.

Moncel's employers, Rod and Teresa Peters, corroborated his testimony. Both testified that Flavor never provided them with the required warnings. (ECF.760 - Ex.180D:10; ECF.760 - Ex.180E:9). During Moncel's employment, Flavor never provided them with the Material Safety Data Sheets for diacetyl. (ECF.760 - Ex.180D:20-21). Flavor never told them that the diacetyl in its products was toxic if inhaled. (*Id*. at 14-15). Flavor never told them that its products could cause lung disease, such as bronchiolitis obliterans. (*Id*. at 16-17). Flavor never provided them with the warnings or information on diacetyl published by NIOSH. (*Id*. at 17-18). And Flavor never told them that workers handling its products needed to wear respirators or take any other precautions. (*Id*. at 13). In fact, Flavor never provided warnings of any kind until 2017, two years after Moncel's employment ended. (*Id*. at 18-19*;* ECF.760 - Ex.180E:8-9). If Flavor had provided any of the

required warnings, the Peterses would have acted to protect their employees, and Moncel would not have suffered injury. (ECF.760 - Ex.180D:21). This testimony provided yet more support showing that Flavor broke its promise and never delivered the required warnings.

Flavor, of course, offered contrary evidence. The company's President, Joseph Staffieri, testified that Flavor did provide warnings. (1/27/22:T.20). But he admitted that Flavor only provided warnings for "substantiated" dangers, and he did not consider the danger posed by diacetyl substantiated. (ECF.760 - Ex.180A:171-72; 1/27/22:T.30-31).[28] Counsel also showed that, despite Flavor's claims, the company never produced any copies of the written warnings it supposedly gave. (1/27/22:T.21, 40). *Cf. In re Engelhardt's Estate*, 272 Wis. 275, 287, 75 N.W.2d 631, 637 (1956) ("In determining the weight of the evidence or its effect in inducing belief, consideration should be given to . . . the existence of lack of corroboration"). No such written warnings exist, either in Flavor's files or in the files on Moncel's employer. Flavor at most created a jury question, and the jury resolved the conflict in Moncel's favor.

[28] Staffieri gave this testimony in his prior deposition, which Moncel's counsel played for the jury as substantive evidence in his case in chief. (ECF.760 - Ex.180A:171-72). Moncel's counsel also impeached Staffieri with the same testimony when he tried to change his story at trial. (1/27/22:T.30-31).

Flavor's briefing simply ignores the record. Flavor doesn't discuss Moncel's testimony, nor does it mention Staffieri's admission that he wouldn't give a warning about diacetyl because he considered its danger to be unsubstantiated. As for Rod and Teresa Peters, Flavor asks the Court to ignore their testimony because they couldn't recall the precise wording on sheets that Flavor provided in 2008-12. *Flavor Brief* at 51. No one could be expected to remember after 14 years the exact content of these sheets, but both Rod and Teresa Peters were adamant that they received no warnings about diacetyl. Again, the jury considered Flavor's arguments and elected to believe the Peters's testimony. It was well within its rights to do so.

## IV. FLAVOR NEVER OBJECTED DURING COUNSEL'S CLOSING ARGUMENT, AND THEREFORE WAIVED ANY RIGHT TO APPEAL THAT ARGUMENT

Flavor's last argument relates to an isolated statement Moncel's counsel made during his closing argument. *Flavor Brief* at 52-53. The Circuit Court denied Flavor's request for a new trial based on that statement, and normally its decision would be reviewed under an erroneous exercise of discretion standard. *Seifert*, 2017 WI 2, ¶ 139. Here, however, Flavor never objected during counsel's closing argument, or at any other time before the jury returned its verdict. That failure is fatal to Flavor's claim: "Improper remarks in closing arguments cannot

be a basis for a motion for a new trial or a basis for an appeal to this court if no timely objection to the argument was made." *Hubbard v. Mathis*, 53 Wis. 2d 306, 306, 193 N.W.2d 15, 16 (1972). And "[t]he time to object to an improper argument to the jury is at the time it is made or at the very latest before the jury returns its verdict." *Id.* Flavor therefore waived its right to raise this issue.

Even if Flavor had objected, the Circuit Court committed no erroneous exercise of discretion in denying a new trial. First, Moncel's counsel made no improper argument. Flavor's motion in limine was directed to "other cases involving diacetyl and other defendants and their outcomes." (ECF.429 at 2, 3). Counsel in closing made no mention of the facts, defendants, or outcomes in other cases. He simply referred to the many observers present throughout the trial, which the jury undoubtedly had already noticed. And second, the Circuit Court made specific findings that: (1) counsel's statements were not "inflammatory in nature"; and (2) "the jury was within its discretion based on the evidence in the record to award the damages that it did." (Doc. 740, pp. 28, 29-30). The jurors scrutinized the impact Flavor's misconduct had on Moncel's life, and there's no basis for awarding a new trial based on the size of their verdict.

## CONCLUSION

Jury verdicts mean something. The jury here listened carefully through seven days of trial and returned its verdict for Moncel. That verdict is entitled to "special deference" and can be set aside only by showing a "complete failure of proof." *Morden*, 2000 WI 51, ¶ 40. Flavor's brief, which just tries to reargue the evidence, falls far short of that standard. For all these reasons, the Circuit Court's judgment for Moncel should be affirmed.

Dated: November 21, 2022

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## FORM AND LENGTH CERTIFICATION

I hereby certify that this brief conforms to the rules contained in s. 809.19 (8) (b), (bm), and (c) for a brief. The length of this brief is 10,956 words.

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