IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA
WESTERN DIVISION

JASON THIELE, Plaintiff, vs. DSM FOOD SPECIALTIES, USA, INC., et al., Defendants.	No. C18-4081-LTS **MEMORANDUM OPINION AND ORDER**

I. INTRODUCTION

This matter is before me on a motion (Doc. 315) for summary judgment by defendant Givaudan Flavors Corporation (Givaudan). Plaintiff Jason Thiele has filed a resistance (Doc. 361) to the motion and Givaudan has filed a reply. Doc. 381. Givaudan has also filed the following motions to exclude expert testimony:

- Doc. 308 – Motion to Exclude the Testimony and Opinions of Plaintiff's Expert Timur Durrani, M.D., as to General Causation and Warnings Related to 2,3-Pentanedione and 2,3-Hexanedione
- Doc. 309 – Motion to Exclude the Testimony and Opinions of Plaintiff's Expert Robert Harrison, M.D. as to General Causation
- Doc. 311 – Motion to Exclude the Testimony and Opinions of Plaintiff's Expert Charles Pue, M.D. as to Specific Causation
- Doc. 312 – Motion to Exclude Dr. Harrison's Testimony and Opinions as to Warnings
- Doc. 313 – Motion to Exclude the Testimony and Opinions of Plaintiff's Experts William H. Rogers, Ph.D. and John O. Ward, Ph.D.
- Doc. 314 – Motion to Exclude the Testimony and Opinions of Plaintiff's

Expert Katie Allison, PT, MS, CLCP

- Doc. 387 – Motion in Limine to Exclude the Testimony and Opinions of Gregory B. Diette, M.D.

Thiele has filed responses to each motion. *See* Docs. 337-339, 341-343, 391. Givaudan has filed replies to all but the motion in limine. *See* Docs. 347, 349-353. Givaudan has also provided notice (Doc. 394) of supplemental authority in support of its motions to exclude the testimony and opinions of Dr. Durrani and Dr. Harrison and its motion for summary judgment. Oral argument is not necessary. *See* Local Rule 7(c).

II. BACKGROUND AND PROCEDURAL HISTORY

Thiele filed his complaint on September 12, 2018, alleging diversity jurisdiction under 28 U.S.C. § 1332. He asserts claims of negligence (Count I), strict product liability – design, manufacturing and inherent defects (Count II), strict product liability – failure to warn (Count III) and strict product liability – failure to instruct (Count IV). Doc. 1. Thiele alleges he developed "flavoring-related bronchiolitis obliterans syndrome" or "flavoring-related lung disease" from occupational exposure to flavors containing the ingredients diacetyl, 2,3-pentanedione (2,3-PD) and 2,3-hexanedione (2,3-HD) while working at American Pop Corn Company (APC) from March 2004 to May 2011. Although Thiele's complaint named numerous defendants, all but Givaudan have been dismissed throughout the course of this case.

III. DISCUSSION

A. Motions to Exclude Expert Testimony and Opinion

1. Timur Durrani, M.D. – Doc. 308

Givaudan seeks to exclude the expert testimony and opinions of Dr. Durrani pursuant to Federal Rules of Evidence 402, 403, 702 and 703. Specifically, it seeks to exclude his testimony and opinions as to general causation and warnings related to 2,3-

PD and 2,3-HD. *See* Docs. 308, 318. Dr. Durrani has opined that (a) 2,3-PD and 2,3-HD can cause bronchiolitis obliterans (BO) and other lung disease and (b) that the defendants should have known, by at least 2002, that 2,3-PD and 2,3-HD were capable of causing BO and other lung disease.

Givaudan notes that in 2000, the National Institute for Occupational Safety and Health (NIOSH) became aware of several former employees of a microwave popcorn facility in Jasper, Missouri, who had been diagnosed with BO. NIOSH was unable to confirm the diagnoses or determine the exact cause of their lung conditions but suspected that the ingredient diacetyl in the butter flavor might be associated with the BO diagnosed in the former workers. BO is a rare, medically-recognized respiratory condition that is found almost exclusively in lung transplant patients as a known complication. Former popcorn plant employees generally do not meet the diagnostic criteria of BO. Dr. Charles Pue, Thiele's specific causation expert, created a diagnosis to reflect the flavoring-related component, which has undergone various name changes, but is now referred to as "flavoring-related lung disease (FRLD).[1]

The parties agree that Thiele must prove general and specific causation through expert testimony to prevail on his claims. Givaudan argues Dr. Durrani's general causation opinion should be excluded because:

a) he conceded that he was not offering any opinions related to FRBOS

b) not a single study he relies on concludes that 2,3-PD or 2,3-HD can cause BO (or any other lung disease)

c) he lacks the requisite knowledge and basis on which to render any general causation opinion with respect to 2,3-PD or 2,3-HD because he admits that he cannot satisfy the two required elements of such an opinion, i.e., he does not know the level of exposure to 2,3-PD or 2,3-HD that is capable of causing harm or Thiele's actual level of exposure to 2,3-PD or 2,3-HD

[1] Dr. Pue diagnosed Thiele with "flavoring related bronchiolitis obliterans syndrome" (FRBOS) but changed the diagnosis to FRLD in his amended report. Dr. Pue states this was just a "change in nomenclature" such that the terms may be used interchangeably throughout his opinion.

Givaudan also seeks to exclude Dr. Durrani's opinion that defendants should have known by 2002 that 2,3-PD and 2,3-HD could cause BO.

a. Applicable Standards

Federal Rule of Evidence 702 governs the admission of expert testimony. The rule states that a qualified expert may testify "in the form of an opinion or otherwise" if:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case

Fed. R. Evid. 702. To be admissible, expert testimony must be both relevant and reliable. *Weisgram v. Marley Co.*, 169 F.3d 514, 517 (8th Cir. 1999), *aff'd*, 528 U.S. 440 (2000). Evidence is relevant if it tends to make a fact more or less probable and is of consequence in determining the action. Fed. R. Evid. 401. Evidence is reliable if it is useful to the fact finder in deciding an ultimate issue of fact, the expert is qualified and the expert's evidence is reliable. *Peters v. Woodbury Cnty.*, 979 F. Supp. 2d 909, 919 (N.D. Iowa 2013), *aff'd sub nom. Peters v. Risdal*, 786 F.3d 1095 (8th Cir. 2015).

Under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the district court must perform a "gatekeeping function" to ensure that irrelevant or unreliable expert testimony is not introduced into evidence. *See, e.g., In re Zurn Pex Plumbing Prods. Liab. Litig.*, 644 F.3d 604, 613 (8th Cir. 2001). The trial court has broad discretion when determining the reliability of expert testimony. *United States v. Vesey*, 338 F.3d 913, 916 (8th Cir. 2003). Doubts as to whether the testimony will be helpful should be resolved in favor of admissibility. *See Shuck v. CNH America, LLC*, 498 F.3d 868, 874 (8th Cir. 2007) (Rule 702 "is one of admissibility rather than exclusion.)" (citation omitted)); *Robinson v. GEICO Gen. Ins. Co.*, 447 F.3d 1096, 1100

(8th Cir. 2006) ("'[R]ejection of expert testimony is the exception rather than the rule.'" (quoting Fed. R. Evid. 702 advisory committee's note)).

When considering expert testimony, the court must determine whether the testimony is both reliable and relevant. *See Barrett v. Rhodia, Inc.*, 606 F.3d 975, 980 (8th Cir. 2010) (citing *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 757 (8th Cir. 2006)).

> To satisfy the reliability requirement, the party offering the expert testimony "must show by a preponderance of the evidence both that the expert is qualified to render the opinion and that the methodology underlying his conclusions is scientifically valid." *Daubert*, 509 U.S. at 589-90. To satisfy the relevance requirement, the proponent must show that the expert's reasoning or methodology was applied properly to the facts at issue.

Khoury v. Philips Med. Sys., 614 F.3d 888, 892 (8th Cir. 2010) (citation omitted, cleaned up). Factors bearing on the admissibility of expert evidence include:

> (1) whether the theory or technique applied can be tested, (2) whether the theory or technique has been subject to peer review and publication, (3) the known or potential rate of error, and (4) whether it is accepted in the relevant discipline.

Kuhn v. Wyeth, Inc., 686 F.3d 618, 625 (8th Cir. 2012) (citing *Daubert*, 509 U.S. at 593-94). The court may also consider "whether the expertise was developed for litigation or naturally flowed from the expert's research; whether the proposed expert ruled out other alternative explanations; and whether the proposed expert sufficiently connected the proposed testimony with the facts of the case." *Presley v. Lakewood Eng'g & Mfg. Co.*, 553 F.3d 638, 643 (8th Cir. 2009) (citation omitted). "While weighing these factors, the district court must continue to function as a gatekeeper who 'separates expert opinion evidence based on 'good grounds' from subjective speculation that masquerades as scientific knowledge.'" *Presley*, 553 F.3d at 643 (citation omitted).

"Expert testimony is inadmissible where . . . it is excessively speculative or unsupported by sufficient facts." *Onyiah v. St. Cloud State Univ.*, 684 F.3d 711, 720

(8th Cir. 2012) (citation omitted); *see also Marmo*, 457 F.3d at 757 ("Expert testimony is inadmissible if it is speculative, unsupported by sufficient facts, or contrary to the facts of the case."); *J.B. Hunt Transp., Inc. v. Gen. Motors Corp.*, 243 F.3d 441, 444 (8th Cir. 2001) ("Expert testimony that is speculative is not competent proof and contributes nothing to a legally sufficient evidentiary basis.") (citation omitted)). An expert's opinion should be excluded only if it "'is so fundamentally unsupported that it can offer no assistance to the jury.'" *Cole v. Homier Distrib. Co.*, 599 F.3d 856, 865 (8th Cir. 2010) (citation omitted). Otherwise, "'[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.'" *Kuhn*, 686 F.3d at 625 (quoting *Daubert*, 509 U.S. at 596).

b. Analysis

I will first address Givaudan's argument that Dr. Durrani does not know either (1) the level of exposure to 2,3-PD or 2,3-HD that is capable of causing harm or (2) Thiele's actual level of exposure to 2,3-PD or 2,3-HD. Dr. Durrani's opinion[2] has been excluded on these grounds in a similar case, as has Dr. Harrison's general causation opinion. *See Downs et al. v. DSM Food Specialties USA, Inc., et al.*, 1:18-cv-33, Doc. 468 (S.D. Iowa Oct. 28, 2021).[3] In *Downs*, the court noted that Dr. Durrani did not identify the level of exposure to 2,3-PD and 2,3-HD that is harmful. Dr. Durrani testified in his deposition that, although a threshold level of exposure at which these chemicals can cause harm exists, he could not identify the threshold level because it is not known to the scientific community and therefore unknown to him. He therefore assumed that occupational exposures to 2,3-PD and 2,3-HD are unsafe and capable of causing lung

[2] Dr. Durrani acknowledged in his deposition that his report in *Downs* is substantially the same or identical to the report he offers in this case. *See* Doc. 308-5 at 4.

[3] The plaintiffs in *Downs* have not appealed the court's ruling.

disease. *Id.* The *Downs* court found that this assumption made Dr. Durrani's testimony speculative and therefore inadmissible. Further, the court noted Dr. Durrani could not identify the level of 2,3-PD and 2,3-HD to which someone working at the same plant as the plaintiffs would have been exposed during work. The court concluded that without this necessary evidence of causation, Dr. Durrani's testimony was not reliable and therefore excluded his opinion. *Id.*

Thiele relies on *Herbst v. Givaudan Flavors Corp.*, No. C17-4008-MWB, 2018 WL 6310271, at *3 (N.D. Iowa Dec. 3, 2018), in which United States District Judge Mark W. Bennett found that Dr. Harrison's general causation opinion was not inadmissible simply because it did not "identify the dosages at which diacetyl may be harmful or the dosages to which Herbst was ever exposed." After that case was reassigned to me, I found no grounds to reach a different outcome on reconsideration. *Herbst v. Givaudan Flavors Corp.*, No. C17-4008-LTS, 2019 WL 6108098, at *3 (N.D. Iowa Aug. 19, 2019). Givaudan argues that the initial rationale for this standard, as explained in *Bonner*,[4] does not apply to this type of litigation, which has now been ongoing for 20 years. Givaudan further contends that neither Dr. Durrani's nor Dr. Harrison's opinions can meet the necessary standard when such opinions offer no specificity about exposure levels. Thiele notes there are no historical measurements of the chemicals at issue during Thiele's employment.

"To prove causation in a toxic tort case, a plaintiff must show both that the alleged toxin is capable of causing injuries like that suffered by the plaintiff in human beings subjected to the same level of exposure as the plaintiff, and that the toxin was the cause of the plaintiff's injury." *Bonner*, 259 F.3d at 928 (citing *Wright v. Willamette Indus.,*

[4] *See Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 928 (8th Cir. 2001) ("We have held, however, that '[t]he 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.") (quoting *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1208-09 (8th Cir. 2000)).

Inc., 91 F.3d 1105, 1106 (8th Cir. 1996)). *See also Bland v. Verizon Wireless, L.L.C.*, 538 F.3d 893, 898 (8th Cir. 2008) (affirming exclusion of expert causation opinion where expert lacked knowledge as to (1) what amount of exposure was capable of causing the alleged injury and (2) what amount the plaintiff was actually or probably exposed). To prove exposure levels, a plaintiff need not produce a "mathematically precise table equating levels of exposure with levels of harm" but must make "a threshold showing that he or she was exposed to toxic levels known to cause the type of injuries he or she suffered." *Mattis v. Carlon Elec Prods.*, 295 F.3d 856, 860-61 (8th Cir. 2002) (quoting *Bednar v. Bassett Furniture Mfg. Co.*, 147 F.3d 737, 740 (8th Cir. 1998)). *See also Bonner*, 259 F.3d at 931 ("it was not necessary that Bonner's experts quantify the amount of FoamFlush to which she was exposed in order to demonstrate that she was exposed to a toxic level of BLO . . . . It is sufficient for a plaintiff to prove that she was exposed to a quantity of the toxin that 'exceeded safe levels.'") (internal citation omitted); *Bednar*, 147 F.3d at 740 ("The Bednars did not need to produce 'a mathematically precise table equating levels of exposure with levels of harm' in order to show Marian's level of exposure to gaseous formaldehyde, but only 'evidence from which a reasonable person could conclude that [the] defendant's emission has probably caused' the harm about which they complain.").

In *Wright*, the court found that "while the Wrights proved that they were exposed to defendant's emissions and that wood fibers from defendant's plant were in their house, their sputum, and their urine, they failed to produce evidence that they were exposed to a hazardous level of formaldehyde from the fibers emanating from Willamette's plant." *Wright*, 91 F.3d at 1107. The court noted that plaintiffs' experts offered testimony about the levels of gaseous formaldehyde that might be expected to cause symptoms like the ones that plaintiffs claimed to have experienced, but they did not claim to be injured from breathing gaseous formaldehyde and made no reference to any studies that revealed the levels of exposure to wood fibers impregnated with formaldehyde that would likely produce adverse consequences. *Id.* at 1107-08. One expert testified that plaintiffs'

complaints "were more probably than not related to exposure to formaldehyde, but the court noted his opinion was not based on any knowledge about what amounts of wood fibers impregnated with formaldehyde involved an appreciable risk of harm to human beings who breathe them." *Id.* at 1108.

In contrast, the plaintiffs in *Bednar* provided evidence of the threshold limit of safe exposure to gaseous formaldehyde approved by the American Conference of Governmental Industrial Hygienists, the average safety limit set by NIOSH for an eight-hour period, and the safety limit recognized by the Occupational Safety and Health Administration (OSHA) for an eight-hour average and any fifteen-minute period. *Bednar*, 147 F.3d at 739. Their experts also testified about symptoms that could be triggered by exposure over certain thresholds and at what point exposure to formaldehyde could cause adverse health effects. *Id.* Finally, the plaintiffs presented evidence of tests conducted by their expert that measured the level of a gaseous formaldehyde that was found in the air of the dresser drawers at issue. *Id.* at 740. This expert also testified as to the levels of formaldehyde that are considered unsafe, and that the gaseous formaldehyde in the drawers exceeded safe limits. *Id.*

In *Bonner*, the court found that the plaintiff presented expert witnesses who testified that her exposure to the product at issue was "of a duration and of a volume sufficient to support a conclusion that she inhaled and/or absorbed through her skin at least a quarter of a teaspoon of FoamFlush when she was sprayed with it." *Bonner*, 259 F.3d at 931. The court stated that "it was not necessary that Bonner's experts quantify the amount of FoamFlush to which she was exposed in order to demonstrate that she was exposed to a toxic level of BLO" and that it is "sufficient for a plaintiff to prove that she was exposed to a quantity of the toxin that 'exceeded safe levels.'" *Id.* (quoting *Bednar*, 147 F.3d at 740).

Here, Dr. Durrani opines that BO and "other lung disease" can occur due to "massive chemical exposure or in a sub-acute chronic exposure." Doc. 308-4 at 6. He states that in 2002, NIOSH identified chronic exposure to diacetyl as the causative agent

in eight popcorn-plant workers in Missouri. *Id.* Peak exposures were measured up to 1230 ppm, such as when opening the lid of a tank of heated flavoring prior to mixing it with heated oil. *Id.* Dr. Durrani then compares the chemical properties of diacetyl to 2,3-PD and 2,3-HD before discussing the Bradford Hill viewpoints[5] for each. *Id.* With regard to 2,3-PD, Dr. Durrani discusses seven studies, none of which identify a level of exposure at which 2,3-PD is harmful to humans. The closest Dr. Durrani comes to providing such information is through the NIOSH proposed recommended exposure limits (REL) for diacetyl and 2,3-PD:

> The agency recommends a[n] exposure limit of 5 ppb for diacetyl as a time-weighted average for up to 8 hours/day during a 40-hour work week and a short-term exposure limit of 25 parts per billion for a 15-minute time period for diacetyl. NIOSH recommends keeping the occupational exposure of 2,3-PD below a level comparable to the level recommended for diacetyl. Because the limit of 2,3-PD is 9.3 ppb, this is the effective REL as a time-weighted average for up to 8 hours/day during a 40-hour work week. NIOSH recommends a short-term exposure limit for 2,3-pentanedione of 31 parts per billion during a 15-minute period. This demonstrates that NIOSH is using the Bradford Hill viewpoint of **analogy** for 2,3 pentanedione to limit occupational exposure.

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[5] The Bradford Hill viewpoints are used as a framework for analyzing causation. Dr Durrani notes these viewpoints are widely accepted in the scientific community, a point that Givaudan does not contest. The viewpoints are:

- Consistency of the observed association
- Strength of the observed association
- Specificity of the observed association
- Temporal relationship of the observed association
- Biological gradient (exposure-response relationship)
- Biological plausibility
- Coherence
- Experimental evidence (from human populations)
- Analogy

Doc. 308-4.

Doc. 308-4 at 9 (emphasis in original). With regard to 2,3-HD, Dr. Durrani's report states:

> In 2017, the National Institute of Environmental Sciences investigated airway injury due to diacetyl as well as 2,3 HD. As expected, diacetyl was able to induce more airway injury than 2,3 HD when human airway epithelium was exposed to similar concentrations of approximately 1000 ppm. Diacetyl was able to induce cell death in the 12 exposures compared to none in the 6 exposures of 2,3 HD. Diacetyl caused histopathologic changes at approximately twice the rate of 2,3 HD in ciliated and goblet cells. The two chemicals were able to induce approximately similar rates of cell atrophy and basal and suprabasal spongiosis. These results indicate, that while diacetyl is more potent than 2,3 HD at equal concentrations, 2,3-HD is still capable of causing disease in a dose dependent fashion.

Id. Dr. Durrani testified that he was not aware of any entity that had established exposure standards for 2,3-HD. Doc. 308-5 at 12. He also testified that he was "not aware of a safe level of exposure to 2,3-PD that is safe for humans." Doc. 308-5 at 10. Dr. Durrani does not have any opinions as to Thiele's actual exposures at APC.

Dr. Durrani acknowledges that the causal relationship between 2,3-PD and 2,3-HD exposure and FRBOS is dose-dependent, meaning someone is more likely to suffer adverse consequences the higher the dose and the longer the exposure. While Dr. Durrani testified there was no "safe" level of exposure, he does not cite any scientific literature in support of that theory. Rather, he relies on the NIOSH REL for diacetyl that was used to draw a comparative REL for 2,3-PD. As for 2,3-HD, he identifies no exposure limits. Because Thiele's alleged injury is dose-dependent, Dr. Durrani must identify levels of exposure that are expected to cause Thiele's alleged injury (BO or FRBOS) and whether Thiele could have been exposed to such levels. *See Bland*, 538 F.3d at 898 (noting a general causation expert must identify (1) what amount of exposure was capable of causing the alleged injury and (2) what amount the plaintiff was actually or probably exposed to).

There is simply too great of an analytical gap for Dr. Durrani to reliably conclude that 2,3-PD and 2,3-HD can cause BO or FRBOS. Dr. Durrani has identified neither the

level of 2,3-PD and 2,3-HD that can cause BO or FRBOS nor Thiele's level of exposure. Thiele's reliance on *Herbst* is unpersuasive, as it involved a different substance (diacetyl) and lacks explanation as to why the expert's opinion met the exposure requirements. Additionally, Thiele's argument that quantification is unnecessary fails to acknowledge that what is necessary is a "threshold showing" that the plaintiff was exposed to levels known to cause the type of injuries he suffered. *See Mattis*, 295 F.3d at 861. For instance, the general causation expert in *Mattis* established that plaintiff has been exposed to dangerous levels of organic solvents by using a vapor concentration test. *Id.* While the expert could not determine plaintiff's exact exposure level, his test showed that solvent vapors accumulated rapidly at extreme concentrations, far in excess of safe exposure levels. *Id.* The expert also testified that plaintiff's exposure levels would have been even higher than the levels in his test because of characteristics of the heated can of cement. *Id.*

Here, even if I accepted that Dr. Durrani had identified the NIOSH REL for 2,3-PD as a safe exposure level (even though Dr. Durrani testified he was not aware of a safe level of exposure to 2,3-PD), Dr. Durrani still cannot identify Thiele's actual exposure levels or the exposure levels for someone working in a similar position at APC. *See* Doc. 308-5 at 5 (Q: "Do you have any knowledge or any opinions as to the level of [2,3-PD] that Mr. Thiele was exposed to at anytime during his employment at American Popcorn?" A. ". . . . I don't know what levels he was exposed to."); *id.* at 6 (Q: "Is it also correct that you have no opinions that Mr. Thiele's exposure to Diacetyl, [2,3-PD] or [2,3-HD] at APC was substantial or harmful?" A: "That's correct, because I haven't seen the levels or gone through any of those other evaluations I don't have any opinion on Mr. Thiele's exposures."). As to 2,3-HD, he offers no exposure standards generally or levels at APC. *Id.* at 11 (Q: "Are you offering opinions on the level of exposure to [2,3-HD] that is sufficient to cause [BO] or any other lung disease?" A: "I haven't described any levels, no."). Without knowing the levels of 2,3-PD or 2,3-HD that workers at APC were exposed to during the time that Thiele worked there, Dr. Durrani

cannot offer a reliable opinion as to whether 2,3-PD and 2,3-HD are "capable of causing injuries like that suffered by the plaintiff in persons subjected to the same level of exposure as the plaintiff." *Mattis*, 295 F.3d at 860. Without evidence concerning levels of exposure at APC, Dr. Durrani's general causation opinion relies on assumptions and speculation and must be excluded as unreliable.

2. Robert Harrison, M.D. – Doc. 309

Givaudan seeks to exclude Dr. Harrison's general causation opinion that diacetyl is capable of causing lung disease for the same reason – Dr. Harrison does not know the level of exposure to diacetyl that is likely to cause lung disease (i.e., the relationship between the dose and the response) or the nature and amount of Thiele's alleged exposure to diacetyl. Givaudan argues that Dr. Harrison's attempt to fill this fatal flaw in his opinion with unsupported, speculative statements about "substantial" and "analogous" exposures makes his opinion unreliable.

With regard to the level of exposure to diacetyl that is capable of causing lung disease, Givaudan argues Dr. Harrison makes contradictory statements that there is no level below which exposure to diacetyl is safe,[6] but that 5 parts per billion averaged over an eight-hour day and 25 parts per billion short-term, as established by the NIOSH REL, are the levels at which diacetyl is capable of causing harm. Givaudan characterizes Dr. Harrison's opinion as a moving target that is inconsistent and unreliable. It notes that courts often exclude dose-response relationship opinions that are based on regulatory exposure levels.

With regard to Thiele's level of exposure, Givaudan argues that Dr. Harrison offers only speculation that Thiele may have been exposed to a "hazardous" level or levels that were "quite high" and offers no scientific testing, measurement or analysis in

[6] Dr. Harrison testified to this effect in his deposition in *Downs*, but not in his deposition for this case. *See* Doc. 309-9 at 6.

support. It contends Dr. Harrison's characterization of Thiele's exposure as "substantial and analogous" is insufficient because the "substantial" aspect relies on the quantity of finished flavors purchased by APC and is based on speculation rather than scientific methodology. The "analogous" aspect relies on exposures measured at APC in 2001 and 2002, two years before Thiele began working there in 2004. Givaudan also notes (1) that Thiele also wore a respirator more frequently than the workers who participated in the NIOSH study in 2002 and (2) Dr. Harrison makes no analogy to any other worker at APC and offers no analysis regarding the conditions at APC in 2004 compared to 2001 and 2002. In addition, Dr. Harrison relies on diacetyl levels at other popcorn facilities but offers no analysis or discussion about how exposures at other popcorn plants were analogous to Thiele's exposure at APC. Finally, Givaudan argues the report related to NIOSH's investigation at the Gilster-May Lee facility in Jasper, Missouri, is not comparable because the levels of diacetyl at APC were "hundreds of times lower than the Jasper plant."

Thiele argues that *Daubert* does not require a medical expert to quantify either the level of exposure that is harmful or his actual level of exposure. He notes that Dr. Harrison's general causation opinion was deemed admissible in *Herbst* and that Givaudan takes issue with Dr. Harrison's conclusions rather than attacking his methodology, which relies on the Bradford Hill viewpoints. Thiele also points out that Dr. Harrison has opined that studies have not shown a level below which diacetyl does not cause lung disease and cites NIOSH investigations into other microwave popcorn workers performing similar tasks.

The *Downs* court considered similar arguments and excluded Dr. Harrison's opinion as unreliable. The court reasoned that Dr. Harrison failed to specify what level of exposure to diacetyl will cause lung disease and declined to accept the NIOSH REL as a reliable threshold to determine level of exposure that would be harmful. *Downs et al.*, 1:18-cv33, Doc. 468 at 14. With regard to Dr. Harrison's methodology, the court observed that Dr. Harrison relied on records of the defendant's sales of butter flavoring

products to the plant during plaintiffs' employment and plaintiffs' statements about their work schedules and job duties. Dr. Harrison also applied quantitative air sampling data of the harmful level of diacetyl in the air of the mixing room at another ConAgra plant to conclude that plaintiffs' exposure at the ConAgra plant where they worked was "substantial and analogous." *Id.* at 14.

The court found that Dr. Harrison failed to account for similarities and differences between the two plants, such as when they were built, their ventilation systems, how many air exchanges occurred in the mixing rooms at the respective plants or anything else related to the specifics of the industrial hygiene systems at the plants. *Id.* at 15. The court further found Dr. Harrison's use of air sampling data from a different plant to be problematic because it was an assumption not based in science. Additionally, air sampling data collected by NIOSH from the mixing room at plaintiffs' plant in 2001 (when plaintiffs were employed there) revealed that the levels of diacetyl in the mixing room were below the level of detection and much lower than the levels measured at the ConAgra plant Dr. Harrison relied on. Another sampling from the plant from February 2005 to February 2007 (when plaintiff Huntley worked there) showed that the level of diacetyl was more than ten times lower than that detected at the plant Dr. Harrison relied on during the same time period. The court concluded that Dr. Harrison's reliance on data from another plant while ignoring data collected from the plant where plaintiffs worked during their periods of employment undermined the reliability of his methodology. *Id.* at 17. As such, the court excluded Dr. Harrison's opinion.

As discussed in the previous section, the relevant questions are whether Dr. Harrison has (1) identified the level of exposure capable of causing harm and (2) made a "threshold showing" that Thiele "was exposed to toxic levels known to cause the type of injuries he . . . suffered." *See Mattis*, 295 F.3d at 860-61; *see also Bonner*, 259 F.3d at 931 ("It is sufficient for a plaintiff to prove that she was exposed to a quantity of the toxin that 'exceeded safe levels.'"). Dr. Harrison does not identify a level of exposure to diacetyl that is capable of causing lung disease in his report. In his deposition, he

explained that "if you go above five parts per billion, your risk is going to start to increase at a level that is unacceptable because of the seriousness of this, the harm that can result." Doc. 309-5 at 13. He added that an exposure of five parts per billion (the NIOSH REL) creates a significant risk of lung disease. *Id.*

Givaudan criticizes five parts per billion as an acceptable "threshold" identified by Dr. Harrison for two reasons. First, it argues Dr. Harrison has been inconsistent in his testimony in various other cases about the level of diacetyl exposure that poses a significant risk of respiratory harm. *See* Doc. 317 at 17 (citing Dr. Harrison's deposition testimony from other cases in which he offers seemingly inconsistent testimony about the level of exposure that can cause lung disease). Second, Givaudan notes that five parts per billion is a regulatory standard and, as such, is conservative and establishes a level below which no individual would be likely to suffer negative health effects. *See Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 991 (8th Cir. 2001) ("The methodology employed by a government agency 'results from the preventive perspective that agencies adopt in order to reduce public exposure to harmful substances.'") (quoting *Hollander v. Sandoz Pharms. Corp.*, 95 F. Supp. 2d 1230, 1234 n.9 (W.D. Okla. 2000)); *Junk v. Terminix Intern. Co. Ltd. P'ship*, 594 F. Supp. 2d 1062, 1071 (S.D. Iowa 2008) ("government agency regulatory standards are irrelevant to Junk's burden of proof in a toxic tort cause of action because of the agency's 'preventative perspective[.]'"), *aff'd*, 628 F.3d 439 (8th Cir. 2010).

Givaudan's first argument is an issue for cross-examination, not exclusion. Givaudan has not identified any inconsistencies in Dr. Harrison's report or deposition testimony in this case. To the extent his opinion conflicts with opinions he has made in other cases, Givaudan can address those differences through cross-examination. As to its second argument, the Eighth Circuit has explained:

> Regulatory standards express risk assessments that are designed to protect public health. "[A] regulatory standard, rather than being a measure of causation, is a public-health exposure level that an agency determines pursuant to statutory standards." *Sutera v. Perrier Grp. of Am. Inc.*, 986

> F. Supp. 655, 664 (D. Mass. 1997) (citation omitted). Thus, a legislature or regulatory agency may set standards – permissible or mandatory – "without having precise data on the question of how much harm, or what kind of harm, some specific amount of that substance might reasonably be expected to cause to . . . an ordinary person." *Wright*, 91 F.3d at 1107.

Kirk v. Schaeffler Group USA, Inc., 887 F.3d 376, 392 (8th Cir. 2018).[7] I need not resolve whether an expert may rely on a regulatory standard to establish a level of exposure that is capable of causing harm because, even if I accept the NIOSH REL as a reliable threshold, Dr. Harrison fails to identify any level of diacetyl to which Thiele was actually exposed.[8]

Dr. Harrison concluded Thiele's exposure to flavorings containing diacetyl was "substantial and analogous to other occupational exposures to flavorings resulting in lung disease." Doc. 309-2 at 36. Similar to his opinion in *Downs*, he considered the amount of flavorings containing diacetyl and other harmful diketones that were purchased by APC (including 466,476 pounds from Givaudan) during the seven years Thiele worked at APC. He also considered Thiele's job duties, when he reported the onset of relevant symptoms, some lung function measurements during his employment, when Thiele wore a respirator, the 2004 NIOSH study results from APC (based on air sampling from 2001 and 2002), including the measurements in the mixing room and elsewhere in the factory,

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[7] In *Kirk*, the court found that the expert testified to "extensive TCE contamination in the Silver Creek community and the many ways Kirk was exposed to that contamination for many years." *Id.* at 391. The plaintiff did not rely solely on regulatory standards to establish general causation but such standards were considered probative evidence to be compared to the concentrations of TCE found in Silver Creek wells in addressing the levels of TCE contamination to which residents were exposed. *Id.*

[8] The requirement that a general causation expert identify the level of exposure differs from specific causation, which addresses whether the toxin actually caused the plaintiff's injury. In order for a general causation expert to opine that a toxin is capable of causing injury in the general population, he or she must identify the level to which the plaintiff was exposed in order to evaluate whether that level is capable of causing harm. *See, e.g., Bonner*, 259 F.3d at 928. Thus, an expert cannot opine as to general causation in a toxic tort case without information as to the relevant exposure and the standard by which to assess its harmfulness.

and NIOSH studies related to whether powdered flavorings can be inhaled. Doc. 309-2 at 36-38. He concluded:

> The manner of Mr. Thiele's exposure to the heated diketone-containing flavorings at APC, his proximity to these heated flavorings, the large amounts of these flavorings used at APC during his employment, and the frequency and length of his exposures are all consistent with other flavoring workers who have developed lung disease caused by their occupational exposures to the same or similar food flavorings.

Id. When asked about his opinion as to Thiele's actual exposure levels, Dr. Harrison testified in his deposition, "when I looked at the study that NIOSH did at APC and the measurements in the mixing room and elsewhere in the factory, the levels there were quite high and I think hazardous, and as I outlined in my opinion, likely exposed Mr. Thiele to harmful levels of diacetyl." Doc. 309-5 at 6; *see also id.* at 10 ("Mr. Thiele's exposure to diacetyl at APC was very much like exposure to other workers who developed lung disease from exposure to diacetyl in popcorn plants as well as many other types of facilities that use diacetyl and workers were exposed, and that is shown by the history that he gave.").

While Dr. Harrison's opinion is based primarily on air sampling data from APC, rather than analogizing it to another facility as he did in *Downs*, his opinion still relies on speculation and fails to account for changes at the facility that could have reduced Thiele's exposure. Dr. Harrison's opinion as to Thiele's exposure level is based on the NIOSH air sampling measurements from 2001 and 2002. Therefore, he speculates that the measurements were the same when Thiele began working at APC in 2004. He failed to account for potential mitigating circumstances – including whether APC had made any changes to the mixing room between 2002 and 2004 – and failed to account for *known* mitigating circumstances, such as the use of air-supplied respirators. *See* Doc. 309-5 at 13. Dr. Harrison admitted that the 6 workers (out of 13) at APC who had been identified by NIOSH as having abnormal lung function and who had any experience as mixers wore respirators less frequently than Thiele. *Id.* at 13-14 (noting the median reported

percentage was 20 percent for all activities except pouring other ingredients into tanks in the mixing room, where the median reported percentage was 50 percent). Dr. Harrison also testified, "[l]ooks like possibly by the time Mr. Thiele started working in 2004 there was a more rigorous respiratory protection program." *Id.* at 14.

To the extent Dr. Harrison attempts to analogize Thiele's exposure to exposures faced by workers at other popcorn plants, those opinions are also speculative. Dr. Harrison testified, "Mr. Thiele's exposure to diacetyl at APC was very much like exposure to other workers who developed lung disease from exposure to diacetyl in popcorn plants as well as many other types of facilities that use diacetyl and workers were exposed, and that is shown by the history that he gave. We just talked about in his deposition testimony the NIOSH study at APC." *Id.* at 10. Dr. Harrison clarified that his second opinion in his report "means that Mr. Thiele was probably in harm's way when he was working at APC." *Id.*

Dr. Harrison's analogy to other popcorn plants to conclude that Thiele's exposure was "hazardous" is unreliable for the reasons described in *Downs* and for other reasons specific to this case. When asked about the other popcorn plants he relied on, Dr. Harrison cited the NIOSH studies at Gilster-Mary Lee and the Marion, Ohio, ConAgra plant, as discussed in *Downs*. Those studies were performed in 2001 and 2004. Dr. Harrison could not identify any comparative analysis in his report between Thiele's exposure at APC and the measures of diacetyl in other popcorn plants beyond citing the NIOSH reports. *See id.* In other words, his opinion appears to be that because a "hazardous" level of diacetyl was found in other popcorn plants, it must have also been present at APC. This methodology is speculative and unreliable. First, NIOSH found that the average diacetyl concentration measured in the mixing room at APC in 2001 and 2002 was hundreds of times lower than NIOSH had measured at other popcorn plants. *Id.* at 16, 21. Second, it fails to take into account any differences between the three facilities. Third, NIOSH made recommendations to APC that would reduce exposure to

diacetyl, but Dr. Harrison did not know whether APC implemented any of those recommendations. *Id.* at 17.

While the Eighth Circuit standards do not require an expert to quantify the amount to which Thiele was exposed in order to demonstrate that he was exposed to a toxic level of diacetyl,[9] Dr. Harrison's opinion presents too great of an analytical gap in light of the data he relies on. Dr. Harrison relies on the NIOSH measurements from 2001 and 2002 and peak exposures in mixing rooms at various popcorn plants (without accounting for use of a respirator). *See* Doc. 309-5 at 6. He acknowledged that with a powered air purifying respirator (PAPR), Thiele would not have been breathing any of the air in the mixing room, but instead the fresh air that was pumped into his mask. *Id.* at 8; *see also id.* at 20 (explaining a PAPR provides a protection factor of a hundred (if used properly) meaning that whatever the air concentration is on the outside should be reduced by a hundred fold in the air that someone is breathing on the inside). He also acknowledged that Thiele testified that he was given a PAPR. *Id.*

Additionally, Dr. Harrison admitted that the 6 APC workers with abnormal lung function in 2001 and 2002 wore respirators less frequently than Thiele, and such respirators were not PAPRs. Dr. Harrison admitted that the levels of diacetyl in the mixing room do not reflect the level of exposure to a person wearing a respirator. *Id.* at 14. Dr. Harrison testified to measure the level of exposure to a person wearing a respirator, one would make certain calculations based on how protective the respirator was. *Id.* at 14. There is no indication in the record that Dr. Harrison performed those calculations to determine Thiele's exposure to diacetyl rather than the level of diacetyl in the mixing room. *Id.* at 20. Dr. Harrison also admitted he did not analyze any changes APC may have implemented, including recommendations from NIOSH, between 2002

[9] An expert must show plaintiff was exposed "to a quantity of the toxin that 'exceeded safe levels.'" *Bonner*, 259 F.3d at 931 (quoting *Bednar*, 147 F.3d at 740). Dr. Harrison has identified a safe level of diacetyl as anything below 5 parts per billion.

and 2004. *Id.* at 19. Finally, based on the readings at the Gilster-Mary Lee plant and the substantially lower diacetyl readings at the APC plant, Dr. Harrison agreed that the risk of developing lung disease in the APC mixing room would be lower than the risk at the Gilster-Mary Lee plant. *Id.* at 21.

In summary, Dr. Harrison uses (1) outdated diacetyl measurements at APC, (2) measurements from other popcorn plants and (3) measurements of general diacetyl levels in the mixing room without accounting for (1) Thiele's use of a respirator, (2) that the levels of diacetyl at APC were a hundred times lower than other popcorn plants and (3) any steps APC took after 2002 to address respiratory health of its workers. Dr. Harrison did not use a "scientifically valid" method for opining that Thiele's exposure exceeded a safe level but instead relied on speculation and assumptions, resulting in an analytical gap between the data and the opinion that is simply too great. For these reasons, I find his general causation opinion is unreliable and must be excluded.

B. Motion for Summary Judgment

Givaudan argues it is entitled to summary judgment on all claims because, based on its *Daubert* motions, Thiele has no admissible evidence that the ingredients to which he claims exposure are capable of causing the injury he claims to have suffered. I agree. Thiele's claims require proof of causation through expert testimony. *See Bland*, 538 F.3d at 899 (affirming district court's decision to exclude expert testimony on causation as well as defendants' motion for summary judgment because plaintiff could not, as a matter of law, establish causation without expert testimony); *Ranes v. Adams Labs., Inc.*, 778 N.W.2d 677, 688 (Iowa 2010) (noting a plaintiff must show general and specific causation in a toxic tort case and that in proving both types of causation, "expert medical and toxicological testimony is unquestionably required to assist the jury."). Because I have determined that Thiele's expert opinions and testimony as to general causation must be excluded under Rue 702 and *Daubert*, Thiele cannot demonstrate a genuine issue of material fact regarding causation. Givaudan is entitled to summary judgment.

IV. CONCLUSION

For the reasons stated herein,

1. Givaudan's motion (Doc. 308) to exclude the testimony and opinions of Dr. Durrani is **granted.**

2. Givaudan's motion (Doc. 309) to exclude the testimony and opinions of Dr. Harrison is **granted**.

3. Givaudan's motion (Doc. 315) for summary judgment is **granted**.

4. All other pending motions (Docs. 311, 312, 313, 314, 345 and 387) are **denied as moot**.

5. The trial of this case, scheduled to begin March 14, 2022, is **canceled**.

6. Because this order disposes of all remaining claims, this action is hereby **dismissed**.

IT IS SO ORDERED.

DATED this 10th day of January, 2022.

Leonard T. Strand, Chief Judge