

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
SENIOR JUDGE WALKER D. MILLER

Civil Action No. 08-cv-00091-WDM-CBS

WAYNE WATSON and
MARY WATSON,

Plaintiffs,

v.

DILLON COMPANIES, INC., d/b/a/ KING SOOPERS, also d/b/a INTER-AMERICAN
PRODUCTS, INC., et al.,

Defendants.¹

**ORDER ON MOTION FOR SUMMARY JUDGMENT
AND MOTIONS TO EXCLUDE TESTIMONY**

Miller, J.

This matter is before me on the Joint Motion for Summary Judgment (ECF No. 572) filed by Defendants Dillon Companies, Inc., d/b/a King Soopers, Inter-American Products, Inc., and The Kroger Company (collectively, the “Kroger Defendants”), Gilster-Mary Lee Corporation (“Gilster-Mary Lee”) and Birds Eye Foods, Inc., (“Birds Eye”). These Defendants have also filed motions to exclude portions of testimony of Plaintiffs’ expert witnesses (ECF Nos. 567, 568, 569, and 570). Plaintiffs Wayne and Mary Watson oppose the motions. A hearing regarding the motions to exclude was held on June 14-15, 2011; witness testimony was presented and exhibits were received into evidence. Upon review of the parties’ filings and evidence presented at the

¹This case includes a number of third-party and other related litigation. However, since the motions addressed here concern only the primary parties, I have not included the related matters in the caption of this order.

hearing, I conclude that no further oral argument is required. For the reasons that follow, the motions to exclude are granted in part and denied in part. The motion for summary judgment will be denied.

Background²

This is a personal injury case arising out of Plaintiff Wayne Watson's respiratory disorders, which he contends are the result of inhaling butter flavoring ingredients contained in microwave popcorn. Mr. Watson prepared and consumed two to three bags of butter flavored microwave popcorn at his home daily for approximately seven years (2000-2007). He has been diagnosed with a rare lung condition called bronchiolitis obliterans; this disease and other airway/respiratory conditions have occurred in statistically significant numbers at factories where microwave popcorn is produced.

Mr. Watson purchased and consumed popcorn sold under the labels "Kroger" and "First Choice." He purchased the popcorn at a King Soopers grocery store in his hometown of Centennial, Colorado. Kroger owns and operates King Soopers and other grocery stores. The popcorn was manufactured by Defendants Gilster-Mary Lee and Birds Eye to be sold by the Kroger Defendants under the private store labels; the packaging for the popcorn did not identify the actual manufacturer of the product and contained only the names of the Kroger entities.

Gilster-Mary Lee makes almost half of all private label microwave popcorn sold in

²The facts set forth here are taken from the parties' briefs and attached exhibits and are undisputed or, where disputed, presented in the light most favorable to the non-moving party.

the U.S. It began making First Choice brand microwave popcorn before 2000. Birds Eye made two of the Kroger popcorn products until 2003; thereafter, Gilster-Mary Lee acquired Birds Eye's microwave popcorn business and manufactured all of the microwave popcorn products consumed by Mr. Watson.

Production of microwave popcorn has some general similarities across plants. In general, workers called mixers measure and mix butter flavorings³ with soybean oil, salt, and coloring, generally in large heated mixing tanks. See, e.g., Ahmed Gomaa, *et al.*, NIOSH INVESTIGATION OF GILSTER MARY LEE, HETA # 2000-0401, TECHNICAL ASSISTANCE TO MISSOURI DEPARTMENT OF HEALTH, INTERIM REPORT (Aug. 22, 2001), Exh. 5 to Pls.' Statement of Facts, ECF No. 600-5, at 5-6. The combination of oil, butter flavoring, salt, and coloring is often referred to in the industry as the "slurry." The slurry is kept heated, at approximately 108 degrees Fahrenheit, piped to a holding tank and then injected into the microwave popcorn bags as they move along the line. *Id.*, at 6. The bags are then sealed and wrapped. *Id.* Quality control ("QC") workers pop finished bags and often pour the contents into graduated cylinders to measure the proportion of popped to unpopped kernels and review other quality issues. The number of bags popped by workers in the QC area varies with the plant, but could be as much as 100 bags per worker per shift.

A relationship between butter flavoring ingredients and worker health was first noted in 1999-2000. In 1999, five employees filed workers compensation claims

³According to testimony presented at the hearing, the formulae for butter flavoring differ across brands and products but there appear to have been some common ingredients, including diacetyl, during the relevant time period.

against Gilster-Mary Lee alleging that they had developed permanent lung injuries from exposures to hazards at a Gilster-Mary Lee popcorn plant in Jasper, Missouri. Exh. 24 to Pls.' Statement of Facts, ECF No. 601-4. Dr. Allen J. Parmet, an occupational medicine physician in Missouri noted a "cluster" of respiratory problems in workers at the same plant in 2000 and brought the issue to the attention of public health officials. Kathleen Kreiss, M.D., *et al.*, *Clinical Bronchiolitis Obliterans in Workers at a Microwave-Popcorn Plant*, NEW ENG. J. MED., Vol. 347, No. 5, 330 (Aug. 1, 2002), Exh. 1 to Pls.' Statement of Facts, ECF No. 600-1, at 337. Nine workers were reported to have bronchiolitis obliterans, a rare but serious lung disease. INTERIM REPORT, *supra*, ECF No. 600-5, at 4. Four of these workers were placed on a lung transplant list. *Id.* The Missouri Department of Health requested assistance from the National Institute for Occupational Safety and Health ("NIOSH"), a section of the Centers for Disease Control and Prevention. *Id.* NIOSH performed a Health Hazard Evaluation to determine whether exposures at the plant contributed to the disease. *Id.* NIOSH conducted environmental assessments and performed medical surveys and other examinations of the workers at the plant. *Id.* at 7-9. It discovered that plant employees had 2.6 times the rates of chronic cough and shortness of breath compared to national data, adjusted for smoking and age group, and that overall plant employees had 3.3 times the rate of obstructive spirometry abnormalities compared to national rates. Kreiss, *supra*, ECF No. 600-1, at 330. Rates of obstruction directly correlated with higher levels of exposure to butter flavoring ingredients. *Id.*, at 332-33. NIOSH also found other statistically significant disparities in worker health at the Jasper plant as compared to national rates. *Id.* at 335.

NIOSH thereafter investigated employee health and plant conditions at a number of other popcorn production plants. See, e.g., NIOSH HEALTH HAZARD EVALUATION REPORT: HETA 2002-0408-2915, AGRILINK FOODS POPOCORN PLANT, RIDGWAY, ILLINOIS, October 2003, Exh. 38 to Pls.' Statement of Facts, ECF No. 601-19 at ii, 12 (finding statistically significant increased rates of chronic cough and airway obstruction in employees); Richard Kanwal, M.D., M.P.H., *et al.*, *Evaluation of Flavorings-Related Lung Disease Risk at Six Microwave Popcorn Plants*, J. OCC. & ENV. MED., Vol. 48, No. 2, 149 (Feb. 2006), Exh. A-2 to Defs.' Statement of Facts, ECF No. 560-14, at 150, 153. More case clusters were found, which were again notable given the age and lack of smoking history of many of the affected workers. NIOSH ALERT: PREVENTING LUNG DISEASE IN WORKERS WHO USE OR MAKE FLAVORINGS, DHHS (NIOSH) Pub. No. 2004-110, Exh. 4 to Pls.' Statement of Facts, ECF No. 600-4, at 3-5. A common feature of such cases was abnormal lung function that did not improve in response to bronchodilator and corticosteroid medications. *Id.* Additional research has shown further inflammatory effects from inhalation of butter flavorings. Muge Akpinar-Elci, *et al.*, *Induced Sputum Evaluation in Microwave Popcorn Production Workers*, CHEST: THE CARDIOPULMONARY AND CRITICAL CARE JOURNAL, 128, 991 (2005), Exh. 9 to Pls.' Statement of Facts, ECF No. 600-9, at 995-96 ("Our analysis showed that high exposure to popcorn flavoring agents is significantly associated with neutrophilic airway inflammation in popcorn production workers. . . . Neutrophilic airways inflammation is a potentially important underlying factor in development of the bronchiolitis obliterans syndrome (BOS) previously documented in workers at this plant.").

From early in the NIOSH investigations and other research studies, attention

focused on diacetyl, a chemical used in artificial butter flavor. Kreiss, *supra*, ECF No. 600-1, at 331. Diacetyl is typically measured in parts per million (“ppm”). Although the U.S. Food and Drug Administration categorizes diacetyl as “GRAS,” or “Generally Recognized as Safe,” this label apparently concerns eating or consumption, and does not necessarily mean that the chemical is safe to inhale. Egilman Report, Exh. 17 to Pls.’ Statement of Facts, ECF No. 600-17, at 19-20. It has a relatively low boiling point and so it vaporizes at temperatures common in food production. Philip Harber, *et al.*, *Diacetyl-Induced Lung Disease*, TOXICOLOGY REVIEW, 25(4), 261 (2006), Exh. 7 to Pls.’ Statement of Facts, ECF No. 600-7, at 262. It also occurs naturally in many foods. *Id.* at 263.

Animal studies have confirmed that diacetyl vapor causes damage to nasal and airway linings of rats. A.F. Hubbs, *et al.*, *Necrosis of Nasal and Airway Epithelium in Rats Inhaling Vapors of Artificial Butter Flavoring*, TOXICOLOGY AND APPLIED PHARM., 185, 128 (2002), Exh. 3 to Pls.’ Statement of Facts, ECF No. 600-3, at 128; Harber, *supra*, ECF No. 600-7, at 265 (diacetyl causes direct injury to airway epithelium, or lining). Diacetyl was the predominant chemical in air sampling of volatile chemicals at the plants. Kathleen Kreiss, *Flavoring-related Bronchiolitis Obliterans*, CURR. OPIN. ALLERGY CLIN. IMMUNOL., 7: 162, Exh. 6 to Pls.’ Statement of Facts, ECF No. 600-6, at 165. Studies at popcorn plants revealed a strong association between exposure to vapors from flavorings, including diacetyl, and decreased lung function. Kreiss, *supra*, ECF No. 600-1, at 333 (“The prevalence of airway obstruction increased with increasing cumulative exposure to diacetyl”); NIOSH ALERT, *supra*, ECF No. 600-4, at 1; INTERIM REPORT (Aug. 22, 2001), *supra*, ECF No. 600-5, at 18 (“The exposure-response

relationship between diacetyl cumulative exposure and pulmonary function was unequivocal”); Harber, *supra*, ECF No. 600-7, at 262 (results of surveys at popcorn plants “pointed to a clear association between a particular chemical agent (diacetyl) and bronchiolitis obliterans”). Studies of emissions from microwave popcorn preparation have shown that the highest levels of release occur when opening the bag after popping. Jacky A. Rosati, *et al.*, *Emissions from Cooking Microwave Popcorn*, CRIT. REV. IN FOOD SCI. & NUTRITION, 47, 701 (2007), Exh. 47 to Pls.’ Statement of Facts, ECF No. 602-7, at 709. It has been established that chemicals emitted during normal popping of microwave popcorn are similar to those found by NIOSH in popcorn manufacturing plants, with the exception of one chemical not at issue here. *Id.* at 706. However, some studies have also concluded that although high levels of diacetyl are emitted in the microwave chamber, the levels are likely diluted by the space between the oven and the user. Roger Pearson, Ph.D, Aspen Research Corp., *Evaluation of Microwave Popcorn Potential to Emit Organic Compounds*, Aspen Project No. 34579 (May 5, 2005), Exh. 51 to Pls.’ Statement of Facts, ECF No. 602-11, at 3-4.

Based on these findings, NIOSH and other researchers have issued recommendations for reducing exposures in the workplace, including better exhaust and ventilation, closed production systems, personal protective equipment, and removal of diacetyl as an ingredient in butter flavoring. NIOSH ALERT, *supra*, ECF No. 600-4, at 3; Harber, *supra*, ECF No. 600-7, at 269; Nancy Sahakian & Kathleen Kreiss, *Lung Disease in Flavoring and Food Production: Learning from Butter Flavoring*, ADVANCES IN FOOD AND NUTRITION RESEARCH, Vol. 55, 163 (2009), Exh. 11 to Pls.’ Statement of Facts, ECF No. 600-11, at 182. Gilster-Mary Lee ceased using diacetyl in its butter

flavoring around 2006-2007. Welge Dep., Exh. 18 to Pls.' Statement of Facts, ECF No. 600-18, at 76; Welge Dep., Exh. 32 to Pls.' Statement of Facts, ECF No. 601-13, at 54.

Although the relationship between exposure to butter flavorings and respiratory problems has been established, there remain numerous unanswered questions about what level of exposure triggers health effects and whether such effects are caused by peak or by cumulative exposures. NIOSH ALERT, *supra*, ECF No. 600-4, at 6; Kreiss, *supra*, ECF No. 600-6, at 165-66; Harber, *supra*, ECF No. 600-7, at 268. There is little dispute that ongoing high levels of exposure leads to problems. The research has shown that mixers, in particular, at all plants had high rates of exposure to the flavoring chemicals and have had correspondingly higher rates of respiratory and airway disorders. Kanwal, *supra*, ECF No. 560-14, at 153; INTERIM REPORT (Aug. 22, 2001), *supra*, ECF No. 600-5, at 17; NIOSH HEALTH HAZARD EVALUATION REPORT: HETA 2002-0408-2915, AGRILINK FOODS POPOCORN PLANT, RIDGWAY, ILLINOIS, *supra*, ECF No. 601-19 (finding high vapor levels in both mixing and QC rooms and high levels of lung disease). Workers who worked near inadequately isolated tanks of flavorings, such as those in the packaging area, also show higher rates of disease and risk. Kanwal, *supra*, ECF No. 560-14, at 155.

Evidence relating to workers exposed at lower levels than mixers is less conclusive. Plaintiffs argue that Mr. Watson's exposure is more similar to that of QC workers, who pop and open popcorn in the same manner as consumers, albeit at much greater rates. Kreiss, *supra*, ECF No. 600-1, at 337 (QC workers' exposures exceed those likely to occur in households "by orders of magnitude"). Exposure levels of QC workers varies across plants; further difficulty in research occurs because in some

plants QC workers also do or have done other jobs and because of differences in the number of bags opened per shift. Kanwal, *supra*, ECF No. 560-14, at 154. At the Jasper plant, for example, workers popped 100 bags of popcorn each shift in a small room with little ventilation and had higher rates of abnormal lung function. NIOSH ALERT, *supra*, ECF No. 600-4, at 46. At that plant, the exposure levels of QC workers were lower than those of mixers⁴ but QC workers still had high rates of airway obstruction. Kreiss, *supra*, ECF No. 600-6, at 165. In contrast, QC workers in other plants, where exposure levels were lower, did not show such high rates of disease. NIOSH HEALTH HAZARD EVALUATION REPORT, HETA # 2000-0401-2991, GILSTER-MARY LEE CORP., JASPER, MISSOURI (Jan. 2006), Exh. 37 to Pls.' Statement of Facts, ECF No. 601-18 at 13; NIOSH HEALTH HAZARD EVALUATION REPORT, HETA # 2001-0474-2943, AMERICAN POP CORN CO., SIOUX CITY, IOWA (July 2004), Exh. 39 to Pls.' Statement of Facts, ECF No. 601-20; Kanwal, *supra*, ECF No. 560-14, at 154. Animal studies have also focused on acute exposures and not on repetitive or low-dose exposures. Harber, *supra*, ECF No. 600-7, at 266. However, researchers from at least one study have concluded that the risk to QC workers, as with mixers, may result from brief, intense exposures to the flavoring chemicals even when low average exposures are maintained. Kanwal, *supra*, ECF No. 560-14, at 156. This study also noted that the risk to QC workers is of a different nature than other workers because they work with the product at much higher temperatures, which increases the volatility of the flavoring chemicals.

⁴While mixers at the Jasper plant had a mean area exposure of 37.8 ppm, with a range of 98 ppm, the quality control room had a mean area exposure of 0.6 ppm with a range of 0.9 ppm. Kreiss, *supra*, ECF No. 600-6, at 165.

Id.; see also WORKER UPDATE ABOUT NIOSH TESTING AT JASPER POPCORN, HETA 2000-0401 (Aug. 2, 2002), Exh. 28 to Pls.' Statement of Facts, ECF No. 601-9, at GML 22302 (opining that QC workers receive peak exposures to flavoring vapors when microwaving the bags, opening the bags, and measuring the hot popcorn as a result of the high cooking temperatures).

I now turn to the evidence relating to Mr. Watson's health history and his diagnosis of bronchiolitis obliterans. Bronchiolitis obliterans is a rare lung disease involving inflammation of the small airways. INTERIM REPORT (Aug. 22, 2001), *supra*, ECF No. 600-5, at 15. It is characterized by airway obstruction which does not improve with use of an inhaled bronchodilator and shortness of breath upon mild to moderate exertion. *Id.* Its known causes include reactions after lung or bone marrow transplants, exposure to certain chemicals (including nitrogen oxides, chlorine gas, ozone, hydrogen sulphide and sulphur dioxide), viral pneumonia and other viral infections, and ulcerative colitis. *Id.*; Harber, *supra*, ECF No. 600-7 at 264. NIOSH and other researchers have concluded that the flavoring ingredients can cause bronchiolitis obliterans in the workplace. NIOSH ALERT, *supra*, ECF No. 600-4, at 2.

Mr. Watson owned a carpet cleaning company from approximately 1998 or 1999 to 2001. He was exposed to carpet cleaning chemicals in the course of that work and did not regularly use respiratory safety equipment, although he testified that he used fans for ventilation and kept windows and doors open while working. As noted above, his heavy consumption of Defendants' microwave popcorn products occurred from around 2000 to 2007.

Mr. Watson's history of respiratory problems goes back some time. He was

diagnosed with asthma and pneumonia in 1998, although no pneumonia was revealed on his chest x-ray at that time. He also had reflux disease. Mr. Watson was diagnosed with pneumonia again in 2000, but the chest x-ray again was not conclusive. His medical records showed additional breathing problems and coughing in 2002 and 2003. In 2005, he began noticing that while singing he could not sustain his notes and that he was short of breath. His records show more evidence of breathing difficulty and coughing in 2006. He consulted a physician at National Jewish Medical and Research Center in May 2006, where he was evaluated for sleep apnea; his decreased pulmonary function was also noted. A lung biopsy was taken, which showed various abnormalities. In 2006, his physician noted that even though Mr. Watson's exposure to carpet cleaning chemicals had ceased in 1999, his shortness of breath had progressed.

Mr. Watson was examined by Dr. Cecile Rose at National Jewish in February 2007. She noted that he consumed large amounts of microwave popcorn on a daily basis and recommended that he stop. He did and began feeling better; his symptoms have apparently stabilized since then. Dr. Rose has worked as a consultant to the flavoring industry with respect to occupational exposure to flavoring ingredients and was already quite familiar with the research concerning respiratory problems among popcorn factory workers. It appears that Dr. Rose diagnosed Mr. Watson with bronchiolitis obliterans and opines that his disease was caused by his exposure to microwave popcorn flavorings. The basis for her opinion is discussed further below.

Mr. Watson has also had heart problems and in 2009 underwent heart surgery for an aneurysm on the thoracic aorta.

On February 22, 2007, John Martyny, Ph.D., an industrial hygienist, performed

an assessment of diacetyl levels in the Watson home before and during the process of preparing two bags of microwave popcorn. Martyny Dep., Exh. 53 to Pls.' Statement of Facts, ECF No. 602-13, at 27. Dr. Martyny used two methods to measure diacetyl levels: (1) an integrated sampling method, used in the NIOSH evaluations of popcorn plants; and (2) an Innova gas monitor to measure peak diacetyl concentrations in various places. *Id.* at 26-27. Using the first method, all of the samples were below the limit of detection. Nestmann Report, Exh. A-8 to Defs.' Statement of Facts, ECF No. 560-25, at 9. Using the gas monitor, a peak diacetyl concentration was measured at 3.045 ppm, which occurred upon opening the microwave door immediately following completion of popping the first bag of popcorn. *Id.* Upon opening the bag, a peak concentration of 1.143 ppm was measured. *Id.* This was similar to background levels measured before popping, see hearing Exhibit 209, which could signify unreliability in the measurement, as Defendants' witnesses suggest, or the presence of residual diacetyl in the Watson home, as Plaintiffs' witnesses suggest.

On July 18, 2007, Dr. Rose wrote a letter to the Food and Drug Administration and other regulatory agencies identifying Mr. Watson as perhaps the first case of a consumer developing lung disease from butter flavorings. Exh. 52 to Pls.' Statement of Facts, ECF No. 602-12 ("We have recently identified a patient with significant lung disease whose clinical findings are similar to those described in affected workers, but whose only inhalation is as a heavy, daily consumer of butter flavored microwave popcorn."). She explains the reasons that she believes his illness was caused by butter flavoring, including his heavy consumption of microwave popcorn, his worsening condition without a bronchodilator response, which is similar to symptoms of popcorn

workers, his CT scan and lung biopsy, the fact that his clinical course was consistent with those microwave popcorn workers who developed bronchiolitis obliterans, the stabilization of his condition with the cessation of popcorn consumption, and the measurement of diacetyl in his home. *Id.* She recognizes the difficulty of making a causal connection from one case study but states she is providing the information to the federal agencies because of the possible public health implications. *Id.*

Defendants seek to exclude much of the opinion testimony of Plaintiffs' expert witnesses based on Rule 702 of the Federal Rules of Evidence and the reliability standards set forth by *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) and its progeny. Assuming that testimony is excluded, Defendants then seek summary judgment in their favor, arguing that Plaintiffs will be unable to present evidence in support of key elements of their claims. Defendants also seek summary judgment on other aspects of the claims.

At the June 14-15, 2011 hearing, testimony was provided by Dr. David Egilman, Dr. Allen J. Parmet, Dr. E. Neil Schachter, Dr. Colin Soskolne, and Dr. Kenneth Kulig. Several exhibits were referenced and the parties have stipulated to their admission into evidence.⁵

Standard of Review

Summary judgment is appropriate when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56. A factual issue is genuine if "the evidence is such that a reasonable jury

⁵The stipulated exhibits are set forth in ECF No. 650.

could return a verdict for the nonmoving party.” *Anderson v. Liberty Lobby*, 477 U.S. 242, 248 (1986).

Where “the moving party does not bear the ultimate burden of persuasion at trial, it may satisfy its burden at the summary judgment stage by identifying ‘a lack of evidence for the nonmovant on an essential element of the nonmovant’s claim.’”

Bausman v. Interstate Brands Corp., 252 F.3d 1111, 1115 (10th Cir. 2001) (quoting *Adler v. Wal-Mart Stores, Inc.*, 144 F.3d 664, 671 (10th Cir. 1998)). Then, “[t]o avoid summary judgment, the nonmovant must establish, at a minimum, an inference of the presence of each element essential to the case.” *Id.*

Rule 702 permits an expert to testify in the form of an opinion if (1) the testimony is based on sufficient facts or data; (2) the testimony is the product of reliable principles and methods; and (3) the witness has applied the principles and methods reliably to the facts of the case.

Under *Daubert*, a trial court faced with a proffer of expert testimony

must determine at the outset, pursuant to Rule 104(a), whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.

509 U.S. at 592-93.

This “gatekeeping” function applies to all expert testimony proffered under Fed. R. Evid. 702. *Kumho Tire Co., Ltd. v. Carmichael*, 516 U.S. 137, 149 (1999) (extending *Daubert*’s holding on scientific expert testimony to all expert testimony). The objective of the function “is to ensure the reliability and relevancy of expert testimony. It is to

make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Id.* at 152.

The two key determinations are whether the expert evidence “both rests on a reliable foundation and is relevant to the task at hand.” *Daubert*, 509 U.S. at 597. Factors that may be considered in determining whether a theory or technique is scientific (or expert) knowledge include whether it can be (and has been) tested, whether it has been subjected to peer review and publication, the known or potential rate of error (including the existence and maintenance of standards controlling a technique’s operation) and whether it has been generally accepted within the relevant expert community. *Id.* at 593-94. These factors are not exclusive and should be applied as relevant to the particular case at hand. *Kumho*, 526 U.S. at 152-53. See also *Daubert*, 509 U.S. at 591 (the theory must “fit” the facts of the case, *i.e.*, be relevant); *Mitchell v. Gencorp Inc.*, 165 F.3d 778, 781 (10th Cir. 1999) (same).

The trial judge has “considerable leeway” in determining how to test an expert’s reliability. *Kumho*, 526 U.S. at 152.

Discussion

Plaintiffs’ Fourth Amended Complaint contains the following claims for relief: (1) negligence; (2) strict liability in tort - design defect; (3) failure to warn; (4) violation of the Colorado Consumer Protection Act (“CCPA”); (5) loss of consortium (asserted by Plaintiff Mary Watson, Mr. Watson’s wife); and (6) recovery of medical expenses. ECF No. 548. Plaintiffs seek recovery of punitive damages against Gilster-Mary Lee. *Id.* Defendants move for summary judgment on several grounds: (1) Plaintiffs cannot

establish general or specific causation for their negligence, strict liability, and failure to warn claims; these arguments are based on the motions to exclude Plaintiffs' expert opinion testimony on causation; (2) Plaintiffs' CCPA claim fails because they cannot establish that Defendants engaged in an unfair or deceptive trade practice that significantly impacts the public; (3) the product liability claim against the Kroger Defendants fails because Kroger did not have actual knowledge of the alleged defect, did not design the specifications relating to the alleged defect, and did not have substantial control over the manufacturing process; (4) punitive damages are inappropriate because Plaintiffs cannot establish that Gilster-Mary Lee was aware of and disregarded a serious risk to consumers from microwave popcorn flavorings.

A. Motions to Exclude

Plaintiffs have the burden of proving that popcorn flavoring ingredients caused Mr. Watson's injury. This requires a two-fold showing: (1) that the substance at issue is capable of causing a particular injury or condition (general causation); and (2) whether that substance caused the plaintiff's particular injury. *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 881 (10th Cir. 2005). Elements that may assist in establishing specific causation include the following: (1) the toxic substance at issue has been demonstrated to cause in humans the disease or illness suffered by the plaintiff; (2) the individual has been exposed to a sufficient amount of the substance in question to elicit the health effect at issue; (3) the chronological relationship between exposure and effect is biologically plausible; and (4) the likelihood that the chemical caused the disease or illness is considered in the context of other known causes. *Henricksen v. ConocoPhillips Co.*, 605 F. Supp. 2d 1142, 1156 (E. D. Wash. 2009) (citation omitted).

Of particular concern is the “dose-response” relationship, *i.e.*, “the relationship in which a change in amount, intensity, or duration of exposure to a chemical is associated with a change in risk of disease” and the amount of the plaintiff’s alleged exposure. *Id.* at 1157 (citations omitted). Nonetheless, “it is not always necessary for a plaintiff to quantify exposure levels precisely or use the dose-response relationship,” provided the methods employed by the expert are otherwise reliable. *Id.*

Plaintiffs have proffered three experts who have opined that Mr. Watson has bronchiolitis obliterans caused by exposure to microwave popcorn flavoring. This is clearly relevant to the issues to be decided; the dispute here concerns only the reliability of those opinions. I will summarize the proposed testimony and opinions of each expert and Defendants’ objections. Defendants do not appear to contend that these witnesses are not qualified to serve as experts but rather take issue with the substance of their proposed testimony. Therefore, I will only briefly review the credentials of each witness.

1. David Egilman, M.D. (expert report attached as Exh. 17 to Pls’ Statement of Facts, ECF No. 600-17)

Dr. Egilman is a medical doctor and Clinical Associate Professor of Community Medicine at Brown University. He is board certified in Internal Medicine and Preventive-Occupational Medicine. He has offered opinions on both general and specific causation.

In his expert report, Dr. Egilman reviews Mr. Watson’s medical records and other evidence pertaining to his medical history. Dr. Egilman also reviews Mr. Watson’s work history, including his time working as a carpet cleaner. He notes that Mr. Watson is a lifelong non-smoker. He reviews the possible causes of bronchiolitis obliterans and

opines that pneumonia was not the cause of Mr. Watson's disease because the diagnoses of pneumonia were not conclusive and there was no evidence of bronchiolitis obliterans in Mr. Watson's tests in 1999 and 2000. He also rules out chemical exposure as a cause because Mr. Watson has not been exposed to the chemicals known to cause this condition.

Dr. Egilman then discusses the research on health hazards associated with diacetyl, particularly in the microwave popcorn factory setting. He reviews two other cases involving consumers claiming to have suffered lung disease as a result of exposure to butter flavoring ingredients.

Dr. Egilman opines on general causation using a model for determining causality developed by Sir Austin Bradford Hill. This model requires examination of temporality, biologic gradient (dose-response), consistency, biologic plausibility, strength of association, analogy, experimental evidence, coherence and specificity, concepts which are explained in detail. Egilman Report, ECF No. 600-17, at 20-25. Applying the framework, Dr. Egilman relies on much of the research cited above to show a strength of association between bronchiolitis obliterans (or other respiratory symptoms) and exposure to diacetyl and butter flavoring. This research has generally shown that workers in higher exposure areas have significantly higher rates of symptoms than those who work in areas with lower exposures. He focuses in particular on the studies at the Gilster-Mary Lee plant in Jasper. *Id.* at 25 (citing Kreiss, *supra*, ECF No. 600-1). He also relies on an article examining data from six separate studies conducted at microwave popcorn plants, which concluded that microwave popcorn workers at many plants are at risk for flavoring related lung disease. *Id.* at 26 (citing Kanwal, *supra*, ECF

No. 560-14).

Turning to temporality, Dr. Egilman notes that diacetyl exposure preceded the occurrence of bronchiolitis obliterans in all studies. He then addresses the question of dose-response, and opines that “diacetyl’s effect on the lung follows a dose-response relationship.” *Id.* at 26. As grounds, Dr. Egilman relies on an animal study showing that diacetyl was shown to cause increased necrosis in the airway epithelia of rates exposed to a higher dose of diacetyl than a lower dose. *Id.* at 26 (citing Hubbs, *supra*, ECF No. 600-3). He also relies on the studies of plant workers that showed that the rates of respiratory symptoms were lower in areas with less exposure to diacetyl; similarly, workers who reported being mixers for longer periods of time had more symptoms than those with less time. *Id.* at 26-27 (citing Kreiss, *supra*, ECF No. 600-1; Kanwal, *supra*, ECF No. 560-14)

He then discusses the consistency of the findings, observing that associations have been found between diacetyl exposure from butter flavoring in at least six popcorn manufacturing plants. He also notes that animal studies have consistently shown a relationship between diacetyl exposure and necrosis of the airway epithelial tissue. He observes that several researchers, including those with NIOSH, have relied on these animal studies to conclude that diacetyl is the mechanism causing damage. *Id.* at 28 (citing NIOSH reports for various popcorn factories). He also cites studies showing that cases of lung disease have been reported in association with diacetyl exposure across a number of food manufacturing industries, including raw material workers, butter flavoring manufacturing, popcorn production, and other flavoring workers. *Id.*

As to specificity, Dr. Egilman states that the adverse effects have been limited to

lung and other mucus membranes where the chemicals have direct contact with human or animal cells. *Id.* at 29. He notes that bronchiolitis obliterans is a very rare disease (other than for organ transplant patients) but has been diagnosed in a number of workers exposed to diacetyl. He addresses biologic plausibility, and cites research from the 2002 Kreiss, *et al.*, study as well as a 2009 study in which the researchers reported that artificial butter flavoring was the causative agent in the cases of bronchiolitis obliterans at the Jasper plant. *Id.* (citing Sahakian & Kreiss, *supra*, ECF No. 600-11). He further notes that diacetyl is an alpha-dicarbonyl compound, which inhibits protection from oxidative stress. *Id.* (citing Kreiss, *supra*, ECF No. 600-1). He argues that this explanation is coherent and has been supported by the animal studies discussed above. *Id.* at 30-33 (citing research on rats, guinea pigs showing direct toxic effect on respiratory linings, as well as other studies showing respiratory health effects on mice). He cites literature noting that although mouse and rat biology is different from humans, the studies “suggest significant amounts of inspired diacetyl penetrate to the bronchioles of the human, with greater penetration occurring during exercise than rest.” *Id.* at 32 (citing Morris, JB, Toxicology Program, University of Conn., Storrs, CT, Abstract: *A PBPK Model for Inspired Vapor Intake in the Human and its Application to Diacetyl Dosimetry*, Society of Toxicology, 2010 Annual Meeting). Finally, he addresses the analogy component of the model, and notes that other substances have proved toxic when inhaled, including substances that cause changes in the respiratory epithelium, and that exposures to these chemicals are accepted causes of bronchiolitis obliterans. *Id.* at 33.

Dr. Egilman then opines that microwave popcorn emits diacetyl vapors when

bags are opened and that diacetyl remains in the air after popping. *Id.* at 33. He relies on a 2007 EPA study which specifically tested chemical emissions in seventeen types of microwave popcorn from eight different brands; all contained diacetyl but in different amounts. *Id.* (citing Rosati, *supra*, ECF No. 602-7). As noted above, the *Rosati* study determined that the highest rate of emission occurred at the stage when the bags were opened, and the second occurred during popping; diacetyl remained in the air for up to 40 minutes after popping.

Dr. Egilman also opines on specific causation. He relies on the levels of diacetyl found by Dr. Martyny and compares the peak levels measured in the Watson home, approximately 3 ppm, to levels at the Gilster-Mary Lee plant. *Id.* at 40. He contends that peak levels in the Jasper plant upon opening a bag and in a QC worker's breathing zone (approximately 4 ppm, 7 ppm, and 13 ppm) are comparable to the peak levels to which Mr. Watson was exposed in his consumption of the Kroger label popcorn. *Id.* He then calculates a daily average exposure for Mr. Watson of 0.0015 to 0.003 ppm for weekdays and 0.0015 ppm to 0.0045 ppm on weekends, and an average cumulative exposure level. *Id.* at 41. He argues that these levels are similar to those found in QC areas of microwave popcorn plants, relying primarily on data from the Jasper plant. He also notes the conclusion of some researchers that "intermittent peak exposure" may increase risk of disease even if average exposures are lower. *Id.* at 41 (citing Kanwal, *supra*, ECF No. 560-14). Dr. Egilman also relies on Dr. Rose's letter to the FDA and her conclusion that it was plausible that Mr. Watson's exposure to butter flavoring vapors caused his lung disease. *Id.* at 42.

I now address Defendants' objections to these opinions. As noted above, the

burden with respect to general causation is to show that “the substance at issue” is capable of causing the kind of harm alleged. Defendants seek to exclude Dr. Egilman’s opinion regarding general causation on the grounds that it has not been shown that the substance that Mr. Watson was exposed to is the same substance that caused illness in microwave popcorn factory workers and because no published research has established any risk to consumers from butter flavorings emitted in preparing microwave popcorn. They further argue that the animal studies cannot be extrapolated to opine on human health effects.

Defendants argue that Mr. Watson was exposed to “microwave popcorn vapors,” and that this differs somehow from the diacetyl or the “slurry vapors” upon which all the referenced animal and epidemiological studies have been based. Defendants rely heavily on *Henricksen, supra*, in which the court found an expert’s causation testimony to be unreliable. The plaintiff had been exposed to gasoline containing benzene; while benzene had been shown to cause harm to human health, no studies had ever linked the plaintiff’s disease to gasoline. 605 F. Supp. 2d at 1161. Noting that the plaintiff had been exposed to gasoline, not benzene, the court concluded that the plaintiff’s expert could not “simply presume that the qualitative toxic and carcinogenic effects of benzene from any source are the same.” *Id.* at 1156. Moreover, all the experts in the case had testified that benzene induced diseases were dose dependent but there was no evidence as to the plaintiff’s actual exposure.⁶ *Id.* at 1162.

⁶As discussed below and as the court in *Henricksen* noted, the level of exposure of the plaintiff and the dose-response relationship generally is a factor with regard to specific causation, not general causation.

While the concern noted in *Henrickson* is important, I conclude that the facts presented here are distinguishable. I agree with Plaintiffs that the “substance at issue” here is vapor from butter flavoring containing diacetyl. The “slurry” in the factory setting is the same combination of ingredients put in the packages of popcorn and so I fail to see a meaningful distinction between the two, particularly since the product consumed by Mr. Watson is the same as that produced in the Gilster-Mary Lee plant in Jasper. Indeed, studies of emissions from cooking microwave popcorn have established that the chemicals emitted are essentially the same as those sampled in the air at microwave popcorn factories. Rosati, *supra*, ECF No. 602-7, at 706. Moreover, the published literature on this issue indicates that the exposure risk from popping may be greater, because the higher temperature involved means greater volatility and release of the chemicals in the flavoring ingredients.⁷ Kanwal, *supra*, ECF No. 560-14, at 156. Defendants’ arguments essentially seek to make a distinction based on quantity or level of exposure, which is clearly greater in the factory setting. That issue, however, is a matter relevant to specific causation, not to the general causation question of whether the chemicals emitted in vaporizing butter flavoring ingredients can cause harm to the human respiratory system.

Defendants next argue that Dr. Egilman’s opinions are unreliable because there are no epidemiological studies showing the effects of vapors from popping microwave popcorn. They argue the studies of QC workers are inapplicable because of the

⁷Although Defendants suggest that the higher heat used in popping the popcorn could theoretically change the characteristics of the chemicals contained in the slurry, the research does not support this hypothesis.

significantly higher number of bags popped per day (often a hundred or more compared to Mr. Watson's two to three) and variations in the workplace assignments and environments. They further note that no studies have been done on consumer exposures. I agree with Defendants that there appear to be few if any epidemiological studies examining the effect of exposure from popping microwave popcorn at the levels that Mr. Watson prepared popcorn. Again, however, I conclude that the level of exposure is an issue going to specific causation, not general causation, and that there is adequate evidence for Dr. Egilman to opine that vapors from butter flavorings can be harmful.

Moreover, the Tenth Circuit has recognized that a medical expert does not always have to cite to published studies on general causation in order to establish causation and, under the right circumstances, a differential diagnosis (*i.e.*, ruling out other possible causes of the condition) may reliably form the basis of an opinion that a particular item caused an injury. *Hollander v. Sandoz Pharm. Corp.*, 289 F.3d 1193, 1211-12 (10th Cir. 2002) (quoting *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1209 (8th Cir. 2000)). "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." *Turner*, 229 F.3d at 1209. Dr. Egilman and Dr. Rose have both discussed why they believe that other known causes of bronchiolitis obliterans have been eliminated, leaving Mr. Watson's exposure to butter flavoring vapors as the most plausible explanation. Accordingly, I conclude that the lack of epidemiological studies on consumers does not mean that Dr. Egilman's general causation opinion is unreliable

or irrelevant. I will discuss the issues regarding the applicability of studies of QC workers to Mr. Watson's condition with respect to specific causation, below.

Finally, Defendants argue that Dr. Egilman's reliance on animal studies makes his opinion unreliable because of differences between the respiratory systems of mice/rats and humans. However, scientists at NIOSH and other researchers have relied on these same studies in concluding that diacetyl is the cause of injury in microwave popcorn workers' respiratory disorders. Dr. Egilman, as well as the researchers he cites, have explained the extent to which these studies are applicable to human health effects. The animal studies have shown that diacetyl has a direct toxic effect on respiratory linings of the test subjects; the limits of the comparisons to humans are discussed and acknowledged. Defendants' disputes regarding animal studies go to the weight of the evidence, not its admissibility.

Given the significant evidence of the toxicity of diacetyl and the epidemiological studies showing health effects from inhalation of butter flavoring ingredients containing diacetyl, I conclude that Dr. Egilman should be permitted to opine regarding general causation.

Defendants also seek to exclude Dr. Egilman's testimony with respect to specific causation, *i.e.*, that inhalation of butter flavoring ingredients from microwave popcorn caused Mr. Watson's disease. First, Defendants argue that Dr. Egilman's opinion is flawed because there is inadequate evidence of a dose-response relationship to show that Plaintiff was exposed to an amount of the substance sufficient to cause his illness. Dr. Egilman opines that "levels of diacetyl exposure around .02 ppm and above have caused [bronchiolitis obliterans] and other respiratory illness." Egilman Report, ECF No.

600-17, at 42. I agree with Defendants that there is little to no reliable evidence establishing a threshold dose and that Dr. Egilman's opinion in this regard is not based on a reliable foundation.

Dr. Egilman establishes this amount based primarily on the data from the Jasper plant, where five of six quality control workers showed evidence of airway obstruction. However, as Defendants note, the QC workers in that plant were exposed to vapors not only from popping bags but also potentially from passing through other parts of the plant where vapors were present and/or from performing other jobs at the plant. Even Plaintiff's own witness, Dr. Parmet, testified at the hearing that all of the exposures at the plant could have contributed to illness of the QC workers, although he believes that most of the exposure came from working in the QC lab. As discussed above, and as acknowledged in Dr. Egilman's report, the average diacetyl air concentration at the Jasper plant was significantly higher than the 0.02 ppm he opines is a threshold; in his report, Dr. Egilman sets the Jasper plant levels at 0.6 ppm. *Id.* at 41. Dr. Egilman then discusses two other plants, one of which had mean diacetyl concentrations of 0.001 ppm and no QC workers with illness, and another with mean concentrations of 0.02 ppm with one of eleven QC workers showing illness. *Id.* (citing Kanwal, *supra*, ECF No. 560-14). The researchers, however, did not consider the results at the third plant to be significant. Kanwal, *supra*, ECF No. 560-14, at 154. These studies do not provide a reliable basis for Dr. Egilman's opinion that 0.02 ppm is the minimum exposure level that can cause illness. It is apparent from the research literature provided that the dose mechanism is not understood at this time. There is no reliable data to show what is the minimum amount of exposure that will trigger respiratory problems and it is apparent

that considerable questions remain regarding whether lower amounts in repetitive or peak dosages will cause disease. Therefore, Dr. Egilman's opinions regarding a specific dose-response or minimum threshold exposure level should be excluded.

Defendants next argue that Dr. Egilman's opinion is unreliable because it relies in part on the results of Dr. Martyny's measurements of diacetyl in the Watson home. Dr. Egilman disregards the non-detectable levels measured in the using the NIOSH 2557 method, claiming this method to be unreliable. However, as Defendants note, this is the method used in the NIOSH studies of the popcorn plants, which Dr. Egilman uses to establish his alleged minimum threshold level. Since I have excluded the opinion regarding the threshold exposure level, I need not address this discrepancy.

Defendants also argue that Dr. Egilman relies on the peak level of 3.045 ppm measured by the second method (using the Innova monitor) but fails to adjust for background levels of diacetyl which were present before any popcorn was popped and the evaluation was in general not a controlled scientific study. I conclude that these are issues for cross examination but do not render all of Dr. Egilman's conclusions inadmissible. Dr. Martyny's measurements are sufficient to demonstrate that Mr. Watson was exposed to some level of diacetyl, although the precise amount is disputed, and Dr. Egilman's opinions are admissible to the extent that they are based on the fact of that exposure.

Defendants further contend that Dr. Egilman cannot rely solely on a temporal relationship between Mr. Watson's exposure to microwave popcorn flavoring vapors and his illness. Were this the only basis for Dr. Egilman's conclusions I would agree. However, this is but one factor that Dr. Egilman considered in his analysis and I see no

reason to exclude his entire causation opinion testimony on this basis, when temporality appears to be a factor taken into account in considering causation.

Finally, Defendants object to Dr. Egilman's differential diagnosis to rule out other causes of Mr. Watson's bronchiolitis obliterans. "Differential diagnosis refers to the process by which a physician 'rules in' all scientifically plausible causes of the plaintiff's injury. The physician then 'rules out' the least plausible causes of injury until the most likely cause remains." *Sandoz*, 289 F.3d at 1209 (citations and internal punctuation omitted). The Tenth Circuit has implicitly approved of the use of differential diagnosis as a method for determining causation in appropriate circumstances. *Id.* at 1211-12.

Defendants argue that Dr. Egilman did not properly "rule out" Mr. Watson's history of pneumonia and his exposure to carpet cleaning chemicals as possible alternative causes of his illness. I again conclude that these are issues that go to the weight of the evidence, not its admissibility, and can be addressed on cross-examination. Dr. Egilman does explain why he has ruled out these possible explanations for Mr. Watson's illness. As to pneumonia, Dr. Egilman opines that the diagnosis of pneumonia was not definite and, even if had this been the cause, there would have been signs of bronchiolitis obliterans soon after the illness in 2000. Dr. Rose also explains why she believes that pneumonia was not the cause of Mr. Watson's illness, specifically that his condition would have continued to deteriorate instead of stabilizing after ceasing to consume microwave popcorn. Similarly, Dr. Egilman explains, albeit briefly, why he does not consider that the chemical exposure from carpet cleaning is the cause: Mr. Watson was not exposed to chemicals known to cause bronchiolitis obliterans. Defendants present evidence that Mr. Watson may have

used a product called polymethyl methacrylate, which can in some cases cause hypersensitivity pneumonitis and that there may be some kind of relationship between hypersensitivity pneumonitis and bronchiolitis obliterans. Mr. Watson has also been diagnosed with hypersensitivity pneumonitis. While this relationship may be something to explore on cross-examination, Defendants have not demonstrated that Mr. Watson was exposed to a chemical known to cause bronchiolitis obliterans in quantities sufficient to cause the condition such that Dr. Egilman's opinion regarding alternative causes is entirely unreliable and inadmissible.

Additional evidence regarding the reliability of Dr. Egilman's methodology in arriving at an opinion regarding general and specific causation was provided at the hearing. Dr. Soskolne was proffered as an expert in epidemiology and testified that he had reviewed Dr. Egilman's report for the purpose of evaluating the reliability of the methods used. He testified that it is entirely appropriate to extrapolate disease causation from the occupational setting to other contexts, as Dr. Egilman did here. Dr. Soskolne also testified that Dr. Egilman's methods for arriving at his opinion, including his use of the Hill factors and a differential diagnosis, were accepted in the field and were applied validly. He noted that Dr. Egilman's source data was provided and that the methods were reproducible, which are the standards that Dr. Soskolne would apply in reviewing an article for publication.

Dr. Schachter was offered by Plaintiffs as an expert in pulmonary medicine. He also had reviewed Dr. Egilman's report and was prepared to testify regarding the reliability of the methodology used by Dr. Egilman. Dr. Schachter also opined that it is an appropriate scientific practice to extend theories of causation from occupational

disease to the same disease occurring other settings. He also explained why it is considered acceptable in medical field to make a causal inference even without knowledge of an exact dose or dose threshold of a particular disease-causing agent. Dr. Schachter testified that Dr. Egilman applied the Hill criteria appropriately and properly performed a differential diagnosis in determining the cause of Mr. Watson's disease.

In rebuttal, Defendants presented Dr. Kulig, an expert in medical toxicology. Dr. Kulig did not question the validity of the use of the Hill factors or of the use of a differential diagnosis in determining causation; indeed, on cross-examination, he admitted that these are commonly used tools in the field. Rather, he critiqued the validity of using Dr. Rose's letter as a "case study" to prove causation, arguing that a true case study involves extensive case history and detail and publication in a peer-reviewed journal so that other practitioners may evaluate the legitimacy of the claimed causal relationship. He argued that key details were omitted from Dr. Rose's letter and that Dr. Martyny's data was unreliable and not a good determinant of Mr. Watson's exposure or of the dose relationship. Dr. Kulig's criticisms again go to the weight of the evidence but do not demonstrate that the basic methodology employed by Dr. Egilman was unreliable or that the data upon which he based his opinion, other than the measurements of diacetyl in Mr. Watson's home, were insufficient.

Given the evidence and authority discussed above, I conclude that Dr. Egilman's opinions regarding both general and specific causation, with one exception, employ reliable methods and are based on sufficient, reliable data. The exception concerns the portions of Dr. Egilman's testimony that purport to establish a minimum threshold

amount of diacetyl sufficient to cause respiratory illness, including bronchiolitis obliterans. These opinions will not be permitted at trial. Otherwise, Defendants' motions to strike Dr. Egilman's opinions are denied.

2. Alan J. Parmet, M.D., MPH (expert report attached as Exh. 36 to Pls.' Statement of Facts, ECF No. 601-17)

Dr. Parmet is another medical doctor who opines on specific causation. Dr. Parmet has significant experience with popcorn flavoring related illness and was the physician who first observed the cluster of cases at the Jasper plant and has remained involved in the study of these conditions.

In his proffered expert report, Dr. Parmet reviews Mr. Watson's medical records and current status. Dr. Parmet also performed a physical examination of Mr. Watson and reports those findings. His diagnosis is "Flavoring-induced bronchiolitis obliterans/bronchiolitis obliterans syndrome/popcorn worker's lung." Parmet Report, ECF No. 601-17, at 12. As grounds, he observes that Mr. Watson's consumption exceeds average consumer intake of microwave popcorn. He notes that Mr. Watson's cough and other respiratory problems from the 1990s were resolved with treatment for reflux. However, he concludes that Mr. Watson's condition has progressed to severe pulmonary abnormalities and that his lung biopsy is consistent with flavoring-induced bronchiolitis obliterans. Other factors include Mr. Watson's lack of smoking history. Dr. Parmet contends that Mr. Watson's exposure to solvents and cleansers as a carpet cleaner was "minor" and "could not possibly [ac]count for the severity of [Mr. Watson's] current lung disease." *Id.* Dr. Parmet concludes there is no other reasonable cause that is demonstrated, particularly since Mr. Watson has responded to all other

treatments of his health conditions.

Defendants seek to exclude Dr. Parmet's evidence as unreliable because no dose-response level has been established and because temporality alone is not an adequate basis to prove causation. As discussed above, the Tenth Circuit has accepted that a differential diagnosis may be sufficient evidence of causation and so the lack of a dose-response level in this case does not preclude all causation testimony. Dr. Parmet's opinion is based on his experience with popcorn workers' exposures and diseases, his review and examination of Mr. Watson's health history and current physical condition, and his differential diagnosis, which is an acceptable methodology under appropriate circumstances.

Defendants also seek to exclude Dr. Parmet's opinion on the grounds that his review of Mr. Watson's medical records was incomplete and because he does not adequately address other causes. Again, with respect to the differential diagnosis, Dr. Parmet has explained why he does not believe carpet cleaning solvents are responsible and Defendants may address this at trial; the jury will give it whatever weight it deems appropriate. The same applies to the records allegedly omitted from the review; given Dr. Parmet's examination of Mr. Watson and experience with the condition, Defendants have not established that Dr. Parmet's omission in this regard renders the opinions unreliable.

3. Cecile Rose, M.D. (opinions contained in deposition excerpts, Exh. 14 to Pls.' Statement of Facts, ECF No. 600-14)

As noted above, Dr. Rose is one of Mr. Watson's physicians and has treated him since 2007. In addition to her practice as a pulmonary specialist, she is a professor of

medicine at the University of Colorado's medical school and the Director of the Occupational/Environmental Medicine Clinical Program at National Jewish. She is board certified in internal medicine, pulmonary medicine, and occupational and environmental medicine. Dr. Rose has been a consultant to the flavorings industry regarding occupational exposures for some time and has read much of the published literature concerning respiratory illnesses among microwave popcorn workers. She is an unretained expert witness in this case. She opines on specific causation, stating to a reasonable degree of medical probability that Mr. Watson's lung disease was caused by his exposure to microwave popcorn butter flavorings. Rose Dep., ECF No. 600-14, at 79.

In her deposition, she explains that she was asked to consult on Mr. Watson's case after his lung biopsy was found to have characteristics of hypersensitivity pneumonitis and Mr. Watson's lung function was continuing to deteriorate. *Id.* at 23. The biopsy also showed signs of bronchiolitis obliterans. *Id.* at 25. She believes that both conditions were caused by his exposure to the butter flavorings. *Id.* at 96. The basis for her opinion on causation is the following: (1) that Mr. Watson's lung disease stabilized when he ceased using the product; (2) there was no other causal explanation; (3) the clinical findings in his lung disease were similar to those that occurred in workers exposed to butter flavorings. *Id.* at 80. She acknowledges that Mr. Watson's exposures to the flavoring ingredients were likely lower than those experienced by workers in production processes. *Id.* at 81. She explains that she rules out pneumonia as a cause because his lung function would have continued to decline; she explains that progressive bronchiolitis obliterans after an infection is difficult to interrupt, but Mr.

Watson's condition stabilized after he stopped consuming microwave popcorn. *Id.* at 107. She also acknowledges his exposure to carpet cleaning chemicals. Rose Dep., Exh. A-15 to Def.'s Statement of Facts, ECF No. 560-37, at 53. She states, however, that she is unaware of any of the chemicals to which he was exposed being potential causes of bronchiolitis obliterans. *Id.* at 54-55.

In challenging Dr. Rose's testimony, Defendants rely on several of the same arguments that I have rejected above. Defendants also argue that Dr. Rose is somewhat equivocal as to the cause of Mr. Watson's disease, claiming that she has stated she is not "sure" of the cause of his disease and arguing that she has not adequately ruled out other causes. Again, I see no basis to exclude Dr. Rose's testimony. There is no requirement that a medical expert be one hundred percent certain as to a diagnosis or cause and Dr. Rose has stated her opinion to a reasonable degree of medical probability. She has also provided an explanation for why other causes are not probable, which Defendants may challenge on cross-examination at trial. The motion will be denied. However, since Defendants were not given a chance to cross-examine Dr. Rose at the hearing⁸, this denial is without prejudice to refile and a future hearing regarding the validity of Dr. Rose's methods.

B. Motion for Summary Judgment

1. Causation

Defendants first argue that Plaintiffs cannot demonstrate causation because the testimony of their expert witnesses on causation should be excluded as unreliable. I

⁸The circumstances regarding Dr. Rose's non-appearance at the hearing are set forth in various motions and orders preceding the hearing. See ECF Nos. 635 & 642.

have addressed the expert issues above and conclude that the opinions are generally admissible.

Defendants next argue that there is no evidence to prove general causation, *i.e.*, that exposure to microwave popcorn vapors can result in lung injury. This is plainly not the case. Defendants' argument, therefore, seems to be that because Mr. Watson popped and consumed fewer bags of popcorn than QC workers at various plants, some of whom were not shown to have higher rates of lung disease and respiratory disorders, his disease cannot possibly have been caused by exposure to microwave popcorn flavoring ingredients. Defendants further argue that Plaintiffs cannot extrapolate from the occupational context to the consumer context because of differences in level of exposures and because a single consumer case, such as Mr. Watson, does not establish general causation. These arguments have been addressed in connection with the expert witness issues and I conclude that there is sufficient evidence on these matters to submit the question to a jury.

Similarly, I agree that Plaintiffs have presented sufficient evidence of specific causation to survive summary judgment. Plaintiffs' evidence is not solely comprised of exposure levels, which as an average appear to have been lower than levels of diacetyl in the plants studied. Plaintiffs' experts have also relied on clinical findings, which are similar to affected popcorn plant workers, as well as differential diagnoses. While Defendants' experts may contest these conclusions based on the same or other evidence, these are issues of fact for a jury to decide and do not show that Defendants are entitled to judgment as a matter of law.

2. Colorado Consumer Protection Act Claim

Plaintiffs' CCPA claim is based on their assertion that Defendants knew or should have known that microwave popcorn containing butter flavoring was unreasonably dangerous and that Defendants failed to provide material facts about the risks of the product in the statements they made to consumers. Plaintiffs broadly allege that Defendants used deception, fraud, false promise, misrepresentation and/or unfair practices in their marketing, promoting, and labeling of microwave popcorn with butter flavorings and that this created or reinforced a false impression as to its safety. Defendants argue that summary judgment on this claim is appropriate because there is no evidence to show that they knew of any risk to consumers from microwave flavorings during the relevant time period. They further contend that Plaintiffs cannot demonstrate a significant public impact.

The CCPA is intended to provide "prompt, economical and readily available remedies against consumer fraud," *W. Food Plan v. Dist. Court*, 198 Colo. 251, 256, 598 P.2d 1038, 1041 (Colo. 1979); I should therefore keep in mind its "strong and sweeping remedial purposes." *Crowe v. Tull*, 126 P.3d 196, 202 (Colo. 2006). To prevail on a CCPA claim, a plaintiff must show: "(1) that the defendant engaged in an unfair or deceptive trade practice; (2) that the challenged practice occurred in the course of defendant's business, vocation, or occupation; (3) that it significantly impacts the public as actual or potential consumers of the defendant's goods, services, or property; (4) that the plaintiff suffered injury in fact to a legally protected interest; and (5) that the challenged practice caused the plaintiff's injury." *Rhino Linings USA, Inc. v. Rocky Mt. Rhino Lining*, 62 P. 3d 142, 146-47 (Colo. 2003). In defining the unfair trade practice at issue here, two provisions of the CCPA appear to be relevant to Plaintiffs'

claim:

(g) [representing] that goods, food, services, or property are of a particular standard, quality, or grade . . . if [the seller] knows or should know that they are of another;

* * *

(u) [failing] to disclose material information concerning goods, services, or property which information was known at the time of an advertisement or sale if such failure to disclose such information was intended to induce the consumer to enter into a transaction;

C.R.S. § 6-1-405(1).

Defendants argue that although the NIOSH investigations into occupational illness at microwave popcorn plants revealed a risk to workers, no research has revealed the same for consumers. Indeed, NIOSH specifically stated in 2008 that consumers were not at risk of lung disease from butter flavoring chemicals. Dr. Rose also acknowledges that there is no published research indicating a risk to consumers from ordinary consumption of microwave popcorn and she was unaware of any such risk until she consulted on Mr. Watson's case.

In response, Plaintiffs argue that the NIOSH investigations and workers' compensation lawsuits were sufficient to put the manufacturers on notice that butter flavoring containing diacetyl was harmful and could cause respiratory damage. They further argue that materials from the flavoring manufacturers informed Gilster-Mary Lee and Birds Eye of the health hazards from the butter flavoring, including the risk of irritation to the respiratory tract, and the need to have adequate exhaust. See, e.g., Flavor Concepts Material Safety Data Sheet ("MSDS"), Exh. 33 to Pls.' Statement of Facts, ECF No. 601-14; Flavor Concepts proposed Diacetyl MSDS Acknowledgement

Form, Exh. 34 to Pls.' Statement of Facts, ECF No. 601-15. I agree with Defendants that there is no evidence that they actually knew of a risk to consumers from butter flavoring ingredients and none of Plaintiffs evidence demonstrates warnings from experts that consumers could receive sufficient exposure to raise concerns about possible health hazards. However, in light of the significant data regarding the risk of the product at *some* level of exposure and the remedial purpose of the statute, I conclude that there is an issue of fact as to whether the Defendants should have known that there was a potential risk to consumers and therefore marketed and labeled their product with appropriate alerts or qualifiers.

Defendants also argue there is no evidence that alleged failure to disclose has affected a large number of consumers or has the potential to do so in the future. In determining whether a practice has a public impact for the purposes of the CCPA, a court may consider: "(1) the number of consumers directly affected by the challenged practice, (2) the relative sophistication and bargaining power of the consumers affected by the challenged practice, and (3) evidence that the challenged practice has previously impacted other consumers or has the significant potential to do so in the future." *Rhino Linings*, 63 P.3d at 149. Plaintiffs have provided evidence of a handful of other consumer cases, two of which have gone to trial in civil lawsuits and failed on the merits. *Newkirk v. ConAgra Foods*, Case No. 2: 08-cv-00273-RMP (E.D. Wash. 2009) (dismissed on motions); *Khoury, et al., v. ConAgra Foods, Inc., et al.*, Case No.0816-CV-31620, Circuit Court of Jackson County, Missouri (jury verdict for defense). Defendants argue that this small number of cases indicates that even if Defendants had not adequately marketed or labeled the product, the impact to consumers is minimal.

Plaintiffs contend in response that a significant public impact is shown because of the large number of consumers who buy microwave popcorn and the serious health risk posed by the product. They also contend that other lawsuits involving consumers alleging harm from microwave popcorn butter flavoring are pending.

Although Plaintiffs do not provide any evidence regarding how many consumers purchase the product at issue and what the potential impact is, I conclude that there is sufficient evidence on this element for the claim to go forward. See *Warner v. Ford Motor Co.*, Civil Action No. 06-cv-02443-JLK-MEH, 2008 WL 4452338 at *15 (D. Colo., Sept. 30, 2008) (because vehicle was sold to the general public and allegedly contained defect capable of causing serious injury, plaintiffs adequately demonstrated that alleged nondisclosure was not “private in nature”). As in *Warner*, the product at issue is marketed to general consumers, which is a large group. Although there is no evidence regarding how many consumers of popcorn use the product in the quantities alleged here, given the seriousness of the harm alleged, *i.e.*, permanent respiratory damage, it is reasonable to assume the potential impact is significant. Therefore, summary judgment on this claim is not appropriate.

3. Kroger Defendants as Manufacturers

Defendants argue that Plaintiffs’ negligence, strict liability, and failure to warn claims against the Kroger Defendants fail because Plaintiffs cannot show that any of the Kroger Defendants is a “manufacturer” under Colorado’s Product Liability Act. Under this statute, no product defect liability action may be “commenced or maintained against any seller of a product unless said seller is also the manufacturer of said product” C.R.S. § 13-21-402(1). A “manufacturer” is defined as:

. . . a person or entity who designs, assembles, fabricates, produces, constructs, or otherwise prepares a product or a component part of a product prior to the sale of the product to a user or consumer. The term includes any seller who has actual knowledge of a defect in a product or a seller of a product who creates and furnishes a manufacturer with specifications relevant to the alleged defect for producing the product or who otherwise exercises some significant control over all or a portion of the manufacturing process or who alters or modifies a product in any significant manner after the product comes into his possession and before it is sold to the ultimate user or consumer. . . . A seller not otherwise a manufacturer shall not be deemed to be a manufacturer merely because he places or has placed a private label on a product if he did not otherwise specify how the product shall be produced or control, in some significant manner, the manufacturing process of the product and the seller discloses who the actual manufacturer is.

C.R.S. § 13-21-401(1).

Defendants contend that there is no evidence that the Kroger Defendants had actual knowledge of the danger to consumers from butter flavoring ingredients until 2007 and did not exercise sufficient control over the product or its production to be deemed a manufacturer. In response, Plaintiffs argue that the Kroger Defendants may nonetheless be considered apparent manufacturers because they did not disclose the actual maker of the popcorn. *Yoder v. Honeywell Inc.*, 104 F.3d 1215, 1223 (10th Cir. 1997) (interpreting the last sentence of section 401(1) as allowing “a seller who places a private label on a product without disclosing the actual manufacturer to be held liable as a manufacturer.”).

I agree with Defendants that Plaintiffs have offered no evidence that would show that the Kroger Defendants actually knew that butter flavoring ingredients in the microwave popcorn they sold posed a potential health risk to consumers, as opposed to

factory workers, until notified of Mr. Watson's case in 2007. Indeed, it is still not proven that there is such a risk. I also agree with Defendants that the evidence indicates that the Kroger Defendants did not control the manufacturing process and offered only general specifications regarding the product (*i.e.*, that it should taste and smell like the national brand target), not specific ingredient lists or the like. There is certainly no evidence that the Kroger Defendants required that the flavoring ingredients include diacetyl. Nonetheless, I agree with Plaintiffs that the Kroger Defendants may be considered an apparent manufacturer under the statute despite this because they did not disclose the actual manufacturer of the product. See Restatement 2d Torts, § 400 ("One who puts out as his own product a chattel manufactured by another is subject to the same liability as though he were its manufacturer."). As noted above, the product label did not provide to the buyer any name other than those of the Kroger entities. It is unclear whether Colorado courts would adopt the Restatement approach in its entirety, but at least one federal court considering the issue has concluded that section 401(1) of the product liability act indicates that Colorado law will permit a product defect action against a seller who holds out a product as his own. *Yoder*, 104 F.3d at 1223. I will leave it to the parties to outline the exact contours of this claim at trial, including whether any other elements are required, such as causation or reliance.

4. Punitive Damages

Finally, Defendants seek summary judgment on Plaintiffs' claim for punitive damages against Gilster-Mary Lee. Colorado law permits recovery of punitive damages against a defendant where the conduct at issue is "wanton and willful." C.R.S. § 13-21-102(1)(a). This is defined as conduct "purposefully committed which the actor must

have realized as dangerous, done heedlessly and recklessly, without regard to consequences, or of the rights and safety of others, particularly the plaintiff.” *Id.* Wanton and willful conduct must be proven beyond a reasonable doubt. C.R.S. § 13-25-127(2). Defendants argue that Plaintiffs cannot show more than negligence because the evidence does not demonstrate knowledge that there was a substantial risk of harm to consumers from butter flavorings released in popping microwave popcorn.

In response, Plaintiffs appear to argue that the severity of the health effects on workers at the Gilster-Mary Lee plant in Jasper, including on QC workers who pop popcorn, and the knowledge that the condition was most likely caused by inhalation of butter flavoring vapors should have led Gilster-Mary Lee to provide warnings to consumers about the potential risk. As noted above, Plaintiffs’ evidence is sufficient to establish that perhaps the manufacturers should have known or should have investigated the risk to consumers given the severe health effects suffered by workers exposed to butter flavoring ingredients. A reasonable jury could find that given the magnitude of the harm and the lack of information about the minimum exposure level capable of causing harm, the manufacturer acted recklessly in failing to investigate or warn consumers of the potential for harm. Accordingly, whether the conduct of Gilster-Mary Lee amounts to willful and wanton conduct is an issue of fact and cannot be decided as a matter of law.

Accordingly, it is ordered:

1. The Joint Motion for Summary Judgment (ECF No. 572) is denied.
2. The Joint Motion to Exclude General Causation Testimony (ECF No. 567) and the Joint Motion to Exclude Specific Causation Testimony of Plaintiffs’

Expert Allen Parmet (ECF No. 569) are denied.

3. The Joint Motion to Exclude Specific Causation of Plaintiffs' Expert Cecile Rose (ECF No. 570) is denied without prejudice. Defendants may refile the motion and schedule a hearing for cross-examination of Dr. Rose if they deem it necessary in light of the resolution of the issues in this order. The court will allow Defendants to claim reasonable expense of travel and lodging for Defendants' counsel for any such rescheduled hearing.
3. The Joint Motion to Exclude Specific Causation Testimony of Plaintiffs' Expert David Egilman (ECF No. 568) is granted with respect to Dr. Egilman's opinions regarding a minimal threshold exposure level sufficient to cause injury. The motion is otherwise denied.

DATED at Denver, Colorado, on June 22, 2011.

BY THE COURT:



s/ Walker D. Miller
United States Senior District Judge