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5 UNITED STATES DISTRICT COURT
6 EASTERN DISTRICT OF WASHINGTON
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8 LARRY I. NEWKIRK and RUTH A.
9 NEWKIRK,

10 Plaintiffs,

11 v.

12 CONAGRA FOODS, INC., a
13 Delaware corporation, et al.,

14 Defendants.
15
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NO: CV-08-273-RMP

MEMORANDUM OPINION AND
ORDER

17 **I. INTRODUCTION**
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19 On June 7, 2010, the Court held a hearing on Defendants' five *Daubert*¹ and
20 two summary judgment motions.² After hearing oral argument and reviewing all
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22 ¹ *Daubert v. Merrell Dow Pharm. Inc.*, 509 U.S. 579 (1993).

23 ² Defendants' Joint Motion to Exclude the Supplemental Opinion of Dr. Egilman
24 (Ct. Rec. 359), Defendants' Joint Motion to Exclude the General Causation
25 Testimony of Plaintiffs' Experts (Ct. Rec. 228), Defendants' Joint Motion to
26 Exclude the Specific Causation Testimony of Plaintiffs' Expert Dr. Egilman
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1 of the memoranda and exhibits that are listed in Addendum A, as well as the rest of
2 the file and pleadings in this case, the Court issued a text order on June 24, 2010,
3 granting Defendants' *Daubert* and summary judgment motions for the reasons set
4 out in this memorandum opinion.
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6 As a preliminary matter, the Court granted the parties opportunities to file
7 overlength briefing (Ct. Recs. 220, 261, 270, and 303) and additional time to file
8 their responses and replies (Ct. Recs. 270 and 300). On May 19, 2010, less than
9 three weeks before the oral argument hearing on the five *Daubert* motions and two
10 summary judgment motions, the Plaintiffs notified the Court and the Defendants of
11 their intention to present the live testimony of Dr. Egilman at the hearing (Ct. Rec.
12 456). The Defendants objected to the Plaintiffs' intentions and moved to preclude
13 Dr. Egilman's live testimony as untimely and prejudicial (Ct. Rec. 470). The
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19 (Ct. Rec. 231), Defendants' Joint Motion to Exclude the Specific Causation
20 Testimony of Plaintiffs' Expert Dr. Pue (Ct. Rec. 234), Defendants' Joint Motion
21 to Exclude the Testimony of Dr. Parmet (Ct. Rec. 237), Defendants' Joint Motion
22 to exclude the Testimony of Plaintiffs' Expert William Ewing (Ct. Rec. 240), and
23 Defendants' Joint Motion for Summary Judgment Dismissal of Plaintiffs' Claims
24 (Ct. Rec. 243), and Defendant Chr. Hansen, Inc.'s Motion for Summary Judgment
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26 (Ct. Rec. 252).
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1 Court concluded that there was a sufficient evidentiary record³ on which to hear
2 argument and granted Defendants' motion to preclude live testimony. *See*
3 *Millenkamp v. Davisco Foods Intern., Inc.*, 562 F.3d 971, 979 (9th Cir. 2009);
4 *Oddi v. Ford Motor Co.*, 234 F.3d 136, 154 (3d Cir.2000).

6 The central issue of all of these motions is whether Plaintiffs' experts should
7 be allowed to testify as to general causation and specific causation in this case.
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9 II. BACKGROUND

10 Larry Newkirk and Ruth Newkirk alleged in their original complaint claims
11 for negligence, strict liability in tort—design defect, failure to warn, violation of
12 Washington Consumer Protection Act, and loss of consortium and medical
13 expenses (Ct. Rec. 1) (filed Sept. 1, 2008). The Newkirks later stipulated to
14 dismissal of the Washington Consumer Protection Act claim (Ct. Rec. 45). On
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16 ³ The parties filed multiple statements of Dr. David Egilman's opinions in the
17 forms of his Rule 26 Expert Report from September 15, 2009 (Ct. Rec. 248-2); Dr.
18 Egilman's April 19, 2010, Affidavit (Ct. Rec. 323); Dr. Egilman's April 26, 2010,
19 Supplemental Affidavit (Ct. Rec. 325); a set of Power Point slides prepared by Dr.
20 Egilman and produced at his January 26, 2010, deposition (Ct. Rec. 361-1); and
21 extensive excerpts from Dr. Egilman depositions (Ct. Rec. 248-19; Ct. Rec. 394-2),
22 and voluminous memoranda and exhibits filed in support and opposition to the five
23 *Daubert* motions and the two summary judgment motions.
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1 November 5, 2008, the Newkirks filed a First Amended Complaint (Ct. Rec. 62) to
2 substitute Chr. Hansen, Inc. (“Hansen”) as a named party for a John Doe
3 defendant. The Newkirks realleged the negligence, strict liability in tort—design
4 defect, failure to warn, and loss of consortium claims in the First Amended
5 Complaint (Ct. Rec. 62).
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8 Among the Newkirks’ factual allegations is that Mr. Newkirk’s “exposure to
9 Defendants’ popcorn and natural and artificial butter flavorings directly and
10 proximately caused . . . bronchiolitis obliterans, severe and progressive damage to
11 the respiratory system, extreme shortness of breath and reduced life expectancy”
12 (Ct. Rec. 62 at 8). ConAgra Foods, Inc. (“ConAgra”) manufactured the Act II
13 Butter and Act II Butter Lovers popcorn that Mr. Newkirk primarily consumed (Ct.
14 Rec. 62 at 4, 6, 8). Defendants Symrise, Inc. (“Symrise”) and Hansen supplied
15 butter flavorings to ConAgra during the time period relevant to Mr. Newkirk’s
16 claims (Ct. Rec. 62 at 6).
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21 **Mr. Newkirk’s Consumption of Microwave Popcorn**

22 Mr. Newkirk alleges in the First Amended Complaint that he “regularly
23 prepared four to six bags of microwave popcorn” sold under labels manufactured
24 by ConAgra “[b]eginning in or around 1989 and continuing into September 2007”
25 (Ct. Rec. 62 at 8). The Newkirks revise their allegation regarding the extent of Mr.
26 Newkirk’s popcorn consumption in their Counter Statement of Material Facts in
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1 Support of Plaintiffs' Opposition to Defendants' Joint Motion for Summary
2 Judgment and Daubert Motions (Ct. Rec. 321) and state that Mr. Newkirk "ate
3 between five to seven bags of microwave popcorn each day for approximately 11
4 years and was eating microwave popcorn before he reached this level of daily
5 exposure" (Ct. Rec. 32 at 10).
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8 Mr. Newkirk began eating popcorn regularly in the late 1980s or early
9 1990s, around the time he quit smoking, to suppress his appetite and avoid gaining
10 weight. Newkirk Dep., Sept. 2, 2009 (Ct. Rec. 249-20 at 819); Charles A. Pue,
11 MD, Expert Report, Aug. 7, 2009 (Ct. Rec. 248-3 at 81). Mr. Newkirk had been a
12 smoker for approximately seven years and quit smoking in approximately 1987.
13 Michael P. Williams, MD, FACC, Consultation Report, Jul. 3, 2003 (Ct. Rec. 249-
14 19 at 808). When Mr. Newkirk popped popcorn at home, he did not routinely
15 stand in front of the microwave. Newkirk Dep., Sept. 2, 2009 (Ct. Rec. 249-20 at
16 821). Instead, while the popcorn was popping, he left the area of the microwave to
17 do something else and then returned and removed the bag a few seconds after the
18 microwave completed its heating cycle. Newkirk Dep., Sept. 2, 2009 (Ct. Rec. 327
19 at 1057). He normally left the kitchen to eat the popcorn either in the living room
20 or in the car on the way to work. Newkirk Dep., Sept. 2, 2009 (Ct. Rec. 249-20 at
21 821, 833; Ct. Rec. 327 at 1057). He opened the bag away from his face, at chest
22 level. Newkirk Dep., Sept. 2, 2009 (Ct. Rec. 249-20 at 821).
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1 **Bronchiolitis Obliterans and Related Diseases**

2 Bronchiolitis obliterans (sometimes referred to by the parties or their
3 witnesses as “BO”) is a relatively uncommon, severe lung disease characterized by
4 two main physiological effects: (1) obstruction to airflow; and (2) air
5 trapping/hyperinflation. Philip Harber, Kaochoi Saechao, and Catherine Boomus,
6 Diacetyl-Induced Lung Disease, 25(4) Toxicol. Rev. 261, 263-64 (2006) (Ct. Rec
7 327-6). A conclusive diagnosis of bronchiolitis obliterans may be made only
8 through a lung biopsy. *See, e.g.*, Allen Parmet, MD, MPH, Dep., Dec. 16, 2009
9 (Ct. Rec. 248-8 at 192). However, a lung biopsy is an invasive procedure with
10 substantial health risks (Ct. Rec. 248-16 at 289). Moreover, a biopsy may not offer
11 a definitive diagnosis in all cases. Kathleen Kreiss & Ann Hubbs, *Letter to the*
12 *Editor RE: Galbraith D and Weill D (2009) Popcorn lung and bronchiolitis*
13 *obliterans: a critical appraisal 82:407-416*, 83 Int. Arch. Occup. Environ Health
14 467 (2010) (Ct. Rec. 327-21 at 224). For some patients who are unresponsive to
15 drug therapies, a pathologic diagnosis does not change the recommended course of
16 treatment. *Id.* (Ct. Rec. 327-21 at 224). Bronchiolitis obliterans primarily arises in
17 the post-infection context, such as after a lung transplant or pneumonia. Richard
18 Kanwal, et al., *NIOSH Health Hazard Evaluation Report, HETA # 2000-0401-*
19 *2991, Gilster-Mary Lee Corporation, Jasper Missouri* (January 2006) (Ct. Rec.
20 248-18 at 316). Bronchiolitis obliterans syndrome is a collection of symptoms and

1 clinical observations of obstructive pulmonary disease that, together, are consistent
2 with bronchiolitis obliterans. Kendall Wallace, PhD, Expert Report, Nov. 4, 2009
3 (Ct. Rec. 250-3 at 965).
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5 **Diagnosis of Mr. Newkirk's Illness**

6 Mr. Newkirk began noticing shortness of breath, chest tightness, dry cough,
7
8 and fatigue during his regular activities sometime between 2000 and 2003. Sanjay
9 Agarwal, MD, Letter (Ct. Rec. 249-9 at 773-74); Parmet Expert Report, Aug. 26,
10 2008 (Ct. Rec. 248-4 at 92). After reading an article in 2007 about a popcorn
11 consumer developing "popcorn lung," Mr. Newkirk went to his family doctor to
12 see whether he, too, might have a disease related to inhalation of butter flavoring
13 fumes. Newkirk Dep., Sept. 2, 2009 (Ct. Rec. 249-20 at 819); Newkirk Dep., Sept.
14 3, 2009 (Ct. Rec. 334-1 at 1052). Mr. Newkirk was referred to Dr. Sanjay
15 Agarwal, a pulmonologist then practicing in Spokane, who diagnosed him with
16 "obstructive lung disease given his significant history of smoking[.]" Agarwal
17 Letter (Ct. Rec. 249-9 at 775-76).
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22 Mr. Newkirk then saw Plaintiffs' expert Dr. Allen Parmet in Missouri, who
23 diagnosed Mr. Newkirk with "[b]ronchiolitis obliterans syndrome/flavoring
24 induced bronchiolitis obliterans (FIBO)[.]" Parmet Expert Report, Aug. 26, 2008
25 (Ct. Rec. 248-4 at 100). Mr. Newkirk also saw Plaintiffs' expert Dr. Charles Pue
26 in Ohio, who determined that Mr. Newkirk's "[c]linical picture is consistent with
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1 bronchiolitis obliterans syndrome from butter flavoring (diacetyl).” Charles Pue,
2 MD, Expert Report (Ct. Rec. 248-3). Mr. Newkirk also was evaluated by
3 Plaintiffs’ expert Dr. David Egilman in Massachusetts, who originally diagnosed
4 Mr. Newkirk with bronchiolitis obliterans. David Egilman, MD, MPH, Sept. 15,
5 2009, Expert Report (Ct. Rec. 248-2 at 52). Other physicians who examined Mr.
6 Newkirk did not diagnose him with bronchiolitis obliterans. *See* James Elmer,
7 MD, Consultation Report (Ct. Rec. 249-10, Consultation Report of Dr. James
8 Elmer); Gregory Doering, MD, Progress Notes (Ct. Rec. 249-11); Timothy Bruya,
9 MD, Expert Report for Defendants (Ct. Rec. 250-7 at 1123); David Weill, MD,
10 Expert Report for Defendants (Ct. Rec. 250-5 at 1062-63); Mark Utell, MD, Expert
11 Report for Defendants (Ct. Rec. 249-23 at 896). However, it is undisputed that Mr.
12 Newkirk has not had a lung biopsy, and, therefore, has not received a conclusive
13 diagnosis of bronchiolitis obliterans.
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19 The connection between obstructive lung disease and microwave popcorn
20 containing butter flavorings became a matter of concern for popcorn manufacturers
21 and their employees in 2000 and 2001. The culprit compound was identified as
22 diacetyl, a flavoring agent used to provide a buttery taste and a sense of
23 “creaminess.” Philip Harber, Kaochoi Saechao, and Catherine Boomus, *Diacetyl-*
24 *Induced Lung Disease*, 25(4) *Toxicol. Rev.* 261, 263-64 (2006) (Ct. Rec 327-6,
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28 Exh. F). The typical microwave popcorn plant has a slurry mixing area where the

1 components of butter flavoring are mixed into a solution and that solution is mixed
2 into vats with heated oil and salt. The plant also has a quality assurance or quality
3 control area, a manufacturing area, a packaging area, a warehouse, a printing press,
4 bag assembly area, and offices. See Richard Kanwal et al., *Evaluation of*
5 *Flavorings-Related Lung Disease Risk at Six Microwave Popcorn Plants*, 48
6 *Journal of Occupational and Environmental Medicine* 149 (February 2006) (Ct.
7 Rec. 248-20); Richard Kanwal and Greg Kullman, *NIOSH Health Hazard*
8 *Evaluation Report, HETA # 2004-0112-2949, ConAgra Snack Foods, Marion,*
9 *Ohio* (December 2004) (Ct. Rec. 249).

13 Quality assurance workers pop dozens of bags of popcorn per work shift.⁴
14 For instance, at the ConAgra plant in Marion, Ohio, each worker popped up to 130
15 bags per 12-hour workshift. Richard Kanwal and Greg Kullman, *NIOSH Health*
16 *Hazard Evaluation Report, HETA # 2004-0112-2949, ConAgra Snack Foods,*
17 *Marion, Ohio* (December 2004) (Ct. Rec. 249 at 573). In Plant F in the Kanwal, et
18 al., report, quality assurance workers popped 130 bags of popcorn in a 12-hour

19 al., report, quality assurance workers popped 130 bags of popcorn in a 12-hour
20 ⁴ Some plant workers work in quality assurance full-time. See Richard Kanwal et
21 al., *Evaluation of Flavorings-Related Lung Disease Risk at Six Microwave*
22 *Popcorn Plants*, 48 *Journal of Occupational and Environmental Medicine* 149
23 (February 2006) (Ct. Rec. 248-20). Other plants have workers who perform
24 quality assurance work on certain days each week or month. *Id.*

1 workshift, but performed that task only 3-4 days per week for 1 out of every 3
2 weeks. Richard Kanwal et al., *Evaluation of Flavorings-Related Lung Disease*
3 *Risk at Six Microwave Popcorn Plants*, 48 Journal of Occupational and
4 Environmental Medicine 149, 156 (February 2006) (Ct. Rec. 248-20 at 505). In
5 Plant D, workers popped 75 bags per 8-hour work shift. *Id.*

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8 Research on safe levels of occupational and consumer exposures to diacetyl
9 has been limited because manufacturers of microwave popcorn, including
10 ConAgra, stopped using diacetyl in or around 2007. Kenneth L. White, et al., 7 J.
11 of Occupational and Environmental Hygiene 185, 185 (April 2010) (Ct. Rec. 477-
12 18 at 206). The scientific community has yet to determine a safe level of diacetyl
13 exposure. *See, e.g.*, (Ct. Rec. 248-8 at 157-61); (Ct. Rec. 248-20 at 505).

16 III. ANALYSIS

17 18 A. *Daubert* Motions to Exclude Plaintiffs' Expert Witness Testimony

19 20 1. Dr. David Egilman's Supplemental Affidavits

21 As a preliminary matter, Defendants filed a Joint Motion to Exclude the
22 Supplemental Opinions of Dr. David Egilman (Ct. Rec. 359). Defendants rely on
23 the expert opinion disclosure requirements established in Fed. R. Civ. P. 26, as
24 well as this Court's prior scheduling orders, as the bases to exclude Dr. Egilman's
25 supplemental opinions.
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1 This case was filed in 2008 (Ct. Rec. 360 at 1). The Court’s scheduling
2 orders established a Plaintiffs’ expert witness disclosure deadline of no later than
3 September 1, 2009, and a discovery cut-off deadline of April 9, 2010. Defendants
4 agreed to extend Plaintiffs’ expert witness disclosure deadline to September 15,
5 2009 (Ct. Rec. at 2).
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8 Defendants argue that Dr. Egilman significantly altered some of his opinions
9 between his September 15, 2009, expert opinion report, and his January 26, 2010,
10 deposition, such as altering his diagnosis of Mr. Newkirk from “bronchiolitis
11 obliterans” to “bronchiolitis obliterans syndrome,” which Defendants argue is
12 substantially different (Ct. Rec. 360 at 5-6). In addition, Defendants contend that
13 Dr. Egilman’s 85-page affidavit, dated April 19, 2010, which Defendants also
14 move to exclude as untimely, contains calculations not previously disclosed and
15 opinions significantly varied from his September 15, 2009, report (Ct. Rec. 360 at
16 6).
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21 Plaintiffs argue that Dr. Egilman’s affidavit of April 26, 2010, is a
22 supplemental report that augments and corrects his previous expert opinion report,
23 as required by Fed. R. Civ. P. 26(e)(2) (Ct. Rec. 476 at 6-7). In addition, they
24 argue that Bronchiolitis Obliterans Syndrome is not significantly different from
25 Bronchiolitis Obliterans (Ct. Rec. 476 at 5). Plaintiffs contend that they would
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1 have been in violation of Fed. R. Civ. P 26 if they had not provided the
2 supplemental affidavit (Ct. Rec. 476 at 7).

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4 Pursuant to Federal Rule of Civil Procedure 26 a party must provide a timely
5 report that includes “a complete statement of all opinions the witness will express
6 and the basis and reasons for them.” Fed. R. Civ. P. 26(a)(2)(A), (B). Failure to
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8 abide by the disclosure requirements in Fed. R. Civ. P. 26 can result in sanctions
9 pursuant to Fed. R. Civ. P. 37.

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11 In this case, the Court concludes that although Dr. Egilman’s supplemental
12 opinions do significantly augment and correct his previous opinions disclosed in
13 his September 15, 2009, report, Defendants have not suffered prejudice as a result.
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15 Therefore, the Court denies Defendants’ Motion to Exclude Supplemental
16 Opinions of Dr. David Egilman, Ct. Rec. 359.

17 18 **2. Legal Standards**

19 **Plaintiffs’ Burden for Proving Causation**

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21 Plaintiffs in toxic tort cases must establish both general and specific
22 causation. *Golden v. CH2M Hill Hanford Group, Inc.*, 528 F.3d 681, 683 (9th
23 Cir.2008). Evidence supporting general or generic causation addresses “whether
24 the substance at issue had the capacity to cause the harm alleged.” *In re Hanford*
25 *Nuclear Reservation Litigation*, 292 F.3d 1124, 1133 (9th Cir.2002). Specific
26 causation, by contrast, concerns “whether a particular individual suffers from a
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1 particular ailment as a result of exposure to the substance.” *In re Hanford*, 292
2 F.3d at 1133. The specific causation issue is “highly individualistic” and depends
3 upon the characteristics of an individual plaintiff, such as his or her overall health,
4 lifestyle, and the nature of the exposure to the substance at issue. *In re Hanford*,
5 292 F.3d at 1133 (quoting *In re Agent Orange Product Liability Litigation MDL*
6 *No. 381*, 818 F.2d 145, 165 (2d Cir.1987)).
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9 **Daubert Legal Standard**

10 The Federal Rules of Evidence allow testimony by a qualified expert who
11 will assist a trier of fact in understanding the evidence or in determining a fact in
12 issue, so long as “(1) the testimony is based upon sufficient facts or data, (2) the
13 testimony is the product of reliable principles and methods, and (3) the witness has
14 applied the principles and methods reliably to the facts of the case.” Fed. R. Evid.
15 702.
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19 It is the trial judge's responsibility to act as a “gatekeeper” by ensuring “that
20 an expert's testimony both rests on a reliable foundation and is relevant to the task
21 at hand.” *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597, 113 S.Ct. 2786,
22 125 L.Ed.2d 469 (1993) (*Daubert I*). In making this determination, the judge must
23 make “a preliminary assessment of whether the reasoning or methodology
24 underlying the testimony is scientifically valid and . . . whether that reasoning or
25 methodology properly can be applied to the facts in issue.” *Daubert I*, 509 U.S. at
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1 592-93. The Court’s gatekeeping function exists to ensure that an expert witness
2 “employs in the courtroom the same level of intellectual rigor that characterizes the
3 practice of an expert in the relevant field.” *Kumho Tire Co.*, 526 U.S. at 152.
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5 Many factors bear on the inquiry into the reliability of expert testimony,
6 including the following considerations: (a) whether the theory or technique can and
7 has been tested; (b) whether the theory or technique has been subjected to peer
8 review and publication; (c) whether the known or potential rate of error for the
9 technique has been addressed; and (d) whether the theory or technique has a
10 general degree of acceptance in the relevant scientific community. *Daubert I*, 509
11 U.S. at 593-94.
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15 A trial court “may consider one or more of the specific factors that *Daubert*
16 mentioned when doing so will help determine that testimony's reliability. But, as
17 the Court stated in *Daubert*, the test of reliability is ‘flexible,’ and *Daubert*'s list of
18 specific factors neither necessarily nor exclusively applies to all experts or in every
19 case.” *Kumho Tire Co.*, 526 U.S. at 141. An expert's testimony, at a minimum,
20 must rest on "good grounds, based on what is known." *Daubert I*, 509 U.S. at 590.
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23 For a scientific opinion to have evidentiary relevance and reliability under
24 Fed. R. Evid. 702, the opinion must be based on scientifically valid principles and
25 the testimony must assist the trier of fact to determine a fact at issue in the case.
26 *Daubert I*, 509 U.S. at 589. Relevant expert testimony “logically advances a
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1 material aspect of the proposing party's case." *Daubert v. Merrell Dow Pharm.,*
2 *Inc.*, 43 F.3d 1311, 1315 (9th Cir. 1995) (*Daubert II*). An expert's testimony must
3 assist the trier of fact and relate to, or "fit," the underlying facts of the case.
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5 *Daubert II*, 43 F.3d. at 1320. This requirement of "fit" or "helpfulness" demands
6 "a valid scientific connection to the pertinent inquiry as a precondition to
7
8 admissibility." *Daubert II*, 43 F.3d at 1317-18 (quoting *Daubert I*, 509 U.S. at
9 592); *see also* Fed. R. Evid. 702.

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11 The party proffering the expert testimony bears the burden of demonstrating
12 that the expert's findings and conclusions are based on the scientific method, and,
13 therefore, are reliable. The court is to conduct a "holistic" analysis of the expert's
14 testimony. *See United States v. W.R. Grace*, 504 F.3d 745, 762 (9th Cir. 2007).

15
16 The court should review the expert's opinion testimony for "overall sufficiency of
17 the underlying facts and data, and the reliability of the methods, as well as the fit of
18 the methods to the facts of the case." *W.R. Grace*, 504 F.3d at 765. When there is
19 too great an analytical gap between the data and the opinion proffered, the trial
20 court may properly exclude the testimony as unreliable. *Joiner*, 522 U.S. at 146.

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1 **3. Motion to Exclude Expert Testimony on General Causation**
2 **and Motion to Exclude Specific Causation Testimony of Dr.**
3 **Egilman**
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5 Defendants assert, and Plaintiffs do not dispute, that Dr. Egilman’s expert
6 opinion testimony is the Plaintiffs’ primary evidence supporting general causation.
7 Defendant’s Memorandum (Ct. Rec. 229 at 3); Plaintiffs’ Opposition (Ct. Rec.
8 320).
9

10 Defendants do not contest Dr. Egilman’s qualifications as an expert. Dr.
11 Egilman received a bachelor of science degree in Molecular Biology at Brown
12 University in 1974, a medical degree from Brown University Medical School in
13 1978, and a masters degree in public health from the Harvard School of Public
14 Health in 1982. Curriculum Vitae (Ct. Rec. 331-11 at 885). He is licensed to
15 practice medicine in three states and is board certified in Occupational and Internal
16 Medicine. Curriculum Vitae (Ct. Rec. 331-11 at 885). Dr. Egilman is a very
17 accomplished scientist who has served as an expert witness in other cases
18 involving microwave popcorn workers and is being proffered as an expert witness
19 in at least one other microwave popcorn consumer case. Excerpt of Dr. Egilman’s
20 Trial Testimony on May 20, 2009, in *Aldrich v. International Flavors &*
21 *Fragrances, et al.*, Case No. A-0700451, Court of Common Pleas, Hamilton
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1 County, Ohio (Ct. Rec. 509-20); Dr. Egilman Dep., April 27, 2010, In the Matter
2 of: *Elaine Khoury, et al. v. Conagra Foods, Inc. et al.* (Ct. Rec. 394-2) and (Ct.
3 Rec. 509-18).

4
5 Plaintiffs retained Dr. Egilman to offer an opinion on general causation as
6 well as to examine Mr. Newkirk, diagnose him, and offer an opinion regarding the
7 specific cause of his condition. The Defendants contend that all of the Newkirks'
8 other causation expert witnesses, Dr. Charles Pue, Dr. Allan Parmet, and William
9 Ewing, assume that general causation already has been established. Memorandum
10 of Defendants (Ct Rec. 229) (citing Pue Expert Report, Parmet Expert Report,
11 Parmet Supp. Expert Report, Ewing Expert Report, Ewing Supp. Expert Report).
12 The Defendants maintain that Dr. Egilman fails to apply proper scientific
13 methodology and that the methodology and reasoning he does apply cannot be
14 properly applied to Mr. Newkirk's claims to support general causation.
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19 The Plaintiffs respond that general causation "as to exposure to butter
20 flavoring" is well established and that Dr. Egilman provides reliable and relevant
21 opinions based on differential diagnosis as well as on his assessment of Mr.
22 Newkirk's exposure levels compared to levels known to cause disease.
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25 General causation in this case demands evidence that the substance to which
26 Mr. Newkirk was exposed by popping microwave popcorn was capable of causing
27 the bronchiolitis obliterans and respiratory ailments that the Newkirks' assert Mr.
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1 Newkirk now suffers. Specific causation requires evidence that Mr. Newkirk
2 suffers from bronchiolitis obliterans or other respiratory ailments and that those
3 ailments developed as a result of Mr. Newkirk's exposures to vapors emitted from
4 microwave popcorn.
5

6 As to general causation, Dr. Egilman forwards the following opinions:

7
8 "There is no known safe level of diacetyl exposure. [Existing scientific] studies
9 also suggest that levels of diacetyl exposure below and around 1 ppm can cause
10 BO and other respiratory illnesses." Dr. Egilman Expert Report, Sept. 15, 2009
11 (Ct. Rec. 248-2 at 25). Dr. Egilman proceeds from that basis to state his opinion
12 on specific causation:
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14
15 Mr. Newkirk's BO is consistent with epidemiological evidence linking
16 exposure of butter popcorn flavoring containing diacetyl to
17 bronchiolitis obliterans. . . . Mr. Newkirk's symptoms first appeared in
18 the early 1990s after years of popping and eating butter-flavored
19 microwavable popcorn. His symptoms are comparable both with other
20 known consumer cases of lung disease from in-home butter flavoring
21 exposures as well as industrial cases of BO and related lung disease in
22 workers exposed in butter flavoring and popcorn production plants.

23 Dr. Egilman Expert Report, Sept. 15, 2009 (Ct. Rec. 248-2 at 26).

24 Dr. Egilman also states his opinions more succinctly elsewhere: "Mr.
25 Newkirk, within a reasonable degree of medical certainty developed lung
26 disease as a result of inhaling flavors released by microwaved popcorn." Dr.
27 Egilman Expert Report, Sept. 15, 2009 (Ct. Rec. 248-2 at 25).
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1 The Court’s inquiry is whether Dr. Egilman’s opinions are (1) based on
2 sufficient facts or data and (2) the product of reliable principles and methods and
3 (3) whether Dr. Egilman has reliably applied those principles and methodology to
4 the facts of this case. Fed. R. Evid. 702. After conducting a holistic analysis of
5 those factors, the Court examines whether Dr. Egilman’s opinions would assist a
6 trier of fact to determine a material question at issue in this case.
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9 In Dr. Egilman’s Rule 26 expert disclosure report dated September 15, 2009,
10 Dr. Egilman articulated three bases on which he relied to determine Mr. Newkirk’s
11 exposure level: (1) a purported study of Wayne Watson’s home by John Martyny,
12 an industrial hygienist working for the National Jewish and Medical Research
13 Center with Dr. Rose; (2) a United States Environmental Protection Agency (EPA)
14 study (a.k.a. the “Rosati Study”) conducted in 2007; and (3) an initial expert report
15 of William Ewing (Ct. Rec. 248-2). In supplemental affidavits, Dr. Egilman offers
16 additional opinions regarding the relationship of diacetyl’s alleged injurious effects
17 in microwave popcorn and in the slurry used in microwave popcorn production.
18
19 *See* Dr. Egilman Aff., Apr. 19, 2010 (Ct. Rec. 323); Dr. Egilman Supp. Aff., Apr.
20 26, 2010 (Ct. Rec. 325). He also offers numerous other bases for and
21 methodologies supporting his opinions, and in some instances offers no basis or
22 methodology to support his opinions, all discussed below.
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1 *Whether Dr. Egilman's opinions are based on sufficient facts or data*

2 The first step of the inquiry is determining whether Dr. Egilman based his
3 opinions on sufficient facts or data. Where there is no indication of the reasoning
4 and methods underlying an expert witness's conclusion, the Court cannot make the
5 necessary findings of reliability and utility to a fact-finder under Fed. R. Evid. 702.
6 Therefore, those conclusions are properly excluded. *Claar v. Burlington Northern*
7 *R. Co.*, 29 F.3d 499, 502 (9th Cir.1994).
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9 To analyze the sufficiency of the underlying facts or data, the Court examines
10 Dr. Egilman's proffered support for his opinions. If Dr. Egilman has not cited to
11 reliable sources for his underlying facts or data, the Court can find that Dr. Egilman's
12 opinions fail the first step of the *Daubert* inquiry. *Claar*, 29 F.3d at 502. The Court
13 notes that Dr. Egilman does not cite to any support for many of his statements. The
14 most critical statement for which Dr. Egilman offers no indication of a basis or
15 methodology for support is that "[t]here is no important (medically relevant)
16 qualitative difference between the vapor from butter flavoring slurry in a mixing vat
17 and the vapor from butter flavoring slurry that is emitted from microwave popcorn
18 that would allow any inference that chemical emitted from popped corn would
19 neutralize the effects of diacetyl and other lung toxins that are emitted from MWPC
20 vapors." Dr. Egilman Aff., Apr. 19, 2010 (Ct. Rec. 323 at 5) (citing nothing). Dr.
21 Egilman also asserts, again without citing to any authority:
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2 The levels of diacetyl following microwave popcorn popping have
3 been found to be similar to those found in popcorn plants. Consumers
4 are therefore, also exposed to diacetyl in butter flavoring as a result of
5 popping microwave popcorn. They are also at risk of having
6 bronchiolitis obliterans and other health problems from diacetyl
inhalation.

7 Dr. Egilman Expert Report, Sept. 15, 2009 (Ct. Rec. 248-2 at 22) (citing nothing).

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9 However, diacetyl is sufficient and necessary to cause lung disease in
10 some people who inhale it, and it is present in microwave butter
11 flavorings above the vat and above the bag of popped corn. Therefore,
12 graphically, the facts are: Slurry=diacetyl=disease (undisputed); and
the same slurry in popcorn bag=diacetyl=disease.

13 Dr. Egilman Aff., Apr. 19, 2010 (Ct. Rec. 323 at 8) (citing nothing).

14 Each of these preceding statements are important foundational assumptions
15 on which Dr. Egilman relies for the remainder of his analysis. However, without
16 citation to any source, the Court must conclude that those foundational statements
17 are not based on sufficient facts or data. Reviewing all of the submitted exhibits
18 and reports that Dr. Egilman purportedly relied on for other portions of his report
19 and affidavits, the only report that appears to support his stated conclusion that
20 "slurry=diacetyl=disease, therefore "same slurry in popcorn bag=diacetyl=disease"
21 is the following statement from a 2007 U.S. Environmental Protection Agency
22 (EPA) study: "Numerous chemicals were measurable in air exiting the chamber
23 during microwave popcorn popping and opening. The predominant emitted
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1 chemicals agreed with those chemicals sampled by NIOSH inside microwave
2 popcorn manufacturing plants (Kullman et al., 2005) with the exception of methyl
3 ethyl ketone (MEK)” Jacky A. Rosati, Kenneth A. Krebs, Xiaoyu Liu, *Emissions*
4 *from Cooking Microwave Popcorn*, 47 *Critical Reviews in Food Science and*
5 *Nutrition* 701 (November 2007) (Ct. Rec. 330-15 at 752).

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8 However, there is nothing to support Dr. Egilman’s conclusion that is at the
9 heart of this case: that the vapors emitted from a microwave popcorn bag contain
10 the same proportion of chemicals or that all of the substances in the two instances
11 are identical. To the contrary, at least one study considering as a side question
12 whether the exposures of quality control workers popping microwave popcorn and
13 mixers of butter flavoring and other ingredients experienced different exposures
14 concluded that it was likely the exposures were qualitatively different: "Quality-
15 control workers may have been exposed to volatile flavoring ingredients that were
16 **qualitatively different** from those to which the other workers were exposed,
17 because of the high temperatures generated by popping the microwave popcorn;
18 however, their exposures exceed those likely to occur in the household by orders of
19 magnitude." Kathleen Kreiss, MD, et al., *Clinical Bronchiolitis Obliterans in*
20 *Workers at a Microwave-Popcorn Plant*, 347 *New England J. of Medicine* (August
21 2002) (Ct. Rec. 327-2 at 28) (emphasis added).

1 If there were sufficient facts or data on which Dr. Egilman could base his
2 formulae that vapors from slurry=diacetyl=disease and the vapors from the same
3 slurry in popcorn bag=diacetyl=disease, then he would have formed an analytical
4 bridge to his conclusions that microwave popcorn consumers are exposed to the
5 same harm from diacetyl in butter flavoring as microwave popcorn workers.
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7 Without support for these assertions, however, the statements illustrate the
8 analytical gap between the existing data and the opinion Dr. Egilman proffers.
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10 *Joiner*, 522 U.S. at 146.
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12 Dr. Egilman also purports to rely on Plaintiffs' expert William Ewing's
13 comparison of the average release of diacetyl in the home of another consumer,
14 Wayne Watson, to the EPA study results. Dr. Egilman Expert Report, Sept. 15,
15 2009 (Ct. Rec. 248-2 at 23). Dr. Egilman concludes regarding Mr. Ewing's study:
16 "[H]is calculations showed that Mr. Watson would have been exposed to levels
17 that have been found to cause disease in manufacturing workers." Dr. Egilman
18 Expert Report, Sept. 15, 2009 (Ct. Rec. 248-2 at 23) (citing "see repost [sic] of
19 William Ewing in this case").
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23 Yet Dr. Egilman's reliance on Mr. Ewing's report to support his conclusion is
24 misplaced. Mr. Ewing makes no reference to Mr. Watson, Mr. Watson's home, or
25 Mr. Watson's personal exposures to diacetyl in either Mr. Ewing's initial expert
26 report dated September 14, 2009 (Ct. Rec. 248-6) or Mr. Ewing's revised report
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1 dated December 14, 2009 (Ct. Rec. 248-7). Even if Dr. Egilman were correct that
2 Mr. Ewing's reports in this case (Ct. Rec. 248-6; Ct. Rec. 248-7) did include
3 diacetyl measurements from Mr. Watson's house, Dr. Egilman's reliance on those
4 alleged measurements would be problematic in light of the contradictions between
5 Mr. Ewing's initial expert report from September 14, 2009 (Ct. Rec. 248-6) and his
6 revised report from December 14, 2009 (Ct. Rec. 248-7). Dr. Egilman's reliance
7 on Mr. Ewing's supposed calculations regarding "Mr. Watson's" exposures is
8 based on insufficient data and facts.
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12 Dr. Egilman's testimony and reports contain many other examples of
13 conclusions and opinions that he fails to document, which are compiled in
14 Addendum B. In addition to not being supported by sufficient facts or data, Dr.
15 Egilman's unsupported statements would not assist the fact finder in deciding the
16 material questions in this case and may be misleading or confusing. *See United*
17 *States. v. Rincon*, 28 F.3d 921, 926 (9th Cir. 1994).
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21 **Whether Dr. Egilman has reliably applied principles and methodology to**
22 **the facts of this case**

23 In addition to determining whether Dr. Egilman's testimony and opinions
24 are based on sufficient facts or data, the Court must make a preliminary assessment
25 of whether Dr. Egilman's reasoning and methodology are scientifically valid.
26 *Daubert I*, 509 U.S. at 597. The Court examines Dr. Egilman's conclusions to
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1 determine whether those conclusions logically derive from the stated bases.

2 Evaluation of an expert’s opinion testimony “requires consideration of the
3 *overall* sufficiency of the underlying facts and data, and the reliability of the
4 methods, as well as the fit of the methods to the facts of the case.” *W.R. Grace*,
5 504 F.3d at 765. “To fulfill its gate-keeping role, the court must strike the
6 appropriate balance between admitting reliable, helpful expert testimony and
7 excluding misleading or confusing testimony.” *Rincon*, 28 F.3d at 926.

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11 In the previous section, the Court documented examples in which Dr.
12 Egilman provides no indication of external support for his conclusions. In other
13 parts of his reports and testimony, Dr. Egilman relies on existing data, mostly in
14 the form of published studies, but draws conclusions far beyond what the study
15 authors concluded, or Dr. Egilman manipulates the data from those studies to reach
16 misleading conclusions of his own. *See Daubert I*, 509 U.S. at 592-93.

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19 Dr. Egilman states that, “Dr. Cecile Rose, a pulmonary specialist from
20 National Jewish in Denver, Colorado, diagnosed and reported the first case of
21 consumer popcorn lung in 2007 in Mr. Wayne Watson of Colorado.” Dr. Egilman
22 Expert Report, Sept. 15, 2009 (Ct. Rec. 248-2 at 10). Dr. Egilman then relies
23 heavily on Dr. Rose’s diagnosis and study of Mr. Watson to support his opinion
24 that consumers other than Mr. Newkirk have developed bronchiolitis obliterans
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1 from microwave popcorn exposure. He writes, “With respect to MWPC⁵ Dr.
2 Cecile Rose determined that a consumer, Mr. Watson, probably contracted BO
3 from exposure to 1-2 bags of popcorn per day for several years. She felt so
4 strongly about this relationship that she reported it to the FDA.” Dr. Egilman Aff.,
5 Apr. 19, 2010 (Ct. Rec. 323 at 34-35).
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8 Dr. Rose wrote to the FDA in a letter dated July 18, 2007:

9 We have recently identified a patient with significant lung disease
10 whose clinical findings are similar to those described in affected
11 workers, but whose inhalational exposure is as a heavy, daily
12 consumer of butter flavored microwave popcorn.
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14
15 (Ct. Rec. 249-5 at 723)

16 We measured airborne levels of diacetyl during microwave popcorn
17 preparation in the patient’s home and found levels similar to those
18 reported in the microwave oven exhaust area in the quality assurance
19 unit of the microwave popcorn manufacturing plant where affected
20 workers were initially described.
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23 (Ct. Rec. 249-5 at 724)
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26 ⁵ “MWPC” is Dr. Egilman’s shorthand for microwave popcorn (Ct. Rec. 323 at 5,
27 note 1).
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2 Dr. Egilman considered Dr. Rose’s findings “evidence that slurry vapors
3 from microwave popcorn can cause BO in some people, including workers and
4 consumers.” Dr. Egilman Aff., Apr. 19, 2010 (Ct. Rec. 323 at 34-35). Dr.
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6 Egilman continues, “It is not surprising that there are few known cases. Even
7 highly toxic substances like asbestos, which most US residents have inhaled,
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9 causes relatively few mesotheliomas in people who have not worked directly with
10 the product.” Dr. Egilman Aff., Apr. 19, 2010 (Ct. Rec. 323 at 34-35).

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12 However, Dr. Egilman’s underlying methodology for his conclusions
13 regarding Dr. Rose’s work is not reliable because he provides no basis to
14 extrapolate from Dr. Rose’s letter regarding a single patient to the conclusion that
15 slurry vapors are the same whether inhaled over a tank at a popcorn plant or from a
16 bag of microwave popcorn, and that those vapors can cause bronchiolitis obliterans
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18 in consumers. In addition, Dr. Egilman acknowledges in his April 19, 2010,
19 affidavit that Dr. Rose did not publish the exposure levels measured in Mr.
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21 Watson’s home (Ct. Rec. 323 at 15). Therefore, Dr. Egilman had no identifiable
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23 data on which to base his conclusions, and the Court has no means to analyze
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25 whether the underlying data is reliable.

26 Dr. Egilman claims that Dr. Rose’s statement that her “conclusions were
27 reviewed by [her] colleagues” is a sufficient basis on which Dr. Egilman can rely
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1 for his conclusions, including: “[c]learly Mr. Newkirk had sufficient exposure to
2 cause disease” Dr. Egilman Aff., Apr. 19, 2010 (Ct. Rec. 323 at 16 and note
3 11). Dr. Rose’s testimony is not the subject of the *Daubert* challenge. However,
4 Dr. Egilman relies on Dr. Rose’s statement without providing any support that
5 such reliance is justified by sufficient facts or data. Dr. Egilman does not provide
6 any of Dr. Rose’s peer review. Although lack of peer review is not necessarily
7 fatal to the admissibility of an expert opinion, “[i]n the absence of independent
8 research or peer review, experts must explain the process by which they reached
9 their conclusions and identify some type of objective source demonstrating their
10 adherence to the scientific method.” *In re Phenylpropnaolamine (PPA) Products*
11 *Liability Litigation*, 289 F.Supp.2d 1230, 1238 (W.D.Wash. 2003). More
12 importantly in this case, Dr. Rose does not even purport to adhere to the scientific
13 method or assert that her conclusions should be extrapolated to other consumers in
14 the absence of publication or peer review, as she herself qualifies her conclusions
15 as follows: “It is difficult to make a causal connection based on a single case
16 report. We cannot be sure that this patient’s exposure to butter flavored
17 microwave popcorn from daily heavy preparation has caused his lung disease.
18 However, we have no other plausible explanation.”
19 Dr. Cecile Rose July 18, 2007, Letter to the Food and Drug Administration (Ct.
20 Rec. 249-5 at 724). That statement does not mean that no other plausible
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1 explanation exists, which appears to be Dr. Egilman's conclusion.

2 Dr. Rose reiterated in a deposition taken on April 7, 2010, that she "wasn't
3 sure" at the time that she first consulted on Mr. Watson's case, nor at the time of
4 the deposition, "what the cause of [Mr. Watson's] condition is" (Ct. Rec. 394-3,
5 Exh. C, Deposition of Dr. Cecile Rose for Watson v. Dillon Companies, Inc., et al.
6 at 99). She added, "But I don't have to be sure" (Ct. Rec. 394-3, Exh. C,
7 Deposition of Dr. Cecile Rose for Watson v. Dillon Companies, Inc., et al. at 99).
8 Dr. Rose was not stating her conclusions for purposes of litigation in federal court;
9 rather she shared her observations with the Food and Drug Administration possibly
10 in an abundance of caution.

11 Dr. Rose's measurements were based on testing conducted by Dr. John
12 Martyny in the kitchen at National Jewish Health in February 2007, not in Mr.
13 Watson's kitchen or in Mr. Newkirk's kitchen (Ct. Rec. 394-4, Exh. D, Deposition
14 of John Martyny at 18). The brands of popcorn Dr. Martyny popped included
15 Orville Redenbacher and Act II Butter popcorn. John Martyny Dep., Apr. 14,
16 2010 (Ct. Rec. 394-4 at 182). Dr. Martyny explained that there were more
17 measurements from some popcorn brands than others because he let certain
18 products pop longer than others or sampled some products more than others. John
19 Martyny Dep., Apr. 14, 2010 (Ct. Rec. 394-4 at 182). He elaborated that there
20 was "no real rhyme or reason" to the methodology and clarified that the testing was
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1 not part of "a huge study or anything We were just simply trying to just see
2 what kind of levels we would see when we popped popcorn from a microwave."
3 John Martyny Dep., Apr. 14, 2010 (Ct. Rec. 394-4 at 182). He further explained
4 that he did not draft a report on his findings based on the kitchen tests or the
5 measurements taken from Mr. Watson's home because the measurements in Mr.
6 Watson's home "weren't, obviously, very significant" and "were all nondetect."
7 John Martyny Dep., Apr. 14, 2010 (Ct. Rec. 394-4 at 183).

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11 Dr. Egilman relies on the findings of Dr. Rose and Dr. Martyny despite their
12 own reflections that the methodology underlying their work with Mr. Watson
13 could not support extrapolating to general causation for a broader group of
14 consumers. Therefore, Dr. Egilman's opinions based on Dr. Rose and Dr.
15 Martyny's examination of Mr. Watson's potential exposures are not based upon
16 sufficient facts or data or the product of reliable principles and methods. *See* Fed.
17 R. Evid. 702.

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21 Dr. Egilman's opinions fall below the threshold standard of scientific
22 validity in other ways. To qualify as "scientific knowledge" under Fed. R. Evid.
23 702, "an inference or an assertion must be derived by the scientific method."
24 *Daubert I*, 509 U.S. at 590. "Coming to a conclusion first and then doing research
25 to support it is the antithesis of this method. Certainly scientists may form initial
26 tentative hypotheses. However, scientists whose conviction about the ultimate
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1 conclusion of their research is so firm that they are willing to aver under oath that
2 it is correct prior to performing the necessary validating tests could properly be
3 viewed by the district court as lacking the objectivity that is the hallmark of the
4 scientific method.” *Claar v. Burlington Northern R. Co.*, 29 F.3d 499, 502-03 (9th
5 Cir.1994).
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8 Dr. Egilman’s conclusions in his September 15, 2009, report that “levels of
9 diacetyl exposure below and around 1 ppm can cause bronchiolitis obliterans and
10 other respiratory illnesses” and that “Mr. Newkirk, within a reasonable degree of
11 medical certainty developed lung disease as a result of inhaling flavors released by
12 microwaved popcorn,” Dr. Egilman Expert Report, Sept. 15, 2009 (Ct. Rec. 248-2
13 at 50), preceded his actual estimation of the levels of diacetyl to which Mr.
14 Newkirk was exposed. Dr. Egilman Supp. Aff., Apr. 26, 2010 (Ct. Rec. 325 at 1-
15 2) and Dr. Egilman Aff., Apr. 19, 2010 (Ct. Rec. 323 at 17). In his affidavit of
16 April 19, 2010, for the first time, he applies a formula to calculate “Mr. Newkirk’s
17 actual exposures” even though Dr. Egilman’s formula is based on a variety of
18 studies that existed prior to his September 15, 2009, expert witness report in which
19 he stated his conclusions (Ct. Rec. 323 at 17) (relying on Richard Kanwal, MD,
20 MPH, et al., *Evaluation of Flavorings-Related Lung Disease Risk at Six*
21 *Microwave Popcorn Plants*, , 48 *Journal of Occupational and Environmental*
22 *Medicine* 149 (February 2006) (Ct. Rec. 248-20); Richard Kanwal, et al., *NIOSH*
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1 *Health Hazard Evaluation Report, HETA # 2000-0401-2991, Gilster-Mary Lee*
2 *Corporation, Jasper Missouri* (January 2006) (Ct. Rec. 248-18), and Richard
3 Kullman, et al., *NIOSH Health Hazard Evaluation Report, HETA #2006-0195-*
4 *3044, Yatsko’s Popcorn, Sand Coulee, Montana* (April 2007). In addition, Dr.
5 Egilman refers to the “attached analysis,” which includes a copy of the report
6 conducted by Dr. Su-Jung (Candace) Tsai and Dr. Michael Ellenbecker at Dr.
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8 Egilman’s direction and is dated April 23, 2010 (Ct. Rec. 326).
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11 In summary, the chronology of Dr. Egilman’s process or methodology for
12 determining consumer exposure levels to diacetyl was as follows. Prior to
13 September 2009, Dr. Egilman relies on studies of diacetyl exposure levels for
14 workers conducted in microwave popcorn plants using a number of different
15 microwave popcorn brands and types. On September 15, 2009, Dr. Egilman drafts
16 his expert opinion report stating that consumer exposure levels to diacetyl would
17 be equivalent to exposure levels to microwave popcorn workers and could cause
18 bronchiolitis obliterans and that Mr. Newkirk contracted bronchiolitis obliterans
19 from microwave popcorn vapor (Ct. Rec. 248-2). In January 2010, Dr. Egilman
20 defends his conclusions in a deposition. Dr. Egilman Dep., Jan. 26, 2010 (Ct. Rec.
21 248-19). Between the January deposition and April, Dr. Egilman commissioned a
22 study by Drs. Tsai and Ellenbecker to “figure out how long diacetyl stayed in the
23 air based on physics and chemistry” and to “actually calculate a dose or an
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1 exposure.” Dr. Egilman Dep., April 27, 2010, In the Matter of: *Elaine Khoury, et*
2 *al. v. Conagra Foods, Inc. et al.* (Ct. Rec. 509-18 at 83-84). Finally, in April 2010,
3 Dr. Egilman augmented his expert opinion through lengthy affidavits in this case
4 and through a deposition in another case providing for the first time calculations
5 based on the Tsai and Ellenbecker formulae developed for litigation purposes. Dr.
6 Egilman Aff., Apr. 19, 2010 (Ct. Rec. 323); Dr. Egilman Supp. Aff., Apr. 26, 2010
7 (Ct. Rec. 325); Dr. Egilman Dep., Apr. 27, 2010, In the Matter of: *Elaine Khoury,*
8 *et al. v. Conagra Foods, Inc. et al.* (Ct. Rec. 509-18 at 83-84). This is not a
9 reliable scientific method of drawing a hypothesis, conducting studies to test the
10 hypothesis, and then arriving at a conclusion. *Claar*, 29 F.3d at 502-03.

15 Dr. Egilman also fails to apply reliable scientific methods when he
16 extrapolates from extremely small samplings to make sweeping conclusions. For
17 example, after reciting that the ConAgra Marion plant had two quality control
18 workers who were potentially exposed to 18 ppb concentration of diacetyl and
19 whose spirometry tests returned abnormal results, Dr. Egilman adopts the position
20 that exposure of 18 ppb is sufficient to cause spirometry abnormalities, despite the
21 fact that a report from only two people is an extremely small sample (Ct. Rec. 323
22 at 40-41). *See Henricksen v. ConocoPhillips Co.*, 605 F.Supp.2d 1142, 1168
23 (E.D.Wash. 2009) (excluding an expert dose opinion where small sample sizes
24 resulted in great uncertainty as to potential rate of error).

1 Similarly, Dr. Egilman refutes Defendants’ statement that “QC workers
2 collected slurry samples” with the following statements: “I have performed a site
3 visit to the Jasper GML⁶ plant and interviewed QC workers. They did not collect
4 ‘slurry samples.’ They did not analyze ‘slurry samples.’ Quality control work
5 consisted of popping and tasting microwave popcorn.” Dr. Egilman Aff., Apr. 19,
6 2010 (Ct. Rec. 323 at 19). The Court finds that Dr. Egilman’s reliance on a single
7 “site visit to the Jasper GML plant” and accompanying interviews is not a reliable
8 method through which to conclude that no quality control workers in any
9 microwave popcorn plant ever collect slurry samples. *See Rink v. Cheminova, Inc.*,
10 400 F.3d 1286, 1292 (11th Cir.2005) (excluding expert testimony because expert’s
11 method of transposing data from other studies based on such conjecture and rough
12 approximation that the method lacked the “intellectual rigor” required by *Daubert*).

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18 Dr. Egilman also relies on Kathleen Kreiss’s study in a misleading or
19 convoluted way to support his general causation opinion that diacetyl causes
20 bronchiolitis obliterans in microwave popcorn consumers. Dr. Egilman Expert
21 Report, Sept. 15, 2009 (Ct. Rec. 248-2 at 42) (relying on Kathleen Kreiss, MD, et
22 al., *Clinical Bronchiolitis Obliterans in Workers at a Microwave-Popcorn Plant*,
23 347 *New England J. of Medicine* (August 2002)). According to Dr. Egilman, the
24 Kreiss article states that “[e]mployees who worked in quality control, maintenance
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28 ⁶ Gilster-Mary Lee

1 packaging or mixing had significantly higher rates of respiratory symptoms than
2 those who worked in other areas of the plant with lower exposures to diacetyl” and
3 that “workers in the higher exposure category were 6.2 times as likely to
4 experience exertional shortness of breath than those working in the low-exposure
5 areas of the plant.” Dr. Egilman Expert Report, Sept. 15, 2009 (Ct. Rec. 248-2 at
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8 42).

9 However, this report was based on survey responses of 117 employees at the
10 Missouri popcorn plant where the cluster of 8 employees with severe bronchiolitis
11 obliterans was first identified in 2000. Kathleen Kreiss, MD, et al., Clinical
12 Bronchiolitis Obliterans in Workers at a Microwave-Popcorn Plant, 347 New
13 England J. of Medicine (August 2002) (Ct. Rec. 327-2 at 21). The study does not
14 address consumer exposure and does not support extrapolating from the
15 occupational context to the consumer context, which is the causation issue in this
16 case. It is true that the study includes the five quality assurance workers who
17 participated in the survey in the following finding: “Workers in the microwave-
18 popcorn production areas (including quality-control and maintenance workers) had
19 significantly higher rates of exertional shortness of breath, regular trouble with
20 breathing, a combination of two or more respiratory symptoms, unusual fatigue,
21 and any systemic symptoms than minimally exposed workers in other areas of the
22 plant” (Ct. Rec. 327-2 at 23). However, the study's central finding was that "the
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1 estimated cumulative exposure to diacetyl was correlated with chronic effects on
2 lung function, in terms of both the rates of abnormalities on spirometry and the
3 average decreases in FEV1 in quartiles of increasing cumulative exposure” (Ct.
4 Rec. 327-2 at 27).

6 The study's measurements of exposure at the plant revealed that air samples
7 in the mixing room work area contained a mean concentration of diacetyl of 32.27
8 parts per million (ppm) while the concentration of diacetyl in the samples taken in
9 the quality control or maintenance work area was 0.56 ppm. The authors'
10 recommendation to "isolate[] . . . ventilation in the mixing room from that in other
11 areas of the plant" indicates that butter-flavoring vapors from the mixing rooms
12 reached other areas of the plant (Ct. Rec. 327-2 at 28). The authors further found:
13 "Quality-control workers may have been exposed to volatile flavoring ingredients
14 that were **qualitatively different** from those to which the other workers were
15 exposed, because of the high temperatures generated by popping the microwave
16 popcorn; however, their exposures exceed those likely to occur in the household by
17 orders of magnitude" (Ct. Rec. 327-2 at 28) (emphasis added).

23 Dr. Egilman then cites a December 2004 NIOSH health hazard evaluation
24 report for one popcorn plant, the ConAgra Snack Foods plant in Marion, Ohio,
25 for the proposition that: “[a]ffected workers have been found at plants with mean
26 area exposures as low as 0.02 ppm.” (Id. at 22). Dr. Egilman's selection of the 0.02
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1 ppm diacetyl concentration measurement is misleading when read in the context of
2 the full Marion report. *See* Richard Kanwal and Greg Kullman, *NIOSH Health*
3 *Hazard Report at ConAgra Snack Foods, Marion, Ohio* at iv (December 2004) (Ct.
4 Rec. 249 at 567).

6 Specifically, NIOSH scientists first visited the Marion, Ohio, ConAgra plant
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8 in January 2003 and observed the following: "[W]orkers handled many different
9 butter flavorings in open containers and poured the flavorings into open tanks of
10 heated soybean oil. The tanks did not have local exhaust ventilation and the
11 workers did not use respiratory protection. Oil and flavoring mixing activities and
12 all heated tanks were located in one room (slurry room) adjacent to the packaging
13 line area, and the air pressure in this room was positive relative to the packing line
14 area." Richard Kanwal and Greg Kullman, *NIOSH Health Hazard Evaluation*
15 *Report, HETA # 2004-0112-2949, ConAgra Snack Foods, Marion, Ohio*
16 (December 2004) (Ct. Rec. 249 at 567). NIOSH staff conducted health and
17 environmental surveys of the plant in March 2003 and found the following mean
18 time weighted average diacetyl air concentrations, according to areas of the plant:
19 (1) 1.14 ppm in the slurry/mixing room, where 3 of the 12 current slurry room
20 workers had health findings "consistent with bronchiolitis obliterans"; (2) 0.02
21 ppm in the packaging area, where five workers had "fixed obstruction on
22 spirometry, normal diffusing capacity, and no history of work in the slurry room";
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1 and (3) 0.018 ppm in the quality assurance lab before an enclosure with exhaust
2 ventilation for the microwave ovens was installed (Ct. Rec. 249 at 581).

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4 Two of the eleven workers in the quality assurance area had abnormal
5 spirometry, with one demonstrating obstruction or mixed pattern abnormalities and
6 the other demonstrating restriction (Ct. Rec. 249 at 588). Between January and
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8 March 2003, ConAgra made adjustments to the slurry room ventilation, and by the
9 time the environmental study was undertaken in March, the slurry room had
10 negative air pressure relative to the packaging area (Ct. Rec. 249 at 567). ConAgra
11 also made changes to the ventilation system between January and March that
12 "decreased the potential for slurry room emissions to contaminate the packaging
13 area." In light of these changes, the NIOSH report proposed that "the March 2003
14 diacetyl air concentrations in the packaging area may underestimate past
15 exposures" and concluded that "higher exposures in the past may explain the
16 greater than expected numbers of packaging-line workers" reporting respiratory
17 ailments, and revealing respiratory obstruction on NIOSH spirometry tests (Ct.
18 Rec. 249 at 581). *See also* (Ct. Rec. 249 at 567).

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20 The Marion study, therefore, does not purport to show an association
21 between the 0.02 ppm diacetyl concentration and the workers' negative health
22 effects, as Dr. Egilman's indicates. *See* Richard Kanwal and Greg Kullman,
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28 *NIOSH Health Hazard Evaluation Report, HETA # 2004-0112-2949, ConAgra*

1 *Snack Foods, Marion, Ohio* (December 2004) (Ct. Rec. 249). Moreover, Dr.
2 Egilman cites no other authority for the analytical step he takes from observing that
3 there is no accepted "safe" level of diacetyl exposure to concluding that even
4 concentrations as low as 0.02 ppm are harmful. There is, then, no reliable
5 methodology supporting Dr. Egilman's opinion that mean time weighted average
6 diacetyl air concentrations as low as 0.02 ppm can cause bronchiolitis obliterans or
7 other airways obstruction.
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11 Dr. Egilman also praises the Marion study for combining into one group the
12 workers in the slurry room and the quality assurance lab workers. Dr. Egilman
13 Aff., Apr. 19, 2010 (Ct. Rec. 323 at 20); Richard Kanwal and Greg Kullman,
14 *NIOSH Health Hazard Evaluation Report, HETA # 2004-0112-2949, ConAgra*
15 *Snack Foods, Marion, Ohio* (December 2004) (Ct. Rec. 249 at 576). However,
16 that study combined slurry room and quality assurance lab workers solely for
17 measurements recorded in a single table that reported the "Numbers of slurry room
18 and QA workers reporting respiratory symptoms and physician diagnosed
19 respiratory disease, and with abnormal spirometry test results, compared to the
20 numbers expected from NHANES III⁷ (adjusted for age, sex, race, and smoking
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24 ⁷ "NHANES III" is the abbreviation for the National Health Examination Survey,
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26 Cycle III. (Ct. Rec. 249 at 573); Centers for Disease Control and Prevention web
27 site, http://www.cdc.gov/nchs/nhanes/nhanes_questionnaires.htm (last visited June
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1 status). (Ct. Rec. 249 at 590). The report explained the decision to combine the
2 slurry room and QA workers as follows: “Slurry room and QA lab workers were
3 combined into one group due to the small numbers of workers in each group, and
4 because of the known occurrence of increased risk in both these groups in other
5 microwave popcorn plants” (Ct. Rec. 249 at 576). Yet Dr. Egilman relies on that
6 statement to support his much broader conclusion that “More importantly, this is
7 further evidence that NIOSH did not consider qualitative differences between
8 exposures for mixers and QA workers to be important.” Dr. Egilman Aff., Apr.
9 19, 2010 (Ct. Rec. 323 at 20). Again, there is an analytical gap between this
10 conclusion and the content of the Marion report.
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15 Nor does Dr. Egilman reliably apply principles and methodologies from
16 animal studies to the facts of this case. Dr. Egilman supports his conclusions
17 regarding the dose-response relationship by citing to an animal study of respiratory
18 symptoms in rats. Dr. Egilman Expert Report, Sept. 15, 2009 (Ct. Rec. 248-2 at
19 43) (citing “Hubbs AF, Battelli LA, Goldsmith WT, et al. Necrosis of Nasal and
20 Airway Epithelium in Rats Inhaling Vapors of Artificial Butter Flavoring. Toxicol
21 Appl Pharmacol 2002;185:128-135”). Dr. Egilman states, “Several animal studies
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<http://www.cdc.gov/nchs/nhanes.htm> (last visited June 22, 2010).

1 have shown a relationship between diacetyl exposure and decreased lung function
2 and necrosis of airway epithelial tissue. Dr. Egilman Expert Report, Sept. 15, 2009
3 (Ct. Rec. 248-2 at 44-46) (citing “Morgan DL, Flake G, Kirby PJ. Respiratory
4 Tract Toxicity of Diacetyl in C57BL/6 Mice. SOT 2006 Annual Meeting, Abstract
5 1029; 22 Hubbs AF. Battelli LA, Goldsmith WT, et al. Necrosis of Nasal and
6 Airway Epithelium in Rats Inhaling Vapors of Artificial Butter Flavoring. Toxicol
7 Appl Pharmacol 2002; 185: 128-135; BASF Department of Toxicology.
8 Confidential Report: Study on the acute inhalation of toxicity LC50 of diacetyl
9 FCC as a vapor in rats, 4-hour exposure. 1993”). Dr. Egilman noted that 2 of 19
10 rats exposed to medium or high (above 285 ppm) exposure of diacetyl died after 6
11 hours of exposure. Dr. Egilman Expert Report, Sept. 15, 2009 (Ct. Rec. 248-2 at
12 45).

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18 Extrapolating from the animal studies, Dr. Egilman draws the following
19 conclusion under the label of “analogy”:

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21 Analogy: Other substances have proved toxic when inhaled, some also
22 causing changes in the respiratory epithelium. O₃ (ozone) has been
23 shown to change the tracheal epithelia of guinea pigs and cause
24 airway reactivity both in vitro and in vivo. [internal citation omitted]
25 Chlorine and other exposures are accepted causes of BO. In all cases
26 these cause-effect relationships were accepted by the medical
27 community based on case reports only. The analysis of the scientific
28 data according to Hill's considerations clearly shows that diacetyl is a
cause or contributing cause of bronchiolitis obliterans and other
respiratory tract disease in humans.

1 Dr. Egilman Expert Report, Sept. 15, 2009 (Ct. Rec. 248-2 at 46-47).

2 Expert opinion relying on animal studies to reach an opinion on causation in
3 humans is usually admissible when the expert explains how and why the results of
4 the animal toxicological study can be extrapolated to humans. *General Electric*
5 *Co. v. Joiner*, 522 U.S. 136, 143-45 (1997) (holding that district court did not
6 abuse its discretion in excluding expert testimony on causation based on expert's
7 failure to explain how animal studies supported expert's opinion that agent caused
8 disease in humans); *Lopez v. Wyeth-Ayerst Laboratories, Inc.*, 139 F.3d 905
9 (9th Cir. 1998) (recognizing that animal studies can contribute to an expert's
10 scientific conclusion as to causation but finding expert's opinions should have been
11 excluded where there was an analytical gap between the study's findings and the
12 experts' conclusions regarding the specific plaintiff); *In re Paoli R.R. Yard PCB*
13 *Litig.*, 35 F.3d 717, 743 (3d Cir. 1994), cert. denied, 513 U.S. 1190 (1995). Dr.
14 Egilman offers no analytical bridge between the animal studies finding harm from
15 diacetyl exposure to rats and his conclusion that those studies demonstrate that
16 diacetyl exposure causes decreased lung function and necrosis of epithelial tissue
17 in humans. He offers no explanation for how and why the results of those studies
18 can be extrapolated to humans. *See Joiner*, 522 U.S. at 143-45. His methodology
19 with respect to relying on animal studies to support his opinions is unreliable for
20 purposes of FRE 702.
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2 Dr. Egilman also cited the "Rosati Study," an EPA study conducted in 2007
3 regarding seventeen types of microwave popcorn from eight different brands. Dr.
4 Egilman Expert Report, Sept. 15, 2009 (Ct. Rec. 248-2, at 48); Jacky A. Rosati,
5 Kenneth A. Krebs, Xiaoyu Liu, *Emissions from Cooking Microwave Popcorn*, 47
6 *Critical Reviews in Food Science and Nutrition* 701 (November 2007) (Ct. Rec.
7 330-15 at 755). In his April 27, 2010, deposition, Dr. Egilman was asked as to
8 whether he considered the ConAgra-commissioned "Aspen" study or the
9 EPA/Rosati studies to be exposure studies, and he replied yes. (Ct. Rec. 394-2 at
10 86) Specifically, Dr. Egilman also was asked the following questions:
11

12 Q. Did you consider the Aspen study to be an exposure study?

13 A. That's how they first defined it, yes.

14 Q. Do you consider the Rosati study done from the EPA to be an
15 exposure study?

16 A. Why don't you define what you mean by exposure.

17 Q. Fair enough. Do you understand that the purpose of the Aspen
18 study, or a purpose of the Aspen study was to do quantitative
19 exposures for a consumer?

20 A. That's my understanding.
21

22 (Ct. Rec. 394-2 at 86).
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24 However, the EPA/Rosati study, by its own terms, is not an exposure study.
25 The study report concludes with the statement: "This was a source characterization
26 study and the potential exposure to the compounds measured and any associated
27 potential risks were not estimated." Jacky A. Rosati, Kenneth A. Krebs, Xiaoyu
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1 Liu, *Emissions from Cooking Microwave Popcorn*, 47 Critical Reviews in Food
2 Science and Nutrition 701 (November 2007) (Ct. Rec. 330-15 at 755). The EPA
3 study made no findings as to whether the amount of diacetyl emitted was enough
4 to cause respiratory obstruction; it did not measure the diacetyl concentration to
5 which a consumer would be exposed during or after popping popcorn in a
6 microwave (Ct. Rec. 330-15 at 755). The EPA instead measured the chemicals
7 emitted from a bag of popped microwave popcorn (Ct. Rec. 330-15 at 755). Dr.
8 Egilman’s characterization of the study as an exposure study when, by its own
9 terms, it is not, indicates that Dr. Egilman did not reliably apply the methodology
10 of that study to the facts of this case. *See* Fed. R. Evid. 702.
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15 Dr. Egilman also includes legal conclusions throughout his expert report and
16 affidavits. Yet Dr. Egilman has not presented any credentials to support his
17 qualifications as a legal expert. Expert testimony is properly excluded where the
18 witness is no more capable than the factfinder to draw a conclusion. *See*
19 *Nationwide Transp. Fin. v. Cass Info. Sys.*, 523 F.3d 1051, 1059-60 (9th Cir.2008)
20 (“[A]n expert witness cannot give an opinion as to her legal conclusion, i.e., an
21 opinion on an ultimate issue of law.”) (quoting *Hangerter v. Provident Life &*
22 *Accident Ins. Co.*, 373 F.3d 998, 1016 (9th Cir.2004)). For example, Dr. Egilman
23 fills his expert report with “opinions” that are actually legal conclusions, such as
24 “Opinion: ConAgra knew that exposures from popping popcorn presented a
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1 potential inhalation health hazard and continued selling butter popcorn flavoring
2 containing diacetyl until 2007. They failed to warn consumers or customers
3 (retailers) about this risk.” (Ct. Rec. 248-2 at 65). Elsewhere he labors to
4 distinguish a case relied on by Defendants’ counsel in their briefing to this court,
5 *Henricksen v. Conoco Phillips Co.*, 605 F.Supp.2d 1142 (E.D.Wash. 2009). Dr.
6 Egilman states that the difference is that “[b]enzene was established as a
7 leukemogen (a leukemia-causing substance) in studies where it was studied alone,
8 not a component of gasoline or any other mixture.” (Ct. Rec. 323 at 9) (citing
9 nothing). However, Dr. Egilman fails to cite to any authority regarding that
10 proposition. In addition, he fails to establish any personal knowledge regarding
11 benzene testing.

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16 **Whether Dr. Egilman’s testimony is the product of reliable principles and**
17 **methods**
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19 The Court concludes that one illustration of lack of reliable methodology is
20 when the expert has arrived at contradictory conclusions using the same
21 methodology. In his April 2010 affidavits, Dr. Egilman discounts some of the very
22 studies he relied upon in his September 15, 2009, expert report and April 2010
23 affidavits with conclusory statements, such as “unreliable due to humidity.” For
24 example, after repeatedly relying on NIOSH data and conclusions he states:
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27 Unfortunately most studies have based exposure measurements on
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1 NIOSH method 2557; the results of these studies have been shown to
2 be unreliable due to humidity. Therefore, most of the dose estimates
3 taken by ConAgra and NIOSH are incorrect and cannot be relied on to
4 establish a dose-response relationship for chronic exposures. Some
5 exposure measurements were taken using a Fourier transform infrared
6 (FTIR) gas analyzer. At the present time, there is no indication that
7 these measurements are inaccurate. These were used to establish peak
8 exposures from slurry vapors emitted from MWPC.

7 Dr. Egilman Aff., Apr. 19, 2010 (Ct. Rec. 323 at 38).

8
9 Another example of internal contradiction is Dr. Egilman's treatment of
10 gastroesophageal reflux disease (GERD) and bronchiolitis obliterans syndrome.
11 He states that the only study that has been released on the subject was published
12 after his first expert report and stated that "prospective studies are now required to
13 investigate a causal association between GERD and the development of BOS"

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15 Dr. Egilman Aff., Apr. 19, 2010 (Ct. Rec. 323 at 72). Despite that quotation from
16 the only published study, Dr. Egilman states: "Acid reflux did not cause BO to
17 occur earlier than it otherwise would have" (Ct. Rec. 323 at 72). Dr. Egilman
18 provides no basis for his confidence in making a conclusion that the authors
19 explicitly stated was premature without additional data.
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23 Dr. Egilman then applies contradictory logic in attempting to distinguish
24 between vapors from microwave popcorn and slurry vapors in the manufacturing
25 work site by stating that "[t]hese vapors have not been tested, and therefore, there
26 is no way to be sure that the composition of inhaled vapors is actually different at
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1 all.” Dr. Egilman Aff., Apr. 19, 2010 (Ct. Rec. 323 at 7). The same logic can be
2 applied to the central thrust of Dr. Egilman’s opinion: if the vapors have not been
3 tested, how can Dr. Egilman assert that the vapors from microwave popcorn are
4 qualitatively identical to slurry vapors and are causing the same harm that slurry
5 vapors likely caused?
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8 Dr. Egilman proceeds to contradict himself again in attempting to explain
9 why exposure to naturally occurring diacetyl through consumption of foods such as
10 “coffee, dairy products, yogurt, wine, beer and other products” does not contribute
11 to lung disease. Dr. Egilman Aff., Apr. 19, 2010 (Ct. Rec. 323 at 70-71). Those
12 contradictions, set out in the following paragraphs, cast further doubt on Dr.
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15 Egilman’s methodology. Dr. Egilman states:

16 It is true that coffee, dairy products, yogurt, wine, beer and other
17 products all contain diacetyl. . . . I am unaware of any peer reviewed
18 published studies that have measured exposures to these other
19 products that cause lung disease. I understand that most of these
20 products release so little diacetyl that it would not be measurable with
21 standard methods (Personal communication with Mark Rigler).
22 Newkirk deposition. Therefore, I consider any exposure to diacetyl
23 that constituted less than .00001 percent of his total exposure to be
trivial, and I would not consider it to be a significant contributing
factor in causing his disease.

24 Dr. Egilman Aff., Apr. 19, 2010 (Ct. Rec. 323 at 70).

25
26 Diacetyl concentrations in naturally fermented products for
27 consumption range from 0.5-1.0 ppM (less than .001%). Apt, C.M.
28 (Ed.). On the other hand, diacetyl comprises 2-10% or more of slurry.
ACT II Butter Lover’s, one of two ConAgra microwave popcorn

1 flavors Mr. Newkirk regularly consumed, contained 28.7 ppM of
2 diacetyl at the point source when a popped bag of microwave popcorn
3 was opened. Watson report attachment B at 38. Therefore, diacetyl
4 exposures from foods are thousands to millions of times lower than
5 those from slurry vapors emitted from microwave popcorn or above
6 mixing tanks. If concentrations of diacetyl in these “natural” products
7 were shown to be comparable to those from slurry, they could have
8 contributed to his lung disease. Under these hypothetical
9 circumstances, Mr. Newkirk’s exposure to diacetyl from naturally
10 fermented products combined with his exposure to diacetyl from
11 artificial butter flavoring in microwave popcorn, would have been
12 joint causes of his lung disease.

13 Dr. Egilman Aff., Apr. 19, 2010 (Ct. Rec. 323 at 70-71).

14 These two paragraphs again illustrate problems in Dr. Egilman’s opinions as
15 a whole. First, Dr. Egilman states that he is “unaware of any peer reviewed
16 published studies that have measured exposures to these other products that cause
17 lung disease” but then asserts that “[d]iacetyl concentrations in naturally fermented
18 products for consumption range from 0.5-1.0 ppM (less than .001%).” Dr.
19 Egilman Aff., Apr. 19, 2010 (Ct. Rec. 323 at 70-71). It is unclear whether Dr.
20 Egilman is saying in the first statement that the products cause lung disease but
21 have not been measured in peer reviewed studies or, alternatively, that there have
22 been no peer reviewed studies that have produced exposure measurements showing
23 that exposure rates to naturally-occurring diacetyl are high enough to cause lung
24 disease. If Dr. Egilman intends to say the former, that exposures to diacetyl
25 through consumption of certain foods have not been measured in peer-reviewed
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1 studies, then his statement a few lines down that “[d]iacetyl concentrations in
2 naturally fermented products for consumption range from 0.5-1.0 ppM” indicates
3 that diacetyl concentrations, to the contrary, have been measured. Dr. Egilman’s
4 vague citation to “Apt, C.M. (Ed.)” does nothing to clarify the matter. Dr. Egilman
5 Aff., Apr. 19, 2010 (Ct. Rec. 323 at 71).
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8 Second, Dr. Egilman provides no explanation for why 1ppm concentration
9 of diacetyl in fermented foods is insignificant when he vigorously opined that
10 “studies also suggest that levels of diacetyl exposure below and around 1 ppm can
11 cause BO and other respiratory illnesses.” Dr. Egilman Aff., Apr. 19, 2010 (Ct.
12 Rec. 323 at 70-71); Dr. Egilman Expert Report, Sept. 15, 2009 (Ct. Rec. 248-2 at
13 50). This is yet another analytical gap in his opinions.
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16 Third, Dr. Egilman asserts that the Act II Butter Lover’s popcorn, which Mr.
17 Newkirk alleges he consumed, released “28.7 ppM of diacetyl at the point source
18 when a popped bag of microwave popcorn was opened. Watson report attachment
19 B at 38.” Dr. Egilman Aff., Apr. 19, 2010 (Ct. Rec. 323 at 71). Point source
20 emissions are not exposure measurements. Jacky A. Rosati, Kenneth A. Krebs,
21 Xiaoyu Liu, *Emissions from Cooking Microwave Popcorn*, 47 *Critical Reviews in*
22 *Food Science and Nutrition* 701 (November 2007) (Ct. Rec. 330-15 at 755) ("This
23 was a source characterization study and the potential exposure to the compounds
24 measured and any associated potential risks were not estimated."). Moreover, Dr.
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1 Egilman relies for support on an attachment that the Court could not find despite
2 diligent searches of the affidavit to which Dr. Egilman claims a Watson report is
3 attached, Ct. Rec. 323 at 70, as well as the extensive other filings regarding the
4 *Daubert* and summary judgment motions.
5

6 Fourth, Dr. Egilman is again using “slurry” and “microwave popcorn
7 vapors” interchangeably without any scientifically sound basis to do so.
8

9 **Not helpful to the trier of fact**

10 Two of Dr. Egilman’s opinions stand out as reliable by being supported by
11 existing data and in line with the expert opinions offered by both Plaintiffs and
12 Defendants in this case. First, Dr. Egilman asserts, “Clinical epidemiology
13 presents sufficient evidence to warrant concern for causation of chronic lung injury
14 (fixed obstructive disease) associated with the production of butter-flavored
15 popcorn in exposed workers.” Dr. Egilman Aff., Apr. 19, 2010 (Ct. Rec. 323 at 5)
16 (purporting to cite Defense expert Dr. Kendall Wallace, but not clearly indicating
17 which document Dr. Egilman is citing). Second, Dr. Egilman concedes that:
18 “ConAgra is correct in noting that, aside from Dr. Rose’s report to four
19 governmental agencies (FDA, CDC, EPA and OSHA), there are no published
20 papers on consumer cases.” Dr. Egilman Aff., Apr. 19, 2010 (Ct. Rec. 323 at 74).
21 Although supported by existing data, these opinions are inadmissible under Fed. R.
22 Evid. 702 on the basis that they would be unhelpful to a trier of fact in this case.
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2 *Conclusion regarding general causation and specific causation testimony*
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4 *of Dr. Egilman*

5 There is simply too great an analytical gap between the existing data,
6 indicating that exposure to butter flavoring vapors in the occupational setting can
7 cause bronchiolitis obliterans, and Dr. Egilman’s opinion that a consumer of
8 microwave popcorn is exposed to a vaporized substance equivalent to production
9 plant butter flavoring vapors at levels sufficient to cause bronchiolitis obliterans.
10
11 *See Joiner*, 522 U.S. at 146. The bulk of Dr. Egilman’s conclusions do not rise
12 above “subjective belief or unsupported speculation.” *See Joiner*, 522 U.S. at 136.
13 His opinion testimony, therefore, is inadmissible under *Daubert* and Fed. R. Evid.
14 702.
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18 **4. Motions to Exclude the Specific Causation Testimony of**
19 **Plaintiffs’ Other Expert Witnesses**

20 Also before the Court are Defendants’ Joint Motions to Exclude the Specific
21 Causation Testimony of Plaintiffs’ Experts Dr. Pue, Ct. Rec. 234, Dr. Parmet, Ct.
22 Rec. 237, and Mr. Ewing, Ct. Rec. 240. Defendants rely on Fed. R. Evid. 702 and
23 *Daubert* to argue that each of these expert’s testimony on specific causation should
24 be excluded because there is an absence of admissible evidence of general
25 causation. The main thrust of Defendants’ argument is that without admissible
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1 evidence of general causation, there is no basis for Plaintiffs' expert witnesses to
2 testify regarding specific causation.

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4 If a plaintiff is not able to establish general causation, it is unnecessary to
5 consider whether the plaintiff can establish specific causation. *See Raynor v.*
6 *Merrell Pharmaceuticals Inc.*, 104 F.3d 1371, 1376 (D.C.Cir. 1997).

7
8 In cases that require medical evidence to establish causation, courts have
9 typically drawn a distinction between "general causation" and "specific
10 causation." Reference Manual on Scientific Evidence 444 (2d. ed. 2000).
11 General causation "is established by demonstrating . . . that exposure to a
12 substance can cause a particular disease." *Id.* Specific, "or individual,
causation, however is established by demonstrating that a given exposure is
the cause" of a particular individual's disease. *Id.*"

13 *Dunn v. Sandoz Pharmaceuticals Corp.*, 275 F. Supp. 2d 672, 676 (M.D.N.C.
14 2003).

15
16 Doctors Pue and Parmet conduct differential diagnoses to conclude that Mr.
17 Newkirk suffered bronchiolitis obliterans and other respiratory ailments as a result
18 of his consumption of microwave popcorn. However, a physician's opinion on
19 causation based on a differential diagnosis must first meet the requirement that the
20 alleged path of specific causation is scientifically plausible. *Navigating*
21 *Uncertainty: Gatekeeping in the Absence of Hard Science*, 113 Harv. L. Rev. 1467,
22 1474 (2000). "Once a plaintiff has shown general causation, the trial court faces
23 the issue of specific causation: whether the alleged cause did in fact produce the
24 plaintiff's injury." *Id. at 1475.*

1
2 *Dr. Pue*

3
4 In addition to Defendants' main argument that each of the expert's specific
5 causation testimony should be excluded because there is no evidence supporting
6 general causation, Defendants contend that Dr. Pue's testimony is barred by Fed.
7 R. Evid. 702, because Dr. Pue's testimony is not the product of reliable principles
8 and methods. Defendants cite the following reasons for concluding that Dr. Pue's
9 testimony should be excluded: Dr. Pue did not establish a safe level of microwave
10 popcorn vapor exposure; Dr. Pue did not establish Mr. Newkirk's actual exposure
11 level; and Dr. Pue did not adequately rule out plausible alternative causes for
12 Newkirk's disease and ailments. (Ct. Rec. 235 at 2).
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16 In his deposition, Dr. Pue testified that he had not been provided with
17 anything that allowed him to quantify the amount of butter flavoring chemicals to
18 which Mr. Newkirk actually had been exposed and that he could only speculate as
19 to the actual exposure of diacetyl and other chemicals. (Ct. Rec. 248-16 at 290-91,
20 Citurs Ex. P, Pue Dep. at 163:2-8, 166:20-167:1). Dr. Pue testified that he had not
21 seen any studies supporting the amount of consumer exposure to diacetyl from
22 microwave popcorn in a home environment (Ct. Rec. 248-8 at 204-05; Citurs Dec.
23 Ex. H, Pue Dep. at 197-198). Dr. Pue further testified that: "There was a
24 gentleman who was seen at National Jewish, and Dr. Rose I understand sent her
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1 industrial hygienist into his house and did sampling of the microwave levels or
2 popcorn levels in his house, and again, I was not allowed to see those results. I
3 asked for them. I'm not allowed to see them.” (Ct. Rec. 248-8 at 205, Citurs Dec.
4 Ex H, Pue Dep. at 198). Dr. Pue also testified in a deposition that he had no basis
5 for knowing whether the chemical exposure to microwave workers was the same
6 chemical exposure as to microwave popcorn consumers or whether there is a safe
7 exposure level for consumers of microwave popcorn vapors. Dr. Pue Dep., Jan.
8 15, 2010 (Ct. Rec. 248-16 at 287).

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12 The Court finds that Dr. Pue's testimony regarding specific causation fails to
13 satisfy the standards set by Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharm.,*
14 *Inc.*, 509 U.S. 579 (1993). First, Dr. Pue's specific causation testimony resulting
15 from his differential diagnosis relied on Dr. Egilman's general causation testimony
16 that the Court excluded. Without general causation established, Dr. Pue's specific
17 causation testimony fails. *See Hall v Baxter Healthcare Corp.*, 947 F. Supp. 1387,
18 1413 (D.Or. 1996)(“Testimony regarding specific causation in a given patient is
19 irrelevant unless general causation is established”(citing *DeLuca v. Merrell Dow*
20 *Pharmaceuticals, Inc.*, 911 F.2d at 958; *Jones*, 933 F. Supp. at 900; *Rutigliano v.*
21 *Valley Business Forms*, 929 F. Supp.779, 783 (D.N.J. 1996); *Grimes v. Hoffmann-*
22 *LaRoche, Inc.*, 907 F. Supp. 33, 38 (D.N.H. 1995); *Hopkins v. Dow Corning Corp.*,
23 33 F.3d 1116 (9th Cir. 1994)). Second, the Court finds that Dr. Pue did not
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1 conduct an independent analysis of general causation pursuant to Fed. R. Evid. 702
2 principles on which to base his differential diagnosis nor base his specific
3 causation opinion on reliable facts and data.
4

5 Therefore, the Court grants Defendants' Motion to Exclude the Specific
6 Causation Testimony of Dr. Pue.
7

8 **Dr. Parmet**

9 Dr. Parmet conducted a differential diagnosis of Mr. Newkirk to conclude
10 that Mr. Newkirk has bronchiolitis obliterans from exposure to butter flavor in
11 microwave popcorn vapor. Dr. Parmet admitted that he was unaware of how much
12 exposure to diacetyl Mr. Newkirk would have had or how much exposure would
13 rise above a safe level to a dangerous level. Dr. Parmet Dep. Dec. 16, 2009 (Ct.
14 Rec. 248-8 at 190, 199). However, Dr. Parmet appears to base his conclusion on
15 an assumption that because microwave popcorn flavor contains diacetyl and
16 because studies have supported the conclusion that workers' exposure to diacetyl
17 can cause bronchiolitis obliterans that Mr. Newkirk's exposure to microwave
18 popcorn caused Mr. Newkirk's bronchiolitis obliterans. Dr. Parmet testified that
19 his assumption was that a consumer's exposure to microwave popcorn butter
20 flavor, at any level, was unsafe unless "Defendants can prove otherwise." Dr.
21 Parmet Dep. Dec. 16, 2009 (Ct. Rec. 248-8 at 211) ("I'm going to make the
22 assumption that [diacetyl] is the cause until proven otherwise."). This conclusion
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1 is not only scientifically unsound, it is legally unsound in light of the plaintiff's
2 burden to prove causation in a toxic tort case. *Golden*, 528 F.3d at 683.

3
4 Similar to the analysis of Dr. Pue's testimony, Dr. Parmet's testimony on
5 specific causation fails to satisfy Fed. R. Evid. 702 requirements. First, Dr.
6 Parmet's specific causation testimony resulting from his differential diagnosis
7 relied on Dr. Egilman's general causation testimony that the Court excluded.
8 Without general causation established, Dr. Parmet's specific causation testimony
9 fails. *See Hall v Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1413 (D.Or. 1996).
10
11 In addition, Dr. Parmet's methodology of concluding that Mr. Newkirk suffered
12 from bronchiolitis obliterans from microwave popcorn vapor exposure without any
13 parameters as to what a safe or unsafe level of exposure would be is not the
14 product of reliable principles and methods based upon sufficient facts or data, as
15 required by Fed. R. Evid. 702.
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19 Therefore, the Court grants Defendants' Motion to Exclude the Specific
20 Causation Testimony of Dr. Parmet.
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22 **Mr. Ewing**

23 Defendants move to exclude the testimony of Mr. Ewing, an industrial
24 hygienist, on the grounds that Mr. Ewing failed to support his opinions with
25 scientifically valid and reliable methodology. Mr. Ewing prepared two reports. In
26 his first report, dated September 14, 2009, Mr. Ewing states that he based his
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1 opinions on Plaintiffs' responses to interrogatories as well as interviewing Mr.
2 Newkirk by telephone (Ct. Rec. 248-6 at 158). As part of his report, Mr. Ewing
3 included drawings, prepared by Mr. Newkirk, that estimate the locations of
4 microwave ovens used in his places of employment and home. Ewing Expert
5 Report, Sept. 14, 2009 (Ct. Rec. 248-6 at 159-60). On the drawings, there are
6 approximate distances noted. Ewing Expert Report, Sept. 14, 2009 (Ct. Rec. 248-6
7 at 160). Mr. Ewing relied on the approximate measurement of the drawings and
8 data that he has taken from other sources, such as the Aspen Report, the NIOSH
9 study, and Dr. Rose's statement to the FDA, to conclude that "It is likely that Mr.
10 Newkirk had peak exposures when opening bags of microwave popcorn similar to
11 the levels found among QC [quality control] workers" Ewing Expert Report, Sept.
12 14, 2009 (Ct. Rec. 248-6 at 166).

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18 However, as Defendants emphasize, none of the studies on which Mr. Ewing
19 relies was constructed to measure a consumer's exposure rate to diacetyl from
20 microwave popcorn vapor. In addition, some of the studies included 17 varieties
21 of 8 different brands of microwave popcorn without differentiating which variety
22 or brand contained specific amounts of diacetyl. *See* Jacky A. Rosati, Kenneth A.
23 Krebs, Xiaoyu Liu, *Emissions from Cooking Microwave Popcorn*, 47 *Critical*
24 *Reviews in Food Science and Nutrition* 701 (November 2007) (Ct. Rec. 330-15 at
25 752). In addition, Mr. Ewing admits that no studies were ever conducted to
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1 measure the amount of diacetyl in microwave popcorn vapor that was released into
2 Mr. Newkirk’s kitchen after popping microwave popcorn. Ewing Dep., Dec. 18,
3 2009 (Ct. Rec. 248-17 at 306).
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5 Mr. Ewing conducted his analysis and provided his expert opinions
6 regarding Mr. Newkirk’s exposure to diacetyl from Defendants’ product without
7 any measurements as to the amount of diacetyl in the vapor of Defendants’ product
8 and without exact measurements as to the size of Mr. Newkirk’s kitchen, among
9 other pieces of essential data that would support that Mr. Newkirk’s opinions are
10 reliable and relevant to this case. The Court finds that Mr. Newkirk’s opinions are
11 not the result of sufficient facts and data or the product of reliable principles and
12 methods as required by Fed. R. Evid. 702. Therefore, the Court grants Defendants’
13 Motion to Exclude Specific Causation Testimony of Mr. Ewing.
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18 **B. Motion for Summary Judgment Dismissal of the Newkirks’ Claims**

19 **1. Legal Standard**

20 Summary judgment is appropriate “if the pleadings, depositions, answers to
21 interrogatories, and admissions on file, together with the affidavits, if any, show
22 that there is no genuine issue as to any material fact and that the moving party is
23 entitled to a judgment as a matter of law.” Fed. R. Civ. P. 56(c). A key purpose of
24 summary judgment “is to isolate and dispose of factually unsupported claims”
25 *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24, 106 S.Ct. 2548, 91 L.Ed.2d 265
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1 (1986). Summary judgment is “not a disfavored procedural shortcut,” but is
2 instead the “principal tool[] by which factually insufficient claims or defenses
3 [can] be isolated and prevented from going to trial with the attendant unwarranted
4 consumption of public and private resources.” *Celotex*, 477 U.S. at 327.

6 The moving party bears the initial burden of demonstrating the absence of a
7 genuine issue of material fact. *See Celotex*, 477 U.S. at 323. The moving party
8 must demonstrate to the Court that there is an absence of evidence to support the
9 non-moving party's case. *See Celotex Corp.*, 477 U.S. at 325. The burden then
10 shifts to the non-moving party to “set out ‘specific facts showing a genuine issue
11 for trial.’” *Celotex Corp.*, 477 U.S. at 324 (quoting Fed. R. Civ. P. 56(e)).

15 A genuine issue of material fact exists if sufficient evidence supports the
16 claimed factual dispute, requiring “a jury or judge to resolve the parties' differing
17 versions of the truth at trial.” *T.W. Elec. Service, Inc. v. Pacific Elec. Contractors*
18 *Ass'n*, 809 F.2d 626, 630 (9th Cir.1987). At summary judgment, the court draws
19 all reasonable inferences in favor of the nonmoving party. If the nonmoving party
20 produces evidence that contradicts evidence produced by the moving party, the
21 court must assume the truth of the nonmoving party's evidence with respect to that
22 fact. *T.W. Elec. Service, Inc.*, 809 F.2d at 631. The evidence presented by both the
23 moving and non-moving parties must be admissible. Fed. R. Civ. P. 56(e).

27 Furthermore, the court will not presume missing facts, and non-specific facts in
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1 affidavits are not sufficient to support or undermine a claim. *Lujan v. Nat'l*
2 *Wildlife Fed'n*, 497 U.S. 871, 888-89, 110 S.Ct. 3177, 111 L.Ed.2d 695 (1990).

3 **2. Application of the Standard to the Newkirks' Claims**

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5 The Newkirks raise the following claims: (1) negligence; (2) strict liability
6 in tort—design defect; (3) failure to warn; (4) loss of consortium and claim for
7 medical expenses. All of those claims require the Plaintiffs to show causation.
8 (Ct. Rec. 62) (First Amended Complaint).

9
10 This Court has jurisdiction pursuant to 28 U.S.C. § 1332. As such, the Court
11 will apply Washington state substantive law. *Erie R.R. v. Tompkins*, 304 U.S. 64,
12 78, 58 S.Ct. 817, 82 L.Ed. 1188 (1938).

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14 To succeed in a negligence claim, “a plaintiff must prove four basic
15 elements: (1) the existence of a duty, (2) breach of that duty, (3) resulting injury,
16 and (4) proximate cause.” *Degel v. Majestic Mobile Manor, Inc.*, 129 Wn.2d 43,
17 48, 914 P.2d 728 (1996) (citing *Tincani v. Inland Empire Zoological Soc'y*, 124
18 Wn.2d 121, 127-28, 875 P.2d 621 (1994)).

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20 The Newkirks' two product liability claims, design defect and failure to
21 warn, also require them to show proximate causation by a preponderance of the
22 evidence to prevail. RCW 7.72.030(1); *Iwai v. State*, 129 Wn.2d 84, 96, 915 P.2d
23 1089 (1996); *see also Lockwood v. AC & S, Inc.*, 109 Wn.2d 235, 245, 744 P.2d
24 605 (1987) (“Generally, under traditional product liability theory, the plaintiff must
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1 establish a reasonable connection between the injury, the product causing the
2 injury, and the manufacturer of that product.”). A product manufacturer is subject
3 to strict liability in tort for a design defect where “a claimant’s harm was
4 proximately caused by the negligence of the manufacturer in that the product was
5 not reasonably safe as designed or not reasonably safe because adequate warnings
6 or instructions were not provided.” RCW 7.72.030(1). As for the Newkirks’
7 failure to warn claim, Washington law has adopted the definition of common law
8 product liability claims of the Restatement (Second) of Torts § 402A (1965), under
9 which a manufacturer may “incur liability for failure to adequately warn of
10 dangerous propensities of a product which it places in the stream of commerce.”
11 *Braaten v. Saberhagen Holdings*, 165 Wn.2d 373, 384, 198 P.3d 493 (2008). The
12 plaintiff must show that the failure to warn of the dangers of a given product
13 proximately caused the plaintiff’s injuries. *Ayers By and Through Ayers v.*
14 *Johnson & Johnson Baby Products Co.*, 117 Wn.2d 747, 752, 818 P.2d 1337
15 (Wash. 1991).

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22 The Newkirks’ fourth claim, loss of consortium and claim for medical
23 expenses, is an element of damages and thus does not create a material question of
24 fact to survive summary judgment if the other claims are dismissed. *See Walker v.*
25 *State*, 60 Wn. App. 624, 630, 806 P.2d 249 (Wash. Ct. App. Div. II 1991).

1 Therefore, in order to be successful on any of their claims, Plaintiffs must
2 prove by a preponderance of the evidence the following elements of causation: (1)
3 general causation; exposure to microwave popcorn vapors can cause bronchiolitis
4 obliterans and other respiratory ailments as alleged by Mr. Newkirk in the
5 complaint; and (2) specific causation; Mr. Newkirk suffered his alleged injuries as
6 a result of his exposure to microwave popcorn vapor. *See e.g., Henricksen.*, 605 F.
7 Supp. 2d at 1155 (citing *Jaros v. E.I. DuPont (In re Hanford Nuclear Reservation*
8 *Litig.)*, 292 F.3d 1124, 1133 (9th Cir. 2002)).

9 In this case, the Court has excluded Plaintiffs' proffered general causation
10 expert witness, Dr. Egilman, as inadmissible. As discussed above, the Court also
11 has excluded Plaintiffs' proffered specific causation expert witnesses: Dr.
12 Egilman, Dr. Pue, Dr. Parmet, and Mr. Ewing. The Court finds that in light of the
13 exclusion of Plaintiffs' evidence, Plaintiffs have failed to provide sufficient
14 admissible evidence to support their burden of proof on any of their claims.
15 Without evidence of causation claims, there is no genuine issue of material fact,
16 and the Defendants are entitled to judgment as a matter of law. Fed. R. Civ. P.
17 56(c).

18 Therefore, the Court grants Defendants' Motion for Summary Judgment, Ct.
19 Rec. 243. The Court dismisses all of Plaintiffs' claims with prejudice.
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IV. CONCLUSION

IT IS HEREBY ORDERED:

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1. Defendants' Joint Motion to Exclude Supplemental Opinions of Dr. David Egilman, **Ct. Rec. 359**, is **DENIED**.

2. Defendants' Joint Motion to Exclude the General Causation Testimony of Plaintiffs' Experts, **Ct. Rec. 228**, is **GRANTED**.

3. Defendant's Joint Motion to Exclude the Specific Causation Testimony of Plaintiffs' Expert Dr. Egilman, **Ct. Rec. 231**, is **GRANTED**.

4. Defendant's Joint Motion to Exclude the Specific Causation Testimony of Plaintiffs' Expert Dr. Pue, **Ct. Rec. 234**, is **GRANTED**.

5. Defendant's Joint Motion to Exclude the Specific Causation Testimony of Plaintiffs' Expert Allen J. Parmet, **Ct. Rec. 237**, is **GRANTED**.

6. Defendant's Joint Motion to Exclude the Specific Causation Testimony of Plaintiffs' Expert William Ewing, **Ct. Rec. 240**, is **GRANTED**.

7. Defendants' Joint Motion for Summary Judgment Dismissal of Plaintiffs' Claims, **Ct. Rec. 243**, is **GRANTED**. Plaintiffs' claims are dismissed with prejudice.

| ADDENDUM A: Filings Related to the Motions Before the Court | |
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| Defendants' Joint Motion to Exclude the General Causation Testimony of Plaintiffs' Experts | Ct. Rec. 228 |
| Memorandum of Authorities in Support of Defendants' Joint Motion to Exclude the General Causation Testimony of Plaintiffs' Expert Witnesses | Ct. Rec. 229 |
| Defendants' Joint Motion to Exclude the Specific Causation Testimony of Plaintiffs' Expert Dr. Egilman | Ct. Rec. 231 |
| Memorandum in Support of Defendants' Joint Motion to Exclude the Specific Causation Testimony of Plaintiffs' Expert Dr. Egilman | Ct. Rec. 232 |
| Defendants' Joint Motion to Exclude the Specific Causation Testimony of Plaintiffs' Expert Dr. Pue | Ct. Rec. 234 |
| Memorandum of Authorities in Support of Defendants' Joint Motion to Exclude the Specific Causation Testimony of Plaintiffs' Expert Dr. Pue | Ct. Rec. 235 |
| Defendants' Joint Motion to Exclude the Testimony of Plaintiffs' Expert Allen J. Parmet | Ct. Rec. 237 |
| Memorandum of Authorities in Support of Defendants' Joint Motion to Exclude Plaintiffs' Expert Allen J. Parmet | Ct. Rec. 238 |
| Defendants' Joint Motion to Exclude the Testimony of Plaintiffs' Expert William Ewing | Ct. Rec. 240 |
| Memorandum of Authorities in Support of Defendants' Joint Motion to Exclude the Testimony of Plaintiffs' Expert William Ewing | Ct. Rec. 241 |
| Declaration of Dr. Kendall Wallace in Support of Defendants' Joint Motions to Exclude Expert Testimony and Dispositive Motions | Ct. Rec. 247 |
| Declaration of Elizabeth J. Citurs in Support of Defendants' Joint Motions to Exclude Expert Testimony and Dispositive Motions (Exhibits 1-21) | Ct. Rec. 248 |
| Additional Attachments to Main Document (248) – Exhibits 1-23 | Ct. Rec. 249 |
| Additional Attachments to Main Document (248) – Exhibits 1-11 | Ct. Rec. 250 |
| Additional Attachments to Main Document (248) – Exhibits 1-29 | Ct. Rec. 251 |
| Errata re Statement of Undisputed Material Facts in Support of Defendants' Joint Motions to Exclude Expert Testimony and Joint Dispositive Motions Pursuant to LR 56.1(a) – with Attachment 1 | Ct. Rec. 283 |
| Errata re Memorandum of Authorities in Support of Defendants' Joint Motion to Exclude the General Causation Testimony of | Ct. Rec. 284 |

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| 1 | Plaintiffs' Expert Witness – with Attachment 1 | |
| 2 | Errata re Memorandum of Authorities in Support of Defendants' Joint Motion to Exclude the Specific Causation Testimony of Plaintiffs' Expert Dr. Egilman – with Attachment 1 | Ct. Rec. 285 |
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| 4 | Errata re Memorandum of Authorities in Support of Defendants' Joint Motion to Exclude the Specific Causation Testimony of Plaintiffs' Expert Dr. Pue – with Attachment 1 | Ct. Rec. 286 |
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| 6 | Errata re Memorandum of Authorities in Support of Defendants' Joint Motion for Summary Judgment – with Attachment 1 | Ct. Rec. 287 |
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| 8 | Plaintiffs' Opposition to Defendants' Joint Motion for Summary Judgment and Daubert Motions (Ct. Doc. 228, 231, 234, 237, 240, and 243) – with Appendix 1 | Ct. Rec. 320 |
| 9 | | |
| 10 | Plaintiffs' Counter Statement of Material Facts in Support of Plaintiffs' Opposition to Defendants' Joint Motion for Summary Judgment and Daubert Motions | Ct. Rec. 321 |
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| 12 | Plaintiffs' Response to Defendants' Statement of Undisputed Material Facts in Support of Defendants' Joint Motion to Exclude Testimony and Joint Dispositive Motions Pursuant to LR 56.1(a)(Doc. 246) | Ct. Rec. 322 |
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| 14 | Affidavit of Dr. David Egilman in Support of Plaintiffs' Opposition to Joint Motion for Summary Judgment and Joint Daubert Motions – Exhibits 1 and 2 | Ct. Rec. 323 |
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| 16 | Supplemental Affidavit of Dr. David Egilman in Support of Plaintiffs' Opposition to Joint Motion for Summary Judgment and Joint Daubert Motions – Exhibit 1 | Ct. Rec. 325 |
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| 18 | Declaration of Christopher R. Miller in Support of Plaintiffs' Opposition to Defendants' Joint Motion for Summary Judgment and Daubert Motions (Ct. Docs. 228, 231, 234, 237, 240, and 243) – Exhibits 1-26 | Ct. Rec. 327 |
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| 20 | Additional Attachments to Main Document (327) – Exhibits 1 -11 (Ct. Rec. 328) | Ct. Rec. 328 |
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| 22 | Additional Attachments to Main Document (327) – Exhibits MM-SS | Ct. Rec. 329 |
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| 24 | Additional Attachments to Main Document (327) – Exhibits TT-ZZ | Ct. Rec. 330 |
| 25 | | |
| 26 | Additional Attachments to Main Document (327) – Exhibits AAA-III | Ct. Rec. 331 |
| 27 | | |
| 27 | Additional Attachments to Main Document (327) – Exhibits JJJ-PPP | Ct. Rec. 332 |
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| 28 | Additional Attachments to Main Document (327) – Exhibits QQQ- | Ct. Rec. 333 |

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| 2 | Additional Attachments to Main Document (327) – Exhibits AAAA-JJJJ | Ct. Rec. 334 |
| 3 | Sealed Documents – Exhibits II, WW, LLL, RRR, SSS | Ct. Rec. 335 |
| 4 | Defendants’ Joint Motion to Exclude the Supplemental Opinions of Dr. David Egilman | Ct. Rec. 359 |
| 5 | Memorandum of Authorities in Support of Defendants’ Joint Motion to Exclude the Supplemental Opinions of Dr. David Egilman | Ct. Rec.360 |
| 6 | Declaration of Elizabeth J. Citurs in Support of Defendants’ Joint Motion to Exclude the Supplemental Opinions of Dr. David Egilman – Exhibits A pgs 5-122 | Ct. Rec. 361 |
| 7 | Reply Memorandum of Authorities in Support of Defendants’ Joint Motion to Exclude the General Causation Testimony of Plaintiffs’ Expert Witnesses | Ct. Rec. 388 |
| 8 | Reply Memorandum in Support of Defendants’ Motion to Exclude Plaintiffs; Expert William Ewing | Ct. Rec. 389 |
| 9 | Reply Memorandum in Support of Defendants’ Joint Motion to Exclude the Specific Causation Testimony of Dr. Pue | Ct. Rec. 390 |
| 10 | Reply Memorandum in Support of Defendants’ Joint Motion to Exclude Plaintiffs’ Expert Allen J. Parmet | Ct. Rec. 391 |
| 11 | Reply Memorandum in Support of Defendants’ Joint Motion to Exclude the Specific Causation Testimony of Dr. Egilman | Ct. Rec. 392 |
| 12 | Affidavit of Dr. John Morris in Support of Defendants’ Joint Motions to Exclude Expert Testimony and Dispositive Motions | Ct. Rec. 393 |
| 13 | Declaration of Micah Hines in Support of Defendants’ Joint Motions to Exclude Expert Testimony and Dispositive Motions – Exhibits A-F | Ct. Rec. 394 |
| 14 | Reply Memorandum in Support of Defendants’ Joint Motion for Summary Judgment | Ct. Rec. 459 |
| 15 | Plaintiffs’ Response to Defendants’ Joint Motion to Exclude the Supplement Opinions of Dr. David Egilman – Appendix A | Ct. Rec. 476 |
| 16 | Declaration of Christopher R. Miller in Support of Plaintiffs’ Response to Defendants’ Joint Motion to Exclude the Supplemental Opinions of Dr. David Egilman – Exhibits A-W | Ct. Rec. 477 |
| 17 | Additional Attachments to Document 477 – Exhibits BB-EE | Ct. Rec. 478 |
| 18 | Reply Memorandum in Support of Defendants’ Joint Motion to Strike the Supplemental Opinions of Dr. David Egilman | Ct. Rec. 508 |
| 19 | Declaration of Corey L. Gordon in Support of Defendants’ Joint Motions to Exclude the Supplemental Opinions of Dr. David | Ct. Rec. 509 |

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| Egilman – Exhibits A-T | |
| Declaration of Wayne Waite in Support of Defendants’ Joint Motion to Exclude the Supplemental Opinions of Dr. David Egilman | Ct. Rec. 510 |

1 **ADDENDUM B:** Additional conclusions and Opinions of Dr. Egilman offered
2 without documentation

- 3 a. Dr. Egilman analogizes diacetyl to asbestos and states that “physicians and
4 courts agree that it is not necessary to know or even estimate exposure levels
5 to determine that asbestos caused or contributed to a mesothelioma” (Ct.
6 Rec. 323 at 33).
- 7 b. “This outbreak was preventable. The diacetyl manufacturing companies
8 should have tested their products for safety prior to sale” (Ct. Rec. 248-2 at
9 51).
- 10 c. “Opinion: The Popcorn Board actively sought to mislead the public about
11 the about [sic] potential negative health outcomes related to popping
12 microwave popcorn” (Ct. Rec. 248-2 at 57).
- 13 d. “Opinion: Mr. Newkirk did not receive adequate warnings about the risk of
14 development of irreversible obstructive lung damage attributable to diacetyl
15 inhalation. In addition the Popcorn Board placed anti-warnings on their web
16 site and in communications to the public.” (Ct. Rec. 248-2 at 57).
- 17 e. “There were no epidemiologic studies done to show that insulin was related
18 to diabetes.” (Ct. Rec. 323 at 49)
- 19 f. “The “poor ventilation” was noted to explain the nature of the exposures to
20 vapor released from popped bags by NIOSH (HHEs [“Health Hazard
21 Evaluations”]). Exposure to slurry vapor would depend on whether or not
22 the QC room was under negative pressure. There is no evidence this was the
23 case at Jasper; thus, there is no evidence of exposure to slurry vapors in the
24 QC room. This is speculation.” (Ct. Rec. 323 at 19-20).
- 25 g. “Popcorn manufacturing companies should have and should warn that other
26 chemicals used in microwave popcorn packaging (Heat resistant bags and
27 adhesive) may put consumers at increased risk for cancer” (Id. at 27).
- 28 h. “Opinion: Like the Popcorn Board, ConAgra actively sought to mislead the
public about the about [sic] potential negative health outcomes related to
popping microwave popcorn.” (Ct. Rec. 248-2 at 41).
- i. “ConAgra claimed to go ‘diacetyl-free’ around the same time that the first
consumer case of BO was diagnosed. Consumers were informed that they
were ‘not at risk’ and implied that Mr. Watson’s exposures were ‘extreme’
because he inhaled the flavors” (Ct. Rec. 248-2 at 41).
- j. “Chris Hansen failed to adequately warn about the risks of diacetyl exposure
from use of its diacetyl containing products to workers and consumers.” Ct.
Rec. 248-2 at 42).
- k. “Since ConAgra did not preserve samples of ACT II popcorn with diacetyl

1 neither the slurry nor the MWPC to which Mr. Newkirk was exposed can be
2 tested” (Ct. Rec. 323 at 58).⁸

3 1. Dr. Egilman recites that the “Popcorn Board” created a “tip sheet” for safety
4 procedures, but then did not distribute the tip sheet (Ct. Rec. 248-2 at 55).

5 Dr. Egilman then concludes, “This was a bad thing to do” (Ct. Rec. 248-2 at
6 55).

7 m. “Opinion: The Popcorn Board expressed that they had a duty to warn. I
8 agree. They did not warn. This is bad.” (Ct. Rec. 248-2 at 31).

9 n. “Because it is agreed that exposure to diacetyl is necessary and sufficient
10 condition for butter flavoring to cause disease, and because there is no
11 accepted (or even publically theorized “safe level of exposure”), ConAgra
12 and other popcorn manufacturing companies have stopped adding diacetyl to
13 their commercial popcorn products. ConAgra’s news release on December
14 17, 2007 [sic] introduced Orville Redenbacher and ACT II microwave
15 popcorn brands “with a New Great Tasting Butter Flavoring with No Added
16 Diacetyl”: “to eliminate even the perception of risk for consumers, and to
17 provide the safest possible environment for workers who handle large

18 ⁸ Evidence in the record directly refutes Dr. Egilman’s claim. Declaration of

19 Corey Gordon in Support of Defendants’ Joint Motion to Exclude the

20 Supplemental Opinions of Dr. Egilman (Ct. Rec. 509 at 16-19) (Asserting that

21 “ConAgra actually did maintain samples of microwave product with added

22 diacetyl, a fact known to plaintiffs since December 29, 2008, when ConAgra so

23 advised plaintiffs in discovery that it had examples it would make available to

24 plaintiffs” but simultaneously noting that the samples may be problematic for

25 testing due to lack of freshness); (Tr. from 6/7/2010 at 135-36) (ConAgra’s counsel

26 explained that his client has preserved samples but that he “just didn’t turn them

27 over to [Plaintiffs’s counsel] without them telling me what they’re going to do with

28 them.”).

1 quantities of diacetyl, the company has decided to eliminate the use of added
2 diacetyl in its microwave popcorn products.” (Ct. Rec. 323 at 37-38).

- 3 o. In analogizing diacetyl exposure to tobacco, Dr. Egilman makes statements
4 like, “. . . all physicians agree that these and in fact, all cigarettes that emit
5 tobacco smoke cause cancer” (Ct. Rec. 323 at 35) (citing nothing).
- 6 p. Dr. Egilman uses a variety of assumptions to calculate TWA exposures,
7 without providing any basis for his assumptions. (Ct. Rec. 323 at 26-27)
8 For example, in his rebuttal of the Lockey Study, Dr. Egilman states “If we
9 divide 800 ppb [parts per billion] by 9.2 to reduce the exposure and divide
10 again by 45 (an approximate lifetime worker exposure), a worker exposed to
11 greater than 1.9 ppb TWA over 45 years would have an increased risk of
12 obstruction” (Ct. Rec. 323 at 26-27) (citing nothing).
- 13 q. Dr. Egilman relies on the 2004 identification of three cases of bronchiolitis
14 obliterans among process operators in a diacetyl plant owned by Dutch
15 company DSM yet cites no study or article supporting these diagnoses (Ct.
16 Rec. 248-2, Egilman 9/15/09 report at 18).
- 17 r. Dr. Egilman argues that there is no necessity in identifying the exact
18 chemical(s) in a mixture that are responsible for disease causation. (Ct. Rec.
19 323 at 7 n 3).
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