

1  
2  
3  
4  
5 UNITED STATES DISTRICT COURT  
6 EASTERN DISTRICT OF WASHINGTON  
7

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

NO: CV-08-273-RMP

MEMORANDUM OPINION AND  
ORDER

---

17 **I. INTRODUCTION**  
18

19 On June 7, 2010, the Court held a hearing on Defendants' five *Daubert*<sup>1</sup> and  
20 two summary judgment motions.<sup>2</sup> After hearing oral argument and reviewing all  
21

22 <sup>1</sup> *Daubert v. Merrell Dow Pharm. Inc.*, 509 U.S. 579 (1993).

23 <sup>2</sup> 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  
27  
28

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.  
5

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  
14  
15  
16  
17  
18

---

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  
25  
26 (Ct. Rec. 252).  
27  
28

1 Court concluded that there was a sufficient evidentiary record<sup>3</sup> 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.  
8

## 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  
15

16 <sup>3</sup> 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.  
24  
25  
26  
27  
28

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).  
6

7  
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).  
17  
18  
19  
20

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  
27  
28

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).  
6

7  
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).  
23  
24  
25  
26  
27  
28

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).  
4

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).  
18  
19  
20  
21

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  
27  
28

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.

14  
15  
16  
17  
18  
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,  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65  
66  
67  
68  
69  
70  
71  
72  
73  
74  
75  
76  
77  
78  
79  
80  
81  
82  
83  
84  
85  
86  
87  
88  
89  
90  
91  
92  
93  
94  
95  
96  
97  
98  
99  
100  
101  
102  
103  
104  
105  
106  
107  
108  
109  
110  
111  
112  
113  
114  
115  
116  
117  
118  
119  
120  
121  
122  
123  
124  
125  
126  
127  
128  
129  
130  
131  
132  
133  
134  
135  
136  
137  
138  
139  
140  
141  
142  
143  
144  
145  
146  
147  
148  
149  
150  
151  
152  
153  
154  
155  
156  
157  
158  
159  
160  
161  
162  
163  
164  
165  
166  
167  
168  
169  
170  
171  
172  
173  
174  
175  
176  
177  
178  
179  
180  
181  
182  
183  
184  
185  
186  
187  
188  
189  
190  
191  
192  
193  
194  
195  
196  
197  
198  
199  
200  
201  
202  
203  
204  
205  
206  
207  
208  
209  
210  
211  
212  
213  
214  
215  
216  
217  
218  
219  
220  
221  
222  
223  
224  
225  
226  
227  
228  
229  
230  
231  
232  
233  
234  
235  
236  
237  
238  
239  
240  
241  
242  
243  
244  
245  
246  
247  
248  
249  
250  
251  
252  
253  
254  
255  
256  
257  
258  
259  
260  
261  
262  
263  
264  
265  
266  
267  
268  
269  
270  
271  
272  
273  
274  
275  
276  
277  
278  
279  
280  
281  
282  
283  
284  
285  
286  
287  
288  
289  
290  
291  
292  
293  
294  
295  
296  
297  
298  
299  
300  
301  
302  
303  
304  
305  
306  
307  
308  
309  
310  
311  
312  
313  
314  
315  
316  
317  
318  
319  
320  
321  
322  
323  
324  
325  
326  
327  
328  
329  
330  
331  
332  
333  
334  
335  
336  
337  
338  
339  
340  
341  
342  
343  
344  
345  
346  
347  
348  
349  
350  
351  
352  
353  
354  
355  
356  
357  
358  
359  
360  
361  
362  
363  
364  
365  
366  
367  
368  
369  
370  
371  
372  
373  
374  
375  
376  
377  
378  
379  
380  
381  
382  
383  
384  
385  
386  
387  
388  
389  
390  
391  
392  
393  
394  
395  
396  
397  
398  
399  
400  
401  
402  
403  
404  
405  
406  
407  
408  
409  
410  
411  
412  
413  
414  
415  
416  
417  
418  
419  
420  
421  
422  
423  
424  
425  
426  
427  
428  
429  
430  
431  
432  
433  
434  
435  
436  
437  
438  
439  
440  
441  
442  
443  
444  
445  
446  
447  
448  
449  
450  
451  
452  
453  
454  
455  
456  
457  
458  
459  
460  
461  
462  
463  
464  
465  
466  
467  
468  
469  
470  
471  
472  
473  
474  
475  
476  
477  
478  
479  
480  
481  
482  
483  
484  
485  
486  
487  
488  
489  
490  
491  
492  
493  
494  
495  
496  
497  
498  
499  
500  
501  
502  
503  
504  
505  
506  
507  
508  
509  
510  
511  
512  
513  
514  
515  
516  
517  
518  
519  
520  
521  
522  
523  
524  
525  
526  
527  
528  
529  
530  
531  
532  
533  
534  
535  
536  
537  
538  
539  
540  
541  
542  
543  
544  
545  
546  
547  
548  
549  
550  
551  
552  
553  
554  
555  
556  
557  
558  
559  
560  
561  
562  
563  
564  
565  
566  
567  
568  
569  
570  
571  
572  
573  
574  
575  
576  
577  
578  
579  
580  
581  
582  
583  
584  
585  
586  
587  
588  
589  
590  
591  
592  
593  
594  
595  
596  
597  
598  
599  
600  
601  
602  
603  
604  
605  
606  
607  
608  
609  
610  
611  
612  
613  
614  
615  
616  
617  
618  
619  
620  
621  
622  
623  
624  
625  
626  
627  
628  
629  
630  
631  
632  
633  
634  
635  
636  
637  
638  
639  
640  
641  
642  
643  
644  
645  
646  
647  
648  
649  
650  
651  
652  
653  
654  
655  
656  
657  
658  
659  
660  
661  
662  
663  
664  
665  
666  
667  
668  
669  
670  
671  
672  
673  
674  
675  
676  
677  
678  
679  
680  
681  
682  
683  
684  
685  
686  
687  
688  
689  
690  
691  
692  
693  
694  
695  
696  
697  
698  
699  
700  
701  
702  
703  
704  
705  
706  
707  
708  
709  
710  
711  
712  
713  
714  
715  
716  
717  
718  
719  
720  
721  
722  
723  
724  
725  
726  
727  
728  
729  
730  
731  
732  
733  
734  
735  
736  
737  
738  
739  
740  
741  
742  
743  
744  
745  
746  
747  
748  
749  
750  
751  
752  
753  
754  
755  
756  
757  
758  
759  
760  
761  
762  
763  
764  
765  
766  
767  
768  
769  
770  
771  
772  
773  
774  
775  
776  
777  
778  
779  
780  
781  
782  
783  
784  
785  
786  
787  
788  
789  
790  
791  
792  
793  
794  
795  
796  
797  
798  
799  
800  
801  
802  
803  
804  
805  
806  
807  
808  
809  
810  
811  
812  
813  
814  
815  
816  
817  
818  
819  
820  
821  
822  
823  
824  
825  
826  
827  
828  
829  
830  
831  
832  
833  
834  
835  
836  
837  
838  
839  
840  
841  
842  
843  
844  
845  
846  
847  
848  
849  
850  
851  
852  
853  
854  
855  
856  
857  
858  
859  
860  
861  
862  
863  
864  
865  
866  
867  
868  
869  
870  
871  
872  
873  
874  
875  
876  
877  
878  
879  
880  
881  
882  
883  
884  
885  
886  
887  
888  
889  
890  
891  
892  
893  
894  
895  
896  
897  
898  
899  
900  
901  
902  
903  
904  
905  
906  
907  
908  
909  
910  
911  
912  
913  
914  
915  
916  
917  
918  
919  
920  
921  
922  
923  
924  
925  
926  
927  
928  
929  
930  
931  
932  
933  
934  
935  
936  
937  
938  
939  
940  
941  
942  
943  
944  
945  
946  
947  
948  
949  
950  
951  
952  
953  
954  
955  
956  
957  
958  
959  
960  
961  
962  
963  
964  
965  
966  
967  
968  
969  
970  
971  
972  
973  
974  
975  
976  
977  
978  
979  
980  
981  
982  
983  
984  
985  
986  
987  
988  
989  
990  
991  
992  
993  
994  
995  
996  
997  
998  
999  
1000

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).

10  
11  
12  
13           Quality assurance workers pop dozens of bags of popcorn per work shift.<sup>4</sup>  
14  
15 For instance, at the ConAgra plant in Marion, Ohio, each worker popped up to 130  
16 bags per 12-hour workshift. Richard Kanwal and Greg Kullman, *NIOSH Health*  
17 *Hazard Evaluation Report, HETA # 2004-0112-2949, ConAgra Snack Foods,*  
18 *Marion, Ohio* (December 2004) (Ct. Rec. 249 at 573). In Plant F in the Kanwal, et  
19 al., report, quality assurance workers popped 130 bags of popcorn in a 12-hour  
20  
21 <sup>4</sup> Some plant workers work in quality assurance full-time. See Richard Kanwal et  
22 al., *Evaluation of Flavorings-Related Lung Disease Risk at Six Microwave*  
23 *Popcorn Plants*, 48 *Journal of Occupational and Environmental Medicine* 149  
24 (February 2006) (Ct. Rec. 248-20). Other plants have workers who perform  
25  
26 quality assurance work on certain days each week or month. *Id.*  
27  
28

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.*  
6  
7

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).  
14  
15

### 16 III. ANALYSIS

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

##### 18 1. Dr. David Egilman's Supplemental Affidavits

19 As a preliminary matter, Defendants filed a Joint Motion to Exclude the  
20 Supplemental Opinions of Dr. David Egilman (Ct. Rec. 359). Defendants rely on  
21 the expert opinion disclosure requirements established in Fed. R. Civ. P. 26, as  
22 well as this Court's prior scheduling orders, as the bases to exclude Dr. Egilman's  
23 supplemental opinions.  
24  
25  
26  
27  
28

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).  
6

7  
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).  
17  
18  
19

20  
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  
26  
27  
28

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).

3  
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  
7  
8 abide by the disclosure requirements in Fed. R. Civ. P. 26 can result in sanctions  
9 pursuant to Fed. R. Civ. P. 37.

10  
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.  
14  
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**

20  
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  
27 causation, by contrast, concerns “whether a particular individual suffers from a  
28

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)).  
7  
8

### 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.  
16  
17  
18

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  
26  
27  
28

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.  
4

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.  
12  
13  
14

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.  
21  
22

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  
27  
28

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.  
4 *Daubert II*, 43 F.3d. at 1320. This requirement of "fit" or "helpfulness" demands  
5 "a valid scientific connection to the pertinent inquiry as a precondition to  
6 admissibility." *Daubert II*, 43 F.3d at 1317-18 (quoting *Daubert I*, 509 U.S. at  
7 592); *see also* Fed. R. Evid. 702.  
8  
9

10  
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 The court should review the expert's opinion testimony for "overall sufficiency of  
16 the underlying facts and data, and the reliability of the methods, as well as the fit of  
17 the methods to the facts of the case." *W.R. Grace*, 504 F.3d at 765. When there is  
18 too great an analytical gap between the data and the opinion proffered, the trial  
19 court may properly exclude the testimony as unreliable. *Joiner*, 522 U.S. at 146.  
20  
21

22  
23 / / /

24  
25 / / /

1                   **3. Motion to Exclude Expert Testimony on General Causation**  
2                   **and Motion to Exclude Specific Causation Testimony of Dr.**  
3                   **Egilman**  
4

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  
22                     
23                     
24                     
25                     
26                     
27                     
28

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.

15  
16  
17  
18  
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.

23  
24  
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.  
28

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:  
13

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  
exposures as well as industrial cases of BO and related lung disease in  
workers exposed in butter flavoring and popcorn production plants.

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

22  
23 Dr. Egilman also states his opinions more succinctly elsewhere: "Mr.  
24 Newkirk, within a reasonable degree of medical certainty developed lung  
25 disease as a result of inhaling flavors released by microwaved popcorn." Dr.  
26 Egilman Expert Report, Sept. 15, 2009 (Ct. Rec. 248-2 at 25).  
27

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.  
7

8  
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.  
23  
24  
25  
26  
27  
28

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).  
8

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:  
22  
23  
24  
25  
26  
27  
28

1  
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).

8  
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  
24  
25  
26  
27  
28

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).  
6  
7

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).  
22  
23  
24  
25  
26  
27  
28

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.  
6

7 Without support for these assertions, however, the statements illustrate the  
8 analytical gap between the existing data and the opinion Dr. Egilman proffers.  
9

10 *Joiner*, 522 U.S. at 146.  
11

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").  
20  
21  
22

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  
27  
28

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.  
9

10  
11  
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).  
18  
19

20  
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  
27  
28

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.

8  
9  
10 In the previous section, the Court documented examples in which Dr.  
11 Egilman provides no indication of external support for his conclusions. In other  
12 parts of his reports and testimony, Dr. Egilman relies on existing data, mostly in  
13 the form of published studies, but draws conclusions far beyond what the study  
14 authors concluded, or Dr. Egilman manipulates the data from those studies to reach  
15 misleading conclusions of his own. *See Daubert I*, 509 U.S. at 592-93.

16  
17  
18 Dr. Egilman states that, "Dr. Cecile Rose, a pulmonary specialist from  
19 National Jewish in Denver, Colorado, diagnosed and reported the first case of  
20 consumer popcorn lung in 2007 in Mr. Wayne Watson of Colorado." Dr. Egilman  
21 Expert Report, Sept. 15, 2009 (Ct. Rec. 248-2 at 10). Dr. Egilman then relies  
22 heavily on Dr. Rose's diagnosis and study of Mr. Watson to support his opinion  
23 that consumers other than Mr. Newkirk have developed bronchiolitis obliterans  
24  
25  
26  
27  
28

1 from microwave popcorn exposure. He writes, “With respect to MWPC<sup>5</sup> 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).  
6

7  
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.  
13

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.  
21

22  
23 (Ct. Rec. 249-5 at 724)

24  
25 \_\_\_\_\_  
26 <sup>5</sup> “MWPC” is Dr. Egilman’s shorthand for microwave popcorn (Ct. Rec. 323 at 5,  
27 note 1).  
28

1  
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.  
5 Egilman continues, "It is not surprising that there are few known cases. Even  
6 highly toxic substances like asbestos, which most US residents have inhaled,  
7  
8 causes relatively few mesotheliomas in people who have not worked directly with  
9 the product." Dr. Egilman Aff., Apr. 19, 2010 (Ct. Rec. 323 at 34-35).  
10

11  
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  
17  
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.  
20 Watson's home (Ct. Rec. 323 at 15). Therefore, Dr. Egilman had no identifiable  
21  
22 data on which to base his conclusions, and the Court has no means to analyze  
23  
24 whether the underlying data is reliable.  
25

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  
28

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  
21  
22  
23  
24  
25  
26  
27  
28

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  
21  
22  
23  
24  
25  
26  
27  
28

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).  
8  
9

10  
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.  
18  
19

20  
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  
27  
28

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).  
6

7  
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*  
23  
24  
25  
26  
27  
28

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.  
7  
8 Egilman’s direction and is dated April 23, 2010 (Ct. Rec. 326).

9  
10 In summary, the chronology of Dr. Egilman’s process or methodology for  
11 determining consumer exposure levels to diacetyl was as follows. Prior to  
12 September 2009, Dr. Egilman relies on studies of diacetyl exposure levels for  
13 workers conducted in microwave popcorn plants using a number of different  
14 microwave popcorn brands and types. On September 15, 2009, Dr. Egilman drafts  
15 his expert opinion report stating that consumer exposure levels to diacetyl would  
16 be equivalent to exposure levels to microwave popcorn workers and could cause  
17 bronchiolitis obliterans and that Mr. Newkirk contracted bronchiolitis obliterans  
18 from microwave popcorn vapor (Ct. Rec. 248-2). In January 2010, Dr. Egilman  
19 defends his conclusions in a deposition. Dr. Egilman Dep., Jan. 26, 2010 (Ct. Rec.  
20 248-19). Between the January deposition and April, Dr. Egilman commissioned a  
21 study by Drs. Tsai and Ellenbecker to “figure out how long diacetyl stayed in the  
22 air based on physics and chemistry” and to “actually calculate a dose or an  
23  
24  
25  
26  
27  
28

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 GML<sup>6</sup> 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*).  
13  
14  
15  
16  
17

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  
25  
26  
27

---

28 <sup>6</sup> 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  
6  
7  
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  
23  
24  
25  
26  
27  
28

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  
27  
28

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).

5  
6 Specifically, NIOSH scientists first visited the Marion, Ohio, ConAgra plant  
7  
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  
18 environmental surveys of the plant in March 2003 and found the following mean  
19  
20 time weighted average diacetyl air concentrations, according to areas of the plant:  
21  
22 (1) 1.14 ppm in the slurry/mixing room, where 3 of the 12 current slurry room  
23  
24 workers had health findings "consistent with bronchiolitis obliterans"; (2) 0.02  
25  
26 ppm in the packaging area, where five workers had "fixed obstruction on  
27  
28 spirometry, normal diffusing capacity, and no history of work in the slurry room";

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).

3  
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  
7 March 2003, ConAgra made adjustments to the slurry room ventilation, and by the  
8 time the environmental study was undertaken in March, the slurry room had  
9 negative air pressure relative to the packaging area (Ct. Rec. 249 at 567). ConAgra  
10 also made changes to the ventilation system between January and March that  
11 "decreased the potential for slurry room emissions to contaminate the packaging  
12 area." In light of these changes, the NIOSH report proposed that "the March 2003  
13 diacetyl air concentrations in the packaging area may underestimate past  
14 exposures" and concluded that "higher exposures in the past may explain the  
15 greater than expected numbers of packaging-line workers" reporting respiratory  
16 ailments, and revealing respiratory obstruction on NIOSH spirometry tests (Ct.  
17 Rec. 249 at 581). *See also* (Ct. Rec. 249 at 567).

18  
19 The Marion study, therefore, does not purport to show an association  
20 between the 0.02 ppm diacetyl concentration and the workers' negative health  
21 effects, as Dr. Egilman's indicates. *See* Richard Kanwal and Greg Kullman,  
22 *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.  
8  
9

10  
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 III<sup>7</sup> (adjusted for age, sex, race, and smoking  
21  
22  
23  
24 <sup>7</sup> "NHANES III" is the abbreviation for the National Health Examination Survey,  
25  
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](http://www.cdc.gov/nchs/nhanes/nhanes_questionnaires.htm) (last visited June  
28

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.  
11  
12  
13  
14

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  
22  
23  
24  
25  
26  
27  
28  

---

22, 2010). The survey “is a program of studies designed to assess the health and  
nutritional status of adults and children in the United States.”  
<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).

13  
14  
15  
16  
17  
18 Extrapolating from the animal studies, Dr. Egilman draws the following  
19 conclusion under the label of “analogy”:

20  
21 Analogy: Other substances have proved toxic when inhaled, some also  
22 causing changes in the respiratory epithelium. O<sub>3</sub> (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.  
21  
22  
23  
24  
25  
26  
27  
28

1  
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

14 A. That's how they first defined it, yes.  
15

16 Q. Do you consider the Rosati study done from the EPA to be an  
17 exposure study?  
18

19 A. Why don't you define what you mean by exposure.  
20

21 Q. Fair enough. Do you understand that the purpose of the Aspen  
22 study, or a purpose of the Aspen study was to do quantitative  
23 exposures for a consumer?  
24

25 A. That's my understanding.  
26

27 (Ct. Rec. 394-2 at 86).  
28

29 However, the EPA/Rosati study, by its own terms, is not an exposure study.  
30 The study report concludes with the statement: "This was a source characterization  
31 study and the potential exposure to the compounds measured and any associated  
32 potential risks were not estimated." Jacky A. Rosati, Kenneth A. Krebs, Xiaoyu  
33

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.  
11

12  
13  
14  
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  
25  
26  
27  
28

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.

12  
13  
14  
15  
16 **Whether Dr. Egilman’s testimony is the product of reliable principles and**  
17 **methods**  
18

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:  
25  
26

27 Unfortunately most studies have based exposure measurements on  
28

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.

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

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

20 Dr. Egilman then applies contradictory logic in attempting to distinguish  
21 between vapors from microwave popcorn and slurry vapors in the manufacturing  
22 work site by stating that "[t]hese vapors have not been tested, and therefore, there  
23 is no way to be sure that the composition of inhaled vapors is actually different at  
24  
25  
26  
27  
28

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?  
6

7  
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.  
13

14  
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  
26  
27  
28

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).  
6

7  
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.  
14  
15

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.  
25  
26  
27  
28

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.  
23  
24  
25  
26  
27  
28

1  
2 *Conclusion regarding general causation and specific causation testimony*  
3  
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.  
15  
16

17  
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  
25 be excluded because there is an absence of admissible evidence of general  
26 causation. The main thrust of Defendants' argument is that without admissible  
27  
28

1 evidence of general causation, there is no basis for Plaintiffs' expert witnesses to  
2 testify regarding specific causation.

3  
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.*  
25  
26  
27  
28

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).  
13  
14

15  
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  
25  
26  
27  
28

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).

9  
10  
11  
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  
24  
25  
26  
27  
28

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  
23  
24  
25  
26  
27  
28

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.  
16  
17

18  
19 Therefore, the Court grants Defendants' Motion to Exclude the Specific  
20 Causation Testimony of Dr. Parmet.  
21

22 **Mr. Ewing**

23  
24 Defendants move to exclude the testimony of Mr. Ewing, an industrial  
25 hygienist, on the grounds that Mr. Ewing failed to support his opinions with  
26 scientifically valid and reliable methodology. Mr. Ewing prepared two reports. In  
27 his first report, dated September 14, 2009, Mr. Ewing states that he based his  
28

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).

13  
14  
15  
16  
17  
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  
26  
27  
28

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).  
4

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.  
14  
15  
16  
17

## 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  
26  
27  
28

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.  
5

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)).  
12  
13  
14

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).  
24  
25  
26  
27

28 Furthermore, the court will not presume missing facts, and non-specific facts in

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**

4  
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).

13  
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)).

19  
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  
25  
26  
27  
28

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).

16 The Newkirks’ fourth claim, loss of consortium and claim for medical  
17 expenses, is an element of damages and thus does not create a material question of  
18 fact to survive summary judgment if the other claims are dismissed. *See Walker v.*  
19 *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  
10  
11  
12 In this case, the Court has excluded Plaintiffs' proffered general causation  
13 expert witness, Dr. Egilman, as inadmissible. As discussed above, the Court also  
14 has excluded Plaintiffs' proffered specific causation expert witnesses: Dr.  
15 Egilman, Dr. Pue, Dr. Parmet, and Mr. Ewing. The Court finds that in light of the  
16 exclusion of Plaintiffs' evidence, Plaintiffs have failed to provide sufficient  
17 admissible evidence to support their burden of proof on any of their claims.  
18 Without evidence of causation claims, there is no genuine issue of material fact,  
19 and the Defendants are entitled to judgment as a matter of law. Fed. R. Civ. P.  
20 56(c).

21  
22  
23  
24  
25 Therefore, the Court grants Defendants' Motion for Summary Judgment, Ct.  
26 Rec. 243. The Court dismisses all of Plaintiffs' claims with prejudice.

IV. CONCLUSION

**IT IS HEREBY ORDERED:**

- 1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  

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.



1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

<b>ADDENDUM A: Filings Related to the Motions Before the Court</b>	
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

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
3		
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
5		
6	Errata re Memorandum of Authorities in Support of Defendants' Joint Motion for Summary Judgment – with Attachment 1	Ct. Rec. 287
7		
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
11		
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
13		
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
15		
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
17		
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
19		
20	Additional Attachments to Main Document (327) – Exhibits 1 -11 (Ct. Rec. 328)	Ct. Rec. 328
21		
22	Additional Attachments to Main Document (327) – Exhibits MM-SS	Ct. Rec. 329
23		
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
28		
28	Additional Attachments to Main Document (327) – Exhibits QQQ-	Ct. Rec. 333

1	XXX	
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 Exlude 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

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

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).<sup>8</sup>

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 <sup>8</sup> 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).
- 20  
21  
22  
23  
24  
25  
26  
27  
28