

No. 10-35667

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

LARRY I. NEWKIRK and RUTH A.
NEWKIRK

Plaintiffs - Appellants,
and

DAVID EGILMAN,

Witness-Appellant,

v.

CONAGRA FOODS INC, a
Delaware corporation; CHR
HANSEN INC.,

Defendants - Respondents. /

No. 10-35667

D.C. No. 2:08-cv-00273-RMP
U.S. District Court for Eastern
Washington, Spokane

**DECLARATION OF DAVID
EGILMAN, M.D., M.P.H. IN
SUPPORT OF OPPOSITION TO
MOTION FOR ORDER TO
SHOW CAUSE WHY APPEAL
SHOULD NOT BE DISMISSED
FOR LACK OF STANDING**

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DECLARATION OF DAVID EGILMAN, M.D., M.P.H.

1. I am a medical doctor and Clinical Associate Professor of Family Medicine at Brown University.
2. I am board certified in Internal Medicine, and Preventive Medicine, and Occupational Medicine.
3. My office address is 8 North Main Street, Suite 404, Attleboro, Massachusetts, 02703.
4. I received a Bachelor of Science from Brown University in Molecular Biology in 1974 and a medical degree from Brown University in 1978. I completed a three-year medical residency in Internal Medicine at Strong Memorial Hospital in Rochester, New York, in 1981.
5. I completed a three-year training program in epidemiology, called the National Institutes of Health Epidemiology Training Program, in 1984. As part of this program, I completed a Master's program in Public Health at the Harvard School of Public Health. At Harvard, I studied industrial hygiene and toxicology, epidemiology, statistics, occupational medicine and law, and public policy with respect to occupational and environmental hazards including regulatory approaches to control, the tort system, environmental law, Food and

Drug Administration (FDA) and Occupational Safety and Health Administration (OSHA) law, the Consumer Products Safety Commission law, and areas that relate to the specialty of preventive medicine including education, product design changes and substitution. One course that I completed during the program relating to the various approaches to control of health hazards was a joint course offered by the Harvard Law School, the Harvard School of Public Health, and the MIT Business School. I completed a third residency in preventive medicine in 1994.

6. I served two years at the National Institute for Occupational Safety & Health (NIOSH), designing and conducting small and large epidemiological studies. I was responsible for interpreting and implementing aspects of the OSHA Act of 1971. While at NIOSH, the most important part of my responsibilities involved education of workers, employers and members of the public on health hazards. I provided this information through a variety of vehicles, including written reports, conferences, mass meetings and face-to-face conversation. NIOSH and the Centers for Disease Control (CDC) provided training on the mechanisms of effective communication.

7. Since 1978, I have published many medical articles on the issues that relate to the manner in which cause-effect determinations are made in medicine (the epistemology of medicine). I have discussed the normal, accepted process of causal determination in medicine in several peer-reviewed articles. In addition, these ideas were accepted for presentation and were presented at the American Public Health Association meetings in 1984. I have also studied, taught and published articles on the history of medical ethics, public health, and corporate responsibilities for and public health approaches to the education of populations and individuals on health hazards and the redesign of products. I have taught and done research on the history and development of medical and corporate practices concerning the need to inform patients and product users of potential health hazards over the past 150 years. I have, on two occasions, testified before congressional sub-committees on the issues relating to informed consent and corporate responsibility to inform members of the public about health hazards. My testimony concerned the history of informed consent. In addition, I have published two papers on the topic of the history and development of informed consent.

8. For the past 25 years, I have taught various courses at Brown University, which deal with the development of medical and scientific knowledge in the modern era (past 150 years). These courses deal specifically with issues of this Daubert motion: the history and development of knowledge of the health effects of various substances, including corporate knowledge, the history and development of government regulations on occupational and environmental safety, and the history and development of contemporaneous appropriate public health responses to information on the adverse health effects of products on users including education of product users and product redesign. My course has covered topics including tobacco, asbestos and diacetyl and flavorings relation to lung disease. I have also published peer reviewed papers on these topics. Egilman DS, Kim J. Proving Causation: The Use and Abuse of Medical and Scientific Evidence Inside the Courtroom—An Epidemiologist’s Critique of the Judicial Interpretation of the *Daubert* Ruling. *Food and Drug Law Journal* 58:2, 2003. My views on the scientific standards for the determination of cause-effect relationships (medical epistemology) have been cited by the Massachusetts Supreme Court (*Vassallo v. Baxter Healthcare Corporation*, 428 Mass. 1 (1998)):

"Although there was conflicting testimony at the Oregon hearing as to the necessity of epidemiological data to establish causation of a disease, the judge appears to have accepted the testimony of an expert epidemiologist that, in the absence of epidemiology, it is 'sound science.... to rely on case reports, clinical studies, in vivo tests and animal tests.' The judge may also have relied on the affidavit of the plaintiff's epidemiological expert, Dr. David S. Egilman, who identified several examples in which disease causation has been established based on animal and clinical case studies alone to demonstrate that 'doctors utilize epidemiological data as one tool among many.'"

9. My views on scientific decision making have also been adopted by the Wyoming Supreme Court.¹ My paper on Daubert issues was cited by the New Jersey appellate court (Cert denied):

"Physicians do not usually require a specific understanding of the underlying mechanism of a... disease before assessing causation.' David Egilman, M.D., et al., Proving Causation: The Use and Abuse of Medical and Scientific Evidence Inside the Courtroom - An Epidemiologist's Critique of the Judicial Interpretation of the Daubert Ruling, 58 Food & Drug LJ. 223, 245 (2003)." ANDREW MCCARRELL, Plaintiff-Respondent, v. HOFFMAN-LA ROCHE, INC., and ROCHE LABORATORIES, INC., Defendants-Appellants. C-938 September Term 2008, 64,031 SUPREME COURT OF NEW JERSEY 199 N.J. 518; 973 A.2d 385; 2009 N.J. LEXIS 584 May 19, 2009, Decided May 21, 2009.

10. The ruling will have adverse impacts on both my ability to testify and on public policy.

11. The Daubert ruling eliminates my ability to testify in this case and in others. I will lose the opportunity to bill for services in this case and

¹ Mary Lou Bunting and Nicholas Bunting, et al. vs. Charles Jamieson, 984 P.2d 467; 1999 Wyo. LEXIS 121; Supreme Court of WY, decided July 16, 1999. This case cites a law review which relied on my affidavit.

in others (although I generally donate most fees related to courtroom testimony to charitable organizations, the lack of opportunity to do so is an injury to me). Based on my experience, it is virtually certain that some lawyers will choose not to attempt to retain me as a result of this ruling. Some lawyers will be dissuaded from retaining my services because the ruling is replete with unsubstantiated pejorative attacks on my qualifications as a scientist and expert. The judge's rejection of my opinion is primarily an ad hominem attack and not based on an actual analysis of what I said – in an effort to deflect the ad hominem nature of the attack the judge creates "straw man" arguments and then knocks the straw men down, without ever addressing the substance of my positions.

12. As a consequence of the judge's attack I am personally, and unfairly, harmed. Any harm that I might suffer if a judge fairly rejected my arguments is something I would have to live with. But harm suffered as a consequence of an ad hominem attack, which I had no chance to refute, is unfair.

13. The fact that the judge denied the plaintiffs' request to allow me to testify at the Daubert hearing and that I had no opportunity to address the judge's concerns or answer any questions concerning my opinions

does not alter the fact that some lawyers will choose not to retain me as a result of this ruling. For example, without citation to any evidence, the judge effectively accuses and convicts me of perjury by stating that:

"Dr. Egilman's opinions fall below the threshold standard of scientific validity in other ways... scientists whose conviction about the ultimate conclusion of their research is so firm that they are willing to **aver under oath** that it is correct prior to performing the necessary validating tests could properly be viewed by the district court as lacking the objectivity that is the hallmark of the scientific method." [Emphasis added] (MEMORANDUM OPINION AND ORDER 30:20)

14. This conclusion will be used to invoke the legal principle "Falsus in uno, falsus in omnibus." Because I testify on cause-effect relationships involving a variety of toxic substances (e.g., tobacco, asbestos and benzene) any explanation will be a diversion from the main issues in other cases. Since these issues are often raised in pre-trial motions, the sponsoring lawyer will be forced to start the case on the defensive and often will not wish to risk his or her case on the possibility that another judge will disqualify me as a result of Judge Peterson's finding.

15. At best, the fact that this ruling will need to be defended in other cases makes it less likely that a lawyer will hire me instead of another witness. This will waste time and detract from my standing before a

future court and jury no matter what the technical legal outcome is in that case.² Indeed I expect that ConAgra, as it has in the past, will introduce similar ex-parte judicial opinions from other cases in response to this affidavit in an attempt to disparage me.

16. For example, when Judge Peterson's opinion is introduced in future cases it will require lawyers who retain me to mount a detailed response which will consume resources and time. I provide one such example here to demonstrate how this will likely unfold.

17. Judge Peterson created a "straw man" theory as the gravamen of my opinion. She claimed that I stated that the vapors from popcorn slurry in microwave popcorn bags ("MWPC vapors") to which consumers are exposed are quantitatively or qualitatively identical to the vapors from butter flavoring slurry in popcorn manufacturing plants ("slurry vapors") inhaled by workers:

"However, there is nothing to support **Dr. Egilman's conclusion that is at the heart of this case**: that the vapors emitted from a microwave popcorn bag contain the same proportion of chemicals or that **all of the substances in the two instances are identical.**" [Emphasis added] (MEMORANDUM OPINION AND ORDER 22:8)

² This will generally not occur in cases heard before Judges where I have already appeared as a witness. For example a New York state trial judge has praised plaintiffs' molecular-biology and public-health expert Dr. David Egilman as follows: "Dr. Egilman is a brilliant fellow and I always enjoy seeing him and I enjoy listening to his testimony . . . He is brilliant, he really is." [*Lopez v. Ford Motor Co., et al.* (120954/2000; *In Re New York City Asbestos Litigation*, Index No. 40000/88).]

18. Neither I, nor the plaintiffs, nor the **defendants** ever framed the question as Judge Peterson did (cf. AFFIDAVIT OF DR. DAVID EGILMAN IN SUPPORT OF PLAINTIFFS' OPPOSITION TO JOINT MOTION FOR SUMMARY JUDGMENT AND JOINT DAUBERT MOTIONS 9:17). Contrary to the judge's portrayal, this question of whether the vapors are qualitatively identical was not one that was even raised in the case, let alone the key question that lays "at the heart of this case" as Judge Peterson claimed. Her characterization contradicts the defendant ConAgra's correct presentation of the key issue in the case: "Plaintiffs' experts do not argue that there is no qualitative difference between slurry and MWPC vapors **(nor could they)**, but argue rather that any difference is insignificant..." [Emphasis added] (REPLY MEMORANDUM OF AUTHORITIES IN SUPPORT OF DEFENDANTS' JOINT MOTION TO EXCLUDE THE GENERAL CAUSATION TESTIMONY OF PLAINTIFFS' EXPERT WITNESSES 7:22).

19. This is akin to ruling that scientists cannot opine that a newly marketed cigarette causes cancer until they show that its smoke is qualitatively or quantitatively identical to smoke used in the epidemiologic studies linking cigarette smoke and cancer, which were

conducted decades ago using products whose contents have since changed. Scientists do not require such precision to conclude that cigarettes that were never included in any epidemiologic or content studies (e.g. Virginia Slims, Obamas, etc.) are also carcinogenic (EXPERT REPORT OF DR. DAVID EGILMAN pg. 15, AFFIDAVIT OF DR. DAVID EGILMAN 7:12, 7:21, 37:11, 72:1). Similarly, it is accepted that asbestos causes cancer in asbestos product manufacturing workers, construction workers who use those products and bystanders like teachers with environmental exposures to the asbestos which all three groups inhaled. Each group was exposed to different concentrations of asbestos and co-carcinogens. For example, many manufacturing workers were only exposed to asbestos while the products contained other carcinogens including silica. Nonetheless it is universally accepted that the asbestos containing products can cause cancer in all three exposed groups (AFFIDAVIT OF DR. DAVID EGILMAN 35:4, 36:9, 57:11, 71:23, cf. 2:25 - a reference to my peer-reviewed article on asbestos exposure and lung cancer).

20. Diacetyl is the asbestos of this case: consumers and workers inhaled diacetyl, the cause of the disease, in similar quantities (cf.

AFFIDAVIT OF DR. DAVID EGILMAN pg. 59-70). Arsenic kills whether it is mixed in milk, tea, or rum and coke (AFFIDAVIT OF DR. DAVID EGILMAN 7:12).

21. I argued, and the defense agreed, that the toxic substance diacetyl is contained in butter flavoring slurries, and that vapors from these slurries can cause disease in workers (TRANSCRIPT OF DAUBERT MOTION HEARING 40:13). The diacetyl is inhaled by workers when they prepare the slurry (MEMORANDUM OF AUTHORITIES IN SUPPORT OF DEFENDANTS' JOINT MOTION TO EXCLUDE THE GENERAL CAUSATION TESTIMONY OF PLAINTIFFS' EXPERT WITNESSES 7:14). The workers put the slurry into bags of popcorn destined for consumers (MEMORANDUM OF AUTHORITIES IN SUPPORT OF DEFENDANTS' JOINT MOTION TO EXCLUDE THE GENERAL CAUSATION TESTIMONY OF PLAINTIFFS' EXPERT WITNESSES 7:21). When the consumer heats the popcorn they heat the slurry. When the consumer heats the slurry, vapors containing diacetyl are released (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) 9:12). The consumer inhales the vapors which contain diacetyl. Diacetyl is the same toxin whether it is contained in vapors inhaled by workers or consumers, and the diacetyl is released from the slurry in the same way in both cases (it is released in vapors by heating the exact same slurry). There are different amounts of the toxin in the different slurries, but all butter flavoring slurries contained diacetyl (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) 7:11). Different amounts of diacetyl are released from different slurries (and there are hundreds of different slurries each with a unique formula) depending on heat, chemical composition, etc.^{3,4} Despite these qualitative and quantitative differences in vapors released from different slurries, the defense concedes that **all** diacetyl containing slurry vapors can cause disease (in workers) (TRANSCRIPT OF DAUBERT MOTION HEARING 40:13, MEMORANDUM OF AUTHORITIES IN SUPPORT OF

³ Aspen Research Corporation. Evaluation of microwave popcorn potential to emit organic compounds. Prepared by Roger Pearson, Ph.D. CAG010699. May 5th, 2005.

⁴Rosati JA, Kreb KA & X Liu 2007. Emissions from cooking microwave popcorn. Crit Rev Food Sci Nutr 47(8): 701-709.

DEFENDANTS' JOINT MOTION TO EXCLUDE THE GENERAL CAUSATION TESTIMONY OF PLAINTIFFS' EXPERT WITNESSES 7:14). What matters is that diacetyl has the same toxicity in all slurries and the same toxic effect on people who inhale it (cf. EXPERT REPORT OF DR. DAVID EGILMAN pg. 22-25, AFFIDAVIT OF DR. DAVID EGILMAN pg. 11-12). The exact chemical composition of the slurry is not the critical factor (cf. AFFIDAVIT OF DR. DAVID EGILMAN pg. 4-11).

22. Judge Peterson repeats this straw man argument throughout her ruling.

As I teach my students, asking the correct question is the most important proposition in science. If, as Judge Peterson has done in this case, one asks the wrong question it will either be unanswerable or the answer will be trivial.

"However, Dr. Egilman's underlying methodology for his conclusions regarding Dr. Rose's work is not reliable because he provides no basis to extrapolate from Dr. Rose's letter regarding a single patient **to the conclusion that slurry vapors are the same whether inhaled over a tank at a popcorn plant or from a bag of microwave popcorn**, and that those vapors can cause bronchiolitis obliterans in consumers." [Emphasis added] (MEMORANDUM OPINION AND ORDER 27:11)

"The same logic can be applied to **the central thrust of Dr. Egilman's opinion**: if the vapors have not been tested, **how can Dr. Egilman assert that the vapors from microwave popcorn are qualitatively identical to slurry vapors** and are causing the same

harm that slurry vapors likely caused?" [Emphasis added] (MEMORANDUM OPINION AND ORDER 47:1)

23. Judge Peterson's invented mischaracterization of the question to be answered is the gravamen of her opinion:

"There is simply too great an analytical gap between the existing data, indicating that exposure to butter flavoring vapors in the occupational setting can cause bronchiolitis obliterans, and **Dr. Egilman's opinion that a consumer of microwave popcorn is exposed to a vaporized substance equivalent to production plant butter flavoring vapors** at levels sufficient to cause bronchiolitis obliterans... His opinion testimony, therefore, is inadmissible under *Daubert* and Fed. R. Evid. 702." [Emphasis added] (MEMORANDUM OPINION AND ORDER 51:5)

24. There was no reason for me or the plaintiffs to address this question in the *Daubert* hearing or affidavits, since ConAgra correctly characterized my argument. The judge never raised this question prior to her ruling and did not permit me to testify at the hearing, denying me any opportunity to correct her mischaracterization of my opinions.

25. Although the judge makes many more misinterpretations of my opinions, this is the most critical. I can expect to be cross-examined on the judge's mischaracterizations and misinterpretations in any future litigation in which I testify. Although I can demonstrate that these statements are false, as I have shown, the time this would require is so burdensome that it greatly diminishes my appeal as an expert witness. Law firms will hesitate to retain me, knowing they

will have to invest significant time fending off these baseless, *ad hominem* attacks contained in the judge's ruling.

26. The judge incorporated unqualified and pejorative language into her ruling. Since Judge Peterson does not cite specific evidence for these attacks they cannot be defended and this will place me at a competitive disadvantage with other witnesses and discourage lawyers from retaining me as an expert witness. A few examples are provided here:

"Dr. Egilman relies on existing data, mostly in the form of published studies, but draws conclusions far beyond what the study authors concluded, or Dr. Egilman **manipulates the data** from those studies to reach misleading conclusions of his own." [Emphasis added] (MEMORANDUM OPINION AND ORDER 25:10)

"Dr. Egilman also fails to apply reliable scientific methods when he extrapolates from extremely small samplings to make sweeping conclusions." (MEMORANDUM OPINION AND ORDER 33:15)

"The bulk of Dr. Egilman's conclusions do not rise above 'subjective belief or unsupported speculation.'" (MEMORANDUM OPINION AND ORDER 51:12)

27. Finally, the judge based some of her criticism on opinions which she acknowledged she did not understand, stating:

"It is unclear whether Dr. Egilman is saying in the first statement that the products cause lung disease but have not been measured in peer reviewed studies or, alternatively, that there have been no peer reviewed studies that have produced exposure measurements showing that exposure rates to naturally-occurring diacetyl are high enough to

cause lung disease" [Emphasis added] (MEMORANDUM OPINION AND ORDER 48:19)

28. The judge goes on to write disparaging remarks and criticisms of me based on her assumption that I take the first of the two interpretations she has outlined. This is an incorrect presumption and reflects a misunderstanding of the written statement I prepared (cf. MEMORANDUM OPINION AND ORDER pg. 47). Had I been allowed to testify I would have explained this. The judge states that her criticism on this issue is representative of "problems in Dr. Egilman's opinions as a whole" (MEMORANDUM OPINION AND ORDER 48:11), but gives no examples or explanation for this unqualified accusation.

29. The ruling will have adverse public policy implications by discrediting my scientific methodology and personally attacking my qualifications and abilities as a scientist. This undermines my extensive academic work, in particular my academic work on the interpretation of the scientific method and public policy including Daubert. As noted above, several State Supreme Courts have directly cited my work (or in the case of the Wyoming Supreme court via a law review which relied on my affidavit to establish Daubert standards for the interpretation of scientific information). The ruling

will also be used in the academic community to undermine the validity of my scientific arguments. This will have adverse impact on the regulation of toxic substances and other public policy with respect to warnings and risk communication.

30. The substance of my appeal extends significantly beyond the purview of the Newkirk's appeal, however I have no control over the Plaintiff's legal decisions in this appeal. If I am not granted independent standing I will be denied any recourse to redress these injuries, in the event the Plaintiff's settle the case or otherwise dismiss their appeal.

I declare under penalty of perjury that the foregoing is true and correct. Executed at Denver, Colorado on November 10, 2010

A handwritten signature in cursive script that reads "David Egilman MD, MPH".

David Egilman MD, MPH