Our reference: 8027

February 15, 2006

U.S. Department of Justice
Washington, D.C. 20530

Re: Expert Report of Dr. Bruce Kelman in the matter of Mitchell *et al.* v. United States

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I have been asked to provide an expert opinion regarding the claims of human health effects from alleged exposure to molds in the matter of Mitchell *et al.* v. United States. I have extensive general knowledge in the field of toxicology and specific knowledge of the effects of mycotoxins from mold in indoor environments. The following report outlines my relevant qualifications and opinions.

Opinions

I conclude, to a reasonable degree of scientific certainty, the following opinions:

- Mold and mold spores are ubiquitous, and the maintenance of a mold-free home environment is not possible.
- Sampling and analysis presented in the report by Mold Lab Int'l is not useful for estimating exposure because of inappropriate sampling techniques, lack of controls, and a lack of laboratory accreditation.
- There are no data showing that mycotoxins were present in the indoor air of the residence at 2063-N Evans Road.
- There are no data showing that there was a sufficient amount of mycotoxin present in the indoor air of the residence at 2063-N Evans Road to have caused any injury to occupants.
- There could not have been sufficient amounts of mycotoxin present at the

subject property to cause any injuries to occupants.

- The symptoms identified by the Mitchell family have many possible causes and cannot be attributed to mycotoxin exposure during their occupancy of the residence at 2063-N Evans Road.

Qualifications

I am a board-certified toxicologist, certified by the American Board of Toxicology. I am a member of the Society of Toxicology, the American College of Occupational and Environmental Medicine, the American College of Toxicology, and the American Society of Pharmacology and Experimental Therapeutics. I am also a Registered Toxicologist in the United Kingdom and EUROTOX Registries. I received a Bachelor of Science degree in Physiology and Biophysics from the University of Illinois in 1969, a Master of Science degree and Ph.D. from the University of Illinois, Department of Physiology and Pharmacology in 1971 and 1975, respectively. I also did a Post Doctoral Study in Toxicology at the University of Tennessee from 1974 through 1976. Currently, I am a Principal of Veritox, Inc. Veritox charges $400 USD for my time. I have attached a true and correct copy of my curriculum vitae, rate schedule, and testimony list to this report (Appendices A – C).

The basis for my opinions in this case includes my education, training in basic science, experience in toxicology in general and as specifically related to mycotoxin exposure, ongoing review and analysis of published literature on the effects of mycotoxins on a broad range of mammalian species including humans, and general knowledge of the adverse effects of chemicals on mammalian species including humans. This training, experience, and study of the published literature include in-depth knowledge of inhalation toxicology, which includes normal respiration and adverse respiratory effects resulting from exposure to chemicals.

Records Reviewed

I reviewed the following records:

- Complaint;
- Answer to Complaint;
- First set of Interrogatories;
- Plaintiffs' Response to Defendant United States' First Set of Interrogatories, Requests for Production of Documents and Requests for Admissions;
- Plaintiffs' Response to Defendant United States' Second Set of Requests for Production;
- Deposition of Brenda Mitchell, dated 10/25/05;
- Deposition of Dominique Mitchell, dated 10/26/05;
- Deposition of Jennifer (Mitchell) Palmer, dated 10/26/05;
- Deposition of Calvin Mitchell, dated 10/27/05;
- Exhibits (1-27) to the Depositions of Brenda Mitchell, Dominique Mitchell, Jennifer Mitchell Palmer, and Calvin Mitchell;
- HHIM Survey Summary Report (Part I-IV), indoor air survey;
- Department of the Army, Department of Preventive Medicine letter to MSG and Mrs. Mitchell from Ms. C. Perry, dated 03/07/02;
- Department of the Army Memorandum for Housing Management Division re: industrial hygiene survey of 2063-N from Ms. C. Perry, dated 06/18/02;
- Aerotech Laboratories, Inc. reports, dated 02/13/02 and 06/18/02;
- Letter from J. Dutcher, Jr. Esq. to claims Judge Advocate regarding claims of the Mitchell's, dated 01/28/04;
- Department of the Army letter from J. Murphy to J. Dutcher, Jr. Esq. regarding the Mitchell's claims, dated 05/04/04;
- HHIM Single Air Sample Report, dated 02/28/05;
- Mold Lab Int'l Environmental Survey, dated 01/27/06;
- Mold Lab Int'l Mold Screening Report, dated 01/30/06;

- Email correspondence amongst C. Mitchell, B. Spencer, C. Ford, R. Means, and K. Kerchief regarding mold and the Mitchell's request for relocation;
- Medical records for Brenda Mitchell
- Medical records for Dominique Mitchell
- Medical records for Jennifer Mitchell
- Medical records for SDM
- Medical records for CAM

Complaint

Based on my review of the above records, it is my understanding that in the summer of 1999, the Mitchell family (Calvin, Brenda, Dominique, Jennifer, SDM, and CAM) moved into 2063-N Evans Road, Fort Sill, Oklahoma.

Plaintiffs admit that the alleged mold incident first occurred in January 2002 (Plaintiffs' Response to Defendant United States' First Set of Interrogatories, Requests for Production of Documents, and Requests for Admissions, p. 11). Mold was again reportedly found by the Mitchell's in early 2003 and 2004 (Deposition of Calvin Mitchell 78:5-88:25, Brenda Mitchell Deposition 95:24-96:19). Hot water leaks were reported in 05/04 and 07/04 (Deposition of Brenda Mitchell 93:3-93:23, 94:4-94:25).

Spore trap samples were collected by the Industrial Hygiene section of the Department of Preventive Medicine on February 7, 2002 and June 11, 2002. VOC air samples were also collected on February 7, 2002 (Department of Preventive Medicine letter to MSG and Mrs. Mitchell from C. Perry, March 7, 2002; HHIM Single Air Sample Report, February 28, 2005; Memorandum for Housing Management Division from CL Perry, June 18, 2002).

According to the plaintiff expert report, on January 25, 2006, Mold Lab Intl' collected

settled plate mold samples (Mold Lab Intl' Environmental Survey Report, dated 01/27/06; Mold Lab Int'l Mold Screening Report, dated 01/30/06).

In January 2003 the mold in the basement, ductwork, and ventilation shafts in the ceilings and floors was allegedly cleaned (Plaintiffs' Response to Defendant United States' First Set of Interrogatories, Requests for Production of Documents, and Requests for Admissions, p. 7). Plumbing and sump pump repairs were completed shortly thereafter (Exhibit 9, LIT 00047).

Analysis of Toxicological Issues

Possible effects of mold exposure are allergies, infections, and toxicity. (Hardin, B.D., B.J. Kelman, and A. Saxon. 2003. Adverse Human Health Effects Associated with Molds in the Indoor Environment. Evidence-Based Statement, American College of Occupational and Environmental Medicine, J Occupation Environ Med. 45:470-478; American Academy of Allergy, Asthma and Immunology. Position Paper. Environmental and occupational respiratory disorders. J Allergy Clin Immunol 117(2):326-333).

Allergy

Molds are common and important allergens. About 5% of individuals are predicted to have some allergic airway symptoms from molds over their lifetime. However, it should be remembered that molds are not dominant allergens and that the outdoor molds, rather than indoor ones, are the most important.

Infection

Fungi are rarely significant pathogens for humans. Superficial fungal infections of the skin and nails are relatively common in normal individuals, but those infections are readily treated and generally resolve without complication. Fungal infections of deeper

tissues are rare and in general are limited to persons with severely impaired immune systems. The leading pathogenic fungi for persons with non-impaired immune function, *Blastomyces*, *Coccidioides*, *Cryptococcus*, and *Histoplasma*, may find their way indoors with outdoor air, but normally do not grow or propagate indoors. Due to the ubiquity of fungi in the environment, it is not possible to prevent immune-compromised individuals from being exposed to molds and fungi outside the confines of hospital isolation units.

Toxicity

Some molds that propagate indoors may, under some conditions, produce mycotoxins that can adversely affect living cells and organisms by a variety of mechanisms. Adverse effects of molds and mycotoxins have been recognized for centuries following ingestion of contaminated foods. Occupational diseases are also recognized in association with inhalation exposure to fungi, bacteria, and other organic matter, usually in industrial or agricultural settings. Molds growing indoors are believed by some to cause building-related symptoms. Despite a voluminous literature on the subject, the causal association remains weak and unproven, particularly with respect to causation by mycotoxins.

As a toxicologist, I evaluated whether or not the environmental conditions could have caused a toxic response in any members of the Mitchell family.

To determine whether exposure to a chemical has caused an injury, toxicologists have reached the following generally-accepted consensus on the methodology to be used. If any one of the following criteria are not met, causation cannot be established (Reference Manual on Scientific Evidence, 2nd edition, Federal Judicial Center).

a. The chemical(s) in question must first be present.
b. Toxicological and/or epidemiological studies must show that the chemical(s) in question are able to cause the claimed adverse effect.
c. Exposure of an individual(s) to the chemical(s) must be in sufficient quantities and sufficient length of time to cause the claimed adverse effect.

d. Exposure to the chemical(s) must precede the claimed adverse effect with an appropriate time frame specific to the individual chemical in which the development of the effect occurs.
e. If the above criteria are met then alternative known causes of the claimed adverse effect must be considered and weighed against the probability that the chemical(s) in question caused or contributed to the adverse effect.

As a toxicologist, I used the above criteria to determine whether or not the plaintiff could have been adversely affected by mycotoxins.

a) Were molds and mycotoxins present?

Were mold spores present and were they higher indoors than outdoors?

Molds are part of the fungi kingdom, which comprises a diverse group of organisms that evolved over 400 million years ago (Sherwood-Pike MA, and Gray J. 1985. Silurian fungal remains: probable records of the class Ascomycota. Lethaia 18:1-20). Mold and mold spores are everywhere around us, and have always been a part of our environment. The air we breathe is a virtual jungle of fungal spores, and we routinely encounter mold spores as part of everyday life both indoors and outdoors. Spore levels may vary seasonally, but some spores are always present (Solomon WR. 1975. Assessing fungus prevalence in domestic interiors. J Allergy Clin Immunol 56(3):235-242). The ubiquitous presence of mold in air and on building materials makes it impossible to construct or maintain a building that is mold-free using standard building design and construction techniques. Even if construction of a mold-free building space were possible, the maintenance of a "mold-free" home environment under normal conditions would be impossible, as many species of mold are naturally present on and in human bodies, potted plants, and on foods such as fresh fruit and cheeses. The most significant source of mold spores indoors is reported to be the outdoor air (Solomon WR. 1975. Assessing fungus prevalence in domestic interiors. J Allergy Clin Immunol 56(3):235-242), and a mold-free building will no longer be mold-free once a door or window is opened, or a person enters.

It is therefore almost certain that mold spores were present in the home environment, and the question is whether there is an increased risk of health effects from indoor levels as opposed to outdoor levels. The maximum concentration of airborne spores measured inside the subject property 2063-N Evans Road was 40,467 spores/m^3 in the basement (as reported for sampling done February 7, 2002 by the Department of the Army Department of Preventative Medicine; Reynolds Army Community Hospital). The maximum concentration of airborne spores measured outside the building on this date was 800 spores/m^3. By this comparison alone, the indoor spore concentration might be initially considered elevated compared to outdoor concentrations. However, the level measured in the basement was 5 – 12 times higher than measurements collected in the actual living and sleeping areas of the house.

Furthermore, the spore concentration in an outdoor sample collected on June 11, 2002 was 53,836 spores/m^3 illustrating the natural variability in spore concentrations. A wide range of indoor and outdoor measurements is often a natural variation from changing indoor or outdoor conditions. Outdoor variation may be due to any number of environmental factors such as proximity to bodies of water (or other sources of humidity), wind patterns around the sampling area, vegetation, or variability of sunlight. Spore concentrations may vary by season and are typically highest in the autumn and summer. Spores may be transported indoors through ventilation systems, or on the shoes or clothing of individuals. The most common airborne fungi, both indoors and outdoors and in all seasons and regions were *Cladosporium*, *Penicillium*, and *Aspergillus*. (Shelton BG, Kirkland KH, Flanders WD, Morris GK. Profiles of airborne fungi in buildings and outdoor environments in the United States. Appl Environ Microbiol. 2002 Apr;68(4):1743-53; Burge HA, Pierson DL, Groves TO, Strawn KF, Mishra SK. Dynamics of Airborne Fungal Populations in a Large Office Building. Current Microbiology. 2000 40:10-16).

Were mycotoxins present?

Mycotoxins are fungal metabolites that may be toxic to humans and/or animals. They are sometimes be produced by molds as by-products of mold's biological processes and are not required to maintain the life of the mold.

No data provided for review indicated that any mycotoxins were present at the subject property. An exhaustive review of the scientific literature indicates there is agreement that mycotoxins are only sometimes produced by molds; they are not always produced (Tuomi T, et al. (2000). Mycotoxins in crude building materials from water-damaged buildings. Appl. Evn. Microbiol., 66(5):1899-1904; Burge HA. (2001). The Fungi -Chapter 45. In: Indoor Air Quality Handbook (Eds: Spengler JD, Samset JM, McCarthy JS). McGraw Hill, P.45-11); Rao CY. (2001). Toxigenic Fungi in the Indoor Environment (Chapter 46). In: Indoor Air Quality Handbook (Eds: Spengler JD, Samset JM, McCarthy JS). McGraw Hill. Pp. 46-2 and 46-4; Ren P. Ahearn DG, Crow SA. (1999). Comparative study of *Aspergillus* mycotoxin production on enriched media and construction material. J. Ind. Microbiol. 209-213).

Thus, exposure to molds does not mean exposure to mycotoxins.

b) <u>Are mycotoxins in a home environment capable of causing the adverse effects claimed by the plaintiff?</u>

The plaintiffs must establish that mycotoxins are capable of causing the health effects claimed to be caused by exposure to mycotoxins. The members of the Mitchell family identified the following injuries:

The Mitchell Family – Brenda, Dominique, Jennifer, SDM, and CAM (as identified in Email from Calvin Mitchell to Ms. Spencer on 5/21/02 (Bates #00033); Plaintiffs' Response to Defendant United States' First Set of Interrogatories, Requests for Production of Documents, and Requests for Admissions, page 8; Deposition of Brenda Mitchell - 99:5-99:21, 103:2-103:13; Deposition of Calvin Mitchell - 29:21-30:20; Claim for Damage, Injury, or Death - Defendant's Exhibit 3):

- Aches
- Bronchitis
- Chest pains
- Colds
- Congestion
- Depressed immune system
- Dizziness
- Fatigue
- Eye irritation
- Gastroenterological inflammation and "problems"
- Headaches
- Infections
- Nausea
- Pneumonia
- Respiratory problems
- Respiratory infections
- Runny nose
- Shortness of breath
- Sinus infections
- Soreness in the leg
- Vomiting
- Weakness

The following injuries were specifically identified for each family member:

Brenda Mitchell (Plaintiffs' Response to Defendant United States' First Set of Interrogatories, Requests for Production of Documents, and Requests for Admissions, page 8; Deposition of Brenda Mitchell - 99:5-99:21, 101:3-102:1, 110:6-110:22, 157:25-158:15; Deposition of Calvin Mitchell - 90:24-91:21, 107:12-107:15):

- Breathing difficulty
- Chest pain
- Memory loss
- Headaches
- Dizziness
- Nausea

- Side pain
- Tiredness
- Deterioration of tissue around heart

Dominique Mitchell (Deposition of Brenda Mitchell -103:14-105:8; Deposition of Calvin Mitchell - 107:16-107:21; Deposition of Dominique Mitchell 14:2-14:15, 17:22-18:1; Claim for Damage, Injury, or Death (Defendant's Exhibit 3)):

- Breathing difficulty
- Cough
- Sinus problems
- Bronchitis
- Runny nose
- Headaches
- Nausea
- Wheezing
- Vomiting
- Dizziness
- Weakness
- Aches
- Depressed immune system

Jennifer Mitchell (Deposition of Brenda Mitchell -103:14-105:8; Deposition of Calvin Mitchell - 107:22-108:6; Deposition of Jennifer Mitchell -15:1-16:3, 31:18-32:20; Claim for Damage, Injury, or Death (Defendant's Exhibit 3)):

- Breathing difficulty
- Sinus infections
- Headaches
- Nausea
- Fatigue
- Cough
- Vomiting
- Dizziness
- Weakness
- Aches
- Depressed immune system

SDM (Deposition of Brenda Mitchell -103:14-105:8, 161:11-161:20; Deposition of Calvin Mitchell - 89:21-90:23, 108:7-108:15; Claim for Damage, Injury, or Death - Defendant's Exhibit 3-):

- Breathing difficulty
- Sinus problems
- Tiredness
- Cough
- Runny nose
- Nausea
- Vomiting
- Dizziness
- Headaches
- Weakness
- Aches
- Depressed immune system

CAM (Deposition of Brenda Mitchell - 103:14-105:8, 160:1-161:1; Deposition of Calvin Mitchell -108:18-108:21; Claim for Damage, Injury, or Death (Defendant's Exhibit 3)):

- Coughing
- Wheezing
- Congestion
- Sinus infections
- Bronchitis
- Headaches
- Nausea
- Vomiting
- Dizziness
- Weakness
- Aches
- Depressed immune system

Based on an exhaustive review of the scientific literature, these illnesses claimed by the plaintiff are not consistent with what is known about the effects of mycotoxins from exposure via inhalation in a residential environment.

Specifically, the symptoms claimed by members of the Mitchell family have not been shown to be caused by exposure to mycotoxins of any kind under any circumstances. I conducted an exhaustive search of the scientific literature and was unable to find any peer-reviewed literature showing an association between inhalation of mycotoxins in a residential environment and these claimed symptoms:

- Bronchitis
- Chest Pain
- Congestion
- Eye Irritation
- Headaches
- Pneumonia

- Dizziness
- Fatigue
- Runny Nose
- Depressed immune system
- Shortness of Breath
- Sinusitis

Coughing, nausea, vomiting, weakness, or immune suppression has been shown to be caused by exposure to specific mycotoxins under specific exposure conditions such as contaminated feed in livestock or accidental ingestion of contaminated food by humans. These are not relevant exposures to the claims being made in this case. Additionally, these symptoms are non-specific, and cannot be attributed to mycotoxins in the absence of specific signs of mycotoxicosis. I conducted an exhaustive search of the scientific literature and was unable to find any peer-reviewed report showing mycotoxins cause coughing, nausea, vomiting, weakness, or immune suppression in the absence of toxin-specific signs of mycotoxicosis. There are no peer-reviewed reports showing inhalation of mycotoxins in a residential environment causes coughing, nausea, vomiting, weakness, or immune suppression.

Allergy induced asthma is a possible outcome of mold exposure in allergic individuals. The presence of asthma alone, however, is not indicative of an environmental allergy, as there are numerous other factors that can cause or trigger asthma including irritants (such as tobacco smoke or strong odors) changes in weather, viral or sinus infections, exercise, medications, food, emotional anxiety, and reflux disease (AAAAI, http://www.aaaai.org/patients/resources/fastfacts/asthma.stm, accessed 2/15/2006).

If a individual's asthma is allergic, allergy testing must be conducted in order to determine what allergens the patient is reacting to. Typical allergy tests screen for dust mites, pet dander, molds, trees, grasses, weeds, and cockroach droppings (AAAAI, http://www.aaaai.org/patients/publicedmat/tips/whatisallergytesting.stm).

An allergy test is necessary to support a claim of allergy to a specific antigen. This information is not available for the Mitchell family. Although we have a records for

Brenda Mitchell who was tested for trees and weeds on March 17, 2004 (Medical Records of Brenda Mitchell, RACH 129), there are no test results showing that any member of the Mitchell family is allergic to molds.

I am a co-author of the American College of Occupational & Environment Medicine Fact-Based Position Statement entitled: Adverse Human Health Effects Associated with Molds in the Indoor Environment (Hardin, B.D., B.J. Kelman, and A. Saxon. 2003. Adverse Human Health Effects Associated with Molds in the Indoor Environment. Evidence-Based Statement, American College of Occupational and Environmental Medicine, J Occupation Environ Med. 45:470-478) which represents the current medical position of the American College of Occupational and Environmental Medicine as to the issue of alleged "toxic mold." This position can be summarized as follows:

1. Mold growth in the home, school, or office environment should not be tolerated because mold physically destroys the building materials on which it grows, mold growth is unsightly and may produce offensive odors, and mold is likely to sensitize and produce allergic responses in allergic individuals.
2. Except for persons with severely impaired immune systems, indoor mold is not a source of fungal infections.
3. Current scientific evidence does not support the proposition that human health has been adversely affected by inhaled mycotoxins in home, school, or office environments.

Additionally, I direct regular searches of the scientific literature for research and reviews investigating possible effects of mycotoxin inhalation on human health effects, and I personally read and review relevant literature. There are many researchers and a great number of experts, publications, and learned bodies that draw the same conclusions and opinions from available data on mycotoxin inhalation and effects in humans.

Most independent researchers and all learned bodies have reached the conclusion that exposure to mycotoxins in residential, office, or school environments has not caused

adverse effects in occupants.

- Assoulin-Dayan, Y et al. 2002. Studies of sick building syndrome. IV. Mycotoxicosis. J Asthma 39(3):191-201.
  - "Although exposure to molds can produce significant mucosal irritation, there are very few data to suggest long-term ill effects. More importantly, there is no evidence in humans that mold exposure leads to nonmucosal pathology."
- Bardana, EJ, Jr. (2003). Indoor air quality and health -- Does fungal contamination play a significant role? Immunol Allergy Clin North Am. 23(2):291-309.
  - "Because fungi are encountered indoors and outdoors, there is no way to ascribe development of sensitivity or adverse health effects to a specific indoor exposure."
  - "A number of investigators have associated subjective complaints of headache, memory loss, lack of concentration, and other nonspecific symptoms as evidence of brain damage caused by mycotoxins or other fungal products. There is no scientific evidence that *Stachybotrys* or other fungal species detected in indoor air or present on building materials cause brain damage."
  - "Fungal contamination in buildings can vary greatly, and their presence in a dwelling does not necessarily constitute exposure. ... The presence of a specific immune response to a fungal antigen only connotes that exposure to one or more related species has occurred, but not that there is a symptomatic clinical state. ... When disease occurs, it more likely is related to transient annoyance or irritational reactions. ... Building-related disease caused by mycotoxicosis has not been proved in the medical literature."
- Bennett JW, Klich M. 2003. Mycotoxins. Clinical Microbiology Reviews 16(3):497-516.
  - "Toxic-mold fears have precipitated a spate of lawsuits. In particular, a Texas case against Farmers Insurance Group has attracted a lot of publicity, and the number of mold damage cases, especially in water-damaged homes, is growing at a rapid rate. Unfortunately, much of the evidence is conjectural. Mycotoxins and other microbial products have been implicated as causative agents, but the

range of symptoms attributed to toxic molds exceeds what can be explained rationally in terms of toxicological mechanisms."

- Burge HA. 2001. Fungi: toxic killers or unavoidable nuisances? Ann Allergy Asthma Immunol. 87:52-56.
  - "The review led to the conclusion that the primary result from fungal exposure is allergic disease, and that the evidence for inhalation disease resulting from mycotoxin exposure in residential and office settings is extremely weak."
- Chapman JA. 2003. *Stachybotrys chartarum* (chartarum = atra = alternans) and other problems caused by allergenic fungi. Allergy Asthma Proceedings 24(1):1-7.
  - "... I have reviewed the literature concerning *Stachybotrys chartarum* and have not found scientific data to support the current public concern about health effects."
- Chapman JA et al. 2003. Toxic mold – phantom risk vs science. Annals of Allergy Asthma and Immunology. 91(3):222-232.
  - "When mold-related symptoms occur, they are likely the result of transient irritation, allergy, or infection. Building-related illness due to mycotoxicosis has never been proved in the medical literature. Prompt remediation of water-damaged material and infrastructure repair should be the primary response to fungal contamination in buildings."
- Fung F, Hughson WG. 2003. Health effects of indoor fungal bioaerosol exposure. Appl Occup Environ Health 18:535-544.
  - "... specific human toxicity due to inhaled fungal toxins has not been scientifically established."
  - "Specific human toxicity due to inhaled mycotoxins is not well understood, and the likelihood that sufficient mycotoxins are airborne despite visible indoor mold remains unproven and controversial."
- Fung F, Clark RF. 2004. Health effects of mycotoxins – A toxicological overview. J Toxicol Clin Toxicol 42:217-234.
  - "Currently, there is no supportive evidence to imply that inhaling mold or

mycotoxins in indoor environments is responsible for any serious health effects other than transient irritation and allergies in immunocompetent individuals."

- Gots RE et al. 2003. Indoor health – Background levels of fungi. AIHAJ 64:427-438.
  - "The data gathered in this review of the literature strongly suggest that current recommendations do not reflect concentrations reported in non-complaint structures or those detected in outdoor environments, nor do they reflect levels that reasonably could be associated with adverse health outcomes." (p 436)
- Khun DM, Ghannoum MA. 2003. Indoor mold, toxigenic fungi, and *Stachybotrys chartarum*: infectious disease perspective. Clinical Microbiology Reviews. 16(1):144-172.
  - "...we have not found supportive evidence for serious illness due to *Stachybotrys* exposure in the contemporary environment."
- Lees-Haley PR. 2004. Toxic mold and mycotoxins in neurotoxicity cases – *Stachybotrys*, *Fusarium*, *Trichoderma*, *Aspergillus*, *Penicillium*, *Cladosporium*, *Alternaria*, *Trichothecenes*. Psychological Reports. 93(2):561-584.
  - "At present there is no scientific basis for claiming that individuals have suffered mental and emotional injuries by inhalation of mold, mold spores or mold metabolites, including mycotoxins in residential or office environments. To the extent that experts express conclusions that mold inhalation in residences or offices caused mental or emotional injuries or brain injury, their opinions are speculation, possibilities, and guesses." (p 579)
- Page EH, Trout DB. 2001. The role of *Stachybotrys* mycotoxins in buildings related illness. Am Ind Hyg Assoc J. 62:644-648.
  - "The literature review indicates that currently there is inadequate evidence supporting a causal relationship between symptoms or illness among building occupants and exposure to mycotoxins."
- Robbins CA et a. 2000. Health effects of mycotoxins in indoor air: a critical review. Appl Occup Environ Hyg. 15:773-84.
  - "...the current literature does not provide compelling evidence that exposure at

levels expected in most mold-contaminated indoor environments is likely to result in measurable health effects."

- Terr AI. 2001. *Stachybotrys*: relevance to human disease. Ann Allergy Asthma Immunol. 87:57-63.
  - "The current public concern for adverse health effects from inhalation of *Stachybotrys* spores in water-damaged buildings is not supported by published reports in the medical literature."
- Terr AI. 2004. Are indoor molds causing a new disease? J Allergy Clin Immunol. 113:221-226.
  - "There is no current body of clinical data defining a disease or pathology in those who claim illness from indoor mold growth because of water intrusion."
  - "Guidelines for the concentration of indoor molds have been published by a number of governmental and nonpublic entities, but to date, *none* of these guidelines are based on scientific data regarding the effects on human health or any specific disease." [emphasis in the original]

Notably, no learned body has reached the conclusion that exposure to mycotoxins in residential, office, or school environments has caused adverse effects in occupants:

- Centers for Disease Control and Prevention (CDC). 2000. Update: pulmonary hemorrhage/hemosiderosis among infants – Cleveland, Ohio, 1993-1996. MMWR 49:180-84.
  - "The reviews led CDC to conclude that a possible association between acute pulmonary hemorrhage/hemosiderosis in infants and exposure to molds, specifically *Stachybotrys atra*, was not proven."
- Texas Council on Scientific Affairs. 2002. Report of Council on Scientific Affairs: Black Mold and Human Illness. CSA Report 1-I-02.
  - "After reviewing available data, the council has concluded that public concern for adverse health effects from inhalation of *Stachybotrys* spores in water-damaged buildings is generally not supported by published reports in medical literature."

- "...the proposition that molds in indoor environments may lead to adverse health effects through mechanisms other than infection and allergic/immunologic reactions is an untested impression."
- "Adverse health effects from inhalation of *Stachybotrys* spores in water-damaged buildings is not supported by available peer-reviewed reports in medical literature."

- **ACOEM. 2003. Evidence-Based Statement. Adverse Human Health Effects Associated with Molds in the Indoor Environment. JOEM 45(5):470-478.**
  - **"Current scientific evidence does not support the proposition that human health has been adversely affected by inhaled mycotoxins in the home, school, or office environment."**
- **AAAAI. Position Paper. Environmental and occupational respiratory disorders. J Allergy Clin Immunol 117(2):326-333.**
  - **"The occurrence of mold-related toxicity (mycotoxicosis) from exposure to inhaled mycotoxins in nonoccupational settings is not supported by the current data, and its occurrence is improbable.**

Further, in an extensive analysis, the Institute of Medicine did not conclude that any adverse health outcomes are caused by the presence of mold or other agents in damp indoor environments. The Institute did find sufficient evidence to conclude that there is an association between certain symptoms (upper respiratory (nasal and throat) tract symptoms, cough, hypersensitivity pneumonitis in susceptible persons, wheeze, and asthma symptoms in sensitized persons) and mold or damp indoor environments, but the Institute makes it clear that "associated with" does not mean "caused by." The Institute also found that the evidence is not sufficient to show even an association between the presence of mold or other agents in damp indoor environments and any other agents in damp indoor environments and any other symptom. (Institute of Medicine; Committee on Damp Indoor Spaces and Health. 2004. Damp Indoor Spaces and Health. National Academies Press Washington, D.C.).

c) Did the plaintiffs have an opportunity for contact with mycotoxins, and if so, did the exposure result in a sufficient dose to cause the claimed adverse effects?

Although there are no data showing that any mycotoxins were present at the subject property, if they were, the mycotoxins would have to gain access to the biological receptor (here, the individuals of the Mitchell family) in sufficient quantities to cause an effect.

The dose-response relationship is the most fundamental and pervasive concept in toxicology and an understanding of this relationship is essential for the study of toxic materials. The fundamental basis of the quantitative relationships between exposure to an agent and the incidence of an adverse response is the dose-response assessment (Casarett and Doull's Toxicology: The Basic Science of Poisons, Fifth Edition. CD Klaassen, ed. McGraw-Hill. 2001). All chemicals have toxic properties that become apparent as increasing quantities are consumed or absorbed. It follows that there are "safe" levels of exposure to even the most toxic substances (Occupational Medicine, Third Edition. C Zenz, ed. Mosby-Year Book, Inc. 1994).

A particularly important term in toxicology is threshold, which means the level of exposure at which an effect is first observed (Occupational Medicine, Third Edition. C Zenz, ed. Mosby-Year Book, Inc. 1994; Casarett and Doull's Toxicology: The Basic Science of Poisons, Fifth Edition. CD Klaassen, ed. McGraw-Hill. 1996). The erroneous opinion that exposure to "toxic chemicals" at any dose produces deleterious effects abounds in the lay public and is prevalent in the medical profession. The fact that dose defines toxicity for all chemicals has been recognized for centuries (Montgomery MR, Reasor MJ. (1994). A Toxicologic Approach for Evaluating Cases of Sick Building Syndrome or Multiple Chemical Sensitivity. J Allergy Clin. Immunol., 94 (2): 371-375).

Exposure-response relationships are among the most important criteria for inferring causality (Patty's Industrial Hygiene and Toxicology, Volume 1, Part B, Fourth Edition. GD Clayton and FE Clayton, eds. John Wiley & Sons, Inc. 1991). **Characterizing the**

dose-response relationship involves understanding the importance of the intensity of exposure, the concentration × time relationship, a chemical threshold, and the shape of the dose-response curve. The metabolism of a chemical at different doses, its persistence over time, and an estimate of the similarities in disposition of a chemical between humans and animals are also important aspects of a dose-response evaluation (Principles and Methods of Toxicology, Third Edition. AW Hayes, ed. Raven Press. 1994).

Neither documented exposure nor odor detection necessarily dictates adverse responses to any chemical. To repeat an overused but often ignored truism: the dose of a chemical determines whether that chemical is toxic or nontoxic. Appreciation and application of this basic tenet of toxicology, the dose-response relationship, are necessary when objectively evaluating chemically mediated effects (Montgomery MR, Reasor MJ. (1994). A Toxicologic Approach for Evaluating Cases of Sick Building Syndrome or Multiple Chemical Sensitivity. J Allergy Clin. Immunol., 94 (2): 371-375).

Mycotoxins are not volatile, and do not evaporate from the mold spore or substrate particles (Schiefer H. 1990. Mycotoxins in Indoor Air: A Critical Toxicological Viewpoint. *In:* Indoor Air '90, Proceedings of the Fifth International Conference on Indoor Air and Climate. pp. 167-172. Toronto, Canada; World Health Organization, 1978. Selected Mycotoxins: Ochratoxins, Trichothecenes, Ergot. *In:* Environmental Health criteria 105. pp. 73-76. WHO, Geneva. WHO, 1990).

In order to determine whether sufficient quantities of mycotoxins have gained access to the biological receptor, **I calculated the maximum dose that would have been possible from the residence of the plaintiffs using the following factors.** Each factor represents a condition far in excess of any condition actually pertaining to the plaintiffs so that resulting calculations are *certain* to over-estimate actual exposure.

- the highest concentration of mycotoxin in spores reported in pertinent scientific literature

- the highest measured airborne spore concentration in the basement at 2063-N Evans Road (40,467 spores/m^3 as reported for sampling done February 7, 2002 by the Department of the Army Department of Preventative Medicine; Reynolds Army Community Hospital)
- the average breathing rate of an individual (varies depending on age and gender of the individual), as reported by the EPA (Exposure Factors Handbook, Update of May 1989 EPA/600/P-95/002Fa. Office of Research and Development, US Environmental Protection Agency (EPA), Washington, DC 20460, Washington, DC)). The average over-estimates breathing rate since it includes both vigorous exercise and resting conditions.
- the greatest possible fraction of the spores that individuals retain by inhalation (100% is assumed although the actual retained dose is not directly proportional to the exposure concentration) (Muhle H. and McClellan RO. (1999). Respiratory Tract (Ch. 15). In: Toxicology (Eds. Marquardt H., Schafer SG, McClellan RO, Welsch F). Academic Press, P. 339)
- the greatest possible length of time for the exposure or the exposure duration (24 hours per day is assumed)
- the body weight of the exposed individual

Using these figures, I calculated a maximum possible dose in a worst-case scenario for a selection of mycotoxins produced by organisms which are known to grow indoors (See Appendix D).

In order to evaluate whether there is a possibility of adverse effects, I compared the maximum possible dose that the plaintiffs could have received from the indoor environment to the lowest dose that is known to produce an effect in animals via inhalation. The maximum doses of mycotoxin exposure calculated for each member of the Mitchell family are very low (See Appendix E).

Since there are no human studies for tremorgens, satratoxins, or trichoverrols (some of

the mycotoxins I selected for the calculations), I considered the mycotoxin aflatoxin B1 which is far more toxic than any of the tremorgens, and is of comparable toxicity to the satratoxins, although it is not found in organisms growing on building materials. It is also the only mycotoxin for which exposure is regulated in the U.S. by the Federal government. Given that the FDA has determined that it is safe for someone of the weight and age of CAM (the most sensitive receptor) to consume 0.0000373 mg/kg/day of Aflatoxin B1, CAM would have to be exposed to 152,312 spores/m^3 for 24 hours per day, with the highest concentration of aflatoxin B_1 per spore reported, with 100% retention of these inhaled spores in order to inhale the amount of aflatoxin considered to be *safe* by the FDA. Environmental testing results provided show that the highest measurement of mold spore concentration from the home to be 40,467 spores/m^3. If CAM were to spend 24 hours per day in the basement containing hypothetical "mycotoxin-containing" spores at the levels measured at the residence, she could only inhale 1/3 the amount of mycotoxin the FDA has determined to be safe (See Appendix F). If she were to spend the whole day in the living area or sleeping area, she could only inhale 1/12 to 1/5 of the amount considered to be safe.

Thus, calculations indicate that the maximum amount of mycotoxin to which the plaintiffs could have been exposed is too small to have caused any adverse effect.

d) Does the exposure precede the claimed injuries? *AND*

e) What alternative causes of the observed adverse effect were considered?

Brenda Mitchell (DOB: July 27, 1962)

Brenda Mitchell has an ongoing history of non-cardiac chest pain since 1987 (Medical Records of Brenda Mitchell, ADMIN 272), headaches since 1982 (Medical Records of Brenda Mitchell, RACH 348), abdominal pain since 1986 (Medical Records of Brenda Mitchell, RACH 234), and back pain since 1982 (Medical Records of Brenda Mitchell, ADMIN 194/192). In 1994, she was diagnosed with spondylolysis (Medical Records of Brenda Mitchell, ADMIN 157), and in 1996 was diagnosed with degenerative disc disease

(Medical Records of Brenda Mitchell, RACH 367).

Brenda Mitchell has been in three motor vehicle accidents since 1985 (1985, 1988, and 1995), the last of which occurred while she was pregnant (Medical Records of Brenda Mitchell, RACH 169-170, 247, 312, ADMIN 165, 212).

Brenda Mitchell was also diagnosed with anemia in 2002 (ADMIN 58, 74-74) and again in 2003 (RACH 107-108), which is a common cause of headaches and fatigue.

A review of her medical records shows that between April 1983 and June 1999 (16 years), she had 2 respiratory diagnoses. The period from June 1999 to March 2005 (6 years) she had only 1 respiratory diagnoses. Similarly, between April 1983 and June 1999 (16 years), she had 11 headache diagnoses. The period from June 1999 to March 2005 (6 years) she had 4 headache diagnoses. These comparisons indicate that Brenda did not experience an increase in respiratory or headache diagnoses when she moved into the home in question in 1999.

Dominique Mitchell (DOB April 1, 1983)

Dominique Mitchell claims that prior to moving into the home at 2063 North Evans Road he was never sick. (Deposition of Dominique Mitchell, 10:6-20), and his medical records between 1983 and 1999 support this assertion.

In August 25, 2002 he was 5'8" with a bodyweight of 189 lbs. (Medical Records of Dominique Mitchell, RACH 00495). In October 19, 2005, he had a BMI of 37, and was undertaking dietary counseling pertaining to obesity (Medical Records of Dominique Mitchell, RACH 00778). In November 22, 2005 his documented weight was 258 lbs. (Medical Records of Dominique Mitchell, RACH 00782). Mounting evidence implicates obesity as a major risk factor for asthma (Shore SA, Fredberg JJ. Obesity, smooth muscle, and airway hyperresponsiveness. J Allergy Clin Immunol. 2005 May;115(5):925-7.) As he also has a strong family history of asthma, Dominique's respiratory symptoms cannot be causally linked to environmental mold or mycotoxin exposure.

Additionally, obese children have more respiratory symptoms than their normal weight peers and respiratory related pathology increases with increasing weight. Obesity produces mechanical effects on respiratory system performance. (Deane S, Thomson A. Obesity and the pulmonologist. Arch Dis Child. 2006 Feb;91(2):188-91.) Dominique's complaints of breathing difficulties and wheezing cannot be causally linked to environmental mold or mycotoxin exposure.

Dominique reports headaches (8/99, 8/00, 3/02, 11/03). His medical records indicate he was experiencing a deterioration of visual acuity in December 1997 (Medical Records of Dominique Mitchell, ADMIN 0000497), and in August 8, 2000, his records note that he gets headaches without vision correction (NOLAN 00003).

Dominique's claim of vomiting appears to be a single incidence of acute gastroenteritis in January 2004 (RACH 00453-455). This does not appear to be a chronic problem.

Jennifer Mitchell (DOB October 11, 1984)

Jennifer has a history of asthma/reactive airway disease since 3/18/1997 (Medical records of Jennifer Mitchell, ADMIN 00536). She has possible allergic rhinitis. Although she did report congestion and upper respiratory infections after 1999, she had 3 respiratory diagnoses in the period between Dec 1996 and June 1999 (2.5 years) and 4 respiratory diagnoses in the period between June 1999 and January 2004 (4.5). Her rate of diagnosis of respiratory ailments was lower when she lived in the residence in question. Jennifer's claims of breathing difficulty, sinus infections, cough, runny nose are likely related to respiratory conditions that pre-existed the claimed exposure and do not appear to be caused by an exposure event beginning in 1999.

A motor vehicle accident in 2003 resulted in headaches, neck and back pain. Her claims of headaches, aches, and possibly fatigue and dizziness are likely related to this incident.

Claims of nausea, vomiting, and depressed immune system are not supported by her medical records.

SDM (DOB April 15, 1990)

SDM has a history of asthma that dates back to at least 1992 when it was identified as a "chronic" disease by Dr. Mark Watkins (Medical records of SDM, RACH 00589). She also has a history of recurring pneumonia (12/92, 9/93, 4/94, 9/94, 5/02), upper respiratory infections (1/94, 2/95, 9/95), and bronchitis (2/95; 12/96, 11/97) prior to 1999.

SDM's claims of breathing difficulty, sinus problems, cough, runny nose are likely related to respiratory conditions that pre-existed the claimed exposure and do not appear to be caused by an exposure event beginning in 1999. A review of her medical records shows that between June 1990 and June 1999 (9 years), she had 20 respiratory diagnoses. The period from June 1999 to March 2005 (6 years) she had only 6 respiratory diagnoses, suggesting that the rate of respiratory incidence may have actually decreased.

A single reported incidence of gastritis and headache on December 23, 2002 (records of SDM, RACH 00669) at the Reynolds Army Community Hospital (James Hapka, PA) appears to be an isolated event and does not support her claim of ongoing nausea, vomiting, dizziness and headache. Similarly, claims of tiredness, weakness, aches, and depressed immune system are not supported by the medical records.

CAM (DOB: February 23, 1996)

CAM has a history of respiratory problems such as bronchitis (12/96), congestion (12/96, 9/97), cough (12/96, 5/02, 8/02, 9/02, 11/02, 1/04), eye problems (red – 7/96, watery – 9/02), in addition to a history of fever (12/96, 2/97, 9/97, 11/02, 3/03, 1/04) and vomiting (2/97, 9/97, 4/01, 8/02, 1/04), many incidents of which predate any potential environmental exposure from the residence in question.

A review of her medical records shows that between February 1996 and June 1999 (2.3 years), she had 2 respiratory diagnoses. The period from June 1999 to April 2004 (4.75 years) she had 7 respiratory diagnoses. Thus, suggesting that the rate of respiratory incidence was not significantly increased.

Plaintiffs' Environmental Report

Dr. George Graham, whose analysis formed the bulk of plaintiff's expert report, appears to have relied on four indoor samples using a settled plate method on January 25, 2006. Although Dr. Graham is identified as the Chief Mycologist of Mold Lab Int'l on the Tennessee Mold Consultants website (http://www.themoldlab.com/mycologist.shtml), he is not a Certified Industrial Hygienist (CIH), and there is no indication that his training or experience qualifies him to sample for mold, recommend remediation techniques, or make claims of related health effects.

Furthermore, as of February 14, 2006, Mold Lab Int'l is not accredited through the Environmental Microbiology Laboratory Accreditation Program (EMLAP) of the American Industrial Hygiene Association (AIHA) or any other recognized accrediting organization.

Samples were collected using a settled plate method which is neither quantitative nor representative of airborne mold spores. He further invalidates his use of a non-standard method by not collecting control or comparison samples.

Estimating Exposure

The sampling and analysis conducted by Mold Lab Int'l is not useful for estimating exposure because of inappropriate sampling techniques, lack of controls, a lack of laboratory accreditation.

One of the roles of sampling is to provide information that will allow health

professionals to determine whether or not there is a possibility of injury due to exposure. In an exposure scenario such as proposed in this situation, exposure would occur through inhalation of spores. Non-quantitative sampling such as interpreted by Dr. Graham does not allow such a determination to be made, and is of no value as a tool for exposure assessment. Any statements relating to exposure and health effects attributed to the results of such sampling are irrelevant.

Health Effects

Dr. Graham states the mold can cause a variety of symptoms and that the air that is breathed must be "healthy" to allow occupants to become "healthier." The files provided for my review (PLF 00613-00623) contains alarmist, unreferenced statements about "Effects on Human Health," "Symptoms Include," "Methods of Transmission," and "Clinical Information." These statements are reflected in the mold references posted at www.tennesseemold.com/mold_ref.shtml (accessed 2/14/06). These statements are not relevant to airborne exposure to molds in indoor environments. Specifically, they provide no context of dose, route of exposure, or other mitigating factors, and suggest that exposure to molds poses a far greater risk than it actually does, as we routinely encounter these mold spores in both indoor and outdoor environments (Solomon WR. 1975. Assessing fungus prevalence in domestic interiors. J Allergy Clin Immunol 56(3):235-242).

As previously discussed, most researchers and learned bodies have reported that current evidence does not support the proposition that molds in indoor environments cause allergies or result in toxicosis. The records provided for my review suggest that Dr. Graham's understanding of molds and mycotoxins, basic mycology, and toxicology is extremely limited.

Dr. Graham relies on his invalid sample results to suggest that the air in the Mitchell home is not healthy and incorrectly indicates that his botanical solutions are the only products recommended.

Personal Property

Dr. Graham makes inappropriate recommendations regarding personal property damage. Specifically, he recommends replacing the car if there is a water leak as "spraying will not be adequate."

The Evidence Based Statement on mold by the American College of Occupational and Environmental Medicine (ACOEM) states, "Colonized porous materials, e.g., clothing or upholstery, can be cleaned using appropriate routine methods, e.g., washing or dry cleaning clothing, and need not be discarded unless cleaning fails to restore an acceptable appearance." Property that has visible mold growth on its surface and/or has a strong, musty odor should be cleaned or discarded. This is due to cosmetic or aesthetic reasons only. Failure to discard these items does not necessarily result in excessive exposure to mold spores.

Unless items are shown to be structurally damaged by mold, contain strong odors of mold, or are shown to give rise to sufficient aerosolization to potentially cause illness, the items need not be discarded and no cleaning other than routine housekeeping is indicated. In the absence of visible mold growth or a moldy odor, the only basis for cleaning or discarding property unfounded perception of risk.

Conclusions

I conclude, to a reasonable degree of scientific certainty, the following opinions:

- Mold and mold spores are ubiquitous, and the maintenance of a mold-free home environment is not possible.
- Sampling and analysis presented in the report by Mold Lab Int'l is not useful for estimating exposure because of inappropriate sampling techniques, lack of controls, and a lack of laboratory accreditation.

- There are no data showing that mycotoxins were present in the indoor air of the residence at 2063-N Evans Road.
- There are no data showing that there was a sufficient amount of mycotoxin present in the indoor air of the residence at 2063-N Evans Road to have caused any injury to occupants.
- There could not have been sufficient amounts of mycotoxin present at the subject property to cause any injuries to occupants.
- The symptoms identified by the Mitchell family have many possible causes and cannot be attributed to mycotoxin exposure during their occupancy of the residence at 2063-N Evans Road.

This report is based on the materials received and analyzed by me to date. Should additional information become available, I reserve the right to amend my opinions accordingly.

Sincerely,

VERITOX, INC.

Bruce J. Kelman, PhD, DABT
Principal

Encl. Appendices A-F

Marianne Dreger

From: Jonathan Borak [jborak@att.net]
Sent: Friday, September 06, 2002 2:45 PM
To: Dean Grove (E-mail)
Cc: Edward J. Bernacki MD, MPH (E-mail); Barry Eisenberg (E-mail); Tim Key MD (E-mail)
Subject: mold

ACOEM Mold - revised draft.rtf...

Dean et al:

I am having quite a challenge in finding an acceptable path for the proposed position paper on mold. Even though a great deal of work has gone in, it seems difficult to satisfy a sufficient spectrum of the College, or at least those concerned enough to voice their views.

I have received several sets of comments that find the current version, much revised, to still be a defense argument. On the other hand, Bryan Hardin and his colleagues are not willing to further dilute the paper. They have done a lot, and I am concerned that we will soon have to either endorse or let go. I do not want this to go to the BOD and then be rejected. That would be an important violation of Bryan—I have assured him that if we do not use it he can freely make whatever other use he might want to make. If we "officially" reject it, then we turn his efforts into garbage.

As this was an effort that you, Dean, asked me to initiate I thought that you might have a good idea about what might be done.

The problem is the same as when this began. Mold is a litigation mine field. Everybody involved in the topic has a strong view and there is little middle ground. If we have a statement that deals only with science, we will be accused of ignoring the "Public Health" issues. If we embrace the Public Health, then we will be regarded as not scientific.

I have not previously been involved in an ACOEM issue that raised provoked emotions among member peer reviewers. My own feeling is that it may not be worth the disruptive effects that might result from forcing the issue. Also, I think that the authors are not willing to let this just sit for awhile. they have done a lot of work and want to see it in print.

For your interests, I have attached the latest version.

Jonathan

Adverse Human Health Effects Associated with Molds in the Indoor Environment

In single-dose *in vivo* studies, *S. chartarum* spores have been administered intranasally to mice[31] or intratracheally to rats.[76,77] High doses (30 x 10^6 spores/kg and higher) produced pulmonary inflammation and hemorrhage in both species. A range of doses were administered in the rat studies and multiple, sensitive indices of effect were monitored, demonstrating a graded dose response with 3 x 10^6 spores/kg being a clear no-effect dose. Airborne *S. chartarum* spore concentrations that would deliver a comparable dose of spores can be estimated by assuming that all inhaled spores are retained and using standard default values for human subpopulations of particular interest[78] – very small infants,† school-age children,†† and adults.††† The no-effect dose in rats (3 x 10^6 spores/kg) corresponds to continuous 24-hour exposure to 2.1 x 10^6 spores/m^3 for infants, 6.6 x 10^6 spores/m^3 for a school-age child, or 15.3 x 10^6 spores/m^3 for an adult.

If the no-effect 3 x 10^6 spores/kg intratracheal bolus dose in rats is regarded as a **1-minute administration (3 x 10^6 spores/kg/min), achieving the same dose rate in humans (using the same default assumptions as previously)** would require airborne concentrations of 3.0 x 10^9 spores/m^3 for an infant, 9.5 x 10^9 spores/m^3 for a child, or 22.0 x 10^9 spores/m^3 for an adult.

In a repeat-dose study, mice were given intranasal treatments twice weekly for three weeks with "highly toxic" s. 72 S. chartarum spores at doses of 4.6 x 10^6 or 4.6 x 10^4 spores/kg (cumulative doses over three weeks of 2.8 x 10^7 or 2.8 x 10^5 spores/kg).[79] The higher dose caused severe inflammation with hemorrhage, while less severe inflammation, but no hemorrhage was seen at the lower dose of s. 72 spores. Using the same assumptions as previously (and again ignoring dose-rate implications), airborne S. chartarum spore concentrations that would deliver the non-hemorrhagic cumulative three-week dose of 2.8 x 10^5 spores/kg can be estimated as 9.4 x 10^3 spores/m^3 for infants, 29.3 x 10^3 spores/m^3 for a school-age child, and 68.0 x 10^3 spores/m^3 for adults (assuming exposure for 24 hours per day, 7 days per week, and 100% retention of spores).

The preceding calculations suggest lower bound estimates of airborne S. chartarum spore concentrations corresponding to essentially no-effect acute and subchronic exposures. Those concentrations are not infeasible, but they are improbable and inconsistent with reported spore concentrations. For example, in data from 9,619 indoor air samples from 1,717 buildings, when S. chartarum was detected in indoor air (6% of the buildings surveyed) the median airborne concentration was 12 CFU/m^3 (95% CI 12 to 118 CFU/m^3).[80]

Despite its well-known ability to produce mycotoxins under appropriate growth conditions, years of intensive study have failed to establish exposure to S. chartarum in home, school, or office environments as a cause of adverse human health effects. Levels of exposure in the indoor environment, **dose-response data in animals, and dose-rate considerations suggest that** delivery by the inhalation route of a toxic dose of mycotoxins in the indoor environment is **highly unlikely at best, even for the hypothetically most vulnerable subpopulations.**

ACOEM References To Dr. Carol Rao's Mechanistic Work, to which Bruce and Brian applied their extrapolations:

76. Rao CY, Brain JD, Burge HA. Reduction of pulmonary toxicity of Stachybotrys chartarum spores by methanol extraction of mycotoxins. Appl Environ Microbiol. 2000;66:2817-21.

77. Rao CY, Burge HA, Brain JD. The time course of responses to intratracheally instilled toxic Stachybotrys chartarum spores in rats. Mycopathologia. 2000;149:27-34.

(77). " We have demonstrated that a single, acute pulmonary exposure to a large quantity of Stachybotrys chartarum spores by intratracheal instillation causes severe injury detectable by bronchoalveolar lavage. The primary effect appears to be cytotoxicity and inflammation with hemorrhage. There is a measurable effect as early as 6 h after instillation, which may be attributable to mycotoxins in the fungal spores. The time course of responses supports early release of some toxins, with the most severe effects occurring between 6 and 24 h following exposure. By 72 h, recovery has begun, although macrophage concentrations remained elevated"

(76.) "We provide evidence that there is a dose-related association between an acute exposure to toxin-containing S. chartarum spores and measurable pulmonary responses. The consequences of low-level chronic exposure remain to be investigated, **as does the relevance of the rodent data to human exposure.**"

4

Toxic Effects of Fungi and Bacteria

Although a great deal of attention has focused on the effects of bacteria and fungi mediated by allergic responses, these microorganisms also cause nonallergic responses. Studies of health effects associated with exposure to bacteria and fungi show that respiratory and other effects that resemble allergic responses occur in nonatopic persons. In addition, outcomes not generally associated with an allergic response—including nervous-system effects, suppression of the immune response, hemorrhage in the mucous membranes of the intestinal and respiratory tracts, rheumatoid disease, and loss of appetite—have been reported in people who work or live in buildings that have microbial growth. This chapter discusses the available experimental data on those nonallergic biologic effects. It first discusses the bioavailability of the toxic components of fungi and bacteria and the routes of exposure to them and then summarizes the results of research on various toxic effects—respiratory, immunotoxic, neurotoxic, sensory, dermal, and carcinogenic—seen in studies of microbial contaminants found indoors. It does not address possible toxic effects of nonmicrobial chemicals released under damp conditions by building components, furniture, and other items in buildings; chemical releases from such materials are discussed in Chapter 2. Except for a few studies on cancer, toxicologic studies of mycotoxins are acute or short-term studies that use high exposure concentrations to reveal immediate effects in small populations of animals. Chronic studies that use lower exposure concentrations and approximate human exposure more closely have not been done except for a small number of cancer studies.

haven't heard it, nor have I read it.
MR. VANCE: Well, you've heard that he has criticized you study, though, haven't you?
BRUCE J. KELMAN: Are you talking about the position statement from the American College of Occupational and Environmental Medicine?
MR. VANCE: Yes, sir, I am. I am talking about that?
BRUCE J. KELMAN: I'm sure he criticized that.
MR. VANCE: All right. So, it doesn't surprise you to learn that he's called it in a speech in Boston, "Undemocratic and not objective"?
BRUCE J. KELMAN: Well, I guess I would have trouble with the characterization from Dr. Yohanning of "unobjective". I'd say critical review by 100 critical, very critical, physicians is quite objective, and I would also have to say that normally when one picks a learned body, you don't do it democratically. You pick the people that have the best scientific credentials and the best knowledge of the area.
MR. VANCE: Well, I certainly don't expect you to ask medical students to participate in this study. I mean, we have other things to do

IN AMERICAN ARBITRATION ASSOCIATION
ARBITRATION

CASE No. 50 180 T 00150 05

SCOTIA PRINCE CRUISES, LIMITED,
Claimant
vs.
THE CITY OF PORTLAND, MAINE,
Respondent.

VIDEOTAPED DEPOSITION OF BRYAN D. HARDIN, Ph.D., taken before Sheri DeBlieux, Notary Public, pursuant to notice, at the offices of Petruccelli, Martin & Haddow, LLP, 50 Monument Square, Portland, Maine, on December 20, 2006, commencing at 9:00 a.m.

APPEARANCES:

James B. Haddow, Esq.
Clifford H. Ruprecht, Esq.

8:12,9,10:17

What was your involvement in the field of mold and mycotoxins prior to June of 2001?

A. None. Well, in my capacity as -- as a supervisor at NIOSH, I had the opportunity to -- to have a supervisory position relative to activities within NIOSH and at C.D.C., but no -- no personal direct involvement.

Q. How did you come to begin working more personally and

directly in the field of mold and mycotoxins?

A. As a freelance consultant, it was -- it was apparent that there was a lot of consulting work to be done in the field, so I began to study it. And I was approached by an industrial hygienist I knew in Atlanta whose company put on periodic training seminars, three-day seminars on mold remediation. And the industrial

hygienist asked me if I'd be interested in presenting a one-hour lecture on health effects of molds, which I did.

Q. So is it fair to say that you became active in mold and mycotoxin research and evaluation because that was an area in which your consulting business had an opportunity to expand?

A. I think so, yes. It was -- it was an area where consultants were needed and so I -- I began to -- to study and develop an expertise.

Q. In your capacity as a consultant starting in July of 2000 -- strike that.

Were the clients of your consulting business who were looking for experts to work with them in the field of mold and mycotoxins primarily individuals or primarily businesses or a mix?

MR. RUPRECHT: Object to the form.

A. Well, the first -- the first engagement was as a lecturer in this periodic training course. As result of that, I began to get inquiries from people who considered engaging me.

Q. BY MR. HADDOW: And is it possible for you to say whether those inquiries were predominantly from employers who were concerned about mold in their workplaces or predominantly from insurers or predominantly from any particular segment of the business population?

MR. RUPRECHT: Objection.

A. I can't say. My recollection is -- and it probably isn't an exclusive representation. But my recollection is that the majority of those who inquired were plaintiff attorneys.

Q. BY MR. HADDOW: And of the plaintiff attorneys who inquired, for how many did you end up performing consulting services?

A. None. Because in the course of the conversation I guess they didn't -- they decided they didn't -- couldn't use my opinion and there was never a follow-up retention.

Q. And up to this point today, have you ever been retained to provide consulting services in the field of mold or mycotoxins by a plaintiff's lawyer?

A. I personally have not.

13:17 14:3

Q. Other than the letter that -- the letter to the editor that you described to me earlier that hasn't been listed on your C.V. as yet, are those four items all of the publications on which you are an author that address issues related to mold and mycotoxins?

A. Yes. Well, I -- we also -- we also wrote another -- we

were asked to write something that would be more generally accessible and less technical for the Manhattan Institute. I don't list that on my C.V.

14

Q. Is that derived from one of the other publications that is listed on your C.V.?

A. Yes. It's derivative from the A.C.O.E.M. statement.

.....

15:20-16

Q. If you look further down the page, the third one up from the bottom, July 17th, 2003, there's a presentation to or presentation at a what looks like a seminar sponsored by the U.S. Chamber of Commmerce (sic) Institute for Legal Reform and the Manhattan Institute Center for Legal Policy. Do you see that one?

A. Yes.

Q. Can you explain to me what that presentation concerned?

A. That was basically a press conference that -- that they held to roll out the publication of two documents, one of which was the one that we had written that was a derivative of the A.C.O.E.M. statement.

Q. What is the U.S. Chamber of Congress Institute for Legal Reform?

A. I don't know very much about them. I'm familiar with the Chamber of Congress of course, but I had never previously heard of the Institute for Legal Reform.

Q. What is the U.S. Chamber of Commerce(sic)Institute for Legal Reform?

A. I don't know very much about them. I'm familiar with the Chamber of Commerce (sic) of course, but I had never previously heard of the Institute for Legal Reform.

Q. And do you know what the Manhattan Institute Center for Legal Policy is?

A. Again, I had never heard of them until we were retained by them to do the work. I don't know very much about them.

Q. Are you under the impression that they are lobbying groups of some sort?

A. Yes.

Q. And are you under the impression that they lobby for -- well, let me strike that.

Is it your impression that the written work that you prepared for them was used by them as part of their lobbying efforts?

A. I would assume so, yes.

Marianne Dreger

From: Jonathan Borak [jborak@att.net]
Sent: Friday, September 06, 2002 2:45 PM
To: Dean Grove (E-mail)
Cc: Edward J. Bernacki MD, MPH (E-mail); Barry Eisenberg (E-mail); Tim Key MD (E-mail)
Subject: mold

ACOEM Mold - revised draft.rtf...

Dean et al:

I am having quite a challenge in finding an acceptable path for the proposed position paper on mold. Even though a great deal of work has gone in, it seems difficult to satisfy a sufficient spectrum of the College, or at least those concerned enough to voice their views.

I have received several sets of comments that find the current version, much revised, to still be a defense argument. On the other hand, Bryan Hardin and his colleagues are not willing to further dilute the paper. They have done a lot, and I am concerned that we will soon have to either endorse or let go. I do not want this to go to the BOD and then be rejected. That would be an important violation of Bryan—I have assured him that if we do not use it he can freely make whatever other use he might want to make. If we "officially" reject it, then we turn his efforts into garbage.

As this was an effort that you, Dean, asked me to initiate I thought that you might have a good idea about what might be done.

The problem is the same as when this began. Mold is a litigation mine field. Everybody involved in the topic has a strong view and there is little middle ground. If we have a statement that deals only with science, we will be accused of ignoring the "Public Health" issues. If we embrace the Public Health, then we will be regarded as not scientific.

I have not previously been involved in an ACOEM issue that raised provoked emotions among member peer reviewers. My own feeling is that it may not be worth the disruptive effects that might result from forcing the issue. Also, I think that the authors are not willing to let this just sit for awhile. they have done a lot of work and want to see it in print.

For your interests, I have attached the latest version.

Jonathan

Marianne Dreger

From: Jonathan Borak [jborak@att.net]
Sent: Friday, October 04, 2002 2:49 PM
To: Marianne Dreger (E-mail)
Subject: FW: Mold position paper

-----Original Message-----
From: Douglas A. Swift, M.D., M.S.P.H. [mailto:dswift@tulane.edu]
Sent: Friday, October 04, 2002 3:36 PM
To: jborak@att.net
Subject: Re: Mold position paper

Absolutely, I realize the process.

I didn't know where along the approval timeline it was.

I appreciate your confidence.

----- Original Message -----
From: "Jonathan Borak" <jborak@att.net>
To: "'Douglas A. Swift, M.D., M.S.P.H.'" <dswift@tulane.edu>
Sent: Friday, October 04, 2002 2:04 PM
Subject: RE: Mold position paper

> Doug:
>
> Thanks for your feedback. I will share it with the authors.
>
> Please do not cite or refer to this document until after the Board of
> Directors has the opportunity to vote -- 10/27. As you appreciate, this
is
> as controversial and litigious a subject as any in our field. It would be
> of potential embarrassment and pain to both the College and the authors if
> it were cited before completion and adoption.
>
> It was sent to you as a peer reviewer. I will let you know when it is for
> public consumption. Thanks for your understanding.
>
> Jonathan
>
>
>
> -----Original Message-----
> From: Douglas A. Swift, M.D., M.S.P.H. [mailto:dswift@tulane.edu]
> Sent: Friday, October 04, 2002 2:47 PM
> To: jborak@att.net
> Subject: Mold position paper
>
>
> Jonathan,
>
> Excellent overview of the topic.
>
> I'm giving a talk to a group of insurance related clients. Is it quotable
> and if so, how should I reference it?
>

Marianne Dreger

From: Harber, Philip M.D. [PHarber@mednet.ucla.edu]
Sent: Saturday, June 15, 2002 11:06 AM
To: 'Marianne Dreger '; "Carson, Arch I' '; "Cowl, Clayton T' '; "Delclos, George' '; "Eschenbacher, William, MD' '; Harber, Philip M.D.; "Jolly, Athena' '; "Jonathan Borak' '; "Larry Lindesmith MD' '; "Lockey, James' '; "Markham, Thomas' '; "McKay, Roy T., PhD' '; "Raymond, Lawrence' '; "Sherson, David' '; "Smith, Dorsett D., MD' '; "Stuart M. Brooks, MD' '; "Townsend, Mary C' '; "Velez, Henry' '; "Wintermeyer, Stephen E' '
Cc: 'Debbie Paddack '
Subject: RE: Lung Committee Review of Position Statement on Indoor Mold

Thank you for sending this for review. A clear, written summary of background and purpose we greatly facilitate review. As most of you know, many consider this issue to be the "asbestos of the decade". Here in California, there are an enormous number of lawsuits involving stachybotrys, and this has become the new issue for Erin Bronkovich. The Los Angeles Times reported that the number of water damage claims has doubled and that many insurers will no longer cover mold damage.

I believe it is therefore essential that the process of development and review be carefully considered. Many of you may recall that the plaintiff bar sued officers of the American Thoracic Society when they released the statement on "diagnosis of non-malignant disease due to asbestos". . Because of the extensive litigation, it is inevitable that our representatives will be subject to subpoena to describe the process.

Therefore, before we focus on the (more important) scientific issues, I hope we can define the process. Specifically: 1. Who appointed this committee? 2. Was this proposed statement developed in response to a request from the Board or Committee, or was the committee approached by its authors? 3. Recognizing the "political" controversy, are we assured that the committee was appointed with attention to balance of viewpoints? 4. Will the document be reviewed by the Industrial Hygienists, since their organization has a somewhat different position statement? (not necessarily a correct one!) 5. Will ACOEM indemnify us as commentators if we are sued in the course of our organizational service? 6.. Should we request disclosure of potential conflicts of interest? (Being involved in litigation should certainly not exclude someone from participating, but failure to disclose soils the process). 7. What is the time course of this project?

Please do not interpret these remarks as negative concerning the substance of the document itself; it makes some very important points which need to be said loud and clear. This is a highly litigated area, and therefore we need to be particularly careful about process. I personally strongly support the need for ACOEM to make a position statement concerning this area.

-----Original Message-----

From: **Marianne Dreger**
To: 'Carson, Arch I'; 'Cowl, Clayton T'; 'Delclos, George'; 'Eschenbacher, William, MD'; 'Harber, Philip'; 'Jolly, Athena'; 'Jonathan Borak'; 'Larry Lindesmith MD'; 'Lockey, James'; 'Markham, Thomas'; 'McKay, Roy T., PhD'; 'Raymond, Lawrence'; 'Sherson, David'; 'Smith, Dorsett D., MD'; 'Stuart M. Brooks, MD'; 'Townsend, Mary C'; 'Velez, Henry'; 'Wintermeyer, Stephen E'
Cc: Debbie Paddack
Sent: 6/14/02 1:53 PM
Subject: Lung Committee Review of Position Statement on Indoor Mold

Attached is a draft of the Position Statement on Indoor Mold that was

prepared for ACOEM by ACOEM members Bryan Hardin and David Kelman, and

by

Marianne Dreger

From: Delclos, George [GDelclos@sph.uth.tmc.edu]
Sent: Sunday, June 16, 2002 2:10 PM
To: Harber, Philip M.D.; Marianne Dreger ; 'Carson, Arch I' ; 'Cowl, Clayton T' ; 'Delclos, George' ; 'Eschenbacher, William, MD' ; Harber, Philip M.D.; 'Jolly, Athena' ; 'Jonathan Borak' ; 'Larry Lindesmith MD' ; 'Lockey, James' ; 'Markham, Thomas' ; 'McKay, Roy T., PhD' ; 'Raymond, Lawrence' ; 'Sherson, David' ; 'Smith, Dorsett D., MD' ; 'Stuart M. Brooks, MD' ; 'Townsend, Mary C' ; 'Velez, Henry' ; 'Wintermeyer, Stephen E'
Cc: Debbie Paddack
Subject: RE: Lung Committee Review of Position Statement on Indoor Mold

I strongly support Phil's comments. In Texas we are facing many of the same issues. The whole process, caveats and contingencies included, should be made clear before a statement such as this is launched into the public domain.

Thanks - George.

-----Original Message-----

From: Harber, Philip M.D. [mailto:PHarber@mednet.ucla.edu]
Sent: Sat 6/15/2002 11:05 AM
To: 'Marianne Dreger '; "Carson, Arch I' "; "Cowl, Clayton T' "; "Delclos, George' "; "Eschenbacher, William, MD' "; Harber, Philip M.D.; "Jolly, Athena' "; "Jonathan Borak' "; "Larry Lindesmith MD' "; "Lockey, James' "; "Markham, Thomas' "; "McKay, Roy T., PhD' "; "Raymond, Lawrence' "; "Sherson, David' "; "Smith, Dorsett D., MD' "; "Stuart M. Brooks, MD' "; "Townsend, Mary C' "; "Velez, Henry' "; "Wintermeyer, Stephen E' '
Cc: 'Debbie Paddack '
Subject: RE: Lung Committee Review of Position Statement on Indoor Mold

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Therefore, before we focus on the (more important) scientific issues, I hope we can define the process. Specifically: 1. Who appointed this committee? 2. Was this proposed statement developed in response to a request from the Board or Committee, or was the committee approached by its authors? 3.

Recognizing the "political" controversy, are we assured that the committee was appointed with attention to balance of viewpoints? 4. Will the document be reviewed by the Industrial Hygienists, since their organization has a somewhat different position statement? (not necessarily a correct one!) 5. Will ACOEM indemnify us as commentators if we are sued in the course of our organizational service? 6.. Should we request disclosure of

Marianne Dreger

From: Jonathan Borak [jborak@att.net]
Sent: Sunday, June 16, 2002 12:22 PM
To: 'Harber, Philip M.D.'
Cc: Dean Grove (E-mail); Edward J. Bernacki MD, MPH (E-mail); John Holland M.D., MPH (E-mail); Tim Key MD (E-mail); Barry Eisenberg (E-mail); Pamela Hymel (E-mail); Marianne Dreger (E-mail); Bryan D. Hardin PhD (E-mail)
Subject: Your comments on Position Statements

Phil:

Your comments below on the Mold position statement raises a number of key issues. I am copying the Exec Committee because the policy implications are broad.

Background: This past February, Dean Grove (as President) asked me (as Chair of CSA) to develop a position statement on indoor mold. With Dean's agreement, I approached Bryan Hardin -- former Deputy Director of NIOSH— to develop such a statement. In return for his efforts, Dean and Barry approved the granting of a one-year courtesy membership to Bryan, who was not then a member (although his co-author, Bruce Kelman, was a dues-paying member).

Since then, I have been approached by others who heard (from Dean Grove) that this was an issue to be addressed by ACOEM. One sent written info, and others expressed interest. Nobody who initiated contact on the issue has been involved in its development.

As is our standard method, the draft has been circulated to members of the CSA with requests that it be distributed to their committee members for comments. I would not normally have sent an ACOEM position statement to AIHA, or ACGIH, or AAOHN, or anyone else unless this was to be a "joint statement" with that other group. On the other hand, I intended to send whatever comes back after the CSA to those members of ACOEM who have expressed interests in the topic. Moreover, I would be open to recommendations of other outside peer reviewers with appropriate academic/scientific expertise.

Your question about disclosure of "conflicts of interest" is interesting, but I am not sure who should be asked to make such disclosure. There are few individuals with the necessary knowledge and willingness to voluntarily author such a detailed position statement who do not already have some vested concerns. Is that an a priori basis to reject? Is your concern that all peer reviewers should disclose their involvement? I hope that a meaningful peer review would protect against scientific error and bias.

As for me, my disclosure statement is simple: I have no business interests in the issue; neither my clients nor my patients have posed related issues or concerns (although my wife currently has a candida paronychia on her right index finger!), nor do I anticipate that this position statement will have any impact upon my financial status (other than the unpaid time devoted to its development).

As for indemnification of officers and others, that is an issue that had not occurred to me. I think it is critical that Bernacki et al consider it. The implication is that ACOEM might need to avoid anything controversial.

As for other issues of "process" implicit in your questions, this has been done in the "standard manner" which means that it is based on tradition, not proscribed protocol. I have no problem adopting a "protocol", and I would be happy to discuss you suggestions or proposals.

The bottom line is that you raise extremely important issues that should be seen as generalized, not related solely to indoor mold or Erin Brockovich. My personal preference would be for those with concerns to perform a meticulous peer review so that we can determine whether this position statement is scientifically correct (as opposed to its political correctness) and that we do it as much as possible within the existing College traditional process. My next preference would be that we develop a new College process and imply it across-the-board. My lowest preference

Jonathan Borak

From: Bryan D. Hardin, Ph.D. [bhardin@adelphia.net]
Sent: Friday, August 16, 2002 2:36 PM
To: jborak@att.net
Cc: bkelman@globaltox.com; ASaxon@MedNet.ucla.edu
Subject: Reaction to Hodgson/Dearborn Letter

Jonathan -- We do not think it appropriate for us to revise the draft ACOEM position paper to incorporate a 'response,' 'rebuttal," or other revision that would address overtly or implicitly the Hodgson - Dearborn letter appearing in the August issue of JOEM.

This letter is poorly focused and more personal and political than scientific in content. While Hodgson and Dearborn suggest they will "lay out" a hypothesis to explain an association between Stachybotrys chartarum and human disease, in fact there is no statement of a hypothesis. Instead, they indiscriminately stir a potpourri of anecdotes, unrelated and irrelevant occupational exposures, and uncritical references to in vivo and in vitro toxicity studies without consideration of dose - the first principle in toxicology. Their letter offers no new data for consideration; it raises no new issues; it marshals no arguments not already addressed in our draft.

Even if the Hodgson - Dearborn letter had scientific merit, we would object to revising our article to respond to it because there always will be another paper. Given the volume of publications in this area, it is unavoidable that meritorious research papers may pre-date the actual publication of the ACOEM position paper but not be included in it. If we were to attempt to avoid that by adding something on the latest new data, then each revision will call for another round of review during which yet another paper may appear.

We are confident that the draft as written is an accurate reflection of the current state of the science. The position we take is, of course, subject to revision if warranted by the accumulation of new evidence, but we have no new evidence here. If we cannot expect to react to every meritorious peer-reviewed research report, we surely should not attempt to react to non-peer reviewed letters to the editor that are of questionable scientific merit.

Finally, we also would object to involving Drs. Hodgson or Dearborn or others outside the normal ACOEM process for position papers. So far as we can ascertain, they have no standing in ACOEM, e.g., as members of your or another committee, the Board of Directors, the JOEM Editorial Board, the House of Delegates, etc. We have welcomed the thorough, impartial, and scientifically rigorous peer review to date, but would think it inappropriate to add ad hoc reviewers who are highly visible advocates for a point of view the draft position paper analyzes and finds lacking. We can be sure that advocates for various points of view will express their opinions in response to the position paper following its publication.

Bryan D. Hardin, Ph.D.
Assistant Surgeon General (Retired)
Suite 4A PMB 344
33 Office Park Road
Hilton Head Island, SC 29928

Telephone / Fax 843-363-9466
Cell Phone 678-770-9150
E-mail BHardin@Adelphia.Net

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

KARI KILIAN, Plaintiff, vs. EQUITY RESIDENTIAL TRUST, et al., Defendants.	CIV 02-1272-PHX-FJM Phoenix, Arizona June 22, 2004 9:32 a.m.

BEFORE: THE HONORABLE FREDERICK J. MARTONE, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL TO THE COURT

VOLUME V
(Pages 749 through 950, inclusive.)

APPEARANCES:
For the Plaintiff:
Law Offices of Richard Langerman
By: **RICHARD W. LANGERMAN**, ESQ.
3216 North 3rd Street, Suite 200
Phoenix, AZ 85012

For the Defendants:
Shorall McGoldrick Brinkmann
By: **TOM SHORALL, JR.**, ESQ.
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Phoenix, AZ 85012

Official Court Reporter:
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Phoenix, Arizona 85003-2151
(602) 322-7249

Proceedings Reported by Stenographic Court Reporter
Transcript Prepared by Computer-Aided Transcription

INDEX OF WITNESSES

INDEX OF EXHIBITS

So they would go to someone and request that they write the statement. Then they would get the statement back, and they would review it, and they often send it out to members of the society for comment. It varies a little bit between societies.

For the American College of Occupational and Environmental Medicine, I've been told that more than 100 physicians looked at this, and most of them critically reviewed it.

Then at that point it goes back to the Council on Scientific Affairs, and I believe the process then is that the council recommends to the college council that -- or the directors of the college of medicine that the statement be accepted.

So at that point it's been extensively reviewed and, although it has been written by someone, it's then a position of the College of Medicine.

Q. Not just Dr. Saxon and Dr. Kelman's position?

A. That's correct. In fact, this is probably the most extensive reviewed peer review publication I've ever done.

Q. In that regard, have you published peer reviewed articles or publications before the one that we're referring to?

A. Oh, certainly.

Q. Have any of them undergone the scientific scrutiny and expansive evaluation and review, to your knowledge, that the

Marianne Dreger

From: Jonathan Borak [jborak@worldnet.att.net]
Sent: Tuesday, April 22, 2003 5:10 PM
To: 'Bryan D. Hardin PhD'
Cc: Barry Eisenberg; Marianne Dreger
Subject: RE: Peer Review

Bryan:

I do not know how many because I do not know how many reviewed the MS and agreed, but did not respond. Also, I have not maintained any of the files or emails. It was certainly more than a dozen: there are more than that on the Board alone.

Jonathan

-----Original Message-----
From: Bryan D. Hardin PhD [mailto:bhardin@adelphia.net]
Sent: Tuesday, April 22, 2003 1:36 PM
To: Borak, Jonathan at Jonathan Borak & Company
Subject: Peer Review

Can you give an idea how many people were involved in the various stages of reviews?

R.J.Reynolds Tobacco Company
Winston-Salem, NC 27102
(919) 777-6000

RJR

December 16, 1987

Dr. Bruce J. Kelman
Manager, Biology and Chemistry Department
Battelle Pacific Northwest Laboratories
Battelle Boulevard
Richland, Washington 99352

Dear Dr. Kelman:

I hope you, your family and your staff are well during this holiday season. Please accept the best wishes of all of us at R.J. Reynolds for a happy new year.

You have asked me several times in the past to notify you if there were some steps that Battelle-Northwest might take to improve the interactions of our two organizations. Until recently no such involvement seemed necessary.

During the past week however, we have been notified that two important deliverables will be delayed by a minimum of six weeks. These include manuscripts describing the conduct and results of two subchronic inhalation studies, and more significantly, the draft final report from our most recent subchronic inhalation study, BNW No. 2311212296. The report was due on 12/1/87, but I understand it will not be available prior to 1/15/88. I am disturbed by several facets of this news.

I am concerned because such information plays an integral role in our business decisions which often cannot accommodate milestone slippage of this magnitude.

I am also concerned because we were not notified until the due date that the report would be late and were not notified of the new anticipated delivery date until mid-December. An early notification of milestone slippage would have provided an opportunity to minimize the impact of the late report and to adjust our internal schedules whenever possible.

R.J.Reynolds Tobacco Company
Winston-Salem, N.C. 27102
(919) 777-5000

RJR

As you know, our decision to work with BNW was not predicated so much on cost as on superior performance and reputation in inhalation toxicology. A reputation which is maintained by excellent cost control, timely delivery and superior quality. I am sure you feel as I do about the importance of complete program performance in optimizing client satisfaction. Therefore, please initiate whatever steps, if any, you feel necessary to minimize any further delays of this report and any future difficulties that might be avoided by additional management control or more integrated scheduling. Because these recent events represent the first time any significant performance decrements have occurred on our 3 year toxicology program, I am optimistic that further problems can be avoided.

Thank you for the time to consider this issue and your effort in making our liaison as pleasant as possible on a program of great importance to our organization. If you wish to discuss this any further please call me at 919-773-5801.

Sincerely,

Arnold T. Mosberg

Arnold T. Mosberg, Ph.D., D.A.B.T.
Senior Staff R and D Toxicologist
R.J.R.-Nabisco, Inc.

cc:A. W. Hayes
G. T. Burger