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) <u>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?</u>

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

Appendix A

Appendix B

Appendix C

Appendix D

Appendix E

Appendix F