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Date

Paul W. Brandt-Rauf, Editor
Journal of Occupational and Environmental Medicine
American College of Occupational and Environmental Medicine
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Subject: Request for Retraction

Dear Dr. Brandt-Rauf,

I am writing as the Chair of the Health Services Committee, Board of Regents of the University of California re:

> **Adverse Human Health Effects Associated with Molds in the Indoor Environment, May 2003 - Volume 45 - Issue 5 - p 470-478 Kelman BJ and Hardin BD of GlobalTox, Inc. and Saxon AJ of University of California Los Angeles, Journal of Occupational and Environmental Medicine (JOEM)**

The University of California recently investigated articles with stated co-authorship of Andrew Saxon, M.D. Professor Emeritus UCLA, regarding adverse health effects associated with exposures to molds and related biocontaminants found in water damaged buildings.

Dr. Saxon is a stated co-author of three articles on the subject: the above noted JOEM article from 2003*;"A Scientific View of the Health Effects of Mold*" published on the US Chamber of Commerce website in 2003; and "*The Medical Effects of Mold Exposure*" published in the Journal of Allergy and Clinical Immunology in 2006.

We find that the subject JOEM article and the two companion articles are compromised. They are used together to promote misuses of a toxicological risk model (hereafter referred to as the "Veritox Hypothesis"); along with misuses of the University of California's valued reputation as a leading healthcare system. Our university name and reputation is being used to erroneously market the Veritox Hypothesis.

The preponderance of the evidence supports retraction of the publications to correct the scientific record and to ensure integrity in healthcare in the future.

The primary problem is that the calculations and conclusions formed by the Veritox Hypothesis have never been validated or duplicated. The JOEM article authors applied extrapolations to data taken from a researcher's study of high doses of mold acutely blasted into the throats of rats. They then leaped to the false conclusion that they had established chronic low dose exposures to mycotoxins in water damaged buildings cannot plausibly reach a level to harm humans. Their calculations and overreaching hypothesis, are:

> "In single-dose in vivo studies, S. chartarum spores have been administered intranasally to mice or intratracheally to rats. High doses (30 x 106 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 106 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 – very small infants,† school-age children,†† and adults.††† The no-effect dose in rats (3 x 106 spores/kg) corresponds to continuous 24-hour exposure to 2.1 x 106 spores/m3 for infants, 6.6 x 106 spores/m3 for a school-age child, or 15.3 x 106 spores/m3 for an adult.
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> If the no-effect 3 x 106 spores/kg intratracheal bolus dose in rats is regarded as a 1-minute administration (3 x 106 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 109 spores/m3 for an infant, 9.5 x 109 spores/m3 for a child, or 22.0 x 109 spores/m3 for an adult.
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> In a repeat-dose study, mice were given intranasal treatments twice weekly for three weeks with "highly toxic". S. chartarum spores at doses of 4.6 x 106 or 4.6 x 104 spores/kg (cumulative doses over three weeks of 2.8 x 107 or 2.8 x 105 spores/kg).The higher dose caused severe inflammation with hemorrhage, while less severe inflammation, but no hemorrhage was seen at the lower dose of s. spores. Using the same assumptions as previously (and again ignoring dose rate implications), airborne S. chartarum spore concentrations that would deliver the nonhemorrhagic cumulative three-week dose of 2.8 x 105 spores/kg can be estimated as 9.4 x 103 spores/m3 for infants, 29.3 x 103 spores/m3 for a school-age child, and 68.0 x 103 spores/m3 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/m3 (95% CI 12 to 118 CFU/m3).
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> 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."**

In direct contradiction to the unsupported conclusion formed by the 2003 JOEM article, the National Academy of Sciences, Engineering, and Medicine (NASEM) Institute of Medicine (IOM) issued a report in 2004 titled "*Damp Indoor Space and Health*". It found that no toxicological risk model had ever been created which accurately reflects human exposure to mycotoxins in the indoor environment. The 2004 IOM Report states:

> "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."

Furthering the understanding that the Veritox Hypothesis adds little to nothing to the weight of the evidence of human health effects associated with exposure to biocontaminants found in water damaged buildings, the United States Federal Government Accountability Office (GAO) issued a report in 2008 titled *"Indoor Mold: Better Coordination of Research Would Improve Federal Efforts* " Again, in direct contradiction to the conclusion formed by the JOEM article, the GAO found:

> "The reviews we examined were largely consistent in their interpretations of the evidence for the role of mycotoxins in relation to adverse health effects. The Institute of Medicine reported in 2004 that **(1) exposure to mycotoxins can occur via inhalation, contact with the skin, and ingestion of contaminated**

food and (2) research on Stachybotrys chartarum (a species of indoor mold that can produce mycotoxins) suggests that effects in humans may be biologically plausible. However, the report also noted that the effects of chronic inhalation of mycotoxins require further study and that additional research must confirm the observations on Stachybotrys chartarum before a more definitive conclusion can be drawn. Among the more recent reviews we examined that specifically addressed mycotoxins, five reached a similar conclusion—that is, that the current evidence is inconclusive or limited." p.15

"On the other hand, another recent review cast doubt on the health effects of mycotoxins in one set of circumstances—specifically, the review concluded that it was improbable for mycotoxins to cause negative health effects through a toxic mechanism when individuals inhale mycotoxins in nonoccupational settings (such as homes). **This review, however, explicitly stated this conclusion did not address adverse health effects of mycotoxins that may be caused by immune-mediated mechanisms or stem from exposure in occupational settings or by ingestion."** [citing to reference 23, which is *"The medical effects of mold exposure,"* JACI vol. 117, no. 2 (2006). It cites to the JOEM article to erroneously suggest that the Veritox Hypothesis can allegedly be scientifically used to conclude that it is "*highly unlikely at best*" mycotoxins play a role in disabilities caused by water damaged indoor environments. p.16

"The effects of mycotoxins in particular remain poorly understood, partly because most of the toxicologic studies on mycotoxins have examined the acute (or short-term) effects of high levels of exposure to mycotoxins in small populations of animals." p.18

Adding further weight to the evidence that the JOEM article and the Veritox Hypothesis should no longer be promoted or used as claimed proof that mycotoxins in the indoor environment can never plausibly reach a level to harm is the 2011 NASEM, National Research Council (NRC) Committee on Science, Technology, Law, Policy and Global Affairs "*Reference Manual on Scientific Evidence Third Edition*". It states:

"…the court stated: 'Humans are not rats, and it is far from clear how readily one may generalize from one mammalian species to another. But in light of the epidemiological evidence [of carcinogenicity] that was not the main problem. Rather it was the absence of data at low levels." Id. at 394. The court remanded the matter to OSHA to reconsider its findings that formaldehyde presented no specific carcinogenic risk to workers at exposure levels of 1 part per million or less. See also Hopkins v. Dow Corning Corp., 33 F.3d 1116 (9th Cir. 1994);

In re AccutaneProd. Liab., 511 F. Supp. 2d 1288, 1292 (M.D. Fla. 2007); United States v. Philip Morris USA, Inc., 449 F. Supp. 2d 1, 182 (D.D.C. 2006);" p.658

"Note that many subjective symptoms are poorly modeled in animal studies. Thus, complaints that a chemical has caused nonspecific symptoms, such as nausea, headache, and weakness, for which there are no objective manifestations in humans, are difficult to test in laboratory animals." p.662

"Advances in human genetics research are providing information about susceptibility to environmental agents that may be relevant to determining the likelihood that a given exposure has a specific effect on an individual." p.674

Additionally, it has stated on the JOEM website that the subject article is copyright owned by ACOEM and marked "CONTENT NOT FOR REUSE". Each page of the article states "*Unauthorized reproduction of this article is prohibited*".

Because it has not been retracted from publication, its summary remains on PubMed and continues to be cited for other articles.[1] It continues to be cited and attached as exhibit in its entirety by defense attorneys in military housing mold litigations.[2]

As such, the Health Services Committee of the University of California requests that the Journal of Occupational and Environmental Medicine retract *"Adverse Human Health Effects Associated with Mold in the Indoor Environment"* from publication; and inform PubMed in writing of the retraction. This is required so the Veritox Hypothesis, found in articles co-authored by Andrew Saxon Professor Emeritus UCLA, is no longer misused as claimed valid reason to deny liability for causation of individual injuries, and is no longer cited and attached for reference by the authors and others.

Sincerely,

Chair, Health Services Committee
University of California

[1] PubMed link to the JOEM article:
[2] G&R's Successful Daubert Challenge in the matter of Phipps v. LMH