A Critique of the ACOEM Statement on Mold:

Undisclosed Conflicts of Interest in the Creation of an "Evidence-based" Statement

JAMES CRANER, MD, MPH, FACOEM, FACP

In 2003, the American College of Occupational and Environmental Medicine (ACOEM) published its evidence-based statement, "Adverse Human Health Effects Associated with Molds in the Indoor Environment," in its *Journal of Occupational and Environmental Medicine* (*JOEM*). ACOEM's author selection, development, peer review, and publication of its mold position paper involved a series of seemingly biased and ethically dubious decisions and *ad hoc* methods. The resulting position paper resembled a litigation "defense report" which omitted or inadequately acknowledged research validating the association between mold and building-related symptoms. ACOEM nonetheless released the paper as an "evidence-based" statement and then published it in *JOEM* without any further changes or conflict disclosure. The Mold Statement has been relied upon by attorneys and expert witnesses representing defendants in mold litigation to disclaim and invalidate individuals', families', and workers' claims of building-related health effects from indoor mold exposure. *Key words:* ACOEM; conflicts of interest; evidence-based statement; indoor air quality; JOEM; mold.

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Many of the documents cited in this Commentary have been produced in litigation and are not easily available. We have posted these documents online at www.ijoeh.com.

Received from: Division of Occupational & Environmental Medicine, University of California School of Medicine. Direct correspondence to: James Craner, Occupational and Environmental Medicine, 5470 Kietzke Lane, Suite 130, Reno, NV 89511.

Disclosures: The author is a member and Fellow of ACOEM. His practice includes a significant amount of clinical and epidemiological evaluation of occupants of mold-contaminated buildings and investigation of "sick" buildings on behalf of individuals, employers, insurers, government agencies, schools, builders and building owners. Over the past 12 years, he has served as a treating physician and consultant, and also as an expert witness on behalf of both plaintiffs (i.e., individual homeowners, tenants, and employees and their representatives) and defendants (i.e., building and property owners and managers, builders, developers, insurance companies, and employers) involved in mold-related construction defect, property and casualty insurance, workers' compensation, and related claims and litigation concerning indoor air quality. He has also published original clinical and epidemiological research on the topic of adverse health effects from indoor mold exposure in water-damaged buildings, and has been a co-investigator in US government-funded research on indoor environmental quality and building energy efficiency. The author has no financial interests, nor has he received any compensation or business inducements related to the publication of this article.

The subject of health effects from indoor mold arising from water-damaged building materials had been recognized and studied as part of the well established field of indoor air quality (IAQ) during the 1980s and 1990s. Mold was the subject of governmental and industrial hygiene guidelines in the United States and worldwide during the 1990s.

In response to increasing mold-related litigation in the United States, the American College of Occupational and Environmental Medicine (ACOEM) leadership proposed to produce a position paper on the subject of mold in the early part of 2002. The ACOEM represents more than 5,000 physicians and other health care professionals specializing in the field of occupational and environmental medicine (OEM).[1] ACOEM describes itself as "the pre-eminent organization of physicians who champion the health and safety of workers, workplaces, and environments."[2]

The ACOEM's "Evidenced-Based Statement: Adverse Human Health Effects Associated with Molds in the Indoor Environment" (the Mold Statement) was released by the organization in late 2002 and was published in 2003 in ACOEM's *Journal of Occupational and Environmental Medicine* (*JOEM*).[3] In stark contrast to both organizational guideline standards and its own prior position papers and guidelines, ACOEM's development of its Mold Statement involved a series of biased and ethically questionable practices centered around undisclosed conflicts of interest. The published document failed to meet professional standards as both a clinical guideline and a peer-reviewed publication. The ACOEM Mold Statement has come to be relied upon by defense attorneys and their litigation experts as the scientific basis for refuting mold-related health claims in construction defects and water loss claim-related litigation against builders, realtors, property insurers, building owners, employers, and others.

The sequence of events that led to these problematic outcomes was not disclosed by the organization or demanded by its membership. Only several years after ACOEM's own internal documents were procured by a 2003 subpoena involving the authors of the Mold Statement serving as expert witnesses[4] could this history be uncovered.

Standards for Creating Evidence-Based Guidelines

Given the professional standards for the creation of evidence-based guidelines and the recognized controversy surrounding mold as an environmental health topic, ACOEM membership would have reasonably expected that any such guidelines issued by the organization would present a balanced and impartial viewpoint. For this position paper to be considered an evidence-based, OEM guidance document, the epidemiological, exposure, environmental, and public health aspects of the issue should have been addressed in a comprehensive, unbiased manner.[5,6] Such a position paper would be reasonably expected to consider scientific uncertainties in a proper clinical and public health perspective in order to assist physicians in the recognition, treatment, and prevention of health risks to their patients, individually and as populations of workers or residents.[7] Evidence-based recommendations should also acknowledge and review the findings and recommendations already published by other national organizations, multi-disciplinary consensus panels, and governmental public health agencies.[8–14]

Generally accepted standards for the creation of evidence-based guidelines by professional organizations and governmental agencies exist to ensure quality, reliability, and independence.[5] The process of creating an evidence-based guideline should begin with identification of and dialogue among various stakeholders—clinicians, patients, and the potential users or evaluators—who "would be covered by the guideline or who have other legitimate reasons for having an input into the process."[5] A description of "anticipated benefits and potential risks associated with implementation of guideline recommendations" should be defined and stated at the outset of the process.[7] Once a representative group of authors has been selected, a systematic review of literature is conducted in order to objectively assess the evidence. The methods of literature review, interpretation, and analysis, as well as the basis of opinions and recommendations should be clearly stated in order to obviate important forms of bias and self-interest in the interpretation of the information.[5,6]

Standardized approaches to the development of evidence-based clinical practice guidelines call for full, truthful disclosure of the credentials and potential conflicts of interest for all the individuals involved in the guideline's development, as well as their specific role in developing and/or writing the guideline, and the funding source(s)/sponsor(s).[7] These measures are paramount to ensuring integrity, balance, and fairness, and have been adopted by most professional medical organizations and specialty societies involved in the creation of evidence-based guidelines.[6]

Organizations which produce guidelines deploying questionable methodologies or bypassing the aforementioned open disclosure and other accountability measures "could undermine their credibility and lead to harm to the patient if the wrong recommendations were put into practice."[15] Evidence-based guidelines are thus distinguished from organizational consensus documents or topic reviews which may not be subjected to the same rigorous methodological requirements. Especially in the specialty of OEM, these negative ramifications extend above and beyond individual physician-patient interactions to the courts, health care policy makers, regulatory agencies, professional and trade associations, and insurers and risk managers, all of which are susceptible to accepting and relying upon professional organizational guidelines as objective, definitive scientific "evidence" under the assumption that an organization's stature and reputation ensures technical quality and reliability as well as ethical integrity and balance.[15]

All of the ACOEM Guidelines, Position Papers and Statements published prior to the Mold Statement share several important characteristics. Nearly all of these preceding ACOEM position statements and guidelines were written on far less controversial issues for which there was already an extensive amount of research, literature, governmental regulations, and a generally accepted approach to diagnosis, treatment, and prevention (Table 1). The lone controversial issue, multiple chemical sensitivity (MCS), was, like mold, heavily litigated in US workers' compensation and civil courts by the time ACOEM developed its organizational position on the subject. All of the authors of the ACOEM's MCS Statement[16] were ACOEM member physicians, and none of the authors was from outside the organization or the specialty of OEM. The MCS Statement presented a balanced, thoughtful discussion of a controversial topic, advising clinicians that even if "controversies about specific theories of disease" remain, clinicians nonetheless have an "obligation to help their patients who suffer from the condition."[16] The MCS Statement placed the public policy and legal implications of this disorder in an appropriate context.

In contrast to professional standards for development of clinical guidelines, the Mold Statement unfairly and inadequately addressed the available epidemiological research on building-related disorders. The purpose, balance, and focus on clinical and public health, epidemiology, exposure assessment and control, and disease prevention, as well as recommendations for taking a leadership role in controlling the environmental hazard, and calling for additional research that were addressed in all of these previous ACOEM position statements and guidelines were conspicuously *absent* from the ACOEM Mold Statement, as summarized in Table 2. The Mold Statement also departed significantly in its scope, tone, and recommendations from all previously published ACOEM statements, position papers, and guidelines.

TABLE 1 ACOEM Evidence-Based Statements and Related Position Papers,* 1998-2006

Title	Date Released	Date Published in JOEM	Lead Author(s) or Committee	Authors ACOEM Member(s)?
Pertussis Vaccination of Health Care Workers	6/27/2006	June 2007	Mark Russi, MD, MPH	Yes
Automated External Defibrillation in the Occupational Setting (reaffirmed May 2006)	5/6/2006	Not published	Larry M. Starr, PhD, under the auspices of the Council on Scientific Affairs	Yes
Genetic Screening in the Workplace	12/13/2005	Not published	ACOEM's Ad hoc Committee on Genetic Screening of the Council on Scientific Affairs. Paul Brandt-Rauf, David C. Deubner, Robert A. Pinter, Benjamin F. Withers, T. Warner Hudson, and Jonathan Borak	Yes
Medical Surveillance of Workers Exposed to Crystalline Silica	6/27/2005	January 2006	Lawrence Raymond, MD, and members of the ACOEM Occupational and Environmental Lung Disorder Committee	Yes
Evaluating Pulmonary Function Change	2/2/2004	December 2005	Mary C. Townsend, DrPH, and members of the ACOEM Occupational and Environmental Lung Disorder Committee	Yes
A Screening Program for Depression	10/30/2002	April 2003	ACOEM Occupational Mental Health Committee	Yes
Noise-induced Hearing Loss	10/30/2002	June 2003	ACOEM Noise and Hearing Conservation Committee	Yes
Adverse Human Health Effects Associated with Molds in the Indoor Environment	10/27/2002	May 2003	Bryan D. Hardin, PhD, Bruce J. Kelman, PhD, DABT, and Andrew Saxon, MD	No**, Yes No
The Attending Physician's Role in Helping Patients Return to Work after an Illness or Injury	04/14/2002	Not published	Work Fitness and Disability Section	Yes
Epidemiologic Basis for an Occupational and Environmental Policy on Environmental Tobacco Smoke*	7/30/2000	December 2000	Alan M. Ducatman, MD, FACOEM; Robert K. McLellan, MD, FACOEM	Yes
Spirometry in the Occupational Setting*	1/4/2000	March 2000	Mary C. Townsend, Dr.P.H.; Lockey, James E. MD, MS, Chair; Velez, Henry MD; Vice Chair; Carson, Arch I. MD, PhD; Cowl, Clayton T. MD, MS; Delclos, George L. MD, MPH; Gerstenhaber, Bret J. MD; Harber, Philip I. MD, MPH; Horvath, Edward P. MD, MPH; Jolly, Athena T. MD, MPH; Jones, Shadrach H. IV MD; Knackmuhs, Gary G. MD; Lindesmith, Larry A. MD; Markham, Thomas N. MD, MPH; Raymond, Lawrence W. MD, SM; Rosenberg, David M. MD, MPH; Sherson, David MD; Smith, Dorsett D. MD; Townsend, Mary C. DrPH; Wintermeyer, Stephen F. MD, MPH	Yes
Multiple Chemical Sensitivities: Idiopathic Environmental Intolerance*	4/8/1999	November 1999	ACOEM Environmental Medicine Committee: Robert Keene McLellan, MD, MPH, Chairman; Charles E. Becker, MD; Jonathan B. Borak, MD; Claudia Coplein, DO; Alan M. Ducatman, MD;Elissa A. Favata, MD; J. Frederic Green, MD; Jessica Herzstein, MD; Athena T. Jolly, MD; Jonas Kalnas, MD; Kenneth Kulig, MD;Howard M. Kipen, MD;David C. Logan, MD; Frank L. Mitchell, DO; Hugh W. McKinnon, MD; Mark A. Roberts, MD; Mark Russi, MD;Howard J. Sawyer, MD;Martin J. Sepulveda, MD;Mark J. Upfal, MD; Maria C. Zepeda, MD	Yes
Guidelines for Employee Health Services in Health Care Facilities*	12/11/1998	Not published	Robert R. Orford, MD, Vikas Kapil, DO Larry Lindesmith, MD, Geoffrey Kelafant MD, Thomas E. Forte, DO; Clara Sue Ross, MD; David Berube, MD, and David Stewart, MD	Yes
Guidelines for Protecting Health Care Workers Against Tuberculosis*	9/1/1998	September 1998	Lawrence W. Raymond, MD and other members of the Occupational and Environmental Lung Disorders Committee	Yes

* Information publicly available at http://www.acoem.org/guidelines.aspx. Several papers were previously listed as of December, 2006 as Evidence-Based papers but are no longer listed at all on the ACOEM Web Site.
**Enrolled as an "honorary member" as of 2002.

TABLE 2 Characteristics of ACOEM Position Papers, Statements and Guidelines

Characteristic	Example	Mold Paper Consistent?
Review of pertinent epidemiology and public health aspects related to policies for environmental controls	TB*	No
Admonition of OEM physicians to take a leadership role in controlling the occupational hazard/exposure	TB*: "Occupational physicians should take a leadership role in promoting an active TB-control program, not only in health care institutions but also in other settings where the workforce includes persons at special risk of acquiring and spreading this infection."	No
Purpose is to assist ACOEM members in implementing effective programs for exposure control and disease prevention	TB*	No
Where scientific aspects of etiology and causation of an environmental health issue remains highly controversial disorder characterized by "subjective" symptomatology to nonetheless describe "both sides" of the issues and admonish physicians to provide compassionate care to patients with the disorder	MCS**: "The diagnosis, treatment and etiologic assessment of multiple chemical sensitivities (MCS) has remained a troublesome medical and social concern for individuals, physicians, government, and organizations. . . . The role of the environment in precipitating complaints continues to be controversial. . . . The pathophysiologic and psychologic mechanisms that may contribute to the development and maintenance of this disorder have still not been definitively elucidated. . . . Controversies about specific theories of MCS, diagnostic approaches, or treatment modalities should not preclude the compassionate care of patients presenting with complaints consistent with MCS."	No
In controversial topic, support scientific research (i.e., funding of ACOEM academic physicians) to elucidate etiological agents, mechanisms and pathophysiology of disease, epidemiological research	MCS**: ACOEM "supports scientific research into the phenomenon of MCS to help explain and better describe its pathophysiologic features and define appropriate clinical interventions. . . . The research agenda should employ 'Modern investigative techniques and sophisticated epidemiology.'"	No
Recognize the use of the Position Paper to assist physicians to help not only their patients but also others in society	The Attending Physician's Role in Helping Patients Return to Work after an Illness or Injury: "ACOEM believes that physicians who follow the principles outlined in this policy will improve the outcomes of their care for their patients and their families, their communities, employers and society."	No

**Guidelines for Protecting Health Care Workers Against Tuberculosis*
***Multiple Chemical Sensitivities: Idiopathic Environmental Intolerance*

Initiation and Selection of the Authors: An Ad Hoc *Procedure*

The ACOEM's *Procedures for Creating ACOEM Position Papers and Guidelines* was released in October 2000. They state that "Position papers typically originate in an ACOEM committee in response to a perceived need or as a directive from the Board of Directors, the House of Delegates, or a Council."[17]

The directive "to develop a *position statement* on indoor mold" originated from the ACOEM President, Dean Grove, MD in February, 2002, and was handed to and implemented by Jonathan Borak, MD, Chairman of ACOEM's Council on Scientific Affairs (CSA).[18] No documents were produced that indicate the request was accompanied by any stipulations for oversight, perspective, scope, or selection of authors.

An appropriate, expedient, and logical first step in creating the organization's Mold Position Paper would have been the identification or solicitation of ACOEM members with credible training, qualifications, and clinical, epidemiological and/or original research experience in indoor air quality (IAQ), sick building syndrome (SBS), and indoor fungal bioaerosols (mold) to serve as the authors.[5–6,19] As of 2001, there were several qualified OEM physicians in the United States, both within ACOEM and outside the organization, who had published original research on these topics in peer-reviewed journals, including articles in JOEM.[20–25] Moreover, highly qualified physicians could have been identified and solicited from other nations where clinical, epidemiological, basic research studies, consensus documents, and review articles on indoor mold, SBS and IAQ had been published.[26–30] Many other experts from

related disciplines, including industrial hygienists, environmental microbiologists, building scientists, epidemiologists, and toxicology chemists, had authored original, peer-reviewed health and environmental research, review articles, and guidance documents.[8,9,23–26,31–33]

Litigation on the mold issue had existed in the United States for several years prior to 2001.[8,34–36] Since OEM is the specialty of medicine most directly involved with IAQ-related health disorders, disease causation, and public health, a reasonable approach to offset any ostensible bias related to litigation would have been for ACOEM to assemble a panel of physicians with perspectives, expertise, and experience on all sides of the issue to help shape a balanced consensus statement reflective of the current scientific evidence.[5,15] Under this scenario, even if a panel member had consulted or served as a litigation expert on either side of the issue, the entire panel of physicians could have collaborated under the auspices of ACOEM to develop a balanced, consensus-based statement reflective of the organization's mission and constituency.[1,2]

While the *Procedures for Creating ACOEM Position Papers and Guidelines*[17] did not explicitly require one or more ACOEM members—including those with residency training and/or board certification in OEM—to author or contribute to a position paper or evidence-based statement, a review of the five previous ACOEM "Position Papers/Statements" published since 1998 reveals that in all but one case, the authors were physicians who were also ACOEM members. In nearly all of these previously published position papers and guidelines, a group of physicians from various ACOEM committees was credited with authorship, and in some the specific contributing authors were not identified by name (Table 1).

In contrast, a vastly different, *ad hoc* route was followed in selecting and directing the authors of the Mold Position Paper(also referred to as the "Position Statement"). With the approbation of President Grove, Dr. Borak approached Bryan Hardin, PhD, a (non-physician) toxicologist, who reportedly was retiring from his position as a NIOSH deputy director, to be the lead author. Dr. Hardin's task was "specifically the preparation of a scientific position paper on the subject of mold, indoor air quality and health, [which] . . . would be prepared by *you and your GlobalTox colleagues*" [emphasis added].[37] GlobalTox was the private consulting firm Dr. Hardin had planned to join after his retirement from NIOSH.

The basis for Dr. Borak's autonomous selection of Dr. Hardin, without consideration or exploration of other potential candidates, is unclear and absent from ACOEM's copious email documentation of its Mold Position Paper's genesis and development.[4] As a readily accessible Medline search would have confirmed, Dr. Hardin had no peer-reviewed publications in the area of IAQ, SBS, or mold, nor had he published on any occupational or environmental medicine topic in the preceding decade. In addition to this dearth of expertise in the subject matter, Dr. Hardin was not an ACOEM member.[38] To overcome this problematic membership issue, ACOEM leadership dispatched a quick fix: "ACOEM will enroll you as an Associate Member (the category for PhDs, as contrasted to MDs) at no cost for the first year. That will be an advance 'thank you' for your contributions. . . ."[37] In addition, Dr. Borak offered Dr. Hardin an endorsement from ACOEM to foster his new consulting career, assuring him that "Once [the Position Paper is] accepted, I will ask Marianne Dreger [ACOEM Director of Publications] to prepare an article about you and your position statement to be published in ACOEM Report, our internal news magazine."[37]

Dr. Hardin's colleague, Bruce Kelman, PhD, a toxicologist and the founder of GlobalTox, was selected to serve as his co-author, in line with Dr. Borak's directive.[37] Dr. Kelman (who was an ACOEM member) and other GlobalTox consultants had been serving for several years as consultants and expert witnesses primarily on behalf of defendants—builders, developers, realtors, home and property insurers, employers, landlords—in construction defect and insurance lawsuits involving mold-related health and exposure claims.

GlobalTox's defense experts' focus was on dismissing mold as a toxicological hazard, in particular by depicting the mycotoxin theory as scientifically untenable and implausible. Dr. Kelman, along with his GlobalTox colleagues and consultants from other firms, wrote a review article, published in a prominent industrial hygiene journal in 2000, which concluded that "the current literature does not provide compelling evidence that exposure [to mycotoxins] at levels expected in most mold-contaminated indoor environments is likely to result in measurable health effects."[39] Soon thereafter, a summary of this article, authored by another GlobalTox principal who was also the lead author of Dr. Kelman's sole publication on mold, appeared as the "dissenting opinion" in the American Industrial Hygiene Association's (AIHA) consensus-based "Microbial Growth Task Force" report in 2001.[34] This "minority report" argued that "mold" was not a valid health hazard, and complained that AIHA's majority recommendations for mold remediation were unfounded because the AIHA document did not undergo a "standard peer-review process."[34]

Aside from this 2000 review article,[39] none of Dr. Kelman's previous publications dealt with mold or any other aspect of IAQ. Dr. Kelman had served as a defense expert witness on behalf of cigarette manufacturer Philip Morris, most recently in 1997.[40] In 2006, under oath in a deposition as a defense expert in a construction defect case, Dr. Kelman admitted that he had been actively involved as a defense litigation expert and consultant prior to and at the time he was invited to co-author the ACOEM Mold Position Paper.[41] He divulged his pre-exist-

ing opinions upon being asked by Dr. Hardin in 2001 to participate in writing the ACOEM Position Paper:

> Actually, at the time I was asked to do this, I didn't have a particular interest in doing it. I was convinced to do it. The idea that mold spores can contain enough mycotoxin in a normal indoor environment to produce a mycotoxicosis is laughable and not of much interest to a toxicologist. I was asked by Dr. Hardin to participate because the subject area was so broad, and I agreed.[41]

When interviewed in 2006 for an article in the *Wall Street Journal* entitled "Experts Wear Two Hats," Dr. Borak stated that the rationale for his selection of Dr. Hardin and his GlobalTox colleagues was that he wanted an author "with no established background record of litigation related to mold."[42] Dr. Borak claimed in the *Wall Street Journal* article that he "didn't know at the time that GlobalTox did mold defense work,"[42] even though his February 27, 2002 email to Dr. Hardin acknowledged Dr. Hardin's extant or imminent affiliation with GlobalTox (which later changed its name to VeriTox).[37] Dr. Borak and ACOEM leadership or staff had ample opportunity, resources, and time to research GlobalTox's litigation activities and track record to uncover any conflict of interest that might exist, let alone to ascertain if the authors met his criterion of having had no actual involvement in mold-related litigation. Apparently no such inquiries were made.

The third author of the ACOEM Mold Position Paper was Andrew Saxon, MD, who was also not an ACOEM member.[38] As chief of the Department of Allergy/Immunology at the University of California, Los Angeles (UCLA) School of Medicine, Dr. Saxon had an impressive record of publications and research in the field of allergy/immunology. However, this did not include any peer-reviewed publications or original research on the topic of IAQ or mold.

In January 2002, one month before the ACOEM Mold Position Paper had been officially conceived, Dr. Saxon (along with one of the co-authors of the 2000 GlobalTox article[39]) had appeared as a defense expert in a construction defect case involving claims of mold-related health effects in Orange County, California.[43,44] The following month, just after Dr. Borak had made his selection and extended his invitation to Dr. Hardin and his "GlobalTox colleagues,"[37] Dr. Saxon was deposed as a defense medical expert in another personal injury case involving health claims by owners of a mold-contaminated residence.[45] In this deposition, Dr. Saxon confirmed that he currently served as a medical expert in eight active cases—all for the defense, and none as a plaintiff expert.[45] When he was asked by the deposing attorney, "Is there any particular reason why you have not acted on behalf of a plaintiff in a mold case?" Dr. Saxon responded, "I say the same thing for everyone in every case. The plaintiffs don't like to hear what I say."[45] In another deposition taken in 2006, Dr. Saxon admitted that he had been actively serving as an expert witness in mold litigation exclusively on behalf of defendants since 1999.[46]

After the first draft of the Mold Position Paper had been circulated, a few ACOEM physician members outside of the CSA and peer review committees became aware through word-of-mouth that such a position paper was actually being drafted by these three authors. When these OEM physicians offered to participate in its development, Dr. Borak declined, stating that, since initiating the process in February, he had "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 the development."[18]

A "Meticulous Peer Review"

The *Procedures for Creating ACOEM Position Papers and Guidelines* in 2002 stated that "Following [peer review] committee approval, the paper, with routing slip attached, is submitted to the appropriate council or, if the committee does not report to a Council, to the responsible officer for approval."[17] Specifically, all peer reviewers of ACOEM position papers and guidelines "should consider whether they have expertise related to the methods or content of the paper that will make their views valuable."[17]

The process of peer review is employed by most medical journals "as an integral part of the scientific process. Peer review plays a key role in monitoring and filtering the quality of research, serving as a constructive mechanism for improving the quality and presentation of research, and as motivation for authors to produce high-quality work."[47] In general, medical journals require reviewers to have sufficient expertise related to the methods or content of the paper, and to provide detailed comments to justify their reviews. Some journals require not only potential authors of papers but also peer reviewers (who remain anonymous to the authors) to disclose any potential conflict of interest, and to decline participation if warranted.[48,49]

Soon after the first draft of the Mold Position Paper was distributed to ACOEM peer review committees,[50–52] Dr. Borak was reminded of the importance of author and peer reviewer disclosure of potential conflicts of interest to ensure integrity, accountability, and transparency by Philip Harber, MD, MPH, an OEM professor from the UCLA School of Medicine. Dr. Harber advised Dr. Borak that because mold-related litigation in California

> has become the new issue for Erin Brockovich, ACOEM should be concerned about the possibility of lawsuits being filed against the organization if it were to take a biased position on this issue—much

like what had happened to the American Thoracic Society on the asbestos issue.[53]

Dr. Harber continued that it "is therefore essential that the process of development and review be carefully considered," and posed the following questions:

> 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 conflict 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 the project?[53]

These well-taken concerns regarding the process of author selection, need for balanced viewpoints, and importance of full disclosure of potential conflicts of interest were reiterated by at least one other reviewer, also an academic OEM physician.[54] Dr. Borak did not dispute these points; instead, he appeared to deflect Dr. Harber's concerns:

> 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.[18]

Dr. Borak voluntarily disclosed that he personally and professionally had no conflict because his consulting practice did not involve any mold issues.[18] Dr. Borak further offered that he "would be open to recommendations of other outside peer reviewers with appropriate academic/scientific expertise," but he called instead for a "meticulous peer review" to obviate the need for peer reviewers' disclosure of conflicts of interest and to "protect against scientific error and bias."[18]

Dr. Harber's cautionings and Dr. Borak's rejoinder notwithstanding, there is no evidence that participation in ACOEM's peer review process of the Mold Position Paper required a disclosure of potential conflicts of interest, including any record of serving as an expert witness in mold litigation, nor did it require potentially conflicted members to recuse themselves from participation in the peer-review process.[17,48]

The first draft of the Mold Position Paper was circulated to the CSA and several ACOEM committees.[50–52,55–57] Although Dr. Borak claimed in the *Wall Street Journal* article[42] that the Mold Position Paper was "peer-reviewed by over 100 physicians," the internal ACOEM documents obtained by subpoena[4] show that fewer than 20 ACOEM members actually provided written comments or critiques.[53,54,58–73] Dr. Borak himself eventually acknowledged that even though he was responsible for collecting the comments, he did not know how many ACOEM members actually reviewed the draft.[74]

Despite Dr. Borak's call for a "meticulous" and "meaningful" peer review, only two of the reviewers had previously published on mold-related topics.[75,76] A Medline literature search reveals that none of the other reviewers had previously published *any* peer-reviewed articles, including original clinical or epidemiological research, case reports, or review articles, on the subject of mold-related health effects related to water-damaged buildings. Four of the peer reviews, notably those that approved the Mold Position Paper in its original (first draft) form, consisted of one-sentence comments, without providing any specific analysis, discussion, questions, references, or recommendations. None of the peer reviewers appears to have questioned the author selection process or qualifications whatsoever.

Of the peer reviewers who did offer substantive critical commentary, some of their remarks were directed not only at the content and scope of the Mold Position Paper, but also its dismissive tone. Robert McLellan, MD, MPH, a future ACOEM President, advised that he "Strongly agree[d] with need to change tone and would start at the first paragraph, which *reads like a defense report for litigation*" [emphasis added].[67] Other reviewers stated their concerns more bluntly, *viz*, "This is a poorly written paper that will need extensive revision."[71] One academic OEM physician noted, "there is a strong epidemiological literature describing an association between respiratory symptoms, and even PFT's [pulmonary function tests], and living in damp or water damaged buildings, a reasonable surrogate for mold exposure. This should be mentioned and discussed."[66] Another reviewer recommended that further research on the topic of mold-related health effects be endorsed.[68]

Dr. McLellan's review succinctly corroborated all of these critiques, offering that there was

> . . . extensive literature that points to an increased incidence of respiratory complaints in damp housing. Again, the tone of this paper seems to be dismissive. Although I agree that there is no convincing evidence that inhaled mycotoxins cause disease, there is good epidemiological evidence that occupying water damaged buildings makes people feel bad. . . . [While the draft provides] a good summary of why current science does not support adverse health effects due to inhaled mycotoxins, . . . it fails to review the excellent building science and epidemiological work that has been done that reflects mainstream opinion that building related moisture problems should be prevented and remediated quickly so as to avoid epidemic respiratory complaints.[67]

In response to the suggestion of an external peer review,[77] Dr, Borak refused:

> For several reasons, I am uncomfortable sending this to outside folks for comment. First, the authors' names are on the manuscript, and that makes the process potentially biased. Second, the manuscript is only being sent to people who are identified on the basis of their scientific expertise and/or ACOEM relationships.[78]

Dr. Borak noted that he would make an exception for non-ACOEM members to review the manuscript only if they were "'world-class' subject authorities."[78]

The following week, Dr. Borak notified Dr. Hardin[79] of a recently received letter to the editor on mycotoxins and building-related illness that had been accepted for publication in JOEM.[80] The letter was written by Michael Hodgson, MD, MPH, and a colleague. Dr. Hodgson, a distinguished, board-certified occupational medicine physician (but not an ACOEM member), had considerable background, original research, and clinical experience in the field of IAQ.[20,23,81] In his letter to the editor, Dr. Hodgson reviewed recent research data regarding the subject of a causal association between mycotoxins and pulmonary disease, and acknowledged that while "From a scientific perspective, the question of the true role of toxigenic fungi in respiratory disease remains interesting and inadequately acknowledged," most recent reviewers and editorials nonetheless "agree that from a public health perspective, the avoidance of unwanted moisture in homes and other construction is the primary goal and the solution."[80]

Dr. Hodgson's letter, together with his "prominence in our field and this publication," compelled Dr. Borak to consider seeking an independent peer review of the Mold Position Paper from Dr. Hodgson himself.[79] Prior to asking Dr. Hodgson for his input, Dr. Borak asked Dr. Hardin to reconcile the discrepancies between his draft and Dr. Hodgson's letter.[79] In response, Dr. Hardin rebuked this suggestion, arguing that it would be "*inappropriate to add* ad hoc *reviewers who are highly visible advocates for a point of view the draft position paper analyzes and finds lacking*" [emphasis added].[82] It is unclear whether the "point of view" the author found lacking was the mycotoxin theory, or a broader recognition that mold in water-damaged buildings is a real health hazard.

By early September 2002, reviews of a revision of the Mold Position Paper had been returned to Dr. Borak, although there is no evidence that plans for an independent peer review by Dr. Hodgson or others were carried out.[83] Dr. Borak and other reviewers felt that the modifications to the draft were substantive.[83] A close inspection of the next two drafts, however, shows no significant change in the overall content or orientation reflective of the ACOEM committee members' peer review critiques.[84,85] The overall dismissive, "defense report" tone[67] remained unchanged, as an apparently frustrated Dr. Borak admitted to President Grove in early September 2002:

> 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 [Board of Directors] 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 otherwise 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. . . . 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 [emphasis added].[83]

Dr. Borak's missive raises the question of whether his concern about satisfying the needs and expectations of the appointed authors outweighed the input of ACOEM peer reviewers who objected to the document's tone. Despite Dr. Borak's acknowledgement of ACOEM peer reviewers' ongoing differences of opinions regarding the draft Mold Position Paper, there is no evidence that further input was sought from other ACOEM members, or anybody else with expertise on the subject prior to the publication of the document. The only additional editing of the Mold Position Paper was some final "rewording" by Dr. Harber in early October 2002,[86] resulting in the final draft in preparation for public release.[87] The position paper was released by ACOEM as an "Evidence-Based Statement" (the Mold Statement) in late October 2002, with the names of the three authors included at the top of the Paper and again at the bottom under "Acknowledgments," with disclosure of their affiliations but without any disclosure of perceived or confirmed conflicts of interest.[88]

From Position Paper to Evidence-Based Statement: Publication in JOEM

JOEM is owned and published by ACOEM.[89] ACOEM's Position Paper policy states that "the Communications

Department will make their changes (if any) and forward the paper to the *JOEM* for inclusion in the earliest issue of that publication."[17] Though *JOEM* has its own, separate peer review process and editorial board, this organizational policy does not recommend or require any independent peer review of any organizational position paper by the *JOEM* editor. Dr. Borak himself had advised Dr. Hardin in February 2002 that the *JOEM* editor "has authority to perform whatever peer review he deems appropriate to publication."[37]

ACOEM's position paper policy provides little guidance on how and to what extent a position paper is to be converted into a journal article. None of ACOEM's prior position papers, statements or guidelines which had been authored by ACOEM members had ever been published in *JOEM* as an "evidence-based" statement (Tables 1 and 2).

Neither do the position paper procedures address how to handle the potential for conflict of interest if a member of the *JOEM* Editorial Board also serves on a peer review committee or on the CSA, the latter of which is responsible for final approval of the paper. On September 11, 2002, Dr. Borak advised Barry Eisenberg, ACOEM Executive Director, that:

> I spoke with Paul Brandt-Rauf [editor of *JOEM*] today. He is open to some sort of expedited publication in *JOEM* (subject to Journal editorial policies and peer review). On Wednesday, I will ask Bryan [Hardin] if that is an acceptable resolution for him. If so, we may be able to broker that solution, put something interesting into *JOEM*, and also keep Bryan as a friend.
>
> *If Bryan finds that acceptable, I will send to Paul all of the accumulated comments from ACOEM peer reviewers, and that might suffice for* JOEM *peer review.*
>
> The problem that I am wrestling with was incisively summarized by Paul when I called him. I said that I had 'commissioned' a review paper on mold for ACOEM, and he immediately asked whether it was 'pro' or 'con.' It seems that on this topic, the science in too politicized to simply be science! [emphasis added][90]

Thus, as both Chairman of the ACOEM's CSA *and* as a member of *JOEM*'s Editorial Board, Dr. Borak not only selected the Mold Position Paper's authors and controlled the peer review process, but also negotiated its acceptance (while still in draft form) in the journal.[42,90]

Apparently in response to the peer reviewers' and other comments, Dr. Hardin first disclosed his and his coauthors' roles in mold litigation in a confidential letter submitted to Dr. Borak in September 2001.[91] Dr. Hardin noted that while he had no track record in mold litigation, "[B]oth Drs. Kelman and Saxon have been retained by both the defense and plaintiff bar in litigation relating to mold," qualifying this disclosure by stating that "their advice and testimony has always been consistent with their evaluation of the science, which is reflected in our draft position statement."[91] This statement appears contradictory to Dr. Saxon's previous and subsequent testimony under oath during depositions that all of his extensive, prior expert consultation and testimony in mold litigation had been exclusively on behalf of defendants.[45,46,92,93]

Dr. Hardin did not provide details as to whether the plaintiffs who hired him and his GlobalTox colleagues were individuals with claims of mold-related illness, or rather insurance companies or general contractors suing or subrogating against third parties, subcontractors, and other entities.[41,94] No attempt to verify the authors' self-prompted "disclosure" appears to have been undertaken by ACOEM. When ACOEM's president, Edward Bernacki, MD, announced the release of the "evidence-based statement" to the organization's membership in early November 2002, he emphasized that a "'Conflict of Interest' statement was obtained from the authors of the paper."[95]

By late October 2002, when Dr. Hardin asked when the Position Paper would be published in *JOEM*, ACOEM Director of Publications, Marianne Dreger, informed him that she had "heard from our Executive Director that this paper is to be referred to as an 'Evidence-based Statement' so I'll fix.[96] Between October 2002 when the Position Paper *cum* Evidence-Based Statement was released by ACOEM and May 2003 when the *JOEM* version was published, the editor of *JOEM* had sufficient resources, time, and authority to independently evaluate the Mold Statement's evidence gathering and analysis process;[6,15] distribute the document for independent internal or external peer review and potential revisions (including soliciting comments for an editorial or rebuttal paper); and perhaps most importantly, ensure and carefully vet the authors' disclosure of conflicts or bias related to litigation and consulting activities. *JOEM*'s editor could have readily solicited highly qualified peer-reviewers not only from within ACOEM's membership but also from among the authors of literature who had recently published articles on mold-related science in other peer-reviewed journals,[28,32] as well as *JOEM* itself.[97] There is no evidence the editor of *JOEM* expressed any concerns to Dr. Borak regarding the selection of the authors and the consequences of resulting potential bias, as Dr. Harber and other ACOEM peer reviewers had raised earlier.[53,83] The final draft of the Mold Position Paper and the version published in *JOEM* are identical.[3,88]

The issue of conflict of interest disclosure for the authors was raised in late January 2003 by some ACOEM physician members who were corresponding on an OEM discussion board. One ACOEM member asked:

> Some weeks ago many of us on the [discussion board] list were anticipating the conflict of interest statements from JOEM in regard to the authors of the "Mold Statement" adopted by the ACOEM. It seems they got lost in the mail.

> This question arises if this is just an oversight, or if such a disclosure of conflicts of interest is purposeful, as many of us who are members of ACOEM who actually see patients with mold exposure were excluded from the discussion.[98]

Based on this writer's experience as an ACOEM member, ACOEM membership never received any such disclosure, nor were they ever further apprised of the Mold Statement's status until after it had been published in *JOEM* a few months later.

Recognizing the Authors

The question of how to credit the Mold Statement's individual authors remained as the May 2003 *JOEM* publication date approached. Dr. Hardin reminded *JOEM* management that "We three authors were expecting that the printed paper would show us as authors, just as authorship is shown on regular papers published in *JOEM*."[99] The following week, Dr. Hardin reiterated his expectation of authorship recognition to *JOEM*, emphasizing that it "was our understanding when we undertook to write the paper."[100] He even solicited ACOEM to reveal the names of the Mold Statement's peer reviewers,[4] apparently in relation to his GlobalTox colleague and coauthor's expert witness case:

> Jonathan—as you can see below, Bruce Kelman is needing to know, for purposes of a declaration in litigation, details of the peer review process for the ACOEM statement. Are you comfortable providing us the membership roster for your Council on Scientific Affairs or other committee that was the peer review body?[101]

When the Mold Statement was published in *JOEM* in May 2003, authorship was acknowledged at the conclusion of the article with the following "disclosure":

> This ACOEM statement was prepared by Bryan D. Hardin, PhD, Bruce J. Kelman, PhD, DABT, and Andrew Saxon, MD, under the auspices of the ACOEM Council on Scientific Affairs. It was peer-reviewed by the council and its committees, and was approved by the ACOEM Board of Directors on October 27, 2002.[3]

Neither the authors' professional affiliations that had been disclosed in the organizational release of the Position Paper (i.e., as members of a private litigation consulting firm, or as a tenured professor), their ACOEM membership status (or lack thereof), nor their role and record in professional consulting and litigation was disclosed in the *JOEM* publication. Even though their names did not appear alongside the title, ACOEM made efforts to ensure they were nonetheless credited and indexed in Medline.[102]

Dissemination of the Mold Statement's Message: The Media

Immediately after the Mold Statement's release by the organization and after its publication in *JOEM*, ACOEM publicly promoted the article and its authors. ACOEM's Director of Publications advised Dr. Hardin that the Statement would be posted to ACOEM's web site only "After you have reviewed and approved the document. . . ."[96] When the document was allegedly released prematurely by ACOEM, the first ACOEM member to have received it and rapidly spread the word throughout the internet was an OEM physician employed at the same litigation consulting firm as the first two authors of the article.[103]

In publicizing ACOEM's release of its new Mold Statement, ACOEM relied on Dr. Hardin to be its spokesperson. The Director of Publications further requested that the authors "assist us with the release by giving a few quotes and by being available to handle any media inquiries."[96] The authors supplied their quotes to ACOEM, which in turn delivered them unedited to the media:

> Mold growth indoors is undesirable but does not warrant the fear that is too often associated with it. A careful review of the science suggests that irrational fear of indoor mold threatens reasonable public policy more than indoor mold threatens public health. (Bryan J. Hardin, PhD)

> It appears to be virtually impossible to inhale sufficient mycotoxins in residential or office environments to produce toxic effects. (Bruce J. Kelman, PhD, DABT)

> Physicians have good tools for the diagnosis of immunologic and infectious conditions. Unfortunately, the misuse of those tools by a limited number of practitioners has contributed to misplaced concerns about mold-related illnesses. (Andrew Saxon, MD)[104]

These media quotes conflict with the supposed purpose of the Mold Statement as an objective, systematic review of available medical and scientific information intended for an audience of physicians and industrial hygienists.[17] In this single, broad brush stroke, most of the earlier "peer review" efforts to tone down the Mold Statement as a "defense argument"[67,83] were effectively superseded. Communicated instead was the bottom-line message that a toxicological etiology for mold-related health effects was scientifically invalid, implying that indoor mold contamination should not be considered a serious or significant public health issue.

The impact on the media was immediate and predictable. Trade associations and magazines whose readership were looking for scientific guidance on mold-related health issues, but who were perhaps not

medically knowledgable or savvy enough to read or critique the Mold Statement itself, were eager to interview the authors to expound first-hand upon their take-home messages. For example, one request came from the editor of a "publication targeted to business people who deal with indoor environment quality issues" for an "interview with [Dr. Hardin] as author of ACOEM's mold paper."[105] In response to the authors' media statements, the trade journal editor queried, "Am I correct that the evidence-based statement indicates it has not yet been proved that indoor mold in buildings is a significant health hazard?"[106]

Capitalizing on ACOEM Authorship

The authors' months of "volunteer" efforts in 2002 were rewarded with far more than a complementary, one-year ACOEM membership.[37] Their recognition as authors of an occupational medicine evidence-based guideline, published in a leading peer-reviewed medical journal, gave them credibility and recognition as the leading authorities on the topic of mold. In the booming mold litigation industry, the market value of such recognition was as good as gold.

In July 2003—just two months after the Mold Statement appeared in *JOEM*—the U.S. Chamber of Commerce's Institute for Legal Reform, partnering with the Center for Legal Policy of the Manhattan Institute, a conservative think-tank, published two papers that allegedly took "a close look at mold litigation and the science of mold."[107] The basis for these documents was the perceived financial threat to the insurance industry and business as a result of mold-related litigation:

> The insurance industry has reported "toxic" mold claims in the billions of dollars. Insurance companies in Texas alone paid $1.2 billion in mold claims in 2001. Is mold the next asbestos?[107]

The first Chamber of Commerce/Manhattan Institute paper was a "non-scientific" article entitled, "New Plague—Mold Litigation: How Junk Science and Hysteria Built an Industry," which was written to inform the business community that mold was a "media-generated fear of alleged health hazards—fear without scientific support."[107] This article dismissed the sick building syndrome as "highly exaggerated—more due to psychosocial factors than to any disease entity."[107]

The second paper, entitled "A Scientific View Of The Health Effects Of Mold," was written by a "team of scientists" who happened to include the same three authors of the ACOEM Mold Statement.[108] These authors succinctly stated the purpose and scope of their paper:

> Judging by what appears in breathless television reports and bold newspaper headlines, the nation's health is under insidious attack by a silent killer: 'toxic mold.' In this paper we will discuss what is real and what is imagined in those reports.[108]

In contrast with their *JOEM* contribution, Drs. Hardin, Kelman and Saxon received full acknowledgement of their authorship: their professional affiliations were listed at the top of this paper, plus full-length biographies at the end. In the Chamber of Commerce/Manhattan Institute paper, the authors concluded that:

> Current scientific evidence does not support the idea that human health has been adversely affected by inhaled mold toxins in home, school, or office environments. Thus, the notion that "toxic mold" is an insidious, secret "killer," as so many media reports and trial lawyers would claim, is "junk science" unsupported by actual scientific study.[108]

These conclusions parallel the same authors' media quotes that they provided to ACOEM. While the content, tone, and conclusions in the article also conspicuously mirror the authors' original draft of the ACOEM Mold Position Paper, the Chamber of Commerce/Manhattan Institute paper contains no reference to the previously published ACOEM Mold Position Paper/Statement. However, in 2004, Dr. Kelman—serving as an expert for the defendant in a mold litigation case—revealed that the Chamber of Commerce/Manhattan Institute paper was actually a "lay translation of the ACOEM paper," and divulged that the Manhattan Institute had paid his consulting firm, VeriTox (formerly GlobalTox), the sum of $40,000 to write it.[94] Dr. Saxon also admitted in a deposition in 2004—once again as a defense litigation expert—that the Chamber of Commerce paper was a "lay version" of the first draft of the ACOEM paper he and his GlobalTox co-authors had written.[92]

Dr. Borak had predicted in September 2002 that the Mold Statement authors' *pro bono* authorship would "have currency for them in other ways and other places."[90] Indeed, the ACOEM Mold Statement authors profited handsomely from their status as newly recognized authorities on the subject of mold health effects. In response to a question in a deposition as a defense expert in 2006, Dr. Kelman admitted that, "In general, there was a huge increase in litigation [–related business] after the [ACOEM] paper was published."[41] Dr. Saxon similarly testified that both he and his employer, UCLA, earned substantial income from his mold-related litigation consulting and expert witness work.[93] Dr. Saxon's deposition testimony revealed that his billable expert consulting work in mold litigation—a little over half of which went to UCLA—exceeded $1 million between 2003 and 2006.[93] After he retired from UCLA in 2006, Dr. Saxon's private expert work continued to generate at least $20,000 per month.[93] All of this expert work continued to be performed on behalf of defendants.[45,46,93]

In 2006, with his newly acquired status as an authority on the subject of mold-related health effects, Dr. Saxon co-authored an allergists' organizational position paper of similar purport to the ACOEM Mold Statement, which was published in the *Journal of Allergy and Clinical Immunology* (*JACI*).[109] The allergists' position paper conveyed similar conclusions to the ACOEM Mold Statement and generated immediate, substantial criticism of its "defense" bias and for the failure of the journal to disclose the authors' conflicts of interest.[110,111] The outcry led one of the allergists' paper's authors to retroactively request the journal to rescind his name as an author of the publication after he discovered that his section had been re-written by Dr. Saxon and published without his knowledge.[112] *JACI* subsequently published a "correction" divulging the authors' own disclosures of conflicts of interest.[113] The ACOEM Mold Statement authors also wrote a letter to the editor of *JACI* defending their stance, and claiming that the three authors "all have been retained by both plaintiffs and defendants."[114]

The Impact of the ACOEM Mold Statement

The ACOEM Mold Statement jeopardizes the "health and safety of workers, workplaces, and environments" that ACOEM purports to champion.[2] The Statement has successfully delivered the message that indoor mold arising in water-damaged buildings is, at most, a trivial allergen by which only a minority of susceptible individuals could be affected. It casts the "so-called 'toxic mold,'" i.e., mold as a potentially toxicological agent, as a "weak and unproven" theory, thus unworthy of consideration for further research or public health control measures.[88,108]

By minimizing the seriousness of "mold" health effects, the ACOEM Mold Statement provides misguided information for physicians who are called upon to evaluate complaints or concerns in an individual or groups regarding building water intrusion (i.e., building dampness), indoor mold contamination or problem (sick) buildings. Through its dismissal of any potential toxicological mechanism or etiology, the Mold Statement implies that only allergen-induced conditions such as allergic rhinitis and asthma are valid mold-related complaints. In contrast with many published studies, the Mold Statement assumes that only a small percentage of individuals could be "sensitized" to mold (as determined by non-specific allergen skin tests), implying that only these "susceptible" individuals—as opposed to all occupants of a water-damaged, mold-contaminated building—may be at risk of adverse effects.[3,8–10,23,26–30,33] The Mold Statement provides false reassurance to physicians to simply treat individuals with building-related symptoms symptomatically (such as with allergy medications), rather than recommending or prescribing the more definitive (but controversial) measure of relocating the patient(s)—and coworkers or other occupants—from a mold-contaminated, water-impacted workplace, school, or residence.

The dismissive content and tone of the ACOEM Mold Statement may similarly encourage building owners and managers to ignore, trivialize, or otherwise fight occupant complaints of water intrusion, mold contamination, and associated building-related symptoms. According to the ACOEM Mold Statement, remediation of surface mold contamination should be undertaken not because of (toxicological) health risks to occupants, but rather because mold physically "destroys the building materials on which it grows, mold growth is unsightly and may produce offensive odors."[3] This spurious rationalization has laid the foundation for insurers and building owners to either refuse to remediate mold—a potentially expensive process when done correctly—or for mold remediators and indoor air consultants to recommend cleaning up only visible surface mold growth in occupied spaces while ignoring hidden mold or non-visible mold spore contamination in other areas of the building and ventilation system.

The chief beneficiaries of the ACOEM Mold Statement have been the real estate and construction industries, and property and business liability insurance companies. In line with its authors' mission and well-established expert testimony records, the Mold Statement has provided defense attorneys with the "peer reviewed scientific evidence" they rely upon in their efforts to exculpate their clients in insurance and personal injury claims involving indoor mold contamination. Defense attorneys have interpreted the Mold Statement much in line with the Statement's authors' press releases, for example, challenging expert witness for the plaintiff to refute assertions such as, "Doctor, isn't it true that the American College of Occupational and Environmental Medicine concluded that there is no scientific evidence that mold causes any serious health effects?"[115] Defense expert witnesses—including OEM physicians—have come to rely upon the ACOEM Mold Statement as a definitive, unbiased, and even "seminal" research document.[116]

The Truth Exposed: ACOEM's Reaction

The 2007 *Wall Street Journal* article, "Experts Wear Two Hats," focused on exposing the conflict of interest of the Mold Statement's authors "who regularly are paid experts for the defense side in mold litigation" with the result that the Statement became a "defense argument" that "has become a key defense tool wielded by builders, landlords and insurers in litigation."[42] The *Wall Street Journal* article explained how the "dual roles" of the Mold Statement's authors "show how conflicts of interest can color debate on emerging health issues and influence litigation related to it."[42]

ACOEM's president, Tee Guidotti, MD, MPH, responded to the *Wall Street Journal* by defending the Mold Statement's development as a "formal and accountable process by which the statement was prepared and finally approved," stating that "the lead author who was chosen (a retired Assistant Surgeon General) had no conflict of interest at the time."[42] Dr. Guidotti asserted that a conflict of interest disclosure was unnecessary "because the paper represents the consensus of its membership and is a statement from the society, not the individual authors."[42]

Dr. Guidotti also responded to the *Wall Street Journal* article by issuing a press release, "Ambush above the Fold," to the ACOEM's membership and the media.[117] A corresponding letter was submitted to (but not published by) the editor of the *Wall Street Journal*, co-signed by ACOEM's then president-elect, Dr. McLellan, as well as Dr. Borak. ACOEM's leadership adamantly denied any wrongdoing or organizational impropriety, either ethical or scientific. The letter alleged that the *Wall Street Journal* article was "highly misleading, with key facts misreported and a pervasive insinuation of conflict of interest."[117]

The ACOEM Ambush letter asserted that the organization's members were offered an opportunity to participate through a "notice" that was published in the ACOEM member newsletter in Fall 2002, as well as through notice of a "session" that was to be held at ACOEM's annual conference in May 2003.[117] ACOEM's internal documents,[69,83,86,99–101] however, show that the Mold Position Paper/Statement was already in its final form for release by the organization, and unaltered in form for publication in *JOEM*, at the times these member "participation" events were alleged to have occurred.

The Ambush letter further disclaimed any misconduct by dismissing the possibility that the adverse health effects of mold could be exerted on a toxicological basis, prognosticating that the scientific evidence set forth by the ACOEM Mold Statement "seems unlikely to shift with new findings."[117] The basis of this exculpation was the 2004 Institute of Medicine's (IOM) publication, *Damp Indoor Spaces*[118] and the aforementioned, highly criticized allergists' position paper co-authored by Dr. Saxon.[109] The IOM chapter, "Human health effects associated with damp indoor environments," however, actually concludes that "There is sufficient evidence of an association between exposure to a damp indoor environment and upper respiratory tract symptoms," and "There is sufficient evidence of an association between the presence of 'mold' (otherwise unspecified) in a damp indoor environment and upper respiratory tract symptoms—as well as similar associations for cough, wheezing, and other (presumed) lower respiratory symptoms."[119] These associations are not contained or even implied in the ACOEM Mold Statement.[3]

Righting the Wrongs: Will ACOEM Do the Right Thing?

According to some of its critics, the ACOEM is a professional association that is unduly influenced by industry interests.[119,120] The ACOEM Mold Statement provides an illustrative example of how industry money and influence pervade occupational and environmental medicine.

The history of the Mold Statement's creation, development and distribution points to a serious problem within ACOEM, with implications that go well beyond this particular occupational and environmental health issue. Through its perhaps well intended but ultimately deeply flawed process of producing an "evidence-based" guideline on mold, ACOEM has undermined its organizational credibility. "Harm to the patient" has been the inevitable outcome as ACOEM recommendations have been put into practice in the courtroom, workplace, home, and in the physician's office.[1,2]

ACOEM members should be disappointed and concerned, if not alarmed, about the process the ACOEM deployed in developing and implementing its Mold Statement. Little substantive reform will happen, however, unless at least some of the membership takes decisive corrective action. Those businesses, professional and trade organizations, institutions and government agencies which have relied upon the ACOEM Mold Statement to guide or justify their policies and practices should similarly demand accountability and meaningful reform.

RECOMMENDATIONS

ACOEM as an organization should not continue to defend its Mold Statement. Instead, it should acknowledge its wrongdoings and retract both the original Statement[88] and the JOEM publication of it,[3] as well as its "Ambush" response.[117] If ACOEM is to salvage any respect as an organization, it must create an open process within its membership to address mold and other controversial issues in a much more balanced manner, consistent with the stated ACOEM mission and generally accepted methods for evidence-based guidelines and peer review.[5–7,47–49]

The events that led to the Mold Statement's publication justify the need for a review and overhaul of ACOEM management and policies. Important questions must be asked from within and outside the organization. As an organization that represents the majority of OEM physicians, ACOEM must find leadership and management that embraces a willingness to accept meaningful, substantive reform to deal with the serious ethical and professional problems of OEM. The following measures would begin the necessary steps toward achieving such reform:

1. The ACOEM should develop a formal process for **Declarations of Conflicts of Interest** for all its members and staff. These Declarations should also be adopted by *JOEM* and its editorial and publications staffs. ACOEM should establish a course of conduct for when potential conflicts of interest influence the practice of OEM, and enforce it accordingly. An expedient but reliable method to verify the veracity and completeness of such declarations, particularly as they relate to disclosure of expert witness work in related litigation, must be developed and consistently implemented.
2. *JOEM* needs to develop a more rigorous system of **peer review**. Management and editorial staff should not make exceptions from the formal review process.
3. The ACOEM should develop a formal **Transparency Policy** to ensure that members are fully informed of all activities and non-members can be informed without impediment. The minutes of various committee meetings should be placed on the website and made available to members. All correspondence between officers, staff, and committee members should be put into electronic format and copied to the website.
4. The **ACOEM Code of Conduct** must be extended to include many topics ignored by the current document. The ACOEM membership should develop a Code that is enforceable, and one that would not allow a recurrence of the problems that have characterized the development of the ACOEM Mold Statement.

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