April 6, 2006

Mrs. Sharon Noonan Kramer
2031 Arborwood Place
Escondido, California 92029
760-822-8026
Snk1955@aol.com

American College of Occupational and Environmental Medicine
25 Northwest Point Blvd.
Suite 700
Elk Grove Village, Illinois, 60007-1030

Mr. Barry Eisenberg, MA Executive Director
Ms. Marianne Dreger, Communications Director
Board of Directors,
Cheryl S. Barbanel, MD, MBA, MPH, FACOEM
Tee L. Guidotti, MD, MPH, FACOEM
Robert K. McLellan, MD, MPH, FACOEM
Kathryn L. Mueller, MD, MPH, FACOEM
Timothy J. Key, MD, MPH, FACOEM
A. Nelson Avery, MD, FACOEM
Julia U. Halberg, MD, MPH, MS, FACOEM
Natalie P. Hartenbaum, MD, MPH, FACOEM
Mark J. Upfal, MD, MPH, FACOEM
T. Warner Hudson III, MD, FACOEM
Robert R. Orford, MD, MS, MPH, FACOEM
Mark A. Roberts, MD, PHD, FACOEM
Gregg M. Stave, MD, JD, MPH, FACOEM
Thomas B. Faulkner, MD, MHA, FACOEM
Pamela A. Hymel, MD, MPH, FACOEM
Stephen F. Wintermeyer, MD, MPH, FACOEM
Mary Yarbrough, MD, MPH, FACOEM

Dear Mr. Eisenberg, Ms. Dreger and Members of the ACOEM Board,

I am requesting permission for an associate and me to come speak before your Board Members at the upcoming May 6th Board Meeting in Southern California. The subject we would like to discuss is the ACOEM's retraction as a Position Statement representative of 7000 physicians, the Adverse Human Health Effects Associated with Molds in the Indoor Environment, Accepted October 27, 2002.

The document has been improperly used to stifle medical understanding and as a legal weapon against the ill, who find themselves caught in the web of the "Toxic Mold Issue". The paper is not based on legitimate scientific evidence. Nor are its findings significant and conclusive enough to be provided the elevated stature of a Position Statement of an influential medical association.

As an example, the ACOEM Mold Statement is frequently cited in litigation as an authoritative reference indicating serious human illness from mold and mycotoxin exposure within an indoor environment is not plausible. Yet, not a single one of the 83 references listed for this document come to this conclusion.

The amount of devastation and misery caused to thousands of innocent families by this improperly written, improperly peer reviewed and improperly Board endorsed paper is immeasurable. I am attaching a document, via email to Mr. Eisenberg and Ms. Dreger that is indicative of much research by numerous individuals, physicians and researchers regarding the ACOEM Position Statement. I am certain Mr. Eisenberg and Ms. Dreger have the capability to forward this letter and the attached emails to the Members of the Board.

The attached document is entitled "ACOEM Exposed - A Case Study in Sham Peer Review and Conflicts of Interest in Modern Medicine" aka – "The Rats That are Saving the Insurance Industry Billions". I extend my apologies for the severity of the very pointed and direct document. But the damage done to thousands by the ACOEM's reckless endorsement of this paper has also been very severe and direct. We have no interest in looking at the past. We have much interest at looking at the future. This document needs to be retracted as a Position Statement of the ACOEM for the betterment of the citizens of the US.

I may be reached at the above referenced contact information. We look forward to presenting information to the Board Members in the hopes that we may all work together to assure people, who have been made ill from mold/mycotoxin exposure, are able to obtain proper medical treatment.

Sincerely,

Mrs. Sharon Noonan Kramer

Attachment via email:

ACOEM Exposed, Parts 3 thru 9
Conflict of Interest Statement

Subj: **RE: Request to Present before the Board of the ACOEM, May 6th Email 1 of 2**
Date: 4/11/2006 10:52:19 AM Pacific Standard Time
From: beisenberg@acoem.org
To: SNK1955@aol.com
CC: mdreger@ACOEM.org, barbanel@bu.edu, eohtlg@gwumc.edu, jborak@jborak.com

Dear Ms. Kramer,

We have received all of your materials. As I relayed to you over the phone, I regret that the agenda for our May meeting (which is less than a full day) has been set for some time and that we cannot accommodate your request.

Best regards,

Barry S. Eisenberg
ACOEM Executive Director

-----Original Message-----
From: SNK1955@aol.com [mailto:SNK1955@aol.com]
Sent: Thursday, April 06, 2006 10:19 AM
To: Barry Eisenberg
Cc: Marianne Dreger
Subject: Request to Present before the Board of the ACOEM, May 6th Email 1 of 2

Dear Mr. Eisenberg and Ms. Dreger,

Attached is a letter and noted references regarding the ACOEM Mold Statement. I am requesting permission to come and speak before your Board.

I believe the attachments may be too large to send in a single email. I will email the remainder in a second email. Please let me know the Board Members' response to this request as soon as possible so we may get our presenting material in concise order.

Sincerely,
Sharon Noonan Kramer

I will also cut and paste the letter here:

April 6, 2006

Mrs. Sharon Noonan Kramer
2031 Arborwood Place
Escondido, California 92029
760-822-8026
Snk1955@aol.com

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Sincerely,

Mrs. Sharon Noonan Kramer

Attachment via email:

ACOEM Exposed, Parts 3 thru 9
Conflict of Interest Statement

Subj: **Re: Request to Present before the Board of the ACOEM, May 6th Email 1 of 2**
Date: 4/11/2006 11:26:11 AM Pacific Standard Time
From: SNK 1955
To: beisenberg@acoem.org
CC: mdreger@ACOEM.org, barbanel@bu.edu, eohtlg@gwumc.edu, jborak@jborak.com, AESPIELS, richard@langermanlaw.com, KahnLawOffice, gkvpc@earthlink.net, hmm@lrolaw.com, scottw@smartlegaladvice.com, jmiller@millerlawinc.com, Coopit2me@cs.com, witzer@witzerlaw.com

Dear Mr. Eisenberg,

Thank you for your prompt reply. I am disappointed in your answer. I believe I could make "my case" for the necessity of an expediant retraction of your mold position statement in less than 15 minutes time.

With the understanding of this short time period required, I am asking again. May I come present before your Board of Directors? Have you forwarded to the board members my request and accompanying documents? If so, I am surprised at your reply. I would be inclined to believe the members of the Board of Directors of the American College of Occupational and Environmental Medicine would understand how many lives continue to be damaged while this inaccurate position statement is allowed to stand by your nationally influential medical association.

Will you please reconsider your response?

Sincerely,

Mrs. Sharon Noonan Kramer

Subj: **RE: Request to Present before the Board of the ACOEM, May 6th Email 1 of 2**
Date: 4/17/2006 12:20:11 PM Pacific Standard Time
From: beisenberg@acoem.org
To: SNK1955@aol.com
CC: mdreger@ACOEM.org, barbanel@bu.edu

Per my previous note, we are not able to comply with your request at this upcoming meeting. I have forwarded all of the materials you've provided to the committee that will be reviewing the statement in question, as part of our regular review process.

-----Original Message-----
From: SNK1955@aol.com [mailto:SNK1955@aol.com]
Sent: Tuesday, April 11, 2006 1:26 PM
To: Barry Eisenberg
Cc: Marianne Dreger; barbanel@bu.edu; eohtlg@gwumc.edu; jborak@jborak.com; AESPIELS@aol.com; richard@langermanlaw.com; KahnLawOffice@aol.com; gkvpc@earthlink.net; hmm@lrolaw.com; scottw@smartlegaladvice.com; jmiller@millerlawinc.com; Coopit2me@cs.com; witzer@witzerlaw.com
Subject: Re: Request to Present before the Board of the ACOEM, May 6th Email 1 of 2

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Thank you for your prompt reply. I am disappointed in your answer. I believe I could make "my case" for the necessity of an expediant retraction of your mold position statement in less than 15 minutes time.

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Will you please reconsider your response?

Sincerely,

Mrs. Sharon Noonan Kramer

Subj: **Re: Request to Present before the Board of the ACOEM, May 6th Email 1 of 2**
Date: 4/17/2006 4:23:55 PM Pacific Standard Time
From: SNK 1955
To: beisenberg@acoem.org
CC: mdreger@ACOEM.org, barbanel@bu.edu

In a message dated 4/17/2006 12:20:11 PM Pacific Standard Time, beisenberg@acoem.org writes:

> Per my previous note, we are not able to comply with your request at this upcoming meeting. I have forwarded all of the materials you've provided to the committee that will be reviewing the statement in question, as part of our regular review process.

Thank you for your reply, Mr. Eisenberg. Did you also share the information with the board members to whom I had addressed the email letter with all the attachments? Are you aware how many people are currently having their workers' comp claims and other insurance claims denied while that document is allowed to stand as a position of the ACOEM? Would you be interested to know? Does the ACOEM board realize the devastation that this document, which is not based on science, is causing to the lives of many?

Sharon Kramer

Subj: **WSJ on the NEJM**
Date: 5/15/2006 12:10:20 P.M. Pacific Standard Time
From: SNK 1955
To: beisenberg@acoem.org
CC: jborak@jborak.com

Dear Mr. Eisenberg,

I wanted you to see how medical associations negatively impact people's health and physicians' treatment protocol when misinformation is promoted.

Did you know that the folly that one can determine absence of human illnesses from mycotoxin exposure - simply from some math applied to a rodent study - was found to be inadmissable "science" in the courts about two weeks ago?

This is the study that got thrown out as junk science through a Kelly Frye hearing:

Robbins CA, Swenson LJ, Hardin BD. Risk from inhaled mycotoxins in indoor office and residential environments. Int J Toxicol 2004;23: 3-10.

It is the same premise used by the same ACOEM Mold Statement/Veritox Inc, authors that is the cornerstone finding of the ACOEM Mold Statement. It is not based on a sound scientific premise.

So now, your mold statement's 83 reference do not conclude human illness is not plausible. And even the one rat study this whole charade is based upon has thrown out as junk science.

When are you going to get rid of that position statement? It is still to this day being used as weapon against the ill. Everyday that atrocity is knowingly allowed to stand as a position of your esteemed association, is another day that innocent people are being hurt.

When is that committee that you gave my doc to going to look at this? C'mon! This is wrong and it is hurting people.

Thanks,
Sharon Kramer

Bitter Pill
How the New England Journal
Missed Warning Signs on Vioxx

Medical Weekly Waited Years
To Report Flaws in Article
That Praised Pain Drug

Merck Seen as 'Punching Bag'

By DAVID ARMSTRONG
May 15, 2006; Page A1

BOSTON -- In August 2001, a Seattle pharmacist called a radio show on which Jeffrey Drazen, the top editor of the New England Journal of Medicine, was appearing. On the air, the pharmacist, Jennifer Hrachovec, begged Dr. Drazen to update an article in the journal that touted the benefits of the painkiller Vioxx while playing down its heart risks.

Dr. Hrachovec had been reviewing data on a Food and Drug Administration Web site indicating that patients in a Vioxx clinical trial had suffered more heart attacks than the journal article about the trial reported. "It bothers me there is more data from the trial than has ever been published and the New England Journal still hasn't published an editorial or any kind of update," she said. "My concern is that doctors are still using this and exposing their patients to higher risks of heart problems and they just don't even know that that's the case."

ON RECORD

Pharmacist Jennifer Hrachovec challenged Jeffrey Drazen, editor of the New England Journal of Medicine, about the Vigor study in a call to a Seattle radio show Aug. 14, 2001. Below, excerpts.

Hrachovec: "With this study in particular, it bothers me that there is more data from the trial than has ever been published and the New England Journal still hasn't published an editorial or any kind of update to let readers and clinicians using this drug and giving it to patients who they think will benefit from a better side-effect profile. My concern is that doctors are still using this and exposing their patients to higher risks of heart problems and they just don't even know that that's the case."

Drazen: "… We can't be in the business of policing every bit of data that we put out. We think that that's the role of people who know the field. And when they think that the field has advanced to the point where something which was true at the time it came out may no longer be true … having brought that evidence to our attention in the form of a manuscript or a letter, we can judge whether there's enough new information and put it out if we believe that the re-analysis is correct."

* * *

Dr. Drazen was dismissive. "We can't be in the business of policing every bit of data we put out," he told Dr. Hrachovec.

Three years later, Merck & Co. pulled Vioxx from the market, citing higher risk of heart attacks and strokes in some patients. An estimated 20 million Americans took Vioxx, and more than 11,500 lawsuits have been filed against Merck alleging death and other damage from the drug.

While Merck has taken the brunt of criticism in the affair, the New England Journal's role in the Vioxx debacle has received little attention. The journal is the most-cited medical publication in the world, and its November 2000 article on Vioxx was a major marketing tool for Merck.

Last December, the journal repudiated the Vioxx article in an "expression of concern," but only after the drug had been recalled and more than five years after the article appeared. Had the journal acted before the recall, its authoritative voice almost certainly would have damped the Vioxx boom.

Dr. Hrachovec's radio-show call was one of several early warnings about the article's flaws including its failure to mention the extra heart attacks. She and a colleague also submitted a letter to the New England Journal, which was rejected for publication. The Journal of the American Medical Association reported on Vioxx's cardiac risk in an August 2001 article. In April 2002 the FDA added a caution on Vioxx's label that warned of cardiovascular risks.

Internal emails show the New England Journal's expression of concern was timed to divert attention from a deposition in which Executive Editor Gregory Curfman made potentially damaging admissions about the journal's handling of the Vioxx study. In the deposition, part of the Vioxx litigation, Dr. Curfman

Listen to the full exchange on the Web site of KUOW, Puget Sound Public Radio. (Hrachovec's call begins at about minute 44:30.)

acknowledged that lax editing might have helped the authors make misleading claims in the article. He said the journal sold more than 900,000 reprints of the article, bringing in at least $697,000 in revenue. Merck says it bought most of the reprints.

Stanford University medical professor Gurkirpal Singh, a rheumatologist who was among the first researchers to raise questions about Vioxx's cardiac risks, says the affair shows that journals need to be more vigilant about problems in what they publish. While praising the New England Journal for eventually taking action, he says "They absolutely should have corrected in 2001." Had it acted earlier, he says, sales of Vioxx "would have been killed."


Jeff Drazen

Dr. Drazen, the editor, says in an interview that the authors of the article, who included Merck employees and consultants, are the ones at fault. "This was an episode where it was clear people had taken data and not reported it fully," he says in an interview. He adds: "I have now learned we need to be much more careful."

The questions about the New England Journal come as the flaws of leading medical journals are receiving greater attention. Many articles lend an academic imprimatur to messages hatched by drug companies as part of publicity campaigns. Sometimes they fail to disclose authors' financial ties to companies or the involvement of company-hired ghostwriters.

Started in 1812, the New England Journal has 200,000 subscribers and is considered must reading for doctors who want to stay current. Its selectivity and editing practices are feared and respected. The weekly rejected 93% of the 3,586 manuscripts it received last year. Accepted papers typically undergo months of editing, including "peer review" by a secret panel of experts and scrutiny by staff editors, many of whom are doctors.

The journal won't disclose its revenue, but its owner, the nonprofit Massachusetts Medical Society, listed $88 million in total publishing revenue for the year ending May 31, 2005.

In May 2000, a team including Merck employees submitted to the journal an article about Vioxx, a painkiller approved the previous year by the FDA. The article presented the results of a human trial called Vigor that showed Vioxx posed a lower risk of stomach ulcers and bleeding than naproxen, one of a class of older pain relievers long associated with such complications.

The article said 0.4% of the Vioxx patients had suffered heart attacks, compared to 0.1% for the naproxen group. It offered several reasons why that wasn't as worrisome as it seemed, including a theory that the difference stemmed from naproxen's supposed protective effect on the heart. The New England Journal published the article on Nov. 23, 2000, and the occasion was celebrated by Merck in a press release.

Merck submitted data from the Vigor study to the FDA because it wanted to add the favorable information about stomach side effects to Vioxx's label. But the data it gave to the

agency, posted on the FDA's Web site in February 2001, did not square with the data in the New England Journal article. Merck said Vioxx takers had 20 heart attacks, which translated into 0.5% of the total, not 0.4% as the article said. The higher figure undermined an assertion in the article that only those who were already at high risk of a heart attack showed an increased risk after taking Vioxx. That's because the extra heart attacks were all in the low-risk group.


Gregory Curfman

The FDA Web site said Merck submitted the revised heart-attack data in October 2000, before the publication of the article. Dr. Curfman, the journal's executive editor and a cardiologist, acknowledges that he reviewed the FDA Web site posting around September 2001. The journal says the editors believed the FDA had posted late data from the trial that had not been analyzed in time to be included in the article's manuscript.

In June 2001, Dr. Hrachovec in Seattle and a doctor reviewing the drug for a Seattle health insurer wrote to the New England Journal, noting the FDA posting. They warned the journal that the Vioxx results it printed were incomplete and made the drug appear safer than it was. The journal refused to publish the letter, saying space was limited. It acknowledges that during this period it never asked Merck, the FDA or the article's authors about the discrepancy, believing that it was the responsibility of the authors to report new data.

Merck says the extra heart attacks, three in total, happened after a predetermined cutoff date for recording events in the trial. Merck says the article was properly done and doesn't require a correction. That puts the company at odds both with critics of the New England Journal and the journal's editors, who now are calling for a correction while defending their failure to ask for one earlier.

Dr. Drazen says journal editors are "just the middleman in picking what goes out there" and "when there are problems the onus lies with" authors to sound the alert. "If you ask me, it is none of our concern about whether [Vioxx] is a cardiovascular risk in the patients that are on trial," he says. The concern was making sure what was published was correct, he says, and "people could have set the record straight."

Early Criticism

Besides the article's possible understating of the heart-attack numbers, its theory that naproxen had a protective effect on the heart also came in for early criticism. "This hypothesis is not supported by any prospective placebo-controlled trials with naproxen," an FDA official wrote in a memo also published on the agency's Web site in February 2001. In September of that year, the FDA sent a public warning letter to Merck, criticizing the drug maker for promoting the naproxen idea without explaining the lack of evidence for it.

Curt Furberg, a Wake Forest University public health professor, says the New England Journal should have challenged the authors on the naproxen theory during the article's editing. "Here we have an editorial board attacking the company when they conducted an inferior review of the article," says Dr. Furberg, who is also an adviser to the FDA on drug safety. "The sad thing is patients have suffered as a result."

In September 2004, Merck withdrew Vioxx, citing the results of a new study that showed the drug raised the risk of heart attack and stroke for those using it at least 18 months.

Both sides in federal litigation over Vioxx conducted a deposition in November 2005 of Dr. Curfman, the executive editor. Plaintiffs hoped to bolster their allegation that Merck's marketing of Vioxx was deceptive.

Although the New England Journal wasn't on trial for anything, the deposition produced a number of damaging admissions by Dr. Curfman. He acknowledged that neither the peer reviewers nor journal editors challenged the authors' heart-attack theory about naproxen as it was presented in the article. "Yeah, we signed off on this," he said, according to a transcript of his testimony. "And I have many times had second thoughts about having done that."

Dr. Curfman also disclosed that the journal sold 929,400 reprints of the article -- more than one for every doctor in the country. Merck says it bought most of them. The reprints brought in between $697,000 and $836,000, using per-copy price estimates provided by the journal. If the New England Journal had questioned the article's findings earlier, the impact of the reprints likely would have been blunted because any corrections or official statements on a study must be included with the reprint. Merck says that after February 2001 it included a letter with the reprints telling doctors about the additional information submitted to the FDA.

FURTHER READING

Read the "Expression of Concern" published by the New England Journal of Medicine Dec. 29, 2005, about the Vigor trial.

The journal's editors grew alarmed about the potential for bad publicity over the videotaped deposition, fearing it could be leaked or played in a federal courtroom session on Dec. 8, according to internal emails and an interview with Drs. Curfman and Drazen. After five years of silence on the article, the editors started racing to prepare an "expression of concern" about it.

The New England Journal says there was a good reason for the sudden decision to rebuke the article's authors. It says Dr. Curfman was surprised to discover from a July 5, 2000, memo he was shown during the deposition that two of the authors who worked for Merck knew of the extra three Vioxx heart attacks well in advance of the November article.

However, that shouldn't have been news to Dr. Curfman since he says he read the FDA documents in 2001 showing Merck submitted information about the three events to the FDA more than a month before the article's publication.

Dr. Curfman says there was nothing in the FDA data to indicate the authors knew of the additional heart attacks. Also, he says, "The data were in the hands of a regulatory agency and we felt it was now up to them to take appropriate action."

Dr. Drazen also received a clear description of the timing in a July 2005 email from Eric Topol, then a Cleveland Clinic cardiologist, who had criticized Merck and Vioxx. Dr. Topol, who had been contacted by a National Public Radio reporter asking about the November 2000 New England Journal article, told Dr. Drazen that the article's authors "clearly had ample time to correct the data when one compares the FDA Submission dates and the galley proofs (as relayed to me by Greg Curfman)."

On the night of Dec. 7, Edward W. Campion, a senior New England Journal editor, sent a note to his staff explaining why the statement had to be released the next day. The explanation didn't involve any late-breaking information obtained by Dr. Curfman. "The reason is that tomorrow's testimony in the Vioxx trial may involve part of a deposition that Greg gave," Dr. Campion wrote. "It will be essential to notify press" about the statement "and make it prominent" on the journal's Web site, he added.

A public-relations specialist who has advised the journal since 2002 predicted the rebuke would divert attention to Merck and induce the media to ignore the New England Journal of Medicine's own role in aiding Vioxx sales.

"I believe that given what a public punching bag Merck has become, there is more than enough information and more than enough context in the statement to drive the media away from NEJM and toward the authors, Merck and plaintiff attorneys," wrote Edward Cafasso, a Boston-based public relations consultant, in a late-night email to journal staffers hours before the expression was released. Mr. Cafasso later added, "In my view, this disclosure may very well be seen as the final straw for Merck on the Vioxx matter."

On Trial

The New England Journal of Medicine and Vioxx

- **May 1999:** Vioxx approved for sale.
- **November 2000:** Journal publishes article saying Vioxx causes fewer stomach problems than older drug, calls heart risk "not significant" for most patients.
- **February 2001:** Food and Drug Administration Web site cites Vioxx heart attacks not mentioned in the article.
- **June 2001:** Journal rejects letter detailing missing Vioxx heart data.
- **September 2004:** Vioxx taken off market.
- **December 2005:** Journal issues "expression of concern," says it was misled by authors of article.

Mr. Cafasso's prediction initially proved correct. The Texas court ended up delaying the release of Dr. Curfman's deposition, and the expression of concern released Dec. 8 received wide media attention.

A Dec. 12 list of talking points circulated among journal editors advised them to deny that the journal's statement was connected to the federal trial. If asked about the release date, editors were advised to say, "We made this information public as soon as we could, without regard to the trial." It isn't clear who wrote the memo.

The editors now concede the timing was connected to the planned release of Dr. Curfman's deposition at the trial. "We wanted a coherent statement to go out before that," says Dr. Curfman. However, they maintain that the statement was motivated by Dr. Curfman's discovery of new information about the Merck authors' advance knowledge of the three heart attacks.

'We Were Hoodwinked'

Dr. Drazen says one discovery he made after the journal's statement was published shows how the authors deceived the journal. He found that the Vigor study of Vioxx continued to tally stomach-related events for several weeks after it stopped tallying heart-related events. "We were hoodwinked," he says. Merck says these cutoff dates were determined ahead of time and weren't designed to reduce the number of heart events included in the totals.

Perhaps the most sensational allegation in the journal's expression of concern was that the authors of the November 2000 article deleted heart-related safety data from a draft just two

days before submitting it to the journal for publication. The journal said it was able to detect this by examining a computer disk submitted with the manuscript.

The statement was ambiguous about what data the authors deleted, hinting that serious scientific misconduct was involved. "Taken together, these inaccuracies and deletions call into question the integrity of the data," the editors wrote.

In reality, the last-minute changes to the manuscript were less significant. One of the "deleted" items was a blank table that never had any data in it in article manuscripts. Also deleted was the number of heart attacks suffered by Vioxx users in the trial -- 17. However, in place of the number the authors inserted the percentage of patients who suffered heart attacks. Using that percentage (0.4%) and the total number of Vioxx users given in the article (4,047), any reader could roughly calculate the heart-attack number.

Dr. Curfman says it would have been easier on readers to give the exact number and admits "both the authors and the editors slipped up" in not including it.

Many news organizations, including The Wall Street Journal, misunderstood the ambiguous language and incorrectly reported that the deleted data were the extra three heart attacks -- which, if true, would have reflected badly on Merck. The New England Journal says it didn't attempt to have these mistakes corrected. Dr. Curfman says the language about the deletions is "very precise and it is correct."

The day after the expression of concern, Mr. Cafasso emailed colleagues: "The story is playing out exceptionally well."

Write to David Armstrong at david.armstrong@wsj.com

Subj: **Kelly Ruling, Sacramento Re: Veritox & ACOEM Mold Statement Authors.**
Date: 6/15/2006 1:26:39 P.M. Pacific Standard Time
From: SNK 1955
To: beisenberg@acoem.org

Dear Mr. Eisenberg,

As promised, here is the information regarding a very significant court ruling in California. As forewarned, it is a very blunt and direct document. It includes writings from Harris Martin Publishing and Center for Science in the Public Interest.

The core document that I have voiced concern about regarding the harm it (and your ACOEM Mold Statement) has done to the lives of many, has now been found by the courts to be not of sound scientific principle to deduce existence or absence of human illness.

If you could retract the ACOEM Mold Position Statement as soon as possible, it would be greatly appreciated. The sooner that erroneous paper goes, the more lives that will not be damaged by the indication that the physicians of ACOEM support this position paper. The sooner physicians will be able to become better educated to the matter.

If you would like to view the judge's actual trial proceedings or the deposition of the defense experts, please let me know. I have many of the documents from this case....and many others.

Sincerely,
Sharon Kramer
760-822-8206

June 15, 2006

Please forward the following information to all interested parties. Ie. Physicians, Researchers, Attorneys, Mold Victims, Health Advocates, Building Stakeholders and Regulatory Bodies.

Are you aware of the Kelly Order, April 14, 2006, Sacramento, CA? It is an issue changing significant finding that will remove 'road blocks' and allow the medical understanding of mold induced illnesses to more easily go forward.

The Kelly Ruling is a huge blow to those who are most concerned about perpetuating the litigation defense myth of serious mold illnesses do not occur from exposure within an indoor environment. The Ruling discredits the entire foundation of All the medical associations, government documents, etc, that illness from inhaling mycotoxins indoors is "not plausible, improbable and junk science". One could say those, who are more concerned of financial liability than they are of the lives and safety of others, just got a "dose" of their own medicine at a "level of which we see effects".

The significance of this Kelly Ruling as it pertains to mold litigation is:

The defense argument of "not plausible, improbable and junk science" has now been determined by the courts to be "not plausible, improbable and junk science".

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Case # 02AS04291, James Harold and D. Lee Harold, Plaintiffs vs. California Casualty Insurance Company and Westmont Construction, Inc., Defendants

Honorable Michael P. Kenny, Judge of the Superior Court of California, County of Sacramento

The Plaintiffs were represented by Peter Alfert, Attorney at Law; Michael J. Cochrane, Attorney at Law, and Karen Kahn, Attorney at Law.

The Defendant, California Casualty Insurance Company, was represented by Stephen M. Hayes, Attorney at Law, and Robert S. McLay, Attorney at Law.

The Defendant, Westmont Construction Company, was represented by Ronald E. Enabnit, Attorney at Law.

Jury award to plaintiffs: $2.3 Million.

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Subject paper deemed not acceptable by Kelly Ruling in the case, April 14, 2006

Title: Risk from inhaled mycotoxins in indoor office and residential environments. Int J Toxicol 2004; 23: 3-10.
Robbins CA, Swenson LJ, Hardin BD (Principals of litigation defense support corp. Veritox, Inc and formerly named GlobalTox, Inc.)

Slang: Veritox, 2004

The above is the review piece that was found not to be based upon sound science and therefore not to be presented in the court before a jury. The judge found it to be a "huge leap", for PhD's to take rodent studies, apply a little math and then write a review that all human illness is not plausible from mycotoxin inhalation within an indoor environment. Dr. Robbins of Veritox, Inc., could not cite anyone else's research or review paper that made the same conclusion. The reason for this is because there are not any.

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Mold Columns
Harris Martin Publishing
May 25, 2006

....Defendants called Andrew Saxon, M.D., of UCLA Medical School; and Coreen A. Robbins, MHS, Ph.D., CIH of Veritox in Redmond, Wash.

Robbins countered plaintiffs'' experts' opinions on mold hazards and the remediation procedures and opined that the couple could have moved back into the house after Westmont's repair work was completed.

Judge Kenney held a *Kelly-Frye* hearing before trial and limited Robbins's testimony by precluding any reference to animal studies of mold hazards.

Reviewing Robbins' deposition testimony, Judge Kenney concluded that the basis for her testimony on mycotoxins and human exposure was a literature review, which he found insufficient.

'Also, when I reviewed the DHS report from April of 2005, DHS, Department of Health Services was talking about the fact that they were unable to establish personal exposure levels at this point in time based on a lack of sufficient information, and yet Dr. Robbins is asking to take an even greater step and go beyond establishing, for example, a personal exposure level and jump to modeling, which is far more tenuous and far more unreliable even in establishing something that is as hard as a personal exposure level. So those are the difficulties I'm having with Dr. Robbins' testimony,' Judge Kenney said.

The judge said that he is familiar with the use of animal studies and derivative models for humans and that such models are commonly accepted in the scientific community, but he said he is not sure such models for mycotoxin exposure would pass a *Kelly-Frye* test for admissibility.

'My fundamental problem is in looking at it from a *Kelly Frye* standpoint I just didn't see kind of acceptance in the scientific community with regard to what she had done that would allow it to be sort of presented as such,' Judge Kenney said.

'Modeling has severe limitations, and one of the difficulties I was having here was this reliance upon animal studies to jump to a modeling conclusion generally with — again, I'm speaking from my own experience because there is nothing here in this transcript — generally one will use the data that one can receive either from animal exposure studies or other information to then input in a model to make a determination with some degree of reliability,' the judge continued. 'Here I'm not hearing any of those things. I'm hearing essentially this jump from a literature review to a postulated model to a no harm result"

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To understand why this is such a boon to move the medical science forward and why it is such a significant ruling - that dispels the myth of serious mold induced illnesses are not occurring, one has to go back to the year 2000:

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2000
Title: Health effects of mycotoxins in indoor air: a critical review. Appl Occup Environ Hyg.2000;15:773-84.
Robbins CA, Swenson, L.J., Nealley, M.L., Kelman, B.J. and Gots, R.E.

Slang: Veritox, 2000
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Robbins, Swenson and Kelman - Principals in defense litigation support corp, Veritox.
Nealley and Gots -Defense experts with International Center for Toxicology and Medicine.

Veritox 2000 is based on the same premise as the Veritox 2004 cited above. Rodents, authors added math, human illness not plausible.

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2002
The American College of Occupational and Environmental Medicine (ACOEM) Mold Statement
Title: Adverse Human Health Effects Associated with Molds in the Indoor Environment
October 27, 2002
Kelman BJ (Veritox), Hardin BD (Veritox), Saxon AJ.(University of California - UC)
Edited & published in the Journal of ACOEM, the JOEM 2003

Slang: ACOEM MS, 2002

"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."

Sole reference for the above statement:
Veritox, 2000. Reference 63
NONE of the other 83 references cited for this 'state of the art review piece' support the above conclusion.

ACOEM MS, 2002 was presented as a position statement purportedly representative of 7000 physicians' understanding of mold/mold toxin induced illness. ACOEM is made up primarily of physicians who evaluate injured workers on behalf of insurers and employers.

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2003
US Chamber of Commerce/Center for Legal Policy -Manhattan Institute Mold Statement
"Center for Legal Policy is a leading voice for reform of America's civil justice system." according to their website.
Title: A Scientific View of the Health Effects of Mold
Bryan Hardin, PhD (Veritox), Andrew Saxon MD (UC), Correen Robbins, PhD, CIH (Veritox) and Bruce J. Kelman, Ph.D., DABT (Veritox)

Slang: USCC MS, 2003

"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."

Sole references for the above statement:
Veritox, 2000 and ACOEM MS 2002

The USCC MS 2003 has been reported by the Veritox authors to be a "lay translation" of the ACOEM Mold Statement. They were 'commissioned' by the political think-tank, the Manhattan Institute to write this lay translation. The authors received $40,000 for interpreting the national protocol writing, medical association's (ACOEM) understanding to mean that all mold illness is based upon 'Junk Science". It was then shared with stakeholder industries (real estate, building, mortgage and insurance) in a fanfare presentation in Washington, DC, July 17, 2003.

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2003
National Association of Realtors (NAR)
Title: Moldy Claims: The Junk Science of Toxic Mold
Kelman BJ.(Veritox) Hardin BD.(Veritox) Saxon AJ.(UC)

Slang: NAR 2003

"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."

Sole references for the above statement:
Veritox, 2000, ACOEM MS 2002 and USCC MS 2003.

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2004
Title: Risk from inhaled mycotoxins in indoor office and residential environments. Int J Toxicol 2004; 23: 3-10.
Robbins CA, Swenson LJ, Hardin BD. (Veritox, Inc. Principals)

Slang: Veritox, 2004

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2003 to 2005
Various Government Regulatory (CDC & EPA), Medical Associations (ACAAI, SOT), Industrial Hygeine Associations (AIHA), etc. make the findings of "not plausible" citing Veritox 2000, ACOEM MS 2002, USCC MS 2003, NAR 2003 and/or Veritox 2004. These five review papers have been cited as authoritative documents by the defense in virtually every mold litigation case in the US.

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2005
Example of Impact on the Courts
Testimony of Bruce J. Kelman, President of Veritox, Inc.
Author of Veritox 2000, ACOEM MS 2002, USCC MS 2003, NAR 2003 & Co-principal Veritox 2004

February 18, 2005, Haynes vs. Adair Homes, Inc. Case No. CCO211573,
In the Court of the State of Oregon.

"Based on the studies that you have done, the literature that you have discussed, and your experience and training, have you formed an opinion based on reasonable scientific probability or certainty as to whether or not there was enough mycotoxin in the home to have caused any illness to Mrs. Haynes, Michael Haynes, or Liam Haynes?" Dr. Kelman's answer: "Yes." The attorney: "And, what is that opinion, doctor?" Kelman: *"There could not be. I mean, the differences between the maximum dose that we could come up with and the level at which we see effects for a broad range of mycotoxins is just too great."*

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2006
American Academy of Allergy, Asthma and Immunology (AAAAI) Mold Position
Title: The medical effects of mold exposure
Bush RK, Terr A.(UC), Saxon AJ (UC) and Wood RA.
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Slang: Quad AI 2006

> “Calculations for both acute and subacute exposures on the basis of the maximum amount of mycotoxins found per mold spore for various mycotoxins and the levels at which adverse health effects are observed make it highly improbable that home or office mycotoxin exposures would lead to a toxic adverse health effects.1, 29
>
> Thus we agree with the American College of Occupational and Environmental Medicine evidence-based statement and the Institute of Medicine draft, which conclude that the evidence does not support the contention that mycotoxin-mediated disease (mycotoxicosis) occurs through inhalation in nonoccupational settings."

Sole reference for the above statements:
ACOEM MS 2002 - Reference 1; Veritox 2004 - Reference 29.

Note: Saxon (UC) is an author of ACOEM MS 2002, USCC 2003, NAR 2003, & Quad AI 2006

Veritox principals are authors of Veritox 2000, ACOEM MS 2002, USCC 2003, NAR 2003 & Veritox 2004.

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2006
Robbins Order, Kelly Ruling, April 14, 2006
Veritox 2004 does not pass Kelly.

Veritox 2004 is the ‘second generation’ of Veritox 2000. Both ‘review papers’ are founded on the same premise that is now debunked as not being of sound scientific protocol to determine absence of human illness from mycotoxin inhalation indoors.

ACOEM MS 2002, USCC MS 2003, NAR MS 2003, and Quad AI MS 2006 are all founded on the Veritox 2004 or Veritox 2000.

Statements of "*not plausible, improbable, and junk science*" within all papers are debunked by the debunking of the Veritox 2004.

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Additional Information of Significance, 2006

The Institute of Medicine (IOM), Damp Indoor Spaces and Health Report, was a primary exhibit in the Kelly hearing that discredited the Veritox 2004.

IOM Executive Summary:

> “Toxicologic studies, which examine such responses using animal and cellular models, cannot be used by themselves to draw conclusions about human health effects.”

IOM Chapter 4 Mycotoxins

Summary:

> “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."

IOM Chapter 4 Mycotoxins
Summary
Considerations in Evaluation of Evidence

"Most of the information reviewed in this chapter is derived from studies in vitro (that is studies in an artificial environment, such as a test tube or a culture medium) or animal studies. In vitro studies, as explained below, are not suitable for human risk assessment. Risk can be extrapolated from animal studies to human health effects only if chronic animal exposures have produced sufficient information to establish no-observed-adverse-effect levels (NOAELs) and lowest-observed-adverse-effect levels (LOAELs). Extrapolation of risk exposure from animal experiments must always take into account species differences between animals and humans, sensitivities of vulnerable human populations, and gaps in animal data."

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2006
Minutes from the US Surgeon General's Workshop on Indoor Air are published

"Dr. Noreen Clark [Chair of the IOM Damp Indoor Spaces and Health Report, 2004] indicated that the report did not consider only respiratory symptoms, but that these were the symptoms for which associations were strongest. *She noted that "absence of evidence is not evidence of absence," and said that the report did not intend to dismiss the possibility of effects for which the existing evidence of association was not strong or for which evidence was not available."*

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2006
State of California Report in Response to A.B. 284, Chapter 550, Statutes of 2001
Indoor Mold: A General Guide to Health Effects, Prevention, and Remediation. (CRB-06-001 , January 2006)
Kenneth W. Umbach, Ph.D., and Pamela J. Davis, R.N., P.H.N.
.
Page 72 "Some experts believe that the ACOEM statement understates risks and effects."

Page 75 "The question of whether health effects result from indoor exposure to mycotoxins is controversial, as stated in the text and is noted above. The conclusion in the present report that such effects are at least plausible reflects, for example ..."There is an accumulated weight of evidence linking indoor airborne mold and/or mycotoxin exposures to multisystem adverse human health effects."

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2006
Center for Science in the Public Interest
Washington, DC

Integrity in Science Watch -- Week of 3/31/2006
Allergy Journal Authors Failed to Disclose Conflicts of Interest

The prestigious Journal of Allergy and Clinical Immunology (JACI) last month failed to disclose two physicians' roles as insurance company defense experts in their scientific review "The Medical Effects of Mold Exposure," which downplayed risks to human health from household mold. According to court documents obtained by the Center for Science in the Public Interest, Dr. Abba I. Terr, Stanford University School of Medicine, and Dr. Andrew Saxon, University of
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California at Los Angeles School of Medicine, were paid up to $600 an hour for testimony in cases brought by homeowners alleging their illnesses were caused by mold. JACI, the journal of the American Academy of Allergy, Asthma and Immunology (AAAAI), requires authors to disclose conflicts of interest to the editor, who then has discretion in publishing them. In a letter to editor Donald Leung, CSPI urged AAAAI to make disclosure mandatory and prevent authors who fail to disclose conflicts of interest from publishing in the journal for three years.

Week of 4/24/06
Allergy Journal Strengthens Conflicts of Interest Disclosure Policy

The Journal of Allergy and Clinical Immunology (JACI), an Elsevier publication, will require greater financial disclosure from authors and automatically publish those disclosures, the editor said. Two mold experts, Dr. Abba Terr and Dr. Andrew Saxon, failed to disclose their roles as defense witnesses in mold exposure liability lawsuits when publishing a review in the journal earlier this year that downplayed the risks from household mold exposure. Editor Donald Leung said future author conflict of interest forms accompanying JACI submissions will now include "specific questions" about expert witnessing and the journal will "ensure that all published manuscripts will carry a conflict of interest statement regarding each author."

Week of 6/5/06
Environmental Journal Retracts Fraudulent Study on Chromium
[Significance: Journal of ACOEM Retracts Fraudulent Study Authored by Expert Defense Witnesses for Usage in Court]

The Journal of Occupational and Environmental Medicine [Journal of ACOEM] will retract a 1997 article on chromium written under the names of two Chinese scientists after a Wall Street Journal investigation revealed that the article was actually drafted and edited by consultants for a major chromium polluter. Chemrisk, founded and directed by Dennis Paustenbach (see http://www.IntegrityinScience.org/), purchased in 1995 JianDong Zhang's original data on the link between chromium-6 in drinking water and cancer in Chinese villages. Chemrisk, which had been hired by Pacific Gas and Electric, the California utility company being sued for chromium contamination, then reworked the data to show that Zhang, who objected to the publication, had reversed his conclusion on the chromium-cancer link The JOEM retraction, signed by editor Dr. Paul Brandt-Rauf, states that the article did not comply with the journal's policy because "financial and intellectual input to the paper by outside parties was not disclosed." Since its publication, the fake article has influenced regulatory decisions on chromium, including being used by a scientific panel for a 2001 report which forced California health officials to revise a recommendation for how much chromium-6 should be allowed in drinking water.

Week of 6/12/06
Top Allergy Journal Will Publish Contributors' Conflicts of Interest

The nation's leading allergy journal now requires authors to publish their ties to industry whenever their articles appear in that journal. The Journal of Allergy and Clinical Immunology, the official scientific journal of the American Academy of Allergy, Asthma and Immunology, recently adopted new guidelines requiring authors to disclose consultant arrangements, stock or other equity ownership, patent licensing arrangements, and expert witness testimony. Editor-in-Chief Donald Y.M. Leung initiated the policy change after the Center for Science in the Public Interest uncovered the journal's failure to report that a review on the health risk of mold exposure had been authored by two key defense witnesses in mold liability lawsuits. (See Integrity in Science Watch, 3/31 and 4/24)

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Summary

Many people have been ill with serious mold/mycotoxin induced illnesses. They have been unable to obtain proper medical treatment prior to the time these illnesses have become progressively and irreversibly debilitating. Many physicians and citizens have been falsely told that mold does not cause serious illness, leaving the medical community and public uneducated and unaware of the true danger.

The medical misinformation promoted for the benefit of the defense in mold litigation has stifled and confused the already young field of science. It has fueled contention. The promotion of the concept "not plausible, improbable, junk science" within the medical community and the general public has been a primary cause for the lack of early detection and timely medical treatment.

This in turn, has cost stakeholders with financial interest in the moldy buildings, unnecessary billions. The misinformation, that has retarded proper medical understanding, has also caused a tremendous increase in financial responsibility for stakeholders. Increased health damages sustained equals increased resultant stakeholder liability. .

Mold itself, has not been the crux of the problem. The denial of illness in an attempt to limit liability has directly caused greater illness - and thereby has caused greater liability. The situation has been wastefully self perpetuating. The defense argument of “not plausible, improbable and junk science” has proven to be its own worst enemy.

Dr Jonathan Borak, overseer for the "peer review process" of the ACOEM Mold Statement, summed the matter up best in an email he wrote in 2002:

> Email September 8, 2002
> From: Jonathan Borak, Chair of the Scientific Committee, ACOEM
> To: Dean Grove, Past President, ACOEM
> CC: Edward Bernacki, ACOEM President 2002; Barry Eisenberg, Executive Director ACOEM; Tim Key, ACOEM President 2003.
>
> "Dean et al:
>
> I am having quite a challenge in finding an acceptable path for the proposed position paper on mold. Even though a great deal of work has gone in, it seems difficult to satisfy a sufficient spectrum of the College, or at least those concerned enough to voice their views.
>
> I have received several sets of comments that find the current version, much revised, to still be a defense argument. On the other hand, Bryan Hardin and his colleagues are not willing to further dilute the paper. The have done a lot, and I am concerned that we will soon have to either endorse or let go. I do not want to go to the BOD and then be rejected. That would be an important violation of Bryan. I have assured him that if we do not use it he can freely make whatever other uses he might want to make. If we "officially" reject it, then we turn is efforts into garbage. ...."

Garbage it was, based on the Veritox 2000 ‘review’ and provided credibility by the imprimatur of ACOEM. Once the credibility was established by the ACOEM, the garbage was then spread to other purported state of the art, mold review papers.

The unscientific concept that one could take a single review of rodent studies with math applied and determine all human illness from inhaling mycotoxins indoors could never happen, took on a
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life of its own and grew. It became understood that one could never become seriously ill from inhaling mold indoors.

No one seemed to remember exactly how this concept came to be. They just knew it to be true because they had read it in many authoritative "state of the art" mold review papers.

The lives, health and financial well being of thousands have been forever damaged because of it.

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And that is the Landmark Significance of the Kelly Ruling on April 14, 2006, Sacramento, California, regarding "Risk from inhaled mycotoxins in indoor office and residential environments. Int J Toxicol 2004; 23: 3-10.Robbins CA, Swenson LJ, Hardin BD. (Veritox, 2004).

The courts have found Veritox 2004 is not plausible, improbable and Junk Science.

Maybe NOW we can get this issue out of the courts and into doctors' offices where it belongs. Maybe NOW we can all stop wasting time, lives and money!

Sharon Kramer
BBA Marketing, University of Mississippi and Advocate for Mold Victims
760-822-8026
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