

Letters

We understand that by publishing contributions on matters affecting public health and the courts and the legislatures, there will be people involved who will react strongly to the articles published. Readers are invited to comment on matters in which they are involved and are urged to be as specific as possible in citing errors and raising criticisms of published work. —*Ed.*

Scientific Method Questioned

To the Editor:—I have carefully read the special issue of your journal (Sept-Dec, 2005) guest edited by Dr. Egilman. Because I know of no similar series of papers to have ever been published in a scientific or medical journal, I feel compelled to offer some comments about it.

For the sake of disclosure, your readers should be aware that the two of us have met and that your students annually visited the occupational health and medical departments of the firm in which I worked (Syntex) many years ago. I have also contributed a chapter on risk assessment to one of your occupational medicine textbooks. In spite of the fact that I respect the contributions you have made to the field of occupational medicine, I am disappointed and concerned about this issue of your journal. I do not believe it was appropriate to have permitted the various authors and contributors to use your journal as a vehicle to legitimize views that were often speculative, undocumented, or simply incorrect.

Unfortunately, one can reach no other conclusion but that this issue was a backdoor method of bettering the position of some of the authors in future litigation by permitting them to claim that their views had been shared in a peer reviewed journal and, therefore, they should be admissible in court. In my view, this is an abuse of the

role of peer reviewed scientific publications and I believe it is inconsistent with the guidelines of the Association of Science Editors. Nonetheless, I do believe that it is useful for scientists and physicians to have a scholarly dialogue about the various topics that are raised in this issue.

I was born in Pittsburgh in the early 1950s and my paternal grandfather died of silicosis from his exposure in a glass factory. I nearly died in an industrial explosion at the age of 22 and I have been sensitized to two or three chemical agents due to workplace exposure. I have taught several college courses addressing occupational disease. During the 1980s, I actively promoted a requirement that all engineering programs in the United States be required to teach a course in occupational health and safety. I feel strongly that corporations should act in a forthright and ethical manner and have urged those which whom I have consulted to do so for more than 20 years.

With that background, I do have some views about why I believe this issue of your journal denigrates the reputation of scientific and medical publications. They are based on 25 years of experience in industrial hygiene, toxicology and almost daily interaction with occupational physicians, as well as having served as an associate editor or having par-

ticipated on the editorial review board of at least six different scientific journals.

a) *A scholarly dialogue is useful but it should be based on facts and not innuendo.* This issue of your journal failed to adhere to the rich tradition of scholars where one may choose to disagree with another's interpretation of data but not question the motives of the individual. Throughout this issue, many of the authors repeatedly suggested, by innuendo or by taking sentences out of context, that fellow scientists made decisions which they knew to be inappropriate, dishonest or unethical. The evidence provided was not sufficient to support such claims and a scientific journal is not the appropriate venue to make such unsubstantiated accusations. The manner in which this issue was orchestrated did not provide a forum where the facts could be presented by both sides and then weighed fairly by the reader.

b) *These were not commentaries:* When you and I discussed this issue of the journal via email, you indicated that these were commentaries and that they were peer reviewed. Although this may have been your goal, that is clearly not what occurred. First, the word commentary is one that is well understood in our field. It has traditionally meant that the views presented are those of the author and not

those of the journal (nor are they usually validated by the classic peer reviewer process). Although you may have intended for them to be commentaries, the word commentary doesn't appear on the front page of the articles (as is the tradition and expectation in our field) nor does that word appear anywhere in the issue. In fact, one can only infer that because these articles were meant to look like scholarly pieces (in some cases, having as many as 80 references) and because you claim they were peer reviewed, one must conclude that they were intended to give the appearance of scholarly work rather than opinion/editorial pieces.

c) *The matter of peer review.* In my opinion, it is not possible that these papers could have received proper peer review. I don't even see how the term could possibly apply since these were fundamentally the opinions of authors backed up with a highly selected and one-sided citations. For the sake of discussion, if peer review had actually taken place with these commentaries, then the peer reviewers would have had to have been familiar with most of the references cited by the authors and the reviewers should have encouraged the authors to present both sides of the fence. It is unfathomable that any peer reviewer could have been in possession of the corporate documents that were cited and it is even less likely that they would have been aware of the many references or documents that would have painted entirely different pictures of what had allegedly occurred (unless he/she had testified as an expert on the other side of the issue). Also, apparently when informed reviewers were used, they may not have always been given serious consideration. As noted by Dr. Finkel (who was apparently asked to peer review an article), his criticisms of the paper he reviewed were completely ignored by the author and the paper published without signif-

icant revision. In short, one can only conclude that these papers were made to look like objective peer reviewed scientific manuscripts although there is little evidence that they could have fulfilled that level of scientific journalism.

d) *Inappropriate and nontraditional format for debate.* The intent of the issue was apparently to stimulate debate. Clearly, a debate about the issues raised could have occurred without allowing the authors to question the integrity of their debate opponents. If stimulating debate was indeed the true purpose, scientific tradition would demand that persons on both sides of an issue present their case in companion articles in the same journal. Although the content of many of the articles could hardly be considered scholarly, the personal attacks offered in these articles is without precedent. Surely, if publication of personal attacks was to be permitted, the profession would have been better served had those on the receiving end been given a chance to have a companion piece in the same issue. To offer anyone a chance to respond to a 12 page article with nearly 100 references via a letter to the editor is clearly inadequate and certainly not equitable.

e) *Nontraditional disclosure of conflicts of interest.* One has to be suspicious of the manner in which acknowledgements were presented for this special issue of the journal. Again, one can only assume that it was intended to conceal from your readers the authors' potential conflicts of interest and, in light of the role some of the authors play in litigation, their financial motivation. Specifically, the acknowledgements or biographies were placed in the back of the journal so that when the manuscript was copied, the disclosure would not accompany the paper. I have never seen such an approach in my 20 years of reading as many as a dozen journals each month. Further, in several articles, attacks were leveled at persons whom the author has, or is likely to

be, offering opinion contrary to theirs in the courtroom (not one of the authors disclosed this fact).

f) *The papers were indictments, not a disclosure of new scientific results or a scholarly analysis.* The writing style used by several of the authors was exactly that used by lawyers in a legal proceeding. The authors often presented half-truths, factoids, sentences taken out of context and outright mischaracterizations as facts. This kind of approach is considered acceptable when lawyers present their claims to a judge in the courtroom. There is good reason that judges tell juries that what lawyers say is not evidence! However, the factual hurdle that is required by lawyers who write these indictments is very low; far lower than a reputable scientist could possibly allow. The use of this approach is completely inappropriate for a scientific journal.

Perhaps contrary to your views, I do believe that every journal or newspaper has a responsibility to protect the reputation of scientists against unjust accusations. That is why there are Boards to which one can take claims when newspaper reporters have got it wrong and that is why lawyers are sometimes needed to protect persons from slander and libel.

I will close by mentioning two statements in this special issue of your journal which appear to represent a theme in this issue but contrary to the very foundation of science. Dr. Egilman states that [b]ut the absence of evidence is not evidence of the absence of an effect (page 360) and [o]nce it is generally accepted that a substance can cause disease in humans, all that is required to establish causation is documentation of exposure to that substance (page 369). Any scientist knows that both claims are flawed. First, although it is true that the absence of evidence does not prove that a causal association may not eventually be recognized, it is not scientifically appropriate to claim that a relationship exists until it is

established using the scientific method. One need only think about the historical view that damp weather was the cause of pneumonia or tuberculosis, or that psychiatric disease was caused by a wandering uterus to understand that his statement lacks merit. Second, if one were to accept his premise that all that is required to establish causation is documentation of exposure, then any physician could testify that it is more likely than not that any cancer is likely caused by a persons chronic ingestion of chef salads since they are known to contain huge amounts of known human carcinogens. In short, much more is needed than simply knowing that there is exposure to a chemical (at any dose) to prove causation.

I encourage you and your journal to create an environment where disagreements regarding the proper interpretation of scientific data can occur. This issue of the journal failed to do that and was a disservice to the rich tradition of the scholarly exchange of ideas.

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In reply:—Paustenbach's accusation that we are not using the scientific method is an excellent example of what Harriet Hardy described as the way corporations [corporate lawyers and scientists] "twist and turn the truth to suit the particular need of the day." He gives the impression that we suggest that cause-effect relationships can be established with little or no evidence when we merely echo Hill's analysis that,

All scientific work is incomplete—whether it be observational or experimental. All scientific work is liable to be upset

or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action that it appears to demand at a given time.¹

Despite his "critique" of our methods, Paustenbach does not name a single factual or methodologic error in the entire journal. This includes the Egilman and Billings article he cites, "Abuse of Epidemiology: Automobile Manufacturers Manufacture a Defense to Asbestos Liability."

There is no dispute that asbestos causes mesothelioma, that brake work exposes workers to asbestos fibers and that there is no known level of exposure to asbestos that does not increase the risk of developing mesothelioma. There are more than 200 published cases of mesothelioma in brake mechanics. Paustenbach's "scientific method" requires that a formal epidemiologic study find an excess in these workers. We disagree. By analogy, once you show that arsenic can kill white women (and you don't need epidemiology to establish this), general causation is established. Once general causation is established, it is reasonable to infer it can kill one-armed left-handed black men without any further evidence. You can then infer it did kill a particular person if you show exposure and rule out other causes, neither of which is difficult for mesothelioma or arsenic poisoning if exposure has indeed taken place. As asbestos is by far the most common etiologic agent of mesothelioma, in almost all individual mesothelioma cases it is the only possible cause for the disease. In the context of mesothelioma in people whose sole exposures to asbestos occurred while working as brake mechanics, it is both good science and common sense to link the disease to those exposures.

Ford, GM, and Chrysler jointly paid their litigation consultant team (Paustenbach, his colleagues,

and their companies) approximately \$23 million between 2001 and April 2006.²⁻⁴ This is more than enough money to conduct a prospective epidemiologic study of brake mechanics. Instead, the litigation consultants used this funding to reanalyze existing general (not brake-worker-specific) epidemiologic and selected brake-exposure data. Tellingly, the manufacturer's defense lawyers—not the manufacturers—funded this "research" and considered its purpose "in connection with the defense of asbestos friction litigation claims."³ exponent apparently had a similar understanding of the process, as they categorized their work for the asbestos defendants under the billing code "Technical Support—Asbestos Litigation."⁴ Two years before the bulk of their research was published, Dr. Patrick Sheehan, a coauthor on some of the papers, provided the lawyers one of several summaries "prepared at the request of counsel to assist with the defense of pending asbestos litigation" and designed "to set forth litigation strategy tasks to assist in ongoing, pending and prospective litigation."⁵ Sheehan also partnered with an automobile defense lawyer to publish an article in an American Bar Association newsletter that explained how this research could be used to put on "a convincing science case" to defend companies in mesothelioma litigation.⁶ Paustenbach claims to champion the scientific method when faced with material critical of the corporate influence on science. However, research carried out with the goal to "assist with the defense of pending asbestos litigation" does not follow the scientific method, which starts with a hypothesis, not a political objective.

Corporations that make dangerous products have a long history of "manufacturing doubt."⁷ They try to create scientific controversy over the health effects of their products and processes in order to delay or avoid the costs of regulation, litigation

tion, and environmental clean-ups. They maximize their profits by shifting, or "externalizing," the costs of human disease and environmental decay onto taxpayers and sickened workers and their families. Pioneering tobacco company public relations firms first fabricated and then popularized a pseudo debate concerning scientific epistemology that invariably defined "proof" as the one piece of evidence that did not yet exist. In cases where human epidemiologic evidence left no doubt about causation, they argued that animal data were required to establish causation (benzene, tobacco, arsenic). More commonly, when animal data, human case reports, and mechanistic understanding established a cause-effect relationship, they claimed epidemiologic studies were required to establish causation. When epidemiologic studies finally supported a casual connection, they claimed the dose was unrepresentative (too high), or, as Paustenbach does, that an epidemiologic study of each and every job category where exposure occurs must be produced to establish a causal nexus for workers in that particular job classification. Then, like Paustenbach, they claimed the moral "scientific" high ground; "it is not scientifically appropriate to claim that a relationship exists until it is established using the scientific method." This "scientific method" says that the key evidence that is required to establish causation is

always the missing evidence. It is often a moving target: epidemiology, epidemiology at the same or lower dose, epidemiology of the same occupational group, epidemiology of the same gender, animal studies, animal studies that show the same cancer that humans get, multiple animal species, and so on. This is not science; it is political and financial stratagems masquerading as science.

As for Paustenbach's other points, we followed submission, disclosure, and peer review policies with great concern for their integrity. Where authors received funding for conducting or writing up their research, that funding was disclosed alongside the text of the article, as is standard practice. In addition, we included a section with contributors' biographies and conflict-of-interest disclosures to provide more author information than is usually included in most journals. We did this because we know that full disclosure is paramount to good science. Perhaps unlike Paustenbach, we believe that a discussion of the corporate corruption of science belongs in *all* health and science journals, not just *IJOEH*. We are heartened by the increasing attention to the issue.

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Differential Peeky Bias

To the Editor:—Since the publication of our paper “Abuse of Epidemiology: Automobile Manufacturers Manufacture a Defense to Asbestos Liability,” legal counsel for the automobile manufacturers have raised several issues with regard to our analysis.¹ We address them here.

In our paper we stated that as of 1978, “McDonald et al. reported ‘only’ 0.4 cases of mesothelioma per 1,000 individuals in chrysotile asbestos factories. . . .”² This number was deaths per 1,000 deaths. While we reported population incidence rates for mesothelioma, we did not directly compare them with McDonald’s death-rate data. At the suggestion of Chrysler counsel, we have now done so. For the year 1979, the earliest year for which data were available, there were 0.18 mesothelioma deaths per 1,000 deaths in the United States.³ This is less than half the rate of 0.4 per 1,000 deaths reported by McDonald, et al. Thus, this comparison provides further evidence for our conclusion that, “the rate reported by McDonald et al. is therefore at least more than double the expected rate.”

In addition, we criticized the McDonald and McDonald study⁴ for limiting the determination of the source of occupational asbestos exposure to the period ten years prior to the subject’s death.⁴ However, McDonald and McDonald present two conflicting explanations for the years-of-exposure categorization. In the text of the Methods section, they state that “analysis of probability of occupational exposure to asbestos for patients and controls during the period up to 10 years before death is presented in Table 2.” We understood this to mean that only the period between death and 10 years prior to death was examined. However, a title caption for another table in the report (Table 3) indicates occupational groups for the study subjects “10 or more years before death.” In either case the years of

follow-up included a ten-year period (10–20 years after exposure), during which time few if any mesotheliomas would be expected to occur. Inclusion of these exposure data would have diluted any potential effect.

Finally, we stated that Goodman et al. used an 11-point scale to rate the studies they included in their meta-analysis. In fact, they used what appears to be a 13-point scale, which was based on 11 criteria.⁵ The maximum score also appears to be 8, not 9. The highest-ranking study therefore garnered a 5 out of 8, and it was the Teschke paper, not the Hessel et al. study.^{6,7} The Hessel paper had a score of 4, which was the second highest.

Goodman et al. relied on personal communications with the authors of some but not all of the papers they evaluated, allowing them to reject articles that otherwise would have been included in the meta-analysis.⁸ The authors based their justification for the exclusion of two studies which were unfavorable to their sponsors’ financial interests on this differential, unsystematic pursuit of additional exposure information.^{10,11} For example, Goodman et al. excluded the paper by Malker et al. (which revealed the highest RR, 2.4, for mechanics) because one of the authors of the study could not document actual brake work among workers in this category.⁹ We have named this differential study evaluation methodologic error (i.e., the selective pursuit of unreported exposure information to enhance favorable data or to discredit unfavorable data) the “differential peeky bias.” We thank

Chrysler’s counsel for their comments and suggestions.

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Correction

An error appeared in Table 3, page 131, of the article, “Linking Environmental Hazards and Birth Defects Data” (Brender et al., *Int J Occup Environ Health* 2006;12:126-133). The first heading, “Residence within One Mile of Hazardous Waste Site” should read “Residence within One Mile of TRI Industrial Facility.”