

### Integrity of Scientific Evaluations of Government Agencies

*To the Editor:*—I don't believe I have ever flinched from an opportunity to denounce efforts of industry or of government (singly or in cahoots) to distort science so as to trivialize environmental or occupational health hazards. Indeed, such advocacy recently caused me to leave government service as a "vindicated whistleblower."<sup>1</sup> *But not all discussions between regulators and regulated parties result in distortion or malfeasance:* sometimes quite the opposite, as the actual events around OSHA's 1,3-butadiene (BD) standard prove. I offer these comments on Dr. Infante's recent article<sup>2</sup> (IJOEH, 11: 372-377) not from an ideological stance to his "right" (welcoming compromise that might lessen worker protection), but from the view that worker protection is more important than (and can be undermined by) mere indignation. Dr. Infante's account misses the mark in three major respects: 1) it presents a jaundiced account of negotiations that the author did not participate in; 2) it neglects to mention an array of benefits that the BD regulation conferred—many of which arose during the very discussions the author decries—and thus it misrepresents an unambiguous victory for worker protection as somehow tainted; and 3) it fails to direct its outrage where it belongs—at OSHA's subsequent failure to enforce a strong standard that industry had accepted without court challenge.

1. Most importantly, it is simply false that OSHA "downgraded its carcinogen classification" for BD, either in response to industry pressure or for any other reason. Neither the 1990 proposed rule nor the 1996 final rule used the term

"known human carcinogen," and OSHA had never stated that "BD causes an increased risk of" specific cancers (contrary to p. 373 of Dr. Infante's article). To be sure, there remain subtle inconsistencies *within* the Preamble to the final standard in how OSHA describes the evidence for BD's carcinogenicity. There are indeed three instances (in a 120,000-word rule-making document) where OSHA describes BD as a "probable" human carcinogen (note the the unwarranted phrase "possibly carcinogenic to humans" in the first sentence of Dr. Infante's abstract appears nowhere in the BD document), but OSHA made various stronger statements as well. In particular, the reader should consider the three instances of the language "OSHA has concluded . . . that occupational exposure to BD is associated with an increased risk of death from cancers of the lymphohematopoietic system," and especially the table (V-4; "Evidence That BD Is a Human Carcinogen") showing OSHA's analysis that BD meets all seven out of seven criteria for causality in humans.

Anyone is of course free to speculate whether this lack of perfect uniformity was due simply to carelessness, to OSHA's desire to blur the appraisal in the hopes that others would latch onto the **stronger** characterizations of BD (thus outsmarting the industry negotiators), or to blur it in hopes that only the "lowest common denominator" would be remembered. As OSHA's primary decision maker in the BD negotiations with industry, labor, and our own Department of Labor (DOL) lawyers, I know first-hand how the preamble and regulatory-text lan-

guage evolved, but rather than relive old memories I will simply point out that even had OSHA's strongest statement been "probable" in 1996 (that is, had all the more definitive statements not also been made), that would simply have placed it in the same position that EPA, NTP, and IARC all held at that time.

But all such speculation misses the point. *OSHA does not classify carcinogens via its rulemaking processes or anywhere else*—scientific heavyweights such as EPA and NTP do so. As OSHA's voting representative on the nine-member NTP Executive Committee, I was pleased in 1998 to offer my Agency's official position on BD's carcinogenicity, casting one of the votes with the majority to upgrade BD to "known" status. So actually, this tale of purported industry influence on the OSHA Preamble wouldn't be particularly compelling even if it had happened as Dr. Infante recounts—any "influence" was short-lived indeed.

The phantom "downgrading" of BD is not the only aspect of Dr. Infante's article that confuses the record on this rulemaking. Space does not permit a full accounting, but consider the following: 1) OSHA staff were not "fearful" about disapproval by the Office of Management and Budget (OMB), as we knew there would be no such review—the estimated costs of the BD standard (\$2.9 million/year) were vastly below the threshold (\$100 million/year) at which OMB considers a regulation "economically significant" and subject to its review authority; 2) to the extent that "career civil servants" may have been "demoralized" by real or imagined discussions between OSHA and outside stakeholders, I

think it important to note that all of the federal participants in the final discussions with industry and labor on BD were *themselves* career civil servants—the political appointee to whom I reported made no attempts to influence me regarding BD, and I have no reason to suspect the same was not also true of my career counterpart in the DOL Solicitor's Office; and 3) OSHA's decision to rely on toxicology rather than epidemiology for its quantitative risk and benefits estimates was wholly unrelated to any deliberation about "known" versus "probable"—we simply did not want to rely on a then-unpublished human study<sup>3</sup> whose *quantitative* interpretation was at the time controversial because of concerns about uncertainty in the exposure estimates, especially given that we computed the risk estimates from that study as "concordant" with (but not larger than) the animal-based estimates we ultimately relied upon.

2. Readers incensed by adjectives in the Preamble that *explains* the BD standard might wish to consider the tangible benefits to worker health contained in the enforceable regulatory text itself, which no one alleges was weakened in any way as a result of discussions among the parties. Indeed, it was only the fact of face-to-face discussions about details of the Preamble that provided OSHA a venue to further strengthen what was already an unusually stringent health standard. Before the final discussions, the assent of the affected industry and labor negotiators had paved the way for the lowering of the permissible exposure limit (PEL) for BD from 1,000 ppm to 1 ppm, and produced the first health standard in OSHA history to require specific control technologies (e.g., leak-prevention devices, double-sealed pumps) even if firms could approach the action level of 0.5 ppm without them. The effective PEL after installation of these mandatory technologies was thus far lower than the limit OSHA's

crusading civil servants were willing to settle for (2 ppm) before the outside stakeholders rescued a process that Dr. Infante correctly describes as "dormant" between 1991 and 1995. If industry *had* offered me a BD standard this stringent and innovative in return for a few adjectival changes in the Preamble, I would have rushed to make this offer irrevocable, but that's not the way it happened.

Moreover, having not been present during the final discussions, Dr. Infante neglects to mention several significant changes OSHA seized the opportunity to insist upon in the regulatory text and Preamble, each of which made the BD standard even *more* worker-protective than the industry-labor agreement contemplated! We added more stringent monitoring requirements (employers must redo all initial and periodic monitoring whenever significant production, process, or personnel changes occur), imposed a stricter schedule requiring replacement of respirator cartridges several times per workshift, and set a major precedent by changing the generic medical surveillance provisions to allow non-physicians working within the scope of their state licensures to perform procedures that only physicians could do under previous OSHA health standards (we used the same language in the subsequent methylene chloride and respirator standards, winning a lawsuit brought by the American College of Occupational and Environmental Medicine in the latter case). Perhaps most far-reaching was another change to the Preamble that Dr. Infante also fails to mention: the first explicit policy statement since the 1980 *Benzene* decision that a lifetime excess risk of  $10^{-3}$  is "the uppermost end of the million-fold range suggested by the [Supreme] Court, somewhere below which the boundary of acceptable versus unacceptable risk must fall." So at least at the time it was promulgated (see below), the BD standard was an occasion for

OSHA civil servants to rejoice in having fulfilled the Agency's core mission and having laid the groundwork for more stringent future standards comporting with *Benzene*, not to dream up new reasons to be "demoralized."

I do agree with Dr. Infante that the public is likely to be more concerned when scientists make predictions about specific types of cancers avoided rather than about "general cancer deaths avoided based upon animal studies." However, I see this is as an indictment of risk communication in general, not as a sensible indictment of the OSHA risk assessment for BD. Rather, given the high correlation between known animal and known human carcinogens, and the relatively poor power of epidemiology to tease out signal from noise—especially when the tumor type involved is common to begin with—we all ought to make less of a fetish about "known" being all that different from "probable." OSHA could have done more to emphasize that *many* EPA Group B carcinogens may well be "known human carcinogens which epidemiology cannot detect," but that is a lapse common to all our standards and to the field as a whole.

3. As a former OSHA chief regulator and Regional Administrator, I am much less concerned about government officials involving industry in *developing* standards than I am about their ignoring industry when it comes time to *enforce* standards. OSHA failed to develop a single new health standard between 1998 and 2006, when it was compelled by court order to produce a hexavalent chromium standard, one that declares the "mission accomplished" with an estimated (lower bound!) excess lifetime cancer risk of more than 1 in 100 at the new exposure limit. Meanwhile, as part of a broad retreat from enforcing its existing occupational health standards, OSHA has essentially stopped looking for BD overexposures and

other possible violations of the standard. Data from OSHA's industrial hygiene database show that between 1985 and 1995, at a time when the PEL for BD was 1,000 ppm and citations for overexposures would have been well-nigh impossible, OSHA inspectors took an average of about 30 BD samples per year nationwide. This is of course a rather small number, but it dwarfs the number of samples taken *after* the new standard came into effect and the chances of finding citable overexposures would only have grown. In 1999 (the last year for which I currently have data, pending the resolution of a FOIA lawsuit I have filed against OSHA), OSHA took only two samples for BD nationwide! I cannot discern from available data when OSHA last issued a citation of any kind under the BD standard, but I can say that no such citations were issued during 2004 and 2005, and that analysis of the roughly 90 inspections conducted nationwide since 1997 in the synthetic rubber production sector reveals not a single citation under this standard. Industry may be in complete compliance with all aspects of this standard, but that would be "out of the goodness of its heart" given OSHA's enforcement posture. And, to the extent that industry might wish to downplay the cancer potential of BD, or any other substance, by adding exculpatory language to the material safety data sheet (MSDS)—a document workers may actually read, as opposed to an OSHA Preamble—they will not be dissuaded by OSHA's extreme reluctance to issue citations for misleading MSDS language. I respectfully suggest that these aspects of the BD saga would have made a much more compelling and forward-looking paper than the one *IJOEH* published.

Finally, and with a high degree of respect for the contributions of *IJOEH* to science and public policy, I note that I raised all of the points above with Dr. Infante and with Dr.

LaDou before publication, with no impact on the original article. I pointed out, to no avail, that Dr. Infante's only "documentation" for his version of events that occurred in a meeting he did not attend was a 1996 self-authored memorandum to me (his reference 23) that I promptly rebutted to at the time. I venture to say that those of us who are proud to be "progressives" often react with scorn at "vanity journals" that favor papers espousing a particular ideology regardless of technical accuracy, and that snub peer reviewers—even those with special expertise or first-hand knowledge—as offering merely "a disagreement over policy." It is disheartening when "our side" does not hold itself to a higher standard of peer review.

ADAM M. FINKEL, ScD, CIH  
*Professor of Environmental and Occupational Health*  
*UMDNJ School of Public Health*  
*(Director of Health Standards Programs, OSHA, 1995–1999)*

#### *References*

1. Business Week. 2005; May 2: 40-1.
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3. Delzell E, Sathiakumar N, Hovinga M, et al. A follow-up study of synthetic rubber workers. *Toxicology*. 1996;113(1-3):182-9.