

nature biotechnology

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Industry opposes genomic legislation

To the editor:

We read with interest Ken Chahine's Business and Regulatory News article "Industry opposes genomic legislation" (*Nat. Biotechnol.* 20, 419, 2002). We were extremely disappointed that Chahine and the editors of *Nature Biotechnology* libelously published the innuendo and "beliefs" of the US Biotechnology Industry Organization (BIO; Washington, DC), suggesting our peer-reviewed work lacks "scientific rigor," that our data were biased "by leading questions (among other things)" and that we violated unspecified internal review board (IRB) "guidelines." BIO (along with Dr. Chahine) was provided on April 8 with a summary of data not included in our February 7 *Nature* article (*Nature* 415, 577–579, 2002). Neither BIO, Dr. Chahine, nor *Nature Biotechnology* requested copies of our interview guide, study protocol, and IRB approval letter. If they had, then they would have recognized that BIO's disparaging statements about our study and about the ethics of our research practices were in reckless disregard of the truth.

We were also troubled that *Nature Biotechnology* failed to include Chahine's corporate title of vice president of business development and intellectual property for Avigen, Inc. The casual reader might easily be misled to think that the writer was an objective reporter instead of a biotechnology company executive.

We believe publication of these unfounded statements and failure to disclose Chahine's employment represents irresponsible journalism hardly befitting a *Nature* journal.

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Nature Biotechnology responds:

Nature Biotechnology prides itself on adhering to the highest standards of journalism in its reporting and takes complaints such as the above very seriously. After careful consideration of the facts, we disagree with assertions that the article is unlawful or unethical. The article reports the industry's response to the Genomic Research and Diagnostic Accessibility Act of 2002, currently pending before Congress. It is newsworthy that world's largest biotechnology industry association, BIO, is critical of the bill and, as the title of the piece makes clear, this is the subject of the report. In retrospect, we agree that Ken Chahine's position at Avigen should have been noted in his affiliation. From now on, author affiliations in Business & Regulatory News Articles will clearly indicate any additional titles or positions held by a freelancer. We hope this information will be useful to our readers. *Nature Biotechnology* is satisfied that Chahine's position at

gene therapy company Avigen did not compromise his objectivity as a reporter in this case.

Ken Chahine responds:

The impact of patents on the cost and availability of genetic testing is an increasingly pressing social issue and one that has attracted the attention of legislators. The outcome of such a debate will have significant short- and long-term impacts on patient care and the biotechnology industry. The goal of my article was to represent the views of academia and industry alike. I am surprised and disappointed that Merz *et al.* claim my article was "irresponsible journalism." The article was based on extensive interviews and research. Drs Merz, Cho, and Leonard were interviewed and given ample opportunity to respond to industry opinion and criticism. For example, they were asked to respond to industry's major criticism—that the conclusion reached in their February 7 *Nature* commentary (*Nature* 415, 577–579, 2002) that patents have a negative impact on the cost and availability of genetic testing is not supported by their data. All three conceded that

the data had its limitations and that they had no direct evidence that the number of genetic tests being performed had actually decreased, or that anyone wishing to be tested had been denied. Merz *et al.* were similarly questioned about a myriad of other industry concerns. As for the report of BIO's opinion that certain IRB guidelines may have been violated, I relied on a detailed multipage outline generated by an industry representative specifically addressing the alleged interview guideline violations. The outline was based on survey information provided by the authors in their *Nature* article. As a reporter, my role is to provide the reader with a balanced view of the issues, not to judge the opinions of credible sources. Notably, Merz *et al.* have not alleged that I failed to present (or that I misrepresented) their views on patents and genetics testing. Having presented the views of academia, it would be remiss of me to ignore the opinions of industry.

The Biotechnology Industry Organization responds:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to respond to the comments of Jon Merz *et al.* in response to Dr. Ken Chahine's article "Industry opposes genomic legislation" (*Nat. Biotechnol.* 20, 419, 2002). BIO is dismayed at the mischaracterization of our request for data as it relates to the author's study. A debate carried out in scientific literature about protocol, process, and content of studies should not be viewed as libel. Instead, a public debate should reflect the opinions of all interested parties.

At BIO, we oppose any efforts to weaken the patent protections afforded to the biotechnology industry. Strong patent protection is essential to promote continued investment in the development of and access to new therapeutics and diagnostic tests. Dr. Merz's study and his letter to the editor miss the fundamental point of Dr. Chahine's article. Legislation, such as the bills introduced by Congresswoman Rivers, would undermine the underlying patent protection of our industry's investment in DNA-based technologies that provide the basis for important medical advances in the future. BIO strongly supports intellectual property, technology transfer, and the critical role of cooperation between the public and private sectors in bringing a product to the market.

It is essential that the public dialogue on genomics legislation include the views of all parties involved. BIO applauds *Nature Biotechnology* for sharing this view and publishing the views of both academia and industry.