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BIO and biogenerics

To the editor:

Your November 2004 editorial "Overdue process" misrepresents the Biotechnology Industry Organization's (BIO, Washington, DC, USA) position on follow-on protein products.

BIO was, in fact, the first organization to call for public debate on safety issues through its Citizen Petition submitted to the US Food and Drug Administration (FDA, Rockville, MD, USA) in April 2003—hardly a delaying tactic.

Also, you claim BIO charges that generic manufacturers are incapable of producing protein copies. For the record, we believe that any review and approval process for such products must require data adequate to show safety and effectiveness to protect patients. Given all the recent publicity about the safety of drugs, prudence, especially with complex biologics, should demand high priority.

Unlike most traditional small-molecule or chemically synthesized drugs, protein products are more complex and fragile. Protein products are typically made in living systems, which have inherent variability. Minor changes made in the manufacturing process can lead to significant changes in the product that can be assessed only in clinical trials.

BIO has worked with the FDA throughout this process and looks forward to participating with the agency in its scientific workshop scheduled for February 2005 where stakeholders will have the opportunity to present what I expect will be a variety of views. BIO's twin guideposts in this discussion are science and patient safety.

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Nature Biotechnology responds:

The creation of an approval process for protein generics is an issue to truly test the vision and resolve of BIO's leadership. Clearly, as reported in a News Feature by Stephan Herrera in the November issue (*Nat. Biotechnol.* **22**, 1343–1346, 2004), many of BIO's most powerful members, such as Genentech (S. San Francisco, CA, USA) and Pfizer (New York, USA), have a strong vested interest in delaying the introduction of a streamlined approval process for follow-on proteins. The question is whether BIO can balance the need for more affordable biotech drugs with "science and patient safety" and the business interests of many of its members to protect their markets and shareholders. Calling for public meetings with stakeholders is a necessary first step. But as long as the discussions continue without an end in sight and little concerted effort to find a workable compromise for brand and generic companies, Congress and the public will perceive that industry is stalling. As Herrera wrote in his article, BIO dithers at its own peril. If biotech firms cannot figure out a way to function in a post-proprietary world like the pharmaceutical industry has, Congress and the courts will show them how.

Good faith gone bad—gone good again

To the editor:

In November of 2000, *Nature Biotechnology* published a commentary of mine entitled "Good faith gone bad" (**18**, 1123) highlighting the problems that can arise when collaborations between multinational pharmaceutical companies and research institutes in developing countries go awry. The article detailed the circumstances behind an "unfortunate misunderstanding" involving the financial compensation due to Alejandro Alagon and the Institute of Biotechnology of the Autonomous National University of Mexico (Cuernavaca), for fundamental scientific contributions to the development of a biologic being commercialized by Schering AG (Berlin). The biologic is a new-generation plasminogen activator derived from the saliva of the vampire bat of the tropical Americas; it promises to compete favorably with the human recombinant tissue plasminogen activator.

Since publication of the article in your pages, I am pleased to be able to write that every aspect of that "misunderstanding" has now been resolved to the complete satisfaction of all the interested parties. When partners in developed and developing countries work together in a spirit of mutual 'enlightened self-interest', indigenous biodiversity can be tapped for the benefit of both local economies and the discovery of powerful new medicines.

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