nature biotechnology

Letters may be edited for space and clarity.
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Laboratory testing

To the editor:

In some way, the article "Physician proposals could cost biotechs thousands," recently published in *Nature Biotechnology*[1], accomplished exactly what the American Society of Clinical Pathologists (ASCP) requested of the US Secretary's Advisory Committee on Genetic Testing—that is, to open a dialogue on the issue of patenting laboratory test methods. Unfortunately, that is where the understanding ends.

In its statement, the ASCP suggested that there are several alternatives that may help alleviate potential problems with the patenting of laboratory test methods. The society did not make any definitive recommendations, but rather suggested ideas that could be further explored. It appears from the last paragraph that we have been successful; ASCP has been participating in a dialogue with the Biotechnology Industry Organization, the Genetic Alliance, the Association of Molecular Pathology, and other groups in the hope of finding some common ground on the subject.

It is our understanding that the "freelance writer working in San Diego," who penned the article, is actually the director of intellectual property for Sequenom. If in fact this is the case, this information should be disclosed to your readers.

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1. Erickson, D. *Nat. Biotechnol.* **18**, 707 (2000).

Nature Biotechnology replies:

Debra Robertson is indeed a director of intellectual property for Sequenom and as such an industry expert. We see no conflict in her writing a piece on the patenting of laboratory methods.

Bad behavior

To the editor:

I read with much dismay your editorial in the June 2000 issue, "In praise of pessimism." The article assails the biotech industry for its inability to report "bad news gladly." I contend that the editorial reports "glad news badly."

Clearly, there is need for greater objectivity in science, whether in industry or academia. That is rather different from praising pessimism. One of the hallmarks of "entrepreneurial" science is the willingness to do research that is too risky for either the government or pharmaceutical industry to support. This springs from optimism in the face of overwhelming odds. The pessimist can find a thousand ways that an experiment won't work; it takes the optimist to find the one way that it will. All, however, must be objective in their analysis.

It is appropriate to be reminded of the perils of allowing objectivity to slip through our hands, for whatever reason. That is the "glad" news reported in the editorial. It is not appropriate to encourage pessimism. It undermines the very reason that we seek knowledge.

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Nature Biotechnology replies:

It is still not clear that biotechnology needs optimists. Biotechnology does need people with vision—as researchers, managers, and investors. But if they see only goals, then their vision amounts to nothing more than good intentions or wishful thinking. If they see only their immediate circumstances, then their vision contributes merely to problem solving. It is those who can anticipate a series of eventualities and prepare themselves for concomitant action that are more likely to succeed in the long run. The risks in biotechnology are undeniable, and they stem from the unknowable of science and commerce. It is prudent to recognize and address those risks, not compound them by overly optimistic or foolhardy behavior.

Objectively assessing bioartificial organs

To the editor:

With the pros and cons of xenotransplantation once again hotly debated[1], the in vitro and ultimately in vivo evaluation of bioartificial organs—transplantable devices containing immuno-isolated tissues for the treatment of hormone deficiencies or neurodegenerative disorders[2]—by regulatory agencies, such as the US Food and Drug Administration (Rockville, MD) and the European Agency for the Evaluation of Medicinal Products (EMEA, London), needs to be reevaluated.

A first step will be to validate indicators (or metrics) that correlate material properties and process conditions to bioartificial organ function. As large-animal and clinical evaluation of bioartificial organs involves lengthy in vivo protocols, and organ manufacture requires enzymatic digestion of scarce tissue resources from auto- or allografts, optimization of a transplantable bioartificial organ will require validated metrics that define transplant mass and site[3], as well as immunobarrier permeability, durability, and size.

As product development costs often prohibit extensive experimental design before testing of a given bioartificial organ, regulatory agencies should make such metrics mandatory as a means of demonstrating, and validating, graft function. Furthermore, a standardized procedure for pre-FDA stage I hypothesis, experimentation, and conclusions should be introduced, and this information should be required as part of the data supplied to the accrediting or regulatory organization assessing a bioartificial organ protocol.

Although the necessity for defining biomarkers as diagnostics for graft rejection and acceptance is widely recognized, there has been little debate on the mechanisms of regulatory overview and the design of standardized metrics (with the exception of ref. 4). Clearly, the FDA, in its existing capacity, can deal with the issue of metric subjectivity and data quality issues; this should be true elsewhere. In this context, I believe the creation of an international monitoring committee that validates indicators for transplanted allograft, xenograft, and genetically modified cellular tissue is warranted. This committee could provide a framework for experimental design protocols and hypotheses establishment.

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1. *Nature* **406,** 661 (2000).
2. Roberts, T., Deboni, U. & Sefton, M.V. *Biomaterials* **17**, 267 (1996).
3. De Vos, P. et al. *Vanschifgaarde, Diabetologia* **45,** 1102 (1996).
4. Waldmann, H. *Nat. Med.* **5,** 1245 (1999).

Corrigenda

In the June 2000 issue of *Nature Biotechnology* (**18**, 630–634), a web URL for access to the yeast signature data (Table 2) was omitted. These data are available in downloadable form at: http://www.lynxgen.com/yeast2000.htm

In the February 2000 issue of *Nature Biotechnology* (**18**, 181–186), "Analysis of vertebrate *SCL* loci identifies conserved enhancers," Dr. A.M. Sinclair was inadvertently omitted from the list of authors.

Erratum

In the May 2000 issue (**18**, 502) Table 2 reported OSI Pharmaceuticals being acquired by Cadus. This is not correct. In July 1999, OSI acquired certain assets from Cadus Pharmaceuticals.