NIH Office of Scientific Integrity: Policies and Procedures

We read with interest the article by Barbara J. Culliton on "legal complaints" about the "NIH misconduct probes" (News & Comment, 20 July, p. 240). We are pleased that these important issues are being given serious consideration, but we feel compelled to comment on several statements about specific inquiries and investigations. We also want to set out clearly the philosophy and position of the Office of Scientific Integrity (OSI) on matters of "due process" and scientific integrity.

Regarding the case of David Bridges (which preceded creation of the OSI), it is true that in the early phases of the investigation, some aspects of the procedures were not in line with existing OSI policies (for example, the policy that interviews be taped and transcribed and that the interviewee be afforded an opportunity to review and comment on the interview transcript). But it is not correct that "NIH issued an official report declaring Bridges guilty as charged" with Bridges not "told precisely what his accusers had said." Early in the investigation, Bridges was informed clearly and specifically about the issues that were the focus of the investigation. Furthermore, the draft report, which Bridges was afforded an opportunity to review and rebut, clearly outlined the issues.

The article also misrepresents more recent developments in the Bridges case. The possibility of reopening the case was based in part on evidence adduced by Bridges after the original panel had concluded its review. The stipulation that interview transcripts would be made if the case were reopened was no "nod to due process," but is a part of our normal procedures. Bridges elected to request a de novo hearing on his proposesd debarment. He did not have to "demand" a "trial-like" hearing. His request was readily granted. A final decision is expected in the coming months.

As for the OSI investigation of possible misconduct in connection with the D. Weaver *et al.* [*Cell* **45**, 247 (1986)] paper, the National Institutes of Health (NIH) did decide to discontinue its *extension of funding* for one of Thereza Imanishi-Kari's two research grants. Grant awards are discretionary, and, in this instance, Imanishi-Kari had been provided extended funding for 9 months beyond the end of her original award. Ultimately, NIH determined that the extended funding was not consistent with our responsibility to the public trust.

Although the OSI investigation in this case is ongoing, a previous NIH panel report found that there were several notable inaccuracies in the *Cell* paper, which was based in large part on Imanishi-Kari's research. Subsequent revelations by Imanishi-Kari indicated her data management practices were unorthodox and unreliable. This, coupled with evidence developed in the ongoing investigation, raised significant questions about her fitness to be the principal investigator on the new grant for which she had applied.

The third matter referenced in the article was the NIH inquiry into research conducted by Robert Gallo and his colleagues. Unnamed "others" reportedly take issue with the notion that it is in fact an inquiry, apparently on the basis of the fact that a number of interviews have taken place and a number of months have elapsed since the inception of the process. It is important to clarify that there is an essential functional difference between an inquiry and an investigation, namely, the former is fact-finding, to determine whether there is a reasonable likelihood that misconduct occurred, while the other is a definitive determination of whether scientific misconduct occurred and, if so, how serious it was and who was responsible for it. Several other OSI inquiries have been of similar duration and complexity. The fact that this matter is being handled as an inquiry accurately reflects its true status.

We also wish to comment on the role and responsibilities of the OSI and the protection provided for individuals who are subjects of an OSI inquiry or investigation. First, neither the OSI nor the NIH office that previously handled cases of possible misconduct is a "fraud office." Neither has there ever been a "fraud division" at NIH, nor are we a"fraud squad." The term "fraud" was specifically *excluded* from the definition of misconduct that is the basis for the rules by which the OSI operates. The preamble to these rules states, "the word 'misconduct' is coming into increasing use because it avoids confusion with common law fraud, which contains certain unique characteristics that have no applicability to what has commonly come to be known as scientific misconduct."

The OSI uses a "scientific dialogue model" in its handling of cases of possible misconduct. This model may be best explained as functioning in the same spirit as would an editor of a scientific journal in reviewing a manuscript submitted for publication. According to the scientific dialogue model, if an author provides a claim unsubstantiated by a presentation of data, the editor can demand that the data be adduced or the paper will not be published —thus the burden of supporting one's scientific claims falls on the person challenged. If the data are provided and are judged to support the scientist's claim, the matter may be concluded; if not, the claim cannot be accepted. The process is one of professional challenge to examine and evaluate data.

The same principles apply in OSI investigations of possible scientific misconduct, that is, a scientist who is accused of misconduct is always asked to provide the data that support the findings and conclusions that are at issue. This does not mean that the burden of proving there is no misconduct falls on the accused. To the contrary, any finding of misconduct must be supported by evidence gathered in a thorough investigation of all pertinent issues.

Finally, we wish to clarify the procedures by which we ensure that due process protections are provided to respondents in OSI inquiries and investigations. The OSI has a detailed set of policies and procedures, adapted from those published in 1986 and soon to be published and widely available. These policies and procedures provide numerous significant protections for a subject of an OSI investigation, including but not limited to the following: (i) Formal notification to the subject of the investigation and a clear and complete statement of the issues that are the focus of the investigation; (ii) opportunity to be represented by counsel, if desired; (iii) opportunity to provide any evidence and information the respondent believes is relevant to the issues and to suggest potential witnesses; (iv) opportunity to respond to the issues and evidence, both in interviews and in written submissions (all interviews are recorded and transcribed, and the person interviewed is afforded an opportunity to review, correct, and comment on the transcript); (v) opportunity to review the draft report and rebut it in writing (on the basis of these comments, the report may be revised and expanded if appropriate; responses and rebuttals are appended to the final report); and (vi) if a finding of scientific misconduct is sustained following the comments and rebuttal by the respondent and if sanctions are proposed, the respondent has the opportunity to review and comment in writing on the proposed sanctions.

Beyond the OSI, additional protections and checks and balances are built into the review process. The findings and recommended sanctions, if any, together with all comment and rebuttal provided by the respondent, are forwarded through the cognizant agency director and the Office of Sci-

entific Integrity Review to the Assistant Secretary for Health, who is the final deciding authority for findings and most sanctions in connection with misconduct investigations. At each stage of the process, the findings and recommendations of the OSI are given an independent review for thoroughness, fairness, and objectivity.

OSI maintains strict confidentiality over the content and process of its inquiries and investigations so as to protect the reputations and privacy of all involved parties. When a respondent has been found not to have engaged in misconduct, the OSI will work with the individual and his institution to restore his reputation, if that proves necessary.

The OSI, in addition to its repsonsibilities to individual scientists, has significant responsibilities to the biomedical research community and the public trust. The public has substantial interest in ensuring that biomedical research is honestly performed and accurately reported and that public monies are provided to those scientists who honor these obligations. At the OSI, we fulfill the public trust, but with an abiding concern for the rights of individual scientists.

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Biomass: Renewable Energy

In commenting on Philip H. Abelson's 30 March editorial, "Uncertainties about global warming" (p. 1529), William M. Kaula asks (Letters, 15 June, p. 1281), "How do biomass techniques help reduce carbon dioxide increase? Today vigorous burning of biomass has put three lesser developed countries (Brazil, Indonesia, and Colombia) in the top ten of atmospheric carbon dioxide contributors."

It is a common misconception that techniques that use biomass as an energy source add to carbon dioxide loading of the atmosphere. It would be ecological and economic folly not to replenish the plant life at the same rate as it is being depleted by burning, hence the name "renewable energy." The net release of the gas to the atmosphere is indeed zero. If the biomass were instead left to die and decay, it would also release the carbon dioxide it had absorbed during its lifetime, but in this case no usable energy would be made available.

The irreversible depletion of forest land by Brazil, Indonesia, and Colombia, and to a comparable extent by the United States in Hawaii and Puerto Rico (*1*), is hardly analogous.

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1. *New York Times*, 24 July 1990, p. A20.

Balancing American Linguists

Merritt Ruhlen (Letters, 27 July, p. 345) chastises Virginia Morell for inaccuracy and lack of balance in her article "Confusion in earliest America" (Research News, 27 April, p. 439). In particular, he writes that Morell does not cite "the recent discovery by L. L. Cavalli-Sforza and colleagues that, on the basis of human genetics, the populations of the New World fall into the same three groups that [Joseph] Greenberg had previously defined on strictly linguistic grounds." Ruhlen then asserts that Greenberg's ambitious linguistic classification (*1*) "is fully and independently corroborated by [Cavalli-Sforza *et al.*'s] study of human genetics" (*2*).

Ruhlen does not state that Cavalli-Sforza *et al.* (*2*) used his summary of Greenberg's linguistic classification (*3*) rather than the original work (*1*). He also ignores the numerous criticisms of Cavalli-Sforza *et al.*'s study that have been detailed in recent publications (*4*) and previously outlined in *Science* (Letters, 31 March 1989, p. 1651). Instead, Ruhlen implies that Cavalli-Sforza *et al.*'s study provides independent empirical support for Greenberg's theory of three successive waves of linguistic (and thereby genetic) migration from Asia into North America, respectively Amerind, Na-Dene, and Eskimo-Aleut (*1, 5*).

Cavalli-Sforza *et al.*'s phenetically constructed tree, ostensibly depicting the historical-genetic relationships of human populations, analyzed Eskimo-Aleut peoples and Na-Dene–speaking Amerindians (*6*) only as single entities, thereby precluding detection of possible multiple origins for these groups. All other Amerindians were assigned to only three geographically delimited groups that unsurprisingly tended to cluster together in subsequent analyses (*2, 4*). Thus, a priori reductionism of individual humans into undefined "populations" was too severe to offer a genuine test of the Greenberg hypothesis. Moreover, Cavalli-Sforza *et al.*'s tree purports to reveal the true sequence of historical divergences of genetic-linguistic groups, yet Eskimo-Aleut is shown to diverge before Na-Dene and Amerind—the converse of the Greenberg hypothesis. In fact, the phenetic tree does not distinguish valuable shared derived characters from historically uninformitive shared primitive characters (*4*).

By terming Cavalli-Sforza *et al.*'s "phylogeny" of human populations a "discovery" and asserting that it has "fully ... corroborated" Greenberg's linguistic classification, Ruhlen awards an aura of proof and certainty to what is actually a set of hypotheses subject to the same degree of criticism (*4, 5*) as the controversial linguistic groupings that he and Greenberg have constructed (*1, 3*).

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REFERENCES AND NOTES

1. J. H. Greenberg, *Language in the Americas* (Stanford Univ. Press, Stanford, CA, 1987).
2. L. L. Cavalli-Sforza, A. Piazza, P. Menozzi, J. Mountain, *Proc. Natl. Acad. Sci. U.S.A.* **85**, 6002 (1988).
3. M. Ruhlen, *A Guide to the World's Languages* (Stanford Univ. Press, Stanford CA, 1987), vol. 1.
4. R. M. Bateman *et al.*, *Curr. Anthropol.* **31**, 1, 177, 313 (1990).
5. B. Bower, *Sci. News* **137**, 360 (1990).
6. Cavalli-Sforza *et al.* tautologically delimited the Na-Dene–speaking Northwest Amerindians as a genetic population on the basis of their possession of Na-Dene languages.

Marx Misstated

In the heat and humidity of the summer, there are more important things to do than correct mistakes in *Science*, but because Daniel E. Koshland, Jr., bats over .300 with me in his editorials, I will go ahead. Koshland's editorial about the three universal laws of sociodynamics (27 July, p. 341) misquotes Marxist philosophy in his second law. Marx said, "*From* each [not "for" each] according to his abilities, to each according to his needs." As an economist and a registered Republican, I can say that Marx is bad enough. To misstate his philosophy is even worse.

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Response: Fulmer is correct. As a proofreader, I hang my head in shame.

—DANIEL E. KOSHLAND, JR.