Medical Humanities Report

This Issue: Scientific Integrity **Spring, 1995**

Scientific Integrity: An Overview

by Rich Sharp, M.A.

In December of 1989, the National Institutes of Health (NIH) announced a significant change in their policies governing institutional training grants, what are known as National Research Service Awards. Effective July 1, 1990 all institutions receiving these grants were required to include "a program in the principles of scientific integrity [as] an integral part of the . . . research training effort."[1] One of the stated aims of the NIH mandate was to encourage administrators, working scientists, and others to explore the difficult issue of ensuring that future researchers understand and appreciate what responsible research involves.

To date, the NIH mandate has brought together professionals from a wide range of perspectives. Administrators, working scientists, and professional ethicists all share an interest in encouraging responsible research. In light of this common interest, it is not surprising that the question of how to best respond to the NIH mandate has fostered a dialogue between these professions. What is perhaps more surprising is that the NIH mandate has sparked a more basic discussion of what scientific integrity involves. Although this discussion is still in the early stages, a number of central issues have emerged.

This article surveys some of these issues in scientific integrity. The hope is to offer a broader audience a glimpse of some current debates in science policy.

Central Issues

To a large extent, it was a change in administrative policy which spurred recent interest in scientific integrity, and many of the topics currently receiving attention continue to focus on administrative or procedural questions. Most prominent amongst these administrative issues are the related topics of *defining and handling cases of scientific misconduct.*

To illustrate some of the difficulties involved in defining scientific misconduct, consider the following definition:[2]

> [Scientific misconduct involves] serious deviation, such as fabrication, falsification, or plagiarism, from accepted practices in carrying out research or in reporting the results of research . . .

Most scientists and administrators accept the claim that falsification, fabrication and plagiarism

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are clear cases of scientific misconduct, and that scientific misconduct may include other sorts of behavior as well. However, the attempt to include other types of misconduct cases under the idea of *serious deviation from common practice* has been criticized as dangerously broad. Some scientists worry that a *serious-deviation* clause might be used to classify certain legitimate, but non-standard, methods of collecting and interpreting data as "misconduct". Stated more generally, scientists are concerned that an adequate definition of scientific misconduct provide a way of distinguishing intellectual disagreements and "honest mistakes" from cases of genuine misconduct. While several definitions of misconduct attempt to satisfy this demand, no current definition has gained widespread acceptance.

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Even supposing that everyone were able to agree on a definition of scientific misconduct, the issue of how to investigate alleged cases of misconduct remains. Here some of the central questions to be resolved include: Should the universities (or research institutions) investigate misconduct allegations or should other mechanisms be set up? How can "whistleblowers" be protected against retaliation? How can we ensure that an accused scientist receives a fair hearing? What is an appropriate punishment for someone found guilty of scientific misconduct?

A second set of issues which have received much attention in recent discussions of scientific integrity relate to *authorship and the allocation of credit*. Here, some of the central problems include: how to assign responsibility for the material presented in multi-authored papers, how to improve the peer-review process, how to determine first authorship in a multi-authored paper, how to eliminate cases of "honorary" authorship (naming someone as an author who does not deserve the citation), and how to prevent authors from republishing data and ideas which have already been published in a slightly different form. A number of these concerns relate to the current need to "publish or perish", which many also regard as the primary cause of recent increases in low-quality publications.

Finally, recent discussions of scientific integrity have focused on *conflicts of interest* which sometimes arise in research settings. It has become increasingly more common for university researchers to be involved in industrial research, both as consultants and as investors. This situation creates certain dilemmas for working scientists, particularly with respect to disclosing information to others. Current discussions of scientific integrity consider ways of promoting openness in situations where potential conflicts of interest may arise, as well as ways of handling such conflicts when they do occur.

The Future

The difficulties presented by these three sets of issues suggest that they will continue to be

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Case Study

To further the discussion of scientific integrity the Medical Humanities Report solicited responses to the following case study* from two scientists and a philosopher.

Gary Grant is a graduate student in the laboratory of Professor Hans Hansen. Grant's project is to determine the factors that are important for the expression of a foreign gene in plants. He is using a bacterial gene, *lac*, introduced into tobacco plants and is assaying the amount of RNA transcribed from the foreign *lac* gene. Among 20 plants he has regenerated with one arrangement of the bacterial gene, two have no detectable *lac* RNA, 15 have low levels, and three have high levels. On the pages in his notebook where these data are recorded, he has written his preliminary conclusion: "Only two of the plants fail to express *lac*; all the rest show significant expression."

As part of this project, the Hansen lab is collaborating with Dr. Ian Ingalls, a new professor in the department who is considered by all to be very bright and destined for greatness. The Ingalls lab has been assaying for the presence of the foreign *lac* protein in the transgenic tobacco plants using antibodies.

When Grant, Hansen, and Ingalls get together to compare data in preparation for publication, Ingalls says that writing the paper will be easy because only three of the tested plants express *lac*. Grant says that while that may be true for the protein, RNA analysis indicates that 18 of the plants have *lac* RNA and so they cannot say that the gene is expressed in only a few plants. Grant suggests that the protein assay is not as sensitive and should probably be rechecked. Ingalls becomes very upset, saying that he did those experiments himself, knows they were right, and doesn't need a graduate student to tell him how to do science. He then demands to see Grant's data, which Grant readily produces. Seeing the lower levels for the 15 plants in question, Ingalls addresses himself to Hansen, saying that these data support what he's just said, that expression is only observed in three plants, and Grant just doesn't know how to interpret data. Grant objects, but Hansen agrees that the low levels detected may be very close to background levels. As the discussion heats up, Hansen eventually excuses Grant from the room, as well as from all subsequent work on the paper.

When published, the paper lists Grant as a coauthor, reports the RNA data in a table as "-" for 17 plants and "+" for three, and concludes that the foreign *lac* gene is expressed in only three plants.

* Reprinted with permission from Research Ethics: Cases & Materials, edited by Robin Levin Penslar. Indiana University Press, 1995. Pp. 60-61.

Commentary One: Jim Miller, Ph.D and Dan Herms, Ph.D.

Our Reference Point

The foundation of scientific research is documenting, and accurately reporting precisely: 1) what was done, 2) how it was done, and 3) what outcomes were obtained. Interpretation of these *facts* is based upon the statistical and logical reasoning powers of the investigators writing manuscripts, peer reviewers, and editors regulating the final form of the resulting paper. Interpretations are necessarily influenced by the conceptual constructs of the time. Data sets from well designed and executed studies can remain highly

(Miller and Herms continued on page 4)

useful, even though the interpretations first accompanying them require revisions. Injecting false data into the literature is an egregious violation of the scientific code of ethics because, until corrected, they can mislead the work of others.

Furthermore, research that is notable, efficient, and explanatory at the level of cause and effect usually employs tests designed to unequivocally falsify or strongly support explicit predictions carefully deduced from defined alternative models (hypotheses) for a nontrivial phenomenon. Verifiability of outcomes is critical to research and requires use of sensitive and calibrated measuring devices used in conjunction with experimental designs allowing powerful statistical analyses. A full suite of controls is required both to calibrate data-collecting tools and to measure variation not due to treatments.

Deficiencies in Scientific Conduct

The Gary Grant ethical dilemma arises from a single experiment out of dozens that will be required for significant progress toward solving the puzzle of what factors are important for expression of a foreign gene in plants. Nevertheless, serious deficiencies in the approach of this team are evident from the start. Given the responses of team members at the data-sharing session, it appears that the forethought and planning for this research were woefully inadequate. Before the experiment was executed, team members should have collectively discussed alternative models for the phenomenon under study, as well as possible outcomes and their respective meanings. Explicit statements should have been agreed upon, *a priori*, for what evidence would be needed to prove: no effect (no *lac* RNA or protein) vs. transcription but not translation (*lac* RNA without protein) vs. transcription and translation (*lac* RNA and protein). The issue of detection thresholds for this given experiment should have been addressed by preliminary experiments and by a suite of positive and negative controls included in the contested experiment.

Despite inadequacies in proving transcription without translation, the experiment under review did prove that this particular construct of the *lac* gene can be expressed and yield the foreign protein in some transformed plants. Beginning the day he recorded the data in his notebook, Grant seems to have lost sight of this unequivocal major outcome. Given the stochastic nature of genetic transformations, it is not biologically significant whether protein expression occurred in precisely three or 10 of 20 plants. All team members seem to have gotten erroneously hung up on the three of 20 result. If the experiment were to be repeated, no one should expect exactly three protein-expressing plants out of 20 total plants.

Even by the standards of a decade ago when plant transformations were novel, this three of 20 result would likely be considered too preliminary for publication in a top journal. A top-notch research group would have repeated the experiment with variations, both to expand the sample size and to resolve the controversy about detection levels for transcription without translation. Ingalls' eagerness to publish a superficial rather than substantial study does not support a reputation of being "destined for greatness."

Allowing that a preliminary note on this research did make it into a journal, Hansen and Ingalls took a reasonable approach in presenting the data. By standards of today, a table having entries of "+" and "-" rather than means accompanied by some measure of variance gives readers a clear signal that the study is considered qualitative rather than quantitative. Thus, the conclusion that the *lac* gene was expressed only in three of 20 plants would probably speak only to strong expression.

A journal with high scientific standards would have demanded the authors document what was done, how it was done, and what data were obtained. In the current case, this should

have included showing pictures of the actual gels from which the interpretations were derived. A responsible journal would have figuratively enabled unbiased reviewers to peer over the shoulders of Grant, Ingalls, and Hansen. If a proper standard of completeness in reporting had been followed, knowledgeable readers could draw their own valid conclusions, even if the interpretations of these researchers and reviewers were in error.

Scientific Misconduct

When a research paper appears in a journal, readers assume that each author listed is in agreement with the content. By brushing aside his concerns and proceeding to publish without working out a compromise, Ingalls and Hansen technically violated Grant's professional rights. Viewed from Grant's individual perspective, the issue is significant and needs resolution. From the larger perspective of threat to science as a body of truth, this case is not very significant because the dispute was scientifically trivial.

As leader and senior scientist on this team, Hansen bears the bulk of responsibility for this professional misconduct that may have been damaging to Grant. Hansen, as major professor and mentor, should have protected his student's professional rights and refused to allow this paper to go to press without adjustments to gain Grant's approval. This should have been done even against the wishes of immature and pugnacious Ingalls. If administration were doing its job well, Hansen and/or Grant should have felt free to rally the support and authority of appropriate administrators in the unit. This could have been a teachable moment for Hansen, Grant, and particularly Ingalls to learn more about the critical importance of thoroughness in planning for and execution of their work, personal and team open-mindedness, interpersonal and communication skills, and appropriate standards for personal and professional conduct. Progress at this level addresses the root of the problem rather than the inevitable symptoms.

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Commentary Two: Fred Gifford, Ph.D.

There are good reasons to require, as a condition for authorship of a scientific paper, a significant participation both in developing the ideas and in writing. For one thing, it is misleading to list as an author someone who was not involved in these things; for another, adding more authors who have done smaller amounts of the work dilutes the accountability for results.

One can argue about exactly where to draw the lines concerning type and degree of contribution. But on a straightforward application of most any reasonable set of criteria to the present case, one would presumably judge that Grant should not be an author. After all, he did not contribute to the writing, did not even see the draft, and presumably disagrees with the interpretation and conclusions.

But of course this would not get at all that is important in this case, nor is it likely to be very fair. As is often true in dilemmas of this sort, there are deeper problems.

The dilemma here arose from a conflict between the people, resulting in a quick decision to dismiss Grant from the project. One has to make some assumptions about the details of the case, but the most natural interpretation is that Ingalls was unreasonable to get so upset upon having his interpretation questioned, and Hansen

(Gifford continued on page 6)

was unreasonable in merely siding with Ingalls and dismissing Grant, rather than doing more to try to resolve the conflict. As a result, Grant finds himself in a situation, apparently not substantially his own fault, where he does not meet the criteria for authorship, even though he had reasonably expected to. Hansen is then left with the problem of making some decision about authorship, a problem that has no good solution.

One lesson here is the need to look ahead, and, ideally, to set the terms of cooperation at the outset. This should include an understanding of the terms of authorship, but what is really relevant here is something more like an understanding of how disagreements will be settled.

Assuming that loss of authorship will have a significant effect on Grant's career, it is difficult to accept not giving it to him. It would not be fair to Grant that he bear this cost. Indeed, since Grant works in Hansen's lab, Hansen has a special responsibility for Grant's professional welfare, and so has a special reason not to allow Grant to be harmed in this way.

If there had been ways Hansen could have counseled him with respect to tact in his conversations with Ingalls, or in the proper interpretation of the experimental results, then he should have done so. But this time is past. (It might be useful to consider how the case might be different if in place of a graduate student, there was someone for whom Hansen didn't have this special mentoring responsibility.)

Nevertheless, the choice to grant authorship is disturbing, since it is misleading and also might suggest a lack of seriousness concerning authorship standards. Indeed, this is especially important for Hansen as mentor, who has an obligation to help his students learn to make judgments of this sort, and to instill into them proper practice.

But what is particularly disturbing is to see the story as one where relatively little if any communication takes place about this, which could indicate that the decision is made in a somewhat cavalier manner. One wonders whether authorship was given in large part to smooth things over, or to avoid confrontation or dispute. This increases the degree to which the action expresses the view that following authorship standards is not that important.

If there were other ways to compensate or help Grant out (perhaps by giving extra help to enable him to complete other projects), this might offer a way out. For this would enable Grant to at least get the generic thing that he loses here, professional credit, but without his having his name on a paper he doesn't agree with, and without going against the authorship standards. Unfortunately, it is not clear that the relationship between Grant and Hansen is such that this is likely to happen.

If authorship is to be granted, it is especially important that it be done openly and explicitly, asking Grant about it beforehand. As well as making sure Grant is willing to be an author -- given that he apparently disagrees with the conclusions -- this is important in relation to Hansen's mentoring responsibilities. Such a specific discussion about it could at least indicate that Hansen takes the issue seriously.

The situation could still turn out awkwardly -- especially if Hansen and Grant are less than completely successful at leveling with each other. Grant may "take the high road", saying that he doesn't think it would be right for him to be an author. Hansen (or we) might then wonder if Grant has done this because he genuinely doesn't want his name on a paper he disagrees with, or because he genuinely believes that one should not violate authorship standards, or because he is mad, or because he feels pressured to do so by being asked the question.

Fred Gifford is an Associate Professor of Philosophy at Michigan State University.

discussed for some time to come. In addition, the debate has now reached a point where a number of other important issues need to be addressed.

First, *how are we to assess the effectiveness of scientific-integrity programs?* In part, these programs were motivated by a concern that informal mentor-mentee discussions needed to be supplemented with other ways of conveying the importance of responsible research. As programs in scientific integrity have become more clearly defined, we are now in a better position to ask whether requiring junior researchers to participate in scientific integrity programs is in fact an effective supplement to the traditional approach. Furthermore, since universities have responded to the NIH mandate in a variety of different ways, we can also ask which of these approaches is most effective.

Related to the issue of assessing the effectiveness of scientific-integrity programs is the question, *who is best qualified to administer these programs?* There may be good reasons for thinking that working scientists should be the primary instructors in courses dealing with scientific integrity. There may also be good reasons for thinking that professional ethicists have an important role to play in these contexts. As particular methods of teaching scientific integrity are developed, the question of "outside" involvement needs to receive more attention.

Rich Sharp is a doctoral student in the Department of Philosophy, Michigan State University.

[1]NIH Guide for Grants and Contracts, vol.18, no. 45, December 22, 1989.
[2]NIH Guide for Grants and Contracts, vol.15, July 18, 1986.

Announcements

"Futility and Hospital Policy," by Tom Tomlinson and Diane Czlonka will appear in the May-June issue of the Hastings Center Report (not in the March-April issue as previously reported).

Judith Andre chaired a session of the Central Conference on Teaching Philosophy at the Central Division Meeting of the American Philosophical Association. Professor Andre is incoming president of the Central Conference on Teaching Philosophy.

Howard Brody will give the 9th Annual Peter T. Bohan Lecture, "Healer's Power: Why Medical Ethics Must Talk About Power," at the University of Kansas Medical Center, Kansas City, KS, May 5.

Tom Tomlinson will speak on "Ethical Issues in Cancer Control Programs" at the CDC-sponsored National Cancer Prevention and Control Conference in Atlanta, May 17.

Howard Brody will speak on "Physician Assisted Suicide and Euthanasia: The Debate Continues," for the International Hospice Institute, Vancouver, BC, July 14.

A Cuban physician has requested our help. He has founded a bioethics center at a pediatrics teaching hospital, and would appreciate books and articles that we might send him. If you have any to donate, send them to Jan Holmes at the Center for Ethics and the Humanities in the Life Sciences, and we will mail them to him.

Coming Events

The Center for Ethics and Humanities is an academic unit whose faculty teach, write, and consult about bioethics and the other medical humanities. Staff members frequently conduct public discussions about a variety of such topics and we encourage our readers to attend and participate in these forums.

Thursday through Saturday, June 22-24: Medical Ethics for the '90's: An Intensive Skill Building Workshop. Fifth Annual Summer Ethics Conference. The keynote speaker will be Professor Thomas Murray, Center for Biomedical Ethics, Case Western Reserve University. This workshop is designed for individuals who serve or expect to be serving as members of institutional ethics committees. Kellogg Center, East Lansing, MI. For conference details contact the Office of Continuing Medical Education, A-118 East Fee Hall, College of Medicine, East Lansing, MI 48824-1316, (517) 353-4876.

Sunday, June 25: Advanced Summer Bioethics Workshop: Ethical Issues in Managed Care. Workshop faculty are Howard Brody, M.D., Ph.D., Leonard Weber, Ph.D., Leonard Fleck, Ph.D., Judith Andre, Ph.D., and Susan Goold, M.D., MSA. Kellogg Center, East Lansing, MI. For conference details contact the Office of Continuing Medical Education, A-118 East Fee Hall, College of Medicine, East Lansing, MI 48824-1316, (517) 353-4876.

September Williams, MD, will teach a course called "Movies and Medicine" next Fall. Dr. Williams is a primary and emergency care physician as well as a scholar and producer of film. She will be a Visiting Minority Scholar in the College of Arts and Letters, and in the College of Communication Arts and Sciences. The course, TC491, will meet on Fridays from 11:00-2:00.

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