COMMENTS

Introduction: Forum on Responsible Conduct in Biomedical Research (44535A)

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The original impetus for convening this symposium was based on the premise that the majority of professional laboratory scientists are unenlightened, confused, and at times embarrassed at the revelations and counter-revelations, concerning the research culture, that have been a focus of attention in the media during the past 2 decades. Therefore, we sought to have the major players in this arena articulate current definitions of ethical problems in the research enterprise, the semantic circumlocutions that have arisen, and the perceived allocation of responsibilities in the ensuing interface between academic research institutions, sponsoring agencies, the Federal Government, and the legal profession. Apart from the high profile cases, which have been examined exhaustively and to which much attention has been devoted, the actual dimensions of a pervasive problem remain inadequately documented. Proposed solutions to probity issues have included data audits, independent review boards, an oversight government agency, a 1% levy on federal research funds to support the effort, more vigilant measures enacted by the publishing industry, and other suggestions.

One pragmatic outcome has been the mandate by government research funding bodies for serious ethical training and discursive exposure to relevant topics for graduate students and fellows during their apprenticeship. It is also pertinent to note that the coalition of groups and the various alliances interested in promoting biomedical research funding have engendered remarkable support in recent years for substantially enhanced funding appropriations from the U.S. Congress. However, this successful and continuing accomplishment has not been achieved without the emergence of opposition from other societal sectors seeking a portion of the budget surplus. Therefore, it is eminently understandable that biomedical professional societies and their membership have been somewhat reluctant to engage vigorously in intramural debate on these issues. The Society for Experimental Biology and Medicine is to be congratulated for the provision of this sphere to commence just such a colloquy.

In the following series of articles the authors elaborate on the basic tenets inherent in the discipline of ethics, an historical appraisal of this particular subject, generic themes, and the current role and interest domains of scientific societies and the Federal government.

Dr. Adil Shamoo, Editor-in-Chief of the first journal addressing these topics, *Accountability in Research*, focuses on the remarkable development and expansion of the research enterprise in the second half of this century and the impact this fact has had on national economic well-being. He emphasizes that corrective measures need to include education, institutional policy reform, and the posting of clear boundaries of normative behavior for individual investigators. With the recent advent of multisite, national, global, and international research projects and the consequent multiplicity of authorship, the possibilities of disconnect between origination of the data and effective stewardship of all aspects of research performance is also considerably augmented. Despite fears of chilling effects on the principle of freedom of inquiry, he strongly advocates the evolution of a self-monitoring system by practicing scientists as a more effective mechanism for the restoration of public confidence in research expenditures when compared with bureaucratic or legal forms of redress.

Dr. Marcel LaFollette, an ethicist and philosopher with a long-standing interest in scientific fraud, plagiarism, and public perceptions of scientific activity directs her attention to the political and cultural milieu in which these events have unfolded. It is becoming accepted that a major motivational drive for many people in choosing a scientific profession is not the economic emoluments that may, but are not likely to accrue, but the psychic income in the form of "credits" for professional attention, citations, and intellectual influence in a particular field. It is not coincidental that the rise in public interest in the integrity associated with research conduct has occurred during a period of enhanced

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sensitivity to ethical behavior in all facets of human endeavor (e.g., politics, religion). Despite the glare of the Congressional spotlight, the biomedical research community continues to assert that effective self-policing could be established in academia and by extended publishing policies relating to authorship, peer review, editorial scrutiny, and sanctions. She also compares and contrasts the alternative surveillance routes initiated and undertaken by the major sponsoring agencies, the National Institutes of Health and the National Science Foundation. She concludes that a more prompt and concerted response by the scientific societies themselves could have averted the cumbersome, controversial, and ineffective regulatory machinery that has been invoked.

Dr. Mark Frankel is the Director of the Scientific Freedom, Responsibility, and Law Program established by The American Association for the Advancement of Science, and he explores the topic of scientific societies as sentinels of responsible conduct. His major thesis is that members of the scientific profession should reexamine their reaction to allegations of misconduct. Instead of a denial, ostrich-like stance, or adoption of inappropriate punitive courses of action, a proactive ethical climate should be actively fostered at all levels. Professional societies provide an important sense of identity to individual scientists in different fields who choose to apply and belong, and the value system and traditions these societies embody define the essence of professionalism. What constitutes acceptable practice and behavioral mores in the diverse spectrum of laboratory benchwork awaits the promulgation of clear, coherent, consensual standards of operation. Such ethical precepts would need to be reviewed constantly, and interpreted as a component of continuing dialogue in the evolution of a body of "case law" documentation and guidance. An original and extremely cogent observation in this contribution is that no scientific society in this country has, as yet, inaugurated a protective supportive mechanism for those of its members who conscientiously report serious misdeeds.

Chris B. Pascal, Acting Director, Office of Research Integrity (ORI), U.S. Department of Health and Human Services, recounts the origins of that office, its mission, and mode of operation, and provides clear guidelines for bench scientists on achieving good scientific practice. In 1992 ORI was created by the coalescence of two previous entities and is located in the Secretary's office of the Public Health and Science. The responsibilities are broad and diverse and range from the scrutiny and amplification of policies and regulations governing scientific misconduct and the oversight of procedures within research institutions, to the internal pursuit of allegations of violations. The definition of scientific misconduct adopted (and not without controversy) in 1989 includes the words fabrication, falsification, plagiarism, "or other practices that seriously deviate from those that are commonly accepted within the scientific community." The phraseology emphasized above has provoked contention in that "commonly accepted practices" have yet to be usefully elucidated. ORI therefore has principally confined its findings of misconduct to those involving fabrication, falsification, or plagiarism. Inevitably, and, perhaps inappropriately in some cases, technical legal precepts such as preponderance of evidence and burden of proof issues have clouded the investigations. The approach developed by the National Science Foundation is considerably more expansive and includes deportment considered to be debasement of the integrity of the research process. In other activities related to education, in 1999 the NIH initiated several new granting programs (e.g., A Mentored Scientist Development Award in Research Ethics and the creation of short-term courses in research ethics). When findings of ORI misconduct are established, sanctions are imposed. These may include debarment from research sources for several years and public retraction of the published material. ORI also strives to promote research integrity by raising consciousness of these issues through collaborative workshops and conferences with academic and research institutions. It is also oriented toward mapping the elusive "standard practices" matter and creating novel methodology for the resolution of integrity disputes.

In summary, the reflections and experiential chronicles of these authors, representing different facets of the concepts and customs relevant to research integrity, attest to the emerging importance of these issues to the future health of the American research enterprise. It is debatable whether or not teaching ethics in a classroom setting will foster the type of lifelong practice of science that is desirable. But the medical and legal professions have developed elaborate codes concerning ethical conduct at the state and national levels. Compared with 50 or 100 years ago, the pursuit of science as a career has evolved into a cooperative, collaborative undertaking, increasingly interdisciplinary in its execution. Accordingly, there is an urgent need to enunciate and integrate code concepts into the warp and woof of the research cultural fabric.

Major policy changes were announced following the symposium, which would create a common Federal definition of research misconduct and would apply not only to the Public Health Service and the National Science Foundation, but also to a large number of other Federal agencies supporting or conducting research. This proposed new definition is limited to "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results" and would drop the "other serious deviation" clause included in the PHS and NSF definitions. Public comments on the proposed definition are currently being considered by the Office of Science and Technology Policy prior to issuance of a final Federal definition and policy on research misconduct. A new PHS policy is also being developed to expand required education in the responsible conduct of research to all research staff who receive PHS funds for research or research training. This policy is consistent with prior recommendations of the Commission on Research Integrity. These policy changes and others are discussed in Pascal's article.