Whistleblowing in Biomedical Research

Policies and Procedures for Responding to Reports of Misconduct

Proceedings of a Workshop

President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research

American Association for the Advancement of Science, Committee on Scientific Freedom and Responsibility

Medicine in the Public Interest

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September 21-22, 1981
Edited by Judith P. Swazey and Stephen R. Scher

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Preface

The purpose of this two-day workshop was to examine the response of research institutions and federal agencies to reports of fraud or misconduct in federally supported biomedical research and to develop suggestions for improving such responses in the future. Incomplete or inaccurate research data, as well as violations of applicable regulations, may pose serious risks to research subjects. In addition, fraud in research may place future patients at risk if decisions to adopt or abandon a particular therapy are based upon incomplete or inaccurate data. More fundamentally, of course, fraud in research deeply affects the structure and conduct of science. Scientists may waste years of work building on false leads, and the scientific enterprise as a whole may lose the confidence and support of the general public.

Each of the groups sponsoring the workshop is committed to maintaining the integrity of biomedical research through a delicate balance of informal and formal systems of control. This balance should foster creative research while maintaining individual accountability for the accuracy of scientific work — and safeguarding the rights and welfare of human subjects. The challenge is in determining how to accomplish these objectives in the context of large research institutions and complex government bureaucracies.

The rights and responsibilities of several parties must be recognized and dealt with in the face of competing interests. Individuals who report or "blow the whistle" on the wrongdoing by their colleagues or superiors may face retaliatory actions by their employers or superiors in the academic hierarchy; they may also encounter difficulties in having their charges taken seriously. Individuals accused of misconduct may believe the allegations to be spurious and may deeply resent disruption of their research during the conduct of an investigation. The federal agencies that disburse public monies to support the research have an obligation to protect the public's interests. These agencies also have an obligation to protect persons who report serious abuses, on the one hand, and not to overreact to unsubstantiated charges, on the other.

How can whistleblowers, scientists accused of misconduct, human subjects, and the public interest best be protected? We believe that an informed discussion will assist both the federal government and the research community in developing policies and procedures for responding to the problem. This volume of workshop papers, commentaries, and summaries of discussion sessions has been prepared to encourage such a discussion.

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President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research

The commission was established by Public Law 95-622 and held its first meeting on January 15, 1980. It is authorized through the end of 1982. Its work continues and expands upon the work of predecessor bodies, such as the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

In response to part of its statutory mandate, the Commission issued a report in December 1981, *Protecting Human Subjects*, on the adequacy and uniformity of Federal rules for the protection of human subjects and on the adequacy of their actual implementation. The Commission's sponsorship of the Workshop on Whistleblowing was part of its inquiry into present practices for responding to reports of misconduct in Federally supported research. Most of the suggestions coming out of the workshop were adopted by the Commission as formal recommendations for improving both institutional and agency responses to such reports. The Report was submitted to the President, the Congress, and each Federal agency to which its recommendations applied.

The Commission

Medicine in the Public Interest, Inc.

Medicine in the Public Interest (MIPI) is a nonprofit organization involved in research and education relating to medicine, science, and society in the United States. Chartered in 1973, MIPI's central purpose is to provide a forum for conducting and disseminating independent, objective studies at the federal, state, or local level that will help to inform the general public and to aid the work of policymakers and those in the health care professions.

MIPI's cosponsorship of the Workshop on Whistleblowing in Biomedical Research grew out of and was partially supported by its Project on Social Controls and the Medical Profession. Funded by a grant from the National Science Foundation and the National Endowment for the Humanities (No. OSS-8016832) this two-year project is concerned with processes of self-governance within the medical profession and attempts to control medical practice through laws and regulations.

The Committee on Scientific Freedom and Responsibility
American Association for the Advancement of Science

The Committee on Scientific Freedom and Responsibility is a joint committee of the AAAS Board and Council. The committee was created in 1976 both to develop policies and procedures to foster scientific freedom and responsibility and to maintain an awareness of actions by U.S. and foreign governments and other groups that restrict the professional activities of scientists and engineers.

The committee works with the affiliated societies of AAAS to examine not only individual cases of infringements of scientific freedom and responsibility, but broad issues of ethical concern in the development and use of scientific and technical knowledge as well. The committee highlights particular problems related to the professional rights and duties of scientists and engineers and, where appropriate, will suggest ways in which these problems can be resolved.

Topics of current concern to the committee include the rights of scientists to disclose important information involving public health and safety concerns (the whistleblowing issue), the effect of national security policies upon the flow of scientific and technical data, and the effect of human rights violations upon the work of foreign scientists.

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The Institutional Context of IRBs

I

Chapter 1

THINKING ABOUT INSTITUTIONAL REVIEW BOARDS

Jerry L. Mashaw

Introduction

I have been asked to examine the Institutional Review Board (IRB) from an administrative agency perspective and to assess the adequacy of current rules and regulations to achieve the results intended. I have not been asked, nor have I attempted, to review all the literature on the structure and operation of IRBs or to do any empirical research on the actual functioning of IRBs in their various contexts. The task, instead, is to provide an analysis of IRBs based on my familiarity with a wide range of agencies that have divergent structures and authorities. I have been tempted to entitle the paper "IRBs: Reflections of a Man from Mars." But I did not want to have the reader abandon hope at the outset that my observations may be of some earthly significance.

The principle purpose of the paper is thus to provide a broader institutional and organizational context within which to evaluate IRB structures and functions. For ultimately this broadened perspective should assist attempts to answer questions such as: "What should we expect from IRBs?"; "What aspects of their structure are likely to impair the achievement of their stated goals?"; and "How can the IRB process be restructured to satisfy a realistic set of expectations and demands?"

The Problematics of the Institutional Review Board

The IRB is obviously a good idea. That we should embed in the increasingly bureaucratic structure of behavioral and biomedical research an institution preeminently concerned with the protection of human subjects is intuitively attractive. But it seems to me predictable that such an institution will fall prey to just the sorts of criticisms that have beset institutional review boards. The IRB will be found to be both an impediment to science and an inadequate protection for human subjects. I say that this will occur predictably because the IRB raises an astonishing number of almost intractable value conflicts. It is the institutional embodiment of compromises among ideals that we hold simultaneously. The uncompromising -- indeed, not only the uncompromising -- critic will often find the IRB's behavior inadequate. Moreover, it is not only a conflict over values or ideals that renders the IRB, as an institution, problematic. There is also the possibility for endless dispute about the predicted effects of the multiplicity of structural, substantive, and procedural alternatives

that might be built into the IRB system in order to implement its multiple and conflicting goals.

I want to discuss these problematic aspects of the IRB under three general headings. The first involves what I will call the "community-versus-society" problem. The second has to do with a necessary compromise among ideals for legitimate public decisionmaking. The third concerns the indeterminateness of various legal and institutional techniques for implementing a regulatory regime of the type that IRBs have in their charge.

The Community-Versus-Society Problem

The general policy of protecting human subjects, both in terms of the consent mechanism and the general social welfare calculation (risk-benefit) that constrains all research submitted through IRBs, expresses broad societal concerns. These concerns are, of course, embodied in national statutes and the regulations of several national administrative agencies. They also represent an international consensus. It may therefore appear strange to have this set of policies administered primarily by boards that are drawn from three overlapping communities: the professional scientific community, the community of beneficiary institutions (largely universities and medical schools), and localities. Why should a federal program expressing national and international social concerns be administered by persons whose primary identification is with specialized or geographically localized communities? Might not the interests and incentives of these special communities interfere with, perhaps wholly subvert, the national standards?

Indeed they might. But the question of who should administer is rather complicated. There are many reasons, some good and some not so good, why federal programs may come to be administered by agencies that are local or made up of either the beneficiaries of federal largesse or the professions that are the object of regulation.

"Localness." Local control of administration is, in fact, the norm in federal programs. Utilization of local boards, commissions, or bureaus responds both to a general American preference for decentralized authority and to a host of particular rationales. Local administration may be preferred, as in the case of local draft boards, because the decisions are so poignant that they are acceptable only if made by persons of recognized status and close association with the local community. Or it may be, as in the Community Action or Model Cities programs, that federal action is primarily "in aid of" the accomplishment of local desires. Indeed, this rationale undergirds a mass of federal programs subsidizing the activities of states and localities in areas such as public works, public education, health care, and social welfare. Even a program having the national significance of the Social Security Disability Program is administered by state officials (state vocational rehabilitation agencies) because of the historically close connection between the national purpose of income support for the disabled and local knowledge of job markets and medical and rehabilitation services.

There are, of course, some nefarious purposes behind local administration as well. The use of local and state personnel may be a device for expanding federal influence without expanding the size of the federal bureaucracy. (One might be tempted to characterize state administration of federal environmental, health, and safety regulation in this fashion.) "Local control" also has a history as a code phrase for opposition to civil rights, which suggests that when federal programs are administered locally,

the realities of politics have yet again interposed themselves between our national ideals and their effective implementation. Nevertheless, it seems perfectly clear that local administration can be readily justified on grounds that (1) legitimacy is aided by familiarity; (2) responsiveness to local preferences and desires is often an important part of a national program; and (3) local personnel will, because of their knowledge and associations, sometimes be more expert at implementing the national program than would persons having a primarily federal allegiance.

All of these justifications seem applicable to IRBs. The legitimacy of local IRB decisionmaking is supported by the consent of both researchers and patients who put their careers and their treatment, respectively, in the hands of the local institution that establishes the IRB. The point cannot be pressed too far; the consent is sometimes oblique and all "subjects" are not "patients." Nevertheless, a board attached to a recognizable, and usually high status, local institution may be the most acceptable organ for making the types of judgments submitted to IRBs. In judging legitimacy, as in evaluating other dimensions of IRB structure and functioning, a choice need not be perfect to dominate the available alternatives.

It also seems clear that on many research issues there is no significant national interest in overriding local preferences or mores. Indeed, some aspects of local or institutional morality affecting research are clearly religious in nature and are entitled to respect as an aspect of American constitutionalism. Perhaps more importantly, ethical review at the local level recognizes the intractable ambiguity of many value questions and reinforces the traditional liberal commitment both to pluralism and to individual moral responsibility.

Finally, local administration recognizes what organization theorists sometimes call "information impactedness." Some information is closely tied to particular persons or organizations. It is difficult to retrieve and utilize effectively from outside. A general "feel" for community norms is certainly such a complex bit of information. But this is also true of information more directly related to research protocols. The members of a local IRB may collectively possess an enormous amount of information -- concerning researchers, laboratories, and the efficacy of quality review and audit procedures -- that will guide their exercise of discretion in approving, modifying, or disapproving research designs. Giving outsiders, persons at FDA, NIH, or the like, a similar grasp of local contexts would be possible only by transforming them into insiders -- that is, "locals."

Beneficiaries and Professionals as Regulators. The rationales for beneficiary or professional self-regulation are often very similar to those that underlie a delegation to local agencies or boards. And like local administrators of federal programs, the beneficiary or professional administrative organ has been criticized for serving the narrow interests of the primary beneficiary class (or of the profession) at the expense of the persons meant to be the ultimate beneficiaries of federal policy. This pervasive claim has, in the past fifteen years, unleashed an avalanche of litigation concerning programs such as Aid To Families With Dependent Children (AFDC), the Hill-Burton Hospital Program, the Food Stamp Program, Model Cities, the federal highway program, various federal housing programs, and other beneficiary-administered programs. There is also the rather common belief, particularly among certain economists, that professional self-regulation has but one objective -- cartelization.

The situation with respect to IRBs is surely not so straightforward. First, in the IRB structure the potential parochialism of "local" interests is

balanced by association with broader perspectives of the beneficiary institutions and research professionals; while research hospitals, universities, medical professionals, and other researchers are attached to particular localities, they are also attached to broader professional and institutional communities and to the highly cosmopolitan world of science. Second, the general reasons that were previously discussed for committing the administration of federal norms to local organizations also obviously support the involvement of institutional beneficiaries and regulated professionals in IRB judgments.

Moreover, there is reason to doubt the insularity or interpositionist posture of such organizations when compared with agencies of a nonbeneficiary, nonprofessional character. It seems unlikely that persons holding views highly antithetical to the federal regulations that are to be administered would gravitate to or remain in positions of power within the IRBs. Examples of such persons can, of course, be found. But it seems peculiar to imagine that many people would make a career of systematically undermining the application of the program with which they are involved. Open opposition invites removal, and covert subversion is difficult to maintain while retaining one's own self-esteem.

There is even some evidence in other contexts that self-regulators may "overregulate" by comparison with external regulators. Classic examples may be cited in the television industry and in the regulations of the National Association of Securities Dealers. Many will recall the now defunct network experiment with censorship in the interest of producing prime-time viewing all of which was suitable for family audiences; this regulatory approach was foreclosed to the FCC by the First Amendment. Less familiar are NASC regulations making brokers responsible for policing the "suitability" of their customers' investments; these requirements go well beyond the Securities and Exchange Commission's apparent statutory authority to regulate broker-dealer activity.

This "overregulation" may stem from the fear of external control, "bending over backwards" to avoid the appearance of impropriety. Or it may simply coincide with the cartelization objectives of the regulator. In either case, such overregulation may nevertheless be highly protective of the ultimate beneficiary class. Researchers want to get on with their research. They also want to work within a structure that protects them, that makes their activities defensible in the face of inevitable challenge. Self-regulation to protect the subject is not incompatible with self-regulation to protect the researcher.

It must also be recognized that the appropriateness of a local, beneficiary, or professional regulator must be judged by comparison with relevant alternatives. There is, to be sure, some difference between being a federal official and being a state or local official or a private individual. Nevertheless, it should be remembered that federal agencies must recruit their personnel primarily from the local area within which a program is to be administered. And to the extent that either professional training and experience or connectedness with other local agencies or groups is important to competence at the regulatory task, those personnel will also have prior attachments to beneficiary or professional communities. In short, if IRBs were federal agencies, their personnel would closely resemble those who currently sit on IRBs.

Finally, one major argument for the "self-regulator" is precisely that he or she is not a professional regulator. Self-regulation may provide a solution to well-known failings of continuing bureaucracies --tunnel vision, self-aggrandizement, and rigidity. Thus, while local, beneficiary, and professional control of the implementation of broad societal goals must

always appear problematic, the problems produced may be less threatening to successful administration than the problems generated by alternative forms of organization.

The "Ideal" IRB

While the question of local, professional, and institutional versus centralized review of the ethics of human subjects research produces a sense of stress in relation to IRBs, the tensions are deeper still; there is the more fundamental question of what we want this monitor of research ethics to be like. When we think of the IRB, are we thinking of an efficient bureaucrat, a paternalistic therapist, a wise judge, or perhaps an astute politician? Do we want all of these? Is that possible in one agency? But the questions are coming too thick and fast. Let me back up to explain both what these various types of models of IRBs might be like and why each has some hold on our imagination.

I begin by assuming that we (and by "we" I mean society) would view a decision by a willing researcher and a willing human subject of that research to engage in some cooperative project as wholly legitimate. That is, I adopt the fundamental presupposition of liberalism that individual autonomy, including consensual collective activity, is desirable and should be protected. We might, of course, be concerned should cooperative behavior negatively affect others, and we might therefore be willing to engage in some regulation of the proposed activity on that basis. But such negative externalities seem not to be an important reason for constituting IRBs.

The primary purpose of IRBs is to protect the subject. For reasons that need not trouble us now, we have rejected sole reliance on legitimation by consent. Or, more accurately, we have found that consent in this context requires support from two directions, namely, (1) by strengthening the consent mechanism itself and (2) by "bounding" the possible arena of consent so that failures of the consent process will not be too distressing. The question then arises: Who is to make the judgment about what consent process to have and what boundaries to put on research involving "consenting" human subjects? In particular, what sort of implementing or administrative organism should make judgments related to those two issues?

What I want to suggest is that there are several legitimate or acceptable forms of decisionmaking that might provide the model for this decisionmaker, a decisionmaker now constituted as the IRB. These models of administrative decisionmaking are "ideal types" in the Weberian sense. They represent coherent conceptual formulations which are, for one reason or another, never quite realized in the real world. Nevertheless, they tell us what we should really like to achieve if we could do so. The problem with these models in relation to the IRB (and most other implementing agencies) is that while they are all attractive, they cannot be realized simultaneously. Indeed, they are quite competitive. When an institutional structure, such as the IRB, adopts portions of all of them, it has necessarily set the stage for institutional stress and for external criticism.

This is not to say, let me hasten to add, that the compromise is wrong-headed. It may indeed be the best decision process that can be constructed, given society's desire to embrace the underlying values of all of the models simultaneously. The point is merely that the best system of administrative decisionmaking that can be devised may fall poignantly short of our conflicting ideals.

I have developed several models of administration that seem generally applicable to the question of how to design public administrative institutions. I call them "the model of bureaucratic rationality," "the model of professional treatment," "the model of moral judgment," and "the model of micro-political accommodation." The models correspond to the more anthropomorphic conceptions of the efficient bureaucrat, the paternalistic therapist, the wise judge, and the astute politician. The four model decisional systems would respectively employ those kinds of decisionmakers. Let me first describe the attributes of the models and some real world approximations of each. I will then discuss their applications to the questions that IRBs confront.

Bureaucratic Rationality. A bureaucratically rational system must begin with specified goals. It assumes that there is some prior articulation of values through an otherwise legitimate political process. In the case of public bureaus this means legislation. Charters stating the purposes, structure, and procedures of the new entity serve a similar function in private bureaus (profit and nonprofit corporations and the like). The special claim to legitimacy of bureaucratic activity is that it accurately implements the values or goals previously specified for the bureau and that it does so at the least possible cost. In this model the bureau's dominant values are accuracy and efficiency. The idea is to minimize the sum of error costs and administrative costs.

The decision structure of a bureaucratically rational agency is almost always hierarchical. Decisions are delegated through various levels of supervisory control, and constant monitoring carried out to ensure that lower level decisions are both accurate and efficient. Because values or goals have already been specified, the bureaucratic process is almost exclusively fact oriented. The function of the agency is to implement the program by making correct or appropriate judgments about how real world behavior will either advance or retard the implementation of those goals.

A motor vehicle safety inspection bureau might exemplify a bureaucratically rational agency. The goal is to keep unsafe vehicles off the road. The bureau may be directed to define "unsafe vehicle" in terms of objective mechanical or physical characteristics. Each inspection decision then matches these characteristics to a particular vehicle and approves or disapproves the vehicle's continued operation. The bureau's infrastructure seeks to make the inspection decisions accurately and to contain costs. The bureau may define costs as direct administrative or budgetary costs or may include such items as the motorist's time and convenience. The bureau may even seek to calibrate its efforts to match inspection costs and accident prevention gains at the margin.

Professional Treatment. The professional treatment model for legitimating decisions relies heavily on the idea of fiduciariness combined with knowledge. The legitimate professional decision is one which brings to bear the appropriate professional knowledge in the context of a single-minded devotion to the client's interest.

At its core the goal of professional activity is to serve the individual client. This goal is perhaps most obvious in medicine, but it is also the defining characteristic of law, the ministry, and the newer professions such as social work. Although one might view the medical profession, for example, as principally oriented toward science and therefore toward knowledge, to do so would be a fundamental mistake. The scientific aspect of medicine, its disease and pathology constructs, is generated more fundamentally by the physician's attempts to treat biological and psychological dysfunction. The physician is committed, however, to treat even those patients whose symptoms cannot be explained by those constructs. The

value the profession serves is the amelioration of the patient's discomfort or disabilities. The objective is to use science to produce a benefit as defined by the patient in consultation with his physician. Achieving this goal thus involves interpersonal and diagnostic intuition -- clinical intelligence -- as well as scientific knowledge. An administrative system for decisionmaking based on a professional treatment model would therefore be patient oriented. It would seek to provide those services a client needs to improve his or her well-being.

Professional treatment is, of course, constrained by costs; the professional must tailor treatment to his and the client's resources. Some clients may be rejected or given less in order that others who are needier may be helped more. The professional views these constraints in terms of the allocation of services among clients, not as trade-offs between professional services and other social values. Unlike the bureaucrat in the bureaucratically rational system, the professional does not attempt to economize on society's overall resources.

Like the bureaucratic rationality model, the professional treatment model also requires the collection of information that is then manipulated in accordance with standarized procedures. The professional treatment model recognizes, however, the incompleteness of facts, the distinctiveness of the client's problems, and ultimately the intuitive nature of judgment. Decisions are not attempts to establish the truth or falsity of some state of the world, but rather prognoses both of the likely effects of some pathology and of the therapeutic value of alternative treatment modalities.

The basic techniques of professional treatment are personal examination and counseling. There is some specialization of functions, of course, but the final judgment of what is to be done is holistic. The professional combines the information of others with his own observations and experience to reach conclusions that are as much art as science. Moreover, the judgment is always subject to revision as conditions change or as attempted therapy proves unsatisfactory or miraculously successful. The application of clinical judgment thus entails a continuing relationship with the client and may involve repeated instances of service-oriented decisionmaking.

An administrative system based on professional treatment would thus have different characteristics than a system supporting bureaucratic rationality. The basic idea would be to use the appropriate profession for the problem at hand. Because these allocational decisions, which involve assessments of need or ability to help, are themselves professional judgments, they would be made best by the relevant professionals in conjunction with clients. Therefore, the administrative structure need merely funnel claimant-clients to multi-professional centers for examination and counseling. Substantive and procedural rules, hierarchical controls, and efficiency considerations would all be subordinated to the norms of the professional culture.

Public hospitals and legal services agencies are examples of the professional treatment model in operation. The professional treatment features of public hospitals, legal services programs, and the like are of course somewhat attenuated. The content of the service ideal, in particular the willingness of professionals in these agencies to consider interests beyond the treatment or counseling of a particular claimant or client, will have a different emphasis than in private professional practice and will vary from institution to institution. But the core of the professional model remains. The dominance of the service ideal and of professional-client relations is visible in the autonomy of the individual lawyer or doctor once the physician-patient or lawyer-client relationship is established. An administrative superstructure may determine the total resources available for treatment,

counseling, or litigation, but the use of these resources is governed by professional judgments that respond to a culture and training acquired independently of the agency and of the agency's mission. The professional defines and legitimates the actions of the agency, rather than the other way around.

Moral Judgment. The traditional goal of the adjudicatory process is to resolve disputes about the allocation of benefits and burdens. The paradigm adjudicatory situations are those of civil and criminal trials. In civil trials the contest generally concerns competing claims to property or competing claims about the rights and responsibilities of the litigants. Property claims such as "It has been in my family for generations" confront counterclaims such as "I have made productive use of it." "The smell of your turkey farm is driving me mad" confronts "I was here first." The goal in individual adjudications is to decide who deserves what or who may do what.

To some degree these traditional notions of justice imply that adjudication or administrative decisionmaking in this mode merely involves ascertaining the facts and applying existing legal rules to those facts. So conceived, the goal of a moral judgment model of legitimacy appears the same as that of a bureaucratic rationality model -- factually correct applications of previously validated norms. But this is an incomplete view. Whereas the bureaucratic rationality model views decisionmaking as the implementation of previously determined values, the moral judgment model views decisionmaking as value defining. The turkey farmer's neighbor makes a valid appeal not to be burdened by the smell, provided that his conduct in locating nearby is reasonable and that he is not being overly sensitive. The turkey farmer has a valid claim to carry on a legitimate business, provided he does not unreasonably burden his neighbors. The question is not just who did what, but who is to be preferred when specific interests -- and the values to which they are connected -- conflict. Similarly, the criminal trial seeks to establish not just whether a harmful and proscribed act took place, but also whether and to what extent the actor was culpable.

The entitlement-awarding goal of the moral judgment model gives a distinctive cast to basic issues of decisionmaking: the deservedness of the parties in the context of the events, transactions, or relationships that give rise to a dispute. The focus on deservedness implies certain things about a just process of proof and decision. For example, fair disposition of charges of culpability or lack of deservedness requires that claims be specifically stated and that any affected party be given an opportunity to rebut or explain. In order for the exploration of individual deservedness to be meaningful, the decisionmaker must be neutral, that is, not previously connected with the relevant parties or events in ways that would bias judgment.

Moreover, given the generally threatening nature of an inquiry into moral deservedness, the parties should be able to exclude from the adjudication all information not directly related to the specific entitlement at issue. This power of exclusion may take the form of evidentiary rules or notions of standing and, more importantly, may permit the parties to remove their dispute entirely from the system by abandoning their claims or coming to some mutually satisfactory agreement on the relevant allocation. The goal of the model is to resolve particular entitlement claims in a way that fairly allocates benefits and burdens, not to make a general allocation of benefits and burdens. The decisionmaker is thus usually passive. The parties determine both how much of their lives or relationships to put in issue and what factual and normative arguments to bring to bear on the resolution of the dispute.

Although these traditional examples of entitlements-oriented, individualized adjudication involve an adversary process, adversariness is not critical. Claims to publicly provided benefits by nonadversary hearing processes may also conform to this model. Indeed, the Supreme Court has come very close to stating that such processes must involve a traditional oral hearing if substantive standards are so open-textured that each decision both defines the nature of the entitlement and awards or denies it to a particular party.

The goals of the moral judgment model may suggest additional decisional techniques and routines designed to preserve party equality and party control of the dispute, to promote settlement, and to protect the authority of the decisionmaker. These details need not detain us here; the important point is that this model's claim to legitimacy inheres in its promise of a full and equal opportunity to obtain one's entitlements. Its authority rests on the neutral application of commonly held moral principles within the context giving rise to entitlements claims.

Examples of the moral judgment model in the domain of administrative law and organization are numerous. Classic examples at the federal level include the Federal Trade Commission and the National Labor Relations Board. The Federal Trade Commission is charged with determining, primarily by an adjudicatory process, whether organizations have engaged in "unfair or deceptive acts or practices" in commerce. The National Labor Relations Board is broadly charged with preventing "unfair labor practices." Although the Federal Trade Commission has some authority to adopt regulations, it has acted primarily by a formal adjudicatory process. And the National Labor Relations Board is the preeminent example (under federal administrative law) of an agency that has developed its statutory mandate exclusively through case by case adjudication. Obviously, what is "unfair" or "deceptive" is highly dependent upon context. And in the broadest sense, the question to be answered is how the parties involved in a particular context "ought" to be treated.

Micro-Political Accommodation. The model of micro-political accommodation is policy oriented. It recognizes that the decision to be made is one which combines issues of fact and value. Moreover, unlike the moral judgment model, the questions to be addressed and decided relate to more than one or a few parties. The issues are polycentric or multi-faceted. A large number of individuals and organizations may therefore have both stakes in the outcome and different perspectives on the appropriateness of the policy. This model recognizes that decisionmaking involves pluralistic politics removed from the macro-political (legislative voting) level to the micro-political or bureaucratic level.

Moreover, the bureaucracy in this model does not engage in tasks that are merely implementing. The search is not for the "right" answer (given the specified goals of the agency), but for a policy that will accommodate the various interests and viewpoints that cluster around the decisionmaking process. The search is not only for the general facts that will permit an adequate definition of the problem and reliable predictions about its likely solutions, but also for the political preferences of the relevant actors. The basic goal is harmonious resolution of differences, thus maintaining the possibility for further cooperative activity for mutual benefit.

The structure of such a decision process is necessarily fluid. From a sociologist's perspective, it might be called a "network," a series of connections that are related both to issues and to personalities --to who they are, what their interests are, what their histories are, and how they have previously related to each other. That is, of course, something quite

different from a hierarchical bureaucratic structure having formal definitions of jurisdiction and role. In this informal micro-political accommodation structure, people might play any role and shift roles over time. There is no reason to specify with any precision what role anybody is playing. Indeed, to so specify, to begin to build hierarchy, is, in some sense, to eliminate possibilities for ultimate harmony and accommodation. The values expressed by various parties indicate the potential relevance of facts, and the discovery of facts reinforces or weakens the salience of the preferences of the parties.

This is not, of course, to say that the process is wholly unconstrained. Legislation may express the general value matrix that both determines the outer boundaries of the relevance of claims and limits to some degree the access of parties to the process of decisionmaking within that matrix. The administrative decisionmaker is also ultimately politically accountable through techniques ranging from removal to budget limitation to alteration of the agency's statutory mandate.

The legitimacy of this model's output -- usually general rules or quasi-legislation -- hinges on the adroitness of the agency's accommodation of multiple and uncertain facts with complex and conflicting preferences. It must somehow extract an approximation of consent to its policy from all the relevant actors.

Obvious real world examples of such agencies and processes do not abound at the federal level. At least the formal structure of most regulatory regimes suggests that the agency is engaged in issuing binding directions based on the subsumption of facts under statutory criteria for judgment. The modern health and safety agencies, the National Highway Traffic Safety Administration, the Environmental Protection Agency, the Occupational Safety and Health Administration, the Consumer Product Safety Commission, and the Food and Drug Administration, are all examples of broad rulemaking powers exercised in an ostensibly bureaucratically rational mode.

But the reality of much of this modern regulation seems to be quite different. The legislation under which these agencies operate requires that they protect the public health and safety, or perhaps more general aspects of public well-being, by adopting and enforcing general regulations. In carrying out its principal statutory mandate, however, each agency is supposed to consider not only the values of health and safety, but also other social values such as individual autonomy, economic development, and the maintenance of a federal, or somewhat decentralized, political process. They are also charged with finding facts that cannot be found and are thus forced to decide critical value questions concerning the level of acceptable risks where facts are uncertain. The issues addressed by these agencies are in the broadest sense political, and the processes employed in decisionmaking (general notices, opportunities for public comment, public hearings, conferences, and negotiations) begin to approximate politics at the legislative level when stripped of the latter's usual partisan flavor.

This is not to say that the exemplary agencies have successfully adopted and employed the model of micro-politics. Indeed, the acceptability of this model, and its relationship to the model of bureaucratic rationality, has been a major battleground of American administrative law during the past decade. Nonetheless, some agencies have been successful in the development of consensus-producing processes that do not at the same time exclude relevant dissenting views. And even the ubiquitous litigation that surrounds rulemaking in agencies like the EPA should not disguise the fact that many issues embedded in a polycentric problem have been resolved by negotiation and political trading.

The Competition for the Soul of the Institutional Review Board

Relevant legislation and regulations seem to give IRBs three tasks: (1) to review all federally funded research involving human subjects; (2) to review all such research on a continuing basis, including a review to determine whether subjects should be given access to newly developed therapies; and (3) to monitor all funded research involving human subjects and to report any serious noncompliance with either the protocol approved for the research or the applicable law and regulations. In carrying out these approval, review, and monitoring tasks, the IRB is asked to address the following questions: (1) whether the research methods employed are appropriate; (2) whether the selection of subjects for research is "equitable;" (3) whether the risks involved in the research are minimized consistent with sound scientific methodology; (4) whether the risks involved in the research are reasonable in relationship to the benefit likely to be obtained by either the subjects or society generally; (5) whether the informed consent procedures to be utilized assure that consent will be voluntary and informed (or, in some cases, whether the research is such that consent need not be obtained); (6) whether there is adequate protection for the privacy of subjects; and (7) whether the applicable regulations for special groups (such as fetuses, pregnant women, prisoners, children, and the institutionalized mentally infirm) will be complied with in the research.

The structure of the board is limited only by some general standards. The board must have at least five members, one of whom is not associated with the institution under whose auspices the research is carried on. Moreover, the board as a whole must be able to consider questions concerning the institution's rules and commitments, the law, standards of professional conduct and practice, and community standards.

Procedurally the board is required only to act as a board and by majority vote (except for some cases subject to "expedited" review). The board must also provide researchers with notice and an opportunity to respond when the board proposes to disapprove or modify a researcher's project.

The IRB operates within a dual administrative structure. It is a part of an institution within which research is conducted and is dependent upon that institution for its appointments, staffing, and facilities. Moreover, the specific procedures of particular IRBs may be governed by institutional regulations. The IRB's access to information, personnel, and other resources may also be subject to the peculiarities of the bureaucratic structure of the institution within which it functions. The IRB is simultaneously subject to the regulation and oversight of the Department of Health and Human Services. That department reviews and approves the composition, standards, and procedures of IRBs, provides some "education" for IRB members, and may subject IRB determinations to a de novo review at the department level.

Given these structures and functions, the IRB might be described in terms of any of the four models for legitimate decisionmaking that have been sketched above. We might, for example, view the IRB as a rational bureaucratic implementor of HHS or local institution rules and procedures. There are, for example, some quite specific requirements with respect to informed consent procedures in the HHS regulations. Similarly, under the recently promulgated regulations on IRB review procedures, there must be a preliminary determination of whether a proposal for research involves any appreciable risk to the subjects or is within a category subject to exemption.

In performing these functions IRBs might be viewed as first-level implementors in a hierarchical structure with HHS at the top. That structure includes both instructions from HHS to the local IRBs and the auditing of IRB functions by HHS through both its de novo review and special site visits to the IRB. Evaluation of the performance of the IRB from this perspective would include the analysis of its capacity to make correct decisions and an evaluation of its efforts to organize its decisionmaking in ways that constrain the costs of those decisions.

The IRB has, in fact, been criticized for its failure to conform to the ideal of bureaucratic rationality. The Michigan Survey Research Center report found that IRBs were not very effective even at the relatively mundane tasks of determining whether the consent froms provided by researchers contained the "barebones" requirements of the regulations. The General Accounting Office has criticized HHS's capacity to audit and monitor the IRB process both in this regard and in others. And the IRB process has been called in question by recurrent, although somewhat isolated, examples of the failure of research to be conducted in conformance with the protocols approved by local IRBs. These criticisms suggest, although they surely do not demonstrate, that the IRB may not be effective in monitoring compliance (either with its own requirements in protocols or with HHS regulations) and that the IRB is not part of an effective hierarchical structure.

On the other hand, the IRB, in its bureaucratically rational mode, has been criticized by those who believe that manner of functioning is too limited. In particular, behavioral and social scientists have criticized the IRB process with respect to consent requirements. In the view of at least some behavioral research scientists, inflexible enforcement of the informed consent regulations may render their research projects impossible. IRBs are thus criticized for being too "bureaucratic," for not adjusting the application of "the rules" to the needs of particular forms of research.

Alternatively, one might view the IRB as standing in a professional service relationship to the subject of human experimentation. The IRB attempts to determine for the subject what the subject needs to know in order to exercise an informed consent. It further attempts both to minimize risks to the subjects consistent with sound professional methodology and to insure that potential subjects are informed of alternative therapies that would be beneficial, even if such information would diminish the likelihood that they will participate in the research. The IRB also attempts to protect subjects from social or psychological harm and to ensure that there is adequate protection of subjects' privacy.

These are all roles that would be perfectly consistent with functioning as a physician, a lawyer, or a psychiatric social worker. Moreover, the basic purpose of the IRB is to substitute itself for a professional relationship that may, particularly in biomedical research, be compromised by the dual role of therapists engaged in research. The IRB is the fiduciary behind the fiduciary.

Viewed from this perspective the IRB is subjected to a different set of criticisms. First, it is criticized for its inability to act in a clinical fashion. With respect to the monitoring of the informed consent process, for example, the IRB focuses primarily on the formal aspect of consent. The Michigan Survey Research Center study finds that most IRB-required modifications in proposed projects are simply modifications in the language of the consent form. But the language of the consent form can hardly be the most important element in obtaining "informed" consent. Whether such consent is genuinely "informed" depends importantly on how the particular person signing the consent form is responding to a whole range of circum-

stances that surround this particular encounter or activity. To make such judgments with any degree of assurance the IRB would have to have -- at a minimum -- a personal relationship with the subject signing the form. But the IRB must deal with human subjects at wholesale, not at retail, and usually only prospectively.

This lack of individualized treatment of subjects in the informed consent review gives rise to a second set of criticisms that tend to characterize the IRB as an incompetent professional. In its paternalistic or fiduciary role the IRB is also deciding that clients must have information and exercise judgment whether or not they prefer to do so. But at the core of the professional treatment model is the notion of yielding authority to a professional whom we view as both trustworthy and as having a competence that may better fit him or her to decide our fate than we are ourselves. The IRB is thus in some sense an obtuse professional who, in the face of the client's (or patient's) preference not to know, nevertheless provides information and demands that the client decide.

Of course, the IRB does not always take such a posture. For example, in preliminary review to determine whether the risks are reasonable in relation to the benefits, it does not thrust upon its clientele a series of unwanted choices, nor is it disabled from making relevant inquiries by the wholesale nature of the questions it addresses. From the position of the professional treatment model it nevertheless is taking up an inappropriate posture; in balancing the risks of the project in relation to its potential societal benefits, the IRB has left its fiduciary role, which is to serve the subjects of research, to take up a much broader role in balancing the risks to subjects against the demands of science and the needs of society. The subject receives professional service in a highly compromised form.

It might be asserted, of course, that the paternalistic function of IRBs, as judged by their operations, is the protection of researchers from ill-advised or poorly constructed experimentation. The facts might even reveal that IRBs perform this paternalistic professional role with great wisdom and success. But if the purpose of the IRB is the protection of human subjects, protection of researchers is not a perfect proxy for the basic goal. And researcher protection may easily conflict with subject protection. Where it does, the paternalistic role in relation to the subjects of research would, again, be compromised.

There are also aspects of the activities of the IRB which are highly reminiscent of a structure for moral judgment. For example, the IRB is asked to determine whether the selection of subjects is "equitable." Presumably this means that the IRB should be concerned with benefits and burdens of particular research projects. Such a concern might be expressed in any number of ways: "Those who benefit should bear the burden;" "The few should not consistently accept risks for the many;" "Burdens should not be disproportionate to benefits;" and so on. But these are not equivalent statements of "equity," nor is their application nonproblematic. The regulations thus leave substantial scope for ordinary moral judgments based on the deservedness of both subjects and others potentially affected by subject-selection procedures.

Other aspects of the IRB's function suggest it should act like an adjudicator exercising a broad moral judgment. Indeed, with respect to every project the multiplicity of criteria for approval add up to a question that might be reformulated: "Is it ethical to proceed, all things considered?" Moreover, a decision that a piece of research is not to be approved is certainly a statement, perhaps a strong statement, about the ethics of a particular researcher. Recognizing this, the regulations require that researchers be given notice and an opportunity to respond to

an IRB decision to disapprove or modify their research projects. Similar judgments may also be made during the course of research when new facts come to light or complaints are made by subjects or by others.

From this perspective one may certainly wonder whether the IRB is well structured to perform its tasks. The quite modest requirements for inclusion of "outsiders" on IRBs suggest that broad community values, as distinguished from professional and institutional values, may be given only modest weight. Nor does it seem commonly the practice to provide IRBs with the sort of investigative, prosecutorial, and analytic staff that might be necessary to deal sensitively and fairly with contested issues of fact.

Finally, it seems clear that the IRB is also in some sense a micro-political animal. The IRB is surely permitted to develop its own general policies and procedures consistent with the requirements of federal regulations and its own institution's rules. In the development of those policies it must respond to a series of differing constituencies or stakeholders: the institution, the medical profession, the behavioral research community, existing and potential subjects of research (including subgroups within that larger body which may have differing interests and preferences), the local community, and the general society's interests in benefiting from additional knowledge.

When engaging in judgments about risks and benefits, for example, the IRB is obviously attempting to respond to and accommodate the divergent demands of these constituencies. But one may certainly wonder whether all of those constituencies are well represented in the policymaking that surrounds the IRB process. Behavioral scientists may be heard to complain that they are being forced into a paradigm of research which is (or may be) an appropriate paradigm for biomedical research, but not for their activities. Those concerned preeminently with the protection of subjects complain that the process of policy development is too heavily weighted in favor of institutional concerns. A similar complaint might be that the composition and orientation of the IRB favor the scientific community as against the lay or local community.

Moreover, to the extent that the IRB as a unit is accountable to anyone, it seems primarily accountable to the institution that appoints, staffs, and funds it. The structure may thus permit the micro-political IRB to vary from institution to institution as it reflects the micro-politics of the institution itself. From this perspective, the attempt by national regulation to alter the micro-political model of research approval in relation to human subjects has merely replicated local conditions.

But I do not want to go on at excessive length about the potential and actual failures of IRBs viewed from the perspective of one or another model of legitimate or acceptable agency decisonmaking. From a reformist perspective, the potential difficulty of responding to them in ways that make one aspect of IRB functioning "better" without making some other "worse" is more important than the accuracy of one or another of these criticisms. The problem is not just that the IRB responds partially or inadequately to each of these various models of acceptable decisionmaking; it is also the case that these models are competitive. An attempt to shore up one model will have consequences, usually negative, for one or all of the others.

Let me give a few obvious examples. Attempts to make the IRB a better rational bureaucrat by clear specification of objective criteria for review of research proposals will (1) make it a worse micro-political accommodator of the various interests that cluster around particular proposals (or groups of proposals) in particular locations and (2) reduce the

possibility for exercising common sense moral or ethical judgments concerning the proposed research. The more decisions that have been made firmly at the top to be implemented by the IRB in the local context, the less there remains open for political accommodation or moral judgment at that level.

Similarly, the more detached we make the IRB from the institution that it serves or from the scientific community (thus shoring up its capacity for independent moral judgment), the more we interfere with the possibility for a sophisticated evaluation of the risks and benefits of proposed research. Quite often that risk-benefit issue is firmly embedded in a methodological controversy that requires the exercise of scientific-technical rather than amateur judgment. Having a professional board review the proposal of a researcher may be a good way to approximate sound professional judgment, but a poor way to engage in micro-political accommodation, rational bureaucratic implementation, or independent moral judgment.

This competition amongst models of legitimate decisionmaking obviously complicates sound institutional design. But the counsel here is not yet one of despair. There may be ways to structure and separate functions so that we can better optimize our competing desires for competing models of decisionmaking. While individuals have difficulty compartmentalizing their personalities, characters, and talents in ways that would allow them concurrently to be good bureaucrats, good judges, good physicians, and good politicians, organizations may have greater capacities for differentiation of functions while managing overlaps and interference. How much progress can be made in that direction awaits further analysis, one that we will take up only after canvassing an additional complication in developing an appropriate design for the IRB.

The Unpredictability of Regulatory Alternatives

Finally, if one looks at the type of job that IRBs are called upon to do and compares that task with other regulatory regimes, one finds a fantastic array of substantive, structural, and procedural alternatives for regulation. And while structure and procedure are in some sense harnessed to tasks or to substantive programs, it is clear that these relationships are far from direct or noncontroversial. In short, experience with other agency processes does not provide unambiguous guidance. Let me give some examples.

Shoring Up the Model of Consent. We originally suggested that the IRB was charged with two basic tasks. The first was to police informed consent; the second, to place boundaries on the consent arena. Within that first purpose, however, there are at least two strategies. The first involves regulation by information transfer, the second regulation by molding the context within which consent and/or information transfer takes place.

A number of federal regulatory agencies concern themselves with the transfer of information. The Federal Reserve Board implements the federal Truth-in-Lending Act by requiring that certain specific information be provided in a highly stylized form. The regulatory technique is to provide a set of instructions which are so objective and uniform that they can be adopted and applied by lenders without any additional bureaucratic routines.

The Securities and Exchange Commission, in regulating the transfer of information from firms to potential investors, takes a quite different approach. Although it does have some specific requirements for a prospectus,

the heart of the regulatory process is review by the staff of the Securities and Exchange Commission of each offering's circular or prospectus. Such review is highly judgmental and based on broad criteria concerning the materiality of information and its potential to mislead or to properly inform in the total context of the securities offering under review.

There are, of course, also the traditional approaches of the Federal Trade Commission in an action to halt a deceptive practice and of the civil courts in fraud actions. In those situations there is no attempt to specify in advance what is or might be misleading. Nor is there an attempt to determine in advance what information is necessary for some judgment or "informed consent." The remedy is post hoc and punitive or compensatory.

There is, in fact, no good information concerning which of these techniques is more likely to mold the primary conduct of regulated parties in appropriate directions or is more effective in transferring appropriate -- and prohibiting the transfer of inappropriate -- information. It is widely believed that SEC disclosure requirements, despite their significant cost, produce no new and useful investment information. The Federal Reserve Board's attempt to objectify disclosure requirements seems merely to have baffled lenders by their complexity and rendered their disclosure statements unreadable by borrowers. FTC consumer protection is by most accounts either misguided or too little too late.

The other major strategy for shoring up the consent process involves contextual modification. Such constraints might operate in terms of setting, personnel, time, or incentives. One can imagine regulating the place where consent may be requested or given; the National Labor Relations Board controls the situs of the election of bargaining representatives. Or it might be plausible to require that transactions go only through intermediaries who are "disinterested," such as in the Securities and Exchange Commission's regulation of mutual fund contracts with investment advisers. It might be advisable to slow down transactions; the Federal Trade Commission requires a cooling-off period for home solicitation sales. Or it might be thought advisable to exclude certain incentives from the consent process (such as the SEC's prohibition on the use of explicit prices in solicitation of proxies) or to exclude whole groups from consenting (such as those who have particularly strong incentives to agree to be the subjects of experimentation). Again, all of these policy options are controversial.

More importantly for our purposes, depending upon which regulatory alternatives were chosen, the IRB would have greater or lesser importance and different structures and procedures. While IRBs currently perform something like the SEC prospectus review in looking at consent forms, a shift to the Federal Reserve Board's uniform contract technique would leave them with only a monitoring or enforcement role. Finally, per se rules (such as cooling off periods) might be prescribed nationally, whereas choices of locations or intermediaries would almost certainly involve highly textured local administration.

Regulating the Substance of Research. In addition to improving the process of informed consent, a number of strategies exist for constraining the arena within which consent can be given to experimentation with human subjects. Regulations already require that the IRB determine that the overall anticipated benefits of research outweigh or justify its potential risks. But there seems no prohibition on the IRB's taking a stricter approach. For example, one could imagine an IRB that refused to approve research in which the direct benefits to participants did not outweigh their risks to the participants themselves. Such institutions would, of course,

be excluded from carrying on some research that FDA regulations require to be done in order to approve a new drug for marketing.

Moreover, it seems possible for an IRB to weigh benefits and costs in terms of its own direct community rather than of the society as a whole. Thus an IRB might refuse to approve projects involving infectious diseases for fear that persons other than those intended to be subjects of the research would be affected. And it seems to be contemplated that IRBs might impose in particular cases some more absolute, but less articulable, moral prohibition on research that is submitted for approval. Thus, for example, an IRB might refuse to approve all research involving the use of narcotics or other controlled substances. IRBs, or the system as a whole, might also bound the economic harm that could result from consent by requiring that treatment and/or compensation be provided to any subject harmed by an approved experiment.

The basic question with respect to all of these possibilities is whether this "bounding" of the consent process, or limitation of the area of approvable research, should be done by the IRB, an entity such as the Department of Health and Human Services, or perhaps the Congress itself. Even if the IRB is the appropriate unit for decisionmaking, there is the further question of whether the IRB should act by adopting general policies concerning its institution's research or should merely operate case by case. The former approach entails the usual problems of potential overgeneralization; the latter entails the conventional difficulties of equity (treating like cases alike) across researchers and subjects.

Within any particular strategy for bounding consent, there are also a series of substantive, structural, and procedural alternatives. For example, if one examines the current requirement that research benefits outweigh risks, a number of issues remain to be addressed by the IRB. What sort of risk-benefit methodology will be used? To what extent should money values be assigned to physical harms or even death? If values are to be assigned, what is the implicit pricing mechanism? How are benefits to be calculated? Are benefits to be assessed only within the context of the research proposal before the IRB, or should the IRB take into account the importance of the research in a process of similar or cumulative experimentation? How can benefits be estimated in a research process in which innovation, and hence the contribution of one bit of research to others, has no obvious path or structure? Should the IRB have a separate staff to conduct risk-benefit assessments? Should there be some form of contentious procedure in which benefits advocates and risk advocates are called upon to develop both plausible and worst-case scenarios? Should the same risk-benefit methodologies or procedures be applied to all research that comes before the IRB?

One might easily respond to these questions that no matter how they are answered, they should be answered uniformly. That is, Health and Human Services should confront these issues and adopt regulations that best specify the necessary substantive, structural, and procedural routines that will, in fact, implement the risk-benefit calculus that it has in mind. Such a conclusion is not, however, inescapable. It forgets two things. First, it forgets that IRBs are radically different in terms of their size, resources, and the number of applications processed per year. The structures and processes that are sensible for an IRB ruling on 1,000 applications per year are quite different than those for an IRB that sees 10.

Second, there may be no one best way to do risk-benefit calculations. Both across and within health and safety agencies at the federal level, one finds an astonishing variety of approaches to the risk-benefit or cost-

benefit analysis. The Food and Drug Administration takes at least four different approaches to these questions within its regulatory regime. The Occupational Safety and Health Administration's approach is quite different from that of the National Highway Traffic Safety Administration (when both agencies are engaged in rulemaking). The National Highway Traffic Safety Administration, like OSHA, may take a different approach in rulemaking than it does in dealing with hazards that are regulated through specific enforcement proceedings.

Evaluating the Institutional Review Board

The IRB is asked to be an efficent bureaucrat, to substitute for or supply "fiduciariness" that may be missing in professional-client relations in an experimental context, to do justice in individual cases, and to achieve adroit political accommodations of conflicting interests and perspectives. The IRB is embedded in several distinct communities simultaneously and is asked to mediate not only their conflicts, but the conflicts between particular community values or goals and the general society's interest in both fostering experimentation and protecting the human subjects of that research. Finally, the IRB is importantly involved in regulating consensual relations in a sensitive area (health and safety combined with scientific progress and intellectual freedom). It must do so notwithstanding the lack of general agreement concerning the efficacy of the substantive, procedural, or structural alternatives through which such regulation might be accomplished. Given all these circumstances the IRB process could be predicted to be the single most controversial public policy in the United States. That it is not could be viewed as a testament to its astonishing success. (IRBs' general irrelevance and the ten-day half life of any public issue in the United States are, of course, alternative explanations for the relatively low level of public controversy.) At the very least, one should be cautious in calling for reform of the IRB process. The old adage "If it ain't broke don't fix it" may be apt here.

If I were to hazard a guess at where appropriate reforms might be made, it would be that some of the tasks of the IRB be spun off to different institutions or that the IRB structure be reinforced to aid it in carrying out its multiple tasks. The IRB seems reasonably appropriately constituted and empowered to carry out its basic approval function. One might want some additional representation of "noninstitutional" interests and insist upon separate boards for behavioral and for biomedical research. But in its basic outline, it seems to me, the process is sound. It is my intuition that the subject's greatest protection lies in continually upgrading the consciousness of researchers. If that is correct, then an approval process that is largely informal, local, and peer-group oriented makes sense. (The institutional attachment that weakens the position of the IRB as a fiduciary for the subject might be significantly ameliorated by requiring that institutions compensate victims of research harms, but exploration of that topic is much beyond the scope of this paper.) The IRB seems at its best in this gatekeeping mode that is a synthesis of fiduciary responsibility, moral judgment, and micro-political accommodation.

It is not at all clear to me, however, that this same group can be an effective enforcer of technical regulations, monitor of projects that are under way, or board of inquiry if something appears to have gone awry in the course of a research project. The first two, enforcing technical rules and monitoring, are staff functions which should certainly not be visited upon IRB members. If the government genuinely believes that its informed consent rules or an effective monitoring program are necessary, it should back that belief with funds for an IRB staff. Constant (and expensive) vigilance is much too easy to demand when it is in someone else's budget.

And if HHS believes, as its regulations suggest, that it knows how consent forms should be drafted to inform subjects, then it can determine documentary compliance by reviewing the consent form when it receives the research application. The IRB is not likely to be good at such technical tasks, and it should not be required to use its energies on them.

There is an additional problem with the monitoring function for IRBs, namely, its tendency to interfere with the sometimes fragile structure of collegial support and criticism in academic and research institutions. The problem here is reminiscent of one that has beset the SEC as it has attempted to make the securities bar the protector of the investing public. Indeed, that example is worth recounting.

To oversimplify the situation, it is roughly this: Companies issuing securities have two major responsibilities. The first is full and truthful disclosure at the time that securities are issued. The second is continuous reporting of important financial information that might affect the value of outstanding securities. The SEC has attempted to put the securities bar in the position of enforcing both obligations. The attempt has succeeded with respect to the first obligation and has largely failed with respect to the second.

The reasons for success and failure are not too difficult to fathom. Review of a client's episodic forays into the financial markets or restructuring of its capitalization through merger can be conducted in an atmosphere in which the attorney has obvious external responsibilities. When issuing opinion letters or drafting disclosure documents concerning these types of actions, there is an underwriter or investor audience clearly in view, and the attorney may incur personal liability for misstatements or omissions. Moreover, the corporation uses the integrity of the law firm to signal capital markets concerning the quality of its issues. The gatekeeping process is clear, and it is functional for both parties. The SEC thus can leverage its regulation through that relationship. In many respects IRB approval is similar; it arose as an aspect of researcher-institutional sponsor relations before it was required by funding sources.

However, the attorney who is intimately involved in the ongoing business of the client has a much more difficult ethical dilemma concerning continuous reporting of information to the SEC. He often cannot serve effectively as a public watchdog and as a trusted counselor. There are too many uncertainties surrounding the questions of the materiality of facts, the appropriate timing and methods of disclosure, the effects of interrelated transactions, and so on, to permit simple "yes" or "no" judgments. Hence, many issues must be resolved in terms of the loyalty of the attorney adviser to either the firm or to the investing public. Since their interests potentially conflict, continuous exercise of fiduciary responsibilities to both is impossible and will undermine the more basic (from the lawyer's viewpoint) attorney-client relationship.

Hence, the bar has (rather effectively) resisted being held hostage by the SEC for its clients' continuous reporting responsibilities. It seems to me likely that the IRB, if appropriately staffed to act as a monitor, would have something of the same difficulty. Researchers need to be able to discuss their ongoing work with colleagues, including colleagues who may be, or may talk to, IRB members, without fearing that every worry, complication, or disenchanted subject's complaint will be an occasion for an investigation or at least for a report. Research should not be conducted in an atmosphere demanding either subjective attention to self-protection or defensive bureaucratic routines to provide an objective "paper trail" available for IRB perusal. Nor can these activities be generated without putting IRBs effectively outside the informal flow of information, thereby dis-

lodging them from the institutional and peer base that is their major strength.

HHS cannot expect to use IRBs simultaneously as a focal point for institutional development of commitment to and transmission of ethical norms and as instruments for internal surveillance. One of these roles will atrophy or, perhaps, never become a significant part of the organization's functioning.

The board of inquiry role raises a similar problem. Peer review and association with institutional colleagues may be effective and acceptable devices for approval or disapproval of planned research and for dealing with changes in any plan that the researcher may want (or should be required) to make. But when the researcher has been accused of wrongdoing (either violating the protocol or continuing the experiment when changed conditions make it unethical to do so), both the common attachment of the researcher and the IRB to the institution and the IRB's prior involvement in approval of the project become something of a liability. Both a structure that will facilitate IRB exercise of an independent judgment and processes that recognize a shift from a cooperative to a contentious endeavor seem necessary to successful IRB action in these circumstances. Devices (such as having a separate "complaints" or "withdrawal" panel of the IRB) and clear procedures for developing evidence and for formal hearings in contested cases might well be advisable.

Conclusions

The upshot of this sometimes extraterrestial survey is quite straightforward: The IRB can easily be overwhelmed by the assignment of incompatible tasks. If we assume that the IRB has one principal function -- protection of subjects through ethical review of research protocols -- then its structure and responsibilities should emphasize that function. The IRB's current structure, therefore, seems generally appropriate. In a complex and pluralistic society, local on-site review is a source of strength in exercising judgments based on common morality. And because reviewing research protocols produces an inevitable association of ethical dilemmas and questions of scientific or clinical methodology, the IRB must command the technical resources necessary to perceive and to understand the issues that particular proposals present. The IRB must attempt to be a wise judge and a paternalistic professional in order to carry out its basic task.

On the other hand, tasks that demand a bureaucratic division of labor and hierarchical control -- monitoring, investigation, review of compliance with technical and objective requirements -- are not likely to be performed well by the IRB. Criticism of IRBs as inefficient bureaucrats may be both valid and irrelevant. At most the IRB might serve as a protective umbrella for a staff that had strictly implementing responsibilities. Nor should IRBs be called upon either to mediate the academic political struggles between biomedical and behavioral scientists or to participate in the inevitable institutional or departmental politics that revolve around the hiring, firing, transfer, or promotion of particular researchers.

The IRB is, after all, but one organization among many concerned with overlapping issues of propriety and competence in scientific research. If it is to do its core job well, we must live with its inevitable incompetence at other tasks. Moreover, we must also live with rather vague regulatory standards and with the continuing inability of the federal funding agencies to know for sure whether IRBs are functioning effectively. If we would have wise judges and paternalistic professionals, we can neither specifically direct nor objectively evaluate their behavior.

Chapter 2

AUTONOMY, ACADEMIC FREEDOM, AND ACCOUNTABILITY: THE UNIVERSITY, THE INDIVIDUAL, AND THE STATE

Virginia Davis Nordin

Introduction

I have been asked to describe the governance structure of universities and how Institutional Review Boards (IRBs) can most effectively be fitted into that structure. Describing governance structures of universities is like describing snowflakes. While they are much the same, the structure of each snowflake is unique and individual. And so it is with universities. It thus is not possible to give a simple formula which describes how IRBs should fit into the structure of universities, but it is possible to describe the forces and traditions involved and to make some useful generalizations.

Does the system of "university governance" protect individual rights? The governance system which pervades all universities, regardless of their organizational charts, is one that is protected by institutional autonomy from outside interference, has developed apart from any legal system, and is based primarily on centuries of unwritten custom and traditions. Human subjects, whistleblowers, and principal investigators may all need protection of their individual rights. Do they get it from the internal governance structures of universities? Or, like the courtiers in the children's fairy tale, do we accept elaborate descriptions and forget to observe the basic truth?

Individual academic freedom has been an enduring value in Western civilization, and university autonomy has developed as a legal principle which helps to preserve that freedom. What is increasingly perceived, however, is that institutional autonomy, established in part by judicial abstention from academic affairs, can be used to deny individual freedom either overtly or by neglect. When this perception is coupled with the view that judicial abstention is based on a misconception of the social history of universities, a different view of IRB functions and their legitimation may appear. A core question is whether the basic functions of IRBs should be mandated despite traditions of academic freedom and autonomy or whether these interests can be harmonized.

Within the university, internal governance was developed only for the benefit of the academic community consisting of tenured faculty, including administrators who are also tenured faculty. Other members of the university community are usually not covered by internal governance rules unless collective bargaining has been instituted, and staff members usually do not participate in the all-important committee structure. Therefore,

human subjects are generally outside the protection of internal governance, whistleblowers probably so, and principal investigators probably within whatever protections the system affords. A few research universities are beginning to institute rules for academic staff, a group which may include more Ph.D.'s than the faculty, but this is not yet a universal practice. The lack of specific procedures to investigate and provide fair protection for researchers accused of misconduct also reflects, in part, an assumption that misconduct is so rare in the hallowed halls of the university that it need not be planned for.

In the context of today's society, a grant of university autonomy may decrease individual freedom in substantial ways if the institution itself ignores individual rights. The university tends not to put a great value on individual rights other than those of research, publication, and teaching. All the individual rights connected with the IRB function need further study in the context of university governance. It may be that internal governance needs not to be adjusted, but reformed.

The Uses of History and Tradition in Governance

In considering how university autonomy and its related perception of individual rights evolved, it is important to remember that universities are very old. The even older "tradition of learning" that began in ancient times transferred to its organizational form, the university, in the twelfth century. In his recent book, Tradition, Edward Shils notes that, "Alongside of the traditions of learning, the universities themselves gave birth to complex bodies of traditions regarding their own structure and procedures. Their long existence endowed them with many secondary traditions aside from the traditions of learning which were their primary responsibility."1

One of the most interesting aspects of the university is that it acts both as a conservator of tradition and a destroyer of the traditional through original research. It is a paradox that the institutions which foster creative thought and new knowledge are governed largely by historical tradition. The history of universities is important to understand in connection with their external legal status (autonomy) and their internal legal structure (governance). American courts have used the history of higher education to justify abstention from interference with the internal decisionmaking of universities. For example, in the district court opinion in Greene v. Howard, Judge Holtzoff wrote:

> The intellectual history of Western Europe and the United States is marked by the establishment and gradual growth of universities that are self-governing, in the selection of their faculties, in prescribing their curriculum, and in administering discipline of their student bodies. This history demonstrates that centers of higher learning can best develop and flourish in an atmosphere of liberty and independence, where they are free from governmental influence in any respect as to any aspect of their activities. A glance at this history is convincing. [European] Universities ...which originated in the Middle Ages were from their very inception and always have remained independent bodies, unfettered by any intrusion on the part of any governmental agency, or of the courts. In this country with the early establishment of Harvard, William and Mary, Yale, Princeton and King's College (later Columbia),this tradition was continued and has prevailed. Such institutions have been free of governmental control.2

This general view of university history, however, does not accurately reflect the balance between individual, university, and government. While autonomy evolved partially to protect the tradition of learning known as academic freedom, there were also unrelated factors that created autonomy. Further, university autonomy originally did not mean a denial of individual rights, but rather a greater protection of those rights through an elaborate university governance system. In earlier days, universities might be viewed as islands of democracy in a sea of feudalism. Some argue that the opposite is true today; the grant of autonomy to universities means a denial of individual rights, contrary to the basic assumptions of our democratic form of government. In a recent article on university problems, Wayne McCormack noted: "Recognizing institutional academic freedom would imply a corresponding reduction in the freedom of university employees or students. The institution could reduce dissent or diversity within its own ranks by asserting the primacy of its institutional interests over those of its individual members."3 This question of protection of individual rights within the university is relevant to the IRB function in several ways, but first, let's look at the historical underpinning of university governance.

The Medieval Institution

Early universities were not created by charters from either Pope or King, but rather evolved as a response to the growing societal need for an educated professional class. These universities were based on the tradition of learning that created schools around well-known teachers such as Abelard, on the Cathedral Schools, on the tradition of medieval craft guilds which had elaborate patterns for internal governance, on the growing teaching tradition of the mendicant friars, and on other traditions and institutions of medieval life. But the university was more than a pragmatic response to the growing need for more administrators, doctors, and lawyers. As Rashdall puts it: "The university . . . represents an attempt to realize in concrete form an ideal of life in one of its aspects. Ideals pass into great historic forces by embodying themselves in institutions. . . . Universities . . . constitute the great achievement of the Middle Ages in the intellectual sphere."4

As the embodiment of an ideal, the university became one of the three powers, Sacerdotium, Imperium, Studium, by whose cooperation the life and health of medieval society was sustained. The early university's position was one of great independence or autonomy, in part because society, particularly government, was generally unorganized. This posture initially was aided by the inexpensive and impermanent nature of the nascent university. Universities that felt overregulated by secular or sectarian authorities used the three powers of strike, cessation, or migration to force the civil or religious authorities to yield. Migration often helped to found additional institutions and also helped establish a legal and political basis for university independence, since almost every migration ended with a legal concession to university autonomy.

The clashes with civil authorities often were over whether members of the academic community would be subject to civil authority or to their own courts. The universities' insistence that scholars be tried by university courts helped establish a comprehensive judicial system as a part of internal governance. Although these courts were partially ecclesiastical, they were really more academic in nature, building on the concept of "scholarly privilege" established by popes and emperors to protect scholars who traveled from one teacher to another at a time when civil rights were grounded in membership in a local community. While this concept of privilege supports the idea of untrammeled personal freedom, it was not a part

of the earliest internal governance schemes. The development of chancellor's courts was particularly strong at Oxford, which was geographically removed from the church's administrative and judicial offices. Most students were only nominally members of religious orders.

Another factor contributing to strong internal governance mechanisms was the use of the well-developed guild model as a method of organizing the masters. Additionally, Bologna, an early model for other universities, was founded by a group of what would now be called "mature learners" who organized into "nations" that ran the university, subjecting students and faculty to extensive internal rules.5

An additional facet of the medieval university which contributes to the nature of contemporary internal governance was the demand for loyalty to the institution. Early medieval universities required their graduates to swear an oath of loyalty to the university at the time of graduation. While the once strong fear of violating the oath is obviously gone, the sense of loyalty to the institution as an independent institution persists. Several commentators on the academic scene have observed the strong sense in universities that the good of the institution is more important than the good of the individual.6 And one commentator concluded that a complete contemporary recognition of constitutional autonomy for universities would lead to a disintegration of individual rights because adequate internal governance rights and procedures do not exist.7

One of the anomalies of the university tradition is the insistence on independence from necessary external funding sources. By and large, universities have been successful in this endeavor. An enlightened recognition that one enclave of free thought and independent research must be maintained may be one reason. Another may be recognition of the strength of Eric Hoffer's assertion that revolutions are always begun by "men of words" and that a stable society is formed by cooperation and harmony between the university and the state.

The strong position of early universities was destroyed not just by the growth of state power, but by the individual university's own arrogance and overextension of its powers. For example, by the time that the king of France was powerful enough to control the University of Paris, the university had existed long enough to truly believe in the inevitable nature of its independence. By pushing the king too far, the university managed to lose most of its prior legal privileges. Later episodes in other institutions lend credence to the idea that when the university forgets that its relationship with the state must be cooperative and harmonious and asserts too rigid and absolute a position, it loses more to civil control than it expects. However, the tradition of independence still operates very strongly to resist any kind of governmental interference, even for the protection of individual rights.

While the medieval balance was among church, state, and university, the parallel contemporary tensions may be seen as among institution, individual, and government. In a democracy the government is the protector of individual rights against the major institutions of society, and there is no doubt that the university remains one of those major institutions. Academics of an earlier day may not have appealed to outside authority because of the tradition of loyalty and because there was a well-developed and sophisticated system of internal governance in universities, containing elaborate legislative and judicial features as well as administrative or executive functions. But the institutions which first developed academic autonomy were structured very differently from today's university and operated in a very different social context. It is a mistake to assume that the tradition should persist when the reasons for it have ceased.

The American University

Writers on the history of American universities have argued that they were modeled, on the one hand, on the great medieval universities or, on the other hand, on the Calvinist city-state universities such as Edinburgh, Dublin, or Geneva. In these universities, funding came neither from a wealthy international church organization nor from a prince, but rather from very local community sources. Whichever model is correct, many early American colleges partook of what we would now call secondary education, and it was unclear whether they were public or private.

Historically, an American university's public or private status and, even more importantly, the nature of its original funding have had an important bearing on the issues of its autonomy and governance. The importance of the original source of funding is seen in the case of Harvard, which, though established by the Massachusetts legislature, was eventually able to establish private status because its first 700 pounds came from John Harvard and the second 400 pounds came from the Massachusetts Bay Colony. If it had been the other way around, the argument would have been more difficult. It nonetheless took over a century of labor by Harvard presidents to establish the private nature of that institution. Nevertheless, as a centuries old private institution, Harvard relies heavily on custom and usage in its internal governance; very little is written down and very little is centralized or coordinated. Even if the actual governance structures of medieval institutions did not transfer, the tradition of the right to resist accountability to the government did.

The establishment of major land grant institutions by the Morrill Act in 1862 gave impetus to the American push toward universal higher education and greatly expanded the research capacity of universities. The infusion of the Germanic ideals of academic freedom (Lehrfreiheit and Lernfreiheit) with the establishment of Johns Hopkins in 1876 again changed the nature of American higher education towards more emphasis on graduate research. Incorporation of the German ideal of the freedom of scientific research8 gave the individual faculty member autonomy within the institution as well as without.

This development strengthened the internal forces which resist the regulation of the university by outside agencies (through IRBs, for example) and also strengthened the idea that research was the most important and overriding function of the university. The major mechanism of internal governance which protects research faculty members is tenure. The concept of tenure as a protection for individual academic freedom was not widely accepted in this country until the 1930s, based on the work of the American Association of University Professors and a law review article in the Yale Law Journal entitled "Academic Freedom and the Law." Tenure, along with both the development of strongly autonomous disciplinary departments within the university structure and the post-World War II phenomenon of money granted directly to individual principal investigators, led to a high degree of autonomy for the individual researcher within the university. Increased external funding and the scarcity of professors to meet the 1960s' boom in graduate instruction completed what Jencks and Riesman refer to as the "Academic Revolution" in their description of the rise of the powers of individual faculty to a position of preeminence within the university structure.

University structure is not hierarchical in the traditional sense. One of the contrasts between a university and a federal bureaucracy, for example, concerns the open access to top level administrators by any member of the university community. According to this policy, faculty members, as well as students, are entitled to make direct contact with the

president and other top officials, and almost all top officials make themselves available for contact in this way. One of the shocks which many academics have in transferring into government bureaucracy is that they must consult intermediate officials before speaking to the top officials in their own bureaus.

Open access is a strongly and widely held principle in research universities, which undoubtedly contributes to the view among analysts of higher education that the university follows a political model rather than a hierarchical bureaucratic or other model. Therefore, in assessing university committees like IRBs, it is important to recognize that each IRB operates in a particular organizational and political context and that the dynamics of the IRB will be affected by extraneous political constraints, which will obviously differ from institution to institution. A single model imposed from outside will not work in all universities.

The Organization of Academic Administration

A study of university organization that could be used for the purpose of defining the best form of IRBs has yet to be made. The following generalization, however, may help those concerned with such a task. Academic administration is like no other form of administration. A paradox lies at the heart of a university as an organized institution dedicated to the development of creative thought. How can the pursuit of curiosity, the essence of intellectual work, be organized or administered into existence? This basic purpose, coupled with the tradition of academic freedom, makes academic administration difficult. Not surprisingly, a great deal has been written by former administrators about academic administration and its contradictions and complexities. The presidents' genre is particularly interesting; one of them speaks feelingly of "government by supplication."

A point often made in recent literature is that different types of postsecondary institutions have different traditions and tend to be somewhat differently organized. While it is true that there are distinct differences in internal governance patterns among major categories of institutions, the major research university, which is most likely to need IRBs, tends to be a model for the other institutions. The following description of university structure relates most closely to research institutions.

The Faculty. Any assessment of university governance must begin with the faculty, who play the role of town citizens in a town meeting form of government. The faculty operate through the academic departments and, in a larger sense, the faculty senate. The faculty have the power to decide which courses will be taught, who will teach them, and, in graduate school, which students will be admitted. The faculty hire, fire, and award salary on a peer review basis. That is why the Supreme Court decided in the Yeshiva case that faculty in a "mature research university" could not be unionized; they hold too much managerial power.

Faculty members tend both to see administrators as those who did not do so well as scholars and to believe that the only good administrator is a reluctant administrator. The view is that since the real work of the university, teaching and research, is done by the faculty, no one really wants to be an administrator -- even though administators are paid more (no doubt akin to hazardous duty pay). Administrators exist to facilitate the work of the faculty. Administrators should not set policy, but since they sometimes are forced to do so, all administrators with any policy-making power should be former faculty, who will represent the faculty's interest. It does not matter that faculty are not trained in administration

since it is not difficult; any faculty member is bright enough to pick it up. What is not to be considered is the professional administrator. Barzun notes the classic academic view: "There have been attempts to raise up a generation of such men, but so far they have failed. One might indeed predict that if preparation succeeded, action would fail; because the very thought of deliberate management aimed at and trained for, would concentrate the spirit of resistance in faculties and bring about the defeat of the certified administrator even before he had framed his diploma."9

Thus, while professionally trained educational administrators have made their way into university administration, they seldom hold policy-making positions. Most faculty are only peripherally aware of the extensive professional administrative staff which keeps the university operating, in part because professional nonfaculty staff have no role in university governance on most campuses. Within the classic university tradition, they simply do not exist.

Organization, If Any. The best way to understand the administrative structure of universities is to remember that in colonial days, when such institutions as King's College (later Columbia University) started with eight students, the president did everything, usually with some help from a treasurer on the governing board since scholars were known to be impractical about money. The various offices in existence today are all spin-offs from the president's function. Leaving aside system-wide administration, which is essentially an evolving job of coordination, we can define a few simple principles of campus administration. One of the difficulties of analyzing academic administration, however, is the semantic confusion which reigns supreme. For example, the head of an institution may be called a chancellor or a president, and the second in command may be called a chancellor or a president, or the opposite to what the head of the institution is called. The second in command may also be called the vice-chancellor, vice-president, provost, dean of the faculty, vice-chancellor for administration, vice-president for academic affairs, or some other variant.

If the head of the campus is the president, the second in command will be the vice-president for academic affairs, executive vice-president, or chancellor. The second in command often is the inside man managing the day-to-day operation of the institution, particularly with regard to the faculty and academic matters; the president is the outside man representing the institution to outside interests and defining its role in society.

The other vice-presidents run out laterally just under the level of the executive vice-president or vice-president for academic affairs and, in a sense, are the president's staff or cabinet. The "cabinet" terminology reflects the idea of the president as head among equals, or nearly so. Under these officers are groups of professional administrators of various types, organized on a more familiar bureaucratic model, who take care of the business side of the university. However, business and academic functions are not so neatly separated as one might think. The keynotes to university structure seem to be historical evolution and practical utility, the later often relying heavily on personal relations and leadership styles.

The academic administrators known as deans run in a line downward from the provost or vice-president. Deans head or represent faculties, except for deans of graduate schools, who have no faculty because the primary loyalty and responsibility of individual graduate faculty members runs to their departments. If there is no vice-president for research, the dean of the graduate school may fulfill that function, which is essentially one of liaison coordination, information, support, and troubleshooting.

This is the office that usually has ultimate responsibility for the IRBs on campus. Again, while every research university will have an officer who fills this function, the name of the office varies widely and may be combined with a number of other offices. Otherwise, the graduate dean fulfills an especially nebulous function in a chiaroscuro organization. The graduate deanship and its vague function relates to the fact that American graduate faculties, unlike their European counterparts, are superimposed on undergraduate colleges primarily for financial reasons.

The dean is the clearest leader of an academic discipline on campus, but he tends to serve as a mentor, coordinator, and budget supervisor rather than as an operating head. Many campuses also have a number of nonacademic deans, such as the dean of students or of continuing education, who are nonfaculty professionals functioning outside the university governance structure. Added to this are any number of associate and assistant deans, often referred to as "baby deans," who are usually, but not always, nonfaculty professionals.

The strongest academic leaders within the university are generally the deans of the various schools. They look in two directions: to the president and to their faculty. While deans report to the president and vice-president, they do not, except very rarely, exist to carry out orders from above. They represent their departments and disciplines to the central administration. The dean of the liberal arts school, which often is as large as a small private college, is an important campus figure, as are the dean of the law school, the dean of the school of education, the dean or the vice-provost at the medical complex, the dean of agriculture, the dean of home economics, and such other related deans as each particular university may require. In most research universities, deans are free to organize their school however they wish within the existing traditions of that discipline. That is why in the very few graduate universities with faculty unions, the law school or the medical school may be in a separate bargaining unit from the rest of the university; it is able to prove that it is so differently organized that no "community of interest" exists with the rest of the university.

The academic department is the arena in which basic decisions have been made about hiring, firing, which subjects will be taught, and the way in which they will be taught, with an occasional override by the dean. Some commentators feel that department autonomy has been a poor idea because it tends to perpetuate the given definition of academic disciplines and to fracture and overspecialize the educational effort. Deans have some influence on departmental structure, but they often are perceived by faculty as only a reactive influence.

The increased administrative load on deans within the total internal structure of universities has probably given them more absolute power in terms of basic responsibility delegated from the board of regents. On the other hand, this increased administrative load has caused deans to lose educational leadership and to leave such leadership even more strongly within academic departments. By the same token, there seems to be relatively little, if any, attempt to coordinate a university's research programs or to discuss which research may be meritorious. This is largely an individual matter even when very large sums of money are involved.

Medical schools are a special example of a university division and, for a number of reasons are considered by the rest of the university to be particularly difficult to administer. First, medical schools evolved out of the desire for both clinical instruction and top-flight academic instruction in the preclinical sciences. This has created a faculty of two types of instructors, with one earning considerably more than the other from their

outside practice. This causes understandable personnel problems. Second, there is the problem of integrating the administration of the teaching hospital with the academic departments. Included in the second problem is the situation (within some, but not all, universities) where the teaching hospital is separated and at a physical distance from the university. The third reason concerns the recent and often problematic attempt to integrate a number of related disciplines together into an allied health center. Fourth, there is the question of whether there should be a separate vice-chancellor, provost, or dean of the faculty for the medical school and/or the health center. While most major universities now have a vice-chancellor for allied health, others feel that a vice-chancellor for the medical center duplicates the function of the vice-chancellor for academic affairs and does not contribute to the institutional cohesiveness of the university. It also makes it more difficult to recruit a strong dean for the medical school since the functions of the dean and the vice-chancellor overlap. A related problem is that the rest of the university faculty generally feel that the medical school faculty are riding roughshod over them in making internal governance decisions because they are highly paid and very autonomous within their own school.

The position of professional staff -- from administrative assistants with secretarial duties to Ph.D. researchers with no faculty appointment -- is a difficult one. Since they are not faculty, in many universities they are totally outside whatever internal governance system may exist. In my opinion, the proper treatment of professional staff is one of the major problems facing universities. And since whistleblowers may tend to come from this group, this problem is importantly related to the role of IRBs and to the handling of research fraud. Professional staff are often in the unenviable mental position of living in a private club which they cannot join. Although many of them have distinguished careers and make invaluable contributions to the universities, they are second class citizens in the eyes of the faculty and often in their own eyes as well.

A few universities, including the University of Wisconsin, have set forth internal governance rules for this group. Additionally, a proposal is now before the Board of Regents at the University of Wisconsin to amend its current rules for academic staff to prohibit the dismissal of an academic staff member in retaliation for whistleblowing. At the same time, professional staff members at the University of Wisconsin are not represented in the Faculty Senate or in any of the other traditional mechanisms of internal governance; they simply have their own rules that were directly adopted by the regents without sanction by the rest of the community. This is an anomaly within the university and raises questions which must be addressed.

Autonomy and Academic Freedom

A great deal of the discussion of academic freedom and university autonomy assumes that they are mutually supportive if not identical. This is not necessarily the case. In fact, they can be quite incompatible. Many administrators and academicians who argue for institutional autonomy do so because they believe that it will better guarantee academic freedom in a complete and absolute sense. However, few absolutes exist in this world, and an absolute individual autonomy known as academic freedom does not either.

History shows that strong institutional autonomy meant very strong and detailed internal governance, with the authority of the university replacing the authority of the state or the church over the individual scholar. Yet today, strong internal governance mechanisms do not always

protect individual rights within the university. The need for IRBs is an illustration of ths problem. The Germanic theory of academic freedom and of the overarching value of pure research has been translated into an organized anarchy that makes little or no attempt to protect the individual. A false tradition has arisen in the name of autonomy that the institution can do no wrong, can make no mistakes. Universities have no Bill of Rights; there is no tradition to protect the individual against institutional will or departmental or disciplinary tyranny. To date, few outside legal mechanisms have evolved either, despite Justice Douglas's observation that students and teachers do not hang their constitutional rights on the schoolhouse gate.10

The balance among individual, university, and government is still evolving. First, it seems clear that the degree of institutional autonomy that society is willing to recognize may depend in part on the effectiveness of the internal governance mechanisms of the university, including their coherence with societal interests in individual rights and with accepted social policies. It also must be seen clearly that institutional autonomy is not necessarily the equivalent of academic freedom. Nonetheless, while all faculty members might not agree with the extent and detail of internal governance mechanisms that somewhat curtail their individual professional lives, probably the whole university community would agree that they would prefer detailed internal rules and regulations to externally imposed regulation.

Second, university administrators are not always totally opposed to external government regulation, even though they may appear to be so. Like some Southern school districts that did not want to bear their constituents' wrath for implementating integration policies, universities may be instituting internal procedures in the name of federal regulatory requirements that they actually want to establish themselves. Thus, for example, administrators may see the need for IRBs but want the support of government regulations to impose them on deans and faculties.

Third, the reluctance of the courts to interfere with institutional autonomy even to protect individual rights has given universities a unique exemption from legal process. This posture of the courts is known as academic abstention or as the doctrine of judicial noninterference. Its fullest or most extreme form may be seen in Judge Holtzoff's opinion in the Greene case involving Howard University:

> It would be a dangerous doctrine to permit the Government to interpose any degree of control over an institution of higher learning, merely because it extends financial assistance to it. . . . Such a result would be intolerable, for it would tend to hinder and control the progress of higher learning and scientific research. Higher education can flourish only in an atmosphere of freedom, untrammelled by Governmental influence in any degree. The courts may not interject themselves into the midst of matters of school discipline.
>
> It would be a sad blow to institutions of higher learning and to the development of independent thought and culture if the courts were to step in and control and direct the administration of discipline and the selection of members of the faculty in universities and colleges. An entering wedge seemingly innocuous at first blush, may lead step-by-step to a serious external domination of universities and colleges and a

> consequent damper and hindrance to their intellectual development and growth.11

Judge Holtzoff's position is referred to in a subsequent case as "a constitutional domino theory . . . under which any collegiate restriction is viewed as an opening fall which will surely tumble the entire institutional array." There the court goes on to state the opposite view:

> We cannot agree that (the) right of academic freedom requires the total preclusion of personal rights, whether they be of faculty, students, or affected members of the public. Where a "right" can be identified, its force and priority must be measured with the conflicting rights of others. These questions of social balance weave through our constitutional texture.12

As with many other questions, the proper application of judicial rulemaking to universities seems to be a question of balance.

Related to the idea of academic freedom and its protection within and without the institution is the concept emerging in some cases and in law review articles of the core or essential functions of the university. Horowitz defines these functions of the university as: (1) the content of courses and curricula; (2) the requirements for degrees; (3) the conduct of research; (4) the policies and procedures of rehiring, firing, and promotion; (5) the internal allocation of resources; (6) the initiation, administration, revision, and termination of academic programs; (7) the establishment of patterns of internal governance; and (8) the determination of academic aspects of admissions criteria.13 A balanced judicial approach would appear to protect both individual rights and core academic functions.

The legal inclination not to interfere with core academic functions is relevant to this inquiry because research is certainly a core area. However, as Horowitz also points out, universities and professors are willing to allow some modification of research or core academic questions in the case of regulating professional curricula for licensing purposes. Protection of human subjects would seem to be a parallel area where universities might themselves agree to more elaborate and effective modifications in their internal governance systems in order to protect the rights of parties such as human subjects, investigators, and whistleblowers.

The Supreme Court itself has recognized the existence and importance of "campus common law" in resolving issues on campus. However, when the campus administration must make hard decisions about the dismissal of faculty or a department chairman due to financial exigency over the objections of the faculty, the courts tend to uphold the managerial prerogative of the regents, president, and dean.

Another relevant strain of thinking among observers of the academic scene is that universities need fuller internal governance systems if they are to avoid more regulation from the outside. The position of some has been that the federal government, for example, should give money without in any way regulating the university, which is a violation of academic freedom. Although it may seem that if someone pays the piper he should call the tune, this position has precedents. Universities have always attempted to establish autonomy from their funding sources in order to protect the essential tradition of learning and free inquiry which has come to be known as academic freedom. The argument is essentially that academic freedom and the ability to do research undirected and untrammeled by any influences whatsoever is a necessity for the advancement of knowledge and for the greatest social benefit.

Other observers, however, point out that autonomy and academic freedom, if used to protect inequities or violations of individual rights, can cause the legally fragile structure of academic freedom and autonomy to come down. A number of academic leaders have suggested further development of internal governance mechanisms by universities to demonstrate to outside regulatory authorities that errors can be taken care of by the institution. Robert O'Neil, former AAUP general counsel and now president of the University of Wisconsin system, has suggested that there be an academic court which would unify the jurisprudence of higher education. Matthew Finkin, also a former AAUP attorney, has made a more elaborate suggestion for a national academic court. These examples indicate that there is a tide flowing in the direction of increased detail in internal governance that can be used to find a place for IRBs and their functions within the governance structure. At the same time, it is important to note that Westin points out in his book Whistleblowing! that many companies traditionally shun mechanisms that could deal internally with whistleblowers. Universities tend to be even more conservative toward change in internal governance systems than are corporations. It may be that the major research institutions will be more likely to institute internal governance mechanisms than will the smaller universities that do not have as great a need for them, but the resistance of inertia should not come as a surprise.

There also is a reluctance to put in place informal procedures that might be given the force of law by the courts and thus reduce the university's ability to govern itself in its own flexible, adjustable way. Indeed, Jaffee recommended this approach in his article on the protection of human subjects. His concept of "extrapolated common law" would have set up existing self-regulatory practices as a legal standard for defining due care. Yet the courts to date have not used the approach at all. As noted above, the greatest single theme in all higher education cases, regardless of the parties or issues involved, is the reluctance of the courts to substitute their judgment on any issue or their administration for that of the university. Even though the Supreme Court did recognize "campus common law" in the Sindermann case, that principle has not been extended to any significant degree. When the surgery department at Arizona went into court to argue that they, not the dean or the president, were entitled to choose their own chairman under the governing rules of campus common law, the federal circuit court observed, "Consultation and compromise with a department head may in the end prove the best way for the President and Board to run the school. Nevertheless, as the ultimate authority, the President and Board are entitled to have a department head follow their orders."14

IRBs and Governance Patterns

Can IRBs be fitted into governance structures in a way that would make them more effective? I think the answer to that is probably not. That is not to say that IRBs could not be more effective, but rather that the problem of their effectiveness is not completely a governance problem. An IRB's structural position will not necessarily alter its status, although the membership of the board and their relations to the community may. The need for reform may be with the governance structure, not the IRB. Responsible researchers today will state that they have done research in the past that they would not undertake now -- simply because they did not think clearly about the risks earlier. Even though many social science researchers presently feel that IRB review is not necessary for their research, as eminent a social scientist as Talcott Parsons observed that "another reason for the increasing concern with these problems is the rapid growth of research in the behavioral and social sciences. Almost in

the nature of the case, such research makes use of human subjects over a wide range. For example, the concern with child development and various aspects of education involves very sensitive areas."15

Despite the homage paid to departmental autonomy and individual academic freedom in the university, protection of human subjects with the aid of structures such as IRBs is a necessity, particularly for high risk projects and for persons with limited capacity or who are susceptible to any form of coercive pressure.

Researchers in a university setting are under pressure to produce research results and justify money for more research. Promotion, tenure, office and laboratory space and equipment, library resources, secretarial help, travel money, salary increases, and other important professional prerequisites depend on research productivity. Simply put, there is a strong conflict of interest that may affect even the best of persons. For example, research shows that medical schools respond significantly to changes in demand from their major funding sources.16 As James Madison said in the Federalist, when men are as angels, government will no longer be needed. We still need IRBs.

The next question is: Should the government be doing this regulating within the university? Are there not sufficient committees that already exist within the university structure? I think the answer is that the government must do it or see that it is done; the university system of internal governance that grants almost complete autonomy to departments and individual researchers may provide inadequate protection for the human subjects of research. For the reasons outlined above, it is difficult, even within each individual institution itself, to determine what protections exist, let alone whether they are adequate.

A university research review committee does not review the legitimacy of research or decide which research directions should be taken by the institution as a whole. Even in public universities there is no hint of the idea that public money must be spent for a public purpose, whatever that may be. Further, the objection that IRBs duplicate already existing committees often runs to peripheral or extended functions of IRBs, not basic human subject protection. Most universities did not have human subject committees before 1966, and, even now, strong university pressures run against the operation of many of these committees. The human subject committees need the legitimacy of governmental sanction to survive the various competing pressures. Despite their expressed outrage, universities do obey the law. It will be interesting to see how many universities continue to review research proposals now exempt from federal regulations.

The question of governmental interference with university autonomy in a similar context was discussed in a recent Harvard Law Review Note about governmental regulations on faculty hiring, also a core function. The Note concluded that while university autonomy did not appear to be clearly established legally, the idea did appear to merit constitutional protection based on an extension of traditional concepts of free speech and free association. Government activities which infringed on core academic functions would have to survive a high level of scrutiny. In the particular area under discussion, however, the Note concluded that any interference with faculty hiring policies was justified by the important governmental interests achieved: equal employment opportunity and education diversity.17 The Note also concluded that such regulations were not unconstitutional conditions, nor was it necessary to base regulation on explicit prior violations. The same conclusions would appear to apply to the protection of human subjects.

In fact, some comparison between human subject protection and affirmative action may be instructive. Both concern federal regulation of a core academic function, but affirmative action is a much larger and better known effort. The negative lessons from the affirmative action function pertain to its failure to penetrate deeply into the fabric of university life. The office tends to be an external bureaucratic growth on the body of the university; a tireless compiler of statistics and reports which are largely unread. And affirmative action officers do not readily transfer into regular administrative positions.

The positive side of affirmative action is its educational value, which to my mind has never been thoroughly utilized. Part of the ineffectiveness of affirmative action to date has been the failure to penetrate the collective faculty consciousness with the underlying issues of equal educational opportunity. I believe that in large measure this is due to the tendency of both academic and professional university administrators to deal with the regulatory requirements without fully involving the faculty. More faculty involvement might lead to a better enforcement of the policy issues involved, even though it might detract from faculty devotion to core functions.

By the same token, I believe that the truest test of whether an IRB is effective rests with the amount of true education or communication of the basic values involved in the protection of human subjects. Brown and Allan have written that "the functions of an IRB are to educate, inform, and assist in protocol preparation in order to ensure that human subjects involved in research are adequately protected. In the course of fulfilling these functions, the board also mediates, exerts peer pressure control of human research, and influences the development of institutional policy.18 Critics of IRB review sometimes argue that once an academic has passed the tenure test, he should not be subjected to further professional review. The argument seems to be that the tenure review guarantees the actions of faculty members for the rest of their careers. This seems to me to be naive to the point of ingenuousness. Faculty members, like other members of the human race, are subject to many pressures. Much more importantly, researchers may not stop to think, or they may not adequately understand the ethical issues involved. Brown and Allan add: "Such an approach requires that feedback from the reviewers be given to the investigators in order to improve their ability to understand and support ethical issues."19 The truly concerned researcher will appreciate another point of view that may cite a perspective he has overlooked.

How Can These Educational Goals Best Be Accomplished?

First, IRBs should be careful to restrain their activities to their primary function, the protection of human subjects in research involving a degree of risk. The object is not risk-free research, but informed consent. Determining whether consent is genuinely informed should receive more attention. If it can be determined that consent, although technically correct, is really not "informed," IRBs should undertake the task of defining better ways to genuinely inform subjects.

IRBs will function better in the university setting if they resist the pressures and temptations to take on related functions that may interfere with existing governance mechanisms. Although the regulations require IRBs to assume a monitoring and reporting function, it is not clear that they are intended to be investigative or adjudicative bodies. Most IRB members who are faculty are burdened enough by the review of proposals without adding additional functions. However, the board should take the responsibility of determining what investigative and adjudicative procedures

exist and how they would operate. In my opinion those functions are better left to another university body or committee, although the IRB should be kept informed by the university of the progress of any investigation that goes beyond informal discussion, and university rules should reflect this informational requirement.

Further, I believe that while IRBs should educate, they should not publicize. Adverse publicity can have negative effects on a university out of all proportion to the good accomplished. Innocent members of the institution and the institution itself may be penalized heavily through little or no fault of their own. For example, universities avoid major law suits because experiece has shown that they not only cost money but create adverse effects on student applications, faculty recruitment, and outside funding. The Labor Department's approach in negotiating and attempting to settle equal pay complaints might be a model in this respect. The protection of human subjects does not require the destruction of an entire institution.

To further the aim of protecting subjects without damaging the university through adverse publicity, IRBs could explore establishing an ombudsman role for the chairman of the committee or for some other committee member who could receive informal reports to be held in confidence. Some preliminary informal investigating might be done by that person. It would be necessary for such an ombudsman to be well respected and technically competent.

Second, I think each IRB should make every effort to integrate itself into the patterns of governance on its own campus; if necessary, a local consultant on governance should be brought in to analyze the existing structure and the IRB position. One very important factor is the membership of the committee. A committee with faculty members on it may not be a faculty committee in the fullest sense of the word if at least some of its members are not elected by the faculty or selected by the executive committee of the faculty senate. To most faculty, however, election by faculty is necessary to legitimate a committee. At the same time, some discretion in appointments seems desirable in relation to the IRB's educational function. Opponents appointed to the IRB tend to become converts or at least more understanding observers.

The third and most important way to make an IRB effective is to educate the community to the underlying moral and ethical issues. No amount of regulations or rules will take the place of informed concern for the protection of human subjects, but regulations can play their part in creating that concern. Obviously, the drafting of a consent form requires researchers to consider the issues involved in whether it will be approved; in that sense, all activities of the IRB are essentially educational.

To me, the best approach to monitoring is also educational. Every effort should be made to inform the community about the role and function of the IRB and about the issues and values involved in informed consent. Yale Medical School's efforts, described by Levine in this volume, provide a good model. Additional activities might include the distribution of the general assurance signed by the head of the institution, the preparation of an information booklet, the posting of the names and telephone numbers of IRB members, and the posting of a short statement of the IRB's purpose.

An IRB obviously cannot actively oversee all ongoing research, and most IRBs do not want to do so. But some method can be developed that will educate the community about the IRB's responsibility for monitoring, hence encouraging self-monitoring. Such a method might be selective, random enforcement, which is now practiced by numerous federal adminis-

trative agencies. Alternatively, occasional monitoring could be limited to high risk projects. Another obvious way to monitor protection of human subjects is to institutionally encourage reporting or whistleblowing by all individuals working on research projects.

This brings us to the problem of whistleblowers, who are not often popular figures. Here again, the first step is to educate the university or other research community to the value inherent in the protection of human subjects. General knowledge of this duty and responsibility would probably eliminate the need for exercising it. "In-service training" at the beginning of each contract year might both help communicate the issues and support the staff in their reporting role. Units on human subjects ethics might be included in curricula of all allied health professions or, if possible, become a part of the certifying or licensing process.

An initial confidential procedure which could screen out uninformed or unfounded complaints seems important. It should become known that any member of an IRB would be available for discussion of whistleblowing issues on an informal basis. Such a confidential complaint procedure, coupled with a random audit method, might allow investigation to take place with relatively little acrimony while the facts are becoming known. Above all, the institution, through the IRB or elsewhere, must make it known that it values responsible reporting of human rights violations. A well-publicized academic-staff rule prohibiting retaliatory termination for the reporting of violations is an obvious mechanism to inform and reassure the community.

At the same time, IRBs should satisfy themselves that fair review procedures exist for those accused of violations. At UCLA, for example, the exisiting faculty grievance procedures are perfectly appropriate to the investigation and review of alleged unprofessional faculty conduct.

Summary

Can IRBs be fitted into the university governance structure so that they operate more efficiently to protect the rights of human subjects, whistleblowers, and researchers? Elaborate descriptions of the sources and patterns of internal governance make it difficult to tell, for they are confusing and mystifying. As one university president has observed: "The longer I am in administration, the more confused I am. . . . After eleven years as a dean and ten years as a president, I still do not know very positively what academic administration is all about and what works most effectively."20

The complexities and beautiful traditions of university governance and the good humored expositions of the foibles and disingenuous confusion of university life should not be used to clothe the naked fact. As far as individual rights go, the emperor still has a few clothes on. IRB rules should require additional educational efforts concerning the IRB's basic functions within the university. IRB rules should also require full individual reports on the status of each IRB within its own university's governance structure, including descriptions of relevant campus committees or review boards with related functions. Finally, IRB rules should continue to require meaningful procedural protections for human research subjects. These protections do not in any way interfere with true academic freedom, which includes academic responsibility. Academic freedom should not protect unthinking, irresponsible treatment of human beings. If institutional governance mechanisms do not protect against such irresponsibility, governmental regulations must do so. Thomas Jefferson wrote, "I know of no safe depository of the ultimate powers of the society

but the people themselves." The university has wisely deposited its ultimate powers in its people, the faculty. But Jefferson adds, "And if we think them not enlightened enough to exercise their control with a wholesome discretion, the remedy is not to take it from them, but to inform their discretion." The IRB must deal most seriously with the informing of this discretion.

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Chapter 3

COMMENTARY: THE CONFLICTING MISSIONS OF IRBs

Spencer Foreman

My own institution is a free-standing institution, a community-based teaching hospital, with a history of its own research. We are affiliated with Johns Hopkins but have always been independent; the two points of view that Dr. Gaintner and I bring to the discussion are those of biomedical research within and without the university structure, respectively.

Professor Mashaw's paper I found to be an elegant analysis of IRBs and their problems. I was intrigued by the remark that he had never had any firsthand experience with IRBs, but I think that his investigation illuminated many issues that I would otherwise never have seen as clearly.

It was a deft dissection of both the physiology and anatomy of the IRB and its problems. I found myself thinking -- in view of his discussion that IRBs have difficulty in meeting their manifold and frequently conflicting missions -- that it was surprising that they work at all. He makes a very strong case for localness. I think his comments that localness strengthens legitimacy, fosters responsiveness to local desires, and ultimately enhances the implementation of national programs are very cogent; they are persuasive arguments against the claims that decentralizing government introduces an unacceptably wide range of enforcement of what should be uniform standards for national programs.

I thought he argued somewhat less persuasively that self-regulation by beneficiaries is not ultimately self-serving. I think it is. It may be less self-serving than some other forms, but I think professionals do in fact organize themselves around their own interests and attempt to build a structure to protect themselves.

Professor Mashaw did argue that self-regulation may be more restrictive than regulation by others and that professionals are responsible to a broad national community, not merely their local university or peer group. I do not think, however, that this is the dominant way that professionals operate in self-regulation.

In sketching the various decisionmaking roles as paradigm cases, the paper vividly brought out our expectations of the various roles and the problems of trying to fulfill these roles. Professor Mashaw analyzes the assigned tasks of the IRB: Are the research methods appropriate? Is the selection of the subjects equitable? Are the risks minimized consistent with sound scientific methodology? Are the risks worth benefits likely to be obtained by either the subjects or society generally? Are informed

consent procedures adequate? Is there adequate protection of privacy? Are special groups properly protected?

IRBs are working on these problems in an atmosphere in which they must consider institutional rules and commitments, the law, practice, and community standards. It would be very difficult to imagine any uniform structure that could meet all those responsibilities against that background of requirements and come up with anything that wasn't controversial.

Professor Mashaw concluded, in my judgment, that in the performance of each of the paradigm roles there are serious shortcomings. As bureaucrats, IRBs have been very inefficient, even in the performance of simple repetitive monitoring tasks like assuring that informed consents are truly being obtained from every subject in a study or assuring that research is being conducted according to the protocol the investigator submitted at the beginning of the research. Those are easy tasks and there is no evidence that they are being done properly.

In their proper relationships and their fiduciary responsibilities, the IRBs, he points out, are seriously compromised by having to conduct risk-benefit analyses in which the risks are borne by the subjects and the benefits (most likely) by society. This separation of the risks and the benefits makes the analysis very difficult. A related problem is that of determining to whom the IRB has the greater responsibility -- to the subjects or to society; it doesn't know to whom it is supposed to be a fiduciary.

Furthermore, in attempting to meet its responsibilities to review the informed consent procedures and to ascertain that consent is really informed, the IRB can't -- in the absence of any kind of continuing staff support -- go beyond the screening of consent forms; it doesn't have the personnel to confront the subjects themselves on an ongoing basis.

The judge's role in value-defining allows broad scope for ordinary moral judgments, perhaps too broad. The IRB also has very broad latitude in determining what is right and holy; this provides the opportunity for widely differing interpretations from institution to institution (and even within one institution or even from case to case) as to what are the standards against which things should be morally evaluated.

Finally, while having some attributes of a political animal responding to various constituencies and stakeholders, IRBs really don't have an equal responsibility to each of their stakeholders. They tend to be more accountable to the institution that supports them and/or staffs them and to their peer groups than to any of the other stakeholders in the process. The presence of one public member is not going to change that substantially.

The essential observation that I found absolutely wonderful was that the better the IRB functions in one role, the worse it functions in others; the various models are competitive. Professor Mashaw suggests that a better way to deal with the various roles would be to partition them among various institutional elements. He observes that considering we expect the IRBs to be efficient bureaucrats, fiduciaries to the subjects and to society, wise judges in individual cases, and to achieve adroit political accommodation in the context of several competing value systems -- medicine, science, and society in general -- with the goal of both fostering research and protecting human beings, they ain't doing bad. As a matter of fact, it is remarkable that they are able to function at all.

The author suggests that IRBs might be helped by shedding some of the tasks and by being reinforced in carrying out others. Such reinforcement would require some staff and other kinds of support. Furthermore, he makes the case that fragile collegial support systems might be damaged or have been damaged by the IRB's trying to have a police and judicial function at the same time; one compromises the roles of IRB members (e.g. as investigators in the university setting) by setting them up as a police-jury-traffic court.

In sum, I certainly agree with his analysis. I will make some suggestions later as to how I think the processes might be improved. But I think the analysis of the IRB is a deft one, and I was intrigued by it.

I will now turn to Ms. Nordin's paper. Her paper, it seemed to me, emphasized that university governance systems are not designed to protect the rights of persons, but to protect university processes and only parenthetically the rights of faculty within those processes. Competing forces within the university are unlikely to permit the IRB to work or even survive without the legitimacy of government sanction.

With noteworthy exceptions, particularly in the conduct of research involving poor persons, the tradition of medicine and biomedical research, at least as it has been conducted in hospital, has tended to protect the research subject to the extent the subject has been seen by the investigator as a patient. That is, to the extent the investigator has recognized the subject as a patient, there are some inherent professional protections related to the basic relationship between the investigator and the subject. That has not always been true, particularly in public general hospitals. It certainly wasn't true with the syphilis study, and it's not always been true in dealing with poor populations in general.

But there is a tradition of medicine that brings to the treatment of human beings in a hospital setting strong protective biases. And it seems to me that IRBs or some successor model would remain even if the government were to suddenly lose interest in the whole business.

How much of a commitment there is to the protection of human subjects we ought to be able to measure by doing some assay of how many research projects involving human subjects are being reviewed by IRBs that don't have to be -- that is, funded from some other source for which there is no mandate. That ought to give us a reasonable guess of what IRBs are committed to doing.

Ms. Nordin, as she pointed out in her summary, saw the functions of the IRB as educational, instructive, but not investigative or adjudicative, those functions being better done by others. She suggested the ombudsman role for the chairman and saw the IRB working best if placed within the governance system of the university. IRB members should be elected by the faculty and have the functions of educating the community in moral and ethical roles. It would be desirable to have selected random enforcement of monitoring functions to encourage self-monitoring. I found that very interesting. The reason I stop at a traffic light is not because I have a commitment to social justice, but because there may be a cop at the light and if I don't stop he'll nail me. That gives you some idea of my biases at the outset.

In thinking about how IRB processes might be improved, I made a note to myself that the regulations governing IRBs mandate that they review protocols, conduct risk-benefit analysis, survey informed consents, and monitor protocols for any change in the risk-benefit ratios.

One of the major problems in monitoring the protocols is related to the amount of work involved; IRB members have other more important work to conduct. Monitoring clearly requires staff. But what I didn't see noted in the paper, or in any of the papers, is the understanding that IRBs have trouble developing a monitoring system because they frequently don't understand the research or what needs to be monitored. If IRBs are to have the responsibility of developing a monitoring system, they must have a very sophisticated understanding of what the project is all about and how to monitor it.

I thought that one of the ways a monitoring system might be built would be to require that an investigator submit along with the research protocol a proposal for a monitoring system, which could then be evaluated along with the proposal. Then the IRBs would have available some reasonable methodology by which the research protocols could be watched.

Furthermore, developing a proper audit of any activity requires the setting of criteria and the monitoring for compliance with those criteria. This is a complicated and burdensome process that in clinical medicine requires a whole quality assurance apparatus. Perhaps the task of monitoring research could be simplified significantly to alleviate a major burden of the IRBs, for example, by having the investigator prepare the monitoring protocol, which would then be transferred to an appropriate staff of trained reviewers, either assigned to the IRB in very large institutions or borrowed from the risk management or quality assurance groups within the hospital, who would perform the actual monitoring tasks and report to the IRB.

There already are these apparatuses in existence. Every hospital in the country that is accredited has a body of staff persons who are basically doing the police work for quality assurance, and they know how to use a protocol and how to do an "all or none" measurement. They don't make judgments; they simply collect data, summarize it in an easily readable form, and present it to whatever professional body makes the judgment. In this case it would be the IRB.

Therefore, I don't think one has to construct a very large staff, at least within a hospital; one has only to integrate the function and fund the existing staff to do it. Whistleblowers then would have the opportunity to report deviations through this staff (or directly to the IRB). Since quality assurance staffs already collect sensitive data from everybody, the whole notion of whistleblowing would disappear. It would simply be one additional information source for the monitoring function.

Finally, I thought one of the principal problems in asking the IRB to function as both the judge and jury is that the members of the IRB could not maintain their professional roles within the institution with so heavy a burden. This is further complicated by asking them to accept the responsibility of reporting their colleagues to the federal government. These are conditions no one could fulfill.

One of the ways to get around that is to preserve the jury function of IRBs without giving them the judge function. If the IRBs had the responsibility of only making a judgment on the facts, e.g. that there was or was not a violation of the informed consent requirement, that the protocol had been altered to materially affect the risks, or that the data appeared to be erroneous, then there could be a transfer of the case to some other institutional entity for action, to an entity more properly structured to handle the evaluative and disciplinary components related to the IRB's factual determination. That entity could be the chancellor's, the dean's, or the hospital director's office. The rules by which the action is

judged could be, for example, the medical staff bylaws, the university bylaws, or the faculty rules. In any case, once the IRB has said, "This research violates what the investigator proposed" or "They aren't getting informed consent," what happens thereafter should go over to an administrative authority that has the responsibility for pursuing the findings of fact, conducting hearings if necessary, and blowing the whistle to the federal government. I think this puts the responsibility for reporting on the institution, where it belongs, i.e. in the hands of the institutional administrator or the institutional governance system.

Chapter 4

COMMENTARY: TEACHING HOSPITALS, IRBs, AND THE PROTECTION OF INDIVIDUAL RIGHTS

J. Richard Gaintner

Since I believe it is important for people to know your biases, let me tell you just a little something about my background. At one time or another I have played all the roles we are discussing except for that of the federal government. I have participated actively in research on human subjects; I have been the subject myself of several research projects; and I have blown the whistle on several occasions. But at the same time, I really am clearly an institutional person, having been in the administration of two different medical schools (the University of Connecticut and Johns Hopkins) for the last twelve years (in addition to my faculty responsibilities), of a community hospital for several years, and of a large university hospital at present. In addition, when I was at the University of Connecticut, I served as chief of staff of the university hospital and had considerable input into the development of the human research protocols in that institution.

My views are my own, although they do result, as Dr. Foreman pointed out, from our conversations as well as from conversations with individuals at Johns Hopkins (both in the medical school and in the hospital) who sit on the IRB and who have been very instrumental in the way it operates.

I did have the privilege of serving for one year as a member of the Johns Hopkins IRB and was also responsible administratively as associate dean of the medical school.

I am bothered a bit by the terms "whistleblower" and "whistleblowing." I think they tend to have pejorative connotations, particularly in the assumption of guilt by the use of the term, which I think is unfortunate. I think that may start the whole process off in the wrong direction.

I will comment briefly about the papers, hopefully emphasizing a few things that Dr. Foreman did not mention. I would then like to comment about the organization and governance of a university medical school and hospital (especially the latter).

I found the papers most interesting, informative, and provocative. In general, I agree with them and feel that Professor Mashaw did a superb job in modeling an extremely complex situation. I would like to quote from the last paragraph of his executive summary: "It is my conclusion that

the current structure and authority of IRBs is generally appropriate" -- with which I agree. "The principal danger to an effective IRB process is institutional overload -- the assignment of tasks to IRBs that are ultimately incompatible with their core functon of ethical review to protect human subjects." I believe that such protection is the core function and that it must be protected.

I also very much agree with his statement, "Ethical review at the local level recognizes the intractable ambiguity of many value questions and reinforces the traditional liberal commitment both to pluralism and to individual moral responsibility."

I think the models which Professor Mashaw discussed -- bureaucratic rationality, professional treatment, moral judgment, and micro-political accommodation -- are very insightful. I think that professional treatment and micropolitical accommodation adjust well to the IRB. I think the moral judgment model is more an institutional responsibility, and we are faced with the question of where bureaucratic responsibility fits into it.

I would underline one other statement Professor Mashaw makes in his paper: "Moreover, to the extent that the IRB as a unit is accountable to anyone, it seems primarily accountable to the institution which appoints, staffs, and funds it." I am a great believer in the adage "If it ain't broke, don't fix it," so I would hope we try to fix the parts that are broken, not the parts that aren't. I would also agree with his statement that "it is my intuition that the subject's great protection is in gradually upgrading the consciousness of researchers." Finally, his conclusion, I think, is important: "If we would have wise judges and paternalistic professionals, we can neither specifically direct nor objectively evaluate their behavior."

Moving on to Ms. Nordin's paper, I think she presents an excellent historical overview of university organization and governance. I certainly agree that university organizations are diverse; it is difficult to generalize. I am not of the belief, however, that universities cannot protect individual rights. I believe that they can. I would not be presumptuous enough to say that they all do. However, in my experience with five different universities, I have felt comfortable that there were processes that protected not only academic freedom, but the individual rights of subjects, of researchers, and of whistleblowers as well. I think the last is the most difficult. I also feel that the IRB can fit into the university organization effectively.

I was particularly struck by Ms. Nordin's remark about faculty perceptions of administrators. "Faculty members believe administrators to be those who didn't do so well as scholars and that the only good administrator is a reluctant administrator." I believe this is true. I believe it is changing. Perhaps it is a self-fulfilling prophesy, but I believe the world is becoming so complex that at least a few of my colleagues at Johns Hopkins think what I'm doing has some intrinsic value and helps them to do what they are doing.

I am also drawn to the part of her summary where she says, "Protection of human subjects does not in any way interfere with true academic freedom, which includes academic responsibility. Academic freedom does not protect unthinking, irresponsible treatment of human beings. . . . If institutional governance mechanisms do not protect against such irresponsibility, governmental regulations must do so."

Although I think the last sentence is true, I would hope we would not immediately jump to the conclusion that institutional mechanisms are inadequate, which would therefore require regulation from the outside.

Although Ms. Nordin's paper is quite accurate with regard to universities, I believe that medical schools as a part of universities are somewhat different. I know I will get into hot water with various university presidents and others, but I think we do have to recognize that they are different. They fit somewhere in between the university in general and the hospital. Although academic freedom and autonomy are protected, medical schools tend to be more hierarchical than universities, but less hierarchical than hospitals.

The academic responsibility of the faculty throughout the university is similar, but most clinical faculty are also very much a part of the hospital organization, are familiar with the organizational form of the hospital, and frequently wear two hats, being faculty members as well as care-providers and participants in the medical staff organization.

I would like to contrast different kinds of hospitals for a moment. Dr. Foreman spoke about his sort of institution, with which I think we are all familiar. I would classify that as an independent or voluntary hospital.

There are probably three models for university-related hospitals. One is the Harvard model, where the university and the hospitals are very separate, but with very strong affiliation; the hospital actually participates in research -- as a recipient of research grants and as an autonomous organization.

A second type is like Johns Hopkins Hospital; although it is a separate corporate entity, it is the primary hospital associated with the university. It is not controlled by the university but is inextricably intertwined with it. The dean of the school of medicine and the director of the hospital are colleagues, meet regularly, and work jointly. Things that are done in the hospital are done with the knowledge, understanding, and (hopefully) support of the medical school and vice versa. We have a series of joint committees. One of our joint committees is the IRB, which is primarily made up of faculty members, most of whom are also clinicians on the hospital staff. It does have the hospital legal counsel sit on it, as well as several other hospital people and outside people.

The third type is the university-operated hospital. I had experience with this model at the University of Connecticut. It is usually a state university that is involved in this type of arrangement.

To contrast these three models, there appears to be more conflict between the care-giving and research functions when the hospital is owned and operated by the university than in the case of either the Harvard or Johns Hopkins model.

Most hospitals are organized aiong either of two lines. One is where the board of directors of the hospital delegates administrative responsibility to a chief executive officer, such as Dr. Foreman, under whom there is a variety of other people. As he mentioned, one of those administrative responsibilities is the quality assurance program. Alongside the administrative structure is the medical structure. The board actually delegates to the medical staff the responsibility for rendering quality care. In a totally independent hospital the physicians are in private practice, possibly with some full-time doctors.

Ours, by way of contrast, is primarily a full-time model, although there are individuals in private practice. The physicians who head up the departments administratively also wear another hat as practitioners responsible for the quality of care. The medical board is made up of physicians responsible directly to the board for monitoring quality.

The interesting person in this model is the department head. That individual is the head of the university department charged with research and other academic activity. That person is also the head of the hospital department responsible for the practice of medicine and for the quality of care. And in our institution we've gone a step further and delegated to that individual the responsibility for the administration and management of those clinical departments. So it is really the place where everything comes together. These individuals are appointed, and they often serve for long periods of time. They do have professional administrators associated with them who bring to bear considerable administrative, organizational, and financial expertise, which is not present in the usual university organization.

I believe that the federal government, through its grants, laws and regulations, should hold an institution -- university, hospital, or both -- responsible and accountable for the pursuit of biomedical research. I think the institution then is accountable through the general assurance statement and through the delegation of specific duties to the IRB, primarily protocol review for protection of human subjects and for research risk-benefit. I agree very much with Dr. Foreman; the IRB should be responsible for the the factual review of whistleblowing, not the judgmental review.

One of the things that the Johns Hopkins IRB does where the anticipated risk is higher than ordinary is to approve on a limited basis. The IRB asks an investigator who has set forth a protocol to work with a small number of subjects, "Why don't you do this with one or two and come back to us and discuss your experience? And we'll go on from there."

I very much support the position that the IRB should not be responsible for the judging function; once the whistle is blown, I believe the IRB should participate in an evidentiary way, but this should then be passed on to the appropriate administrative mechanisms within the institution. I think that then the institution is responsible for reporting to the government with regard to any violations.

With regard to the monitoring function, I would like to underline what Dr. Foreman has said. In talking about this we recognized that within the hospital there is usually a fairly elaborate quality assurance mechanism. There are staff people (frequently nurses) who continually go to the floors, review charts, and so on. It seemed to us this would be an excellent mechanism to formally plug into the monitoring function. The only other approach, it seems to me, would be to add staff to the IRBs. I think the cost of that would be prohibitive, at least in terms of a cost-benefit analysis.

I think that the dean and the executive faculty committee, plus the hospital director and the medical board, should review cases where there were problems. Frequently we have done this through ad hoc committees, which report to the executive faculty and medical board. Then a judgment, hopefully protecting the due process of the accused, the whistleblower, and the institution, would be carried forward. I think also in most institutions there are elaborate appeal mechanisms that could be brought into play, all the way up to the board of trustees. Then the institution would notify the government of any wrongdoing.

In summary, my general feeling is that although there have been some very significant and serious problems, in general the system has worked quite well. I strongly favor institutional responsibility and accountability and would be vehemently against the imposition of onerous additional governmental bureaucracy. As someone mentioned earlier, I too believe that in the final analysis, peer pressure is more effective on the kind of people we are talking about than any threat of legal action.

Chapter 5

DISCUSSION

PROF. GRAD: I am a bit puzzled. We seem to be discussing two separate issues. On the one hand, the IRB has to evaluate the risk to the subject and has to determine whether the risk-benefit ratio is reasonable. For example, is the subject open to enormous risks for relatively minor benefits? On the other hand, there are issues concerning the integrity of and the wisdom of the research and study itself. The IRB I work on has generally avoided these latter issues concerning the scientific design and value of the research itself. Such avoidance seems appropriate, given the IRB's role of protecting subjects; evaluating research design and value is the proper business of the granting agency

The distinction between the protection of subjects and the scientific integrity of the research relates directly to whistleblowing, the calling of attention to the fraudulent misrepresentation, misconstruction, or misalignment of data. The problem is that the protection of subjects is not inherently related to the bona fides or fraudulent aspects of the research itself. In other words, a subject may be properly protected even though the research is phony or crooked, and a subject may be at risk in a very well designed study.

I can't find anything in the HHS regulations that concerns the bona fides, the regularity, or fraudulent representation in the study itself. If there is anything in there, then it is in there by implication. As a lawyer I am rather good at discerning implications, and I just can't find any. If so, it is perhaps wise to deemphasize the role of the IRB in dealing with whistleblowing and fraud in research. In addition, IRBs are not equipped to deal with such issues. It would take a good deal to equip them to do the very detailed kind of scientific investigation to make sure that the results are borne out by the data, that no undue claims are made, or that there is no fraudulent data.

MS. MISHKIN: You will find in the HHS regulations more explicit directions for reporting to HHS both unanticipated adverse effects or unanticipated problems that seem to pose risks to subjects. There are also directions concerning the continuing and serious failure to comply with the regulations or with the IRB's directives.

Because these are new provisions in the regulations and haven't been in practice for very long, it is not clear what the department's intent is with respect to these provisions. The President's Commission has addressed some questions to the department for clarification. One question

we should address here is to what extent it is realistic to ask IRBs to perform these functions, which are now quite clearly in the regulations.

PROF. GRAD: I fail to find anything in the new HHS regulations that deals with the regularity of research. There is continuous review, monitoring, and so on, but it does not impose on the IRB any obligation to monitor the bona fides, originality, or lack of fraud in the research itself.

MS. MISHKIN: You are correct in saying that there is nothing specific. The commission has expressed itself on this particular problem to the extent that fraudulent data may pose a risk to subjects because of decisions with regard to continuing or terminating a research project. Fraudulent data may also affect decisions with respect to what is the better of two treatments. If the data are fraudulent, all those decisions may be misguided to the detriment of the patients participating in the research and ultimately to patients down the line. That is the connection as the commission sees it.

PROF. ROBERTSON: Let me also respond to Professor Grad's point. He said as a lawyer he is very good in finding implications. Both Professor Glantz and I, who are lawyers, picked up our regulations and started leafing through them. I think one can find the implications that Professor Grad misses. For example, look at 46.111(2), which concerns the benefit-risk ratio. Risks should be reasonable in relation to anticipated benefits. If there is fraud, the benefits will not be very great. Therefore, it may not be ethical to submit people to the risks associated with such research. This gives IRBs a reason to be concerned with fraud.

PROF. GLANTZ: It seems to me that the regulations set the minimum requirements for what an IRB can do, but the IRB can also do other things. One of the questions here is what those other things should be.

DR. FOREMAN: The IRB has the obligation to understand sufficiently the nature of research to understand the risks and benefits in broad terms. The value of the research to society in general usually falls to the internal review processes of the department that sponsors the research and ultimately to the funding agency. But the IRB needs to know enough about the research to understand what benefit could reasonably be anticipated by an honest researcher. The risk must then be measured against that benefit. This is much easier to say in this conference than it is to do in the IRB.

DR. SWAZEY: I would like Dr. Gaintner and Dr. Foreman to discuss the lines of responsibility within the hospital-medical school structure. There are people wearing many hats; there are many roles. Focusing for a moment on whistleblowing -- which I think is distinct from monitoring, consent forms, and so on -- people might want to report not only fraud in research, but other types of perceived unethical conduct with patients, for example.

It seems to me the hospital-medical school structure is so complicated that there are no clear lines of responsibility. This creates a problem with "passing the buck." There are suggestions, however, in some of the conference papers that department chairmen should be recipients of complaints and be responsible for monitoring.

I was wondering what Drs. Gaintner and Foreman see as some workable mechanisms for dealing with whistleblowing and the consequences of whistleblowing.

DR. GAINTNER: Let me look at it from the side of the medical school and then the side of the hospital.

I think that in our medical school, at least, there is a fairly strong departmental and subdepartmental organization and tradition. There are intradepartmental mechanisms, traditions for dealing with misconduct at the level of the division head, the department head, and of the dean. There is also something analogous to a faculty senate. In addition, the department heads gather as an advisory board. Finally, there is a formalized grievance procedure.

Outside the medical school, there are also university mechanisms. The president's office will frequently be the place where people will go to report problems. It is not unusual for a faculty member who is concerned about something to go directly to the president about it.

It seems to me, therefore, that there are both informal and formal mechanisms to deal with misconduct. This does not assure, of course, that the rights of the accused or the whistleblower are protected. But with the various modes of appeal and so on, I think there are at least reasonable chances that that is the case.

Let me now turn to the hospital setting. We became very interested in risk management several years ago for purely economic reasons. Our malpractice bill was going to be $3.5 million. We subsequently became self-insured and are now members of a consortium with four other hospitals who have set up a captive insurance company.

What we have done internally is to establish what we call a "risk-management program." We have an "incident review committee" (composed of medical staff) to whom the law office of the hospital brings incidents.

This committee then tries to deal with two things. First, how is that particular incident being looked at and dealt with by the department and the institution? Second, what kinds of generic issues does this bring up that we perhaps ought to look at? One recent generic issue, for example, concerned two different things that had labels that were practically the same. One was very dangerous when administrated intravenously; we got the company to change the labels.

The incident review committee is not formally responsible for misconduct in biomedical research. But there was an incident brought to the attention of the in-house counsel where an investigator did something that was not part of the protocol. This was then dealt with as an incident related to potential medical risk management rather than to the biomedical research per se.

There is also -- above this incident review committee -- what we call a "joint committee on professional liability," which, in addition to having faculty, medical, and administrative people, has trustees from both the university and the hospital sitting on it. As you might expect, at least one of those trustees is an attorney. And the trustees are obviously concerned about institutional responsibility, accountability, financial affairs, protection of human rights, and so on.

Within the hospital there are also mechanisms similar to what I described within the university, e.g. departments and departmental structures, an executive committee, and a medical board. There are also other people, including attorneys, who are concerned about quality control issues. We have a full-time physician in infection control issues. We have a full-time physician who is dealing with issues of medical practice evaluation. And we are going to have a full-time clinical pharmacologist employed by the institution to examine issues of drug therapy and so on.

In sum, I think our problem is not the lack of formal and informal procedures. But we have failed to take the steps required to make these procedures formally applicable to research misconduct.

PROF. ROBERTSON: Have you had experiences with whistleblowing concerning medical malpractice or patient care?

PROF. GAINTNER: Yes. That's the model to which I am specifically referring.

MR. ROBERTSON: Aren't those cases where a suit has been filed?

DR. GAINTNER: We have a system that attempts to identify incidents by whatever mechanism we can. We have what are called "incident review coordinators" (who now have been merged with our quality assurance group -- primarily nurses) who review things on the units. These coordinators review records and get to know the nurses on the units. This is an attempt to encourage internal whistleblowing so we can identify incidents. This is enlightened self-interest because the more we know about incidents, the more we can do to avoid litigation and to take care morally of problems that occur.

PROF. ROBERTSON: So you do have some kind of system set up?

DR. GAINTNER: Yes.

PROF. ROBERTSON: Independent of suits being filed?

DR. GAINTNER: Yes. The suit mechanism now is less than five percent of the way we track incidents. And that is why this program has resulted in our medical malpractice insurance costs being less than a million dollars a year now.

DR. FOREMAN: Can I comment on a different aspect of this? Without a definition of "whistleblowing," it seems to me we are seven blind men and an elephant. I don't define in my own mind a whistleblower as someone who communicates the truth. I define a whistleblower as someone who communicates the truth when the institution resists it. It is an Emile Zola "J'accuse" situation. If you find an institution which actively attempts to collect data and somebody drops some data into it, that person is not a whistleblower. That is, if I post a suggestion box on the wall and somebody drops a suggestion in it, then I can't call that person a complainer. He is a suggestion-giver.

It seems to me the thrust of some of the mechanical changes in process that we have been talking about is to desensitize the process, which is what Dr. Gaintner has done at Johns Hopkins. The hospital administration is saying, "We want to know what's going on." That changes the character of information collection, changes the character of whistleblowing from rat-finking to submitting wanted information as part of an established and accepted process. If an institution establishes a legitimate process to welcome that information, that is all the protection a whistleblower ever needs: "Come tell me." If the whistleblower is telling the truth, that should be the end of it if the institution genuinely wants the information. If it doesn't want the information, of course, that is a different issue.

The question becomes: What do you do when you find someone who is doing bad things consciously, when the research is fraudulent, or when subjects' rights are being willfully abused? What is there that exists within the hospital to deal with the researcher? It depends on who the

researcher is. Ms. Nordin's description of the difference between university staff and university faculty is analogous to differences that exist in hospitals as well.

The medical staff, which includes physicians, dentists, podiatrists, and Ph.D.'s, is a self-governing entity with its own rules and regulations sanctioned by the institution, which operates on the assumption of peer review. Non-medical-staff researchers are like the nonfaculty staff in Ms. Nordin's description. Their rights are the rights of any employed person in the institution, and they may be governed either by personnel policies or contracts, depending on the arrangements by which they are brought on.

In fact, however, virtually no significant human research in hospitals is conducted without a principal investigator who is a physician. There is always somebody at the top (whether he or she is actually conducting the research) who bears the responsibility and who is governed by the medical staff bylaws.

I cut and pasted a couple of things out of our own bylaws to give you an idea of what you have to do to be forced off the medical staff. It is interesting that in the membership section of our bylaws, Section (a), says: "The code of ethics which shall govern these bylaws is the code of ethics adopted by the American Medical Association, the American College of Surgeons, and the American Dental Association."

Our bylaws thus define what ethical codes we are going to be governed by. Presumably the dentists will be governed by the dentists' association, surgeons by the surgeons' association, and everyone else by the AMA.

There are two reasons for automatic recommendation for expulsion from the medical staff. The first one is to lose one's license to practice medicine or dentistry. The second is to fail to pay your dues. In addition, "Discretionary recommendation for expulsion or suspension shall be drawn from one of the following four charges: To act in a manner tending to impair his ability to practice medicine or dentistry; to act in a manner violating the code of ethics of a member's profession; to fail to accept reasonable and customary duties; to commit other violations of these bylaws." When one looks at the charges by which you may be brought to trial in our hospital, there are only three significant ones: You've lost your license; you are acting erratically because you are either physically or mentally ill; or you are acting in an unprofessional or unethical way. And we have defined in our bylaws what we will hold as the canon of ethics against which a person should be tried.

Now, it is my guess, without having reviewed each of those three ethical precepts, that nowhere among them is there an explicit statement regarding ethics in biomedical research.

PROF. ROBERTSON: Is there something to the effect that you could be kicked out for a violation of institutional rules?

DR. FOREMAN: Yes.

PROF. ROBERTSON: Wouldn't that encompass it?

DR. FOREMAN: Perhaps. I am only suggesting that institutions that do biomedical research ought to have a specific code of ethics applicable to such research. The other codes are simply too vague to provide any guidance for the proper treatment of research subjects or for evaluating

research misconduct. Nor does the State of Maryland medical practice act, for example, provide any such guidance.

MS. MISHKIN: Another important issue concerns the responsibilities of a physician acting as a principal investigator for the conduct of other members of the research team. Some of the principal investigators who have been accused of misconduct in research have blamed junior members of the team and have simply disclaimed any knowledge of what was going on. But the principal investigator is, at least to a certain extent, accountable to his institution and to the funding agency.

PROF. WEINSTEIN: I have three comments. First, when we are looking at hospitals as research institutions, we need to recognize their special structure. And with regard to disclosure of improper acts on the part of physicians, nurses make very good informants simply because the relationship between doctors and nurses is, as we all know, full of antagonisms, hatred, mistrust, and so on. But we cannot assume that that kind of relationship exists in other kinds of research settings. The antagonistic relationship between physicians and nurses encourages whistleblowing. It helps to have that kind of antagonistic relationship.

Second, it is not clear to me that fraudulent research is always useless. Such research may be quite useful even though it would be fraudulent by any scientific standards. For example, fraudulent drug protocols may expedite FDA approval of a drug that has already proved effective in other countries.

Third, no matter what procedures for reporting research misconduct are established within an institution, these procedures will not be effective unless persons in authority are genuinely interested in receiving such reports. The attitudes of persons in authority are crucial to the success of the procedures for reporting and dealing with research misconduct.

DR. MEDEARIS: I would like to return to something Professor Grad mentioned. What happens when a physician-scientist sitting on an IRB has doubts concerning the scientific merits of a research project?

PROF. GRAD: Research proposals are usually passed on to the IRB through a particular department of the hospital. The proposals have therefore already been reviewed; the principal investigator has discussed and reviewed the project with a particular section chief. In other words, it comes to the IRB with a number of endorsements. Nonetheless, a proposal is sometimes returned to the department with a request to explain further the scientific rationale or justification for the research project.

PROF. GLANTZ: Concerning who the whistleblower is, I would like to make two brief definitional remarks. First, a person who has a specific responsibility for reporting something wrong in an institution is not a whistleblower. It is only persons who have no such responsibility who "blow the whistle" in reporting misconduct.

Second, the more a person stays within the institution, the less likely he or she is to be considered a whistleblower. The less a person jumps over levels of the bureaucratic structure, the less likely he or she is to be considered a whistleblower.

MS. MISHKIN: I think that's a good distinction. We can see how well it works as we go through the rest of the sessions.

DR. McCARTHY: I have several comments. First, could IRBs exist or continue to exist unless they were bolstered by federal regulations? We

have done some historical work in our office, and I have evidence that IRBs go back to at least 1929. I have no reason to assume that that is necessarily the first instance, although they weren't called IRBs until the legislation back in 1974. There were human subject protection committees or committees with similar titles to review research back all the way to 1929 in some of the California schools. At the time that the possibility of a federal policy was under discussion in the early 1960s, we had a group at Boston University look into the matter. They identified some sixteen institutions that had IRBs or some equivalent.

Thus, there was a strong institutional tradition of reviewing research. One of the reasons we have hoped that the federal regulations may be effective is that they were developed and designed with the intention of building onto an already acceptable type of institution rather than creating something de novo.

Second, Ms. Nordin raised in her paper the question of informing faculty members, as well as subjects and others, where they might report information. I would simply call your attention to our new regulations that require that the general assurance, once negotiated, be circulated to all investigators in the institution and to staff who are associated with research. They also require that the consent documents that are used to inform patients or used as part of the information process be given to the subjects. These documents must contain, among other things, the name and phone number of a person to whom they can address complaints.

Third, several persons have discussed the monitoring function of IRBs. I would simply call your attention to the fact that the word "monitor" is nowhere found in HHS regulations. The phrases "annual reporting requirement" and "reporting as appropriate" are found in the regulations, but "monitoring" is not, except in one context that is probably irrelevant to this discussion; the IRB may, if it chooses, ask the investigator to establish a data and safety monitoring function, often involving a separate committee. This seems to us to be very appropriate in multi-center research projects where the data is perhaps not in the possession of any single individual. Therefore, if an alarming trend should occur, it might not be known unless there is a central monitoring function that can pick up data from a large, multi-centered clinical trial.

The phrase "continuing review" occurs in the context of annual reporting. One might infer a lot from that, but I suspect that the writers did not so intend. The reporting responsibility, at least in the drafters' minds, was primarily one for institutional officials. The language, however, is somewhat ambiguous: "The IRB is responsible for reporting to the appropriate institutional officials and the Secretary any serious or continuing noncompliance by investigators." We understood the normal way of reporting would be through institutional officials. But we had at least one case where the IRB had reported to the institutional officials and no action was taken. We wanted to allow for that kind of jumping over the administration if this appeared to the IRB to be the only way that appropriate action could be taken.

Fourth, it is not quite correct to say that federal responsibilities have been delegated to IRBs. We simply have set conditions that institutions must meet if they wish to qualify for federal funds. Thus, in my view, IRBs are not extended arms of the federal government.

Fifth, with respect to principles that investigators should follow (or a code of ethics), we have asked that the general assurance establish a set of principles that will govern the conduct of investigators in the institution.

MS. OAKES: First, I think Dr. Foreman's definition of a whistleblower is too narrow. I would suggest that the definition of a whistleblower has to include somebody who complains -- even internally -- about alleged wrongdoing among his or her colleagues. For our purposes I don't think it makes much difference if the complaint is made to the institution, to a governmental entity, or to a state licensing board.

Second, despite the optimistic descriptions of systems already established at Yale, Johns Hopkins, and elsewhere, it seems to me that it is not enough to rely on the institution itself to handle allegations of wrongdoing; there is a built-in conflict of interest, a perfectly understandable one. The individuals on the committees that Dr. Gaintner mentioned have their primary loyalty to the institution, which is as it should be. But this may lead to a perhaps subconscious reluctance to investigate or to get to the unpleasant truth of the matter.

Third, if I were a whistleblower or if I were someone who had been accused of wrongdoing, I would not want to rely solely on the existing institutional mechanism. And I find it somewhat interesting here that the mechanisms at Boston University and at Yale, for example, have been set up after the crisis has come and gone. The problem is that insofar as I know -- and my knowledge admittedly is limited in this field -- the majority of institutions do not have adequate mechanisms.

Fourth, I don't think it is possible to find out how much fraud occurs; I suspect there is somewhat of a chilling effect that exists now. That is to say, a number of would-be reports of wrongdoing are never made because the potential whistleblower fears that he or she will suffer disastrous professional consequences. Similarly, since adequate mechanisms may not exist, the potential whistleblower may reason that there is no purpose in putting his or her career on the line. Therefore, I would suggest that there have to be formal, structured mechanisms outside the institutional setting for receiving complaints.

MS. MERTON: It seems to me when one tries to set up a system for detecting fraud and misconduct either within the institution or outside the institution, one has created another class of people who have a stake and an interest in discounting the validity of what the whistleblower claims; their job or function has been taken over by the whistleblower. It reflects poorly on their performance of their own task and function if a whistleblower comes forward with other allegations.

If you have such a system for detecting fraud or, as in New York, the Hines Commission set up to detect fraud, the response might be, "If there had been any fraud we would have picked it up, so you must be wrong." In sum, it is worth noting that setting up such a system creates another stakeholder, which is an unanticipated consequence.

Fraud and Whistleblowing: Local Institutional Roles and Responses

II

Chapter 6

MISCONDUCT BY RESEARCH INVESTIGATORS, BREACH OF RULES FOR PROTECTING HUMAN SUBJECTS, AND THE INSTITUTIONAL REVIEW BOARD

Herman S. Wigodsky

The best means of assuring that whistleblowers who report alleged research misconduct will be heard and, if necessary, protected is to utilize existing channels of communication, supplementing them as needed to make them more effective, rather than to introduce a new channel or entirely new reporting mechanism. In a system which covers a variety of institutions, there obviously will be no single solution to any administrative problem; that solution will work best which works within an existing administrative pattern.

Since a concern of institutions and their IRBs is the protection of human research subjects, and since a great deal of therapy or research has some degree of risk (and opportunity for malpractice), any institution engaged in human research must or should have a risk-management system. It would be unusual if such a system did not already have the capability for reporting unusual incidents, which is the essence of whistleblowing.

To be effective, the reporting system must be readily available; have easy entry; provide for anonymity if necessary; be capable of determining facts quickly and of responding very promptly when necessary; have immediate access to the highest administrative authority of the institution; be effective in resolving problems on a factual basis; provide feedback to those who report, including whistleblowers; and, above all else, provide immediate protection to the human research subject concerned. If such a system functions properly, it also will protect the investigator(s) and institution from unjust embarrassment or harassment. The system also should include an appeals system that provides for due process.

The Institutional Review Board

Since they were first introduced by the U. S. Public Health Service in 1966, institutional requirements for review of research projects involving human subjects have undergone a number of changes to increase their effectiveness and comprehensiveness. Formal bodies known as Institutional Review Boards have been established and their membership has been broadened to include noninstitutional members, nonscientist members, and others to represent the local community as well as the community of scientists. The prestige and dignity of the IRB must be concerns of the institution if the IRB is to function effectively and is to represent, at least in higher educational settings, the high principles of the institution itself.

Diligent, generally intelligent work on the part of scientists and administrators within and without the federal government culminated in the two major sets of revised regulations that went into effect July 27, 1981. These regulations govern the establishment, objectives, and operation of IRBs in institutions either receiving federal support for medical, biomedical, or behavioral research involving human subjects or conducting research on medical drugs or devices necessitating the use of human subjects. A fundamental difference of philosophy, allegedly due to statutory requirements, prevented complete congruence in the two sets of regulations, promulgated by the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA). IRB regulations also have been published by other federal agencies which, fortunately, generally accept the principles of the HHS regulations. All stress the role of the parent institution in the protection of human subjects in research and the relationship of the IRB to the parent institution.

The principal difference in philosophy between the HHS and FDA regulations lies in the HHS's assumption that the institution, its IRB(s), and its research investigators will conduct themselves in an ethical manner in accordance with the institution's assurance to the secretary. The FDA approaches the same institution and IRB(s) with an adversarial attitude that seems to characterize regulatory agencies. The fact that HHS deals primarily with educational institutions and the FDA deals more with industrial organizations is not an excuse for this difference in attitude.

Although the regulations do not speak to the relation of the IRB to whistleblowers, there are reporting requirements in both sets of regulations: "Be responsible for reporting to the appropriate institutional official and the Secretary (or the Food and Drug Administration) any serious or continuing noncompliance by investigators with the requirements and determinations of the IRB."1 This reporting requirement, coupled with May 1981 testimony before a congressional committee by an FDA official that "there is no legal barrier to FDA notification of parties who have legitimate interest in our preliminary observations,"2 emphasizes the necessity of institutions having a means to investigate immediately rumors or allegations of research misconduct to make certain that all of the facts are known to the institution and that any action(s) taken is based wholly on facts. Only in this way can institutions meet the prompt reporting requirements and prevent the spread of rumors. The institution has the obligation not to embarrass its research investigators or the institution itself with groundless accusations.

Compliance and Monitoring

Both sets of regulations provide for periodic review of ongoing research to determine whether the research investigator is complying with the regulations and with the stipulations issued by the IRB to insure compliance with the regulations. Each regulation states:

> An IRB shall conduct continuing review of research covered by these regulations at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.3

The manner in which such continuing review is to be made is not specified.

Many individuals and institutions believe that the IRB will function best if it is not both "judge and sheriff." The institution should have established means for determining compliance with any of its regulations; those regarding the conduct of research are only a special set of regulations. Cannot a case be made, therefore, for monitoring research and measuring compliance within the existing administrative structure of the institution? Should not the responsibility for monitoring and compliance be given to the same individual(s) responsible for compliance with other professional responsibilities?

Unfortunately, no universal answer can be given to these questions because of the nature of the institutions. In general, they may be divided into the following categories: universities or colleges, university or university-affiliated hospitals, independent hospitals, independent research establishments, industrial research establishments, and governmental research establishments.

Universities and colleges in many instances have become complex organizations with large budgets, whose administrative structures vary widely. In general, the trustees or corresponding body are now keenly aware of their ownership responsibility for this complex enterprise. Once below the level of the presidents and vice-presidents, any comparison with the usual administrative pattern of industry breaks down primarily because of the traditional roles of faculties -- even though traditional roles of faculties are becoming difficult to identify. However, to a greater or lesser degree, the administrative structure can be identified down to the level of departmental chairmen as witnessed by their functions as budgetary officers in the dispersal of funds, their roles in the employment of professional and nonprofessional personnel, and so on. Departments generally are strongest at the larger universities.

Despite many variations, departmental chairmen on the whole have a decisive influence on budgeting, staffing, planning, reporting for the department to the next person in the scalar organization, and directing research. To the degree that departmental chairmen recognize their administrative responsibilities, they can implement institutional policies better, on the one hand, and participate creatively in formulating policies, on the other. To the extent that "publish or perish" has become a (unwelcome?) way of life in American universities, so has attention to research demanded an increased share of departmental chairmen's time. Taking these considerations together, it appears that colleges and universities have an administrative mechanism that could make departmental chairmen responsible for the conduct of research in every sense.

Since research has become "big business" in many colleges and universities, central offices with responsibility for assisting research investigators in obtaining research grants have been established. The duties of such offices vary widely from identifying sources of funding to establishment of research policy and control of research funds. Generally, such offices report to an individual in the scalar organization at the level of a vice-president and are recognized as an "administrative" office. Such offices have the potential of coordinating the monitoring of and compliance with IRB-approved research protocols.

Unfortunately (for many reasons), many colleges and universities have not developed quality control offices that might include the monitoring and compliance responsibilities under discussion.

Research grant offices and quality control offices usually are handicapped by not having individuals with the requisite expertise in human subjects research immediately available, which means that delays may be

encountered when such offices are utilized for monitoring and compliance. A strength of giving departmental chairmen such responsibility is the advantage of departmental expertise and the use of peers in establishing and evaluating the facts of a given situation.

University or university-affiliated hospitals, because of accreditation requirements, generally have well-defined departments under the leadership of well-defined heads. Frequently the head is the chairman of the corresponding department in the university. The hospital usually is divided sharply into the hospital administration and the medical staff, with the latter responsible for the professional conduct of its members. However, at this time it generally is recognized that the board of trustees of the hospital also has a responsibility for the conduct of the medical staff.

Hospitals are required to conduct utilization reviews and to be concerned with quality assurance. Here, then, is an administrative mechanism capable of expansion to include monitoring of and compliance with regulations for the protection of human research subjects. In addition, departments are required to conduct monthly professional meetings that provide chairmen with an excellent opportunity to include discussion and review of research protocols conducted in the department.

Although independent hospitals generally are not as tightly organized or administered as are university hospitals, they are obligated to conduct monthly departmental meetings, utilization reviews, and quality assurance reviews. The trustees of independent hospitals have become very aware of their responsibilities for the quality of care given by, and the professional conduct of, medical staff through recent malpractice case decisions that have defined some of the board's responsibilities. In general, then, administrative channels for monitoring and compliance also exist in the independent hospital.

Independent research establishments may or may not have a departmental conformation, although those organized for profit generally have a well-defined administrative and departmental structure. If independent establishments engage in research utilizing human subjects, they usually have established in-house IRBs and well-defined administrative mechanisms for quality control. Thus, in this setting also, the potential exists for establishing monitoring and compliance responsibilities separate from the IRB and within existing administrative channels.

Industrial research establishments are subject to pressures from a number of directions that have sometimes led to questionable judgments. Unfortunately, the publicity surrounding such events has obscured the many great accomplishments of industrial research establishments in pharmaceutical and other research related to the improvement of the human situation. No research in the U.S., in industry or elsewhere, sets out to destroy life or to maim or injure human subjects, but such unfortunate events have occurred. The rate of occurrence has been extremely small; the question is whether there is tolerance for <u>any</u> error.

IRBs in industrial research establishments, more than any others, should not be burdened with the tasks of monitoring or compliance. Industry is noted for its quality control efforts, to which the monitoring and compliance functions can and should be added in order to assure protection of human research subjects. Administrative mechanisms within the industrial research establishment generally are well defined, and their maximal usefulness requires exploration.

Governmental research institutions are unique enterprises in that their purpose usually is set forth in legislation and is made more precise

by periodic public and legislative review of the individual agency's activities. "Sunshine" laws, freedom of information acts, and other demands make these institutions operate in almost full view of the public, creating unusual demands for conformity as exemplars of the public conscience. The reputations of the National Institutes of Health are a source of considerable pride among scientists and the population generally. Within such institutions, administrative channels generally are as well defined as in industry, and professional personnel are an integral part of the administrative structure with well-defined administrative functions. This structure is readily adaptable to the separation of the judgelike functions of the IRB from the sherifflike functions of monitoring and compliance.

If, in each of the categories of institutions affected, the administrative mechanisms exist for separating the judgelike functions of the IRB from the sherifflike functions of monitoring and compliance, why has this not happened? The solution of this problem is fundamental to the ready identification of the very occasional researcher who ignores some part of the regulations regarding protection of human research subjects or who engages in other unethical conduct such as data falsification. How can the potential channels of administrative solutions be brought into reality?

Institutional Acceptance of Responsibility

If administrative mechanisms exist for the separation of judicial and enforcement functions in the protection of research subjects, how can they be brought into operation to enhance such protection and not divert the attention of the IRB from its primary purpose?

The first and most obvious answer is to make institutions aware of their own potential by posing the problem to them forthrightly, informing them of their own ability to solve the problem, and encouraging them to exercise their prerogatives in doing so.

Awareness of the problem of overextending the IRB is not going to effect an overnight change in the governance of universities. But the presence of federal regulations and the urgency to forestall the establishment of additional bureaucracy in an already overregulated area should be sufficient, if properly exploited, to raise the problem to the conscious level of university and other research administrations. The key to the success of such a venture is communication and education. How can the university, for example, best be encouraged to recognize the role of the departmental chairman in the execution of an administrative duty? Will the university respond when it previously has not generally been willing to insist upon the departmental chairman's accepting and discharging the chairman's role in the university's scalar organization of administrative responsibility? Federal bureaucracy is such an anathema to most university personnel that the threat of a new area of bureaucratic intrusion may be all that is required to initiate a helpful, useful response!

Similarly, other groups may be stimulated to open the necessary channels or expand the duties of existing offices or personnel to provide monitoring and compliance, rather than be faced with additional federal regulations and concomittant bureaucracy.

Reporting Channels for Whistleblowers

What are the problems to be resolved vis-a-vis the whistleblower that relate to the monitoring and compliance processes?

The following discussion assumes that:

1. The monitoring of, and measurement of, compliance with research protocols will not be a function of the IRB.

2. Within institutions, administrative mechanisms and channels exist that can assume the research monitoring and compliance functions, which will be carried out by departmental chairmen, quality control offices, research grants offices, and so on, or combinations of these.

3. Institutions can be stimulated to take the necessary actions to expand existing mechanisms or establish new ones to accomplish monitoring and compliance.

4. Whistleblowers can be dealt with best by providing an administrative mechanism that is readily accessible, is responsive, protects the whistleblower, determines facts, and provides feedback.

5. Institutional actions, both investigatory and disciplinary, can and will be prompt, based upon facts, and handled within recognized administrative channels.

6. Both investigators and institutions will be protected from unjust harassment.

7. An appellate mechanism will be in place and operative to provide prompt relief to investigators or others where justified.

In universities and colleges a great many disciplinary problems involving faculty are handled on an ad hoc basis, generally under the assumption that they occur so infrequently that no formal ongoing mechanism is required. The following extract from a statement by a university hospital's physician-in-chief (at a June 5, 1981, hearing of the President's Commission for Study of Ethical Problems in Medicine and Biomedical and Behavioral Research), concerning charges of research misconduct at his institution, exemplifies what probably is a fairly widely held opinion:

> A given medical institution will rarely be called upon to deal with allegations of research misconduct. Moreover, the few reported instances of research misconduct in the United States reveal that the nature of the alleged misconduct and the attendant circumstances will vary greatly from instance to instance. For example, the alleged misconduct may or may not involve compromise of good patient care; the alleged improprieties may range from relatively minor, inadvertent, technical deviations from established protocols to flagrant dishonesty, falsification of data, or major, hazardous deviations from approved procedures; and the individual(s) accused of misconduct may admit or may deny the allegations.
>
> Because misconduct at any given institution will be infrequent and will vary greatly in nature, it is my opinion that individual medical institutions should not be required to establish a specific, fixed mechanism to deal with allegations of research misconduct. Rather, the institutions must be prepared to deal with allegations on a case-by-case basis, while keeping certain guiding principles in mind.

First, . . . if the allegations suggest that the health or safety of individual patients may be adversely affected, evaluation of patient care must be given first priority. The group charged with this task must be assembled rapidly and have the expertise to determine whether immediate corrective measures are required to protect patients still under study.

Second, the integrity of research data must be evaluated, so that appropriate groups such as organizers of multi-institutional studies, funding agencies and the scientific community at large can be informed if inaccurate, misleading or invalid data have been published or have been submitted to groups or agencies who might rely on the data.

Third, efforts to determine whether misconduct has in fact occurred and to assign responsibility for improper practices must be carried out in a manner which protects the rights of accused individuals. If those accused of the improprieties admit their involvement, corrective action is simplified. If, on the other hand, those accused deny complicity, they are entitled to disciplinary proceedings in accordance with elaborate written mechanisms in place at nearly all medical institutions.

Fourth, individuals who have made legitimate complaints must be protected against unfair retaliation.

Fifth, the reputation of the institution must be protected against unfair, overly sensationalized or misleading publicity.

Sixth, once the appropriate institutional authority has decided that the allegations have substance, the decision or action should be reported to appropriate non-institutional groups such as the organizers of multi-hospital studies, research funding agencies and governmental bodies.

In my view, these multiple goals are best handled by establishing an ad hoc evaluation group set up to handle the requirements of the particular situation. Rigid regulations which require institutions to use a specific type of evaluating mechanism would be counterproductive. . . . Administrative mechanisms brought to bear should be determined by the nature of the alleged misconduct. The individuals who make up the evaluating group should have strong reputations for probity and fairness; have sufficient stature so that they are relatively immune to pressure from the institution; and have no direct or indirect connection with the research program under evaluation. The evaluating group must have the confidence of senior administrators who will be able to act promptly and effectively, if required. The group should have the expertise necessary to evaluate the medical, scientific, and technical aspects of the allegations.

> In addition to investigating specific allegations, the institution has two further obligations. First, it must recognize the limits of its authority. Institutions are responsible for selecting and maintaining their staff and for the conduct of research within their walls. In order to do so, they must make determinations of fact and set internal institutional policy. An institution has no authority nor should it, in my opinion, to set policy for other institutions who may consider appointing its former staff; for agencies which fund research; or for licensing bodies. An institution must simply be prepared to provide objective information to any such groups that have a legitimate interest in the matters at issue.
>
> Second, institutions conducting medical research have a societal responsibility to maintain an environment in which excellent biomedical investigation can continue. Procedures for monitoring the safety and propriety of research protocols and their conduct must be in place and enforced vigorously but must not become so onerous as to demoralize investigators responsible for the conduct of research.4

Ad hoc means for investigating alleged research misconduct, however, cannot be relied upon to provide the kind of prompt response required to deal intelligently with the protection of human subjects. Ad hoc means do not provide the kind of well-defined, widely understood administrative mechanism necessary for any successful reporting system and for dealing with rumors and whistleblowers. When prompt action is not essential, perhaps a well-defined reporting and investigatory system can occasionally be supplemented by an ad hoc group to deal with particular problems requiring outside assistance.

In the statement quoted above there is no discussion either of how research misconduct comes to the attention of the institution or of the HHS and FDA regulations for IRBs concerning monitoring and compliance. If institutions undertake to monitor research utilizing existing channels, they will be able to ensure (1) the least interference possible with investigators and their research consistent with complying with the regulations; (2) a nonaccusatory, nonadversarial attitude; and (3) the maintenance of "an environment in which excellent biomedical investigation can continue." If departmental chairmen can be made aware of the alternatives, perhaps this in itself will be sufficient stimulus to undertake the task of monitoring and compliance.

There is a general impression that the new IRB regulations have not been sufficiently disseminated within institutions to all investigators, research nurses, technicians, and others concerned with research involving human subjects. Nor has information regarding the regulations generally been formally incorporated into graduate training programs, so that an understanding of them can become a part of the training of researchers. It should not be difficult to stimulate wider dissemination.

It would be extremely helpful if some additional actions were taken, reduced to writing, and distributed concurrently.

The general assurance given by the institution to the secretary of HHS should be a document of great interest to all within the institution who are engaged in research utilizing human subjects, for it outlines the philosophy of the institution and the specific general actions it will take to

protect human subjects. The assurance should contain a statement regarding monitoring and compliance, what it will consist of, and how and by whom it will be carried out. In addition, the mechanism for corrective action should be described.

The regulations and the assurance give the minimal standards and courses of action for the institution. They leave a number of related decisions to be made by the institution and then transmitted to the IRB and other agencies and personnel as guides for implementation. Questions to be resolved include whether the IRB will be responsible for reviewing and approving all protocols involving human research subjects regardless of source of funding and whether the IRB will review protocols for research claimed to be exempt from the regulations to determine if such a claim is proper.

It would serve the purposes of the institution and the IRB well if the institution provided the IRB with a "charter" or written set of directions spelling out the IRB's responsibilities, its organization, qualities for and appointment of membership, method of selection of the chairman, terms of office, methods of operation, support to be given to the IRB, reports to be rendered, educational programs to be conducted, and its relationship to the administration of the institution and to those individuals or agencies designated to carry out monitoring and compliance functions. If such a charter was widely distributed along with the institution's assurance, there would be little room for misunderstanding on the part of research investigators as to the place and function of the IRB in the administration of the institution.

The institution must decide which individuals or agency in the institution will carry out the monitoring functions required by the regulations and assess the compliance of investigators with the standards contained in the institution's general assurance. Decisions about monitoring and compliance also should be disseminated widely in order that all concerned will be informed how the institution intends to carry out these functions, who will be responsible, and their authority. It is to these individuals or this agency that whistleblowers should report any apparent research misconduct.

Hospitals have a dual system for dealing with alleged misconduct on the part of physicians. The medical staff of the hospital is responsible for maintaining discipline among its members, and the chiefs of the various services are expected to maintain surveillance of their service for appropriate behavior by service members. For other personnel, the hospital administration delegates to the director of the nursing service the responsibility for discipline among the various nurses who report to the director; laboratory technicians generally report to the pathologist; and other technical and professional personnel report to various members of the hospital administration team. There are, then, fairly well-defined channels within which whistleblowers among nonphysician hospital personnel already report (or are supposed to report) suspected or actual deviations from hospital policy or irregular conduct or orders. As stated in a recent publication, for example:

> Not only does a nurse have the legal obligation to perform the practice of nursing within a certain standard of care, the nurse also has a responsibility to bring appropriate matters of health care to the attention of a physician, the hospital administrator, or both. In such a position, the nurse is a 'watch-dog' for ensuring that the patient has the proper care.5

In university or university-affiliated hospitals, the chiefs of service generally will be the chairmen of departments of the medical school, which again emphasizes the administrative responsibilities of the chairmen. Since the bulk of human subjects research involves hospital patients, the importance of the departmental chairmen in maintaining discipline among the professional staff of the department is evident.

It follows that hospitals already have administrative channels for maintaining discipline and for affording whistleblowers an opportunity to be heard. These same channels are available for discipline in research and for protection of research subjects. The problem is to raise this responsibility to a level of awareness that will insure that the protection is carried out and that the alleged infractions are investigated promptly and efficiently. There is no question that medical staff are reluctant to criticize and to correct the actions of peers, but there also is no question that failure to deal with problems arising out of research will endanger all research, invite bureaucracy, and expand the already serious problems of malpractice liability for research investigators, the institution, and hospital board members.

Hospitals have offices concerned with risk control, utilization review, professional standards review, and other aspects of quality control. But to expand the functions of any one of these to include responsibility for research monitoring and compliance is an unsatisfactory second choice compared to giving the responsibility to the chiefs of services. Since these offices have little or no research expertise, they would have to depend upon the various services to provide such expertise on an ongoing basis, which would be a dubious and inefficient system.

To ensure that all hospitals provide for and carry out monitoring and compliance, it would be well for those functions to be included in the standards established, and inspected for, by the Joint Commission on Accreditation of Hospitals.

The problems of independent laboratories and industrial laboratories are more difficult, but not insoluble. Both must be concerned with quality control or they will compromise their existence. Depending upon the size and complexity of their organization, channels of responsibility already exist that can be expanded to include monitoring, compliance, and provisions for reporting by whistleblowers.

Government laboratories generally are highly organized with channels already existing for monitoring and compliance.

Institutions will fail in this enterprise if they do not identify and keep clear the roles of the IRB and the monitoring and compliance agency. They must provide for the interdigitation of the functions so that each is made aware of the actions of the other and, most importantly, so that required reports to the secretary of HHS or FDA are made through the administration of the institution. In this way, the IRB can meet both its obligations under the regulations and its obligations to the institution. The institution also will meet its obligations under the regulations and its assurance, where applicable.

To Be an Effective Whistleblower

Whistleblowers can be divided into those acting out of genuine concern (not necessarily founded in fact) for the protection of human subjects and for the uncompromising nature of research and those acting out of discontent, malice, pique, revenge, or desire to harass or embarrass. Errors

or misconduct can be divided into errors made in good faith and errors of fraud or knowledgeable misconduct.

Those acting out of genuine concern sometimes do not understand the research protocol, the objectives of the research, and so on. Better dissemination of information about research projects to all concerned personnel will assist in allaying fears and preventing misunderstanding or false, albeit not malicious, charges of misconduct. Sharply drawn and carefully explained criteria for inclusion or exclusion of subjects and for risks and risk management, as well as the display of genuine concern and involvement of principal investigators, are important in preventing false accusations. Where applicable, ready availability of a manufacturer's protocol for drug trials or investigations of devices, or the availability of oncology group protocols for cooperative oncology studies, would provide helpful secondary sources of information and reference.

The IRB can assist both by encouraging investigators to enlist the cooperation of all concerned through better communication and by encouraging institutions to explain to all research personnel the immediate availability of channels for investigating and acting on suggestions of misconduct. One or two actual demonstrations of the swiftness, fairness, and effectiveness of the system will do a great deal to assuage anxiety and reduce misunderstandings. The IRB must be prepared to forward complaints made to it to the designated individuals or agency in the institution responsible for such investigations.

Investigators themselves are the most effective individuals for preventing or dealing with questions raised by peers and coworkers. Monitoring and compliance are facts of life. To prevent the addition of more bureaucracy, investigators must take seriously the responsibility for communicating with coworkers, being open and available to answer questions, protecting human research subjects, seeking IRB approval of protocol changes, reporting promptly any untoward incidents, and taking prompt action to prevent repetition.

The institution must make clear to all engaged in research that whistleblowing should be a positive action, seeking to bring to the attention of the proper personnel a potential source of difficulty and to institute corrective action as promptly as possible. Every effort must be made to differentiate whistleblowing as a positive act from being a "tattletale."

The second group of whistleblowers, who act from malice, pique, discontent, revenge, and so on, are destructive individuals who are using whistleblowing for personal ends. Such persons tend to disregard channels established to investigate and take corrective action. They often seek media coverage to gain maximum personal publicity, to force institutions into reacting instead of acting, to establish an adversarial position, and to substitute emotional responses for reasoned actions. It is doubtful that much can be done to prevent this destructive form of whistleblowing. If the institution has clear, explicit channels for dealing with whistleblowers, the best that can be done is to try to guide this type of individual into the regular channels, to act promptly in uncovering the true facts of the situation, and to move as swiftly as possible in a reasoned course. At a time when sensational journalism seems almost to be the rule, it is difficult for institutions to pursue a reasoned course, which can be followed if the institution has provided the necessary mechanism and has made certain that all concerned are acquainted with and have faith in the mechanism as a workable, fast-responding, factual, and fair system. Patience and tact in dealing with the malicious whistleblower obviously is the course of choice.

The IRB can assist by acting in the best judicial manner consistent with its being an institutional agency dedicated to protecting human research subjects as promised by the institution's assurance to the secretary of HHS.

Summary and Conclusions

The protection of human research subjects can be divided into two systems. The first, the IRB, is concerned with scientific soundness of research protocols, minimization of risks to the human subjects, maintenance of their dignity, and assurance of their freedom to give informed consent to participation in the research; the IRB reviews research protocols to make certain that standards for protection of human research subjects established by the federal and other governments and by the institutions will be met by the research investigators.

The second system, monitoring research for compliance, is primarily the responsibility of each institution and will reflect the standards and mechanisms of the institution. Standards will vary somewhat from institution to institution, as will the mechanisms for monitoring compliance. The monitoring system provides a recognizable means of communication with the administration of the institution and should be the principal means for individuals to communicate to the administration concerns regarding any breaches of protection of human research subjects. The monitoring system, obviously, should also provide information to the IRB in order for it to meet its responsibilities to the institution and through the institution to the secretary of HHS.

The monitoring system should be highly recognizable to all institutional personnel, including whistleblowers, and, insofar as possible, whistleblowers should be encouraged to utilize the monitoring system to report to the administration of the institution.

It would be unreasonable for the secretary of HHS to establish standards for monitoring systems or to require that all institutions have identical monitoring systems. It would not be unreasonable, however, for the secretary to request from each institution, as a part of its general assurance, a brief description or general outline of how monitoring will be conducted. In this way each institution would acknowledge its responsibility for monitoring but would be free to establish and utilize its own unique system to meet its unique problems.

It is unlikely that any except an extremely complex and costly monitoring system would be effective in detecting fraud in research. Fortunately, fraud is a rare occurrence and generally will be detected by other means, particularly by scientific peers of the investigator who perpetrates it. Although the monitoring system should be aware of and on the lookout for fraud, the secretary of HHS would be well advised not to attempt to establish standards for its detection through the use of systems for monitoring compliance.

Departmental chairmen in academic institutions, or the equivalents of departmental chairmen in hospitals, independent research institutions, industry, and so on, probably are the keys to the most efficient and economical research monitoring systems. The regulations governing IRBs, as well as the institution's general assurance, standards for research conduct, and system for monitoring compliance, should be disseminated widely to all persons engaged in the institution's human research enterprises.

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Chapter 7

COMMENTARY: THE ROLE OF THE IRB IN MONITORING RESEARCH

Leonard H. Glantz

For the most part I agree with Dr. Wigodsky that the IRB is not properly constituted for continuous monitoring and for discovering fraud if it should occur. The IRB's role, through the regulations and the way they have been designed, is to do before-the-fact review. Additionally, with the membership that is required by the regulations, IRBs generally do not have adequate expertise to do the sort of detailed record review that would be necessary for adequate monitoring or ongoing surveillance.

In commenting on the role of the IRB in relation to dealing with fraud in research, however, I would like to depart from theory. I come from an institution that has been through the real thing, and I would like to share with you some of the problems that we have had and tell you how we have responded to them.

In the wake of the oncology research data falsification episode, known as the "Straus Case," one of the things that has occurred is the establishment of a monitoring system at Boston University Medical Center-University Hospital by action of the executive board of the hospital. The system uses the quality assurance unit, a preexisting mechanism to monitor research. Every time a patient is accessed into a protocol, it is the responsibility of the principal investigator or his designate to notify the quality assurance unit that a particular patient is now a research subject. Within twenty-four hours someone from the quality assurance unit, whose staff is on the floors regularly anyway, checks a number of things.

They check, first, to see whether or not the patient is eligible to be in the protocol in terms of age criteria, type of disease, and so forth. They also examine the informed consent form to make sure that it is the one that has been approved by the IRB and that it has been signed by the patient and investigator. The monitor also looks for any indications that the patient was not competent to make the decision to participate in the research.

The monitor's tasks also include preparation of what is called a risk-event monitoring form, on which principal investigators are asked to check for expected risks and to list any unexpected risks or untoward events that occur in the course of the research. The principal investigator is responsible for reporting these "risk events," as they are called, to the quality assurance unit. Patients in at-risk protocols also have their records checked at the time of discharge to determine whether or not any

risks have occurred that have not been brought to the attention of the quality assurance unit.

Finally, after protocols have been in effect for at least six months and have accessed at least twenty patients, the quality assurance unit randomly monitors compliance with IRB-approved research designs.

The quality assurance unit acts as an agent of the IRB. It reports to the IRB, which has the power to stop specific research at any time, as does the director of the quality assurance unit if he feels on an emergency basis the research must be stopped to prevent injury. There also is an appellate mechanism to the IRB's executive committee.

The monitoring system has been set forth in a document that is sent to everyone who does research with human subjects in the institution.

The monitoring system, however, cannot detect systematic fraud and probably cannot detect research that is going on without having been reviewed by the IRB. It is designed to protect against and discover good-faith errors and omissions.

Monitoring is not whistleblowing. They are very different, and it seems to me that whistleblowing comes about when a monitoring system doesn't work or doesn't discover certain problems. People then have to go outside the existing system to make their point.

A monitoring system, at least the one that we have implemented, is designed primarily to protect the patient and to see that research is performed as it was approved by the IRB. But it will not catch fraud, and there are those who argue that fraud is a rare enough event that you can't come up with a system to prevent it or readily detect its occurrence. I don't know that we have sufficient information to assess the validity of this argument.

Rather than having regulations that set forth a specific monitoring mechanism, it seems to me that the general assurance system should require institutions to formulate a plan for monitoring research and for actions to be undertaken if and when fraud occurs. This should provide institutions with needed flexibility, while mandating that some monitoring system must exist.

I also believe that institutions in some way have to support the idea that either being a whistleblower or participating in monitoring provides a service to the institution. When allegations of research fraud were first made at my institution, that was not the reaction. Nobody said, "Thank you very much for bringing this to our attention; we are very happy to hear about it," and then went on to deal with the problem. Rather, and probably typically, it caused a tremendous rift among the people who worked there.

It has to be recognized that allegations of research fraud deeply shake an institution. An institution is concerned about many things, including its reputation in the community and the related question of whether patients will be referred if the charges of research irregularities become public knowledge. "What effect will it have on the institution?" So the charges in the Straus case were not dealt with matter-of-factly; there was chaos.

The IRB was totally excluded from any investigation. Although I don't think IRBs should necessarily be the investigatory body or the monitoring body, they should be involved in some way in the process of

investigating charges of research fraud. At the very least there should be somebody from the IRB designated to sit on the investigatory body and to report back to the IRB. The IRB is the symbol of the protection of human subjects. Since the IRB plays a powerful expressive role as the body of people who are centrally concerned with the protection of human subjects, it should be involved in all procedures that deal with protecting human subjects.

The institution itself has to be supported in dealing with and disclosing cases of fraud or other problems of unethical research, mistakes, neglect, and so on. The relevant federal agencies have to make it clear that when an institution goes to them, they will be responsive to the problem instead of saying, "We don't want to hear about this either. We are not sure how we go about handling it, and all you're doing is taking your can of worms and turning it into our can of worms."

Research institutions rightly feel that disclosing a problem of research fraud will affect their future reputation and quite possibly their future eligibility for grants, and therefore they are extremely concerned about how to deal with fraud. Should it be dealt with purely secretly, as has been tried in the past, or totally openly? There has to be a message to institutions that they will not be punished for doing good.

An institution that finds fraud has a system, though perhaps informal, for finding fraud. When an institution demonstrates that it can detect fraud -- or recognize poor research or unethical activities generally -- it has certified that it is willing to uphold stringent standards. The institution should be "rewarded" in some way and, at the very least, not be penalized.

Chapter 8

COMMENTARY: THE EXPERIENCE OF YALE UNIVERSITY SCHOOL OF MEDICINE

Robert J. Levine

One of my purposes in telling you of some of our recent experiences with whistleblowers at Yale Medical School is to show that something can be done -- and is being done -- to deal effectively with allegations of improper conduct within the academic medical community. Another purpose is to demonstrate that the nature of the allegations and of the whistleblowers is so diverse that it is difficult to imagine a standardized approach to dealing with all such problems. I shall close with a suggestion that we should restrain ourselves from developing regulations in this field prematurely.

Most of you, I presume, are familiar with the published details of Yale's famous data-faking case, news of which received prominent attention in The New York Times and in Science. I think that one of Yale's major errors in its handling of this case was to depend upon outside review of the problem, which led to undue delay. As a consequence of this delay there was undue embarrassment and damage to the careers of some very good people. Subsequently, we have developed a procedural mechanism for prompt internal review. It is used only when necessary and, in each case, review is conducted by an ad hoc group of persons who are most capable of making the necessary technical and value judgments.

The Department of Internal Medicine at Yale developed a document entitled: "Procedures of the Department of Internal Medicine for Dealing with Challenges to Academic Conduct." It states:

> 1. Any serious challenge to the academic conduct of one of our Department members should be reported immediately to the Department Chairman.
>
> 2. The Chairman should then communicate the charge to the affected individuals and ask for a written response.
>
> 3. A committee of senior faculty members would then be convened to review the question raised and the response to those questions.
>
> 4. Involved individuals would be interviewed and the committee would have access to any other information it deemed necessary.

5. After deliberation, the committee would make recommendations for action in writing. The recommendations would be reviewed with the involved individuals, who would have an opportunity to respond, and then the recommendations would be forwarded to the Department Chairman.

6. The Chairman would review these recommendations with the Dean, and then take appropriate action.

7. Any outside individuals involved would be notified in writing by the Chairman of the inquiry conducted and its results, as well as of any actions taken.

8. The Department would then be informed of all actions.

9. No contested studies may be published until all issues have been resolved.

In the first case that was reviewed according to these procedures, the whistleblower was an NIH official who was involved in the review of applications for grant support. I shall call him "Dr. O." He contacted the chairman of our Department of Internal Medicine to inform him that a study section had found that a New Investigator Research Award application by "Dr. J" duplicated substantial portions of a research grant application that had been submitted earlier by "Dr. R," also a member of the Department of Internal Medicine at Yale. At the time Dr. J wrote the grant (NIRA) application in question, he was Dr. R's research fellow. Since plagiarism of a grant application is a serious charge, the department chairman activated the review procedure. An ad hoc committee of senior faculty was appointed, of which I was a member. It was appointed within a day or two and filed its final report in approximately two weeks.

The committee found that Dr. R had encouraged Dr. J to do the plagiarism; apparently this was based upon a misunderstanding. The NIRA was, at the time, a novel form of application for a grant designed to support investigators in their first independent studies. Dr. R advised Dr. J as if the NIRA was to be written according to the traditions of application for a research fellowship award. In such applications the fellow is expected to work on projects originated by the senior faculty member. The main problem apparently was that Dr. R had failed to read and follow the instructions for the NIRA. In its review the ad hoc committee discovered that Dr. R also had failed to follow some other specific directions in the grant application. For example, he did not make it clear that he had written other applications seeking funding for the same research projects. On the review of Dr. R's other grants, it was found that in several cases he failed to mention that funds were being sought from multiple sources to do the same work. When confronted with this, Dr. R stated his view that this was common practice around the country and within the department. In his view, if one reported completely the various sources of funding that were being sought to do a project, it would jeopardize one's chances of having a successful application.

As a consequence, the ad hoc committee conducted a rather extensive examination of a random sample of grant applications written by members of the same section and also by members of other sections within the department. We found no other applications that failed to make such disclosures. When Dr. R was confronted with this, he acknowledged that his impression of the prevailing behavior within the department was incorrect.

The ad hoc committee reported its findings according to the departmental procedural document. After consultation with the dean, the department chairman took the following actions:

1) Dr. R was asked to write to Dr. O at NIH explaining that he, not Dr. J, was responsible for Dr. J's application and that the problems with that application resulted from Dr. R's negligent supervision of Dr. J.

2) Dr. R was placed on academic probation for a period of two years. During this time he may not be considered for promotion and may not serve as the sole supervisor of students or fellows. At the end of the two-year period he must be reviewed by a second ad hoc committee before being removed from probation. During the first year of the probationary period, Dr. R was to withdraw all pending grants from NIH and other funding agencies. He will not be permitted to submit any further requests for funding during that first year. All grants submitted during the remainder of the probationary period must be reviewed and cleared by his section chief.

3) Dr. J also was reprimanded. However, it was decided that he acted largely out of naivete and that he had been poorly advised by Dr. R. Thus, no further action was taken against him. In fact, the record shows that we are to take steps to "attempt to salvage his potential for a career in academic medicine."

At no time was there any question about the veracity of any data reported by either Dr. R or Dr. J.

I have chosen not to identify the principals in this case because word of this story is already "out" among members of the national community of persons engaged in research in the specialty field. There have been severe and, I believe, unwarranted repercussions. For example, on one of his recent papers submitted to a distinguished scientific journal, Dr. R received a letter from the editor that contained only minor criticisms of its scientific aspects. However, it presented a detailed list of questions and innuendos about the ethical aspects of the research. I have reviewed the manuscript and compared it to others previously submitted by Dr. R to the same journal. The earlier manuscripts which were accepted without any question of their ethical propriety do not differ in any important relevant respect. In addition, the same journal has published and continues to publish reports of the work of other authors using the procedures questioned in Dr. R's manuscript.

Study sections, in their review of applications naming Dr. R and members of his group as investigators, have raised similar questions about the ethicality of the work. Copies of these reports are, of course, sent to Yale by NIH's Office for Protection from Research Risks. I have reviewed these and concluded similarly that the criticisms are largely unwarranted.

I shall now turn to some other situations in which allegations of improper conduct came to light in the course of routine interactions that I believe are characteristic of academic medical centers. In these cases the formal procedures were not necessary to bring about successful resolutions to the problems.

"Dr. D" is an assistant professor who had been on the faculty for three and one-half years. His credentials were presented to a meeting of the professors in the department along with a recommendation that he be promoted to associate professor of clinical medicine. Promotion at this level is ordinarily not particularly controversial in that it entails no tenure commitment.

It was generally agreed that his research credentials were satisfactory; letters from outside consultants compared him favorably in this regard with rather distinguished members of the same specialty, some of whom were chiefs of their services at university medical centers. However, several professors within the department pointed out that he had violated various standards and expectations. It was alleged, for example, that he had brought investigational drugs into the hospital and given them directly to patients rather than following our rule that they be stored and dispensed by the hospital pharmacy. The professor who made this allegation stated that he had resolved the problem by talking with Dr. D and by alerting the staff nurses to keep an eye on him for such behavior. Another professor alleged that there were some irregularities in Dr. D's dealings with the IRB. The protocols and consent forms he presented were consistently poorly written. It was a matter of particular concern that he seemed to have no sensitivity to the need to provide clear and complete information in the consent forms. Moreover, the same errors were repeated in each of his multiple protocols; there was no evidence of learning or of a willingness to learn even in the face of stern admonitions from the IRB. The most serious allegation -- in that it could have jeopardized the well-being of sick patients -- was that he once left the hospital, signing out to a junior colleague, without so informing the attending physician and house officers on the service for which he was responsible.

The professors decided to table discussion of this promotion. Each person who had charged Dr. D with misconduct was requested to put the charge in writing and to include evidence that his or her charge was correct. At a subsequent meeting all documented charges were reviewed.

The professors decided that there was evidence of a serious problem and that we were partially at fault because we had not provided adequate official feedback. We should have reported this behavior to the department chairman earlier and put Dr. D on notice that he must correct his behavior if he wanted to be promoted or to remain a member of the department. Consequently, we voted not to promote him for the usual term of five years. Rather, we voted -- not unanimously -- to promote him for a period of three years and to put him on official notice that he must correct his various unacceptable behaviors if he wanted to have his membership in the department extended beyond that.

The department's recommendation was forwarded to the medical school's Appointments and Promotions Committee, which reviewed the matter and voted against the promotion. This action was tantamount to firing Dr. D. He had only one year remaining of his original five-year term, and according to university rules the appointment can be extended only for a maximum of one additional year.

So far the whistleblowers have been NIH officials and full professors of medicine. Ordinarily, one is not concerned that such people will suffer retaliation from their professional community. In another case, the whistleblower was much less securely established in the community.

"Dr. A," a senior resident in medicine, contacted the lawyer-member of the IRB to say that she had been ordered by her attending physician to give a patient an intravenous injection of a drug. The drug was being administered as part of a research protocol. The patient had been invited to participate in the protocol and he had refused. According to Dr. A. the attending physician ("Dr. C") stated that the drug in question was the drug of choice for the patient's disease. Moreover, he claimed that the patient was senile and therefore incompetent to decide about his therapy. Dr. A argued unsuccessfully that there should be authorization

by the patient's family to give him the drug and to involve him in the protocol.

Therefore, she telephoned the lawyer to get support for her position that such behavior was illegal. She also reported that Dr. C had written a do not resuscitate order on this patient without authorization from, or even discussion with, either the patient or the family.

I was assigned responsibility for investigating this matter. Upon review of the medical record I found that Dr. A's allegations were correct. I reported this to the department chairman, and we canceled the improper orders immediately.

Dr. C was a new member of the department and this was his first attending rotation. He had had no recent attending experience, having spent the preceding three years in a basic research laboratory. We explained our usual procedures for getting consent when patients seem to be incompetent. We also explained our procedures for determining whether a patient who seems to the physician to be incompetent is, in fact, incompetent for such purposes. The entire matter was resolved within a day. Dr. C resumed his attending physician responsibilities with no further complaints from the house officers or, for that matter, anyone else.

There was no retaliation against Dr. A. In fact, the department chairman commended her for her actions in this affair.

In 1976, I wrote a paper entitled "The Institutional Review Board" for the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Describing what I call our informal monitoring system, I pointed out that our IRB commonly receives reports from various members of the institution about what they see as infractions of institutional policies. The informal monitors include doctors, nurses, social workers, students, house officers, and so on. We nurture this informal monitoring system by taking every report seriously and by investigating it carefully. Almost always we find no wrongdoing; rather, there is a misunderstanding that can usually be cleared up readily. Occasionally, we do find a serious problem.

There are many other stories I could tell relating to whistleblowing and how it is handled at Yale Medical School. What these stories suggest, I believe, is that we are learning how to deal with allegations of misconduct within our institution. We have made some mistakes, but I think we are improving. The fact that we take each allegation seriously and that there is no retaliation against sincere whistleblowers has had an impressive effect in our medical center community. It is difficult to describe this effect. It impresses me, however, that the junior members of our community -- particularly the students and the house officers -- are impressed that certain sorts of values are taken very seriously. This has an effect on their behavior which, in turn, influences behavior throughout all levels of the institution.

I hope that as we are learning to tend to this aspect of our business, we will not be frozen into inflexibility with regulations. I am particularly concerned that there might be regulations calling for some sort of police functions. As I have written in several places, if various agencies within the institution, such as the IRB, come to be seen as police acting on what appears to be presumptions of mistrust, we shall lose what I call our informal monitoring system.* Replacements who are equally qualified to serve as monitors probably could not be found. And if they could be found, their employment would be most expensive indeed.

*See, for example, Levine, R. J., Ethics and Regulation of Clinical Research (Baltimore: Urban and Schwarzenberg, 1981), pp. 231 ff.

Chapter 9

INVESTIGATING FRAUD IN CLINICAL RESEARCH: THE ROLE OF HOSPITALS, STATE LICENSING BOARDS, AND PROFESSIONAL SOCIETIES

Charlotte B. Cloutier

Regulation, which is one type of formal social control in medicine,[1,2,3] contributes to the development and exercise of professional norms and values by setting standards, monitoring performance, arbitrating conflicts, and dealing with unprofessonal practices or behavior. The resolution of conflicts presumes a determination of which interests shall prevail. Allegations of fraud or unethical conduct in clinical research pose complex problems for regulatory agencies because of the various interests involved and difficulties in determining the best course of action to resolve the conflicts that may be created for the institution, the researcher, the research subject, the research sponsor, and the scientific community. Factors that may alter the course of an investigation include its impact on scientific research, the researcher, his colleagues, the institution, the hospital, the granting agency, and research subjects. The credibility of both the accused and the whistleblower are also factors that must be dealt with in investigations of alleged research misconduct.

This analysis of some of the formal mechanisms for investigating charges of research fraud will focus on alternatives available to a hypothetical whistleblower who has "good-faith" reasons to believe that some of the data derived from clinical investigations in which he is participating have been falsified. His decision to blow the whistle is an act based on a judgment that someone's actions are unethical and that withholding the information in order to avoid personal or professional difficulties would be equally unethical and inappropriate. The whistleblower may rightfully expect that his allegations will be investigated and the case resolved in a just and equitable manner. As will be demonstrated in this paper, however, his expectations of a prompt and acceptable resolution of the matter are unlikely to be met, given the current organization and workings of formal social control agencies in medicine. His complaint may remain pending for years, perhaps never to be resolved.

Hospitals

Membership on a hospital staff is granted to physicians on the basis of their education, postgraduate training, past experience, and good professional reputation. Full staff privileges often are granted after a one-year probationary period. The granting, curtailment, and revocation of physicians' hospital privileges are governed by duties, rights, and procedures defined in bylaws, to which a hospital's governing board must

adhere in order to protect the rights of physicians and avoid judicial review of the institution's actions.

Hospitals have numerous committees and other formal and informal procedures for reviewing a physician's performance. If incompetent performance or unethical behavior is detected, and if a decision is made to report it, the hospital itself is the most logical place for the whistleblower initially to forward his allegations, provided he can identify a committee which has jurisdiction over the matter.

Mechanisms established for quality control in an effort to avoid malpractice claims and to satisfy the Joint Commission on Accreditation of Hospitals' standards for reaccreditation focus mainly on conformity to established criteria for quality of care. Professional standards committees and tissue committees, for instance, review patient records both for adherence to standards of care established by the medical profession and by the committees themselves and for instances of questionable or unnecessary surgical procedures. Adverse findings usually are reported first to the physician in question, but cases of unnecessary surgery or gross incompetence should be reported to the hospital's governing board.

Regional professional standards review organizations have authority to delegate their responsibilities to hospitals, which already have a utilization review board. Such reviews are intended to analyze the quality of care and cost of medical services rendered to patients whose care is partially paid for by the federal government. As a result, medical records are scrutinized for appropriateness of hospital admissions, length of stay, services rendered, and quality of care delivered by individual physicians and institutions. Medicare and Medicaid recipients often serve as research subjects, yet nonadherence to research protocols and fraudulent entries in medical research or patient records would not ordinarily surface because of the structure of these utilization audits.

Institutional review boards should be the most informed of all hospital committees about research protocols. But the primary role of IRBs is to review research protocols and informed consent forms before the commencement of and during the performance of research involving human subjects. It is not their function to monitor research for potential fraud or to investigate allegations that fraud has occurred.

The established chain of command within the hospital would normally require that a complaint or allegation first be forwarded to the departmental chairperson, then to the hospital director. An allegation also could be forwarded to the medical staff committee or to the hospital's governing board. Complaints related to medical competence usually are received by the medical staff committees, who investigate them and make recommendations to the executive committee and then to the hospital governing board.

Cases of fraud in medical research are somewhat different from cases involving medical incompetence, and lines of authority over the former matter are not clearly delineated. First, a grant supporting the research in question is likely to have been awarded to the hospital or the university where the research is conducted, rather than to the individual investigator. The whistleblower's allegations do not call in question the hospital, but rather deviations from established professional norms and practices by a researcher who has a hospital appointment and consequently falls under the hospital's jurisdiction. Second, the medical staff committee may see its primary duty as protecting the profession's or institutions's reputation and insuring continued care of research subjects. The hospital's first concern may be the protection of the institution's reputation. It is conceivable that actions and decisions by various committees within a hospital may be

governed by what they perceive is their duty to the professional community and institution, rather than what society would expect of them as arbitrators of a dispute for which they should provide a fair hearing with adequate due process safeguards.

Investigating allegations of research fraud is costly for a hospital. Action against a physician would not be initiated unless the hospital's counsel had substantive evidence to support the allegations of fraud. Extracting such evidence from medical records is a long and difficult process; special committees may need to be appointed and outside consultants hired. The researcher may claim that the product of his research is his and that he has the right to determine who should have access to his files; documents then must be subpoenaed. Hospital politics may interfere with the proper conduct of the investigation, and any publicity about the matter is likely to be viewed as injurious to the hospital's reputation.

Faced with the dilemmas and difficulties in conducting a thorough investigation, the hospital may suggest and accept the resignation of the physician against whom the allegations have been filed, or the accused may simply offer his resignation. Such a resolution of the crisis is unsatisfactory for all parties involved. First, resignation from hospital privileges in lieu of a hearing may enable the accused physician to remain engaged in research, but it does not resolve the truth or falsehood of the allegations pending against him. Second, failure to investigate may well discourage individuals likely to discover fraud or other unethical conduct from blowing the whistle; if allegations are not investigated, why should the whistleblower expose himself to the possiblity of retaliation for his act and to possible litigation as well? Third, failure to hear the evidence raises questions regarding the integrity of research files, the validity of experimental results, and the medical profession's ability to regulate itself. Finally, the hospital places the burden of investigating the matter on other bodies such as state licensing boards and federal funding agencies.

The relationship between hospitals and state licensing boards is weak. When resignation from a hospital appointment precedes a formal investigation, the matter usually becomes moot, and a report based solely on a preliminary action seldom is filed with the licensing board. Based on the results of a June 1981 survey by the author, only thirty-two states currently require hospitals to report revocation of hospital privileges to licensing authorities. Moreover, the relevant statutes, except for those of Massachusetts,4 do not require reporting the reduction of privileges or a resignation while a complaint is pending. The hospital's investigation, which is closed upon resignation of the accused, usually is not pursued by a state licensing board unless someone forwards a formal complaint. If our hypothetical whistleblower wants the matter pursued, he now must confront the institution or involve an outside agency. The need to forward the complaint outside the traditional institutional hierarchy stems from the fact that, in the whistleblower's judgment, internal mechanisms have failed to resolve the conflict in an impartial and satisfactory way.

State Licensing Boards

State licensing boards receive a mandate from their legislatures to regulate certain aspects of the practice of medicine for the health and welfare of the public. Their mandate is twofold: (1) to insure that uniform standards and criteria for licensure to practice medicine within a state are formulated and met; and (2) to discipline physicians who are incompetent or unethical by imposing sanctions ranging from reprimand or censure to suspension or revocation of the license to practice.

A variety of factors affects a board's effectiveness in investigating disciplinary matters. These include the scope of the state medical practice act, the willingness of physicians, patients, and various agencies to forward complaints and cooperate during an investigation, the administrative environment in which the board functions, the board's composition, and the availability of funds to finance the board's activities.

Most state medical practice acts include "unprofessional conduct" and "violations of medical practice acts or professional ethics" as grounds for disciplinary action. A smaller number include "conviction of a crime." Complaints alleging fraud and unethical conduct in clinical research may fit into any one of these categories. While statutory authority grants most boards the power to proceed with the investigation of any complaint, not every board is compelled by law to investigate all the complaints it receives. Some boards have the statutory discretion to dismiss a complaint or to take no action.

A board's composition may be a factor in the decision to pursue or not pursue a case. In general, boards are made up of members of the licensed profession, who are appointed by the governor for a variety of reasons. The appointments to boards have been highly criticized in the past, and the addition of public members is a recent development to balance overrepresentation from the regulated profession. Unless public members are carefully selected, however, they may play a minor role in the disciplinary process simply because they are inept or outnumbered by the members of the profession. Parenthetically, they may be in the position of becoming whistleblowers themselves when a board, for no justifiable reason, decides not to proceed with the investigation of a case.

Most complaints forwarded to state licensing boards come from the public. In general, no investigation is initiated unless a complaint is in writing and signed by the complainant. According to my survey, thirty-seven states provide immunity to those reporting complaints to medical licensing boards.5 Immunity means only that the statute provides for the defense of an informer if the complaint has been forwarded in good faith and without malice. Whistleblowers risk legal action when reporting information; immunity gives them grounds for their defense, but they may be faced with a long and costly legal battle nonetheless.

Reporting requirements for various institutions and professional societies vary from state to state.6 For instance, forty-two states have adopted some form of mandatory reporting law, but only fourteen states specify that medical societies are required to notify the licensing board of any disciplinary action taken against a physician. Only thirty-two states require that hospitals report loss of admitting privileges, and only ten states require the reporting of a court conviction.

The inefficiency and ineffectiveness of medical boards in resolving both simple and complex complaints is legendary. While boards' functions are similar, the degree of authority granted to each board varies substantially from state to state. In order to be able to comprehend the apparent inconsistencies in the choice of cases investigated, it is important to understand the administrative structure in which boards perform their duties. The Council of State Governments has identified five types of administrative structures for professional and occupational boards, according to their level of autonomy and the degree of authority of centralized agencies performing administrative functions for the boards:7

Model A -- Boards are completely autonomous.

Model B -- Boards are mostly autonomous, but a central agency is responsible for such housekeeping matters as providing space, answering routine inquiries, collecting fees, issuing licenses and renewals.

Model C -- Boards are autonomous and have decision-making authority in many areas, but the central agency may control budgets, personnel, and records. Complaints may be investigated by agencies, but boards make final decisions with respect to disciplinary actions.

Model D -- Boards are not fully autonomous and do not have final decisionmaking authority on all substantive matters. Boards may be delegated functions such as preparing exams and recommending professional standards and disciplinary sanctions to the central agency. Under this model, certain board actions are subject to review by the central agency.

Model E -- The regulatory system is run by an agency director, commission, or council, with or without the assistance of the board. Where boards exist, they are strictly advisory. The agency director, commission, or council has decisionmaking authority on all substantive matters.

Model A exists predominantly in the South (64.3%) and least often in the East (9.1%). In the West, Model A is found in 23.1% of the states and Model C in 53.8%. In the Midwest, 50% of the states are best described by Model A, while the other 50% are divided among Models B, C, and E. Nationwide, 52% of all states fit Models A or B, while 48% fit Models C, D, or E.8

Although these classifications are somewhat arbitrary and represent only major administrative characteristics, they explain the different criteria and standards applied in evaluating complaints. In Massachusetts, for instance, the decision to proceed with an investigation is made by the board's complaint committee, while in Florida it is made by a central administrative agency. Whether the validity of the complaint is established by a subcommittee of the board, the full board, or by an administrative agency, the decision to proceed is often not made until it is known that manpower and funds are available.

Lack of money and manpower can impede a board's willingness to pursue a difficult case. If the board has a separate budget, the request for additional funds to proceed with a complicated case can easily be singled out by legislators and defense attorneys, which leaves the board in a vulnerable position. Not appropriating funds means that the investigation must be suspended, since it is illegal for most state agencies to spend money not appropriated and encumbered. Centralized administrative agencies are protected from unwarranted budget manipulations, but problems of equitable allocation of resources among various boards arise, particularly when it is anticipated that a single case will consume a large portion of the agency's budget.

Because of the cost of investigating complicated complaints, boards tend to proceed with cases that are simple to prosecute, while complex cases await the availability of more resources. Evidence of this selection process is demonstrated by the number of licenses revoked nationwide for unauthorized prescription of drugs and for Medicare or Medicaid fraud. Among ten categories of grounds for disciplinary actions complied by the Federation of State Medical Boards, narcotic violations and Medicare/Medicaid fraud were the basis for 31% of license revocations in 1978 and 45% in 1979. They were also the basis for 47% of license revocations

stayed with probation in 1978 and 33% in 1979 and for 48% of license suspensions in 1978 and 54% in 1979.9 In these cases, investigations were done by federal and state agencies, and the information was forwarded to state boards by the agency conducting the investigation or by the courts pursuant to convictions. Since some states include in their medical practice act "conviction of a crime or a felony" as a basis for disciplinary action, administrative process consists of issuing an order to show cause, which states the board's authority to take action and the basis for the court conviction. Frequently, the parties stipulate to the facts and the board proceeds immediately with sentencing.

To evaluate the degree of involvement of licensing boards with cases alleging fraud in clinical research, I surveyed state licensing boards to learn if such complaints had been received in the past five years and, if so, how they had been handled. A brief questionnaire was sent to the sixty-three medical and osteopathic boards, asking about the number of such complaints received, their source and nature, and the disposition by the board. All state medical boards answered the questionnaire.

Only five states (Alaska, Iowa, Massachusetts, New York, and Pennsylvania) reported that they had received complaints of this type. Additional information was obtained by correspondence and telephone interviews for Alaska, Iowa, New York, and Pennsylvania and by review of documents in Massachusetts for one of the two cases reported. The case in Iowa involved diversion of controlled substances from a clinical laboratory, and the case in Alaska involved a physician conducting investigative tests on patients in an intensive care unit without a protocol or proper consent. A brief description of the cases in Massachusetts, New York, and Pennsylvania follows:

Massachusetts. Two complaints were received, one involving research protocols and informed consent, the other, fraud in research.

Case 1. On April 2, 1978, the Board of Registration and Discipline in Medicine (now the Board of Registration in Medicine) censured a physician for failure to have research protocols properly reviewed and failure to obtain written informed consent from his subjects before involving them in a Phase III drug test. His principal defense was that he was ignorant of the law and that his actions were not an attempt to evade his responsibilities or to take advantage of the subjects he used in his study. He believed that it was permissible to obtain verbal consent in dealing with a geriatric population. The research activities of this physician (soon to retire at the age of seventy-one) came under the scrutiny of the Massachusetts Department of Mental Health because of the sudden death of two of the research subjects. The matter was investigated by a committee of the Department of Mental Health, and it was determined that the deaths were not related to the drug study. It was discovered in the course of the investigation that protocols were not in the files, that approval of the protocols could not be verified in the minutes of the meetings of the IRB, and that no informed consent forms had been signed. The commissioner of mental health reported these violations to the attorney general, who prosecuted the case in the district court. The court convictions were publicized in a local newspaper and brought to the attention of the Board of Registration in Medicine by one of its public members, who was also the chairperson of the complaint committee. He instructed investigators to obtain copies of the convictions and reports from the Department of Mental Health. The case was prosecuted on the basis of these documents, and two years later the board issued its order of censure.

Case 2. This case involves allegations of data falsification in clinical research. The matter was brought to the attention of the board by three persons professionally affiliated with the institution where the research was conducted. One of the whistleblowers also reported Case 1. Although this case was filed with the board prior to the passage of a law requiring confidentiality of all complaint files,10 the board has determined that all documents in the case, which at one time were public, are now confidential. The investigation is still pending, and according to the former chairperson of the board, staff and resources are not available to proceed with such a complicated investigation.11

New York.

The case in New York involved a physician licensed in New York and Florida who was testing drugs for a private pharmaceutical company. The case, which was prosecuted and subsequently overturned in Florida, came to the attention of the New York state board because of the publicity involved. The New York state board closed its case when it learned that the Florida court had failed to find sufficient evidence to support the allegations.

Pennsylvania.

The board has received complaints against three physicians who have been disqualified as researchers by the Food and Drug Administration. The information was transmitted by a Washington correspondent of the Philadelphia Enquirer to a reporter in Philadelphia. The latter followed the story and pressed the medical board to find out what it would do. One of the cases has been referred for criminal prosecution. The board's investigator has stated that his case will not proceed until the outcome of the criminal case is known.

The effectiveness of medical licensing boards can be assessed both on an individual basis and as part of a network of regulatory agencies, particularly with respect to the level of cooperation and exchange of information between boards and between boards and other agencies.

Very few medical licensing boards have adequate resources to perform their disciplinary functions. For the majority, it appears that effectiveness in dealing with complaints varies in inverse relation to the complexity of the case. Complaints involving fraud and unethical conduct in clinical research would appear to be among the most difficult to investigate. If an accused physician leaves the state where the allegations have been filed, the board usually closes its investigation because the accused is no longer practicing within the state. As a rule, a state board does not see efforts to protect the citizens of another state as part of its mandate.

State licensing boards lack an effective mechanism for sharing information that would enable them to function as a network. This lack of communication is evident in both licensing and disciplinary functions. Assuming that a board does proceed with the investigation of allegations of fraud and revokes a physician's license, it then decides which other agency or state will be notified of its action. There is no national policy or standard reporting procedures for the boards. Some states such as California and New York circulate notices of their disciplinary actions among all state licensing boards. But the information is often useless to boards, particularly those without access to data processing, as it requires manually checking rosters of licensees to see if a physician listed on the

notice is licensed in the state. The process is tedious and often inaccurate. If boards know that a physician is licensed in several states, they will notify all jurisdictions upon completion of a disciplinary case. Although information on how many state licenses a physician holds is collected at the time of initial licensure, it may not be updated through a reregistration process. As a result, the physician is often the only person who knows in how many states he is licensed; he is free to move from one state to the other, and information on a case pending against him in one jurisdiction will not be forwarded unless specifically requested; details of an investigation-in-progress are shared between licensing boards unless the information is considered confidential.

A central data bank for disciplinary actions is not yet operational. The Federation of State Medical Boards has been developing a central registry of disciplinary actions and expects to enter the information in its computer in the next three years. However, the federation does not have the power to compel state boards to report disciplinary actions; as a result, the list it publishes is incomplete.

Information on disciplinary cases is not always available to a licensing board at the time a new license is issued. Some boards do not inquire about pending complaints in other jurisdictions on their application for licensure.12 The Federation of State Medical Boards verifies that no derogatory information has been received when issuing a verification of FLEX grades. However, not only is the list of disciplinary actions incomplete, but only 30% of the licenses issued annually to physicians are granted on the basis of the FLEX examination.13 The National Board of Medical Examiners, which certifies the grades of other applicants for licensure, does not report disciplinary actions.

The relationship between state medical boards and other state and federal agencies is not formally defined. Licensing boards are usually notified of cases of Medicare and Medicaid fraud and narcotic violations by state and federal agencies or by the courts. Investigators usually share their work product, but questions of jurisdiction often arise when deciding which agency should bear the cost and manpower investment of long and complicated investigations.

Another example of lack of coordination between federal and state regulatory agencies pertains to disqualification of physicians as clinical investigators by the Food and Drug Administration. Twenty-one physicians have been disbarred in the last five years;14 yet only three cases have been reported to a state licensing board, and those reports were forwarded by the press. The Food and Drug Administration makes available, upon request, the names of physicians who have been disbarred, but does not automatically notify state licensing boards when their proceedings are completed. It is interesting to note that four out of the twenty-one disbarred physicians had been disciplined by their licensing board for reasons other than fraud or incompetence in clinical research. Listed as the basis for these disciplinary actions were "failure to conform to minimal standards of acceptable medical practice and unauthorized surgical procedures," "conspiracy to commit burglary," "misinterpretation of educational qualifications," and "Medicaid fraud." Two FDA disqualifications preceded board actions, and two were subsequent to them, with no apparent correlation.

Specialty Boards

Specialty boards differ from hospitals and state licensing boards in that they are voluntary associations of physicians who share expertise and

scientific interest in specialized fields. Members are either elected or recommended for membership by their peers and are bound together by the ethical code of the medical profession, usually modified for each individual specialty and generally modeled after the principles of medical ethics adopted and recently revised by the American Medical Association.

Specialty boards are "private non-profit organizations without any governmental authority."15 They have three main functions: (1) setting the requirements both for admission into postgraduate medical education and for the postgraduate medical training programs themselves; (2) assessing a physician's competence and knowledge when he enters the specialty by administering a certifying examination; and (3) in some instances, setting criteria for those boards requiring periodic recertification.

The primary concern of specialty boards is the evaluation of competence before granting certification. As a result, grounds for revocation of such certificates are usually limited to instances where a candidate has improperly stated his qualifications at the time of certification. Specialty boards do not view the evaluation of physicians' performance as one of their functions. Because of their limited scope of authority, revocation of a certificate for reasons other than problems related to credentials usually takes place only upon notification of formal action taken by an agency such as a regulatory body.

The American Board of Medical Specialties is composed of twenty-three specialty boards. Each board has adopted its own bylaws, criteria for certification, and basis for disciplinary actions, which vary from board to board.16 The American Board of Dermatology, the American Board of Otolaryngology, the American Board of Radiology, and the American Board of Thoracic Surgery will revoke their certification if a physician has had his license to practice medicine revoked or suspended, if he has been censured by a state licensing board, or if he has been convicted of a felony or of a misdemeanor involving "moral turpitude." Four other boards (the American Board of Orthopedic Surgery, the American Board of Preventive Medicine, the American Board of Psychiatry and Neurology, and the American Board of Urology) will revoke a certificate if its holder has had his license to practice medicine revoked or suspended or if he has been censured by a state licensing board. Three other boards state failure to maintain moral, ethical, or professional standards as grounds for revocation (the American Boards of Anesthesiology, Obstetrics and Gynecology, and Urology). Lastly, the Boards of Ophthalmology and Obstetrics and Gynecology list suspension or expulsion from a medical society as grounds for revocation.

The Massachusetts Board of Registration in Medicine reprimanded four members of the American Board of Thoracic Surgery in 1980. Upon asking the specialty board whether or not it had taken any action pursuant to the state licensing board's action, it was discovered that no information was forwarded to it from the state board.16 The state board's files showed that only three agencies, the Massachusetts Medical Society, the Massachusetts Division of Registration, and the Federation of State Medical Boards, had been notified.17 Another Massachusetts case involved revocation of the license of a physician certified by the American Board of Obstetrics and Gynecology. Information received by the specialty board revealed that notification of the reinstatement of the license had been received before the specialty board had time to take action on the revocation; the case therefore was closed.18 A check of the state board's files showed that the specialty board was not included in the list of twelve agencies notified of this revocation of license.19

Specialty Societies

Specialty societies, which are voluntary associations of physicians, currently number twenty-four and are loosely affiliated as members of the Council of Medical Specialty Societies. Bylaws vary from one society to the other, but in general their goals are to: (1) promote research and educational activities; (2) improve the quality of patient care; (3) improve communication between physicians and the public; and (4) participate in policymaking and legislative activities that affect the practice of the specialty.

In preparing this paper, a survey of specialty societies was conducted to learn whether their bylaws had provisions that would enable them to take disciplinary actions against one of their members. Thirteen societies answered the inquiry, and only two stated that no such provisions were included in their bylaws.

Societies that do undertake disciplinary actions will receive complaints directly, and formal notification from hospitals and state licensing boards is not required before a society takes action on a disciplinary matter. The societies have various methods of handling investigations; complaints may be investigated by the board of directors of the society or may be referred back to the hospital or to the state or local medical society. Only two societies have district branches to investigate complaints; cases are then referred to ethics committees and final determinations are usually made by the board of trustees or the executive committees. Although five societies reported that they have taken disciplinary actions against some of their members in the last five years, information on the number and reasons for action is not available.

Medical Societies

State and county medical societies have authority, by virtue of their bylaws or state statutes, to exercise discipline over their members. Some societies participate in state boards' disciplinary activities, while others are empowered only to discipline their members. Grad has identified three types of medical societies according to their statutory functions: (1) those required to report information on a physician's misconduct to the state disciplinary body; (2) those which must report and conduct examinations of "sick" physicians; and (3) those which have received authority to act as the state disciplinary body or assist the licensing authority in making disciplinary decisions.20

Most medical societies have two separate committees charged with reviewing complaints: the grievance committee and the committee on ethics and discipline. Grievance committees review complaints forwarded to their chairperson by physicians, patients, or insurance carriers. According to Grad, "in a study of five state and county medical societies in the Washington metropolitan area, and in another study of four county societies in the New York City area, it was found that complaints by third parties and patients dealt nearly exclusively with the fee that a physician had charged."21 More serious complaints are forwarded to the committees on ethics and discipline rather than the grievance committee. Should this committee decide to proceed with an investigation, the case is assigned to a member. After appearance of all parties, the case may be dismissed, settled, or referred to the executive committee for formal action, which may include censure, probation, or expulsion from the society.

Complaints alleging fraud or other unethical conduct in research are unlikely to be filed with medical societies. Those who are likely to discover incidents of falsification of data or inadequate consent forms know that the medical society is not prepared to handle such complex complaints. First, if the complaint is filed with the society, there is no assurance that it will be considered. If an investigation is undertaken, no one but members of the profession will be involved; they all serve on a voluntary basis and their time and resources are limited. Medical societies cannot compel their members to participate in the disciplinary process, and resignation may be the option of the physician against whom allegations are filed. Finally, medical societies have no jurisdiction over nonmembers. While reliable statistics are not available on medical societies' memberships, it is estimated that in New York State only about 60% of licensed physicians are members of the medical society,22 and in Massachusetts only 53%.23

Medical societies, specialty boards, and specialty societies generate professional norms and standards to which members should adhere. In addition, they have the legal authority and mechanisms to discipline their members. They are not, however, perceived by the public as eager to act, and they do not publicize the fact that they can resolve certain complaints. According to Grad, "one survey found that only 10% of the people interviewed know that they could file complaints about a physician with a local medical society."24

Voluntary associations have little or no authority over their membership. Nonadherence to ethical standards of the profession usually results in minor sanctions (such as probation or censure) if the accused physician cooperates in the disciplinary process. Otherwise, the only form of punishment may be expulsion. Disciplinary proceedings of professional societies are abruptly terminated when the accused physician withdraws his membership from the society. In this instance, which is similar to withdrawing from the staff of a hospital, information on the disciplinary proceeding would not be forwarded to the state licensing board, for the physician is no longer a member of the society. Forwarding information on a nonmember would expose the society to legal action.

Conclusions

Regulations governing physicians have been designed by society and by the profession to insure conformity to established norms and values. Statutes, rules, and regulations are the end product of negotiations between the profession, the public, and the latter's elected officials on what ought to be accepted norms of conduct and what the interrelationship between the profession and society should be.

Four major points emerge from this discussion of the role of hospitals, licensing boards, and professional associations concerning allegations of fraud in clinical research. First, all the agencies, institutions, and professional associations discussed in this paper have the power and authority to take some form of action upon receiving the complaint of the whistleblower. Second, various factors can alter the course of action of these agencies and institutions. For the hospital and the medical society, resignation from the staff or the society closes the investigation. State licensing boards often either wait for the findings of other agencies or proceed only on the basis of court convictions. Third, these agencies do not form an interrelated network; they have no formal mechanisms to share information and do not coordinate their efforts in dealing with complicated cases. Such is the case, for example, of state licensing boards and the Food and

Drug Administration. Fourth, the whistleblower faces an incredible administrative and legal hassle when he reports allegations of fraud. Should the reward for his willingness to blow the whistle be years spent dealing with various agencies which, in the end, may not resolve the situation either for the accused or the whistleblower?

Fraud and other unethical conduct in clinical research are problems that transcend the parameters of institutions and local, state, and federal agencies; inaccurate and fraudulent data that serve as basis for new methods of treatment of human diseases may affect the health, safety, and welfare of all citizens. It is essential to determine which institutions or agencies should be responsible for investigating and adjudicating an allegation of fraud in clinical research. In instances of fraud involving a licensed physician, the case may become the responsibility of the licensing authority, at least if it can be demonstrated that the fraudulent activities are not consistent with the good moral character required for licensure. The responsibility for preserving the integrity of research data should, in turn, rest with the funding agency. Guidelines and procedures need to be formulated to protect both the researcher and the whistleblower. The researcher must be protected from unwarranted and malicious attacks that can destroy his professional reputation; the whistleblower needs to be protected from retaliation; and the evidence needs to be preserved to ensure that the matter is investigated thoroughly and prosecuted promptly.

The legislative negotiations that result in the enactment of new laws, the formation of new agencies, and the formulation of new policies are usually initiated under the pressure of an impending crisis. Much of the regulation of medicine is aimed at solving immediate problems rather than creating a consistent coordinated system to protect the public. As a result, the proper resolution of a complicated complaint is a chance event rather than the outcome of planned regulatory activities.

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Chapter 10

COMMENTARY: PROBLEMS IN INVESTIGATING FRAUD IN CLINICAL RESEARCH

Frank P. Grad

Are Existing Formal Control Mechanisms Appropriate?

The formal controls discussed in Ms. Cloutier's paper are those applicable to the regulation of medical practice. The overwhelming majority of physicians are involved in the treatment of patients and not in scientific investigation. Hence, the regulation and control of the medical profession's scientific research endeavors make a very minimal claim on the attention of the formal control mechanisms. These controls -- which do not work very well even in the area for which they were designed -- have a minimal impact on scientific investigation.

Even in the limited area where clinical investigation has become the subject of regulatory attention -- the requirement of informed consent by the research subject -- the HHS regulations emphasize patient or subject protection, not the integrity of the scientific investigation. It should not be much of a surprise, therefore, that existing formal controls have not helped whistleblowers or safeguarded the integrity of research.

Should Existing Controls Be Strengthened?

There is a real question as to whether the integrity of research should be supervised by formal control mechanisms as these are presently constituted. State medical practice boards are not even adequately staffed to carry out the job for which they were designed. They simply do not have the personnel, or the capacity to train personnel, to make even preliminary findings that a particular research project falsified or manipulated data or was otherwise dishonest in recording or reporting results. The same is probably true of PSROs. Medical societies and specialty boards have paid little or no attention even to problems of inadequate medical practice, and it is overly optimistic, not to say unrealistic, to expect them to develop a passion for the supervision of research integrity. Hospitals should and do supervise research, but only university-connected teaching hospitals are likely to have adequate supervisory capability (which they are often not too anxious to exercise, anyway).

Overall, then, I would agree with Ms. Cloutier that the formal controls over medical practice are inadequate to deal with fraud in research. And I would go further and say that I do not believe they can be rendered adequate, certainly not at the present time.

Do We Need Formal Mechanisms to Give Whistleblowers a Forwarding Address for Their Report?

I wonder whether there is a large enough problem with research fraud to require the establishment of a watchdog agency. Such a new agency would be called for only if it could be shown, first, that there is a great deal of fraud in medical research and, second, that whatever fraud there is cannot be adequately dealt with by existing informal peer review methods. To discover fraud in research is not an easy matter (nor is it easy to discover inadequate medical practice). There can be sharp differences of scientific opinion on whether certain scientific findings are reliable, accurate, and reproducible, whether they are the result of error and inadequate technique, or whether, indeed, they are the result of intentional fraudulent manipulation of data. Existing formal agencies that regulate medical practice lack the necessary sophistication to undertake the inquiry, and unless there is a demonstrated substantial need for such controls, it is questionable whether it would pay to establish new formal agencies with such expertise. It may be possible, however, to provide more effectively for the referral of problem situations to existing scientific and educational institutions that have the necessary knowledge.

The Whistleblower -- Where Shall He Blow His Whistle?

With formal control mechanisms largely unable, and sometimes unwilling, to be effective in reviewing the integrity of scientific research, the whistleblower has a difficult time. Aside from the awkwardness of turning in a colleague and the likely disapproval of many persons who regard the whistleblower as a common snitch or a rat fink (though he may also be praised and admired by others), he will have the problems of making a case and finding the proper forum to present it. With formal mechanisms largely unsatisfactory, the academic world and its scientific publications offer the only realistic opportunity.

When scientific work is part of an educational degree program or of research in a teaching hospital, institutional peer review procedures may provide an adequate forum. Perhaps governments and foundations that support research also should exercise greater control and review results more than they usually do. The whistleblower could quite effectively call such funding agencies' attention to fraud or other lack of integrity. The effectiveness of such a complaint, if it is proved to be justified, would then be the denial of future funding to the fraudulent researcher.

The problem of the speedy disposition of the whistleblower's complaint is difficult, because the more unstructured the process and the more difficult and sophisticated the issue, the longer the disposition is likely to take. Prompt disposition of a whistleblower's complaint is infrequent even in much simpler situations. The person who reports a corporate officer's business fraud -- a criminal matter -- is not likely to see a prompt disposition of his complaint, although he will have less trouble in finding a well-structured system to receive his message. The whistleblower who carries an accurate report of misdeeds is entitled to be heard, and should be encouraged, regardless of his motives. It is not at all clear, however, whether new formal structures are needed to provide that opportunity.

Chapter 11

DISCUSSION

MR. CAPRON: Granting that justice should be tempered with compassion, particularly in a small social setting with ongoing relationships such as a research hospital, and that identity with the accused ("There but for fortune . . .") is a good source of compassion, I still wonder whether the deep involvement of the "judges" in the actions of the "accused" that are under scrutiny doesn't raise some issues worthy of further thought.

I was struck by the extent to which those who had to discipline a "wrongdoer" were implicated in the alleged wrongdoing, principally in having failed to provide adequate prior explanation of expected standards, but also in failing to exercise necessary oversight.

DR. LEVINE: In one of the cases I presented, it was not that we had not explained the expected standards; each of us who alleged that there was some wrongdoing had seen only one minor infraction, any one of which might not have called for any particular disciplinary action.

In the case of Dr. C it occurred to us at the meeting that what we each should have done was to discuss these infractions directly with him and to report them to the department chairman, who then might have come to realize that there were a number of minor things going on which, taken together, indicated that there was a problem. We did feel a sense of complicity. And that is why I say we are beginning to learn how to do things. From now on we are going to report things earlier so that we don't get stuck in such a situation again.

Another question is: Why, in the case of Dr. R, had the section chief or department chairman not previously taken steps to stop this "double billing" when they signed off on grant applications. In big bureaucracies like Yale Medical School, many of our senior administrators sign many more pieces of paper each day than they can possibly read. Our IRB guidelines used to state that we would have the department chairman sign off on every protocol to provide reassurance that the scientific design passed the department chairman's standards, and so on. About eight years ago, in recognition of reality, we changed our guidelines to read that the department chairman should sign each protocol in order to give him an opportunity to become aware of what is going on in his department.

Although, as Ms. Oakes said earlier, it may seem that we don't begin to do things until after a big crisis, that is not correct. We didn't draw up a formal procedural document at Yale until after the big crisis, but I wrote the paper on informal monitoring for the National Commission in 1976. And we have been doing little things in an informal way for a long time. The first meeting of the Federated Society of Experimental Biology that I went to was in 1962. An abstract on the program by a postdoctoral fellow in biochemistry looked very exciting. The person who appeared on the platform was, instead of the fellow, the chief of the laboratory in which that fellow had done his work. And the chief said, "You're not going to hear this paper presented because we found out that he had faked his data." That fellow was finished. I have never heard of him again.

Finally, I'd like to comment on the question of whether or not people can zip from school to school. Whenever somebody is recruited from one faculty to another, it is in the interest of most of us to write honest letters of recommendation. Most of us would rather not get identified as writing dishonest letters of recommendation. In the case of Dr. C, for example, when he applies for a job at another university and our department chairman is asked to write a letter about him, the chairman is going to describe the circumstances under which his employment at Yale was terminated.

DR. MEDEARIS: As I reflect on what I have heard both today and in meetings of the President's Commission, I sense there is a majority opinion, if not a consensus, that there ought not be a set of specific regulations issued by the government to further define obligations and responsibilities of IRBs. Instead, there should be a statement within the general assurance that there is an institutional process by which questions having to do with protection of subjects -- because of fraudulent or other kinds of inappropriate activity -- can be heard and decided, with appropriate actions taken.

If that is an accurate presumption, I wonder how one would reconcile it with certain concerns that one might raise about this process being intrainstitutional. I want to ask Dr. Levine and Professor Glantz if they see some way of getting external representation into the process. Is external representation acceptable to you as you now see the issue?

DR. LEVINE: In each of our cases, the person, when confronted, acknowledged that the allegations against him were correct. If we ever had a case where the alleged wrongdoer did not acknowledge this, I suppose we would involve outsiders. And I suppose we will not develop a formal procedure for doing that until we are confronted with it, although we probably should.

PROF. GLANTZ: It is a difficult question. I understand that the institution has its own needs. I think it depends on what the issue is, and that never has been made clear.

At the President's Commission's hearing in Boston, Marc Straus claimed he had never had peer review, and he wanted such review with subpoena power. The question is: Why do you need peer review? I think it depends on what the allegations are. If the charges are data falsification, why do you need an outside person?

DR. MEDEARIS: I'd next like to ask Ms. Cloutier and Professor Grad if they think the commission should develop a statement about the need for communication between various regulatory agencies if it were determined from within an institution that inappropriate behavior such as fraud had occurred.

PROF. GRAD: One conclusion that emerges from studies like those Ms. Cloutier and I have done is, "For God's sake, fellows, why don't you get together. Even if you have adverse information, you keep it under your hat and don't pass it along."

The communications network aspect is very, very important, and it is one of the relatively easy ones to put into effect. More difficult is the problem of what the institution is going to do once it has the information. Many operate in the most primitive fashion. Many don't even have an updated card catalogue with physicians' names on it. The person's name is removed when he or she dies. They have files going back to the beginning of time, and nothing ever changes in those files. It is not a question of throwing money at the problem, but simply of implementing what is there.

If you are looking for recommendations, just as the federal government said to institutions, "If you want research funds you have to set up Institutional Review Boards," I see nothing wrong with saying, "We don't tell you what kind of system to set up, but you'd better set up some kind of system to make sure that the research product we get back from you has indeed been subjected to some kind of institutional review process." This should not cause any enormous harm, because theoretically this is what is going on anyway.

Another point is, quite simply, that there is a responsibility on the part of administrators -- if not to read what they sign -- at least to know what they sign. From the point of view of the administrator, the buck stops right there. If he cannot rely on his underlings to give him papers that he can live by, then I think it serves him right if he gets hung up on it.

MS. NORDIN: I don't think a general assurance statement about internal procedures will be adequate. From my own observations there are many institutions that, with relatively little thought, say, "We have internal governance mechanisms," without thinking deeply about whether they go to the point of protecting the whistleblower or the accused -- because that question has never come up.

I think perhaps there should be a regulatory determination as to whether those internal procedures are adequate. That might be difficult to determine, but somebody has to do it. The next and even tougher question is: If an institution doesn't pass such a determination, then what do you do? I think that is when you say, "We'll tell you what to do because we feel that, given every opportunity, you couldn't do it."

MS. CHALK: Is there any system used in screening complaints or alleged incidents? In my own experience looking at whistleblowing cases, it is the screening criteria which are the most difficult to define in deciding when an allegation is serious enough to merit investing resources to establish the true facts of the situation.

PROF. GLANTZ: One of the points I tried to make is that the procedures set up at Boston University were totally nonresponsive to the case that caused them to be set up. They were set up to produce an ordinary, everyday monitoring system that would catch good-faith errors. It does not address the question of what will be done if somebody reports something to the system. Not only aren't those kinds of standards set up, but the overall standard for how you deal with an allegation of wrongdoing has not been specified.

PROF. WEINSTEIN: If we look at comparable situations regarding when and why an inspector general's office chooses to take a case, we find a similar lack of standard procedures.

DR. LEVINE: One of the things I should have made clear is that we have no screening criteria at Yale; we take all allegations seriously. One of the reasons that we have made a conspicuous display of taking every complaint seriously is because we wanted to encourage this sort of reporting.

DR. GAINTNER: With respect to the risk-benefit malpractice issues that I talked about, the hospital's legal counsel's office basically takes every instance seriously, looks into it, and then brings it to the attention of the incident review committee. The incident review committee then attacks it on two bases. First, is the incident itself being appropriately pursued within the institution? That is, is the departmental review, risk-management process taking it seriously? Second, we look at generic aspects of the particular situation. That is, are there certain things that have gone wrong here because equipment has malfunctioned? Or is there another type of problem?

The committee, the chairman, the in-house counsel, and I (who represent administration) will follow those issues through to the point where we feel that they have been fully explored. If, in fact, there is serious wrongdoing, the institution has dealt with it -- perhaps for no other reason than that it is in the institution's financial self-interest to do so in terms of malpractice rates and liability.

PROF. GRAD: Too much is generally made of the whistleblower's motive. If, indeed, the whistleblower has gotten hold of something which is real, then who cares what his motive is? The motive is relevant in civil litigation only if the whistleblower is then sued and if it is discovered that he told a fairy tale and he told the tale for wrong motives. But otherwise the motive is entirely beside the point. From the point of view of the institution, having ambitious people tell on each other is probably a good thing because it protects you over the long run. Maybe it doesn't make for great collegiality, but it certainly makes for institutional protection.

MR. RISEBERG: It is now a felony to provide the government with false information. If the government is funding a research project, to what extent does the institution have an obligation to tell us that an incident has occurred that might violate one of the criminal statutes, and at what stage?

In discussing this you should understand that when we discover such a problem, we are under instructions from the Justice Department to immediately report it to them, and they will decide whether the FBI investigates it or whether we send out investigators who have a less specific expertise. When a problem is discovered, for example, in a federal intramural program or in grants or contracts, it is taken very seriously, and we can't even look into it until the Justice Department gives us permission.

On the other hand, when a grantee stumbles across some type of fraud, I get the impression that the institution undertakes a very informal process with no sense of obligation to get in touch with us.

DR. SWAZEY: I'd like a little clarification on who is liable for the felony charges. Does that potential liability extend to other people who have signed off, as one says, on pieces of paper if a false statement is made in a grant application or a progress report?

MR. RISEBERG: It depends on how willfully and knowingly they were involved in the activity. If we stumbled across it, we wouldn't be sure just how the facts are going to come out, but we have to get the clearance from the Justice Department to look into it. We are not supposed to resolve all the facts and say, "Here, Justice Department."

DR. GAINTNER: When I was talking about the risk-management situation, I was not talking about the whistleblowing related to biomedical research. But I think when the whistle is blown you cannot assume guilt; you cannot assume that the facts are necessarily as the whistleblower states them. The institution is obligated to establish that it feels that the facts as presented by the whistleblower are credible before it takes the step of reporting it to an external agency.

My other comment has to do with the business of signing off, which I did for three-and-a-half years as the institutional officer in the school of medicine. I believe I was signing on behalf of the institution, and I clearly believe it was my responsibility to see to it that what I was signing was in fact correct, that we had reviewed it, and so on. If the intrainstitutional mechanism was not doing that, then I think the institution and I should have been liable for a problem such as fraud.

DR. MEDEARIS: Does anyone know whether there have been whistleblowers who were research subjects?

DR. LEVINE: Yes, we have had such cases.

DR. GAINTNER: Sure.

DR. McCARTHY: We have, I suppose, half a dozen a year on the average who come to us about real or imagined abuse. Sometimes the cases seem very far-fetched to us, but we do check into each one. We don't feel we have discretion to say, "This sounds so far out that we can't even bother with it."

More often than not, we are not able to either substantiate the claim or disprove it. That is quite unsatisfactory for everybody concerned, because the investigators and others associated with the research feel they ought to be somehow given a clean bill of health. But we end up simply saying, "The evidence is inconclusive, and the cost-benefit does not justify the additional expenditure of personnel and dollars to try to find out something that may in the last analysis not have sufficient proof to make a decision." The benefit of the doubt is given, I suppose, to the investigator, but investigators are not happy with that, either. They would like some kind of clear answer, but in most cases we don't end up with anything other than saying we are dropping the case because of insufficient evidence. In a few cases we have found there was wrongdoing and took some action.

DR. MEDEARIS: In addition to what most institutions have as a part of the usual informed consent form, has anything different been done in the last year in terms of informing subjects that there is a way of bringing such concerns to somebody's attention?

DR. McCARTHY: I think many institutions have routinely notified subjects where they might make a report if untoward or inappropriate procedures are occurring or if they have problems. That is now part of the new regulations, but what is in the regulations was already anticipated by a significant number of institutions.

MS. MISHKIN: Dr. Medearis, did you have something in mind like a statement on the bottom of the consent form that, in addition to contacting so and so at the institution, this research was funded by HHS and you can get in touch with Dr. McCarthy? That is important because if you have a latent injury and it doesn't manifest itself until four or five years later and Dr. X has left the university, you may not know to whom to turn.

DR. MEDEARIS: I meant my question to stimulate that kind of thought.

DR. McCARTHY: Ms. Mishkin, your example was an example of an injury. At least as presented, I wouldn't classify that as whistleblowing.

MS. MISHKIN: It might or might not be, depending on how the subject perceived it.

DR. McCARTHY: If it resulted from negligence, I think it might be, but in such a case I think the negligence might be known a lot earlier.

MS. CHALK: The American Psychology Association is in the process of developing what they are calling a consumer version of their code of ethics, which will be required to be posted in the office of every psychologist licensed through the APA. The purpose of that consumer version is to alert clients to the fact that there is a code of ethics to which the psychologist is bound and that if there is any complaint or any questionable conduct, the client has a right to file a complaint with the national association.

DR. SWAZEY: Let me come back to Mr. Riseberg's question, because I think it very much relates to the point Professor Glantz made about incentives or disincentives for an institutional official to pick up a phone and call the NIH or general counsel's office. I think Mr. Riseberg is asking: How is the institution supposed to know when it has something to report to the general counsel's office that may involve a felony charge? I believe that not many institutions are going to leap eagerly to the phone unless they are fairly secure in their evidence.

DR. GAINTNER: I feel that the IRB should be responsible for looking at the situation and establishing whether the evidence is such that they agree with the whistleblowing contention. At that point I think the information should be passed on to existing institutional mechanisms. And if the institutional mechanisms substantiate the charges, then I believe the institution is obligated to make appropriate notification.

MS. MISHKIN: It seems to me that Mr. Riseberg's point goes quite the other way; liability for a felony is a very strong incentive to report to the federal government a discovery of what looks like strong misrepresentation. If the institution has knowledge of such action, it seems to me it would be seriously liable if it failed to report it.

PROF. GRAD: There are clear cases of felony or larceny, e.g. somebody made off with $25,000 from the kitty. You wish the other cases were as clear, but they aren't. Misrepresentations for obtaining funds may involve the kind of mild exaggeration and superlatives all of us use in grant applications, which nobody ever uses in everyday conversation or any other written form. It is a form of creative writing; let's accept that. There also can be rhapsodic and hyperbolic statements which are related somewhat to the truth. And there are even all kinds of exaggerated, way-out statements. But you are never quite sure what is true or false until you know more about the study.

When you get into misrepresentations during the course of the study, can anybody here honestly say that every progress report they have made was pure truth from beginning to end? Or take what we do in terms of asking for postponements. The deadline is a week or a month hence, so you ask for a three-month extension. You know you need another six months, but you say you can do it in three because you know you intend to ask for a second three-month extension at the end of it. That's life as it is led at the university. Very few people lead life differently.

None of these are criminal violations. At what point do they become criminal? When nothing has happened, when you are building a fantastic tale of the amount of work that has been done, and when the research funds were spent on a ski vacation in Cortina.

MS. MISHKIN: I didn't mean the reporting of self-aggrandizement. It is a judgment call on the part of institutional officials and committees that make decisions. If they conclude that some conduct has occurred that fulfills this definition, then I think they have adequate incentive to report that to the federal agency rather than saying, "We have taken care of it, and the scientific community knows this so everything is fine."

PROF. GRAD: That's right, but I think in many instances that represents a substantial investigation. That is my point. You know, if somebody commits an aggravated assault or makes off with $25,000, that is a clear crime and you go call the cops. But this is not the kind of situation where you can so readily call the cops.

MR. RISEBERG: There is the question of who should be the decisionmaker as to whether a prosecution occurs or not. If the university does not report it, the university is making the decision that this is not a matter that should be brought to a prosecutor's attention. I am simply raising the question of whether universities should bring a decisionmaking process other than their own into the picture.

DR. GAINTNER: In our situation we would have in-house counsel advise us in this regard. As soon as an issue like that came into the dean's office of the school of medicine, if it had been referred from the IRB, in-house counsel would be involved from the very beginning. Her interest is to look out for the well-being of the institution. If we are advised to report at that time we'd do so, and if we are advised not to, then we would act on counsel's advice.

DR. MEDEARIS: Let's assume for the moment that the allegations made against Marc Straus are shown to be valid. Is there anything in a grant application he would submit from the institution where he is now working that would disclose a prior instance of data falsification?

DR. McCARTHY: I don't think there is anything that states a past record. If a person has been disqualified, for instance, by FDA on grounds of some kind of mishandling of data, that name is in our computer. And if an application comes in, then at least an administrator is notified that somebody whose track record has been poor has now applied for a grant. The administrator then must make some decision whether or not to take further action or make further inquiries. But other than that, I know of nothing.

DR. MEDEARIS: It is interesting that we ask for such information in applications for drivers' licenses and insurance policies, but in something involving millions of dollars we don't do it. My perception is that if data falsification in research involving human subjects had been shown to occur, it should be a part of the record.

DR. McCARTHY: Suppose the falsification involved research with human subjects, and the investigator later came back and wanted to do basic research not involving human subjects? Those are the kinds of questions I think we would have to ask. How large or how small is the universe that you want to capture? And what do you do with the information when you get it?

DR. MEDEARIS: I think if as scientists and doctors we want to maintain the reputation we think we now have, we'd better work very hard at it. I don't think fraud and deceit are rampant in medicine, but I think we should work harder than we have at uncovering it and trying to act more appropriately.

MS. MISHKIN: OMB has issued a proposal for both a unified federal standard for disqualification from contracts and a unified list; for example, if a person is disqualified by the Defense Department from doing anything under contract, he would automatically be disqualified from doing it for any other executive agency.

The commission inquired as to whether there is any interest in extending such a standard to grants as well, so a disqualification from HHS, a suspension or disbarment, would go on a list that would be accessible to the National Science Foundation, the Defense Department, the Veterans Administration, and so on. So, there is some movement within the federal government to consolidate and inform at least the agencies of the executive branch.

Fraud and Whistleblowing: The Federal Government's Role

III

Chapter 12

PROTECTING THE RIGHTS OF WHISTLEBLOWERS AND THE ACCUSED IN FEDERALLY SUPPORTED BIOMEDICAL RESEARCH

An Examination of Case Studies, Existing Protections, and Suggestions for Reform

Andra N. Oakes*

Case studies demonstrate that existing procedures for resolving complaints of misconduct in federally funded biomedical and behavioral research are inadequate to protect either those who complain of misconduct or the accused. With few exceptions, state protections do not fill the gap. Professional societies lack sufficient support services to provide meaningful assistance. Federally established systems, such as the Office for Protection from Research Risks, debarment procedures, IRBs, and the Office of the Special Counsel, while potentially useful, are understaffed, underutilized, or misdirected.

A comprehensive federal mechanism should be created to investigate and adjudicate complaints of misconduct and claims of reprisal against whistleblowers in the field of federally funded biomedical and behavioral research. Both state and federal laws should be amended to prohibit retaliation and unjust dismissals. Institutional procedures should be redesigned to assure confidentiality and full procedural rights, as well as to protect all parties against punishment for their participation in the complaint process. Only through such reform can society properly balance the personal interests of the whistleblower and the accused while encouraging full exposure of misconduct in biomedical and behavioral research.

Introduction

Allegations of misconduct in federally funded biomedical and behavioral research have a profound impact on the professional, personal, and financial fortunes of both the "whistleblower"1 and the alleged wrongdoer. Motives and reputations of the complainant, the accused, and the affected institution are inevitably called into question. Both whistleblower and accused face academic censure, dismissal, professional "blackballing," and expensive and time-consuming lawsuits. Fear of reprisal undoubtedly has had a chilling effect on many potential complainants.2 In light of these problems, this paper will examine methods of striking a balance between the competing interests of the whistleblower and the individual accused of wrongdoing, while at the same time protecting the public interest.

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The whistleblower's primary personal interest is to protect himself against economic loss or professional penalties resulting from his disclosure. If exposure of misconduct is to be encouraged, protective mechanisms must be accorded any whistleblower who makes a good-faith allegation of serious wrongdoing against a colleague or superior. These include the right to have his identity kept confidential unless the merits of the charge cannot be investigated without disclosure; to submit the allegation to a neutral third party; to disclose all relevant documentation obtained in the performance of his duties to the appropriate investigative authority without fear of civil liability; to receive specific and enforceable written assurances that no retaliatory action will be taken against him for filing charges; to be kept informed as to the outcome of the investigation; and to recover damages, costs, and attorneys' fees if retaliation does occur.

The individual accused of misconduct, however, has at least an equal interest in preserving his privacy, protecting his professional reputation, and obtaining a full and fair opportunity to respond to the charges against him. Quite apart from the legal requirements of "due process," which at minimum call for "some kind of notice and . . . some kind of hearing,"3 protective mechanisms for the accused should include advance notice of both the specific charges against him and the standards by which his conduct will be judged; a formalized appellate process; the right to examine all documentary evidence relied upon; the right to a hearing; the right to representation of his choice; the right to cross-examine witnesses; and the right to present evidence on his own behalf, as well as to compel the production of evidence and witnesses necessary for his defense. In addition, to the extent permitted by law, his identity should not be made public unless and until a final decision is reached.

This paper will explore, through selected case studies and a brief survey of existing law and practice, what safeguards exist at the institutional, associational, state, and federal levels to protect the interests of both whistleblower and accused when allegations of research misconduct and allegations of reprisal for whistleblowing occur. The paper will also review some existing federal mechanisms for protecting other categories of whistleblowers, i.e. mechanisms that are potentially applicable to whistleblowing in biomedical research. The paper will conclude with suggestions for reform at the federal, state, and institutional levels.

Three Case Studies

Three case studies from representative areas illustrate the problems of handling both allegations of misconduct in biomedical research and charges of retaliation against whistleblowers. As these case studies suggest, existing procedures at both institutional and governmental levels may fail to protect adequately both whistleblowers and those accused of misconduct.

1. University of Kansas -- Failure to Protect the Whistleblowers?

In early 1977, Elizabeth Murray and Nancy Sempolski, two doctoral candidates in anthropology at the University of Kansas, a state-supported institution, reported possible irregularities in the research of Dr. Michael Crawford, an anthropology professor studying sickle cell anemia in Belize under a federal grant from the Department of Health, Education and Welfare (now HHS). The students alleged, among other things, that Dr. Crawford allowed volunteers in the research to be misled into thinking that they were being treated by medical specialists, that informed consent was never obtained, that Dr. Crawford employed an untrained person for the

screening test, and that the genetic and health counseling given to the volunteers was potentially harmful.4

Murray and Sempolski were aware of no established procedure through which their allegations could be investigated. Initially they sought assistance from the university's Graduate Student Council, which mediated interpersonal, contractual, and academic disputes between students and faculty. Two members of the council reported Sempolski's and Murray's concerns to several university administrators, including William Argersinger, vice-chancellor for research and graduate studies and dean of the graduate school. The council members did not reveal the names of the complainants or their department. Argersinger, however, agreed to an "unofficial meeting."5

In March 1977, Murray and Sempolski met with Argersinger. The vice-chancellor informed them that there were no formalized, established procedures for investigating allegations involving unethical research practices, but he advised them to present the charges to the acting chairman of the anthropology department, Robert Squier. Argersinger reportedly assured Murray and Sempolski that the case would be treated discreetly. He promised the students that the university would protect them from retaliation, although he admitted that the school could do nothing about gossip and could not ensure that they would receive complimentary letters of recommendation from the faculty.6

Sempolski and Murray followed Argersinger's suggestion, taking the charges to the chairman of their department. He recommended a hearing within the department to investigate their allegations and asked them to draw up a written list of the irregularities they believed were involved in Crawford's research. After they had complied with this request, the administration appointed an ad hoc committee of anthropology faculty members to hear the charges. One committee member was replaced at the students' request.7

In early April 1977, Murray and Sempolski requested a meeting with Squier and Dean T. Wilson because the two women believed the investigation of their charges was not proceeding expeditiously. At the meeting, Squier maintained that the department handled only grievances dealing directly with "academic matters," which he felt did not include the kind of issues raised by the students. He suggested that Murray's and Sempolski's allegations be investigated by a university official designated to settle disagreements within the university community. The dean suggested "mediation." Squier and the students agreed that Dean Frances Horowitz would be a good mediator.8

Murray's and Sempolski's charges were discussed in a series of meetings chaired by Horowitz.9 No transcripts were kept of any of these meetings, and no statements were taken under oath. Squier accompanied Dr. Crawford as his representative. Two members of the Graduate Student Council helped Murray and Sempolski explain their charges. On April 9, Horowitz chaired a five-hour meeting. Horowitz read aloud the students' written allegations and Dr. Crawford's written rebuttal. The students were given a copy of Dr. Crawford's rebuttal after the meeting was completed. In an April 11 session, all of the graduate students under Dr. Crawford's supervision were questioned in Dr. Crawford's absence about his research practices. Like Argersinger, Squier reportedly promised the students that the controversy would be kept as quiet as possible and that the department would protect them from retaliation, although it could not ensure that they would receive favorable letters of recommendation.10

At the conclusion of these "mediation" sessions, Horowitz referred the allegations to the vice-chancellor who, in turn, referred the issues concerning the possible misuse of human subjects to the university's Advisory Committee on Human Experimentation (ACHE).11 ACHE, which is the university's institutional review board (IRB), was composed of fifteen members, the majority of whom were faculty members, one of whom was Murray. An ad hoc ACHE subcommittee of four members, appointed by the chairperson, held a "hearing" in early June. A tape recording of this "hearing" has since disappeared.12 Murray and Sempolski were not advised of the purpose of this meeting. They assumed that its purpose was to set up procedures for a future hearing and therefore did not bring witnesses or documents. The subcommittee did not speak with those whom the students asked the subcommittee to contact.13 It did accept written statements on Dr. Crawford's behalf that Murray and Sempolski were not allowed to see. Dr Crawford was allowed to talk to the subcommittee privately for fifteen minutes, an opportunity not extended to the students or their representatives.14

The subcommittee's final report, which was adopted by ACHE, supported Dr. Crawford's position. It found some irregularities in his research and some violations of university regulations, but it concluded that the deficiencies did not endanger the human subjects or affect the validity of the consents given by volunteers.15 Vice-Chancellor Argersinger accepted these findings, concluding there was not substantial basis for the charge that informed consent was not obtained. Argersinger did not comment on the allegations regarding untrained operators working with human subjects because of the absence of evidence of harm or "significant hazard" to the subjects.16 He noted, however, that Dr. Crawford's research had not "undergone the prior review demanded by university regulations" and that "Professor Crawford was less than candid when he indicated on his general research fund application . . . for a portion of the project that it did not involve human subjects." Dr. Crawford was warned in writing that such action constituted a violation of university regulations.17

Ms. Murray alleges that Dr. Crawford was given access to the evidence collected and documents prepared by the university throughout its investigation.18 The students reportedly had great difficulty obtaining the same documents. They charge that Dr. Crawford obtained a copy of the students' written allegations within days after Murray and Sempolski submitted them to the chairman of the department. They, however, claim that they were not given a copy of Dr. Crawford's response until a week after he had used it to rebut the charges in the April 9 meeting with Horowitz.19 The students say that they were not permitted to examine the documents relied upon by the ACHE subcommittee or given access to any other evidence until Dr. Crawford sued the students. At that time, the attorney general's office requested all pertinent material from the university.20

In March 1977, Sempolski and Murray brought their allegations against Dr. Crawford and charges of academic retaliation by Dr. Crawford and others to the attention of the American Anthropological Association (AAA). AAA formed an ad hoc committee to investigate. The committee found no retaliation. Murray and Sempolski were not allowed to hear or respond to the testimony of Dr. Crawford and the witnesses who testified on his behalf.21 The students have since learned that the chairman of the AAA committee sent a letter critical of the students to at least one journal in which Sempolski and Murray would be likely to publish their work.22

The students also filed a complaint before the local branch of the American Association of University Professors (AAUP), alleging that Dr. Crawford and the university impaired their academic freedom by retali-

ating against them.23 The AAUP refused to investigate the merits of the allegations against Dr. Crawford, but did investigate the University of Kansas procedures.24

In September 1977, Sempolski and Murray informed the Office for Protection from Research Risks (OPRR) of the National Institutes of Health (NIH) of the possible irregularities in Dr. Crawford's research. Several months later (before OPRR's investigation had begun), the inspector general (IG) of HEW requested OPRR to delay until the IG's office had completed its own inquiry into separate allegations of financial misconduct by Dr. Crawford. The reason for this request was a desire not to "beleaguer" the university with two separate, concurrent investigations.25 If the students had alleged that Dr. Crawford's misconduct had actually harmed human subjects, the IG probably would not have requested the delay.26 Under the circumstances, however, OPRR agreed to the request. Two years later, OPRR began its investigation.27 OPRR has gathered documents from the two students and from the university, spoken at length on the telephone with university personnel, and plans an on-site visit.28

Sempolski and Murray believe that as a result of their allegations they have been the victims of attempted and actual reprisal.29 Sempolski states that she has been informed by a university official that Dr. Crawford wanted to dismiss her from her position as his research assistant, but was dissuaded from doing so. (Research assistants at Kansas have no contractual protection from unjust or retaliatory dismissal.)30 Professors on Sempolski's doctoral committee who have requested university funding for Sempolski's own research have been turned down, although Sempolski believes similar requests made by those professors have never been denied before.31

In July 1977, Murray and Sempolski applied for a transfer to the Systematics and Ecology Department. The chairman of the admissions committee of that department telephoned Squier for information about the two applicants. Squier reportedly would not talk about their academic records, but discussed at length their involvement in the Crawford matter. The chairman of the admissions committee then mentioned a report in which the students were characterized as "troublemakers."32 Sempolski and Murray also believe that because they were labeled as "troublemakers," Sempolski was not admitted to the Systematics and Ecology Department.33 Believing these statements to be in violation of the promise of confidentiality they had received from the university, Murray and Sempolski contacted local newspapers. Their decision to speak with the press was also motivated by Vice-Chancellor Argersinger's comment to them (during discussions about alleged retaliation) that the university did not want to spend additional resources on their case.

Sempolski claims that she has been "repeatedly harassed" by department faculty.34 Sempolski was put on probation by the department, although her grade point average, she says, was no lower than it had been before the students raised questions about Dr. Crawford's research and her academic performance was not supposed to be reevaluated until those questions had been fully resolved.35

Murray and Sempolski have reportedly been threatened with lawsuits by university officials.36 Dr. Crawford has filed a $1.5 million tort action against them, alleging defamation, "malicious prosecution," and intentional infliction of emotional harm. The case is, at this writing, at the discovery stage.37 Kansas law provides legal representation for state employees in lawsuits arising out of acts performed pursuant to their official duties.38

Thus, the student-defendants are represented by the state attorney general's office.

Individuals who associated themselves with the students' complaints may also have been victims of attempted retaliation. Jack Husted, Murray's husband and a special student in anthropology, was told by the anthropology graduate coordinator that the department has "decided to terminate any and all affiliations"39 with him. After both Sempolski and Husted complained to the university ombudsman, Husted's termination was rescinded.40 Henry Lundsgaarde, an anthropology faculty member whose testimony at the AAA hearing supported Sempolski's allegations of retaliation and who agreed to act as chairman for Sempolski's dissertation committee, did not receive appointments and salary increases that other faculty members received.41 Husted, Lundsgaarde, and two other persons who questioned Dr. Crawford's research practices were named as defendants in Crawford's suit against Murray and Sempolski.42 Husted has since been dropped as a defendant because of lack of proper service.

At the time Murray and Sempolski first accused Dr. Crawford of misconduct, the university had no formal procedure for investigating alleged irregularities involving research with human subjects. ACHE has recently adopted specific guidelines for receiving and investigating such allegations in the future. While the university now provides an internal review procedure for such complaints, the reviewers may well be close professional or personal colleagues of the parties involved. By requiring all complaints to be signed and documented, the university would appear to preclude the possibility of anonymous reporting or confidentiality for complainants.43 According to the ACHE chairman, the guidelines now contain no systematic investigative procedures and no mention of a right of cross-examination, right to counsel, or right of hearing for those implicated.44 Claims of retaliation must be processed through established grievance procedures.45 Although these grievance procedures are elaborate and allow for a hearing, the right to counsel, the right to review all pertinent evidence offered by the other side, a written record, and anonymity for the person charged,46 it is unclear whether a member of the university community who alleges retaliation because of whistleblowing within the university would have a cognizable complaint before the hearing board; neither the university bylaws nor the ACHE guidelines specifically prohibit retaliation.

2. Boston University -- Failure to Protect the Accused?

In June 1978 three nurses and two physicians at University Hospital of Boston University (BU), a private institution, presented documents to Dr. Jay Coffman, associate chairman and acting chief of BU's Department of Medicine, which they believed evidenced research misconduct in the Division of Medical Oncology.47 They alleged that the division had improperly accepted patients for treatment, that informed consents were not obtained from the patients,48 and that the reports contained falsified data.49

Dr. Coffman asked the five complainants to present their allegations the next day to an ad hoc committee consisting of himself and two other physicians not in the Department of Medicine.50 Within a few days, BU officials advised Dr. Marc Straus, the physician directing the Oncology Research Unit, to resign.51 No appeal of the decision was allowed.52 Before his forced resignation, Dr. Straus was not given a detailed written statement of the charges against him or an opportunity to cross-examine witnesses, to review the evidence against him, to prepare a defense, or to provide witnesses on his own behalf.53 The Coffman committee did not accept the evidence that Dr. Straus wanted to present54 and did not meet

with staff members whom Dr. Straus wanted to question.55 Several persons who met with the committee felt that the investigators were uninterested in testimony indicating that the allegations were unfounded.56 The hospital bylaws did not provide for any kind of trial-type, evidentiary hearing.57

One of the complainants, Dr. Robert Polackwich, has alleged that he was "kicked off" the oncology unit -- and asked to remove his belongings from the hospital by Dr. Straus's administrative assistant -- on the day he spoke to the Coffman committee.58 One of the three nurses who raised questions about Straus's research was reprimanded. The other two were discharged.59 All five of the complainants are now being sued by Dr. Straus for "interference with [the] advantageous . . . and contractual relations" he had with BU.60 Dr. Polackwich has filed a counterclaim for defamation.61

After Dr. Straus resigned, he requested at several different times external peer review of the charges against him.62 BU refused.63 Dr. Straus believes that the internal evaluation of his work was tainted because of investigator bias and lack of protection for the records.64

There is a troubling question about the procedures used by the hospital to reserve the integrity of evidence involved in the case. The day after the Coffman committee heard the charges against Dr. Straus, records of the oncology department's research were taken from the department and entrusted to the care of two of Straus's accusers.65 Straus asserts that someone has tampered with the documents.66

OPRR is currently conducting an investigation of the allegations against Dr. Straus. It has relied heavily on the Division of Management Survey and Review (DMSR) to obtain relevant documents and records. OPRR has reviewed most of the records, has conducted a number of interviews, and is planning more. Preliminary, nonpublic findings have been completed.67

There was substantial confusion among IRB members concerning their proper role in the Straus investigation.68 The IRB was not involved in the investigation. The members heard about the allegations informally, sought a "liaison" with the investigation, and were given an oral report by the chairman of the Department of Medicine. The IRB's request to examine the consent forms used in the research was never granted. One board member's offer to assist in the investigation was declined.69 In November 1978, the IRB was informed by the hospital that continuing review was not a responsibility of that body.70 The IRB never received a response to its written questions to the hospital administration about the investigation.71

3. The Baslow Case -- Failure of Administrative Protections?

For five years, Dr. Morris Baslow was a senior scientist with a private marine research firm. In the late 1970s Baslow's company developed a report for Consolidated Edison (Con Ed) to submit to the Environmental Protection Agency. The report indicated that Con Ed's discharge of heated water into the Hudson River would cause only negligible damage to marine life. Dr. Baslow's own research on the Hudson River conflicted with the data in his company's report. Accordingly, he believed that his research should also be reflected in the material submitted to EPA. After the scientist tried unsuccessfully for almost two years to convince his employers to include data from his research in testimony to be given in EPA administrative proceedings,72 he ultimately threatened to provide the information to EPA himself.73

On his way to work one day, Baslow mailed a letter to the administrative law judge presiding at the EPA proceedings, stating that his company may have perjured itself because the testimony it had prepared was "not valid."74 On the same day, Baslow was dismissed, allegedly for unsatisfactory performance on another project. Baslow believes he was dismissed because of his intention to testify that, in his view, Con Ed's testimony may have been perjured.75

Baslow had no contractual agreement with his firm regarding job security.76 He was employed, essentially, on a day-to-day basis. The company could dismiss him for alleged performance deficiencies or for any other reason not specifically prohibited by law. The Federal Water Pollution Control Act, however, prohibits retaliation against employees who report possible violations of the act. Following procedures described in the act, Baslow applied to the Secretary of Labor for a review of his dismissal.77

The Department of Labor did not complete its initial investigation of Baslow's case for six months. In April 1980, the department informed the scientist's former employers that Baslow had been the victim of unlawful discrimination (retaliation). The department ordered the firm to reimburse Baslow for legal expenses, give him back pay and a salary until he found a new position, and give him a good recommendation.78

Baslow's former employers appealed the Department of Labor's determination and requested a hearing, as authorized by statute and regulations. Legal maneuvers of the firm, however, delayed the hearing; the company went so far as to bring suit to postpone the hearing. Although the department set a date for the hearing three times, it was never held.79

When Baslow refused to accept what he describes as a "minimal settlement," his former employers sued him for defamation.80 The suit was not pursued, however, after Baslow obtained pro bono legal representation.81 Baslow's adversaries also requested the Federal Energy Regulatory Commission (FERC) to order the scientist to return documents he allegedly "stole" from the company to support his allegations of company wrongdoing. Since Baslow could not afford to have an attorney represent him in that proceeding, the administrative law judge informally required lawyers from FERC (which was a party to the proceeding) to assist the scientist.82 After over a year of legal battles, Baslow settled his DOL complaint and the company dropped its lawsuit.83 The terms of the settlement remain confidential.

Despite the existence of federal protections for whistleblowers like Dr. Baslow, the disparity in resources of the individual and the affected institution may defeat the intent of the law. The mere threat of a defamation suit may keep individuals like Morris Baslow from coming forward. Attorneys' fees awarded under federal protective statutes such as the Water Pollution Control Act usually range from $2000 to $3000. Baslow's legal expenses for just the proceedings within the Department of Labor totaled almost $20,000.84 Baslow, who is still unemployed, was fortunate in finding an attorney who was willing to work largely on an unpaid basis. One solution to this problem would be to give whistleblowers in Baslow's situation the opportunity to be represented by government attorneys once it is determined that their allegations are not frivolous and have been made in good faith.

Delays in administrative proceedings also affect the complainant adversely. Baslow's search for a new position was made more difficult because the question of whether he was dismissed in retaliation for whistleblowing or because of poor performance remained unresolved for over a year.85

Existing Protections for the Whistleblower and the Accused in Biomedical and Behavioral Research Cases

Institutional Protections

Protections for the whistleblower and the accused are first tested at the institutional level.

Although the Manual of the Joint Committee on Accreditation of Hospitals provides that hospital bylaws shall include provisions for "fair hearing and appellate review mechanisms"86 in connection with denial of staff appointments or curtailment of privileges, the specifics of implementation are left to individual institutions. Frequently, individual hospital bylaws are no more specific than the JCAH guidelines themselves.87 Moreover, the affected staff member must often request a hearing within ten days of the action, or his right to a hearing is waived.88 Hearings are generally ad hoc and conducted without legal counsel.89 Because hearing boards have no subpoena power, the burden of compelling needed testimony and presenting documentary evidence falls exclusively on the complainant and accused. Hospital bylaws do not, as a rule, guarantee a staff member90 accused of improprieties the right to prepare by reviewing all the evidence against him, nor do they guarantee the right to confront accusing witnesses. On the other hand, bylaws rarely contain provisions that guarantee anonymity for "whistleblowers" or prohibit retailiation against them.

A number of states require hospitals to have "reasonable" regulations. These states also prohibit discrimination against certain medical school graduates or other categories of physicians who apply for staff privileges.91 Similarly, some state courts have struck down arbitrary denials of staff privileges by both public and private hospitals on the theory that even private hospitals are imbued with a public purpose, have a fiduciary obligation to the public, and thus cannot act unreasonably or in a manner inconsistent with the public good.92 State action sufficient to trigger liberty and property interests protected by the due process clause of the federal constitution has also been found by some federal courts in cases involving private hospitals receiving substantial amounts of federal funds (under the Hill-Burton Act, for example) and subject to extensive federal regulations.93

These cases, however, appear to be contrary to the trend of recent United States Supreme Court decisions. In 1980, for example, the Court held that "[g]rants of federal funds generally do not create a partnership or joint venture with the recipient, nor do they serve to convert the acts of the recipient from private acts to governmental acts absent extensive, detailed, and virtually day-to-day supervision."94 It is unlikely, therefore, that an aggrieved researcher in a private institution who is involved in a federally funded biomedical or behavioral research project can show a sufficient "nexus" between the state and his employer's activity to be able to claim federal constitutional protections.95

Protections Offered by Professional Societies

A number of voluntary societies in the scientific and engineering profession have promulgated a statement of ethical principles or rules of conduct for their members.96 These societies, however, have devoted few resources to providing support97 for victims of retaliation or for members accused of wrongdoing. Nor have many established formal procedures for those who wish to file a complaint relating to research misconduct.

An AAAS survey of complaint procedures over the last decade98 reports that less than 30% of the 146 societies responding have established investigative or hearing procedures.99 Only 44 societies have any mechanisms for informing members and the public about complaint procedures.100 Many of the societies handle complaints "informally" or on a "personal diplomacy basis." Some have no formal criteria for evaluating complaints,101 and only 12.3% of those having appeal procedures reported granting them on request.102 Most significantly, only about 25% report having support services,103 and only one-third of the societies that make such services available have actually used them.104 Research societies in the medical and health science field reported both the greatest number of support actions available and sanctions applied,105 although only 3 societies in the medical and health fields reported a total of only 12 instances when support actions had actually been employed.106

Medical and health-related professional societies reported the greatest number of complaints of misconduct.107 The AAAS survey, however, concluded that, in general, the budget and staff they devoted to ethics enforcement is small;108 only one-fifth of the social and behavioral societies and less than half of the medical and health sciences organizations that responded reported having such a staff. Moreover, they have made little attempt to inform members of existing complaint procedures or support services.109 The survey reported that there is

> little evidence of strategies or mechanisms for implementing or enforcing ethical rules in the scientific or engineering societies. Formal complaint procedures, safeguards respecting the rights of all parties, and sanctions and support actions rarely are available and even more rarely used.110

The belief that complaints involving ethical violations should be handled privately,111 fear of litigation,112 and the substantial commitment of time and money that would be involved in monitoring, investigating, and adjudicating complaints113 (with even minimal due process protections) probably explain the inactivity of the societies in assisting members who file complaints about ethical misconduct or who are accused of wrongdoing. Furthermore, dissent or public exposure of members continues to be equated with disloyalty among some leaders of such organizations. This attitude serves to reinforce the institutional procedural impediments, causing societies to be reluctant in coming to the defense of "whistleblowers" who criticize the actions of fellow members.114

Protections Afforded by State Law

Federal, state, and local employees are entitled to due process and First Amendment protections granted by the Constitution.115 More than half of all state and local employees and over 90% of federal employees are protected against arbitrary or unjust dismissals through civil service tenure and other statutory safeguards.116 Employees in the private sector are not so fortunate. Approximately one-third of those in the nonagricultural sector are covered by collective bargaining agreements; the rest must, as a rule, look to the private employer's own guidelines or to their individual contracts for protection.117

Private employees in the United States, and especially professional employees without fixed-term contracts, have traditionally been subject to the "employment at will" doctrine, which holds that in the absence of statutorily prohibited discrimination, an employer may discharge an employee "for good cause, for no cause, or even for cause morally wrong

without being guilty of legal wrong."118 A majority of states adhere to this rule.119 The Alabama Supreme Court, for example, affirmed the dismissal of a hospital employee's suit alleging retaliatory discharge because of her refusal to falsify medical records.120 Recently, however, a few state courts have begun to reject the doctrine in the case of retaliatory dismissals. They have reasoned that such discharges violate public policy, at least when the action for which the employee was allegedly dismissed is supported by clear legislative policy.121

A number of states protect employees from discharge or other retaliation for having invoked statutory protections regarding their work conditions.122 Only one state, however -- Michigan -- has a comprehensive "Whistleblowers Protection Act"123 for employees in the private sector.

The Michigan act, which went into effect in early 1981, applies to any person (except state civil servants, who have separate statutory protections) who "performs a service for wages or other renumeration under a contract of hire, written or oral, express or implied."124 It prohibits discharges, threats, or discrimination against employees who report or "are about to report" violations of law, rules, or regulations to "public bodies" or who are invited to testify by a public body in a hearing, inquiry, investigation, or proceeding.125 Within ninety days after a violation of the act, an aggrieved employee may bring suit for injunctive relief, compensatory damages, attorneys' fees, and costs.126 The employer may be liable for civil fines as well.127 Employers are required to post notices to keep employees informed of their rights and obligations under the statute.128 Employees who make allegations that they know are false are not protected,129 although those who make false statements in good faith are protected. Under Michigan rules, employees who bring "unreasonable" lawsuits for violations of the act may find themselves liable for the defendant's costs, including reasonable attorneys' fees.130

The statute safeguards the employment rights of any Michigan employee reporting alleged research misconduct to a local, state, or law enforcement entity. It does not, however, protect those who report abuses to their own institutions, nor does it protect allegations made to the public via the press or to federal agencies not involved in law enforcement. The act was strongly supported by, among others, the Michigan Nurses Association (MNA), which reported that it had been receiving an average of five calls a week from nurses having knowledge of abuses that constituted violations of law.131 Because of the fear of reprisal, the callers were unwilling to document their charges. MNA claimed that as a result, violations routinely went "unreported and [consequently] the patient suffer[ed]."132

Although it is too early to evaluate the effectiveness of the Michigan act, half a dozen other jurisdictions have expressed interest in the legislation. It may well become a model for other states desiring to protect whistleblowers' employment rights.

Tort litigation for defamation may provide another remedy for whistleblowers and accused persons whose good name and professional reputations have been publicly called into question. The threat of being sued by the accused may forestall some whistleblower complaints of misconduct that lack evidentiary support. However, once litigation begins, it rarely ends in favorable judgment for the plaintiff. A broad range of privileges and immunities is generally available to the defendant in such suits. Moreover, the risk of defeat posed by the existence of these privileges and immunities may discourage the legal representation on a contingency or pro bono basis of anyone desiring to bring suit for defamation. As a practical matter, the expense and difficulty of retaining counsel may hamper resort to the courts.

The tort most clearly relevant to allegations of research misconduct is that of defamation. Ordinarily, statements made by individual supervisors or employees about the character of other employees are conditionally privileged; that is, the aggrieved employee will not prevail in litigation if the offending statements were made in a reasonable manner and for a proper purpose.133 A qualified privilege applies where "the communicating party and the recipient have a mutual interest in the subject matter or some duty with respect thereto."134 Where research misconduct is concerned, the "interest" or "duty" may arise from the accusing employee's duty to keep his employer informed135 or from a duty owed society generally to expose unethical behavior or to report violations of the law.136 So long as his communications are made in good faith, they are protected even if false. Communications made to governmental bodies and information required by law are also conditionally privileged.

The courts will, under some circumstances, extend protection to statements made with malice; the law is in flux and varies from jurisdiction to jurisdiction.137 For example, when an accusation by an employee's supervisor is recklessly made, the institutional employer may escape liability on the grounds that the supervisor was not acting within the scope of his or her employment.138 Similarly, absolute immunity may be afforded to those who testify about research misconduct in legislative, judicial, or quasi-judicial administrative proceedings.139

The rule extending absolute immunity to testimony or statements made to legislative, judicial, or quasi-judicial administrative bodies is not uniformly applied. Generally excluded from absolute immunity are statements made in ad hoc and informal meetings.140 A number of states have granted absolute immunity to semiformal peer review or hospital committee review groups.141 At least one court has held letters sent to disciplinary committees and professional societies alleging professional misconduct by a physician to be absolutely privileged.142 Other courts, however, have held that the absolute privilege should be strictly limited to pure judicial or formal governmental bodies and have found only a qualified privilege for statements made in hospital professional regulatory committees.143 The majority of states, however, grant at least qualified immunity to statements made to disciplinary boards or agencies or review committees.144

In order to prevent unfair "trial by press" and to protect the integrity of judicial and quasi-judicial proceedings, the courts have not immunized defamatory remarks disseminated to third persons who are not proper parties to a proceeding (e.g. the news media). Similarly, extraneous remarks irrelevant to a proceeding or to the inquiry at hand do not fall within the reach of either a conditional or absolute privilege.145

Immunities parallel to those discussed above exist if the aggrieved sues for interference with contractual relations with an employer rather than for defamation. Proof of the defendant's malice146 and proof that the defendant intentionally caused the contractual interference147 are ordinarily required. The courts have also established a number of readily available defenses, e.g. that the interference had a proper purpose, even if ill will was also involved.148 In addition, if the defendant can demonstrate either that his actions were, in part, motivated by a desire to protect a third party towards whom he had a legal or ethical responsibility or that the public health or welfare was involved, his actions will probably be immune from suit.149

Federally Established Protections

Federally established mechanisms afford little effective assistance or protection to those who wish to report research misconduct, to those who

have been retaliated against for such reporting, or to those accused of research misconduct.

1. OPRR

The Office for Protection from Research Risks (OPRR) of the National Institutes of Health has been delegated authority from the secretary of HHS to investigate research practices allegedly in violation of either HHS regulations or institutional assurances in order to provide facts necessary for the secretary's decision whether to terminate federal funding for the research.150 OPRR has never recommended a funding suspension as a result of its investigations into alleged research misconduct.151

Until recently, OPRR received no more than two or three complaints a year pertaining to alleged noncompliance with federal research regulations. Currently, OPRR receives five or six complaints annually.152 These low numbers are probably due, in part, to the fact that OPRR does not publicize its functions and that most research personnel are not aware of its existence.153

OPRR holds no hearings. It depends in the first instance on voluntary investigation and corrective action by the institution involved. If the institution's inquiry is not satisfactory, OPRR itself conducts on-site reviews, informal interviews, and obtains voluntary production of documents from institutions and individuals.154 OPRR has no subpoena power. There are no formal deadlines for the completion of investigations.155 A copy of a preliminary report on the alleged research misconduct is sent to the accused for correction of factual errors. The accused usually has the right to see the evidence against him, although OPRR protects the anonymity of its sources.156 Even though the final reports are available for public inspection, the identity of researchers implicated in misconduct is protected from disclosure to prevent unwarranted invasions of their personal privacy.157

OPRR has no authority to investigate charges of retaliation by complainants or to impose sanctions on institutions that do retaliate. It cannot require institutions to establish procedures for reporting alleged research violations,158 although it encourages them to do so.159 OPRR does not have adequate personnel or funding to investigate promptly or with any regularity cases of the complexity of those at Kansas or Boston University.160

2. Debarment

The debarment regulations of HHS provide detailed procedural mechanisms for individuals engaged in HHS-funded research who are suspected of financial fraud or abuse and who thus may face loss of eligibility for HHS grants.161 Although the regulations are primarily intended to protect the government against financial irregularities, the procedures may also be triggered for "[a]ny other cause significantly affecting responsibility as a recipient or participant under a federal program of sufficiently serious nature . . . to warrant debarment."162 Thus, those accused of significant research misconduct currently have available the following protections, at least where debarment for that misconduct is being considered by the secretary.

The individual is entitled to advance written notice setting forth the reasons for the proposed debarment and informing the accused of the right to a prompt hearing, if requested.163 The secretary must prove a violation by "clear and convincing" evidence.164 The researcher has the right to counsel, the right to a transcript,165 and the right to seek review of

the hearing officer's decision by the secretary.166 Interim suspension is possible, but it must be based on "reasonable evidence" of a serious violation, and the researcher has the right to a hearing on whether the interim suspension should be continued.167

HHS also may either withdraw a researcher's authority to obligate monies from a curent grant168 or withdraw such authority pending corrective action by the individual169 if the researcher has materially failed to comply with the grant's terms. The researcher is entitled to notice and a statement of reasons for the proposed action170 and has the right of appeal.171 The researcher may present his case either in writing to an appeals board panel or in an informal conference, and he may be represented by counsel. Where the panel believes oral testimony would be helpful, an adversary hearing is available.172 Any person "directly and adversely affected" by the proposed debarment may be a party to the proceedings.173 The parties may submit written comments on the panel's decision to the head of the agency, who may modify the decision with a written statement of reasons.174

Similarly, when the FDA receives information that a drug investigator has repeatedly or deliberately failed to comply with regulations or has submitted false information, the investigator is provided an advance written notice of the charges and an opportunity to submit an explanation.175 If the explanation is not accepted, a hearing is provided176 at which the investigator may present evidence, cross-examine witnesses,177 and be represented by counsel.178

3. Institutional Review Boards (IRBs)

Under federal law, institutions must establish IRBs to review federally funded research involving human subjects. Although a detailed examination of the powers and functions of IRBs is beyond the scope of this paper, it appears that IRBs do not provide, and are not generally equipped to provide, adequate protections to either whistleblower or accused on allegations of research misconduct.

By regulation, the IRB must provide some procedural protection to those investigators whose proposed research activity the IRB has disapproved. The investigator must be given a written statement of reasons and an opportunity to respond in person or in writing.179 If the IRB suspends or terminates its approval of ongoing research "that has been associated with unexpected serious harm to subjects," the IRB must simply notify the investigator in writing of the reasons.180 However, without drastically increased resources and a changed mandate, IRBs are ill prepared at present to assume an active, independent investigatory or quasi-adjudicatory role in complex factual disputes between whistleblower and accused.

IRBs themselves are largely dominated and controlled by the institutions they represent, a factor that makes them unlikely to persuade either the whistleblower or the accused of their impartiality. Moreover, IRBs are volunteer, part-time bodies meeting relatively infrequently, having no special investigative expertise, and having limited staff. They are frequently overworked, and, of necessity, their reviews of protocols have been rather perfunctory.181 Furthermore, they have no enforcement powers and must rely on the institution's willingness to supply information. Perhaps most significantly, the IRB's primary function is not to protect the rights of researchers and investigators, but to ensure the protection of human subjects.182

4. The Office of Special Counsel

The Civil Service Reform Act of 1978 (CSRA)183 authorizes the Office of Special Counsel, an independent office within the Merit Systems Protection Board, both to receive and investigate allegations by a federal employee that the discloser "reasonably believes evidences a violation of any law, rule or regulation; or mismanagement, . . . an abuse of authority, or a substantial and specific danger to the public health or safety"184 by government employees and to protect both the discloser of such information from retaliation and the alleged wrongdoer from unwarranted publicity and arbitrary sanctions during the investigation.185

Most federally employed hospital physicians, investigators, and other personnel connected with biomedical research projects fall within the special counsel's protections.186 They may submit complaints of research misconduct or retaliation for "whistleblowing" to the special counsel, who must notify the affected agency and may order a report and, in some cases, an investigation by the agency.187 Researchers who are not federal employees, but who are under grants or contracts from NIH or other federal agencies, may also submit whistleblowing (but not reprisal) complaints to the special counsel; however, the special counsel's office has no power to protect grantees against reprisal.88 (CSRA does give the special counsel the power to seek a stay of retaliatory conduct taken or threatened against federal employees.)189

The names of individuals associated with allegations of government misconduct (but not formally charged) will not ordinarily be disclosed by the special counsel unless there is a substantial public interest in disclosure that outweighs the invasion of personal privacy that would result from the disclosure.190 Federal employees accused of misconduct by whistleblowers may not be disciplined without the special counsel's express approval.191 If the special counsel decides to seek sanctions against an alleged wrongdoer, the latter is guaranteed a "reasonable time to answer orally and in writing and to furnish affidavits and other documentary evidence in support of [his] answer, to be represented by an attorney or other representative, to a hearing before the [Merit Systems Protection] Board or an administrative law judge . . . , to have a transcript kept of any hearing, to a written decision and reasons therefor, and a copy of any final order."192 He or she also has the right to inspect all documents relied upon by the special counsel but may not, as a rule, learn the identity of the complainant or other sources except when necessary as a matter of due process.193

The special counsel's policy is to keep confidential the identities of whistleblowers and other sources, except that sources are advised that their affidavits may be used in subsequent administrative proceedings.194 Complaints may be filed anonymously.195 Witness statements are not routinely made available to the agencies, but this policy is a flexible one in which the seriousness of the allegation and the consequent public interest in the investigation, coupled with the "likelihood" of obtaining "corrective action," is balanced against the possibility of harm to the individual from the disclosure of his identity.196

Suggestions For Additional Protections

Additional protections are needed at the federal, state, and institutional levels to protect the rights of both whistleblowers and the accused in biomedical and behavioral research.

Reform at the Federal Level

The case studies and survey of existing protections indicate that new federal protections are needed specifically to prohibit retaliation against those who report unethical conduct or possible violations of the law in biomedical and behavioral research. New legislation and implementing regulations should establish formalized procedures both to receive, investigate, and adjudicate complaints of reprisal for such reporting and to enforce sanctions. The burden and cost of investigating and enforcing the antiretaliatory and remedial provisions should be borne by the government rather than the whistleblower.

The specific mechanisms for providing such new protections are not novel. In enacting remedial legislation to protect public health and safety, Congress has long recognized the need to protect those who bring violations of the law to public attention. Models for providing protection can be found in the antidiscrimination provisions of a number of federal environmental and occupational welfare statutes.197 Since whistleblowers in the area of federally funded biomedical and behavioral research serve similar public needs to whistleblowers in other public health areas, federal protections for them can usefully draw on existing federal models.

The original federal model, the Federal Coal Mine Health and Safety Act (CMHSA), contained substantive and procedural protections for whistleblowers that could well be adapted to the area of federally funded biomedical research. The current version of the act specifically prohibits198 firing or other retaliation against any miner, applicant, or representative because he has "filed or made a complaint" related to, inter alia, "an alleged danger or safety or health violation in a coal or other mine . . . ," because he has caused proceedings to be instituted, or because he has or is about to testify in any such proceeding.199 Miners may file complaints of reprisal with the Secretary of Labor, who must order a prompt investigation (to begin within fifteen days).200 If the secretary finds interference or retaliation, he must seek appropriate relief through an administrative proceeding.201 The worker may be ordered reinstated on an "expedited basis" pending final order as long as the retaliation complaint is "not frivolously brought."202 If the secretary refuses to proceed on the worker's behalf, the latter still has the right to a hearing.203 The final administrative order may include reinstatement, back pay, interest, costs, and attorneys' fees.204 The act's protections apply to miners who have been penalized for having filed even frivolous complaints of safety violations.205 These protection illustrate the kind of integrated safeguards that are necessary to protect whistleblowers' rights effectively.

A variety of other federal statutes and regulations also provides specific procedures which may be appropriately included in any regulatory scheme governing whistleblowing in the area of biomedical and behavioral research. For example, one set of regulations implements the antireprisal provisions of six different environmental statutes. The regulations establish a formal mechanism for investigating and punishing a broad range of conduct, including intimidation, threats, blacklisting, and, of course, discharge for whistleblowing.206 The federal administrator has the power to compel "production of any documentary or other evidence" deemed necessary to determine whether retaliation took place.207 Witnesses and sources other than the complainant are entitled to confidentiality upon request.208 The administrator, acting on behalf of the complainant, is required to attempt to conciliate the dispute.209 Once settlement proves impossible, and before the order to abate the violation becomes final, a hearing may be conducted by a neutral third party (an administrative law judge) under rigid time deadlines. Hearings are fully recorded, and all

parties have the right to counsel.210 If a violation is found, the Secretary of Labor has the power to order appropriate relief211 and may sue on behalf of the complainant for enforcement of his order.212

Other statutes include additional useful protections. Employers covered by the Surface Mining Reclamation Act are required to provide a copy of the applicable rules to all employees.213 OSHA's protections apply even if the complaint that triggered the alleged reprisal was reported to the employer or to state or local agencies.214 Employees do not waive their rights under the act by pursuing remedies available under grievance or collective bargaining procedures.215

The Baslow case (pp. 117-8 supra) illustrates that existing federal procedures may prove less than completely effective in protecting whistleblowers in private industry. However, by adopting the administrative procedures outlined above and amending existing legislation216 to include specific antireprisal and enforcement provisions, Congress can extend some additional needed relief to whistleblowers who have reported ethical or legal violations in federally funded biomedical and behavioral research projects. An alternative approach would be a federal procedure modeled after that employed by the special counsel's office, requiring the affected institution to make an investigation and report; the government should retain subpoena power, the right to order depositions and/or interrogatories, and the right to take testimony under oath if the report submitted is inadequate.217 Federal law and regulation should make it clear that as long as retaliation for good-faith whistleblowing was a substantial reason for a federally funded employer's action, relief should be available.218

Any federal system adopted for receiving and investigating complaints of research misconduct should be formalized and well publicized. If OPPR is to play a meaningful role, its staff must be sufficiently large and adequately trained to investigate and resolve complex factual complaints expeditiously. Subpoena power is essential. If there is reasonable cause to believe that an individual has violated federal law or regulation, the accused should be afforded the right to be represented by counsel and to have a full evidentiary hearing with the right to cross-examine, to present his own expert witnesses, and to compel the production of documentary evidence before a formal report or a recommendation for sanctions is issued. The procedures now used for debarment (see pp. 123-4 supra) might be usefully employed even when debarment may not be contemplated.219 Since the accused may not be willing to cooperate for fear of engendering damaging and unfair publicity based on unwarranted disclosure of the allegations, neither the allegations against him nor his identity should be disclosed to the general public.

Like a federal employee charged with employment discrimination,220 the accused in biomedical and behavioral research cases should be entitled to review all written allegations against him (but not to learn the identity of sources) and to file a written response to the charges before the hearing.221

In order to encourage reporting of research misconduct and to protect the anonymity of the whistleblower, NIH may also wish to establish provisions for anonymous reporting. This is most effectively accomplished through the use of a well-publicized, toll-free "hot line" or through a system by which the reports are directed to a third-party agency. The information provided through these procedures should not be used for civil enforcement purposes because of potential reliability and hearsay problems; the information is to be used simply to identify situations requiring correction and to encourage unencumbered reporting to the regulating agency.222

Federal immunity provisions might also be appropriate for whistle blowers in the area of biomedical research. The Social Security Act, fo example, grants qualified immunity to persons furnishing information t professional standards review organizations.223 The paramount social goa of uncovering and correcting research abuse would be encouraged b extending statutory immunity from civil suit based on reporting researc violations to institutional or federal officials.

Reform at the State Level

Enactment of state statutes modeled after the Michigan Whistleblower' Protection Act would afford significant protection to whistleblowers em ployed by private institutions engaged in biomedical and behavioral re search. Such statutes should prohibit retaliation against good-faith alle gations to state or federal authorities or institutional officials and shoul provide less expensive alternatives to litigation, such as arbitration c administrative hearings at the state level. To protect the interests of th institution and the accused, however, state remedies should require whis tleblowers to exhaust whatever internal administrative procedures ar available, unless resort to such mechanisms would be clearly futile.

More comprehensive protection to both whistleblower and accused ma be provided through enactment of state legislation providing protectio against unjust dismissals. The burden should be on the employee to sho that his dismissal was improperly motivated or was otherwise in violation c the standards of "fairness" or "reasonableness" set forth by the legisla ture.224 Consideration should also be given to providing statutory im munity to employees who provide research records or other confidenti documents to appropriate officials in connection with allegations of mis conduct in biomedical and behavioral research. This principle shoul apply only if the individual had access to such documents in connectio with the performance of his duties and responsibilities and if disclosure c the information was reasonably necessary to substantiate the allegations c to defend against the charges.

Reform at the Institutional Level

All institutions involved in federally funded biomedical or behavior research should be required to have a clearly defined, well-publicized, an easily accessible mechanism for receiving, investigating, and adjudicatin allegations of research misconduct and complaints of retaliation agains whistleblowers. The mechanism should be separate from regular grievanc or peer review procedures in order to encourage confidence in the syste and to ensure maximum impartiality.

Federal intervention on behalf of either whistleblower or accuse should ordinarily be conditioned on the employee's having first made good-faith attempt to obtain redress through his institution.225 It i important to give the accused an opportunity to present his case in th relative privacy of an institutional setting, especially where the allegation involve ethical or judgmental factors. If review at the institutional level i first required, a formalized but noncumbersome system is essential.

Rules recently promulgated by the Nuclear Regulatory Commissio (NRC)226 provide a useful frame of reference. The NRC's new procedure are intended to encourage expression of "differing professional opinions (DPOs) while ensuring freedom from retaliation for those submitting com plaints in good faith. In order to provide accountability, the NRC mar dates a written record of all actions taken on the complaint, provides fc

alternative channels for expressing dissenting views (either on the record or anonymously), explicitly prohibits retaliation against those who submit DPOs, and authorizes sanctions against those individuals responsible for any such retaliation. Perhaps most significantly (for both whistleblowers and accused), the NRC directive allows DPOs to be presented to an impartial peer review group for review and comment and emphasizes that it is "not only the right but the duty of all NRC employees to make known their best professional judgments on any matter related to the mission of the agency."227 NRC procedures guarantee complainants -- and institutions should guarantee the accused -- adequate staff time and administrative support for the preparation of their views, written notification of the final "resolution," access to pertinent documents, the right of appeal, and the right to seek redress for alleged retaliation. "Frivolous" use of DPOs are prohibited, as is the use of the DPO to mask an ordinary personnel problem.

Whatever system the institution employs, it should guarantee swift, but fair, resolution and should avoid public disclosure of the identity of the whistleblower and the accused. Each researcher and staff member should be required, on pain of possible sanction, to maintain confidentiality until all internal proceedings are complete. All employees should be protected by contract against reprisal. Similarly, the accused should be safe from disciplinary action prior to a formal evidentiary hearing unless there is a reasonable possibility that serious harm to human subjects will result if he is not removed immediately from the project in question. A full evidentiary hearing, as well as the right to appeal, is especially important where dismissal is threatened. Formal peer review, however, may be unnecessary as long as the accused has the opportunity to present his own expert witnesses and has the right of cross-examination.

In the interest of both keeping the inquiry focused on the alleged misconduct (rather than on the personalities involved) and protecting against retaliation, the identity of the complainant should not be revealed to the accused unless confidentiality is impossible as a practical matter or the accused clearly demonstrates that he cannot adequately respond to the charges without knowing the identity of the complainant. (This general principle is followed by the OSC, EEOC, and OPRR.) Fairness to the accused requires that he be fully informed of the basis of the charges and that he be permitted to see all relevant documentation and to cross-examine all adverse witnesses if the investigation proceeds to a formal hearing. If these protections are afforded him, learning the identity of the particular individual who filed the complaint will, as a rule, serve no useful purpose.

In an effort to encourage maximum cooperation, institutions may also wish to consider a policy of leniency towards certain employees (especially those in nonsupervisory positions) who voluntarily come forward with evidence of serious wrongdoing, even if the reporter was involved in the misconduct. The interest in disclosing and correcting abuses promptly and with minimal disruption seems more important than punishing those at lower levels, who hold little discretionary responsibility and may have felt coerced into participating in the questionable activity.

As a general policy, each institution should inform all researchers and their staff, through written directives, of: (1) the obligation of each individual to report evidence of serious research misconduct; (2) the identity of the person(s) designated to hear the complaint; (3) the scope of responsibility of each team member; and (4) the possibility of disciplinary sanctions for any person found to have harassed or retaliated against a complainant. Finally, institutions might require the investigator (as a condition of working on a federal grant project) to waive claims against

any person submitting complaints to appropriate officials about the investigator's possible research misconduct. The waiver might be similar to waivers now commonly used in applications for hospital staff privileges.228

Conclusion

The ad hoc systems currently used to process whistleblowing complaints and complaints of reprisal in federally supported biomedical research have proved generally unsatisfactory. The internal political structures of institutions and the lack of independent third-party arbitrators preclude the appearance of impartiality. External pressures and aversion to publicity may lead to hasty or superficial judgments without adequate regard for the rights of the whistleblower or those implicated in the misconduct. As a result, whistleblowing disputes have fanned an adversary relationship between complainant and accused and encouraged "self-help" measures such as private tort litigation and sensationalist publicity.

No longer should the handling of these difficult and delicate issues be considered the exclusive prerogative of the affected institution. Alternative channels for complaints, antidiscrimination measures at both state and federal levels, and insistence on additional protections within the institutions themselves are needed now229 and are feasible without unduly impinging on institutional autonomy. Providing additional protections to both whistleblower and accused will help focus attention on the merits of the charges instead of on the personalities. It will discourage unnecessary litigation and destructive publicity and will assist in carrying out the federal regulatory goal of discovering and correcting serious abuses in federally supported biomedical research.

References

1. The term "whistleblower" as used in this paper refers to an individual who alleges irregularities in federally supported biomedical or behavioral research projects to his or her employer, to a governmental body, to a professional society, or to the general public.

2. This may explain why whistleblowing in the biomedical and behavioral research area is a relatively uncommon phenomenon. See Testimony of Norman Levinsky before the President's Commission, Boston, June 5, 1981, at 234.

3. Goss v. Lopez, 419 U.S. 565, 579 (1975) (emphasis added). See p. 119 and n.94, infra.

4. "Documentation Pertinent to Specific Allegations," undated two-page summary of charges prepared by Murray and Sempolski for the American Anthropological Association, and "A Narrative Account of Events in Belize, Central America in 1976," undated four-page statement.

5. Telephone interview with Elizabeth Murray, July 21, 1981. We also attempted to conduct a telephone interview with Dr. Crawford in order to (1) obtain his views on the adequacy of the procedural protections afforded him at UK and elsewhere in connection with the Murray-Sempolski

charges and (2) obtain his comments on Murray-Sempolski's account to use of the procedural history of this case. Through his attorney, T. Dale Nicklas, Esq., Dr. Crawford declined to be interviewed. (Letter from T. D. Nicklas, Esq., to John Hammell, July 30, 1981)

6. Ibid.

7. Ibid.

8. Ibid.

9. Memorandum of January 10, 1978, from Argersinger to Sempolski, Murray, and Crawford, at 1.

10. Telephone interviews with Murray, supra n. 5, and Nancy Sempolski, July 24, 1981.

11. Argersinger memorandum, supra n. 9, at 1.

12. Telephone interview with Murray, August 3, 1981.

13. Telephone interviews with Murray, supra n. 2, and with Robert Casad, chairperson ACHE subcommittee, August 3, 1981.

14. Telephone interview with Murray, supra n. 5.

15. Ibid., telephone interview with Casad, supra n. 13.

16. Argersinger memorandum, supra n. 9, at 3.

17. Ibid. at 34.

18. Argersinger memorandum, supra n. 9, at 24.

19. Telephone interviews with Murray, supra nn. 5 and 12.

20. Ibid.

21. Telephone interview with Murray, August 11, 1981.

22. Telephone interview with Murray, supra n. 12.

23. Telephone interview with Sempolski, supra n. 10.

24. "AAUP to Investigate Complaint Procedures," University Daily Kansan, September 18, 1979; telephone interview with Murray, August 3, 1981; see letter from T. D. Nicklas, Esq., to J. Hammell, July 30, 1981.

25. Telephone interview with Charles MacKay, Deputy Director, OPRR, August 3, 1981.

26. Ibid.

27. Ibid., telephone interview with Sempolski, supra n. 10. On October 9, 1981, the Washington Post reported that NIH has completed a preliminary review of the allegations against Dr. Crawford. The draft report has been obtained by Rep. Albert Gore, Jr. (D-Tenn.). According to the Post, "[p]reliminary staff findings, said Gore, ... found that Crawford took unauthorized blood samples from more than 500 children, putting them at additional risk, and used unproven genetic screening and counseling procedures." "NIH Continues to Finance Scientist While Investigating Him,"

Washington Post, October 9, 1981, at A-12. According to Rep. Gore's office, the NIH final report will be issued in the next few weeks. (Telephone conversation with staff of House Subcommittee on Investigations and Oversight, November 5, 1981)

28. Interview with MacKay, supra n. 25.

29. Telephone interviews with Murray and Sempolski, supra nn. 5 and 10.

30. Telephone interview with Sempolski, supra n. 10.

31. Ibid.

32. Telephone interview with Murray, supra n. 5; report of the American Anthropological Association Ad Hoc Committee of Inquiry Regarding Allegations of Unprofessional Conduct leveled against Michael Crawford ("AAA Committee"), at 23-26.

33. Telephone interview with Murray, supra n. 5.

34. Telephone interview with Sempolski, supra n. 10.

35. Telephone interview with Murray, supra n. 5. See also AAA Committee, supra n. 32, at 21-22.

36. Telephone interviews with Murray and Sempolski, supra nn. 5 and 10.

37. Ibid., telephone interview with Bruce Miller, Esq., Kansas attorney general's office, July 24, 1981. See letter of T. D. Nicklas, Esq., to J. Hammell, July 30, 1981.

38. Kan. Stat. Ann. § 756108 (1980 Supp.).

39. Telephone interview with Murray, supra n. 12; AAA Committee, supra n. 32, at 27.

40. Telephone interview with Murray, supra n. 22. Sempolski, however, was kept on probation, although the university claimed it was not an "official probation." Ibid.

41. Ibid.

42. "Anthropology Professor Files Slander Suit for $1.5 million," University Daily Kansan, October 15, 1980, at 1.

43. Telephone interview with John Brandt, chairperson, Advisory Committee on Human Experimentation, University of Kansas, July 6, 1981.

44. Ibid. Mr. Brandt stated that the responsibilities of the institutional bodies involved in investigations of possible research irregularities are explained in the university's "Institutional Guidelines for Research" and that the guidelines do not detail the procedures to be used by those bodies. Carolyn Hallenback of the university's Office of Research Support claimed in a telephone interview on August 13, 1981, that existing formal grievance procedures could be used in future complaints involving alleged research misconduct.

45. Article V, University of Kansas Bylaws.

46. Ibid.

47. Testimony of Robert J. Polackwich, M.D., before the President's Commission, Boston, June 5, 1981, at 270-271 (hereafter Hearings).

48. Hearings, supra n. 47, at 252-259.

49. "Cancer Research Data Falsified; Boston Project Collapses," Boston Sunday Globe, June 29, 1980, at 1.

50. Hearings, supra n. 47, at 271; at 391; at 255 (testimony of Polackwich, Moran, Levinsky).

51. Written statement of Stephen Straus, M.D., submitted to the President's Commission on June 5, 1981, at 1; "Five Oncologists Who Took Action at BU," Boston Globe, September 29, 1980, at 15.

52. Hearings, supra n. 47, at 383.

53. Statement of S. Straus, supra n. 51, at 1. Hearings, supra n. 47, at 353; at 346 (testimony of Good, M. Straus).

54. Hearings, supra n. 47, at 346 (M. Straus testimony).

55. Ibid., Hearings, supra n. 47, at 395; at 391 (testimony of Fleit, Moran).

56. Hearings, supra n. 47, at 391-392; at 395-396 (testimony of Moran, Fleit).

57. Hearings, supra n. 47, at 271, 286-87 (Polackwich testimony).

58. Ibid.

59. Ibid. at 271-272.

60. Complaint, Straus v. Polackwich, C.A. No. 81-1406-N (D. Mass., filed June 5, 1981).

61. "Defendant Robert J. Polackwich's Answer and Counterclaim," Straus v. Polackwich, supra n. 60 (D. Mass., June 25, 1981).

62. Hearings, supra n. 47, at 349, 370-372, 375-378 (M. Straus testimony).

63. Ibid. at 349.

64. Ibid. at 349-350.

65. Written statement of Jody Fleit submitted to the President's Commission on June 5, 1981, at 1-2.

66. Hearings, supra n. 47, at 348 (M. Straus testimony).

67. Telephone interviews with MacKay, supra n. 25, and on August 5, 1981.

68. Hearings, supra n. 47, at 299-300 (Glantz testimony).

69. Hearings, supra n. 47, at 292-295 (Watkins testimony).

70. Ibid. at 297.

71. Ibid. at 296.

72. Holden, "Scientist with Unpopular Data Loses Job," Science 210 (Sept. 10, 1980), 749; telephone interview with Morris Baslow, July 30, 1981.

73. Holden, supra n. 72.

74. Ibid., Consolidated Edison Company of New York, Inc., Project No. 2338, Order Compelling Response to Interrogatories (Administrative Law Judge Stephen Grossman, Federal Energy Regulatory Commission, September 10, 1980), at 3.

75. "Pasztor, Speaking Up Gets Giologist into Big Fight," Wall Street Journal November 26, 1980, at 29; telephone interview with Baslow, supra n. 72.

76. Telephone interview with Baslow, supra n. 72.

77. See 33 U.S.C. § 1367.

78. Holden, supra n. 72, at 750.

79. Telephone interview with Baslow, supra n. 72.

80. Ibid. Holden, supra n. 72, at 750.

81. Telephone interview with Baslow, supra n. 72.

82. Ibid.

83. Holden, supra n. 72, at 750.

84. Telephone interview with Baslow, supra n. 72.

85. Ibid.

86. Medical Staff, Standard IV, Accreditation Manual for Hospitals, Joint Commission on Accreditation of Hospitals (1980 ed.).

87. Telephone interview, Dr. Jack Ransone, Medical Field Surveyor, JCAH, July 21, 1981; F. Grad & N. Marti, Physicians' Licensure and Discipline 207 (1979) (hereafter Grad and Marti).

88. Ransone interview, supra n. 87.

89. Ibid.

90. The definition of who is protected by the grievance procedures may be quite limited, e.g. it may extend only to persons licensed to practice nursing or medicine or to those given "clinical privileges."

91. Grad and Marti, supra n. 87, at 207 and n. 598.

92. Grad and Marti, supra n. 87, at 209 and cases cited at n. 608.

93. Ibid. at 209-210 and cases cited at nn. 610-611.

94. Forsham v. Harris, 445 U.S. 169, 180 (1980) (citation omitted). The general rule is that purely private entities are immune from the reach of the Constitution. See Moose Lodge No. 107 v. Irvis, 407 U.S. 163 (1972);

Jackson v. Metropolitan Edison Co., 419 U.S. 345 (1974). A private organization is not made "federal" by the fact that it is heavily funded and regulated by the federal government. E.g., United States v. Orleans, 425 U.S. 807, 816 (1976); Forsham v. Harris, 445 U.S. 169 (1980). Private entities, by exercising functions that are traditionally exclusively reserved to the government, have sometimes been considered "public" and thus subject to constitutional strictures. Cf., e.g., Evans v. Newton, 382 U.S. 296 (1966). This category, however, is extremely limited. See, e.g., Flagg Bros., Inc. v. Brooks, 436 U.S. 149, 160 (1978); Hudgens v. NLRB, 424 U.S. 507 (1976); Jackson v. Metropolitan Edison Co., 419 U.S. 345 (1974). University and medical research institutions, which traditionally are private and retain their independence from governmental interference, cf. United States v. Orleans, 425 U.S. 807, 816 (1976), do not appear to fall within that category.

95. Of course employees of governmental institutions are protected by the federal Constitution. See p. 120, supra, and n. 115, infra.

96. See generally R. Chalk, M. Frankel, S. Chafer, Professional Ethics Activities in the Scientific and Engineering Societies, AAAS Professional Ethics Project, American Association for the Advancement of Science (December 1980), at 21-29 (hereinafter AAAS Report). As defined by the AAAS Project, "'professional ethics' refer to those principles intended to define the rights and responsibilities of scientists, engineers and practitioners in their relationship with each other and with other parties, including employers, research subjects, clients, students, etc." AAAS Report at 17 (emphasis added).

97. AAAS Report at 39, 42, 43. Examples of support include legal aid, counseling, financial assistance, referral, arbitration, etc.

98. Ibid. at 29-50.

99. Ibid. at 34-37.

100. Ibid. at 33. Thirty-one societies that reported complaint procedures indicated that they had no method of informing members or nonmembers about their own procedures.

101. Ibid. at 38.

102. Ibid. at 40.

103. Ibid. at 54.

104. Ibid. at 44.

105. Ibid. at 45.

106. Ibid. at 45.

107. Ibid. at 31, 35.

108. Ibid. at 52.

109. Ibid. at 33.

110. Ibid. at 99.

111. Ibid.

112. Ibid. at 102.

113. Investigative and adjudicative functions should be virtually full-time jobs. Voluntary, part-time panels are ill equipped to handle the complexities these responsibilities entail. The AAAS report "question[ed] whether 'borrowed' staff can acquire the skills and sensitivity required for the investigation of ethics complaints and for the mediation of disputes." Ibid. at 53-54. The American Association of University Professors, one of the societies most actively concerned with questions involving ethical issues, does receive complaints, but conducts formal investigations in few cases, relying mainly on the institution involved to handle the complaint as it sees fit. AAUP merely suggests procedural guidelines to be followed and provides counseling and some financial assistance to affected members. Ibid. at 78-79.

114. See R. Chalk. "Due Process for Dissenting Whistle-Blowers," Technology Review, June-July 1979, p. 52.

115. E.g. Arnett v. Kennedy, 416 U.S. 134 (1974) (where statute provides discharge for cause only, property interest in continued employment is constitutionally protected and minimal procedural requirements must be met); Perry v. Sindermann, 408 U.S. 593 (1972) (de facto tenure system could trigger right to procedural due process under 14th Amendment); Pickering v. Board of Education, 391 U.S. 563 (1968) (firing of public school teacher for public expression of disagreement with school board violative of First Amendment). But see Bishop v. Wood, 426 U.S. 341 (1976) (no property or liberty interest infringed where state employee holds job at pleasure of city and where there is no public disclosure of reasons for the discharge).

116. Peck, "Unjust Discharges from Employment, A Necessary Change in the Law," 40 Ohio St. L.J. 1, 8-9 and n. 49 (1979) (hereafter Peck).

117. Peck, supra n. 116, at 8; Summers, "Individual Protection against Unjust Dismissal: Time for A Statute," 62 U. Va. L. Rev. 481, 482 (1976) (hereafter Summers).

118. E.g. Payne v. Western & Atl. R.R. Co., 81 Tenn. 507, 520 (1884). See also Geary v. United States Steel Corp., 456 Pa. 171, 319 A.2d 174 (1974) (discharge in retaliation for internal complaints about unsafe products is not actionable).

119. Summers, supra n. 117, at 486.

120. Hinrich v. Tranquilaire Hosp., 352 So.2d 1130 (Ala. 1977).

121. E.g. Palmateer v. Intl. Harvester Co., 49 U.S.L.W. 2707 (Ill. 1981) (discharge for reporting suspected criminal activity of fellow employee to law enforcement authorities and for agreeing to cooperate in investigation is actionable tort, as there is a clear public policy favoring investigation and prosecution of criminal offenses); Sventko v. Kroger Co., 69 Mich. App. 644, 245 N.W. 2d 151 (1976) (discharge for filing successful compensation claim unlawful); Accord, Frampton v. Central Ind. Gas Co., 260 Ind. 249, 297 N.E. 2d 425, 428 (1973); Petermann v. Teamsters Local 396, 174 Cal. App. 2d 184, 344 P.2d 25, 27 (1959) (discharge for refusing to commit perjury, unlawful); Nees v. Hocks, 272 Or. 210, 536 P.2d 512 (1975) (discharge for satisfying jury duty may be subject to suit for damages); Monge v. Beebe Rubber Co., 114 N.H. 130, 133, 316 A.2d 549, 551 (1974) (firing motivated by bad faith or malice or based on retaliation... constitutes a breach of the employment contract"; suit for damages

in a sexual harassment case allowed); Jackson v. Minodoka Irrigation District, 98 Idaho 330, 563 P.2d 54 (1977) (when discharge motivated by condition violative of public policy, employment at will doctrine is inapplicable) (dictum). But see Adler v. American Standard Corp., 50 U.S.L.W. 2069 (Md. Ct. App. 1981) (discharge for discovering bribery and falsification of corporate records insufficient to state cause of action for wrongful discharge; allegations suggest "serious misconduct" only, not violation of any specific law).

122. Peck, supra n. 116, at 15.

123. 1980 Mich. Pub. Acts No. 469.

124. Ibid., Sec. (1) (a).

125. Ibid., Sec. (2). A "Public Body" includes the legislative, executive and judicial branches of state government and extends to, inter alia, persons, commissions, municipal corporations, law enforcement agencies, councils, or departments. An employee who goes to the press presumably would not be protected.

126. Ibid., Secs. (3) and (4). If the employee alleges unlawful discrimination because he was "about to report" a violation, his burden of proof by "clear and convincing evidence"is heavier. An initial draft of the bill placed the burden of proof in all cases on the employer to show by a "preponderance of evidence" that sanctions were not imposed for invalid reasons. H.B. 5089, Sec. (3).

127. Ibid., Sec. (5).

128. Ibid., Sec. (8).

129. Ibid., Sec. (2).

130. Mich. Gen. Rules 111.6.

131. Letter from W. Ludwig, director, Legislation and Government Relations, MNA, to Sen. Allen, Michigan State Senate, Dec. 10, 1980.

132. Ibid.

133. Prosser, Handbook of the Law of Torts § 115 (4th ed. 1971); see Restatement of Torts 2d § 595, § 600 (1977 ed.).

134. Sindorf v. Jacron Sales Co., 27 Md. App. 53, 67, 341 A. 2d 856, 866 (1975), aff'd., 276 Md. 580, 350 A. 2d 688 (1976). See also Restatement of Torts §§ 593-598 (1938); F. Harper and F. James, The Law of Torts, §§ 5.25-5.26 (1956); Prosser, supra n. 133, at § 114, 115.

135. See Prosser, supra n. 133, § 115; Restatement of Torts § 595, comment h at 252-253 (1938). Sindorf v. Jacron Sales Co., 27 Md. App. 53 341 A. 2d 856 (1975), aff'd., 276 Md. 580 350 A. 2d 688 (1976) (former employer privileged to tell plaintiff's new employer that plaintiff was thief).

136. See, e.g., Fresh v. Cutter, 73 Md. 87, 94-95, 20 A. 774 (1890).

137. See generally, Hall, Hospital Committee Proceedings and Reports: Their Legal Status, 1 Am. J. Law and Med. 245, 258-62 (1975) (hereinafter Hall).

138. Pirre v. Printing Devs., Inc., 432 F. Supp. 840, 842-43 (S.D.N.Y. 1977).

139. Hanzimanolis v. City of New York, 88 Misc. 2.d 681, 388 N.Y. S.2d 826 (1976) (adversary, administrative hearing); e.g. Corbin v. Washington Fire & Marine Ins. Co., 278 F. Supp. 393 (D.S.C.) aff'd., 398 F.2d 543 (4th Cir. 1968) (board of arbitrators); Prosser, supra n. 133, § 114.

140. E.g., McMann v. Wadler, 189 Cal. App. 2.d 124, 128-9; 11 Cal. Reptr. 37, 41 (1961).

141. See, e.g., Ascherman v. Natanson, 23 Cal. App. 3d 86l, 100 .Cal. Rptr. 656 (1972); Schechet v. Kesten, 3. Mich. App. 126, 141 N.W. 2d 641 (1966). Franklin v. Blank, 86 N.M. 585, 525 P.2d 945 (Ct. App. 1974); Cf. McAfee v. Feller, 452 S.W. 2d 56 (Tex. Civ. App. 1970) (defamatory statements sent to a Bar grievance committee in reference to the Plaintiff attorney absolutely privileged). See also Hall, supra n. 137, at 258, 262-64.

142. Franklin v. Blank, 86 N.M. 585, 525 P.2d 945 (Ct. App. 1974).

143. See, e.g., Hackenthal v. Murdoch, 24 Cal. 3d 55, 154 Cal. Reptr. 4223 (1979) (statement to hearing commission of private medical society, not a formal governmental entity); Schoonfield v. Mayor and City Council of Baltimore, 399 F. Supp. 1068 (D.Md. 1975) (quasi-judical proceeding conditionally privileged); DiMiceli v. Klieger, 58 Wis. 2d 359, 206 N.W. 2d 1984 (1973) (hospital executive committee not quasi-judicial body, communication with committee not absolutely privileged).

144. State licensing or disciplinary boards, which are extensively regulated by state statutes, afford detailed protections to physicians accused of professional misconduct who are summoned before these bodies. Protections vary from state to state, but usually include the right to a formal adjudicatory hearing before revocation of a license (unless the public health or safety requires emergency revocation, the right of rehearing, the right of adequate advance notice of the hearing and of the specific charges, the right to counsel, to cross-examination, the right to present evidence, and the right to a written decision. Some states provide that the investigative and adjudicative functions be separated, but most board members are involved in investigative, prosecutive, and adjudicative functions. Rules of evidence at the hearing are loosely applied. Most states also provide for subpoena powers by the agency or board on behalf of the accused and for a formal transcript. Grad and Marti, supra n. 87, at 141-158.

145. Prosser, supra n. 133, §114, 115; See also Asay v. Hallmark Cards, Inc., 584 F.2d 692, 698 (8th Cir. 1979) (dissemination of allegedly defamatory pleadings to third parties not privileged); Kennedy v. Cannon, 229 Md. 92, 182 A.2d 54 (1962) (interpretive comment by attorney to newspaper not privileged).

146. Prosser, supra n. 133, §129.

147. Ibid.

148. Ibid., §129, n. 93 and cases cited therein.

149. Ibid. §129, nn. 97-99. See also Bentley v. Teton, 19 Ill. App. 2d 284, 153 N.E. 2d 495 (1958) (civil servant reporting misconduct of nurse to supervisor protected from liability); cf. Porter v. King County Medical Society, 186 Wash. 410, 58 P.2d 367 (1936) (ethical rules of medical society immune from challenge by injured third party).

150. See 45 C.F.R. §46.123

151. Telephone interview with Charles MacKay, Deputy Director, OPRR, August 11, 1981.

152. Telephone interview with MacKay, August 3, 1981.

153. Ibid.

154. Ibid., telephone interview with MacKay, August 11, 1981.

155. Telephone interview with MacKay, August 5, 1981.

156. Telephone interview with MacKay, supra n. 152.

157. 45 C.F.R. §5.16. The Freedom of Information Act, 5 U.S.C. §552(b), provides an exemption for mandatory disclosure of, inter alia, investigatory files the disclosure of which would cause an "unwarranted invasion of personal privacy."

158. Telephone interview with MacKay, supra n. 152.

159. See, e.g., Sample Institutional Assurance, §I.C.8, OPRR (July 3, 1978).

160. OPRR currently has a 15-person staff.

161. 45 C.F.R. Part 76.

162. 45 C.F.R. §76.10(g).

163. 45 C.F.R. §76.14.

164. 45 C.F.R. §76.11.

165. 45 C.F.R. Part 76.

166. 45 C.F.R. §76.15.

167. 45 C.F.R. §76.22.

168. 45 C.F.R. §74.115.

169. 45 C.F.R. §74.114.

170. 45 C.F.R. §74.114-115.

171. 45 C.F.R. Part 16.

172. 45 C.F.R. §16.8.

173. 45 C.F.R. §16.58.

174. 45 C.F.R. §16.10.

175. 21 C.F.R. §16.10.

176. Ibid.

177. 21 C.F.R. §16.60.

178. 21 C.F.R. §16.62.

179. 45 C.F.R. §46.109(d).

180. 45 C.F.R. §46.113.

181. Robertson, "The Scientist's Right to Research; A Constitutional Analysis," 51 So. Cal. L. Rev. 1203, 1266 n. 289 (1978); Robertson, "The Law of Institutional Review Boards," 16 U.C.L.A. L. Rev. 484, 548 (1979).

182. See 45 C.F.R. §46.111.

183. Pub. L. 95-454 (1978).

184. 5 U.S.C. §1206(b)(1)(A).

185. See 5 U.S.C. §1206-1208.

186. Telephone interviews with Office of Special Counsel; Office of Personnel Management; NIH (August 14, 1981). Whether CSRA applies to a particular individual depens upon the enabling legislation for the agency for which he or she works.

187. 5 U.S.C. §1206(b), (2) and (3).

188. Telephone interview with Louis Clark, director, Government Accountability Project, August 14, 1981; see letter from Mary Eastwood, acting special counsel to Louis Clark, June 9, 1980.

189. 5 U.S.C. §1208.

190. 5 C.F.. App. IC(B) to Part 1261. See also 5 C.F.R. Part 1253.5(b)(2).

191. 5 C.F.R. Part 1255.5.

192. 5 C.F.R. Part 1254.5.

193. 5 C.F.R. App. I(B) to Part 1261. According to the Office of Special Counsel, allegations of reprisal usually require disclosure of the complainant's identity; other types of allegations usually do not. (Telephone interview, July 30, 1981)

194. 5 C.F.R. App. I(B) to Part 1261.

195. 5 C.F.R. Part 1253.2(a)(1).

196. 5 C.F.R. App. B. to Part 1261.

197. E.g., Toxic Substances Act, 15 U.S.C. §2622; Occupational Safety and Health Act, 29 U.S.C. §660; Federal Mine Safety and Health Amendments Act of 1977, 30 U.S.C. §815(c); Surface Mining Reclamation Act, 30 U.S.C. §1293; Water Pollution Control Act, 33 U.S.C. §1367; Safe Drinking Water Act, 42 U.S.C. §300j-9; Energy Reorganization Act of 1974, 42 U.S.C. §5851; Solid Waste Disposal Act, 42 U.S.C. §6971; Clean Air Act, 42 U.S.C. §7622.

198. 30 U.S.C. §815(c)(1).

199. Ibid.

200. Ibid., §815(c)(2).

201. Ibid.

202. Ibid.

203. Ibid., §815(c)(3).

204. Ibid.

205. See Munsey v. Federal Mine Safety & Health Comm'n, 595 F.2d 735, 742-43 (D.C. Cir. 1978). See also 115 Cong. Rec. 27948 (1969) (remarks by Sen. Kennedy).

206. 29 C.F.R. §24.2(b).

207. 29 C.F.R. §24.4(b).

208. 29 C.F.R. §24.4(c).

209. E.g., 15 U.S.C. §2622(b)(2)(A); 42 U.S.C. §300j-9((i)(2)(B)(i); 42 U.S.C. §7622(b)(2)(A).

210. 29 C.F.R. §24.5.

211. 29 C.F.R. §24.6(b)(2).

212. 19 U.S.C. §600(b).

213. 29 C.F.R. §1977.

214. 29 C.F.R. §1977.9(b), (c); see also Marshall v. Springville Poultry Farm, Inc., 445 F. Supp. 2 (M.D. Pa.) (1977).

215. 29 C.F.R. §1977.18(a), 9(b).

216. E.g., The National Research Act, Pub. L. 93-348, 88 Stat. 342 (1974) (amending The Public Health Service Act, as amended 42 U.S.C. §201-300t) (1976).

217. See 5 C.F.R. Part 1255.2-3.

218. See, e.g., R. J. Frazier et al., MSPB Order No. SC79-3 (Dec. 17, 1979) (if the prohibited discrimination is a "significant factor" in the challenged action, the employee will prevail.)

219. The question of what sanctions other than debarment the federal government may appropriately assess is beyond the scope of this paper. In view of the inadequacy of institutional procedures, however, a formalized federal fact-findng mechanism would serve a valuable function regardless of the penalty imposed.

220. 29 C.F.R. §1613 et seq.

221. F.P.M. Letter 713-72.

222. See generally Aviation Safety Reporting Program, Advisory Circular AC00-46B, Department of Transportation, F.A.A., 6/15/79. NIH's Office of the Inspector General has a hotline, but it is not toll free, not widely publicized, and is designed to receive allegations of fiscal fraud and mismanagement rather than charges involving abuse of human subjects and fraudulent research.

223. Such a requirement might not apply if the misconduct is already known to the appropriate officials or if filing an internal complaint would be reasonably likely to cause destruction of relevant evidence.

226. See generally N.R.C. Personnel Manual, Ch. 4125 (Sept. 19, 1980).

227. Ibid..

228. See Robertson, "The Law of Institutional Review Boards," 26 U.C.L.A. L. Rev. 484, 530, and n. 234 (1979).

229. Although the Straus and Crawford cases may be unusual in their complexity, it cannot be assumed that misconduct in federally funded biomedical research is too rare a phenomenon, or too insignificant a problem, to warrant recommendations for procedural reforms. Senate Hearings in 1981 on the NCI's contracting and grant procedures revealed "as many as 31 investigators from different settings involved in the fabrication of data." National Cancer Institute Contracting and Procurement Procedures, 1981, Hearings before the Senate Committee on Labor and Human Resources, An Examination of the National Cancer Institute Contracting and Grant Procedures, 97th Cong., 1st Sess. 116 (1981) (Statement of Sen. Kennedy). In his testimony before the Committee, Dr. DeVita, Head of NCI, remarked: "I believe that we do have to depend on the whistleblowers. I, too, am glad that there are people at places like Boston University who find data that does not fit with what it is supposed to be and call it to our attention. I do not know that we will ever be able to do without them entirely." Hearings, at 118. If Dr. DeVita is correct and if, as is likely, future incidents like those at Boston University and the University of Kansas are inevitable, the need for more effective protection for both whistleblower and accused is not only timely, but urgent.

Chapter 13

COMMENTARY: WHISTLEBLOWING, DUE PROCESS, AND "INSTITUTIONAL TARPAPER"

Alan F. Westin

The paper by Ms. Oakes is an excellent overview of the state of the law and the state of institutional arrangements and practices. I particularly liked the three case studies that she presented because if you are not careful, you can have a lot of high-flying discussion about general principles and ethical directives and norms; it's only when you look at real people involved in ethical choices, the institutional tarpaper that they get stuck on, the problems of doing justice to the various participants, and so forth, that you begin to realize the nature of the problem you are trying to understand and respond to.

I think there are some good examples of weaknesses in existing structures and institutions that her paper summarizes. Then, as I understand it, she opts for what could be called the "high due process model" for the solution of the problem, that is, the ACLU-Ralph Nader approach of establishing a federal mechanism or state mechanisms that would provide the maximum kind of due process protections for the whistleblower, as well as for the accused.

Since the role of a commentator is to raise questions, pose problems, and try to reflect on where some of the analysis and the recommendations would lead us, it is really in that setting that I'd like to make some comments derived from my own experiences. One of these days I am going to go to a conference in which I don't feel conflicted, in which I can see absolute truth, beauty, and the American way on one side -- and I hope I will be sitting on that side -- and the forces of evil and darkness on the other. But my lot is I find myself in conferences that are a lot more complicated than that; my own experiences push me one way and pull me another.

I have been a member of a community as a professor for about thirty years. I have been the principal investigator or director of a dozen research projects, not in medical research, but social science and law. I have been writing about privacy and have been a civil liberties activist for a number of years. As a political scientist, I am very interested in the assessment of the role of law, legislation, judicial systems, and regulation in the governance of society and in the operation of private institutions and governmental machinery. I have written a book on whistleblowing by employees in a business corporation, which I will turn to in a moment for some comparison with the situation with which we are concerned here. This situation also concerns me directly since I have just been made a member of the IRB at Columbia University.

It helps me to talk at the outset about the setting that we are discussing here, which is the starting point for Ms. Oakes's paper. It seems to me we live in a very complicated time for making judgments about the way in which research should be conducted. We have new technologies that pose very different kinds of questions than in the days of the Greeks, of the Middle Ages, or of early capitalism. These technologies have very much more awesome effects on subjects, on society, and on the institutions involved. These are not at all easy questions that a quick reference to some fundamental book of morality helps one to resolve.

In the last twenty to forty years the field in which I work, the social sciences, has increased enormously the scope of its inquiries, looking at deviant behavior and at the real working of institutions as opposed to their formal operations, for example. Those pose very difficult ethical problems when you go in the front door and ask people to cooperate, when you adopt various poses to gain entry to institutions, or when you ask people to tell you things, especially when you wear the mantle of the institution that sponsors your research or of the foundation or federal government that funds it. There are also some tremendous pressures on researchers today in terms of what wins money, what wins grants, what wins success and esteem among peers, what wins you promotions at your university.

And for any who assume we are saints and are oblivious to this, I suppose the little text one could start with is the Double Helix and other books that remind us of the motivations and complications in research. The examples are legion of the kinds of pressures that drive the famous and would-be famous in the field of research.

I also assume the presence of public funds and social or public responsibility for protecting human subjects creates the need for public definition and public oversight and that the argument that institutions are entitled to autonomy simply does not fly, at least as a total exemption or request for total exemption. We have socialized this area, for better or for worse, without in any way passing on what the definition of standards should be or what the means of oversight should be. We have moved from a private setting to a socialized setting in terms of how these issues are to be dealt with.

I think, on the other hand, it is important to focus on what the responsibilities of a socialized setting are. I would think that there are five objectives that I start with when I think about remedies as Ms. Oakes's paper goes on to do.

First, we have to define standards that are socially acceptable and acceptable to the particular communities of scholarship and research that are involved. That is extraordinarily difficult if you accept what I said a moment ago about changing technology, changing forces of peer pressure and research ethics, and so forth. And how to define those standards, who defines them, and how they are brought to some point of statement is the first and not at all the easiest of the requirements.

Second, those standards have to be widely disseminated, analyzed, and criticized; the research community must accept and acknowledge the strengths and the weaknesses of any formulation of what is right or wrong to do in a given setting.

Third, you have to have some mechanisms for setting the rules. The funding sources, the courts, or whatever the agency is that is going to apply the standards has to promulgate the interpretive regulations and the rules that then become the operative standards in place in various settings.

Fourth, you need a mechanism (or several mechanisms) for adjudicating disputes.

Fifth, something I am going to try to stress in my remarks, you need a way to get feedback and measure the effects of what you are doing so you can revise your standards and procedures in an intelligent way. And I think at the moment that is where we are the very weakest and where I would hope a lot of attention would be put.

With the above points in mind, let me make a quick definitional comment. I think one has to be very careful when putting grapes, pomegranates, and watermelon into one basket and saying, "We've got fruit here." You have several different problems involved. First, you have fiscal fraud, the kind of thing that clearly involves misconduct in the use of funds, the following of funding and granting directions, and so forth. This is the age-old problem of managing monies, a discrete problem having its own appropriate remedies.

Second, you have the question of the protection of the rights of the subject. Society says there are people who are powerless or who do not have the information to make intelligent decisions. Society must see that the researcher does not use his or her expertise, the reputation of the institution, or the good intentions and ethical imprimatur that researchers carry in order to use people in unethical, harmful, and potentially dangerous ways.

Third, you have research misconduct, which is often talked about in terms of fraudulent research techniques, misuse of data, or misreporting of results -- violations of the canons and standards of the research community and the ethical community.

The above three types of situations have been reported by whistleblowers in the area of biomedical research, as well as in most other areas of government and industry. But I think each type of situation calls for very different mechanisms and very different procedures; it is important to try to sort those out.

One point I'd like to make, still by way of introduction, is that I think I would be very careful not to leap too quickly to impose on biomedical research, for example, the same mechanisms and the same standard-setting approaches that we use in government, where you are dealing with whistleblowing by government employees -- who are employed with public funds, who hold a public trust, whose duty in a sense runs to the public and the people -- and by the people who are in office -- the officeholders, the administrators, and others who are supposed to be surrogates and executors of that public will. That is one setting.

Another setting is that of corporate employees who are, under most of American law -- unless they are protected by unions or unless you are dealing with some violation of something like equal employment opportunity law -- at will employees of private employers. As Ms. Oakes's paper points out, that is still the overwhelming doctrine of the state courts. Therefore, in the corporate setting you have a very different set of relationships and rights and powers than in the government.

A third type of setting is that of university researchers, whose relationship to the university is, in part, one of employment. Despite this similarity to employees of the government and of corporations, there are extremely important differences, especially between, on the one hand, the social values to be served by protecting independence, even deviance, in scholarly research and, on the other hand, the role of innovators in government and in the corporate community.

Such differences affect the legal solutions that we might want to impose. It is always tricky to compare two different institutions. The minute you touch a similarity, a difference occurs to you, and I am sure we could have an endless debate about where corporations and university research situations are similar and dissimilar. But here are some things that seem to me important by way of differences that could matter insofar as legal solutions and institutional solutions are concerned.

Obviously, in the corporate world, if you look first at the pattern of authority and of power to make things happen, you are dealing largely with a hierarchical system with a pyramid at the top. Whatever kind of decentralization is the vogue in corporations today -- profit centers and regional centers -- and the extent to which this is being driven by change in technology, the corporate model is that of the chief executive officer (occasionally restrained by the board of directors) as the driving mechanism of authority and as the rulemaker. The decisions that are taken by the head of the corporation are authoritative.

On the other hand, it seems to me the university has a highly decentralized and fragmented authority structure. Even accepting the fact that universities are different in style and in organization, the roles of the president and dean are very different in some state universities than in some small private institutions or large Ivy League institutions. If you have lived in the university world, you know that authority is often distributed and divided so greatly that it is difficult to accomplish anything other than just teach your classes and meet the payroll. If anything, the university world suffers from an inability to act, to organize itself efficiently, and to pursue some rational model, whereas the corporation -- for better or worse -- is extraordinarily rationalistic. You may not like its decisions, but it sure makes them and it sure is able to get things done.

The corporate employee's duty of loyalty is also different from that of the university researcher. The corporate world is no longer one that requires that an employee be the "organization man" William White wrote about or a man in a "gray flannel suit." IBM has come a long way from the singing of the company song and the absolute white shirt throughout the IBM enterprise. But the fact is that the assumption of loyalty in the corporate world is still the dominant approach, and people know that their career advancement, especially if they are in the professional and executive ranks, depends on showing that they know how to carry themselves forward in the corporate environment. They must know how to behave and how to advance themselves, they must be skillful at the testing points for executives or professionals, and so forth.

Again, I think the contrast with the university world is important. The university world is a place in which being very loyal to your university administration is probably two strikes against you in the community of scholars on that campus. Such persons are known as company men, and it is not accidental that that is the image used in the corporate world. Most of the university world prizes dissent, deviance, a wide range of rather free-swinging opposition to anything that the university authorities do; therefore one has to be very cautious in increasing the authority of the university when the ethic of the professions that make up the teach-and-research arm of the university is not one of loving loyalty to the institution but instead treasures the right to criticize and the right to be a nonconformist towards the institutional authority itself.

Inside the university world, if we shift now to the degree of fair hearing and administrative due process, most universities provide a considerable amount of due process for those who are academics or researchers. The corporate world, for the most part, is still operating in

the old open-door mode, that is, "My door is always open to you. Come in if you have a complaint or go up the chain of command if you have a problem." But a recent cartoon in the Wall Street Journal showed an executive sitting behind his desk and the employee standing in front of him. The executive said, "Fosdick, I thought you understood when I said my door was always open I meant it was for air, not for complaints." Contrasted with the corporate world, the university has provided a considerable amount of fair procedure and regularity.

Corporations, with some exceptions -- the IBMs, Citicorp, Aetna Life & Casualty, the fifty or so good corporations -- do not provide meaningful due process for employees, and reprisal is rampant throughout the corporate world. Apart from something very loosely called "business morality" -- which I think we'd all, including business leaders, have a hard time in pressing very far -- standards of ethical conduct in business are generally defined by law (OEO, occupational safety and health legislation, disclosure rules, accounting rules, foreign agent bribery rules, and so on). Morality as it operates to limit corporate decisionmaking is legislatively mandated and mandated through court enforcement, whereas the university likes to believe that there are ethical standards that grow out of professional norms, the endeavor itself, the scientific inquiry. While there is a certain amount of pretentiousness in that claim that academics are a self-governing, ethical elite, it is, in fact, a true enough statement of the historical tradition; and it is reinforced by certain vows, if not of poverty and chastity, at least of dissent and separation from big money-making that the corporate world provides.

Finally, the responsibility of members provides an interesting contrast between the two worlds. In the scientific and research communities, people have a genuine sense that they have a duty to come forward if a central important principle or tenet of their discipline, their organization, or their ethical commitment has been violated.

The whistleblowers in the corporate world that I am familiar with -- and I met several hundred of them in producing a book on whistleblowing and in a project we are now working on -- are really quite unusual in the corporate world in believing they had a duty to question the safety of trucks being produced by the firm, to question what was being dumped into a local water supply, to question the safety of the Ford Pinto design, or to report a violation of women's rights, e.g. sexual harassment or discrimination against women. That is, in the corporate world they were quite an unusual minority in that they said, "I can't accept the corporation's definition of what the cost-benefit equation is."

The man in the Ford Pinto case, for example, was told that a certain number of people would have to die or be seriously hurt because there would be a flame-out in the back of the Pintos because of the way the engine was designed. The premise was that to correct the design would cost so much that the Pinto wouldn't be successfully marketed. Therefore, "We'll pay off the people who are killed, or their heirs, and those that are injured. That is the way the cost-benefit equation has to be filled out. We live in a risk-filled world." Usually someone is in a distinct minority when they challenge that kind of reasoning. We have been engaged in countering that approach through external law and external protection of those in the corporate world.

Let me now turn to some of the recommendations made in Ms. Oakes's paper and explain where I come out on them. I strongly agree that the way you change the behavior of voluntary institutions that are used to autonomy, e.g. corporations and university research bodies, is by making credible the presence of somebody that will look over their shoulder, force

them to be visible, and judge the sensitivity of their decisions in a way that will put them, if necessary, to a public defense. Thus, I want to find mechanisms that don't require every decision, by any means, of the voluntary bodies to be made public, but that will make it clear that regularly, from time to time, cases will move into the public arena that test the standard, test the procedures, test the balance of justice that the institutions have the first responsibility to apply.

In that sense, I quite agree that the Michigan statute, which I testified in support of and believe is three-quarters a good statute, is a very important state intervention; perhaps a federal counterpart to it, as Ms. Oakes suggests, would be an important way to provide that credible ultimate mechanism that would drive the institutions to be more aware that they can be brought to judgment.

There is a recommendation Ms. Oakes makes that I agree with and urged on the Michigan legislature. But they got in a rush to pass the legislation and were not able to add it even though the sponsors favored it. In order to use that kind of whistleblower protection statute, there should be an obligation on the part of the individual to have used the internal mechanisms that are available within a corporation, a government agency, or an institution as long as certain conditions are met. In particular, there must be a mechanism in place that is well known, that is formalized, that guarantees against reprisal, and that provides a chain of hearing and appeal that is outside the line-management situation. That is, it has the elements of dissent or separateness that are important.

In the corporate world, for example, Citicorp created a worldwide whistleblower protection mechanism after they got burned by a case that made the headlines, one in which a Citicorp employee alleged there was misconduct by the Swiss branch of Citicorp. Although Citicorp officials were convinced his allegations were incorrect and they could defend everything that was done, the fact they did not have a mechanism by which he felt he was being heard inside the top management of Citicorp led him to go public. And in a good reading of the situation they said, "We have to have something that will apply to every Citicorp employee and executive, where a person can raise questions of unethical or illegal conduct by the corporation."

I agree with Ms. Oakes where she states that requiring the use of such an internal mechanism should not be a prerequisite if the situation would make it futile to do so. For example -- and this is a real case -- if you are a driver of a chemical company in New Jersey and would like not to dump chemicals at midnight into places that have been absolutely forbidden by the state government and the federal authorities, but you happen to know the Mafia has taken over your firm and you are going to get dumped in with the chemicals if you try to raise the issue inside your company, then you should not be required to exhaust your internal remedies before reporting this to public authorities. In general, however, I think it is very important that the internal exhaustion of the remedies be an essential part of the system.

There are two things I'd like to suggest in closing that go along with many of Ms. Oakes's good suggestions about how to structure the external and internal rules relating to whistleblowing.

First, I am dismayed -- although I suppose a social scientist should never be -- at what a tremendously small empirical base we have to start with in trying to understand how widespread fiscal misuse and abuse of human subjects are in the research community. We deal in a handful of anecdotes. If we like to think that research has something to say, why

don't we do research using samples of survey work and other techniques in order to establish how widespread these problems are and what their contours are? I have a terrible sense that we are blind people feeling the elephant here, trying to make wise policy without understanding how widespread these problems are and so forth. And for God's sake, let somebody fund some empirical research to try to understand what is going on out there. It could be drawn from knowledgeable people. It could be done in various ways that would get us a lot further.

Second, I am convinced that there are good models out there. Some innovations have been discussed here, and there are others that I know of. One of the most important things we must recognize is that there are predominantly sins of omission, not commission, in institutional settings. I think you have a bunch of rank amateurs, myself included, being called on to serve in IRBs who don't have the raw material to work with. We don't have the well-crafted case studies of how good systems work and how would-be-good systems have failed. What we need is case studies of real situations, the problems posed, how they were dealt with, what machinery seems clearly inadequate. For example, we are told in Ms. Oakes's paper that many things we have today don't work. I don't know that I'd accept that just on what is in the paper. I'd like to know where it has failed and why and what the context of those assumed failures is before I would be able to say, "Yes, a convincing case has been made that this, that, and the other mechanisms have failed." It may be they are working very well, given the nature of the whole problem against which the particular performances in a given case were measured.

I would hope very much that there would be a much better way to gather an empirical sense of what is going on. This would provide a sense of useful, down-to-earth models of good internal procedures, of their failures, and of ways to improve them. Those could be the tools that people could use to work with.

Chapter 14

THE NATIONAL INSTITUTES OF HEALTH'S PERSPECTIVE ON MISCONDUCT BY GRANTEES

William F. Raub

Like most people in the scientific community, we at the NIH have regarded the incidence of real or apparent scientific misconduct as of low frequency, but nevertheless of extraordinary seriousness when it occurs. The NIH, like much of the academic community, has tended to treat these matters on a case-by-case, ad hoc basis. We have come to believe rather strongly that there is a need for more effective means, more nearly equitable means, and more efficient means for the handling and resolution of these matters. On the one hand, I have a few mea culpas with respect to how individual cases have in fact turned out.

Hindsight clearly shows that in a number of cases, "we," including the NIH, but also academic institutions and the larger scientific community, might have done better, might have worked more promptly, and certainly would have done some things differently. But, on the whole, I believe the outcomes in the array of cases with which I have had contact have been such that an overall apology is not now required.

The NIH is now engaged in an effort to expand and refine its procedures in order to provide a better body of guidance for itself and its awarding institutes and scientists in handling these matters. Specifically, we will be looking for ways to impart greater knowledge, such as what constitutes real or apparent scientific misconduct and what one does when one encounters it or thinks one has encountered it. We will be looking for a slightly greater degree of formality in our handling of misconduct in our relationship to the various parties -- informants, accused, and the like. In general, we will be looking for ways to increase sensitivity and to sharpen reflexes on the part of all of the participants. At the moment our interests focus on four distinct but related areas:

1. The identification phase. We believe we need to give better and more specific guidance to our awardee principal investigators and our awardee institutions with respect to how to identify these issues, what general performance parameters we would hold out for the institution, and specifically what kinds of matters should be brought to the attention of the NIH.

In parallel with that, we are working on a set of guidelines for our own staff. At any number of levels in the administrative hierarchy, real or apparent misconduct is identified, sometimes in response to a whistleblower or other informant, sometimes in the normal course of monitoring

progress reports or otherwise interacting with the scientific community. For the purposes of distinguishing the frivolous from the nonfrivolous, deciding when to act, what to do, and who else should be engaged, we believe that we need a stronger and more predictable procedural framework.

We are also examining the issues of false reporting of information to the federal government. There are several statutes, as I understand them, that make it a felony to provide false information knowingly to the federal government. Those considerations are often lost sight of in the heat of discussion and debate over an alleged incident of scientific misconduct. Nonetheless, to the extent that a progress report on a grant or application for a new award contains information that was knowingly false -- let's say fabricated, for example -- then among other things there is at least a technical violation of a criminal statute; there is a body of process and procedure involving at least the Office of the Inspector General, if not the Department of Justice, that properly needs to be invoked, and promptly so.

A related practical issue is how much fact-finding is appropriate and necessary before one reports something. On several cases that I have handled individually, I have found it necessary, and in retrospect desirable, to do a certain amount of inquiry from the informant or from other sources with respect to the incident that was involved, to take some of the rough edges off the original statement, and to be able to make the decision whether this was potentially serious or not. This enabled me to determine which other components of the organization should be involved.

2. The investigation phase. When it has been determined that some apparently significant malfeasance or misconduct has occurred and a decision has been made to begin a formal inquiry into the matter, there are a number of complexities involved.

One is the need to identify just how complex the task is likely to be. Traditionally, our practice has been to invoke an investigation or an inquiry, but otherwise let whatever systems were in place run. When the matters have been either fiscal audits that might culminate in some major cost disallowance or hotline calls to the inspector general that can often be resolved rather quickly, there has been little practical detriment in letting the system idle wherever it is while these inquiries are played out.

When the case is extraordinarily complex, like several that have been in the public press recently, and the inquiry itself may go on for many months or even longer, there are practical problems created by the seeming indifference of a funding agency. This is especially the case when public funds continue to be spent and there are many critics -- both in the public and in the Congress particularly -- who wish to see some interim action in the interest of what might be perceived as proper stewardship of the public's money.

When it is determined that some interim action is necessary, there are a variety of other issues that develop. In some cases it has seemed appropriate to ask the principal investigator of a grant to step aside, to make arrangements for alternative leadership on an interim basis, and to let the scientific activity play out while related matters are questioned. In some cases it undoubtedly will be necessary in the future to suspend activity under a given grant while inquiries are played out.

All of this obviously needs to be done in close collaboration and in full communication with the awardee institution and the affected scientist. There also needs to be some response, at least in the way of summary

progress reports, to individuals who may have called the problem to the attention of the funding agency in the first place.

3. The postinvestigation phase. In those cases where investigation has led to the conclusion that there was significant misconduct, there are the considerations of what number and kind of sanctions, if any, need to be taken. In some cases the NIH has elected to continue funding of a particular scientific project, but to subject it to either special reviews or other prior approval considerations that are tailored to the particular case. In some cases we have identified individuals in a central alerting system that we maintain, which allows us to keep track of individuals who are either under investigation or who were the subject of a recently completed investigation from which some sanctions have resulted. And we use that alerting system as a way to bring to the attention of my office and of the appropriate NIH funding components any grant applications or contract proposals with that individual as the principal investigator or project director. In an extreme case it may be necessary to invoke the debarment procedures that were published last year but have not been exercised to date.

In parallel with any NIH actions that are needed, there frequently are institutional sanctions of various kinds, which are sometimes more stringent than those the funding agency will choose to apply. Such institutional sanctions may take the form of a proscription on the array of activities that that individual may engage in for the next several years; proven misconduct may lead, of course, to the dismissal or to an invited resignation of the individual. In the case of allegations about falsification of scientific data or about plagiarism, those academic sanctions are often sufficient to prevent the individual from reentering science, at least in the near future.

4. Interagency coordination. To date, the best developed of our procedures involve our interactions with the Office of the Inspector General. And that is not surprising in that our approaches to handling incidents of possible scientific misconduct, especially where there seem to be technical violations of criminal statutes, have built fairly naturally on the established procedures for potential fiscal abuse. We will no doubt continue to work with those offices and the Department of Justice whenever such seems appropriate.

Where matters involve clinical research in general and the protection of human subjects in particular, especially where investigational drugs are involved, our links with the FDA need to be refined. There is now in process a series of discussions, for which Dr. Nightingale and I happen to be the principals representing our agencies, of specific ways of looking at cases to be sure that the proper exchange of information at the proper time occurs.

Another area that has not in recent years been one of major concern, but for the sake of completeness needs to be addressed, is our linkage with other research agencies whose missions complement and juxtapose ours in certain areas.

One of those agencies is within the U.S. Public Health Service, namely, the Alcohol, Drug Abuse and Mental Health Administration, where there is not a particular overlap, but a close similarity and common interest in certain areas related to the functioning of the central nervous system. Another such agency is the National Science Foundation. There are some areas in fundamental sciences, as well as in behavioral science and neurobiology, where from time to time there are close common interests of the agencies.

The four above areas, as I indicated, are the subject matter of some procedural developments now going on within the NIH. Our plans are to involve the leadership of our various institutes, as well as our major advisory groups and our contacts within the scientific community (both the institutional leadership and scientists), in the comment, critique, and progressive refinement of those policies. In the meantime, in handling particular cases we will continue to apply our evolving ideas with a view to both resolving those cases and testing what seem to be some theoretically sound concepts.

Chapter 15

WHISTLEBLOWING IN BIOMEDICAL RESEARCH: THE ROLE OF THE FOOD AND DRUG ADMINISTRATION

Stuart L. Nightingale

Although the term "whistleblower" has obviously found a secure place in our language, I would like to point out that, to the best of my knowledge, the term "whistleblower" appears nowhere in the more than 3700 pages of FDA regulations.

From our perspective, the act of whistleblowing represents a breakdown of systems whose very goal is to make sure that misconduct does not occur in the first place. An acknowledged problem is that in many situations, there either are no systems for communication or the channels for making problems known are not well defined or well understood by those who have information to share. FDA does have systems, some of which are evolving, to receive, share, and act on information that can lead to halting sloppy data collection and the submission of faulty data, thereby curbing activities that threaten the protection of human research subjects. These systems are embodied in our Bioresearch Monitoring regulations and our Investigational New Drug (IND) and New Device (IDE) regulations and in programs to enforce them. Those systems, however, are not perfect; they are continually being examined, tested, and improved. But they exist, at least in part, to make the occasion and the need for whistleblowing -- what we would define as a failure of the systems in existence -- as infrequent as possible.

FDA, like any agency accountable to the public, knows perfectly well that there can, will, and must be occasions when an individual feels an overriding responsibility to cry "foul," to make accusations of wrongdoing through whatever medium will bring his or her charges to the attention of responsible officials or the public. These should be situations where the established systems, for whatever reasons, have failed to serve their purpose.

Fortunately, there have been comparatively few instances in which whistleblowers or other sources (including our own surveillance) have disclosed substantial and significant problems involving FDA-regulated research -- a rather remarkable fact when one considers both that the FDA regulates goods that account for some 25 percent of all consumer spending in this country and that we monitor and pass judgment on the research, manufacturing, labeling, and distribution that makes those products available to the public. Rare or not, however, any complaint of wrongdoing is taken very seriously by FDA.

Let me describe, albeit briefly, the scope and objective of our involvement in biomedical research, specifically research involving human subjects. I will use the example of clinical drug research, with the understanding that essentially the same requirements and responsibilities apply to clinical investigators conducting research involving biologics, medical devices, radiation-emitting products, food additives and colors, and other products subject to FDA regulation.

No investigational drug may be administered to a human being until FDA has sanctioned both the agent to be studied and the protocol for the investigation. Any use of an investigational drug without FDA approval is a violation of law, specifically provisions of the 1962 amendments of the federal Food, Drug, and Cosmetic Act, which brought clinical drug experimentation under close FDA scrutiny.

Before a clinical investigation may proceed, FDA must satisfy itself that sufficient laboratory and animal studies have been conducted to warrant a clinical trial, that the investigators involved are well qualified to engage in this kind of research, that the proposed study will yield information with a potential value which justifies the risks involved, and that the rights of the persons who will receive the drug are, and will continue to be, fully protected.

In practical terms, again in keeping with provisions of the New Drug Amendments of 1962, a drug sponsor, usually but not always a drug manufacturer, applies to FDA for a Claimed Exemption for an Investigational New Drug (IND), which amounts to a license to carry out clinical studies of a drug that has not been approved for marketing by FDA. Before the agency will allow a proposed clinical study to begin, it must satisfy itself that (1) preclinical research raises no questions about the appropriateness of commencing human studies of the drug and (2) the proposed study will be reviewed and approved by an IRB.

While it is not appropriate to review the functions of IRBs at this time, I would like to emphasize the importance of the specific requirements that outline the purpose and composition of IRBs, as well as the overall role they play in the protection of human research subjects. I would call your particular attention to a significant provision of the IRB regulations published by FDA in the Federal Register of January 27, 1981, which went into effect on July 27 of that year. Subpart C of the regulation, "IRB Functions and Operations," includes, at Section 56.108, the following language:

> "In order to fulfill the requirements of these regulations, each IRB shall:
>
> (c) Be responsible for reporting to the appropriate institutional officials and the Food and Drug Administration any serious or continuing noncompliance by investigators with the requirements and determinations of the IRB."

In effect, then, we fully expect that IRBs will be prepared to notify their institutions and FDA of circumstances that, in the judgment of the IRB, constitute or raise serious suspicion of a departure from protocols or practices which the IRB has examined and approved.

As you can appreciate, so little time has elapsed since these regulations became effective that we cannot yet determine whether this provision will, in fact, accomplish its purpose. And I would point out that the responsibility of the IRB in this regard is to report, and not necessarily to

investigate, evidence or suspicion of noncompliance. In our view, the primary responsibility to investigate resides with the institutions themselves and with FDA. We have the legal mandate and authority, and we have the trained investigators necessary, to evaluate the conduct of clinical research: to determine if protocols are being followed; to establish whether the requirements for patient protection are being scrupulously adhered to; to judge whether necessary records are accurately and faithfully maintained; in short, to determine whether or not a study is being conducted in accord with laws and the regulations which FDA has promulgated and is charged with enforcing.

We do not see this overall investigational responsibility as falling to IRBs. On the contrary, it is the responsibility of research institutions, sponsors, and monitors of FDA-regulated clinical research (as per the IND regulations) and of FDA to ascertain whether serious misconduct has occurred and to take appropriate corrective action.

As I noted, the IRB regulations call on IRBs to report to "appropriate institutional officials" and to FDA instances of serious or continuing noncompliance by investigators. I will admit that that language leaves room for interpretation. For example, what is a "serious" instance of noncompliance? And what is FDA's role if the instituton, having been informed by its IRB, takes what it considers to be appropriate remedial, corrective, or punitive measures?

There are no ready answers for such questions. I submit that answers will have to evolve through experience. But it is clear, nonetheless, that FDA will not abrogate its responsibility to investigate charges of noncompliance with its regulations and to take appropriate and necessary action. The existence and proper operation of IRBs should, as I suggested earlier, make the need for "whistleblowing" a good deal less than it would be otherwise. Moreover, their presence should lead institutions to be even more attentive and responsive to the need to monitor research under their jurisdiction and to protect those who take part in such research.

While the above comments stress the role of institutions and FDA in investigations of misconduct, the implication is that the IRB would have to have some means of ascertaining whether the specific noncompliance is or is not "serious" or "continuing." This area is not well defined in regulation or current policy.

Inspections for compliance with regulations governing clinical research are carried out by FDA field investigators in conjunction with headquarters scientific personnel. Such inspections are of two kinds. Routine surveillance inspections are intended primarily to determine the validity of data submitted to the agency in support of claims of the safety and effectiveness of products under review. "For cause" inspections, on the other hand, are very often prompted by information suggesting that some aspect of a regulated clinical study or of the behavior of the clinical investigator may represent a serious or continuing departure from regulatory requirements.

If FDA determines that the investigator has seriously breached his or her responsibility in the conduct of clinical studies involving a regulated product, the agency can propose to disqualify the investigator -- in effect, to bar him or her from further clinical research using investigational products regulated by FDA. The investigator is entitled to a hearing before the commissioner or his representative and is accorded all the rights of due process, including the right to seek and obtain reinstatement

following disqualification. But the point is that it is neither the "whistleblower" nor the IRB that makes and must substantiate a charge of noncompliance. It is the appropriate bureau of the FDA -- the Bureau of Drugs, for example -- that brings and must support a case for disqualification. It should be emphasized that disqualification is not punishment, but a means to protect research subjects. Criminal statutes are available to deal with fraud, and prosecution has been carried out in several cases.

None of this, I realize, guarantees that the hypothetical "whistleblower" will not suffer, even if his or her allegations are completely borne out. Nothing in our regulations specifically addresses that point. We would expect that the "whistleblower's" personal standing would rest on the merits of his or her case and on the good offices of the institution, which manifestly has a duty to protect persons who conscientiously and in good faith point out departures from legal and ethical requirements.

For our part, it is FDA's policy and legal duty to preserve the privacy of information about individuals in the agency's records. Obviously, by the nature of our work, we do collect records which contain names or other means of identifying persons involved in clinical research. In keeping with the Privacy Act of 1974, however, we scrupulously guard this information, making it available only to those persons who have an absolute need to know because of their law enforcement or administrative responsibilities.

Our concern is that research involving the products we regulate should meet the highest standards of scientific integrity and protection of human subjects. This concern is motivated by the realization that good science is essential to establishing the safety and effectiveness of those products. To the extent, therefore, that "whistleblowing" can disclose serious flaws in the research on which FDA's decisions are based, we welcome it. As I have tried to suggest, we believe that established systems for the monitoring of research can make "whistleblowing" all but unnecessary. But in the realization that no system is perfect, we are prepared to respond to information that comes to us through or outside those systems.

Chapter 16

COMMENTARY: WHISTLEBLOWING AND THE ROLE OF THE FEDERAL GOVERNMENT

John A. Robertson

I would like to make some remarks about the themes raised in the papers of Drs. Raub and Nightingale and about the discussion of whistleblowing generally.

My main point concerns the problem of defining the meaning of "whistleblower." Perhaps the metaphor itself causes problems. It is evocative. One imagines a person with a whistle around his neck, blowing it in a peremptory or even arrogant way, perhaps even tooting short sharp blasts that disturb our workday tranquility.

But we may gain some insight into the concept and the role of the whistleblower if we pursue the whistleblower image literally back to its original source. Let us consider the basketball referee, who legitimately carries and blows a whistle when fouls occur.* Or the lifeguard who blasts the whistle to signal that a person has overstepped the bounds of the permissible swimming area and must return. Their whistleblowing is not the least problematic, for their social role is to watch for and identify rule violations. (In both instances they then proceed almost immediately to the enforcement or sanctioning stage without a hearing or any accoutrement of due process.)

These examples show us that whistleblowing is a specialized role that is part of a particular kind of system for regulating human behavior -- regulation by rules. Behavior control through rules necessarily requires that someone observe behavior and identify violations of the rules, so that sanctions can be imposed to deter future deviations. Whistleblowing is a formal or informal role that arises in and may even be essential to rule systems, for the whistleblower functions to generate information about violations in order that sanctions or feedback to shape human behavior can occur.

*I am reminded of the envoi I overheard at an airport between two college basketball referees who had come to town to officiate a game the previous night and were now going their respective ways to the next game. As one was leaving the other he said, "Keep blowing that whistle."

With this analysis in mind, we can now see more clearly what the institutional relation to whistleblowers -- to those persons who identify norm violations -- should be. To the extent that an institution both regulates behavior by rules or norms and sets rules for behavior of its members, it needs information about rule violations. Institutions that carry on scientific research have among their goals the production of reliable scientific knowledge by methods that protect the rights and welfare of human subjects. They expect their scientists to follow certain norms or rules of conduct for these activities. The norms may be implicit, such as to not falsify data. Or they may be the formal regulations of a government agency that the institution has adopted as its own (the federally induced IRB system for protection of human subjects). A "whistleblower" of scientific fraud or unethical research practices performs for the institution the useful function of bringing information about possible rule violations to the attention of the relevant authorities.

If the system of institutional rules is to work, the institution needs to utilize the whistleblower's services. It should take action to investigate the alleged violation and should impose appropriate sanctions consistent with fairness to the person accused. In addition, if it is serious about its rules, it must also protect the whistleblower against retaliation.

I think it helpful, then, to think of whistleblowing as one part of a regulatory system based on rules. While the announcement of rules alone will have some behavioral impact, rules that are not enforced are not likely to be effective. Violations must be noted and appropriate actions taken. It is here that the whistleblower fits in, as an integral part of a regulatory system based on rules for guiding behavior.

When we take this approach to whistleblowing, the appropriate role for the federal government becomes clearer. Since the federal government has an interest in how research is conducted, it too is involved in setting norms and rules for scientific behavior. For its regulatory system to work, it must deal with the cases of fraud or unethical conduct brought to its attention. This means prompt attention, including investigation and imposition of sanctions where needed.

But the federal government has a further important role. It can, through its funding power, encourage institutions to create procedures for implementing and enforcing institutional rules about research. It can require that institutions communicate or publish the rules in question, so that affected parties know the norms that apply to them. (Unlike the norm of data falsification, some scientists may not be aware of the rules of ethical research or of their implications in particular cases.) It can also require that institutions protect from reprisals persons who allege norm violations, that violations be investigated, and that sanctions, where appropriate, be imposed. In this way the federal government can see to it that the rules for the scientific enterprise are followed in practice.

Viewing whistleblowing as the identification of norm violations, and thus as the occasion for investigation and possibly sanctions, shows that it is an essential ingredient of regulating human behavior through rules. An institution that seriously intends to prevent scientific misconduct needs to recognize that it is involved in applying rules to human behavior; the institution thus needs the services of the whistleblower to provide information necessary for its rules to be enforced. The role for the federal government in this picture is to encourage institutions to structure themselves so that scientists are aware of the norms that will be applied, so that information about violations will be forthcoming, so that complaints will be investigated, and, finally, so that sanctions will be imposed.

Chapter 17

DISCUSSION

DR. LEVINE: I have several questions. What does the bioresearch monitoring program cost? And how many people do they catch doing something serious enough to disqualify them?

I am also concerned with policies of both agencies that permit what seems to me to be punitive action before anything is proved. HHS regulations permit suspension of an investigator during the investigative process. Isn't that somehow incompatible with our usual notions of due process? And as I understand, the FDA is considering publicizing the names of those against whom there are allegations in order to allow sponsors to defend their own interests.

DR. NIGHTINGALE: I am not prepared to give you the cost of the bioresearch monitoring program. For those who don't know it, that is a series of regulations that includes good laboratory practices, the IRB informed consent regulations, the sponsor monitoring regulations (which are still proposed), and the clinical investigator regulations (which are also still proposed). But the program essentially involves field inspectors from FDA who go out, using a compliance guide based on the regulations, and look for problems of noncompliance. There are surveillance inspections and "for cause" inspections when a particular problem is found.

MS. MISHKIN: Do you have a response to his other questions?

DR. NIGHTINGALE: With respect to publicizing the names of those who are being considered for disqualification, for example, that is something that is an internal FDA policy during the investigation. For example, if the person has been thought to be involved in research misconduct serious enough that the bureau (whichever bureau it is) decided to initiate Part 16 regulatory hearings, at the time the notice is sent out the sponsors who are involved could be so notified. There has been an evolving policy along these lines. Similarly, at the time the bureau contemplates bringing the person in for discussion, there may be some need to share that information with certain individuals, primarily with sister federal agencies, sponsors, and so on. I don't want to give you a specific response as to just when we do what, because that is an evolving process which we have to articulate and make widely known. It is part of the sharing of information relative to what we are going to be doing in a regulatory sense.

When somebody is disqualified, of course, that is public information, and not only is the fact that the person is disqualified public, but the document on which disqualification is based is freely available. This document could be a 60- or 100-page report dealing with all the violations of the FDA regulations, explaining what the charges were and what the response was to those and then presenting the ultimate decision made by the commissioner of the FDA. And as you know, there are proposed clinical investigator regulations that are not finalized. We do make the attempt to convey information concerning disqualification to the state licensing board or to the agency in which the person may be employed. Disqualification has no direct bearing on the license to practice medicine, however. It is entirely up to the recipient of the information to take whatever action might be warranted. It is a matter of sharing the information. As Dr. Raub said, we are working closely with NIH in terms of developing our own procedures for sharing information in all stages of investigations.

DR. LEVINE: The other component of my question was how many people have your bioresearch monitors caught that ended up being disqualified? I understood from something you said that most of your actions arise from complaints that come in from sponsors, for example.

DR. NIGHTINGALE: Or that are picked up through routine surveillance inspections we conduct ourselves.

DR. LEVINE: Do you have any idea of how many persons the monitors identified for potential misconduct?

DR. NIGHTINGALE: I think since the mid-1960s there have been over forty persons. I'm afraid it is difficult to get more precise figures, particularly in terms of active studies. As you mentioned, the bioresearch monitoring program became quite active (in terms of setting up a program per se) in 1976 and 1977. I believe since 1977 about half of that number would have been disqualified, so it's much more active currently. We conduct three or four Part 16 hearings per year. Mostly the data is on drugs. As these new regulations come into effect, we would expect other products to be monitored.

If you want to use some index of the severity, there are very few clinical investigators who have been prosecuted, the case being good enough to submit to the Department of Justice. I think there have been two clinical investigators who have been found guilty. One has served time in jail.

Many of the people who have been disqualified have been conducting very sloppy research. It may even have been quite well intentioned, but they were carrying out ten studies at one time and were not able to pay enough attention to them. The common explanations that people give us during the various procedures that go on typically include, "Well, I thought my assistants were doing all this. I explained it to them and they were monitoring it. I am not responsible."

MS. MISHKIN: I'd like you both at some point to discuss what you think is the proper accountability of the principal investigator for what goes on in his research unit.

DR. NIGHTINGALE: I think the FDA is different in that the persons conducting the clinical research sign a form that they are the clinical investigators. By doing that they are responsible for everything that occurs. And even if they had nothing to do with it, they could end up being disqualified because of the activity.

PROF. GLANTZ: Disqualification is the most serious sanction. I am wondering if you find more than forty cases in which you take some action, whether formal or informal, which is less than disqualification.

DR. NIGHTINGALE: Well, the regulations don't provide us with anything of that sort. In fact, people who are in the midst of a disqualification procedure are perfectly free to get investigational drugs until that time, right up to the time the decision is made. And as a matter of fact, the Bureau of Drugs, for example, can recommend disqualification, only to have us reverse that decision in certain cases; until you get to the final decisionmaking process, you can't say what could or should be done.

Again, as far as FDA is concerned, I think institutions have been developing their own procedures, sanctions, and so on, which, of course, is very helpful and very useful. We mentioned that disqualification has no bearing on the license to practice medicine, and nobody has come forward to say it should.

PROF. GLANTZ: You don't send out "you should clean up your act" letters in cases that are not serious enough for disqualification?

DR. NIGHTINGALE: That is happening all along. At the end of an inspection, when the FDA field inspector leaves the premises, he issues a notice of the findings. If there are serious problems of noncompliance there, the researchers find out what the problems are. There is then a series of review procedures that take place within FDA, for example.

The next step would be when the Bureau of Drugs, or whatever bureau is involved, determines that these are very serious violations and sends a letter out listing them and asking the person to come in and respond in informal conference at the FDA. At that point the person has a chance to explain all the alleged violations. Thus, if there is not a problem, it can be taken care of right there. Many cases don't go any further than this informal conference in the bureau.

Thus, when a case gets to the commissioner's office, it is deemed to involve quite a serious problem.

MS. MISHKIN: But they are either disqualified or deemed okay by the FDA?

DR. NIGHTINGALE: Yes.

PROF. ROBERTSON: To whom does the inspector speak? The IRB?

DR. NIGHTINGALE: They go in and talk to the clinical investigator.

PROF. ROBERTSON: When do you use the IRB?

DR. NIGHTINGALE: We might talk to the executive secretary of the IRB.

PROF. ROBERTSON: But nobody else in the institution?

DR. NIGHTINGALE: I really don't know what the specific policy is. I know when we were inspected at our IRB (I am chairman of the IRB), they spoke only to me and to the executive secretary. We were inspected by the field office in Baltimore. And we passed. I think in many cases the hospital administration has to be part of that, and many of you may know more about that than I do.

MS. MISHKIN: I would like to give Dr. Raub an opportunity to respond to the questions as posed, and then we'll go on and let other people ask additional questions.

DR. RAUB: With regard to the responsibilities of the principal investigator, the NIH position, I believe, is unequivocal and is that the principal investigator is responsible for the conduct of all aspects of scientific activity under that grant.

To the extent that an incident that occurs is found to have been serious and the personal responsibility is placed on someone other than the principal investigator -- let's say some junior associate falsified data --that would be taken into consideration when the postinvestigational decisions are made regarding sanctions or other administrative actions. But there is no disputing, in my judgment, the responsibility of that principal investigator.

What Dr. Nightingale has been describing is a set of procedures associated with the regulator-regulatee relationship. For the NIH, the world is necessarily quite different. It is the relationship between the sponsor and the performer. There is, therefore, not the same degree of formality. Such formality has not traditionally been perceived as necessary. And I would continue to argue that the monitoring systems that are generally found to be necessary for the enforcement of regulations are neither necessary nor desirable in the fostering of laboratory or clinical science.

Nonetheless, we do need an array of procedures and reaction mechanisms that allow us to spot or react to the identification of real or potential problems. It is important that we seem to know what we are doing, as well as to actually know what we are doing, when we play out the hand on these.

The question Dr. Levine raised had to do with a provision in the debarment regulation. Would it be worth a minute or two?

MS. MISHKIN: Would you talk about it, please.

DR. RAUB: The debarment regulation focuses on the eligibility of individuals or institutions to be considered for financial assistance by the department. That is a code word for grants primarily but also involves a new instrument called the "cooperative agreement" that we have made only limited use of to date.

The debarment regulation provides a predictable, explicit due process. It can be triggered by the federal government. A debarred institution or individual would be unable to apply for financial assistance for a specified period of time. It is not saying, in effect, on an existing award, "We will cancel this." That is a whole different set of decisions and considerations. Rather, it is saying that if, as a result of this process, an individual or institution is judged unfit, we will not receive grant or cooperative agreement requests from that individual or institution for a prescribed period of time.

The regulation lays out a hearing process and other steps that most people I know are comfortable with in the procedural sense of building the kind of evidentiary base, providing for some structured interchange between the accused and the funding agency, and leading to some formal decision by a hearing examiner or other official.

The provision in question is the element in the regulation that would allow a suspension, which would temporarily close the door to an individual or institution pending the playing out of the process.

I should mention that associated with that provision is the requirement for expedited handling. The intent of the regulation is certainly not to invite caprice on the part of the federal agencies, but rather, when it is judged necessary to invoke the suspension decision, to get on with a full hearing as quickly as possible.

That provision is there primarily for the sake of completeness, for there could be circumstances where the fiscal abuse seems to be so severe, or the apparent violation of the rights of human subjects seems so heinous, that one would not want to await the playing out of the hand on the hearing process, thereby allowing the activity to go on or allowing that individual to continue to importune the agency for funding. Otherwise, all of those decisions would be caught up in what is normally the technical assessment through peer review.

The expectation is that suspension will be used quite rarely, but it was viewed by the drafters of the regulation, and ultimately by the secretary, as a necessary provision. It has elicited more adverse commentary than any other provision. Last fall when these regulations were imminent, either Dr. Fredrickson, then the director of NIH, or I visited with each one of the national advisory councils throughout our institutes to discuss these pending regulations, their particulars, the scientific and social and public milieu in which we viewed them. We elicited commentary and criticism. In those forums, it was frequently mentioned that suspension seemed like an undesirable, unnecessary process and violated at least the lay person's view of due process and proper quasi-judicial practice.

On another front, I testified before a hearing in the House of Representatives last spring and found that the most evocative element of our prepared testimony was the phrase "presumption of innocence." We were lectured rather sternly by several lawyers on the panel that we were well-intentioned lay persons incorrectly throwing around terms that are properly applicable only to the judicial system, that these concepts of guilt and innocence belong there only, and that in the arena of administrative practice we had best be prepared to engage in some more expedited, albeit equitable, set of processes.

I have come to understand the principle on which the above criticisms are based and believe that, as stewards of the public money, we can and must design administrative practices that provide expeditious handling, as well as answers to the substantive questions. We should not tie ourselves up in the phraseology of guilt and innocence but deal with the facts (and the appearances) related to misconduct. We should find paths that simultaneously attempt to protect the rights of the accused and the informant (as the case may be), as well as the rights of the public, who may feel that their tax dollars are being spent indiscriminately while this administrative procedure grinds on, rarely at a pace that will satisfy any of the observers.

PROF. GLANTZ: Just a question to clarify this. All that is happening in the expedited matter is that the investigator can't apply for future funds, not that he can't continue the experiment?

DR. RAUB: That is right. Our previously existing regulations for grants, but not for cooperative agreements as well, give us the authority to terminate an existing grant or suspend activity under it if there is some apparent material failure to comply with the terms and conditions of that grant.

The likelihood that we would be faced with closing the door on an application, as distinct from acting on an existing award, is rather low.

It is more likely the issues will concern whether we stop a grant that is ongoing or suspend activity under that grant. And there already was a regulatory base from which to do that.

DR. MEDEARIS: In regard to the FDA, are there provisions under which you might receive either expressions of concern or allegations from subjects of research? And, if so, have you? Or even if there aren't, have you? And to what extent?

DR. NIGHTINGALE: We would receive questions, problems, allegations from whatever source had them to offer. I think that each bureau has its own bioresearch monitoring unit that deals with allegations from whatever area they come. Although the usual channels are through the routine inspections and reports, we would entertain allegations from any quarter. This would be at FDA here and at the district or regional offices of FDA.

DR. MEDEARIS: But in terms of the actions that you carry out at the central level, is there anything directed at eliciting concerns from the subjects of research, independent of whether they would submit this to the investigator, to the institution, or to you?

DR. NIGHTINGALE: There is a particular study that comes to mind where an allegation by the parent of a research subject was sent in to the FDA. That led to an investigation, for example. So it is something that can happen in the normal course.

There are some situations, albeit rare, in which the research subjects might be contacted by the FDA. When it is done, it can only be done with the concurrence, for example, of the bureau director at FDA. This would be an attempt to match up what was present in the files of an investigator with the patient. There are, then, some rare circumstances where it would be necessary to go back and verify what happened with the subject of research.

DR. MEDEARIS: Do you know whether in any of the roughly twenty instances in which investigators have been disqualified since 1977, the event that initiated that action was reported by the subject?

DR. NIGHTINGALE: I don't know. I probably could find that out by going back into the files.

MS. OAKES: I have two questions. One is: Have the debarment regulations ever been used in connection with misconduct other than strictly fiscal misconduct? I know you said there is a catch-all provision.

DR. NIGHTINGALE: Our debarment regulation has never been used at all.

MS. OAKES: Is it too recent?

DR. NIGHTINGALE: It was published last winter. The advice of our legal counsel has been that even if we regarded some of the ongoing cases as over the threshold to trigger it, the fact that those incidents occurred prior to the publication of the regulation would introduce a new legal cloud as to whether the whole process would be valid. Since their publication last November or so,we have not had an incident that we would regard as serious enough to invoke that procedure for any purpose.

MS. OAKES: But you expect the regulations can and will be used not only for fiscal misconduct?

DR. NIGHTINGALE: My fond hope is that they will never be used at all. In reality, I think they will be used, and they will be used much beyond fiscal misconduct.

MS. OAKES: The second question: Has NIH ever recommended funding suspension as a result of research misconduct?

DR. RAUB: I can't think of a case where we have ordered the suspension of activity under a particular grant. Most of our actions have taken the form of some tailor-made sanctioning to govern prospective interactions with the group or the individual, as the case may be, regarding that particular line of research. In several cases we might have been in a situation to take that action, but the institution acted to remove the individual from a position of responsibility or otherwise made changes that rendered moot any action on the part of the NIH.

PROF. WEINSTEIN: Dr. Raub said that the principal investigators are held responsible for what goes on in their labs or in their research, whether or not they have engaged in misconduct themselves. Dr. Raub also said that institutions can be debarred. Are institutions held responsible in the same way principal investigators are held responsible, or do they have to do something positive like saying, "Yes, we know this is fraudulent, but don't you dare say anything"?

DR. RAUB: Theoretically, the institution shares that responsibility with the principal investigator, particularly with respect to the management of the funds that are involved.

In a recent highly publicized case that came to a speedy and, I believe, almost textbooklike resolution, one of the residual questions was: Given that an individual has actually confessed to falsification of data, should there be a return of the funds on the grounds that if the research at the institution was conducted under false premises, the institution shared that responsibility with the principal investigator. We therefore had to consider the issue of the recovery of funds.

On the basis of legal counsel's advice, we decided not to recover the funds; we believed that the institution had no real way of detecting this substantially earlier than it did. Its actions were not only prompt, but sound in every way. The institution was an effective partner in the resolution of the case. We chose not to attempt to recover the funds.

PROF. WEINSTEIN: It would, then, be signs of commission by the institution that would lead you to hold the institution culpable, as opposed to signs of omission, e.g. not having your nose in every lab site individually or not doing constant on-site investigations.

DR. RAUB: In general, yes.

MS. CHALK: One of the factors we have noted in previous discussions is the importance of the access to the research data that is being called into question in any charge of fraud or falsification. I wonder, Dr. Nightingale, if the trade secret legislation has had any effect on your investigating charges of misconduct.

The tag-on question is: If that is so, if the trade secret legislation presents an obstacle in confirming or denying the truth of an allegation of this sort, will there be a need -- as corporations begin to move into funding biomedical research -- for some kind of conditions or structure that would allow independent observation, independent review, of data that would normally be held under a trade secret umbrella.

DR. NIGHTINGALE: The trade secret issue is not an important one to us; we have answers to it in regard to what is going on in an investigation. If it is under our jurisdiction, clearly there is no problem in going in and looking at the records.

We, of course, are not allowed to divulge anything; we are not allowed to disclose anything that is a trade secret, for instance, in product review. In that sense, it is no different from any other activity we are involved in.

As I mentioned earlier, we send the information or the records on which any kind of case is being based back to the investigator prior to the beginning of the more formalized Part 16 hearings. Thus, the process as a whole presents no problem concerning trade secrets or related commercial interests.

MS. CHALK: You would use your own investigators rather than any kind of independent team?

DR. NIGHTINGALE: That is the way we operate. We do have a field force for compliance activity. If we ever do get into a situation where we want to bring in some outside consultants to testify on our behalf, for example, they become for those circumstances special government employees and are covered by the same kinds of prohibitions concerning the release of information. This, of course, comes up in the general product review that we undertake at FDA.

DR. RAUB: Informants of many different sources have been a useful element in the management of our programs and, at least to date, have been, in my judgment, in reasonable balance. There is, as many of you know, a hotline that the inspector general operates. Each of the episodes involved in that hotline gets some follow up.

MS. OAKES: Doesn't the Office of the Inspector General usually concern itself with allegations of fiscal misconduct, rather than improper research?

DR. NIGHTINGALE: Yes, its principal concern is financial misconduct, but its charter is broader than that. Financial misconduct is one type of statutory violation that is of interest to our agencies and the Department of Justice.

In recent months the tendency of the Office of the Inspector General has been to want to know as early as possible of a situation in which there may be something other than financial malfeasance, such as potentially fraudulent research results. But, in general, the office has been content not only to allow, but to encourage, the NIH to make some appropriate follow up and handling of that, with periodic reporting to the Office of the Inspector General. There are several reasons for this. First, the inspector general's office, as I understand it, wants to concentrate its resources on the cases where there are large amounts of money involved, primarily for the deterrent effect it would have. Second, we believe NIH is in a better position, with its greater array of expertise, to deal with the scientific and technical instances that may be associated with a case of falsification. Nevertheless, a close coordination is essential because nothing we do should be allowed to harm the position of the Justice Department, which may wish to take prosecution. We therefore try to lay out the scenario in each case and obtain the concurrence of the inspector general.

MS. CLOUTIER: I would like to ask Dr. Gaintner what steps the risk-management committee takes after it has received several complaints on the same physician that indicate he or she is incompetent?

DR. GAINTNER: The risk-management committee provides a potential method of dealing with this particular issue. There are several individuals who are involved in more than one problem. In each instance the chief of that particular department is intimately aware of the problem, as are the dean of the school of medicine and the director of the hospital. But beyond such notification, there have been no specific actions taken to discipline the physician. Our general approach is to try to correct the behavior that is leading to the problem. Only where that would be impossible would the institution take more drastic action, such as expelling a physician from the staff or asking him or her to resign. It is best to deal with those instances of behavior within the institution, where the physician's behavior can be monitored and hopefully improved.

DR. NIGHTINGALE: At what point would you, Dr. Gaintner, decide to go to the peer review committee of a state medical society in a case like that? After you have finished with your own procedures, concurrently, or what? I happen to know Maryland has an active peer review committee.

DR. GAINTNER: You're not talking about arbitration?

DR. NIGHTINGALE: No.

DR. GAINTNER: To my knowledge, we have not gone to the existing Maryland peer review group, but generally I think we'd like to try to deal with our problems within the institution.

DR. MEDEARIS: In regard to whom you send disqualifications, are the drug companies who are sponsors interested in how many you have disqualified?

DR. NIGHTINGALE: Yes, they are very interested.

DR. MEDEARIS: Does Squibb want to know what DuPont has done?

DR. NIGHTINGALE: The more basic issue is that the drug company that has marketed a drug has to go back and make sure that there is other information on which to base their current marketing. Otherwise, they might be in a situation where a drug has to be withdrawn from the market based on faulty data submitted. Other drug companies are interested because they don't want to get involved with a clinical investigator who has been disqualified.

DR. MEDEARIS: Do I assume correctly that the varous pharmaceutical companies write you regularly to get the list of those who have been disqualified, or do you send the list to the American Pharmaceutical Association?

DR. NIGHTINGALE: I don't think there has been any distribution of that list. It has been read only in congressional hearings. If they want it, I assume companies could have that list.

Again, what is the appropriate method, if any, of circulating something which is freely available as public information? And should state licensing boards be notified? Do you just send the notice of disqualification to the state clinic that has carried out the clinical investigations? But perhaps the investigator now lives in a different state. It would clearly make more sense to send the notice to some kind of central group like the National Federation of State Licensing Boards.

DR. MEDEARIS: Were any subjects injured in the research conducted by investigators who were disqualified?

DR. NIGHTINGALE: I know there were patients who were placed at risk. For example, one of the major deficiencies found in cases of disqualification has been the lack of obtaining informed consent; patients may have been injured in studies that they would not have participated in had they been informed of the risks and benefits.

Fraud, Whistleblowing, and Professional Norms

IV

Chapter 18

THE WHISTLEBLOWER AS A DEVIANT PROFESSIONAL: PROFESSIONAL NORMS AND RESPONSES TO FRAUD IN CLINICAL RESEARCH

Judith P. Swazey and Stephen R. Scher

I. Introduction

In recent months the mass media and professional publications, hearings by the Congress and the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, and investigations conducted by the Food and Drug Administration and the National Institutes of Health have drawn professional and public attention to the occurrence of data falsification and other unethical conduct in clinical research.

Whether the reported cases represent relatively rare, isolated events or are a "tip of the iceberg" phenomenon pointing to deeper structural problems in scientific and clinical research is a question that is debated and extremely difficult to resolve. Although fraud and other unethical conduct in scientific research and in clinical research with human subjects are not new phenomena, the incidence and prevalence of misconduct are unknown and are difficult to estimate accurately for a number of reasons.1 Two reasons for this, which we will discuss in some detail in this paper, involve norms dealing with obligations of loyalty and with the autonomy and self-regulation of scientists and physicians.

Other reasons include the fact that, even for researchers expert in a given field, it can be enormously difficult to distinguish between honest error in raw or published data and the types of specious findings that Woolf describes as due to deliberate falsification, "culpable carelessness," or "egregious self-deception."2 When problems in the quality of research data are detected, it can also be difficult to determine whether they may be either the inadvertent result of what seems to be, at least in clinical research, a widespread lack of methodological sophistication or advertent instances of what Langmuir termed "pathological science."3 In the case of fraudulent research, difficulties in ascertaining the nature, extent, and seriousness of the problem are further compounded by definitional disputes, both technical and normative in nature, as to exactly what constitutes fraud or "serious" fraud. Anecdotally, at least, scientists and clinicians are aware of and will discuss a spectrum of deviations from the scientific canon of strict integrity in the generation, analysis, and reporting of data. These deviations range from outright fabrication to what they describe as more "minor" and more common "massaging" or "manipulation," e.g. moving a decimal point, "juggling" statistics to produce more

positive results, or "bending" the criteria for the inclusion of patients in a clinical research protocol.

Finally, although the ethos and methods of modern science contain many mechanisms to detect and eliminate error or fraud, several aspects of innovation and research in clinical medicine seem to mitigate their effectiveness. On the one hand, for example, many innovative procedures in medicine are developed, diffused, and adopted on the basis of informal clinical work and judgment instead of more rigorous methods of research. Once accepted as routine aspects of medical practice, such procedures are seldom rigorously evaluated. On the other hand, the "organized skepticism"4 of modern science about the reliability and validity of data, which calls for the validation of research through replication, usually does not operate in large-scale collaborative clinical research studies. The cost, duration, and complexity of these studies means that they are seldom repeated, making the detection of error or fraud by a process of reexperimentation unlikely.

The occurrence of fraud in research raises complex sociological and ethical issues concerning the motivation to engage in fraud, the problems of detecting and verifying its occurrence, and the methods that are or should be used to deal with fraud when it is discovered. In this paper we will focus on patterned responses by clinical researchers to the issue and occurrence of fraud, to legitimate or good-faith whistleblowers,5 and to the individual alleged or known to have engaged in fraud. We will also discuss professional values, such as loyalty, autonomy, and self-regulation, that are implicit in these responses.

The literature on fraud and other forms of deviance6 in science is relatively sparse, especially in the area of clinical research. Most of the literature is anecdotal or case study in nature, dealing with particular known (or suspected) historical or contemporary instances, with little in the way of systematic analysis of clusters of cases or of the patterned variables that they may reveal. The literature on whistleblowing or "professional dissent" also is slim, although it seems to be expanding. The majority of this literature is also either anecdotal or of the case study variety, with only a few works attempting to analyze the patterns to be found in the genesis and consequences of the whistleblowing act.7 The literature on whistleblowing, moreover, deals predominantly with government and industry and has not, to our knowledge, examined this phenomenon in basic scientific or clinical research beyond an occasional passing reference. Much of the available writing on whistleblowing deals with legal issues, such as the need for due process protection, but not with what we see as the important sociological and ethical issues contained in the events that generate and are set into motion by whistleblowing.

In many respects, then, this paper is a speculative essay. In preparing it, we have drawn on the relevant literature, including anecdotal reports, case studies, legal and policy analyses, the sociology of science and medicine, and moral philosophy. We have also drawn extensively on the work that we are conducting in our project on "social controls and the medical profession," particularly concerning the norms and processes involved in physicians' efforts to self-govern or self-regulate their work and behavior as professionals. Finally, we have drawn on several years' experience of one of us (JPS) as a whistleblower in a case of fraud and other unethical behavior in clinical research that is currently the object of extensive commentary and investigation. This "participant-observer" experience provides us with a body of at least quasi-sociological data on fraud and whistleblowing in clinical research.

II. Science and Medicine: Professional Values and Norms

A central thesis of this paper is that the responses of scientists and physicians to research fraud and to whistleblowing are patterned by various sets of their professional values and norms. In this section we will explore three dimensions of being a researcher that seem to us most relevant to understanding the morally and sociologically complex responses to fraud and whistleblowing in the context of clinical research: the ethos of modern science concerning the integrity of research; autonomy and self-regulation as principal professional values and norms; and moral obligations to one's professional group or community. Then, in Sections III and IV, respectively, we will examine moral justifications for whistleblowing and responses to research misconduct and whistleblowing.

The Ethos of Modern Science

The process of becoming a research scientist involves (1) learning values and attitudes concerning the character of scientific investigation and the growth of scientific knowledge, (2) acquiring scientific knowledge and technical skills, and (3) learning standards of personal conduct concerning relations with other individual members of the scientific community and with the scientific community as a whole.

Merton's analysis of the ethos of modern science relates to the values and attitudes in (1).8 The values Merton views as central to scientific activity are:

(a) universalism, i.e. claims of truth are subject to universal criteria;

(b) communalism, i.e. the findings of science are a product of social collaboration and belong to the community of science;

(c) disinterestedness, i.e. claims are based on the testable character of science, with scientists being accountable only to their fellow experts; and

(d) organized skepticism, i.e. there are methodological and institutional mandates to suspend temporary judgments and to test beliefs in terms of empirical and logical criteria.9

This analysis of the values underlying scientific activity has been subject to cogent criticisms by philosophers of science as being conceptually inadequate and by social scientists as being a naive, inaccurate account of the behavior of the scientific community. Nonetheless, Merton's analysis is helpful in understanding the moral and social aspects of scientific activity generally and of whistleblowing in particular.

The knowledge and skills in (2), which are acquired during scientific training and apprenticeship, enable and qualify a scientist to engage in independent scientific investigation. Such knowledge and skills concern experimental design, the recording and analysis of data, and the presentation of research results in a form that makes the results accessible to and reviewable by other members of the scientific community.

In the context of this paper's focus on clinical research, it is important to note that there are significant differences between the values of scientists whose professional training was in a particular field of science and those who have entered research after training in medicine. In particular, the central value in what might be called the "ethos of modern medicine" is to benefit patients rather than to produce new scientific knowledge. Providing competent medical care, for example, requires that physicians assess both the risks and benefits of available therapies. Questions concerning the adequacy or inconclusiveness of current clinical research are among the factors that must be considered in planning treatment; in medicine, the "organized skepticism" of modern science is subordinated to the goal of providing medical care. It is therefore reasonable to expect that clinical researchers with professional training in medicine will tend to assess the activities of colleagues in terms of the benefit or harm to patients rather than in terms of the values elaborated by Merton. As a consequence, physician-scientists occupy a position that places them under two different and somewhat conflicting systems of values.

Autonomy and Self-Regulation

The standards of personal conduct in (3) above have been analyzed by Barber, following Parsons, in terms of a self-regulating "company of equals."10 Barber's focus is on the social and intellectual relations among scientists as equal members of or participants in the scientific community. The community of scientists is one in which each member

> is roughly equal in authority, self-directing and self-disciplined, pursuing the goal of developing conceptual schemes under the guidance of the scientific morality he has learned from his colleagues and which he shares with them. The sources of purpose and authority are in his own conscience and in his respect for the moral judgments of his peers. If his own conscience is not strong enough, the disapproval of others will control him or lead to his exclusion from the brotherhood of science.11

Central to this analysis of the relations among scientists is the claim that scientists have an obligation to respect other scientists and their work. The primary forms of social control are the process of scientific training itself and peer pressure or criticism by other scientists. Barber also argues, correctly we think, that the scientific community resists and rejects control by external authorities.12 Implicit in this view is the claim that scientists have an obligation as members of the scientific community to resolve problems and conflicts by means available within the scientific community itself rather than by seeking redress outside the community. More generally, Barber's notion of a self-regulating company of equals accurately describes the social and moral values implicit in any community of persons pursuing a particular activity, especially a community whose members have undergone a rigorous process of training and socialization. Thus, the communities of physicians, lawyers, clergy, or academicians can each be viewed as a self-regulating company of equals.

As the foregoing suggests, one of the strongest professional norms of both scientists and physicians is that of autonomy or individual sovereignty over one's work, an emphasis that structures and guides the systems of professional social control or self-regulation for both communities. In research, it is "assumed that the individual scientist knows, accepts, and follows [the] unwritten rules of scientific behavior"13 that constitute the ethos of modern science. This assumption that science operationally

must and morally should operate by individual self-regulation was stated forcefully by the physicist Percy Bridgeman:

> The process that I want to call scientific is a process that involves the continual apprehension of meaning, the constant appraisal of significance, accompanied by the running act of checking. . . . This checking and judging and accepting that together constitute understanding are done by me and can be done for me by no one else. They are as private as my toothache and without them science is doomed.14

Physicians also view self-regulation and autonomy as the hallmarks of their professionalism. And, just as Bridgeman asserts the need for and the right of scientists to self-regulate primarily through the control of themselves as individual professionals, so physicians place major importance on autonomous self-regulation by the individual physician, an orientation that is strongly emphasized and reinforced by physicians' formal training and informal socialization. In this context, based on his study of the development and exercise of social controls in a surgical residency training program, Bosk draws an important distinction between professional-self control and professional self-control. By professional-self control Bosk refers to individuals' internal control of themselves as professionals, based on both personal values and the technical and moral standards acquired during professional training. Professional self-control refers, in turn, to the shared exercise of controls among physicians, which are necessary to maintain professional standards in the group. The term "professional self-control," as Bosk points out, "underscores the corporate responsibility of the profession to regulate its own internal affairs." And, as he notes, our knowledge of how physicians manage this duty suggests that "there is a hypertrophy of professional-self control and an atrophy of professional self-control."15

In sociological terms, physicians are viewed as the dominant professionals16 within our system of medical care. Given this real authority within medicine and, more generally, the symbolic authority of physicians in our society, it is reasonable to argue that physicians are in an even more powerful professional position than scientists to exercise their claimed rights of individual autonomy and collective self-regulation in dealing with problems such as professional deviance -- despite the fact that such problems may be more visible in the area of patient care than in the relative seclusion of the scientific laboratory.

Science, Medicine, and Clinical Research

In terms of their role, clinical researchers or physician-investigators straddle the professional communities of science and medicine. However, by virtue of their training and socialization, physicians who engage in clinical research would seem to belong primarily in the occupational group of medicine with its norms, values, and institutions, rather than in that of science. While science and medicine share many norms and values, such as those concerning loyalty, autonomy, and self-regulation, we will argue that certain professional and institutional differences between them can be important variables in response to our paradigm case, viz. alleged or documented fraud by a physician-investigator (and consequent whistle-blowing) in a hospital-based clinical research setting.

It is our sense -- primarily experiential and impressionistic in nature -- that honesty in research work as a fundamental moral rule is

valued more strongly among scientists than among physicians. The explanation for this probably relates to differences in the professional socialization of the two groups; physicians tend to evaluate research in terms of harm or benefit to patients rather than in terms of adherence to the rigorous norms of scientific investigation. As we noted above, however, this creates a tension between the training and socialization of physician-investigators, on the one hand, and their role as research scientists. Adopting the position of a clinical researcher makes a physician subject to the standards of the scientific community in addition to those of the medical community. Indeed, since it is primarily practicing physicians who will be using the results of clinical research, the medical community itself relies upon the physician-investigator's conducting research in accordance with the highest scientific standards.

Membership in the Scientific Community

Both physician-investigators and scientists trained in a particular area of science become members of the scientific community through an extended training process followed by a commitment to pursue scientific research. This commitment is the source of both moral rights and moral obligations;17 one acquires the obligation to treat -- and the right to be treated by -- other members of the community with respect and in accordance with the informal rules for conflict resolution discussed by Barber. One also acquires the obligation of loyalty to the community and to its members. Membership in the scientific community morally obligates a person to conduct research in accordance with the standards accepted by the community. So conducting research is itself a condition of continuing to be a member of the community; a scientist who falsifies data or engages in other forms of unethical conduct disqualifies himself from membership and is therefore no longer entitled to claim the associated rights.

As is the case with any moral rights and obligations, those associated with membership in the scientific community are prima facie ones; they can be overridden, defeated, or counterbalanced by other rights, obligations, or by other moral considerations. Even if a person has, for example, a prima facie obligation to do something, this might not be the person's obligation, all things considered. Other moral considerations might be so important as to morally require a person to do an act that prevents him from acting in accordance with a prima facie obligation. The prima facie obligation to keep promises is not, for example, an obligation, all things considered, in a case where keeping one's promise would prevent a person from saving three innocent lives. The obligations and rights a person has as a scientist, therefore, do not prohibit him from taking into account other moral obligations and rights which he has as a citizen, friend, relative, or simply as a person.

III. Whistleblowing and the Moral Obligation of Loyalty

The history of whistleblowing as a social phenomenon, including the usage of the term itself, has yet to be written.18 In the corporate sphere, Westin notes that a series of cases in the 1960s and 1970s represent two stages of "the contemporary whistle-blowing phenomenon in American industry." The 1960s phase, he writes,

> was led primarily by employees who were impelled to action during the consumer-protection, civil rights, and antiwar movements of the 1960s. There were the

> first people to break out of the "Organization Man" ethos of total company loyalty that corporate policy dictated and social mores accepted in the forties and fifties. Almost all of these first-stage protestors lost their jobs, and also any protests they took to the courts. . . .
>
> The second stage of corporate whistleblowing, from the early 1970s down to the present, has been marked by two parallel trends: the enactment of dozens of major new employee-protection and public-protection laws by Congress and the states, and a steady rise in whistleblowing episodes. The fact that whistleblowing increased while the laws defining and forbidding corporate misconduct also increased may seem paradoxical. But the explanation lies in the fact that many corporate managements were still operating under the old assumptions and that effective legal-appeal mechanisms outside the corporate walls had not yet taken hold. The result was that most whistleblowers of 1970-1979 fared only a little better than their predecessors.19

The many documented cases of legitimate whistleblowing in industry and government during these two decades suggest that those who choose to protest what they see as illegal, dangerous, or immoral actions within their organizations can expect to face what are often extensive and enduring sanctions. These sanctions, which can be either informal and formal in nature, will usually be levied in response to internal, as well as to more public forms of, whistleblowing. Commenting on ten cases of corporate whistleblowing discussed in an anthology that he edited, for example, Westin observes:

> What is especially striking in these accounts is the identical way that these employees, slowly and in disbelief, came to realize that nothing was going to be done to correct the wrongdoing that they had identified and had brought to management's attention. Each had been warned to let it drop, to go along with management's judgment and get back to work. Some were offered inducements of salary increases and favorable job opportunities if they cooperated. Others received threats of reprisal and dismissal if they didn't shut up. All went home and pondered what continued dissent would mean to their careers and personal lives. Each also considered what a willingness to be silent would mean to their consciences, their sense of professional integrity, or their own safety at work. Each chose to go on with the protest, and, eventually, to become a whistleblower. Of the ten whistleblowers in this book, only one was able to win reinstatement, and only two others have secured partial damages in court for what happened to them. The other seven have been unable to obtain reinstatement, damages, or vindication of their professional reputations.20

Clearly, the social role of the whistleblower is subject to differing interpretations. The whistleblower may be -- and within his group usually is -- perceived and treated as a Judas Iscariot who has committed a disloyal, indeed treasonable act. Less frequently, he is seen as a Paul Revere who has sounded a tocsin against an imminent danger or as a Daniel Berrigan acting in civil disobedience for a just cause.

Both the negative responses to and sanctions against the whistleblower, we will suggest in this section, seem to have two major sources. First, in terms of group or organizational norms, the whistleblower is seen by those within the group as having violated a moral obligation of loyalty, particularly if he goes public.21 Second, if whistleblowing occurs in the context of a professional group, such as scientists or physicians, it is seen from within the group as violating professional norms of autonomy and self-regulation.

Loyalty

The obligation of loyalty is one of the obligations created by membership in the scientific community. The character of this obligation requires careful elaboration in order to understand whistleblowing and its associated phenomena. The justification for and the importance attached to the obligation of loyalty become apparent when one looks at the contexts in which issues of loyalty and disloyalty arise. It is typical for members of a community to respond to a disloyal act by asserting that the disloyal person should have used the means available within the community itself to resolve whatever problem motivated the act. Disloyal acts directly or indirectly threaten the freedom or continued existence of the community or its ability to pursue its explicit purpose or goal. Perhaps the paradigm case of disloyalty is treason, which is usually construed as a direct threat to the stability of a country. Analogously, the act of whistleblowing, which calls into question the scientific community's ability to regulate or control its own activities and members, undermines the scientific community's claim of independence from external interference, supervision, and control, i.e. its claim to be a self-regulating company of equals. A loyal member of the scientific community will, other things equal, not engage in such acts; he will attempt to resolve problems through the mechanisms for control accepted by the community as a whole.

In addition to the obligation of loyalty owed to the scientific community, a scientist that works as a member of a research group also has an obligation of loyalty to the group. This requires, other things equal, that he not engage in acts that undermine the ability of the group to engage in its research activities. For example, difficulties arising within the group should, if possible, be handled by dealing with other members of the group, rather than by seeking correction or redress by formally complaining in the first instance to persons who are not members of the group.

In the following three subsections, three separate ethical approaches to whistleblowing will be discussed. The first approach deals with cases of whistleblowing in which the research misconduct is reasonably expected to either create risks for or cause harm to persons outside the scientific community. The second approach is to analyze whistleblowing as an attempt by the whistleblower to alert the scientific community to unethical research activity in order to motivate the community to deal with a scientist's failure to observe the standards of research conduct accepted by the community. This second approach does not depend upon the expectation of harm to persons outside the scientific community; the whistleblower is calling on the community to reassert its allegiance to its own standards of research conduct. The third approach is to analyze whistleblowing as a report of unethical research conduct requiring disciplinary action by the community itself.

Whistleblowing and Harm

Whistleblowing often occurs when unethical conduct in scientific research is expected to create risks for or cause harm to persons, institutions, or interests outside of the scientific community. In such cases, a

person who, in good faith, is considering the act of whistleblowing is in a situation of moral conflict; his obligation of loyalty to the scientific community conflicts with his other moral duties or obligations, for example, his duty to prevent harm to other persons. The central issue is whether the accepted and available forms of social control within the scientific community are adequate to avoid risks or harm to persons or interests outside the community. If the potential whistleblower can act within the scientific community to avoid the harm in question, his obligation of loyalty would require him to use the available internal mechanisms for dealing with the problem about which he is concerned. If the scientific community's standard methods of control are inadequate fo purpose of avoiding the harm, then the potential whistleblower's duties or obligations to nonscientists might either override his obligation of loyalty (making it morally required to blow the whistle) or at least make it morally permissible to do so.

How effective are the means by which the scientific community controls the research of its members? It is reasonable to argue that such controls are quite effective provided that one condition is satisfied, viz. that scientists conduct and report research in good faith and in accordance with the accepted standards of scientific investigation, including the presumptions of veracity and trustworthiness.22 For example, a publication reviewing a submitted article is quite limited in its ability to determine whether the article is an honest report of research that the scientist has conducted. The reviewers would have considerable difficulty detecting fabricated or falsified data unless there was some other ground for suspicion, e.g. extremely counterintuitive results. In general, while the system of peer review is capable of reviewing the quality of good-faith research, this system is relatively ineffective in detecting fraud and other forms of research misconduct.

Research fraud may eventually be discovered through the inability to replicate substantive results. This method of discovering and thus controlling research misconduct is quite time-consuming, however, and, as we have noted, may not operate in the context of large-scale clinical trials. Given that the results of clinical research often have a rapid impact on persons outside the scientific community, e.g. patients, detection of misconduct through a failure to replicate results is not an effective control on fraud in clinical research.

Depending upon the time available to prevent the predicted risks or harm, the potential whistleblower may be morally required to take several actions within the group (sometimes referred to as "internal whistleblowing") before blowing the whistle outside the research group or institution.23 The first step would be, other things equal, to approach the scientist suspected of engaging in misconduct. The moral basis for this would be that members of the scientific community have an obligation to treat, and a right to be treated by , other scientists with respect and as members of a self-regulating company of equals. This step would not, however, be generally required in the case of dealing with a scientist engaged in research fraud. First, cogent evidence that a scientist is so acting defeats the presumptions that he is acting responsibly and that he will respond in good faith to criticism by a fellow scientist. Second, cogent evidence of misconduct negates a scientist's claim or entitlement to be treated as a member in good standing of the scientific community. Third, approaching the scientist would probably be ineffective. There is no reason to think that the scientist would take appropriate corrective action to avoid the predicted harm. Indeed, the potential whistleblower's action might provide the unethical researcher the opportunity to destroy the evidence of misconduct. Therefore, at least in cases where there is cogent evidence of fraud or other types of misconduct in research, a potential whistleblower is not morally required to discuss such misconduct with the scientist(s) directly involved.

The second step morally required of the whistleblower is, other things equal, to approach senior members of the research group; it would be disloyal to the group to fail to make an attempt to deal internally with the research misconduct. The same factors as those mentioned in the preceding paragraph may negate the group's right to deal internally with problems arising within the group. In addition, if the group fails to take effective corrective measures even when informed of the misconduct, it is reasonable to argue that the potential whistleblower has discharged his obligation of loyalty to the group. In any case, the potential whistleblower's duty to prevent harm, for example, may override or counterbalance whatever obligation of loyalty he still owes to the group.

The third step for the potential whistleblower is to report the research misconduct to persons outside the group, but within the research institution. If (1) there is cogent evidence of unethical conduct in research, (2) the whistleblower's actions within the group were appropriate in light of the factors discussed in the preceding two paragraphs, and (3) no actions have been taken by the scientist engaged in misconduct or by the group to avoid the predicted risks or harm, then the act of informing other members of the research institution is morally justified, all things considered. If conditions (1), (2), and (3) are satisfied, it is also reasonable to argue that the whistleblower has discharged -- and has not violated -- his obligation of loyalty to the group.

Even when colleagues or others in research institutions are aware of unethical research conduct, however, there are strong professional and institutional pressures to deal with unethical activity within the confines of a research group or institution. The public availability of information concerning fraudulent research, for example, undermines the reputation of the group and institution, as well as their ability to secure research funds. The self-interest of a research institution and its scientists in suppressing information about unethical conduct in research thus tends to prevent the group or institution from taking the steps required to ensure that no one is injured by the results of unethical research.

How can a potential whistleblower justify making his information known to persons outside the research institution? This depends upon the institution's response to his charges. Has the institution taken appropriate action, e.g. by investigating the charges, disciplining the scientist if the charges are found to be accurate, notifying licensing boards or sources of funding if appropriate, insuring that appropriate retractions are made in published papers, and reviewing current research data for accuracy? If the institution has failed either to carry out a good-faith investigation of the charges or to take appropriate action in order to protect the public against the foreseeable consequences of the research misconduct, the whistleblower is morally justified in making his information available to the scientific community or to the public; he has discharged his obligation of loyalty by having already used the available informal and formal institutional means of dealing with research misconduct.

Blowing the whistle to persons outside the scientific community can thus be understood as reflecting a judgment that neither the members of the scientific community nor the community's background institutions have dealt or will deal effectively and promptly with an alleged case of research misconduct having potentially harmful consequences for the public. It is also reasonable to conclude that such whistleblowing is not a disloyal act when the whistleblower has so acted to provide the relevant persons and institutions an opportunity to take appropriate corrective action in response to his charge that a fellow scientist has engaged in research misconduct.

Whistleblowing and the Autonomy of the Scientific Community

In the preceding subsection we focused on cases in which the unethical research conduct is likely to harm persons, institutions, or interests outside of the scientific or medical community. This places the potential whistleblower in a situation in which his obligation of loyalty to the scientific community and its members conflicts with his duties or obligations to the rest of society. He discharges his obligation of loyalty by pursuing various corrective measures to the research misconduct within the research community, consistent with the time constraints associated with the need to avoid the predicted harm.

Whistleblowing also may be morally justified in cases of unethical research conduct even when no harm to the outside community is foreseen. Research misconduct is itself a violation of the research standards of the scientific community; such misconduct violates a scientist's obligations to the scientific community and its members to conduct and report research in accordance with accepted scientific standards. The act of whistleblowing can be morally justified as a demand upon the scientific community to exercise its authority as a self-regulating company of equals by taking effective measures to deal with the unethical conduct of a member of the community. Drawing an analogy with civil disobedience will be helpful in elaborating this justification for whistleblowing.

Rawls defines civil disobedience as a

> public, nonviolent, conscientious yet political act contrary to law usually done with the aim of bringing about a change in the law or policies of the government.24

A civilly disobedient act is a demand to the public that it change a law or policy that is contrary to the principles of social justice. Although such an act is contrary to law, it is guided and justified by the moral principles that underlie the system of law. Civil disobedience is a call upon society to modify its social institutions so that they satisfy the society's underlying moral principles.

Whereas the principles of social justice are the relevant moral standards for criticizing social and political institutions and for guiding change, the standards of scientific investigation and the goal of scientific discovery and progress are the relevant standards for criticizing and guiding the scientific community as a self-regulating company of equals. The scientific community justifies its autonomy, its relative freedom from external controls, in terms of its ability to thereby pursue scientific investigation effectively and responsibly. This is the moral justification, the public franchise, for the authority of the scientific community to regulate its own affairs.

A whistleblower is thus in a position to justify his conduct by invoking the scientific community's moral obligation to regulate scientific activity effectively and responsibly. The act of whistleblowing, whether within or without an institution, draws attention to a failure of the scientific community to so regulate; the whistleblower demands that the community (or its members) investigate and take appropriate action to deal with the unethical conduct of a member of the community.

The purposes of whistleblowing are, in this analysis, to improve the efficacy of the scientific community's methods of self-regulation and thereby to legitimate, justify, and preserve the autonomy of the scientific community. These purposes have been achieved if the scientific community

proceeds to take appropriate action in response to the specific charges of the whistleblower.

If one analyzes whistleblowing as sugested above, it is interesting to note that the act of whistleblowing is, in fact, an expression of loyalty to the scientific community as a self-regulating company of equals pursuing scientific activity. In the same way that a person who engages in civil disobedience violates the law in order to make the legal system more just, so is a whistleblower willing to violate (or to be perceived as violating) his obligations to colleagues and to the scientific community in order to make that community regulate itself more responsibly, thus protecting the autonomy of the community itself.

Whistleblowing and Disciplinary Action

A final moral justification for whistleblowing concerns the possible authority of the community to discipline its members. The scientific community has traditionally used informal methods of social control, relying on the scientific conscience of its members, complemented by a variety of other mechanisms such as peer pressure, the concern for academic advancement, and the need to obtain research funds. In the case of unethical research conduct, these forms of control have failed.

We argued earlier that engaging in research fraud or other forms of misconduct disqualifies a scientist from membership in the scientific community, at least insofar as one views such membership as entailing moral rights and moral obligations. An investigation of the whistleblower's charges is, we believe, morally appropriate in order to determine whether the accused scientist is entitled to continuing membership in the scientific community.

At present, of course, reporting a colleague for possible disciplinary action is viewed as "bad form" or worse, and there are few, if any, formal mechanisms in place for conducting the requisite investigations. But the attitudes of scientists appear to be changing. Senior scientists have begun to blow the whistle, to make public the misconduct of colleagues. This suggests that the scientific community is beginning to recognize its obligation to ensure that its members act responsibly and ethically. Furthermore, the public censure of unethical colleagues suggests that members of the scientific community are coming to perceive membership in the community as conditional upon good-faith conduct in scientific research.

IV. Professional and Institutional Responses to Fraud and to Whistleblowing

Fraudulent Research and Whistleblowing as Professional Deviance

The researcher who falsifies data violates the obligation of scientists to be scrupulously honest in their work. This obligation, along with the presumption that scientists will so act, provides the basis for trust among colleagues and for the reliance by the public that scientists and the scientific community will regulate scientific activity effectively, both individually and collectively. The act of whistleblowing is seen by members of the scientific community as violating the obligation of loyalty to the community and as undermining the community's values of autonomy and self-regulation, especially when the whistleblower makes public his charges of malfeasance by a researcher.

On this analysis, both the person who commits research fraud and the whistleblower are defined by their reference group or groups as falling on the outer ends of a bell-shaped curve of professionally appropriate behavior. In terms of their adherence to the norms and values of their community, both are deviant professionals. Moreover, for our central case of clinical research, the anecdotal evidence suggests that in terms of physicians' norms, the whistleblower may be seen by the group as more deviant than the miscreant researcher and thus be sanctioned more strongly for his "misconduct."

Professional Attitudes toward Clinical Research Fraud

When discussing the actual or possible occurrence of fraud in research, physicians seem less distressed morally than do scientists. With respect to what is often termed "massaging data" -- as distinct from what apparently is the more negatively viewed occurrence of outright data fabrication -- the physician reactions that we have heard (and that others have reported to us they have heard) indicate a pattern of indifference: "So what? It happens all the time."

The ethos of modern science with respect to the integrity of data may also be weaker among nonphysician researchers who work in clinical settings than it is among basic or laboratory-based researchers, probably because the former absorb the prevailing norms of their physician colleagues. For example, in a conversation about the data falsification component of the Boston University Medical Center oncology research case, a well-known, hospital-based biostatistician said to JPS that he was not surprised that "corners had been cut." He also mentioned that the types of falsification he was aware of, such as changing a patient's age for protocol inclusion or "shading" responses to treatment on protocol sheets, did not "seem to be very serious."

A second frequent response by clinicians to the issue of data falsification is to offer counter "horror stories" of negligence and incompetence in clinical practice. Here, physicians seem to be implicitly invoking direct harm to patients, a central element in their professional ethic, as the yardstick by which malfeasance should be judged. If one cannot demonstrate that data falsification or other unethical conduct in research (such as failing to have a protocol reviewed by an institutional review board or to obtain informed, voluntary consent) resulted in proximate harm to patients or subjects, then the deviation from accepted norms is not considered extremely serious.

The above reasoning reflects a predominant biomedical concern with harm to the "biological person," as distinct from a concern about harm to the "social person." Analogously, MacIntyre distinguishes between "morally wronging" and (literally) harming a person.25 In this moral framework, physicians seem reluctant to assess data falsification in terms of (1) violations of moral rules or principles (independent of consequences), (2) consequences in terms of possible harm to patients who might receive a falsely validated treatment, or (3) its consequences in terms of harms either to the communities of scientists, clinical investigators, or physicians or to society more generally. The harms in (3) may include, for example, wasted expenditures of time, funds, and personnel in following a specious research trail or the diminished public trust in the integrity of scientific and medical research. The failure to appreciate the above three reasons to morally condemn data falsification is evident, for example, in an official statement by the Massachusetts General Hospital that falsified data published in the Journal of the National Cancer Institute by a physician-investigator on their staff had caused no harm "even in the field of science."26

A third type of reaction to research fraud is the tendency to "medicalize" the reason for its occurrence. That is, when scientists or clinical investigators deviate from proper conduct, their behavior is often explained in terms of a medical problem or illness, for example, "bending" under the stress of a highly competitive academic research career or manifesting a hitherto latent idiosyncratic personality "defect." In effect, this medicalization places the individual in the sick role and thus absolves him of moral blame or personal responsibility for his act.27

This type of exculpation occurred, for example, in the widely publicized 1974 case of fraudulent research by Dr. William T. Summerlin at the Sloan-Kettering Institute for Cancer Research. In his formal statement on May 28, 1974, Dr. Summerlin explained that his "painted mice" -- intended to demonstrate successful skin allografting -- and his promulgation of falsified data about corneal transplant experiments were due to the fact that

> for a considerable period of time I have been under extreme personal and professional stress, which led to both mental and physical exhaustion. Obviously, I regret these incidents and take full responsibility for my actions, but my major regret is that, as a physician, I was unable to recognize the symptoms of acute mental exhaustion which were overtaking me prior to committing these otherwise unthinkable acts.
>
> The causes for this situation are two-fold. . . . First, as the youngest member of the Institute, I was charged with the responsibility of heading a laboratory at the Institute, while serving as head of a clinical service at Memorial Hospital. Within my lab there were 25 separate research projects being conducted. . . . Further, I was personally engaged in 26 collaborative efforts with scientists in ten countries. My clinical load averaged six hours out of a day that usually began at 5 A.M. . . . Obviously, I was physically and mentally exhausting myself with this regimen.
>
> Secondly, this personal pressure generated by my schedule was aggravated by the professional pressure which is regrettably so much a part of medical research. Time after time, I was called upon to publicize experimental data and to prepare applications for grants from public and private sources. There came a time in the Fall of 1973 when I had no new startling discovery, and was brutally told by Dr. Good that I was a failure in producing significant work. Thus, I was placed under extreme pressure to produce.
>
> Because of these pressures, I became frustrated and distraught, and this culminated in the state of complete mental exhaustion which even the Center recognizes as being the only rational explanation for the incidents outlined above.28

Dr. Sumerlin's analysis of his motivation for engaging in fraudulent research activities was shared by the peer committee appointed by Dr. Lewis Thomas, president of the Sloan-Kettering Institute, to review the case. In their May 17, 1974, report to Dr. Thomas, the committee of four M.D.'s and one Ph.D. recommended that

> Dr. Summerlin be offered a medical leave of absence to alleviate his situation, which may have been exacerbated by pressure of the many obligations which he voluntarily undertook. For whatever reason, he has been led to irresponsible conduct that is incompatible with discharge of his responsibilities in the scientific community.
>
> It is the opinion of the committee that it is in the best interests of both Dr. Summerlin and of Sloan-Kettering Institute that his association with the Institute be terminated. A main factor in deciding the date of this termination should be whether Dr. Summerlin assents to the need for medical leave of absence expressly for the reasons set forth in this report.29

In clinical medicine, the needed and legitimate recognition of the problem of the impaired physician has nonetheless evoked some concern about the extent to which instances of physician incompetence, negligence, or immoral behavior are being inappropriately ascribed to psychiatric or other causes of impairment.30 Similarly, it is important to assess the appropriateness of explaining fraud and other forms of unethical conduct in research in terms of impairment, which substantially influences, in turn, the posture of colleagues, institutions, and regulatory agencies toward the researcher. There is also a need, as we shall discuss more fully, to consider the differential ways that medicalization may be used in the cases of the whistleblower and of the miscreant researcher.

It is important to note that medicalizing the occurrence of fraud or other problems in research and medical practice is sometimes legitimate and appropriate. Nonetheless, in science and medicine, as well as in other arenas of society, medicalization is also used in what we see as inappropriate ways to exculpate individual behavior and to protect individuals (and sometimes their social groups) from disapproval, punishment, or other sanctions. This is one source of the concern from many quarters that American society has become "overmedicalized." In this context, Kittrie has described a "continuing process of divestment" away from sin and crime and toward illness as the explanatory concept for various types of deviant or abnormal behavior.31 Similarly, Sedgwick has expressed his concern about "the progressive annexation of not-illness into illness," that is, our tendency to define more and more behavior and problems as due to illness rather than nonmedical causes.33

Responses to the Whistleblower in Cases of Clinical Research Fraud

The almost universal experience of whistleblowers, as we have noted, is that their actions generate a vehement, angry, and often punitive response by colleagues and superordinates. The basis for this response lies, in part, in the judgment that the whistleblower has violated his obligation of loyalty to the research community. The reactions of the scientific and medical communities to acts of whistleblowing are quite different in character and intensity, however, from those that would be expected if a physician or scientist had simply violated a moral duty or obligation, for example, by committing a crime, embezzling grant funds, or even mistreating human research subjects. While such actions would obviously be condemned, scientists and physicians would not respond to them as being malevolent attacks upon the professional community. What, then, accounts for this response?

Perhaps the most important factor in understanding the intensity of the research community's response to whistleblowing is that researchers value scientific knowledge very highly and value the research community as a means of achieving such knowledge. Researchers typically derive a sense of personal identity from their work, which is a central part of their lives; researchers achieve and maintain self-esteem through their own research achievements and those of the research community as a whole.

The act of whistleblowing calls into question the capacity of scientists and physicians to regulate themselves effectively; this charge implies that the research community has failed to pursue scientific activity autonomously and as a self-regulating group. In addition, the malfeasance of one researcher can be taken by the public as reflecting on the presumed good faith and integrity of all members of the research community. Whistleblowing thus threatens both the individual self-esteem of members of the research community and the continued prestige and existence of that community as a self-regulating company of equals, especially when the whistleblower makes his charges public.

The negative reaction to and sanctions levied against whistleblowers, as Raven-Hansen suggests, also serve as an ad hominem defense by the research community against charges that imply a failure of individual and group norms. That is, by focusing attention on the whistleblower as the deviant group member and attacking his motivations and actions, attention may be diverted, at least for a time, from the substance of the disclosure to the discloser himself.33

We commented earlier on the tendency to medicalize the occurrence of fraud in research; researchers who have committed fraud, as well as physicians who have practiced negligently or incompetently, are often placed in the sick role by their colleagues in a positively supportive way. The researcher's professional deviance is viewed as the result of impairment, which excuses what he has done. The researcher thus needs medical care, and disciplinary sanctions are inappropriate. When the professional deviance of the whistleblower is medicalized, however, he is often labeled pejoratively as "psychotic," "crazy," or "sick," a stigmatization by his colleagues that may have enduring consequences for his professional career.34

Not all acts of whistleblowers or of those they accuse of wrongdoing are medicalized, and not all attempts to medicalize such acts are successful or even appropriate. The most common alternative to medicalization is to view the whistleblower, the accused researcher, and the behavior or events that have been reported as unique or idiosyncratic. The whistleblower, for example, is seen as having been motivated by spite, professional jealousy, bad judgment, or moral self-righteousness. The accused is seen as the rare "bad apple" or flawed professional whose technical or moral shortcomings had not been previously apparent to his peers. It must be noted, however, that perceptions of the whistleblower and the accused serve to focus attention on the individuals involved in whistleblowing, thereby diverting possible criticisms that the occurrence of misconduct in research evidences systematic or structural problems in the research community.35

The negative reaction to the whistleblower as a violator of group norms of loyalty, autonomy, or self-regulation also seems to be related, in part, to the status of the whistleblower. That is, most cases to date have involved whistleblowing "from the bottom up," i.e. with subordinates calling attention to suspected or known misconduct by superordinates. In business or government, as Ewing observes, the occasion for whistleblowing "from the top down" is likely to be rare "because it is relatively

easy to police lower-echelon employees who step out of line."36 The same holds true, we suggest, in professional contexts, particularly in a field such as medicine, given the physician's professional dominance.37

If whistleblowing becomes accepted within government, industry, professional groups as a normatively appropriate act -- which, as we have argued, it should be on moral and sociological grounds -- then we would expect an increased incidence of whistleblowing involving persons having comparable professional roles and status. Such a trend should, in turn, change colleagues' reactions to the whistleblower's actions, a change that may result in the replacement of the term "whistleblower" itself.

The Whistleblower's Perception of Himself

The research community's hostile response to whistleblowing often has a devastating psychological impact on the whistleblower himself. Despite the fact that a whistleblower has acted in good faith, as a matter of principle, on the basis of compelling evidence, and out of deep concern for the goals of the scientific community and for the community itself, he may continue to be plagued by self-doubt concerning the moral propriety of his act. The hostile reaction of his fellow researchers and the associated claim of disloyalty tend to be perceived by the whistleblower as a charge that he has been a bad member of the community, that he has unjustifiably threatened the community. Even though the charge of disloyalty is itself only a claim that the whistleblower has violated a moral obligation, the charge has the consequence of calling into question both the whistleblower's sense of identify as a good-faith member of the research community and his sense of worth or self-esteem. The same psychological phenomena therefore underlie both the response of scientific and medical communities to the act of whistleblowing and the response of the whistleblower to the charge that he has been a disloyal member of the community.

Conclusion

Whether fraud or other unethical conduct in research are relatively rare or relatively prevalent phenomena, it seems to us to be a profound moral and sociological error for professionals, hospitals, and other social organizations to treat instances of such misconduct and consequent whistleblowing as idiosyncratic events. Such a response both ignores the normative patterns that underlie the responses to the parties involved in whistleblowing and diverts attention from the troubling issues of professional, institutional, and societal responsibility and accountability that the phenomenon of whistleblowing throws into sharp relief.

References

1. The history of science is sprinkled with instances of alleged or documented cases of "cooking," "fudging," or falsifying data. Some historians, for example, have argued that there is evidence indicating that such eminent figures as Ptolemy, Newton, and Mendel engaged in data falsification. Documented cases include the famous Piltdown Man Hoax and the fabrication of data on I.Q. and social class by the eminent psychologist Sir Cyril Burt. Occasionally, revelations of fraud in research generate a

flurry of discussion and debate about the causes and magnitude of the problem. One such recent bout of concern about fraud occurred in the mid-1970s following the disclosure of the Summerlin case at the Sloan-Kettering Cancer Institute, data falsification charges filed by the FDA against G. D. Searle and Co., and several other cases (B. Rensberger, "Fraud in research is a rising problem in science," New York Times, Jan. 23, 1977, p. 1). Most recently, debate about the magnitude of fraud in clinical research was triggered by 1980-81 accounts of and investigation into four cases (W. Broad, "Fraud and the structure of science," Science 212 (Apr. 10, 1981), 137-144). Each disclosure or set of disclosures about research fraud generates assertions and counterassertions about the magnitude of the problem, ranging from the insistence of Dr. Philip Handler, President of the National Academy of Sciences, that "the fraud issue is grossly exaggerated" to the equally strong conviction of noted microbiologist Ernest Borek that "those of us in the biological sciences know that [the reported] cases are but the tip of the iceberg." (W. Broad, "Congress told fraud issue 'exaggerated'," Science 212 (Apr. 24, 1981), 421; E. Borek, "Cheating in science," New York Times, Jan. 22, 1975.)

2. P. Woolf, personal communication.

3. Langmuir, I., General Electric Research and Development Center Report 68-c-035 (1968, unpublished transcript).

4. Merton, R., "Science and technology in a democratic order," J. of Legal and Political Sociology 1 (1942): 115-126.

5. We use the term "legitimate whistleblowing" in recognition of the fact that some whistleblowers are motivated by spite, jealousy, an attempt to avoid facing justified sanctions for their own ineptitude or misconduct, etc., rather than by a genuine moral conviction that a problem exists that demands responsible attention and action.

6. We are using the term "deviance" sociologically to mean departing in some way from an ideal norm or standard of behavior. That is, society or given groups in society have sets of norms or rules, and those who violate those rules are defined as deviant. The vast body of research on deviance, until the 1970s, focused primarily on the questions "Who breaks rules?" and "Why are rules broken?" More recently, sociologists have asked two other questions that have provided new perspectives on deviance: "When is norm violation held to constitute deviance?" and "Who makes such decisions?" See R. Hingson et al., In Sickness and In Health: Social Dimensions of Medical Care (St. Louis: C.V. Mosby Co., 1981), pp. 104-110.

7. See, for example: Chalk, R., and von Hippel, F., "Due process for dissenting whistle-blowers," Technology Review, June-July 1979 pp. 49-55; Ewing, D., Freedom Inside the Organization (New York, McGraw-Hill, 1977); Westin, A., Whistle-Blowing! Loyalty and Dissent in the Corporation (New York: McGraw-Hill, 1981).

8. Merton, R., "Science and technology."

9. Ibid.

10. Barber, B., Science and the Social Order (Glencoe: Free Press, 1952), pp. 139-156.

11. Ibid., p. 144.

12. Ibid.

13. Nelkin, D., "Social controls in the changing context of science." (Draft paper for Medicine in the Public Interest project on Social Controls and the Medical Profession, June 1981)

14. Quote in G. Piel, "Sciences policy as cargo cult," Lecture to 31st National Conference on Advancement of Research, Alburquerque, N.M., Oct. 5, 1977, p. 8.

15. Bosk, C., Forgive and Remember: Managing Medical Failure (Chicago: University of Chicago Press, 1979), pp. 182-183.

16. Freidson, E., Professional Dominance: The Social Structure of Medical Care (N.Y.: Atherton Press, 1970).

17. For an illuminating discussion of the moral aspects of membership in a community, see Ladd, J., "The Concept of Community: A Logical Analysis," in Community (Nomos II), ed. Friedrich, C. (New York: Liberal Arts, 1959), pp. 269-293.

18. As Westin notes, the idea of an employee or professional "blowing a whistle" "is actually a rather strange image to use. Normally, someone who blows the whistle is the dominant authority in a social situation," such as a referee or policeman. But those who blow the whistle to protest wrongdoing are "not invoking the whistle of authority but the whistle of desperation." Westin, Whistle-blowing!, pp. 1-2.

19. Ibid., pp. 13-14.

20. Ibid., pp. 132-133.

21. One of our favorite statements of the demand for loyalty to one's group is the following rule of a private bus company: "The company requires its employees to be loyal. It will not tolerate words or acts of hostility to the company, its officers, agents, or employees, its services, equipment or its condition, or... criticisms of the company to others than...superior officers." (Quote in Ewing, Freedom Inside the Organization, p. 9).

22. These presumptions have been mentioned in the context of whistleblowing. See Hixson, J., The Patchwork Mouse (Garden City, N.Y., Anchor Press/Doubleday, 1976), p. 218.

23. These moral requirements are prima facie ones that may be defeated or overridden by other factors.

24. Rawls, J., A Theory of Justice (Cambridge: Harvard U. Press, 1971), p. 364. Rawls discusses civil disobedience in Sections 55 (pp. 363-368) and 57 (pp. 371-377).

25. MacIntyre, A., "Commentary: does risk-benefit analysis apply to moral evaluation of social science?" (Presentation at conference on ethical issues in social science research, Kennedy Institute of Ethics, Georgetown University, Sept. 1979)

26. New York Times, June 28, 1980.

27. Fox, R. "The medicalization and demedicalization of American society," Daedalus 106 (1977):9-22.

28. Hixson, Patchwork Mouse, pp. 220-221.

29. Ibid., p. 201.

30. American Medical Association, Council on Mental Health, "The sick physician: impairment by psychiatric disorders, including alcoholism and drug dependence," J. Amer. Med. Assoc. 223 (Feb. 5, 1973), 684-687.

31. Kittrie, N., The Right To Be Different: Deviance and Enforced Therapy (Baltimore: The Johns Hopkins Press, 1971).

32. Sedgwick, P., "Illness -- mental and otherwise," Hastings Center Studies 1 (1973):19.

33. Raven-Hansen, P., "Dos and Don'ts for whistleblowers: planning for trouble," Technology Review, May 1980, p. 4.

34. The long-term effects of the act of whistleblowing on an individual's career can be understood sociologically in terms of Goffman's concept of putative social identity. By this term Goffman refers to the way that we structure our relationships with people we do not know well by giving them a social identity and then structuring or interpreting their behavior in terms of that putative identity. Putative identities related to what is socially defined as deviant behavior are particularly powerful and enduring. For example, we think of Mr. A and define his behavior in terms of his being "an alcoholic," or Mr. B. as an "ex-convict," or Mr. C. as "a whistleblower." Goffman, E., Stigma (Halmondsworth, England: Penguin Books, Ltd., 1968).

35. For a discussion of possible structural problems in science, see Broad, W., "Fraud and the structure of science," Science 212 (April 10, 1981), pp. 137-141.

36. Ewing, Freedom Inside the Organization, p. 75.

37. Instances of whistleblowing that involve parties of equal or comparable status are, to our knowledge, relatively rare. In terms of an action such as filing a formal complaint with a state board of registration in medicine, for example, we are aware of only one such complaint signed by a physician against another physician in the Commonwealth of Massachusetts. That case involves allegations of fraud and other unethical conduct in clinical research, and the complaint was cosigned by one professor of legal medicine and one of medical ethics (which many within the institution involved in the case viewed as a particularly unholy trinity).

Chapter 19

COMMENTARY: BUREAUCRATIZED SCIENCE AND RESISTANCE TO WHISTLEBLOWING

Deena Weinstein

My responses to this fine paper come from two separate areas.

First, I have done a lot of research on bureaucratic opposition, of which one type is whistleblowing, in all sorts of organizations; I am interested to see that scientists in their roles as members of organizations don't differ particularly from members of other organizations.

Second, I have done some work on fraud in science, looking at the reasons for it and trying to get some assessment of how extensive it is. I think that I am about to give up on the latter question. In a study done by the British journal, New Scientist, some years ago, subscribers (scientists) were asked to answer anonymously a questionnaire of their personal knowledge of intentional fraud in science. This survey included not just biomedical science, but all of the natural sciences. And of the respondents, 92 percent claimed to have personal knowledge of it. There are methodological difficulties with the study, but it is suggestive.

I suggest that rather than concerning ourselves with the extent of fraud in science, we recognize that fraud does occur from time to time and treat the issues raised in Drs. Swazey's and Scher's paper in that context. I don't think that IRBs, no matter how we reform them, are going to be able to monitor things to the extent required to prevent fraud; there will always be fraudulent research that gets through various nets. Sometimes fraud will come out in the wash. That is what the sociologists of science have always supposed, that work is always going to be replicated. Lots of work isn't replicated, so not everything comes out in the wash. But blowing the whistle, as we have been calling it, is another way in which to expose fraud in science.

The paper of Drs. Swazey and Scher deals with an underlying structural conflict in institutional science between the loyalty to a group of scientists -- whether that group be the immediate work group, the employing organization, or the scientific community as a whole -- and commitment to the norms of classical science, particularly what Merton calls organized skepticism, that is, not to believe that what you are reading is the God-given truth.

As science becomes an increasingly complex endeavor that depends on the support of external institutions, the perpetuation of the means to conduct scientific activity has become a more important norm of science

than any of those norms identified by Merton, which are identified as the means of pursuing the truth. The idea of keeping the project going becomes a goal in and of itself, in addition to what the project is supposed to be looking for. As the authors correctly point out, whistleblowers in science are considered to be treasonous by their colleagues; the basis for this treason is that they are going against the group, not the ethos of science per se. In terms of classical science, whistleblowing would merely be an example of the norm of organized skepticism. Therefore the whistleblower should be the hero but is not.

Resistance to whistleblowing makes sense in a structural context as a way of protecting science, which has been organized into bureaucracies, from external scrutiny, control, and negative sanctions. As science has become more and more integrated into the rest of society -- which I think is unavoidable, but terrible for science -- science needs to have more and more protection from that society in order to retain its identity as science (lest it become a handmaiden to politics, industry, or other interest groups).

In classical science there is a loyalty to the pursuit of truth, not to any group of persons or to any organizations. Loyalty to the scientific community comes within classical science only when institutions outside of science attempt to dictate the conduct and results of inquiry. In present institutional science there is such interpenetration of science with other institutions that science is always politicized and is always struggling to maintain its control of resources and discretion, just like other institutions.

In some sense, what science has been doing is using the ideology of classical science to defend its own autonomy today. If those of you who are familiar with various congressional hearings do a content analysis of why we scientists claim to need all sorts of money for science, you will find that we are using classical science as our ideology and making the assumption that this is all for the pursuit of truth. But then we tell them, "No, basic research will always have a payoff to society as well."

The authors seem to imply that it is to everyone's benefit that there are whistleblowers. But I don't think everybody is benefited by whistleblowing, despite the fact I think it's a good thing. And to recognize the negative consequences of whistleblowing is important in considering what recommendations we would make with regard to it.

Obviously, a specific institution (for example, a university research institute) is harmed when whistleblowing is made public, and specific researchers are harmed as well. It is not in their best interest. It may also not be in the best interest of science, which is a pursuit that requires the support of society; as more and more whistleblowing is made public, there are negative reactions to science. Such reactions threaten the continued funding of research and undermine society's trust in science and its findings.

That the whistleblower is seen as more of a traitor than the miscreant who is exposed is because the whistleblower's actions cause more harm to bureaucratized science than the fraud itself. Science, of course, will remain bureaucratized and retain a vital social function; it is naive to believe that it will be able to police itself. Whistleblowing is one way of controlling scientific activity that does not require a policeman in every laboratory -- if there are proper receptive channels to receive the whistleblower's information.

The authors of the paper are somewhat caught between the acceptance of the premise that loyalty is owed to a particular group of scientists by the individual scientist and the premise that scientists should conform to the norms prescribing disinterested pursuit of truth. Loyalty and disinterestedness do not necessarily, or even most often, coincide, and as social beings we have a difficult time dealing with the disinterested pursuit of truth when it conflicts with loyalty to people.

At one extreme, the loyalists will do everything to safeguard and expand the budget of a research project, even if that means covering up fraud or inventing excuses for it. At the other extreme, the disinterested person will follow the norms of science, including skepticism, as a means to an end.

The authors also point out the position of the doctor-researcher, who has another ethic, viz. helping patients, that often supersedes the ethic of disinterested truth. Thus we have three different values that can be conflicting, in addition to the fact that very little research is conducted by a single individual; in any given research lab, you have people who are walking around with different ultimate values concerning ongoing research.

I think this situation is usually healthy. It also explains why whistleblowing sometimes occurs. Most scientists will find themselves in between, acting as neither the yogi nor the commissar. Disinterested science is universalistic, whereas loyalty to a particular scientific group is particularistic. Whistleblowers, whatever their motives may be, ground their actions in universalism.

Whistleblowers tend to be straight arrows. They tend to be somewhat naive about the political system. They probably wouldn't blow the whistle if they were less naive. In interviewing whistleblowers, I asked them if they would do it again: they would think twice about it.

If we can distinguish the personal motives of the whistleblower from the grounds of their bureaucratic opposition, we can ask whether their actions are grounded in fraud or not, i.e. whether their opposition has a legitimate basis. The legitimate basis of their opposition may not be the actual psychological motive of whistleblowers. The actual motive, the psychological motive, might be: "He has refused my sexual advances" or "I want his job." There's a whole range of possible psychological motives, none of which wants to be seen in the light of day. But I think it is irrelevant to even concern ourselves with the motives; the legitimate grounds are the only things with which we need to be concerned.

Some oppositionists are motivated by legitimate grounds. That is, they are very much concerned about the goal of science -- the truth --and will oppose or report misconduct because of their interest in truth. Others will oppose misconduct because of other reasons, but their actions nonetheless have legitimacy in terms of science's concern for truth.

The dilemma of the whistleblower concerns how much to concede to particularism. How much research misconduct do you let go by? To what extent are you obliged to go through all of the channels in reporting the misdeed?

The authors describe the modus operandi of the whistleblower who first confronts the person doing the misdeeds and then goes to one superior after another until the whistleblower finds somebody who will listen to him or her and take the charges seriously. How many of these channels should the whistleblower be expected to go through, especially if those channels are not going to be responsive?

One need not be all that sophisticated to recognize that this is the way they have done things in this lab for years; persons in positions of authority will not consider condemning a researcher who pulls in a lot of grants. They often believe that one should just let him do his own thing and not make any trouble.

In looking at attempts to oppose some fraudulent research, it is important to distinguish between two modes of operating. One is to inform, and the other is to take some other kind of direct action. In informing, if you go up through channels within the organization, when does it start to be called whistleblowing? When do you start being seen as a traitor to your group? That depends on how that group is defined. To whom do you go when you inform outside? Do you go to the federal government? Some people have gone to professional organizations, and professional organizations have become concerned about how they should respond to whistleblowers in given situations.

Direct actions include things like a lab assistant's destroying the research data itself, sabotage, and sending out the research report to a journal with obviously wrong figures or statistics. I am not advocating such actions, but they are ways in which one can prevent fraudulent science from being accepted as gospel. My information on those sorts of activities comes from people who have a master's degree (or less) and work as lab assistants. I also have a couple of cases where people have told me of their own direct actions.

Finally, whistleblowers expect retaliation; they can't ever be fully protected. I think we should recognize that. But they can be at least formally protected with regard to their occupatonal positions. You can't do anything about people liking or disliking them. Nor can you control, for example, the quality of the letters of recommendation that whistleblowers will receive.

Chapter 20

DISCUSSION

PROF. ROBERTSON: We are dealing with two themes here. One is fraud in research; the other is unethical research. Whistleblowing can apply to each.

The paper and the comments have focused on whistleblowing in cases of fraud. I wonder if your same analysis would apply to whistleblowing in unethical research when we are not dealing with the same accepted kind of classical science, finding out the truth, but with a set of norms that is not totally accepted by many scientists. I wonder if the same thing would occur.

In the Straus case at Boston University, had there not been any fudging of data, but merely failure to go through the IRB and not getting consent in some cases, do you think that would have surfaced and posed the same problems?

DR. SWAZEY: If the Straus cases had only involved "not getting consent," I doubt that the problem would have surfaced. Failures concerning consent appear to be fairly common and are probably not viewed as a serious breach. When whistleblowing does occur in cases of ethical misconduct other than data falsification, I think the patterns are much the same.

DR. SCHER: Certainly the part of the paper dealing with harm to individuals outside the scientific community is applicable, independent of the specific type of violation that leads to whistleblowing.

On the other hand, the justification which concerns adherence to the standards of the scientific community itself may not apply; the community is not going to perceive that as a clear or important violation of its own standards.

DR. SWAZEY: The applicability of our analysis may also depend upon what community -- scientists or physicians -- one is talking about.

PROF. ROBERTSON: Is the whistleblower on unethical research seen as more deviant?

PROF. WEINSTEIN: No, if you consider unethical research that harms patients in some way, this violates the norms of medicine. When the

violation is grounded in the norms of bureaucracy, however, few people would view the violaton as being serious.

MS. MISHKIN: That would only be, it seems to me, if people perceive what you call bureaucracy as not grounded in preventing harm to the patient or subjects.

PROF. ROBERTSON: Here we get into the difference between a harm and a wrong, and in the ethics of research many things may be harms and not wrongs. There is less motivation to report wrongs. And if somebody does, he is just complaining about a wrong though nobody is hurt. Thus, he is seen as more deviant, and his position is all the more precarious. It is therefore less likely that people will come forward with complaints of that sort.

DR. SWAZEY: I think Dr. Scher and I tried to explore what we see as a differential response among physicians and scientists to issues like data falsification. The scientific community sees it as a very strong violation to fake data, but physicians do not view it as that serious.

DR. GAINTNER: I disagree. Faked clinical data would be harmful to the patient.

DR. SWAZEY: I don't agree with it either. I am saying that is a response we have heard quite often. I am being the messenger, not the advocate, for the position.

DR. LEVINE: I believe Dr. Swazey is correct; scientists see data-faking per se as the most egregious offense, and physicians do not. I think most physicians would see data-faking as an offense, but not quite a violation of the rules of conduct of the profession. This may relate to the tradition in medicine of benevolent lying, withholding the correct diagnosis, and so forth. Physicians have become experienced at lying for the good of others.

PROF. GLANTZ: People are considered whistleblowers when they disclose intentional wrongdoing. People who are whistleblowers are not disputing scientific subtleties and are not just saying, "I disagree with your interpretation of the data" or "Even though it was done in good faith, your research wasn't that good."

Whistleblowers deal with people who try to hide what they have done or deal with intentionally falsified or fraudulent data of some sort. Therefore, it seems to me the accused are acting outside of science, acting in the guise of scientists at that point, but they are not scientists when they make up their own data.

I am wondering: When that is exposed, why should the whistleblower's act be perceived as an attack on all of science?

PROF. GRAD: Whistleblowers in science are not so generically different from whistleblowers in industry and whistleblowers in government. It is simply how you define the loyalty to the group. I would suggest that if you take a look at what happens to whistleblowers inside a religious community, it is also very similar. I think the reactions are also very similar in these different contexts.

We educate our kids to be good little politicians. I think that is why the reactions to whistleblowing are so similar, despite superficial differences in settings. The business of playing along to get along is inculcated very early. "Don't make trouble and don't call undue attention to

yourself in ways which are different from the group norm." "Tell the truth but for God's sake don't tell it out loud in the wrong place at the wrong time." We, in effect, discourage whistleblowing from a very early age. We shouldn't be surprised, then, if people who do blow the whistle are regarded as poor sports, as oddballs, outside the educational norms that keep our society glued together.

Again, I am in favor of whistleblowing, but one should not be surprised that whistleblowers are not universal heroes. It seems to me they have violated what our society has taught them. If we want to have more effective whistleblowing and if we want to have more honesty in government and science, for example, I suspect we'd better start with the educational and school system. That is a very, very long way to go.

MS. MISHKIN: But, on the other hand, it is alright to have disagreements with people over data interpretation and to have those disagreements in the open. It is only when the person you are disagreeing with is a bad actor or person that your motives for exposing him or her in public come into question.

I think there is an assumption that whistleblowers are blowing the whistle for illicit reasons of some sort, either to advance themselves or because they have some personal problems with the investigator. Later on we might discover there are other motives.

DR. SWAZEY: To expand on Ms. Mishkin's remark, the ascription of such unsavory motives to the whistleblower is part of their treatment as deviants. "We don't have to take what they are saying seriously because they are motivated by X, Y, and Z." It is part of the pattern of response. And whistleblowers obviously violate various norms, whether in government, industry, academia, or the hospital.

PROF. GLANTZ: Which norms?

DR. SWAZEY: Most importantly, misplaced norms of loyalty to colleagues and to the institution.

DR. GAINTNER: It is not so much that the whistle is blown, but to whom. Where do you blow it? I believe that the community of scientists would look favorably on -- and strongly support -- the whistleblower if that whistle were blown in the community of scientists. "Let us take care of our dirty linen. Let's not air it outside."

If whistleblowing is kept within the scientific community or within that institution, the individual is not considered deviant. It is when the individual skirts that system, goes outside, that one says, "Hey, what did we do wrong? Maybe we need to clean up our system inside."

MS. MISHKIN: Can you elaborate somewhat on what you have seen as a result of your risk-management program?

DR. GAINTNER: I would say internal whistleblowing -- that is, pointing out to the appropriate institutional authorities where there have been serious problems related to medical management -- is a very common phenomenon. If that individual, however, goes out to an attorney or goes to the state commission, for example, then that person's behavior would be considered deviant; the assumption is that the institution has an effective process to deal with such problems. And the question is: Why go outside? It seems to me that the legitimate purpose of going outside is to

rectify the situation. And it seems to me that there is an institutional obligation to bring misconduct to the attention of persons having institutional authority, which would enable them to deal with the problem and perhaps avoid its recurring.

It has seemed to me that within the natural sciences, the people who have exposed data-fakers -- not especially publicly but within the community of natural scientists -- have generally been the most senior people. We have seen them show up at meetings and withdraw papers from programs, for example, whereas within medicine the whistleblowers, it seems, have a tendency to be the younger people.

I wonder if Professor Weinstein has noticed any systematic differences between natural scientists, social scientists, physicians, and so on.

PROF. WEINSTEIN: In most of the data I have collected, it has been the underlings who have been the ones who see what is going on.

DR. SCHER: I want to underscore a recurrent theme in our paper. The norms of the scientific and medical communities reflect a presumption that members of the community will act in good faith. The whistleblower is claiming, however, that a scientist or physician is not acting in good faith. This allegation throws everything out of kilter. For example, the usual rules for relations among colleagues are based on respect and autonomy. But suddenly you have a colleague who does not, at least allegedly, deserve the respect of other members of the community. How should this misbehaving colleague now be treated?

The same presumption of good faith underlies the emotional reactions and perceptions of the people in the community. Scientists perceive colleagues in terms of this presumption of good faith. When fraud or some other unethical conduct occurs, I think the tendency is to continue to perceive the misbehaving member of the community as acting in good faith. This underlies, in part, the community's hostile reaction to the allegations of the whistleblower.

Professors Grad and Weinstein suggested that whistleblowing in science is the same as whistleblowing in other occupations. I think it is not. In business settings, for example, contractual or legal obligations tend to replace the moral duty of loyalty, the sense of community that exists among doctors, scientists, or other professional groups. Therefore, I think that one has to be careful in applying our analysis to other occupational settings.

PROF. GRAD: I would say that in business the issue of loyalty depends on what level of the corporate organization one is talking about. When one is talking about the higher levels of the corporate organization, I think the true religion, the true unity of the organization, is as strong as, or perhaps even stronger than, in science. It depends on what community you identify yourself with.

The top echelons in the corporate hierarchy differ very little from the scientific ones. On the other hand, if one takes the lower level of the organization, I think Dr. Scher's point is well taken. But I think that is also true in the scientific enterprise. The lab technician who sees wrongdoing has no particular loyalty to the institution, or at least need not have the same kind of loyalty as someone who is a scientist in the same institution.

I regard the similarities as stronger than Dr. Scher, though there are obviously some differences as well.

MS. OAKES: First, the line between professional disagreements and professional misconduct is frequently blurred. Thus, a favorite tactic of the institution or of the respondent to a whistleblower's charge is to say, "Ah, you don't understand. You have simply a different point of view. There is nothing here that is fraudulent or wrong or unethical."

Second, I want to respond briefly to one of Dr. Gaintner's remarks: "Institutions have a process, so why doesn't the whistleblower come to us first?" This assumption may be correct in the case of Johns Hopkins or Yale but is often not true of other institutions. At least in my experience, whistleblowers do not go outside the institution unless they are forced to do so. They do not lightly rush to court or rush to the newspapers. They do so only when they perceive that there is no realistic alternative. That perception may be incorrect, but usually it is a good-faith perception.

DR. LEVINE: How does that make Johns Hopkins and Yale different?

MS. OAKES: Both institutions appear to have an extraordinary commitment to receiving complaints of wrongdoing and to doing something about them. That may have something to do with the ethos of the particular institution or with your personal support for the whistleblower or complainant. I do not think that this same commitment exists in a majority of institutions.

DR. GAINTNER: Is there any data on this?

MS. CHALK: The Merit Protection Board, I think, did a survey of government employees about knowledge of wrongdoing within their government offices and about what kind of response the employees, acting for themselves, would make in response to that knowledge. The survey seems to show that a large percentage, 70 or 80 percent of the employees interviewed, had knowledge of some kind of wrongdoing within the government. A very limited number of those employees who claimed such knowledge indicated they would act upon it, but not for fear of retaliation. The predominant factor seemed to be apathy. They believed if they brought their concerns to the attention of someone else, nothing else would be done in response to it.

Based solely on that survey, there is the belief that there needs to be a commitment by the instituiton to making some kind of response to the allegation. That seems to be one of the critical factors in encouraging employees to bring their knowledge to the attention of the institution.

MS. NORDIN: There seems to be a pattern that an institution reacting poorly the first time subsequently builds a good system. Many institutions apparently believe, "That wouldn't happen here, and therefore we don't need to worry about it." There are a number of major research institutions that are totally unprepared for an occurrence of research misconduct.

PROF. GLANTZ: I would like Dr. Gaintner to clarify a point. He was talking about a risk-management system that many hospitals have. But it seems to me the risk management may come about from patient injuries, neglect, or accidents -- someone slips and falls on waxed floors -- not intentional wrongdoing. Thus it seems that the Yale system is set up for a different purpose than Johns Hopkins' risk-management system. Can you tell us, Dr. Gaintner, if that system is designed for the type of whistleblowing that we are talking about here, somebody doing fraudulent work in a laboratory.

DR. GAINTNER: I agree, but the reason I mentioned it here was to see if there were some possible application to fraudulent research.

MS. CHALK: I have two questions for Drs. Swazey and Scher. First, is there anything to show how uniquely American the whistleblowing phenomenon might be? Have you looked at any cases involving fraud or falsification of data in any other country, for example, to see if there is a different kind of response in terms of the norms that are involved?

Second, what are some of the factors that influence the whistleblower to seek reform, rather than saying, "This is a bad situation; I don't want to be part of it," and resigning.

The book Resignation in Protest describes what seems to be the British response to a bad situation: to speak loudly about it after you've left.

DR. SWAZEY: I think resigning in protest raises very interesting issues. Anecdotally, it appears that many whistleblowers feel that resigning is analogous to the common medical response, "Get the miscreant physician out of the hospital and the problem is over. He has gone away and that's the end of the case." I think many whistleblowers feel they have a moral obligation to stay there and try to do something about it.

PROF. WEINSTEIN: There seems to be very little difference between whistleblowers in Britain and in the United States.

PROF. ROBERTSON: Most institutions do not have any mechanisms set up to receive complaints, to protect complainants, or even to take appropriate action. Most IRBs don't know what to do.

DR. GAINTNER: I think that most institutions do have ways of responding to inappropriate behavior on the part of faculty and students. I think it is inappropriate to say that because an IRB has not responded, institutions are therefore incapable of responding.

PROF. ROBERTSON: I am not saying institutions are incapable of responding to misconduct. I hope they are capable of responding to it. The point is that they haven't set up mechanisms, procedures, or structures for so responding. An if the IRB is not able to respond, it may be that no one else in the institution is, either; no one other than the IRB may have given much, if any, thought to the problem of unethical research.

DR. LEVINE: I want to suggest that one of the reasons there seem to be such differing perceptions of what institutions do or are capable of doing is that we are in a time of rapid change. We are in a time of rapid change because, among other reasons, there has been substantial publicity given to some issues. And I think there are also other things going on in the background that are causing us to think about these issues.

For example, Dr. Gaintner has discussed self-insurance and risk management at Johns Hopkins. In the past you almost never saw a physician claim that another physician had done anything wrong. The lawyers here will probably testify to the fact that that made some of their malpractice litigation very, very difficult. Physicians are still rather reluctant to go to court and testify that another doctor did something wrong. But physicians are willing to go to the risk-management office within their hospital and say, "Hey, there's something going on here that we'd better clean up or else we are going to be in trouble (rather than the Aetna Insurance Company)."

At Yale we never had any mechanism to deal with allegations of sexual harassment until we were sued. We had five women and one man allege that our faculty was engaging in sexual harassment. After the university won the case, a sexual harassment committee was established. We had been writing "do not resuscitate" orders ever since respirators were invented, but we never did anything about it until two events struck our community. One is that a lawyer lectured to the nurses saying that if they followed an unwritten "do not resuscitate" order and the doctor then denied having spoken it, the nurse could be held independently liable. The nurses demanded that we have a formal policy. And the other concerns one of my distinguished colleagues who reported to the newspaper -- and got banner headlines -- that M.D.'s have a license to kill. In the aftermath of these developments, we began to develop procedures and take them seriously.

Chapter 21

WORKSHOP RECOMMENDATIONS*

After two days of discussion, participants in the workshop reached consensus on several major points concerning issues related to misconduct in biomedical research. Additional issues were identified; there were strong minority views, but no consensus, regarding possible solutions.

Consensus Recommendations

1. IRBs should not be expected to perform monitoring, investigative, or adjudicative functions. Applicable regulations should be clarified as to what is intended (and not intended) by the charge to IRBs to perform "continuing review" and to report serious and continuing noncompliance. Reasons given in support of this recommendation include the fact that IRBs do not have the time, the resources (staff, money), or the expertise to perform such functons. In addition, adoption of the monitoring role would conflict with the primary role of IRBs: to educate and advise research scientists and to resolve problems in a constructive way. Finally, many, if not most, institutions already have appropriate quality assurance mechanisms in place. (This is clearly true in the case of hospitals; it may not hold for the majority of universities. See Recommendation 2.)

IRBs should be kept informed of all allegations of misconduct in research with human subjects and of investigations, as well as findings, relating to such allegations. Perhaps an IRB member should sit on the institutional quality assurance committee. The IRB might also be consulted as to the seriousness of misconduct found to have occurred.

2. Institutions receiving federal research grants and contracts should be required as part of the assurance process to describe to the funding agency their procedures for responding to reports of misconduct. This should include:

(a) A specific office designated to receive and investigate complaints;

*Adapted from a memorandum by Barbara Mishkin to members of the President's Commission, September 28, 1981.

(b) mechanisms for assuring a prompt investigation;

(c) an impartial adjudicator;

(d) full opportunity for the complaining parties and the accused to explain their positions, present evidence, call witnesses, and so on; and

(e) protection from reprisals for the good-faith complainant and for witnesses.

Information about these procedures should be widely disseminated throughout the institution so that all persons who might be involved in research with human subjects (including subjects, staff, nurses, etc.) will know what office to contact and what their rights and protections will be, should they wish to report problems or concerns relating to such research. The IRB could also receive reports and then forward them to a designated office.

In its description of the mechanism, an institution should make clear the nature and extent of the IRB's involvement in the process of resolving complaints and in determining whether the findings should be reported to the funding or regulatory agency.

3. Institutional administrators, principal investigators, and research personnel should be made aware of their responsibilities to the scientific community and to federal agencies. Education and attitude can play a large part in encouraging adherence to professional norms and standards. Administrators should understand that their responsibilities to funding agencies include prompt and appropriate action when misconduct is reported. More importantly, they can establish for their institutions a clear commitment to upholding professional standards and enforcing federal regulations. This can be done by taking reports of problems seriously and by acting promptly and fairly to resolve complaints. Every effort should be made to encourage staff to report problems through internal channels. This can be achieved by protecting those who report in good faith, by resolving problems informally to the extent possible, and by imposing appropriate disciplinary measures for serious acts of misconduct. In addition, information about where to report problems or perceived misconduct and about procedures for doing so should be widely circulated and posted. Procedures to protect against reprisals should also be publicized, and all staff should understand their obligation to assist the administration in upholding high standards of conduct.

Serious misconduct should be reported to the cognizant federal agency after a formal determination has been made. Administrators and scientists should understand that they have a legal obligation to do so. In fact, knowingly to provide false information to the federal government is a felony. If an institution makes a formal finding that false information has been submitted in a grant application, annual report, or data submitted to a regulatory agency, the institution may incur criminal liability if officials fail to report such a finding.

Professional societies and state licensing boards can also encourage adherence to scientific norms and compliance with federal regulations governing research with human subjects. Professional codes of ethics should include such principles, and licensing bodies might consider making training in research standards and ethics a prerequisite for licensure. In addition, misconduct in research could be identified as a basis for disciplinary action by state licensing boards and by professional societies and specialty boards.

4. Federal agencies should respond to reports they receive in a consistent, fair, and timely manner; final determinations that misconduct has occurred should be made known to other federal agencies, state licensing boards, and appropriate professional societies. The NIH and FDA should continue their efforts to clarify standards and procedures for response to reports of misconduct in research under their jurisdiction. They should work together, with a uniform set of standards, on investigations of incidents in which both agencies have a regulatory interest. Procedures to protect both those who are accused and those who make good-faith reports of misconduct should be developed and made known to all agency staff who might receive such reports or participate in the subsequent investigation. Formal determinations of misconduct should be actively shared with other federal agencies, state licensing boards, and national organizations such as professional societies and pharmaceutical manufacturing associations, as appropriate. (Currently, such information is available on request, but no attempt is made to forward reports to other agencies or boards unless a specific request is made.)

Additional Concerns

1. The term "whistleblower." A few participants objected to the term "whistleblower," but no alternatives were suggested. Some participants felt that it is important to define "whistleblowers," but no consensus was achieved. To some, "whistleblowers" are those who report outside normal channels (e.g. to the press, the federal government, or scientific societies) instead of going through appropriate channels within their institution. Some would even designate as "whistleblowers" those who go immediately to university deans, vice-chancellors, and so on, without reporting first within their own departments. Others felt that anyone who makes a complaint or a report about an individual of senior or equivalent rank should be considered a "whistleblower," while supervisors filing reports about junior staff would not be considered whistleblowers.

Still other participants felt that it is not necessary to define whistleblowers; rather, what is important is to encourage reporting within normal channels and to reduce the perceived need to report externally instead of proceeding through internal mechanisms.

2. Protecting the identity of the person filing a report. Some participants felt that confidentiality must be assured those who report misconduct in order to encourage such reports and to protect against retaliation. In addition, it was suggested that keeping the names out of the investigative process would assure focusing on the alleged misconduct and avoid the defense of personal animosity or interpersonal conflict.

Others felt equally strongly that fairness requires that the accused be permitted to know who has made the accusation, to cross-examine, and to know the basis of all charges. A possible compromise was suggested: that the identity of the person making the report be protected until a preliminary investigation has been completed. If it is then determined that the charges have sufficient basis to warrant a formal hearing or review, then the person accused should have access to all information about the charges, including the identity of the person(s) making the accusation. No consensus on any position was achieved, although all participants considered the problem important.

3. Additional federal or state remedies. Some participants strongly recommended that the President's Commission encourage federal and state legislation to protect whistleblowers from retaliation. The recent Michigan

statute was cited as a possible model.* In addition, it was suggested that the Public Health Service Act be amended to provide appeal to the Secretary of Labor for any employee who suffers retaliatory action as a result of good-faith reporting to an appropriate federal agency. It was pointed out, however, that if protection is afforded those who report to federal agencies, but not those who file reports within their own institution, that would encourage individuals to avoid internal channels in favor of external ones -- the opposite of what all agreed should be the preferred response.

Other participants felt that a call for such legislation (either state or federal) is premature until more data are available as to the incidence of serious misconduct.

All participants felt uneasy about the lack of data but agreed nonetheless that the consensus recommendations summarized above were reasonable ones. Whether further measures would be advisable if the incidence of research misconduct was demonstrated to be substantial was a matter upon which no consensus was reached.

*1980 Mich. Pub. Acts No. 469.

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