Politicized Approach to Mortal Illness Threatens Many Lives — P. 4

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Exclusive:
Scientific ‘Misconduct’ Investigators Discover Pitfalls in Ad Hoc Methods

Washington

Based on federal laws passed in the 1980s and regulations issued under them by the U.S. Public Health Service (PHS), the National Science Foundation (NSF), and other science agencies, a wide administrative network is being set into place to detect and investigate “scientific misconduct” and punish malefactors (PROBE, August). This enterprise encompasses all research and treatment institutions that receive federal funds — which is virtually all the big ones.

Errors are rife, a leading investigator says. Ad hoc procedures are frequently used.

“Scientific misconduct” is a euphemism for scientific fraud that sidesteps many of the legal consequences — and safeguards for the accused — that are attached to criminal and civil definitions of fraud.

Standards Are Imposed

In essence, a newly codified standard of scientific rectitude and professional conduct is being imposed upon science by its principal external funding source, the U.S. government. The “research integrity” effort, as the PHS designates it, uses as its main sanction the disbarment of individuals, or of institutions, from federal funding. For individual researchers, this can mean blackballing — no jobs — in science, even before a final verdict is reached on charges (PROBE, Nov.).

The scientific misconduct system is separate from, but may be linked to criminal charges by federal prosecutors: They can use information generated in a misconduct investigation to seek an indictment.

Misconduct investigations also are linked to individual research institutions’ rules and procedures: Intramural complaints of misconduct, which now must be investigated according to strict federal standards, are the major source of misconduct cases that then are re-evaluated on the federal

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Gallo Charges Dropped; He’s Unhappy

We spoke briefly with researcher Robert Gallo, M.D., at a recent AIDS meeting in New York. It was the evening before the U.S. Public Health Service’s Office of Research Integrity (ORI) was to announce whether it would proceed with — or drop — its case of scientific “misconduct” against Gallo for alleged misrepresentations in a key research paper.

The ORI’s case clearly was in trouble. A PHS appeals board — a panel of government lawyers that was to judge the case — had said ORI would have to show, by a preponderance of evidence, that Gallo intended to misinform readers of the article. It was fairly clear that ORI had no means to do so.

We congratulated Gallo, saying it looked like he soon would be off the hook. But he was not pleased.

Seeking Exoneration

He said he did not want the charges dropped. He wanted his “day in court,” so he could be fully exonerated. A scientist’s reputation is very fragile, Gallo said. He was worried that he could preserve his reputation only if he were
Follow-Up...

The small controversy that we raised about Bill Moyers' TV special "Healing and the Mind" — and the companion book that has since enjoyed a long run at the top of the New York Times best-seller list — has resurfaced:

We pointed out (PROBE, March) that some claims made by Moyers for alternative medicine were deceptive, empty, or unproven. We pointed out, too, that the TV series, as well as a report on alternative medicine in the New England Journal of Medicine (Jan. 28), and the book Mind/Body Medicine, published by Consumers Union and excerpted in its magazine Consumer Reports (Feb.), had, similarly, promoted a dubious mix of established and alternative treatments.

We also pointed out that all three media presentations — TV special and book, medical journal article, and consumer information publications — were supported financially by the Fetzer Institute, of Kalamazoo, Mich. Fetzer champions alternative healing methods and wants to add a spiritual dimension to medical care. A Fetzer spokeswoman said this media blitz was planned and coordinated in advance.

‘Quackery’ Charged

It appears that we were the only science publication to criticize this alternative medicine blitz at the time. Recently, however, our fellow newsletterist, psychiatrist Stephen Barrett, M.D., publisher of Nutrition Forum (POB 1747, Allentown, Pa., 18105) joined us. He attacked alternative medicine and the mind/body movement as unscientific “quackery” in Sciencewriters (Summer/Fall), published by the National Association of Science Writers (NASW), of which we both are members.

A rebuttal was written by Joel Gurin, the Consumer Reports (CR) medical editor, who is an editor of CR’s mind/body book and author of the derivative article; he, too, is a member of NASW. Gurin asserted that “the real challenge is to sort out the valuable lessons of alternative medicine — and there may be many — from the deceptions and delusions that plague [it].”

Gurin asserts that “mind/body approaches are rationally based.” But in his rebuttal he does not cite any one of them that has been shown to be effective and safe according to scientific standards like those CR routinely uses to rate health products.

Fetzer’s Role Described

Speaking to an issue that both we and Barrett raised, Gurin offers “one point for the record: The Fetzer Institute — which gave Consumer Reports Books some funding toward the development of Mind/Body Medicine — had absolutely no editorial input into either the book or the article in Consumer Reports.”

What Gurin does not say in Sciencewriters is that, as he told PROBE, he had been a fellow of the Fetzer Institute on a pro bono basis.

Jackets Are Different

Fetzer, what is more, appears to differ with Gurin on the role it played in the project. The cover of Mind/Body Medicine distributed by Consumers Union ($24.95) lists only one organization on the front of the dust jacket: Consumer Reports Books. But the Fetzer Institute also distributes the book. The top credit on the front dust jacket of these copies says: “A Project With THE FETZER INSTITUTE.”

The important point, we think, is not whether Fetzer had direct input into the book’s content. We’re willing to stipulate with Gurin that it did not.

Much more important is Fetzer’s success in coupling its name — and the alternative medicine agenda — to those of Consumers Union and Consumer Reports. They are famous for their adherence to scientific methods; they develop highly-technical new tests to evaluate products on a nitty-gritty, data-driven basis. For Fetzer and the data-poor mind/body medicine movement to have their names coupled “with” Consumer Reports Books is triumph indeed.

It’s a public relations coup!

Review in Nature

Buoys Our Spirits

Sharp-eyed readers will have noticed from the Page 1 dateline that this issue brings us into our third year of publishing PROBE. We’re happy to have reached this way point!

Our anniversary pleasure has been boosted by a long, thoughtful review of PROBE that appeared recently in Nature (Oct. 7), the pre-eminent scientific journal. Nature news editor David Dickson praised — and also found some fault with — our “zealous” and “lively” approach to issues in science. He faults us for defending the scientific establishment (which is not what we think we’re doing).

The Nature review is enclosed with this issue. We welcome your comments.

We’d like to acknowledge the work and support of PROBE’s production chief, Angela Darling. Copy Editor Susan Hansen and Circulation Manager Tom Gilgut are judicious professionals; we value their input highly. Lynne Lamberg compiled our excellent annual index.

Most of all, we are grateful to you — our readers! We welcome the chance to inform and (we hope) entertain you — and we send you here our Holiday Greetings! — D.R.Z.
Low-Calorie Diet Claims Debunked; Dieters’ Lost Pounds Are Soon Regained

Philadelphia
Contrary to a manufacturer’s claim, very-low-calorie (VLC) diets don’t work very well. Dieters do lose significant poundage. But most of them regain much or all of it after they stop using the costly liquid preparations and return to eating food.

These dismal findings have emerged from the first large, long-term study of patients who used the 26-week Optifast Core Program (Sandoz). It provides 800 calories, or less, daily in liquid form.

The Federal Trade Commission, which has investigated VLC diet claims, had requested such a study.

Internist Thomas J. Flynn, M.D., of Orange Park, Fla., told reporters here that, “contrary to the advertising,” patients who had successfully lost weight in the Optifast program that he ran “have very poor long-term maintenance.”

Claims Cited
He conducted his study at the weight loss clinic of the Orange Park Medical Center and described it in the AMA’s Archives of Family Medicine (Oct.). He said at a press briefing that Optifast ads claim that 85% of patients lose 40 or more pounds; and 60% maintain the lower body weight they achieve.

But among the 255 consecutive, “well-motivated” men and women whom Flynn contacted, 2-1/2 years after they started his program, the results were far less encouraging: Only 60% had lost 40 or more pounds, and only 14% — or one in seven — were maintaining their lower weight.

The cost, in dollars, was high:
Patients or their insurers paid $55 per pound of initial weight loss, when the bills for the Optifast, medical monitoring, and nutritional and behavioral counseling were tallied. The cost for weight loss that was maintained for 30 months was $180 per pound. Looked at in another way, Flynn said, each 1% of body weight lost and maintained cost the successful dieter almost $200.

Exercise Is Key
Men weighed more at the start, and lost and maintained more weight loss than women. The men maintained 30% of their original weight loss; the women maintained only 8%. Participants who exercised regularly maintained twice as much weight loss as those who didn’t.

Now, he added:
“We do not recommend VLC diets.”

Sandoz, in rebuttal, issued a statement headlined “VLC Diets Can Be Effective Long-Term.” The company claims that in an unpublished study that it performed, half of the 475 patients who completed Optifast treatment sustained weight loss of 10% or more of their body weight after two years.

But, a company official acknowledged, Sandoz agrees with a recent National Institutes of Health task force report, which concluded: “Long-term maintenance of weight loss with VLC diets is not very satisfactory, and is no better than with other forms of obesity treatment.”

Gallo . . .
continued from page 1
judged and found innocent of the charges.

Gallo said a third of his time in recent years has been spent answering charges raised by journalist John Crewdson of the Chicago Tribune, Congressman John Dingell (D-Mich.) and the PHS investigation that was being handled by ORI. The disruption of his laboratory at the National Institutes of Health (NIH), has set back AIDS research, Gallo added.

Short of full exoneration, Gallo said, ORI, or others, could continue to fault him, even though they could not convict him.

Gallo was quietly but determinedly angry.

Standards Disputed
The next afternoon, ORI dropped the charges. ORI’s director, psychologist Lyle W. Bivens, Ph.D., said the chief reason was because the appeals board “now applies different standards from those applied by the ORI.”

The “ORI maintains that the standards applied by the [appeals] panel reflect a fundamental disagreement with ORI as to the importance of clarity, accuracy, and honesty in science.”

As he feared, then, Gallo was convicted by Bivens’ inuendo of violating scientific standards.

Lawyer Disputes Bivens
Gallo’s lawyer, Joseph Onek, disputed Bivens, saying the appeals board had invoked no novel standards:

“It is simply requiring the government to prove its case,” he told Philip J. Hilts of the New York Times (Nov. 13). “For years, ORI has been making false and irresponsible charges,” he said. “When the time came to put up or shut up, in a hearing before a fair and independent tribunal, they dismissed their own case.”

The lawyer hinted to the Associated Press that Gallo may sue his antagonists.

“He never got his day in court,” Onek said. “But that may happen yet.”

Gallo told AP:
“I am delighted that ORI has dismissed the case against me and that I have been completely vindicated.”

The standard ORI used is that a scientist is guilty of misconduct if he “knew or should have known” that a published statement was false. The definition used by the appeals board, based on legal due process in cases of fraud, required ORI to prove “deliberate intent to deceive” by a preponderance of evidence.
A major public policy error was made with AIDS. This same error — politicization — now is being made with breast cancer. Much human suffering is likely to result.

"We came to think of AIDS as fundamentally a crisis in human rights that had some public health dimensions, rather than as a crisis in public health that had some important human rights dimensions."

Analysis

This is the succinct and we think excellently stated assessment of the error by public health expert Stephen Joseph, M.D., a former New York City commissioner of health; he is quoted by University of California anthropologist Nancy Scheper-Hughes, Ph.D., in a recent Lancet report (Oct. 16, pp. 965-67) on AIDS in Cuba. She adds, trenchantly:

This perception [of AIDS as pre-eminently a human rights crisis] is reflected in the mountain of uninspiring social science literature on AIDS, a morass of repetitive, pious liturgies about stigma, blaming, and difference. These writings conceal a collective denial of the impact of AIDS. While all of us can learn to overcome (or at least deal with) stigma and social exclusion, few can beat the virus [emphasis added].

This deadly distortion was initially triggered by society’s — including the medical establishment’s — prejudicial disinterest in AIDS. Since then, however, the public agenda has been largely shaped by homosexuals and their political supporters, to the exclusion of standard public health measures based on previous epidemics and increasing AIDS data that might have been used to control the disease.

Anthropologist Scheper-Hughes cites these mistakes:

• Blood screening was delayed because of the implications of asking donors their sexual practices and drug habits.

• HIV testing was not added to the work-up of every newly hospitalized patient.

• Neighborhoods with a superabundance of HIV infections were not targeted for intensive treatment and prevention programs.

• Even today, public health systems in the U.S. and most other countries place no demands on individuals to be tested, and none either on those found to be HIV positive.

In contrast, Scheper-Hughes says, Cuba is the only nation that has incorporated the key elements of the classical public health tradition in a national AIDS prevention program. These elements she identifies as routine testing, tracing of sexual contacts, partner notification, and close medical surveillance and partial social isolation of all infected people.

Confinement Required

Scheper-Hughes has visited the sanatorium in Cuba where newly-diagnosed HIV-positive individuals are confined for six months, and are drilled in safe-sex attitudes and practices before they can return home for visits. The anthropologist dislikes this coercive system. But, she notes, Cuba has had less than a thousand cases of HIV infection and only 187 AIDS cases (with 111 deaths) in a population of 10 million. In nearby Puerto Rico, by contrast, there have been 8,000 AIDS cases in a population of 3.7 million.

Low HIV and AIDS rates also are found in Sweden, according to infectious disease specialist Johan Giesecke, M.D., of Stockholm, in a commentary accompanying Scheper-Hughes’ Lancet report (p. 942). Testing is voluntary in Sweden, he notes. But HIV-positive individuals must seek medical treatment. They can be confined in a hospital if they don’t.

The excellent results in Cuba and Sweden, vis-à-vis the U.S. and other nations, Giesecke adds, would not have been possible without previous strong confidence in a benevolent and non-discriminatory state and health care system.

These prerequisites have been lacking in the U.S., at least since Ronald Reagan became president. It is not clear yet whether the Clintons will rebuild and restore confidence in the public health system. What is clear is that abandoning classic public health methods — and relying on the nebulous concept of “education” — has cost America tens of thousands of lives and immeasurable suffering.

# # #

Breast cancer is certainly as terrifying to women as AIDS is to male homosexuals. This has led many women to become breast cancer activists, borrowing chapters on organization and tactics from the AIDS activists’ book: Marches. Rallies. Lapel ribbons (pink, instead of the AIDS activists’ red). Pressure groups — an organization called the National Breast Cancer Coalition (NBCC) claims 70,000 members. And anguished and angry demands for action.

Some of the press is catering to this campaign. New York Newsday, whose parent paper, on Long Island, serves areas continued on next page
**Conflicting Public Health Strategies Defined**

Swedish infectious disease specialist Giesecke discerns two opposing public health strategies for containing the AIDS epidemic (*Lancet*, Oct. 16, p. 942). The first is being used in the U.S. and most other countries:

[**[All citizens should live as if they or their partners were HIV positive.** Since everyone has to take precautions to stop the spread of the virus, whether an individual is [infected] or not becomes immaterial, and HIV testing adds nothing to prevention. Information and education become the sole public health tools.**]

The alternative strategy is being used in Cuba and to a large extent in Sweden:

As for other communicable diseases, AIDS is best prevented by localizing infected individuals, charting chains of infection, and trying to minimize spread from those infected to those susceptible. Even if education of the public is an additional preventive tool, HIV testing is needed to identify symptom-free but presumably infectious people and to target them for special interventions.

The second classical strategy, Giesecke says, is proving to be more successful.

with high rates of breast cancer, ran a Page 1 headline: "Breast Cancer Research: How Women Are Shortchanged," based on an incendiary story by staff writer Michelle Slatalla. She charges that promising breast cancer studies "were abandoned or delayed" because of government policies that focused on treatment rather than prevention (Oct. 3).

Slatalla allows, however, that more money has been spent on breast cancer since 1980 than on any other type of cancer.

The NBCC president, Frances M. Visco, said recently:

"The scientific community historically has been making decisions about how to spend research money without any oversight... We're saying, 'You're not going to be able to do that any more. We're saying, 'Let's focus on breast cancer! It's the time we do that."' (*N.Y. Times*, Nov. 23).

**Delays Attacked**

The activists' anger is directed particularly at the long postponement of a massive study of 63,000 women, called the Women's Health Initiative (WHI). Its purpose is to see if switching to a very low fat diet — 20 percent or less of calories from fat — will cut older women's breast cancer risk. This 14-year study is budgeted at $625 million; it could cost $1 billion.

Earlier studies have shown that diets as low as 30% of calories from fat do not appear to be protective (PROBE, Nov. '92). The far more stringent 20% standard would approximate the diets in some under-developed countries where breast cancer is much less common that in the West. But the key question may not be whether conforming to these standards — perhaps throughout life, as well as in middle and old age — will protect against cancer. Possibly it will.

The key question, rather, is whether American women are willing to live this frugally. Immigrants from the poorer, low-breast cancer nations who come here are not: They come, they adopt western diets — and their breast cancer rates rise.

**Critics Are Adamant**

For these reasons, and some others, NIH dragged its feet on the WHI study. But under prodding from former NIH-chief Bernadine Healy, M.D., it has now been started. The criticism continues:

At Congress's request, the Institute of Medicine (IOM), an arm of the National Academy of Sciences, in Washington, D.C., convened a panel of experts — the majority of them women — to review the WHI. In their report, released last month, they say:

If a low-fat diet in adulthood affects breast cancer risk, most epidemiologists agree that this effect is likely to be small. Thus, the diet-based hypothesis is considered [by the panel] to be quite weak... Much of the information could be obtained in better designed, smaller, more focused studies that could have a greater chance of success, and probably be less costly.

The critical report stops just short of recommending that the study be cancelled; it suggests instead that the focus be shifted from diet-and-cancer to diet-and-heart disease.

In short, the anti-cancer diets and other efforts that are visible enough to have become activist symbols of progress seem unlikely to yield the major advances that the women seek. But activists rely on symbols in order to reach large numbers of poorly informed followers — and so are reluctant to drop them.

Is there a better way? The terrible truth is that nobody knows how to prevent breast cancer, albeit mammograms, breast exams and self examinations do help. But if there is to be an answer, we think that at this point it is more likely to come from basic research on cancer causation than it is on huge studies aimed at some high-profile risk factor like fat.

None of the above is particularly good news. It would be desperately bad news if women's hopes and a big chunk of the breast cancer budget were to be tied up in a long study that shows little promise. But this is what the activists demand.

What, then, can women activists do now? They certainly can and should lobby for more money for basic research on breast cancer, and for better clinical services for women who get it. But if the goal is an immediate one, of saving women's lives, there is something else women can do:

They can stop smoking. And they can help other women stop. According to CDC figures, in 1950 the breast cancer death rate for white women was 26.4 per 100,000. In 1990, the rate was essentially the same, 27.4 percent. In 1950, the lung cancer death rate for white women was 9.9 per 100,000. But by 1990 it had increased six-fold to 32.1 — due to cigarette smoking. The figures for black women are comparable.

The lung cancer death rate thus is now higher than that for breast cancer. Many breast cancer deaths are not preventable. Most lung cancer deaths are.

Women can stop them.
For reasons that should be clear from the Page 1 news story, the federally-driven science misconduct apparatus is dangerous — and ought to be dismantled. It brings Big Brother into the scientific laboratory and academic classroom.

Congress enacted the misconduct legislation in response to a few dramatic cases of major fraud by medical and scientific researchers, particularly cardiology investigator John Darsee, M.D.; he placed dishonest papers in major medical journals a dozen years ago. But it is not clear that the current apparatus will stop dedicated cheats like Darsee.

What are coming to the surface instead are a host of relatively minor torts, such as cribbing from others’ grant applications (PROBE, Sept.). The risk to science that is inherent in the complex (and costly) integrity process far outweighs the benefits of catching minor miscreants whose influence is virtually nil. The sensational misconduct allegations against scientific leaders like Robert Gallo are not standing the test of careful scrutiny — further reason to doubt or dismiss the process (see story, page 1).

Judgments Sought

Attorney Tina Gunsalus of the University of Illinois and other advocates of scientific integrity have insisted that misconduct judgments be made on scientific rather than on legal grounds. As interpreted by the Office of Research Integrity (ORI), this means that a scientist is guilty if he (or she) “knew or should have known” that a published statement for which he has some responsibility is false.

This is an extremely loose standard. It requires the accused to prove that he or she is innocent, rather than placing the burden of proving guilt on the accuser(s) and authorities who bring charges.

All scientists work in a setting in which they are required to prove their assertions, by collecting and marshaling appropriate evidence. So it has seemed to us that they should anticipate using comparable rules of legal evidence when they make, or are the target of accusations that can destroy a scientific career.

Asked to comment on this point, Gunsalus said, in Washington, that she does not see an affinity between science and law. “The cultures are different,” she said. “The mind-sets and the paradigms are different.”

Need Cited

The new scientific integrity system is needed, Gunsalus explained, because “the disputes are basically scientific, not legal issues. I think it’s better for communities to police themselves, based on their own disciplinary principles.”

The problem with this reasoning is that science is set up to judge error, but not misconduct. Error does not equal misconduct, although this is what the ORI essentially alleges.

Science’s error-correcting and error-to the complex — and personally volatile — complaints of research transgressions. The answer to most questions of what to do, she said, is:

“It depends.”

The typical case, as Gunsalus described it, is brought by a frightened, ambivalent graduate student, who claims that his or her professor or laboratory director is exploiting, and perhaps also sexually harassing him or her. The older person also is publishing findings that contradict the scientific data (or for which there are no data), or is stealing lines or ideas from the student or other colleagues’ work to use in his own research grant applications. This scientist, who may be a well-regarded faculty member, also may be embezzling research or university monies for self-indulgent purposes.

The complainant almost always is crying and distraught. “I keep a supply of Kleenex on my desk!” Gunsalus said. As UI’s point person for these charges, Gunsalus said, she handles between 30 and 60 complaints a year, on a campus that has 36,000 students and 2,100 faculty members.

“Almost every problem,” Gunsalus said, “started with a...
forgetting methods do deter — albeit not always immediately, or wholly successfully — misconduct and fraud: You don’t win the Nobel prize. You don’t get grants. You don’t get promoted in your department, or elected to honorary societies if your work is suspect. These are relatively silent but quite powerful sanctions.

Proofs Are Legal

The ORI standards for misconduct — particularly fabrication, falsification, and plagiarism — are based on legitimate scientific concerns. Plagiarism is sometimes, but not always self-evident. But fabrication and falsification often will require proofs that are outside the realm of science — but within the realm of law.

Operationally, the new integrity system is animated by legal, political, and bureaucratic interests — particularly Congress’ stated concern for the taxpayers’ money — and not in scientific ones. It is vulnerable to political pressures; the cases against Drs. Robert Gallo and Mikulas Popovic (PROBE, Nov.) would not have gone forward without strong pressure from Rep. John Dingell (D-Mich.).

Contrary to what Gunsalus is saying, therefore, this is a quasi-legal system, not a scientific one. If the system is continued — and we think it should not be — then all parties will have to accept that this is ultimately a legal process. They will have to accept, too, the cost in time and in money that such a process entails.

Inquiries Required

Under the “federal regulations [that] are a driving force in this,” she explained, she must conduct inquiries into these complaints. An administrative inquiry is the first step in the quasi-legal misconduct “process.” Preparation for an inquiry may include sequestering of research data and must include notification of the accused.

Then there is a hearing before a small panel of faculty members. The panel decides if there is probable cause of misconduct that would justify the institution moving to the next step in the misconduct process, and the investigation. The inquiry panel thus functions somewhat like a grand jury in the criminal system, in deciding whether an indictment is warranted.

An inquiry, Gunsalus stipulated, must be independent, expert, appropriate, and fair. She said that on the huge UI campus the roughly three inquiries she has conducted in each of the last several years have led to about one investigation every two years. In other words, roughly 1 percent of complaints eventually in a misconduct investigation (60 to 120 complaints each 2 years — 6 inquiries — 1 investigation).

Asked if misconduct cases are on the rise, Gunsalus said no. The “baseline” is the same, she said. But people’s awareness and response to these problems are changing — toward greater accountability.

The misconduct officer’s primary responsibility is to his or her institution, and to the government, Gunsalus stipulated — not to the complainant or the respondent. These proceedings are “painful” for everybody, she said, and can be permanently damaging to the targeted individuals.

“You’re never going to restore the reputation of a person who’s been accused and it’s become public,” she said, even if the individual is exonerated.

Job Is Stressful

Gunsalus said that her two qualifications for the job were her boss’s strong backing for what she is doing, and her high level of tolerance for personal conflict and stress.

She said that she had — and had exercised — significant administrative discretion in running the inquiries. And she said that the accused person and his or her lawyer could be barred from an inquiry hearing.

“You don’t want to end up in the room with some high-powered attorney who is blowing you out of the water!” she said.

“You don’t mean me!” quipped defense attorney Mishkin — drawing laughter from the audience.

Mistakes Are Common

Gunsalus said, candidly, that she and other misconduct officers often have erred procedurally: “There are a lot of...”
Misconduct . . .

continued from page 7

mistakes to be made," she said. There are some "egregious cases out there where institutions really have blown it."

Gunsalus depicted an investigational process that leaves significant room for errors and for ad hoc decision-making. But a federal misconduct investigator took sharp issue with her. Biologist Barbara Williams, Ph.D., a chief investigator for the ORI division of research investigations, said emphatically:

"An inquiry is a formal process, the beginning of a potential investigation." It's "a very formal thing!"

The school administrators and lawyers all appeared comfortable with the misconduct process, and several said they were eager to learn to apply it correctly.

After the practicum adjourned, however, one medical educator revealed a significant ambivalence: He said he did not want to discuss the specifics of his situation. But, he explained, while he was attending as an institutional administrator, he also had once been an active research scientist.

He said that his name appeared, as a senior researcher, on a paper written with a younger colleague. A third researcher charged that the work was fraudulent, and, after an institutional investigation, the case was forwarded to ORI.

None of the charges against the researchers have held up, this practicum participant said. But years have now gone by — and ORI has yet to dismiss the charges and close the case.

Through the years of waiting and worrying, this scientist said, he has lost the zest with which he once approached research work.

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