

*Sounding Board***THE MESSENGER UNDER ATTACK —
INTIMIDATION OF RESEARCHERS
BY SPECIAL-INTEREST GROUPS**

ATTACKS on health researchers are not new. Pierre Louis, for example, was vilified nearly two centuries ago for suggesting that bloodletting was an ineffectual therapy.¹ In an open society such as ours, controversy is common and often socially useful. The fact that scientists are sometimes challenged by special-interest groups should be no surprise. However, with widening media coverage of health research, growing public interest in health hazards, and expanding research on the outcomes of clinical care, such attacks may become more frequent and acrimonious. The huge financial implications of many research studies invite vigorous attack.

In Marcia Angell's recent Shattuck Lecture, she argued that litigation, fear, bias, and greed interfere with scientific efforts to answer questions of importance to public health and that an antiscientific social attitude encourages premature or ill-informed political and legal solutions to medical questions.² She noted that intimidation may cause investigators and institutions with access to critical sources of data to shy away from conducting research on controversial topics.

Studies of health hazards are illustrative of this problem. Media and courtroom approaches rapidly overshadowed clinical and epidemiologic studies of the potential adverse effects of breast implants.^{2,3} The lead industry hobbled the work of Needleman and colleagues on the health risks of low-level lead exposure and intimidated others through coordinated attacks at scientific meetings and skillful manipulation of the procedures for investigating scientific misconduct.⁴⁻⁶ The National Rifle Association and its allies, angered by studies funded by the National Center for Injury Prevention and Control, part of the Centers for Disease Control and Prevention, that demonstrated the risks to family members posed by guns in the home, tried to eliminate the agency that provided the funding.⁷

Such attacks often focus on "hot-button" policy issues (chemical exposure, firearm injuries) or on data relevant to large disability or liability claims (breast implants). Three recent experiences involving our institutions illustrate how vituperative such attacks may be and the range of tactics employed. Such episodes warrant close scrutiny, because intimidation of investigators and funding agencies by powerful constituencies may inhibit important re-

search on health risks and rational approaches to cost-effective health care.

CASE REPORTS**Case 1: Spinal-Fusion Surgery**

Deyo et al. published several studies indicating that spinal-fusion surgery has few scientifically validated indications as yet and is associated with higher costs and more complications than other back operations.⁸⁻¹⁰ The research was supported by the Agency for Health Care Policy and Research (AHCPR), whose mandate from Congress includes research on outcomes. Two members of the research team participated in a multidisciplinary AHCPR-sponsored panel that conducted an exhaustive literature search, identified the highest-quality studies, and developed guidelines for managing acute back problems. Non-surgical approaches were recommended in most circumstances. The research and guidelines inspired a letter-writing campaign to members of Congress by the North American Spine Society (NASS), which protested the research team's alleged bias and ineptitude and criticized guidelines it regarded as biased against its preferred form of therapy. This campaign culminated in the founding of a lobbying organization called the Center for Patient Advocacy by an orthopedic surgeon on the NASS board.

According to its fund-raising letters, the Center for Patient Advocacy is devoted to eliminating funding for the AHCPR and curtailing the powers of the Food and Drug Administration (FDA). The FDA was targeted because of its failure to approve (beyond narrow applications) the use of pedicle-screw devices, implants that are sometimes used in spinal fusion. The House of Representatives passed a 1996 budget with zero funding for the AHCPR. Only after great efforts in the Senate to expose the reasons for the attacks was it possible to preserve the AHCPR, though with substantial cuts to its budget. The intimidation led the AHCPR to end its guideline-development work.

Meanwhile, a manufacturer of pedicle screws faced lawsuits by patients alleging poor results from the devices. The company's attorneys subpoenaed documents from several investigators at the University of Washington Schools of Medicine and Public Health. The investigators' response to this subpoena required an enormous effort. Another manufacturer of pedicle screws unsuccessfully sought a court injunction to prevent the AHCPR from publishing or disseminating guidelines for the treatment of lower back pain.

Case 2: Multiple Chemical Sensitivity

Simon et al. conducted a controlled evaluation of immunologic, psychological, and neuropsychological function in patients with a diagnosis of the mul-

multiple chemical sensitivity syndrome.¹¹ Among other findings, this study cast doubt on the value of the immunodiagnostic tests used to support disability and liability claims for chemical sensitivity.¹¹ The investigators were attacked by parties whose financial interests depended on immunodiagnostic testing: plaintiffs' attorneys, advocacy organizations for people with chemical sensitivity, representatives of immunologic-testing laboratories, and prominent expert witnesses. Actions included multiple complaints of scientific misconduct to the sponsoring institutions and the federal Office of Research Integrity, requests to the medical disciplinary board of Washington State that investigators' licenses be revoked, and distribution of materials at scientific meetings that accused investigators of fraud and conspiracy. Laboratory records were sequestered by the University of Washington under the rules of the National Institutes of Health and the Office of Research Integrity. Individual patients at Group Health Cooperative, where Simon worked, were contacted and encouraged to attack his credibility.

Because the accusations were so widely broadcast, the investigators underwent separate inquiry proceedings at three local institutions, the state medical disciplinary board, and the Office of Research Integrity. These institutions were poorly prepared for outsiders' relentless use of procedures designed primarily to deal with internal whistle-blowers and disputes within research groups.¹² Although extensive inquiry by all five institutions found no basis for a full-scale investigation, individuals and organizations continued to file complaints and publicly accuse the researchers. Because of the large numbers of complaints, the inquiries lasted more than 13 months, despite institutional policies requiring resolution of the inquiry phase within 30 days. The process consumed substantial amounts of the investigators' time and of institutional resources. A local trial lawyer subsequently sponsored a workshop promoting the use of allegations of scientific misconduct as a method for disputing unwelcome research findings.

Case 3: Pharmaceuticals

At a meeting sponsored by the American Heart Association, Psaty et al. presented a case-control study assessing the association between myocardial infarction and antihypertensive therapies.¹³ As compared with diuretics and beta-blockers, short-acting calcium-channel blockers were associated with a 60 percent increase in the risk of myocardial infarction. Adjustment for potential confounding factors, including blood pressure, did not change the findings. The American Heart Association identified the abstract as potentially newsworthy, and a news release requested by the association was made available to the press. The findings became the subject of front-

page stories, which were generally accurate but lacked the caveats and context of the observational findings. The investigators were flooded with calls from upset patients and physicians. The news story soon became focused on how the media had covered the findings rather than on the evidence comparing the safety and efficacy of antihypertensive agents.

Within weeks, Psaty received requests from several pharmaceutical manufacturers for documents, tables, manuscripts, and new analyses. Through freedom-of-information provisions, one manufacturer requested

all records relating to study design and methodology, study protocol(s), individual data for all study results and data, data sets, statistical calculations, methodologies, and analyses; correspondence, meeting minutes, notes and other documentation of Dr. Psaty and any other University researchers, any departmental staff or other research committees; meeting minutes, reports and other documentation by Institutional Review Board and/or any other oversight committees within or outside the University.

The university and the investigators were obligated to negotiate a response, and after several months of negotiations, the company formally withdrew its request.

Academic consultants to companies manufacturing calcium-channel blockers issued blistering critiques, publicly questioned the investigators' integrity, and emphasized dubious contraindications to the use of low-dose thiazides and beta-blockers, generally without disclosing their company ties. At least one mass mailing to physicians by an opinion leader in the field of hypertension management gave no indication that its distribution was supported by pharmaceutical companies.¹⁴ Psaty had advised that patients follow the recommendations of the Joint National Committee on the Detection, Evaluation, and Treatment of High Blood Pressure, but manufacturers and their consultants ignored these recommendations as well as earlier evidence that some short-acting calcium-channel blockers were associated with increased mortality in patients with coronary disease.¹⁵⁻¹⁸

While the manuscript describing the study was under editorial review, pharmaceutical manufacturers tried to discover the identity of the journal to which it had been submitted, and it appeared to the investigators that opponents were trying to interfere with the publication of the study.¹⁹ Numerous channels were used, including pressure exerted through the principal investigator's dean.

TERMS OF DISCOURSE

The common theme in these examples is an attack — through marketing, professional, media, legal, administrative, or political channels — on scien-

tific results that ran counter to financial interests and strong beliefs. In each case, funding for the research involved peer review and the offending results were published in peer-reviewed journals. The interested parties had financial stakes in maintaining their market share or the legitimacy of a model of illness or a particular treatment. Their responses, which bypassed peer-reviewed scientific debate and further research, were nonscientific and aimed at discrediting the findings, investigators, or funding agencies. In each case, the attacks intimidated investigators, discouraged others from taking up the same lines of investigation, and took up the time of investigators and staff with legal, professional, and media responses.

These experiences are analogous to the strategy embodied in so-called SLAPP suits (strategic lawsuits against public participation).^{20,21} These suits are brought by private financial interests against activists who have opposing points of view and engage in such activities as circulating petitions or testifying at public hearings. The intent is to turn the tables on claimants, force them from a political to a judicial forum, and cast them as defendants. This strategy masks the original issue, transforms a legitimate public dispute into a matter for legal adjudication, and undermines the resources, commitment, and vocabulary of opponents. Although most such lawsuits are dismissed, the financial cost, lost time, and emotional burdens imposed on their targets often achieve the goal of “chilling” public discussion.^{20,21} In our cases, freedom-of-information requests, subpoenas, and complaints to the Office of Research Integrity were analogous to SLAPP suits. (In a recent issue of the *Journal*, Black discussed the misuse of subpoena power.²²)

The investigators in these three examples were trained in a method of scientific discourse that is generally cautious in interpreting data, acknowledges faults and limitations, and places findings in the context of other scientific knowledge. In contrast, when these topics became public controversies, opponents engaged in a combative style of discourse under very different rules — more like the aggressive marketing hyperbole, entrenched positions, and relentless character attacks of political campaigns and high-profile courtroom battles. The nonacademic style of communication left the investigators feeling relatively defenseless.

COSTS TO SOCIETY AND POSSIBLE REMEDIES

Harassment of researchers and funding agencies is a substantial disincentive to pursuing certain research on medical care or health risks. In effect, special-interest groups with money and power want to define acceptable questions and shape the range of acceptable answers. Eliminating public, peer-reviewed

funding would slow the production of objective knowledge, force investigators to seek funding that may not be free of conflict of interest, and leave patients, physicians, and insurers without essential scientific evidence. University faculty members are governed by financial conflict-of-interest rules intended to prevent them from conducting research in which they or their relatives might have a financial stake. Thus, the elimination of public research support and the intimidation of independent investigators are inimical to larger social interests. Professional societies, universities, and the government need to weigh in quickly and heavily against strategies and specific cases of intimidation and vengeful budget cuts. We offer suggestions for protecting findings, investigators, and funding agencies, and we encourage the discussion of other responses.

Protection of Findings

Research findings should be kept in the peer-review process, free from external influences, until they reach the public domain. Although researchers should be discouraged from presenting results outside scientific venues, scientific presentations are an integral part of peer review. Professional societies and service organizations sometimes promote news reporting at scientific meetings in the interests of publicity and fund-raising. Investigators should work with the press to provide a context for findings from individual studies. They should participate in press conferences only after careful preparation, realizing that reporters do not write their own headlines and understanding that secondary reports will surely lack the context of explanations during a press interview. To distinguish clinically important findings from the results of preliminary investigations and new hypotheses, journalists and headline writers need some understanding of the rules of scientific evidence.

We recognize that there is a delicate line — one that is viewed differently by scientists and journalists — between cautious, peer-reviewed consideration of new findings and the withholding of information from the public. The uproar that followed the release of the findings on calcium-channel blockers illustrates this dilemma. News releases based on abstracts and oral presentations are potentially hazardous, because the results and analyses are often preliminary. It would be preferable to base public accounts on final, peer-reviewed publications and to place findings in the context of other scientific literature.

Inquiry may be warranted concerning the extent to which special-interest groups block or delay the publication of unwanted findings. Journals may need to make a special effort to avoid relying on otherwise highly qualified reviewers and editorialists who have financial conflicts of interest, especially consultants

to firms whose products receive negative evaluations. Journals may also need to set up defenses against potential threats of withholding advertising.

Protection of Investigators

We favor a better screening process for allegations of misconduct, because the costs to the innocent are so high. Reporters and administrators should be alert to outside manipulation of procedures for maintaining scientific integrity. No evidence is necessary to bring charges of scientific misconduct; in the early rounds of the investigation process at the National Institutes of Health, the presumption of innocence is reversed; and closed investigations and lack of legal counsel for the accused are dangerous policies.⁶

Institutions need organized ways of supporting and advising faculty members who come under attack. In the controversy over calcium-channel blockers, the National Heart, Lung, and Blood Institute reduced the pressure on the investigators by identifying the study as disinterested research and placing it in a broader scientific and policy context.^{23,24} Institutions may also need to revisit procedures for claims against disinterested investigators, so that reputations, ongoing work, and the public interest are not damaged by unwarranted attacks.^{6,12,25} Professional societies must not let the fear of lost revenue from industry sponsors influence nominations of officers or committee members. Even so, investigators should be aware that applied research is not for the naive or faint of heart.

Investigators themselves have vested interests in the results of their research — their careers may depend on the results, their funding may come from those who benefit from the results, or they may supplement their incomes by serving as consultants and expert advocates.²⁶ The latter situations should be disclosed to parent organizations, funding agencies, editors, and the press. Our university has more stringent rules to prevent financial conflict of interest for clinical research and materials testing than for basic research.

Protection of Funding Agencies

When funding agencies come under attack from groups with narrow interests, prompt and unambiguous responses from universities and professional organizations are needed. Self-interested attacks must be pointed out to politicians, who may otherwise be unable to distinguish self-interested parties from disinterested ones. This is especially true when organizations adopt misleading names, as in the case involving spinal-fusion surgery. Consumers of research, including insurers and the public, should strongly support disinterested funding for research. The peer-review process for research proposals and findings must be insulated from politics, marketing

issues, and the actions of academic consultants with financial interests.

THE NEED TO SUPPORT DISINTERESTED RESEARCH

Producing new knowledge in an unbiased setting is a primary role of research universities. Research on efficacy, safety, and cost effectiveness in the trillion-dollar health care industry frequently has important financial consequences, and cost containment inevitably involves painful choices. Investigators in this field need support now more than ever, including sources of funding without proprietary interests. Universities and professional organizations should assist investigators who address safety and efficacy in health interventions and should help to prevent special-interest groups from determining funding priorities, research topics, or what results are acceptable.

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WHITHER SCIENTIFIC DELIBERATION IN HEALTH POLICY RECOMMENDATIONS?

Alice in the Wonderland of Breast-Cancer Screening

"Let the jury consider their verdict," the King said, for about the twentieth time that day. "No, no!" said the Queen. "Sentence first — verdict afterwards." "Stuff and nonsense!" said Alice loudly. "The idea of having the sentence first!" "Hold your tongue!" said the Queen, turning purple. "I won't!" said Alice. "Off with her head!" the Queen shouted at the top of her voice.

Lewis Carroll,
Alice's Adventures in Wonderland

AT 9 a.m. on January 23, 1997, after two days of speeches and presentations at a consensus-development conference sponsored by the National Institutes of Health (NIH), the conference panel presented its draft report and listened to comments from the audience. The panel then met in an executive session and at 1 p.m. held a news conference to announce its conclusions. This process reflects the time-honored approach followed over the past 20 years by more than 100 consensus-development panels. The response to the panel's report, however, was anything but time-honored. For some of those who were present that day, what took place seemed more akin to the Queen's order in *Alice's Adventures in Wonderland*: "Off with her head!" Thus began the latest round in the debate over recommendations for breast-cancer screening.

The NIH Consensus Development Conference on Breast Cancer Screening for Women Ages 40 to 49 was convened at the request of the director of the National Cancer Institute (NCI), with the hope of resolving the long, and at times acrimonious, debate about breast-cancer screening for women in their 40s. Over the past decade, groups of experts have differed in their recommendations, with the American Cancer Society, the NCI, the American Medical Association, and the American College of Radiology, among others, recommending that routine mammographic screening begin at the age of 40 years and the U.S. Preventive Services Task Force, the American College of Physicians, and the Canadian Task Force on the Periodic Health Examination recommending that routine mammographic screening begin at the age of 50. The debate heated up in 1993, when the NCI withdrew its blanket recommendation to begin screening at the age of 40, stating, "There is insufficient evidence to make an informed decision regarding efficacy of screening as measured by reduction in breast cancer mortality in women aged 40–49 years."¹ This change oc-