Report Absolves Harvard in Case of Fakery

But NIH official "disappointed" with panel's report chides Harvard on national television for delay in reporting incident of fraud

A blue-ribbon committee has absolved officials at the Harvard Medical School of any blame in allowing John R. Darsee to perform research for 6 months after he confessed last May to the fabrication of data. The eight-person committee,* appointed by Harvard Medical School dean Daniel C. Tosteson in December 1981 and chaired by Richard S. Ross of the Johns Hopkins School of Medicine, included five members of the Harvard faculty.

After the admission of fakery, Darsee was stripped of his appointment by his superior, Eugene Braunwald, but continued publishing papers and working in one of Braunwald's cardiovascular labs at the Brigham and Women's Hospital, on a $724,154 multicenter study financed by the National Institutes of Health (NIH). The lab at Brigham is run for Braunwald by Robert A. Kloner.

"The responses of the institution seem reasonable in relation to the information available at the respective times," says the committee in its 12-page report. "In retrospect, it is clear that Drs. Braunwald and Kloner felt in May and June that they were probably dealing with a single bizarre act by a young man who had performed exceptionally well previously. In light of this consideration, the plan selected in June seems to be reasonable in that it provided an opportunity to assess the extent of the damage and also to provide for a period of observation under supervision."

The committee also found reasonable Harvard's decision not to notify NIH in May that an admitted data fabricator was working on a federal study, but an NIH official did not. "I was disappointed," William Raub, head of extramural affairs for NIH, told *Science*, "that the report was not explicit about informing the sponsor." Although the Ross report does address the general question of who should have been informed, it makes no mention of federal collaborators. Raub appeared on a CBS news program to say that Harvard had an "obligation" to immediately inform NIH of the admitted fabrication. The committee did reprove Harvard's failure to notify Darsee's Harvard collaborators, but this tepid criticism was for the most part lost in the report's overall exoneration.

The 6-month "period of observation" revealed that two studies, including the NIH multicenter project, contained what the Ross report calls "unusual results which are highly suspect." Darsee in meetings with the committee denied any improprieties except for the one admitted fabrication in May.

According to the committee report, Braunwald decided that Darsee should continue to work on the NIH study "under close supervision" during the summer and fall for two reasons. "First, the study was heavily dependent on constant procedures and techniques, and a change in investigator in one of the collaborating laboratories might jeopardize the entire study. Second, the study was randomized, blind, and carried out simultaneously at four independent laboratories, and the results were analyzed centrally at the NIH. Therefore, any mishandling of data should be readily apparent from a comparison of results from different laboratories."

"On the other hand," notes the Ross report, "this course of action was not without cost. Darsee's presence in the laboratory environment after the events of May proved to be damaging to the morale and productivity of the laboratory."

Although as of 30 June Darsee was no longer officially a member of the Harvard staff, he was paid privately, according to the Ross report, from a "gift account" which Braunwald managed.

The silence of the Ross report on the issue of federal notification is curious because one area where the committee suggested "ways in which the institutional response could have been improved" was in the notification of Darsee's collaborators—but only collaborators at Harvard. "In May a systematic search should have been conducted to notify all persons within the institution with whom Dr. Darsee had collaborated," it said. The reason for the committee's mild reprimand is that at least one collaborator of Darsee's did not hear about the problems until November—some 6 months after Darsee confessed to the original fakery. In this collaboration—carried out with Leonard Holman of the nuclear medicine division at Brigham, a division Braunwald does not head—the committee found that the data "appear to have been manipulated." At a Harvard news conference held when the report was released on 25 January, Braunwald said he was not aware of Darsee's collaboration with Holman and therefore did not inform him of the problems.

Aside from the issue of collaboration, the blue-ribbon panel's only other point that bordered on criticism of Harvard's handling of the Darsee affair was that "a small committee of senior professors from within the University, but outside the involved department, should have been consulted immediately after the discovery in May. . . . Such a committee, be it standing or ad hoc, could have shared the burden with the Dean, the Chairman of the Department, and Laboratory Director and offered objective advice concerning management of the problem."

Not a hint of criticism is found in the report over the issue of supervision or laboratory standards. Two members of the blue-ribbon panel, Robert I. Levy and A. Clifford Barger, visited the Brigham laboratory on the morning before Christmas and subsequently reported to the full committee that "the present problem does not appear to be at all referable to the existing Cardiac Research Laboratory standards, policies or procedures nor to overt pressure provided by its Director or Dr. Braunwald. Dr. Robert Kloner and the Cardiac Research Laboratory have maintained an extremely effective system for data collection, analysis and storage."

On a related issue, the report noted

*Richard S. Ross, chairman and dean of Johns Hopkins School of Medicine; A. Clifford Barger, professor of physiology at Harvard; Baruj Benacerraf, professor of comparative pathology at Harvard and president of the Sidney Farber Cancer Institute; Burton S. Dreben, professor of philosophy at Harvard; Saul J. Farber, dean for academic affairs at New York University School of Medicine; Gerald Frug, professor of law at Harvard; Robert I. Levy, dean of Tufts University School of Medicine; and Joseph B. Martin, professor of neurology at Harvard.

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that raw data were missing for each of the suspect studies. However, it does not speak directly to the overall issue of whether the original data for many of Darsee's dozens of other experiments at Harvard were unaccountably missing—a contention of sources quite close to the laboratory (*Science*, 29 January, p. 478).

Nonetheless, the nearly 100 papers and abstracts published by Darsee were judged by the committee to be in order. "A systematic review of all work involving Darsee has been conducted by Drs. Kloner and Braunwald. Primary data have been reviewed and Darsee's coworkers have been questioned. The committee is convinced that Drs. Braunwald and Kloner have documented the extent of the irregularities and properly concluded that the previously published work from the laboratory in which Darsee was a member of the group is accurate. None of the work under suspicion has been published. The papers and abstracts containing fabricated data have been withdrawn."

The report makes no mention of the possibility of future publications. A review of the literature, however, might lead one to believe that Darsee will continue to present papers based on his work at the Brigham. The advance program for the 31st annual Scientific Session of the American College of Cardiology lists an "original contribution" from Darsee and Kloner, scheduled to be presented at the Atlanta meeting in April 1982. Braunwald, however, told *Science* that this and any other work by Darsee that was in the mill has been withdrawn.

Another issue not addressed by the committee in its report is the fact that the colleagues of Darsee's who witnessed the "single bizarre act" soon afterward told Kloner and Braunwald that they suspected Darsee was systematically faking a major part of his prodigious output. According to chairman Ross, the committee did not meet with any of these colleagues.

At the Harvard news conference, Braunwald emphasized the lack of evidence of widespread problems in May and explained why he chose not to make the case public. "At the moment we had a brilliant person," he said. "He clearly was one of the most outstanding, or the most outstanding, of the 130 research fellows I have been privileged to work with. Public disclosure would have ruined him for life. We felt that to do this on the basis of a single incident would have been extreme. So we took a guarded position."

"Institutional Response"

The majority of the section of the Ross committee report that deals with Harvard's "institutional response" follows:

The committee examined the response of the Harvard Medical School to the Darsee incident from the date of discovery on May 22 to the present time. The purpose of this examination was to determine whether any future steps should be taken, whether Dr. Darsee had been treated fairly and what lessons might be learned with regard to the handling of such unfortunate events if they should occur in the future.

The response of the Harvard Medical School should be considered in two phases in accordance with the information available at that time. The first phase response began in late May and early June, following discovery and admission of data falsification by Dr. Darsee. Dr. Darsee's fellowship was terminated on June 30, and his faculty appointment, which had been offered for the following year, was withdrawn. The Dean's Office was notified, and abstracts of work in question were not submitted. Unfortunately, Dr. Holman, Dr. Darsee's collaborator in the Division of Nuclear Medicine did not learn of the fabrication of data in the "Extension vs. Expansion Study" until November and was not informed that Dr. Darsee's appointments had been terminated.

The second phase response occurred in October and November and was initiated by the discovery of the irregularities in the data [for two studies]. At this point in October and November, when it seemed likely that more than one episode was involved, the granting agency [the National Heart, Lung, and Blood Institute] was notified and two manuscripts . . . were withdrawn. Dr. Darsee agreed not to present any papers originating from the Harvard laboratories at the annual meeting of the American Heart Association. Officials at Emory University were notified that there were questions about Dr. Darsee's work. . . . In November, the Dean of the Harvard Medical School, Dr. Tosteson, decided that the matter was of such importance that a committee from within and outside Harvard University should be appointed. . . .

The committee questioned the reason for the delay between the initial event and response in May and June and the full-scale investigation in November. In retrospect, it is clear that Drs. Braunwald and Kloner felt in May and June that they were probably dealing with a single bizarre act by a young man who had performed exceptionally well previously. In the light of this consideration, the plan selected in June seems to be reasonable.

A systematic review of all work involving Darsee has been conducted by Drs. Kloner and Braunwald. Primary data have been reviewed and Darsee's co-workers have been questioned. The committee is convinced that Drs. Braunwald and Kloner have documented the extent of the irregularities and properly concluded that the previously published work from the laboratory in which Darsee was a member of the group is accurate. None of the work under suspicion has been published. The papers and abstracts containing fabricated data have been withdrawn.

The committee believes Dr. Darsee has been treated fairly. For several months he was dealt with in a manner consistent with his assertion that he was guilty of only one isolated act of data fabrication. The committee approves of the conscientious and responsible attitude of Drs. Braunwald and Kloner in this troublesome affair.

The committee suggests that there are two ways in which the institutional response could have been improved: First, a small committee of senior professors from within the University, but outside the involved department, should have been consulted immediately after the discovery in May. In any case, such a committee, be it standing or ad hoc, could have shared the burden with the Dean, the Chairman of the Department, and Laboratory Director and offered objective advice concerning the management of the problem. The second suggestion has to do with internal communications. In May a systematic search should have been conducted to identify all persons within the institution with whom Dr. Darsee had collaborated, and these persons should have been informed confidentially. . . .

NIH officials stress that their only criticism of the report and Harvard's behavior has to do with the issue of federal notification. Any other possible comments will wait, they say, until the NIH investigation of the affair is finished. A four-member team† of advisers to NIH will meet in February for initial review of the case and then travel to Harvard in March to conduct an investigation. NIH has not yet decided whether the report will be made public.

†Howard E. Morgan, chairman of the committee and professor of physiology at Pennsylvania State University; Francis J. Klocke, professor of medicine at the State University of New York at Buffalo; John T. Sheperd, dean of the Mayo Medical School; C. Kern Wildenthal, dean of Southwestern Medical School, University of Texas at Dallas.

On the issue of notification, however, the NIH has taken a strong stance. Raub appeared in a live interview on the news program "CBS Morning with Charles Kuralt and Diane Sawyer" the day after Harvard released the blue-ribbon committee's report. Asked if Harvard or any medical center using federal funds had "a legal or at least an ethical or moral responsibility to notify NIH when something like this happened," Raub replied: "They do have an obligation, and we in turn have an obligation to the public whose tax money this is to ensure that every case of real or apparent misdoing in science is identified and dealt with promptly and forcefully." Raub later told *Science* that in the Harvard case the prompt notification of federal officials applied even if the contentions of Darsee's colleagues were ignored or the questions about the retention of raw data were left unanswered. "Where an incident is witnessed, where it is admitted—that is enough to go over my threshold," says Raub, who spoke on the subject for NIH at a 1981 congressional hearing on fraud in biomedical research. "The event itself is then worthy of notification. On the other hand, reporting it doesn't necessarily mean banishing the guy into the outer darkness. I think they could very well expect the feds to participate in a positive effort to try to help deal with the individual."

—WILLIAM J. BROAD

"Prevention of Dishonesty in Science"

In addition to evaluating Harvard's response to the recent incident of fraud, the blue-ribbon committee offered suggestions about preventing dishonesty in research and also called for a national conference to consider several important questions about the scientific environment and the responsibilities of institutions in which dishonesty occurs. The essence of their statement follows:

. . . The committee believes that the preventive measures most likely to be effective are those directed at the circumstances and practices in the laboratory which stimulate dishonest behavior in some people. In addition, observing the behavior of investigators working in the laboratory can be helpful.

The committee observed that a reported major scientific discovery will be confirmed or refuted rapidly because of the great impact it will have on the direction of science and the strong motivation of other laboratories to verify important data. The probability that spurious or fraudulent results will be discovered by others relates directly to the significance of the report and the number of scientists working in the same field. Therefore, the practice of reporting research results in small segments affords an opportunity for dishonesty because such reports are less likely to be verified by others.

The following measures are suggested as helpful in preventing dishonesty and its detection if it does occur:

- Special attention should be given at the time of recruiting to the motivation and integrity of the applicant through careful examination of credentials and claimed accomplishments.
- Written, detailed, explicit procedures for data gathering, storage, and analysis are essential and should be available in all laboratories.
- Fellows should be supervised by experienced scientists in the laboratory including regular, in-depth scrutiny of the primary data and the calculations leading to the presentation of results. The laboratory director should, by example, develop in the fellows a respect for primary data and its preservation.
- The conduct of studies which are blind or coded, and the exchange of reagents or methods between laboratories should be encouraged. The repetition of research in the same laboratory and by different research teams is desirable whenever possible.
- Fellows should be encouraged to work with other colleagues, to share data and to engage in free discussion of results. Secrecy about methods and data should be discouraged.
- Emphasis should be placed upon the quality and significance of research rather than on quantity and visibility. The laboratory director should accept responsibility for the quality of the work reported from the laboratory and should actively discourage the submission of multiple abstracts to national meetings. Abstracts should be considered as reports of results worthy of publication and as forerunners of complete papers rather than as bids for appearance on a national program.
- There should be close personal interaction between faculty and fellows. Among the many benefits of such close interaction could be the early detection of personal problems or unusual personality traits.

We further suggest that a national conference involving the NIH and universities be convened to consider a number of unanswered questions:

- Are there steps which could be taken at the national level to encourage the evaluation of young scientists on the basis of quality rather than numbers of publications? These policies must be addressed not only by universities, but also by editorial boards, granting agencies, and study sections. It has been suggested that scientists who fragment their results into many papers should be criticized rather than rewarded.
- Should national societies examine their policy regarding limitation of multiple abstracts with the same first author?
- What is the responsibility of the institution discovering dishonesty in scientific research to other institutions, to the scientific and medical community, and to the public at large?