Imbroglio at Yale (I): Emergence of a Fraud

Outrageous charges, at first pooh-poohed, have led to talk of a far-ranging federal audit of medical research at Yale

An irate letter charging two Yale faculty members with plagiarism arrived in March 1979 on the desk of Robert W. Berliner, dean of the Yale University School of Medicine. The invective, penned by a 29-year-old female physician at the National Institutes of Health (NIH), accused the Yale researchers of lifting more than a dozen passages from a manuscript of hers and putting them into a paper of their own. It went on to question the "authenticity" of their data, implying that the Yale study had materialized out of thin air. The letter closed with a request for an investigation.

Berliner, 64, an urbane pipe-smoking administrator who for two decades held top positions at NIH, including deputy director for science, glanced at the two manuscripts that were enclosed and immediately concluded that things had been overstated.

The so-called plagiarism consisted of a few unimportant phrases containing, in total, some 60 words. Such cribbing was clearly improper, but it was hardly criminal and was in fact understandable. The lead author, after all, was Vijay Soman, 37, a well-respected assistant professor who had come to the United States in 1971 from Poona, India, and who was still uncomfortable with the English language. In addition, it was highly improbable that the study had not been done. The coauthor and senior investigator was Philip Felig, 44, a distinguished researcher with more than 200 publications who held an endowed chair at Yale and was vice chairman of the department of medicine.

Just to be sure, Berliner requested from the researchers copies of the data sheets, the scientific foundation of the manuscript. The sheets told of experiments of six women with anorexia nervosa. Thus equipped, he wrote to the young NIH researcher, saying there was no question that the study had been done. Soman, moreover, had been reprimanded. "I hope," he wrote, "you will now consider the matter closed."

On 5 August 1980, after some 2 months in the position, Philip Felig was forced to resign as chairman of medicine at the Columbia College of Physicians and Surgeons. At issue was a scandal that rocked the laboratory of one of Felig's junior associates and coauthors back at Yale medical school, where Felig previously worked and has now returned.

The first installment of this two-part series looks at the way in which the scientific problems unfolded at Yale. The second will focus on the ensuing controversy at Columbia and why it resulted in Felig's resignation.

The Yale part of the story is a case study in how a busy senior investigator lost touch with the laboratory of a junior associate. It raises serious questions about the career pressures that lead to coauthorship and about the health of team research in general.

She did not. For the next year and a half Helena Wachslicht-Rodbard wrote letters, made phone calls, threatened to denounce Soman and Felig at national meetings, and threatened to quit her job. She wanted an investigation, and she eventually got it.

The upshot has been considerable. Two audits of the Soman research, one in February and one in March 1980, have revealed fudging, fabrication, and widespread destruction of laboratory data. Eleven papers* have been retracted from the scientific literature, nine because Soman's data have disappeared from the face of the earth. Of these nine, seven are coauthored by Felig. Soman has resigned from Yale and returned to India. Felig, who had gone on to become chairman of medicine at the Columbia College of Physicians and Surgeons, has been forced to resign. Rodbard herself has left NIH and research in general.

The casualties, great enough at the moment, may yet increase. During his tenure at Yale, Soman coauthored not only with Felig but with close to a dozen faculty members from the Yale medical school, and this association with Soman is apparently making some federal administrators uneasy. A wide-ranging audit of Yale biomedical research is a "distinct possibility," according to William F. Raub, an associate director of NIH. "We need to be sure that the incident of falsification is, in fact, confined to Dr. Soman."

Why did Soman fudge his data? Why did Rodbard suspect that the Soman-Felig study had not been done? Why was the investigation of Soman delayed for almost a year? Much of the record is clear, but fundamental questions remain. Had the original Soman study, for instance, ever been done? The initial auditor, Jeffrey S. Flier of the Harvard medical school, did not press this issue back in February 1980 after it became clear that there was trouble enough with the data sheets available in New Haven. "God only knows," he says, "if the data were from patients with anorexia." It now turns out that at least one patient in Soman's study claims never to have had the disease.

Questions about the Yale research came in the aftermath of an old-fashioned battle in 1978 between Soman and Rodbard for priority in publication.

Rodbard came to NIH in 1975 as a fellow, and in 1977 started to work in the laboratory of Jesse Roth, then 42, chief of the diabetes branch of the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD). Roth's lab had pioneered studies in receptor physiology, insulin binding, and defects of insulin binding in obese patients. A logical extension of this work was to look at insulin binding in patients with anorexia nervosa, a psychological disorder that is accompanied by an acute loss of weight.

As lead author, Rodbard on 9 November 1978 submitted a manuscript on this subject to the *New England Journal of Medicine*. Entitled, "Insulin receptor abnormalities in anorexia nervosa: Mirror image of obesity," the manuscript was coauthored by Roth and another researcher. The study was reviewed for the *New England Journal* by two referees, one recommending acceptance, the other rejection. On 31 January 1979, Arnold Relman, editor of the *New England Journal*, wrote to Rodbard apologizing for the unusual 2½-month delay, saying her study had "engendered considerable

*For a complete list see: *Diabetes* **29**, 672 (1980); *American Journal of Medicine* **69**, 17 (1980); *Journal of Clinical Endocrinology and Metabolism*, in press.

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differences of opinion among our referees." A third review, he wrote, had been necessary, and the editorial board of the *New England Journal* had decided the manuscript would not be acceptable unless it was revised. He did not mention that the negative review came from Soman and Felig.

Soman came to the United States after teaching for 3 years at B. J. Medical College in Poona, India. He worked hard and rose rapidly. In 1975 he accepted a fellowship at Yale, and in 1977 took the position of assistant professor. That year Soman won support from NIH for two grant proposals, one of them, entitled "Glucagon and insulin receptors in glucose homeostasis," picking up a much-coveted Clinical Investigator Award. By 1980 he had coauthored 14 papers and was receiving close to $100,000 in NIH support.

In 1976, Soman received permission from the Institutional Review Board at Yale to perform an insulin binding study on patients with anorexia nervosa. For more than 2 years he seemed in no haste to write a paper. Then, at the end of November 1978, Felig received from the *New England Journal* Rodbard's manuscript for review, and, as is common practice, he passed it on to Soman for his comments. The study was identical to the one that Soman had first conceived back in 1976 and on which he had allegedly been working ever since. Soman started assembling data. Lacking a sufficient number of subjects, he took at least one patient, Karen Agapiou, who he had been following for another condition, and, for the purposes of this paper, called her anoretic. "Her weight has always been just right," says her mother. Karen herself says that she was studying at Central Connecticut State College in New Britain during the period that Soman allegedly performed the binding studies on her in New Haven.

Felig returned Rodbard's paper to the *New England Journal*, recommending that they reject it. He did not mention that his junior associate, Soman, was working on an identical study.

Unbeknownst to Felig, Soman had made a Xerox copy of the Rodbard manuscript and was using it in preparation of his own.

In late December 1978, just 1 month after reviewing the Rodbard manuscript, Soman mailed off a paper entitled "Insulin binding to monocytes and insulin sensitivity in anorexia nervosa." Soman was listed as lead author, Felig as coauthor. The manuscript was sent to the *American Journal of Medicine*, where Felig is an associate editor.

Whether or not Felig was party to the battle for priority is a contentious issue. Felig maintains that Soman was his own master. Felig, with more than 200 papers to his name, claims he had no reason to vie for priority. Soman, in contrast, clearly had a motive. He was pushing himself hard, working his way into the higher reaches of the U.S. academic hierarchy. Did Felig fuel his ambition? Soman made a vague and perhaps self-serving reference to this in February 1980, after admitting to Flier that he had fudged his data. "[My] actions," he said, "were done in the midst of significant pressure to publish these data as fast as possible so as to obtain priority. . . ." He never spelled out the nature of that pressure.

In any event, the manuscript that Soman mailed to the *American Journal* was sent off for review, and, as fate would have it, the manuscript was sent to Roth at NIH. He in turn passed it on to his junior associate, Rodbard.

She was aghast. Here was her paper, complete with verbatim passages. Having received her own paper back from the *New England Journal* only days earlier, she guessed, correctly, that Soman and Felig had written the negative review. Rodbard then fired off a letter on 12 February 1979 to Relman at the *New England Journal*, enclosing a Xerox copy of the Soman-Felig manuscript. She accused Felig and Soman of plagiarism and of a conflict of interest in reviewing her paper. Relman in part agreed. "The plagiarism was really trivial," he says. "I thought it was bad judgment for an Indian associate of Felig's to copy some of the standard phrases, but it was not a lethal accusation." For Soman and Felig to review her paper, however, was "a conflict of interest that was direct and immediate. It wasn't just a question of working on the same subject, but a question of timing and priority, putting them head to head."

"Surprised and disappointed," Relman called Felig on 27 February to talk over these issues and Rodbard's charges. Felig replied that the review had been based on the merits of the Rodbard paper, and that the work by Soman had been initiated 2 years previously. He also told Relman that their work had been completed before receipt of the Rodbard manuscript—a statement Felig later found out to be incorrect.

Relman was upset by all this, and soon after published the Rodbard paper, though he now denies that the conflict-of-interest revelations prompted this action. (On 19 April 1979, the Rodbard paper appeared in the *New England Journal* in revised form.)

Felig also got a call on 27 February from Rodbard's boss, Roth, at NIH. Felig and Roth were not only friendly competitors, they were good friends who had grown up together in Brooklyn, even going to the same grade school. Roth said on the phone that he had no doubts about the independence of the Soman observations, but that they ought to discuss it further. Felig subsequently flew down to NIH for a study section meeting, and on Saturday 3 March Felig and Roth met at the Holiday Inn in Bethesda, Maryland.

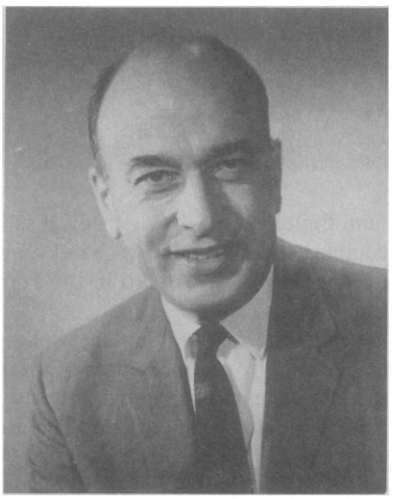

Photo by E. A. Hubbard

Robert W. Berliner: "I hope you will now consider the matter closed."

Up to this point, Felig had not compared the Soman manuscript to the Rodbard manuscript. At the Holiday Inn, Roth gave him a copy. Roth pointed out the similarities, and Felig agreed to go back and confront Soman. Right then and there, Felig also came up with a three-point plan to "avoid even the perception of impropriety on our part." He told Roth he would (i) revise the Soman-Felig manuscript to give reference to the work of Rodbard, (ii) delay publication until 1980 so that Rodbard's paper would have clear priority, and (iii) mention Rodbard's work in his presentation at the American Federation of Clinical Research meetings that were scheduled to be held in May. As a final concession, Felig promised to withhold publication of the manuscript "so long as any legitimate questions" remained about the independence of the work.

Back in New Haven on Monday 5 March, Felig met with his Indian associate, and Soman confessed to having kept a copy of the Rodbard paper and to using it as a crutch to prepare his own.

How had Soman been able to perform his misdeeds without Felig knowing? Felig now says one factor was geography. Soman worked at a laboratory in the Far-

Philip Felig: 200 publications, an endowed chair at Yale, and a paper with doctored data.

Photo by W. J. Broad

num Building of the Yale medical school complex, some two city blocks away from where Felig worked in the Hunter Building.

Upon confronting Soman, Felig demanded copies of the laboratory notes so that the dates when Soman studied the patients could be established. That same day, Felig got a call from Roth at NIH who said that Rodbard now believed that the Soman-Felig paper had been entirely fabricated from her paper. Roth said he was dissociating himself from those charges. Roth wrote to Felig later that day saying he had no doubt that the Soman-Felig studies had been initiated independently and "were largely or entirely completed" before Rodbard's manuscript had been reviewed. This 5 March 1979 letter was written without benefit of the actual evidence. On 13 March, Felig sent Roth copies of the data sheets, with a cover sheet that showed the dates of the studies.

Frustrated with things on the home front, Rodbard at this point presented her case to Berliner. Writing on 27 March, she asked him "for assistance in resolving a serious ethical matter." She mentioned the plagiarism, and went on to discuss why an investigation was needed to establish "the authenticity of the data." Among her reasons:

- "The names of the physicians and/or psychiatrists responsible for conducting behavior modification therapy were not specified, nor was the hospital where the studies were performed."
- "There were a number of unusual aspects of the data. Remarkably, all patients resumed menses following therapy contrary to general experience."

The first point is significant in several respects. Both Soman's and Rodbard's studies on insulin binding were allegedly done on patients who initially had anorexia nervosa, but who, with psychological treatments, returned to normal weight and eating habits. Such recovery is usually difficult to attain, often calling for close attention by an attending physician or psychiatrist. Rodbard's subjects, for instance, were studied while they were in-patients in the NIH Clinical Center; and one of Rodbard's coauthors was Howard A. Gross, a psychiatrist at the National Institute of Mental Health.

Conspicuously absent from Soman's paper is this type of information. There was no mention of where the patients came from or who performed the "behavior modification."

Berliner at this point requested from Felig the names of the patients, and the dates on which they had been studied. Felig sent him this information and the data sheets he had received from Soman. Berliner wrote on 17 April to Rodbard at NIH, saying "the data were collected over a period going back to November 1976 . . . all but one of the studies were complete before your paper was submitted to the *New England Journal*." This one patient was Karen Agapiou. Referring to the Roth-Felig agreement that called for a mention of Rodbard's work at the May clinical meetings, Berliner said he thought this "a very generous resolution of the matter."

Not Rodbard. She complained to Roth and told him that if there was not an investigation she would stand up at the clinical meetings and denounce the Soman-Felig study. Roth eventually conceded, telling her before the meeting that he would arrange an investigation.

In June 1979, Roth proposed that an audit at Yale be conducted by his superior, Joseph E. Rall, 59, director of intramural research at NIAMDD. Both Felig and Rodbard accepted this arrangement. Everyone seemed to think, however, that Rodbard was overreacting. Roth had been satisfied with the data sheets supplied by Felig. Rall too thought an audit would be a wasted effort. "I just found it hard to believe that Felig had engaged in any hanky panky," he says. "I saw the validity of the complaints in the Rodbard letter, but my feeling by and large was that people don't falsify data and don't plagiarize things."

A busy administrator at NIH, Rall gave the visit low priority, saying he would get around to it in the fall. Meanwhile, Rodbard quit NIH in July and started to practice medicine in Washington, D.C. September came and went, as did October and November. By the time December rolled around, and the audit still had not materialized, Rodbard picked up the pace of her phone calls to her former boss at NIH, Roth, complaining about the lack of action. Roth eventually confronted Rall, and Rall said he did not think he was going to be able to get to New Haven. Maybe it would be better, he said, to get someone "more familiar with the subject matter."

In January 1980, Roth contacted Flier, 31, an assistant professor at Harvard medical school and chief of the diabetes branch at Beth Israel Hospital. Flier said he would perform the audit in February, and send the results directly to Roth, with a copy to Felig.

During this protracted process of finding an auditor, Felig apparently felt that the upcoming exercise would reveal no wrongs. One indication of this is that in January 1980 the *American Journal of Medicine* published the Soman-Felig paper on anorexia nervosa and insulin binding, despite the fact that Felig had promised to withhold publication as long as "legitimate questions" remained about the independence of the work.

Defiance also lurks within the printed pages of the Soman-Felig study. They include all but two of the passages lifted from the Rodbard manuscript.

On 5 February 1980, almost 1 year after Rodbard originally called for an investigation, Flier visited New Haven. Soman was present, but Felig was out of town. Later, Flier sat down and typed out a four-page, single-spaced report of his findings.

Flier first looked at medical records of patients from the Yale-New Haven Hospital. The charts had been supplied by Soman. Though the published study contained six patients, Soman presented only five charts, and had no explanation for the missing one. In analyzing these charts, Flier became "convinced that there were at least four patients with . . . anorexia nervosa who had been followed at Yale Medical Center by Felig and Soman." In addition, he found that "in all cases I examined" the patients resumed their menses. He now says this was two cases.

Looking over the lab notebooks, Flier

found "an insulin receptor study on peripheral monocytes was carried out at times which suggested coincidence with the appropriate weight status of the patients described in the paper."

As Flier analyzed the data, however, it became increasingly clear that the raw data curves did not conform to the published mean curves. The published paper, he later said, was a "gross misrepresentation" of the actual data. "The [raw] data had nothing to do with what the published results showed." As Flier confronted Soman with the disparities, Soman admitted that the data had been fudged. He said he could not justify his actions, since he knew them to be wrong. Soman did, however, mention the "pressure" and that he felt his doctoring of data was not significantly different from what went on elsewhere.

One week after the audit, on 12 February, Felig returned to New Haven and heard about the results of the Flier audit. On 14 February Felig went into conference with Berliner and Samuel Thier, chairman of the Yale department of medicine. That same day, Soman was asked to resign, which he did. He also agreed to sign, along with Felig, a letter of retraction to the *American Journal of Medicine*. In addition to all this, Soman's data books were impounded and put in Berliner's office. This was in preparation for another outside auditor who would investigate all of Soman's work—a decision reached by Felig, Thier, and Berliner. On 10 March, as the raw data sheets and laboratory notebooks were being collated in preparation for the next audit, it became clear that data sheets and books for nine of Soman's papers were missing. Soman subsequently wrote a letter to Berliner saying he had "discarded" most of the original data more than a year earlier.

Amid this upheaval at Yale and the concomitant stir at NIH, a rather remarkable observation noted in the Flier audit seemed to escape notice. "It would appear that the insulin receptor studies that were performed were carried out during out-patient visits to the Diabetes Unit at Yale-New Haven," Flier wrote, "as there were no specific notations in their medical records regarding blood drawn for insulin receptor studies." In other words, the audit showed that four patients in the Yale-New Haven Hospital had clearly been followed by Felig and Soman, but there was no evidence, other than that submitted by Soman in his notebooks, that they had been the object of insulin binding studies. "It was a rather remarkable thing," Flier now says. "Nobody else made a big deal about that, but it bothered me a lot."

Even as questions raised by the first audit receded into the distance, the second was being planned. Berliner on 25 February wrote to Jerrold M. Olefsky, 37, a professor of medicine at the University of Colorado and head of endocrinology at the University of Colorado medical center.

On 22 and 23 March, Olefsky examined all of the Soman data available, and Soman himself was not present. Data for five manuscripts had been laid out in Felig's office. There were problems. Olefsky found that even in these papers that did have data sheets, from 25 to 50 percent of the data were missing.

During his 2 days at Yale, Olefsky found three of the five manuscripts credible, "if one assumes that the missing data were reasonably compatible to the results available for review," he later wrote Berliner in a three-page, single-spaced letter. In the fourth, he found "the conclusion that the reduction in binding was due to decreased receptor number is not supported by available data, and in fact, the results strongly indicate that the decreased binding is due to reduced receptor affinity." He recommended retraction of this paper, for which Felig was not a coauthor. For the fifth manuscript, in press, he could not find enough data for an evaluation, and he recommended it be pulled.

> "[My] actions," Soman told an auditor, "were done in the midst of significant pressure to publish these data as fast as possible so as to obtain priority. . . ."

Getting wind of the Olefsky audit, Rodbard called him at the University of Colorado on 17 April and heard for the first time about the missing data books. She then wrote to Berliner on 30 April, saying that this lack of data for nine papers meant that the Olefsky audit had been restricted to looking at only the "tip of the iceberg." Her understanding of the agreement for an investigation, she wrote, was that "the data as published in the literature must be a faithful representation of the real data, or else the papers must be withdrawn."

On 7 May 1980, more than $1\frac{1}{2}$ years after Rodbard had submitted her own paper on the same topic, a letter was sent from Yale to the *American Journal of Medicine* retracting the paper that had started the uproar in the first place. On 20 May, letters started going out from Yale to other journals, retracting what has now become a total of 11 papers.

Sometime in the spring, Soman returned to Poona, India. A few months after that, Felig was forced out of Columbia, and both Yale and Columbia are still trembling from that ordeal. With the possibility of an impending NIH audit, the toll may mount even further. Had the original Soman study been done? Notes for one patient are missing. Data for another patient were faked. Charts for the four other patients have nothing written in them about such a study. The evidence at hand, while clearly suggesting a fair amount of fabrication, is not conclusive. As yet there is no proof that the whole study was not done.

Why did Soman doctor so much data? Why did he plagiarize? Questions of motive are not easily answered, of course, especially secondhand. The record does show, however, that two principals in the drama, Flier and Felig, inquisitor and associate, heard strikingly different stories from Soman on this subject. When Flier caught Soman red-handed, with the fudged data sheets spread out before them both, Soman started talking about the cutthroat pace of research. Maybe he didn't need to continue it, he said. Maybe practicing clinical medicine would be enough. "Earlier in his scientific career," Flier recalls, Soman "felt that he had been totally reputable, but that something that led him to fabrication came over him in this busy group."

On the subject of why Soman doctored data, the recollections of Felig are much different, not including anything about pressure or the cutthroat pace of research. Felig asked Soman why he had done it. Soman replied that it was his fate. Every time Felig brought up the subject, the reply was always the same. Fate. One day, however, Soman told Felig a story about how his father in India had been trained as an engineer, but made his living as a farmer. Soman's father did this, Felig recalls, because he felt that a person who engaged in a profession other than farming would sooner or later be corrupted.

—WILLIAM J. BROAD