

Few patients experiencing transient ischemic symptoms have 70% to 99% stenosis in the corresponding arterial territory. Carotid artery stenosis in excess of 50% has been estimated to occur in 40% of such patients. Complete carotid occlusion accounts for an additional 10%. Less than 50% stenosis is found in the other half of patients.⁵ Endarterectomy was effective in reducing stroke incidence when the stenosis exceeded 70%. The Veterans Affairs Cooperative Study found no benefit when stenosis was in the range of 50% to 69%. There are insufficient data from the European and North American studies to evaluate endarterectomy when stenosis is between 30% and 69%. The European study found no benefit when stenosis was less than 30%. The data from all three studies indicate that, when the morbidity and mortality of vascular studies and endarterectomy are weighed against medical treatment, there is a 2-year statistical advantage in favor of endarterectomy if the degree of stenosis is between 70% and 99%. Coexistent diabetes mellitus, hypertension, heart disease, and age determine long-term survival and morbidity. In fact, myocardial infarction remains a more

frequent cause of death than stroke among patients with transient ischemic attacks.

Endarterectomy adds a little—but not a lot. It is useful to a small proportion of patients but can subject persons who are not eligible for endarterectomy to the risks of angiography. The benefits are temporary. Endarterectomy can improve the quality of life for a small number of carefully selected patients by preventing a recurrence of stroke for 2 years.

Lewis L. Levy, MD

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The Cantekin Affair

In this issue of THE JOURNAL we publish an article by Cantekin and colleagues¹ on the utility of amoxicillin trihydrate in otitis media: an article that was submitted to *JAMA* in 1987 and that had already become the center of a dispute about scientific misconduct. Why has it taken so long for this article to see the light of day? Why are we publishing it?

The Cantekin Case

Developments in the Cantekin case have been reported from time to time over the last 5 years in the lay and scientific press. Readers of *JAMA* will find much of it rehearsed by Cantekin et al² in March 1990, and they will be able to get the flavor of this bitter dispute from the correspondence that followed.^{3,4} Two congressional hearings have touched on aspects of the case.^{5,6} In the briefest terms, in 1980, Dr Charles Bluestone set up the Otitis Media Research Center (OMRC) within the Department of Otolaryngology at Children's Hospital of Pittsburgh, Pa. Dr Erdem Cantekin, who has a PhD in biomedical engineering, had worked with Bluestone in Boston, Mass, and was brought to Pittsburgh at Bluestone's invitation in 1975. Cantekin was promoted to assistant professor at the University of Pittsburgh in 1976; associate professor with tenure in 1979; and, in May 1985, full professor. He had been research director at the OMRC from the start.

See also p 3309.

Disagreements had arisen between Cantekin and his fellow investigators, including Bluestone, who was the principal investigator, over whether their data showed that amoxicillin was effective in the treatment of otitis media with effusion in children. The two protagonists each developed a manuscript

based on common data, and Bluestone sent his manuscript, the first author of which was Dr E. M. Mandel, to the *New England Journal of Medicine (NEJM)* in June 1986. The first that any journal editor heard of the dispute was in July 1986, when the editor of the *NEJM* received a manuscript from Cantekin and two coauthors, neither of whom had been involved with the research, which showed that amoxicillin was ineffective. The manuscript was accompanied by a letter of submittal clearly pointing out that the manuscript was a reanalysis and reinterpretation of the same data that Bluestone and his coworkers had already described in a manuscript sent to the *NEJM* some 4 weeks earlier. It further pointed out that Cantekin had been a coinvestigator with the authors of the other manuscript and that Cantekin had been unable to get the other authors to take his dissenting views into account. Cantekin wrote that he had given the other authors drafts of his manuscript 2 weeks before for their comments. (Indeed, though the letter did not state this, Bluestone and his colleagues had removed their names from earlier drafts of the manuscript.) The manuscript itself did not refer to Bluestone and his coauthors.

Dr Arnold Relman, the editor of the *NEJM*, wrote to the University of Pittsburgh and the Children's Hospital saying that only one manuscript could be considered, as "there could be only one responsible investigator or team of investigators officially recognized by the sponsoring institutions." Which, he asked, was the official version? Both institutions replied that Bluestone's study (the manuscript by Mandel et al) was the one they had authorized, so this manuscript went through review and revision and was published in February 1987.⁷ Cantekin's manuscript was returned to him unreviewed. Cantekin tried *The Lancet*, again enclosing a covering letter pointing out that this was a competing manuscript, and this time also enclosing a copy of the article by Mandel et al, which by that time had been published. *The Lancet* told Cantekin to put his dissent in the form of a letter to the editor of *The Lancet* or the *NEJM*. Cantekin chose instead to submit his

From the Office of the Deputy Editor (West), *JAMA*, and the Institute for Health Policy Studies, University of California at San Francisco.

Reprint requests to American Medical Association, 515 N State St, Chicago, IL 60610 (Dr Rennie).

manuscript to *JAMA* in June 1987.

Meanwhile, back at Pittsburgh, Cantekin had been dismissed from his position at the OMRC in August 1986, shortly after the submittal of his manuscript to the *NEJM*. He had then complained of censorship of information obtained using public funds, limitation of academic freedom, and punitive action against him for his dissent. These complaints were leveled against Bluestone and Dr Eugene Myers, chairman of otolaryngology. These complaints were dismissed by a university panel in June 1987.

Just after this, the manuscript came to us, accompanied by a long covering letter that described the circumstances, as well as a copy of the published article by Mandel et al. Again, Cantekin's manuscript contained no reference to the article by Mandel et al. We had the manuscript reviewed and then, in a letter to Cantekin, asked for revisions, one of which was that the manuscript "must show complete cognizance of the article which has already been published, describing circumstances in the introduction and referencing it appropriately." Cantekin resubmitted two successive revisions, which included appropriate citation to the article by Mandel et al,⁷ in December 1987 and March 1988.

JAMA would have published the article but was forced to postpone further consideration of it indefinitely. The reason was not the scientific quality of the article, but simply that in late January 1988 (shortly after Bluestone had declined to review this article for *JAMA*), a charge of "research misconduct" was brought against Cantekin by his superiors at the University of Pittsburgh. It was alleged that Cantekin had acted with malice in a disruptive and unprofessional manner and with reckless disregard for the truth. *JAMA* knew of this because Cantekin himself sent *JAMA* a copy of the charges. The first University of Pittsburgh review panel found, at the end of March 1988, that Cantekin had been "guilty of several instances in which academic integrity has been seriously breached." *JAMA* knew about that because Cantekin himself sent *THE JOURNAL* a copy of the findings. By now, the editor of *JAMA*, Dr George Lundberg, was left with little choice but to tell Cantekin that publication of the manuscript could not be considered until he was sure that Cantekin possessed all the data and until the misconduct issue had been resolved by the University of Pittsburgh and by the National Institutes of Health (NIH).

In May 1987, Cantekin complained to the Public Health Service of censorship by the University of Pittsburgh and of his dismissal. He also alleged that the validity of the OMRC's research "had been compromised by the mixing of private and public funding."⁸

Meanwhile, the University of Pittsburgh convened a formal hearing board to look into the Cantekin affair. In April 1989, the university hearing board found Cantekin to have been guilty of "unethical practice, academic misconduct, and breach of research integrity" and decided that he, rather than Bluestone, had "behaved in direct violation of accepted professional, ethical and collegial standards of the university."^{9(p8)} The panel members decided that Cantekin's *NEJM* manuscript was misrepresented by Cantekin et al as the "official" report of the research and did not represent itself as a dissent from the official publication. They decided that it was an attempt to "derail" the official publication. "For Dr Cantekin to write a parallel publication, presenting the data as if he and his coauthors were solely responsible for it, and without

letting the intended readers know that he was challenging the official report of the research, is unethical professional behavior and, accordingly, a breach of scientific and academic integrity."^{9(p10)}

In the 13 months it took for this board to deliver itself of a report, the NIH decided to look into both the allegations against Cantekin and those against Bluestone. At about the time that Pittsburgh rendered its decision, the Public Health Service, in response to allegations from Cantekin, issued a report saying that Bluestone had in fact not reported adequately his funding from pharmaceutical companies, and conditions were placed on his future funding.⁸ These complaints included the charge that Bluestone and his coauthors had a bias in favor of the drug, a charge that was not supported by the evidence, as well as a conflict of interest, in that they were heavily supported by the company that made the drug.

An appeals panel at the University of Pittsburgh found, in April 1990, that Cantekin had "engaged in uncollegial, presumptuous, and inappropriate conduct," although one of the panel members dissented, pointing out that Cantekin had in fact sent with his manuscript a letter of transmittal explaining that it was an alternate interpretation of the data in the article by Mandel et al, and Cantekin had offered in writing authorship to both Drs Mandel and Bluestone, both of whom had declined.^{9(p16)}

The newly formed Office of Scientific Integrity (OSI) assembled a scientific panel "to evaluate the scientific allegations raised by Dr Cantekin" ("that the University of Pittsburgh had censored his attempts to publish a dissenting manuscript") "and the counter allegations from Dr Bluestone that Dr Cantekin had inappropriately manipulated the data to obtain the results he desired," as well as the propriety of his submitting his manuscript to the *NEJM*. This OSI panel decided that the *NEJM* submission was misrepresented by the authors as the official report, and that may have been an attempt to "derail or delay" the article by Mandel et al.^{8(p28)}

The OSI, noting the findings of its panel, decided that Cantekin's actions were "inappropriate and represented significant departures from the standards of collegiality, mutual respect, and honest debate that should be the hall mark of collaborative research." The report noted that this was a pity because he had "raised legitimate concerns about the biologic and clinical significance of the data." They found no actual wrongdoing.^{8(p33)} They had criticisms of Bluestone's evaluation of the data and objectivity^{8(p33)} and noted various methodologic weaknesses. The OSI report added that "the coincidence of the large pharmaceutical company honoraria to Dr Bluestone and the less than objective reporting of the efficacy of pharmacological treatments present[s] the appearance of conflict of interest."^{8(p35)} (Approximately \$260 000 in personal honoraria between 1983 and 1988 and \$3.5 million in grants to the OMRC had been paid by pharmaceutical companies.¹⁰) Both Cantekin and Bluestone were put under some sort of oversight, Bluestone by the NIH at the OMRC, and Cantekin by the University of Pittsburgh.

The Role of Editors

More than 4 years before, the editor of the *NEJM* had been faced by two competing manuscripts. What alternatives were there? The editor could have sent both manuscripts out to review (either to the same or to different reviewers, the reviewers being blinded or not to the authors' names and

institutions) and, if both passed review, publish them both, with an editorial note to tell the reader what was happening. Or he could have replied that dissent is traditionally expressed in a letter to the editor. In the event, he properly concentrated on the issue of responsibility, and he proposed that the authors' institutions decide this. After all, editors have no power or ability to investigate on the spot and can certainly not get into the business of deciding who had done the work and who owned the data. In this case, the matter was decided easily, because both Cantekin and Bluestone shared the same institutions. Both institutions replied that Bluestone was the official author. And if Cantekin and Bluestone had belonged to different institutions, the editor would presumably have decided the matter on the basis of which manuscript carried the name of the person who took overall responsibility for the entire research: the principal investigator, who was Bluestone. I suspect that in 1986, in his position, I would have done the same. I now believe I would have been wrong.

Why Are We Publishing This Article?

We received the present version of the 1986-1988 article in January 1991, accompanied by a letter from Cantekin explaining what had happened in the interim and by the completed reports of the Pittsburgh and NIH/OSI investigations. The manuscript was little changed from the one we were unable to publish nearly 3 years before. Once again, we had it reviewed and revised, but this time we are publishing it.

The fact that it is at least 4 years out of date does not deter us. The news is still relevant to current therapy. Nor is such a delay unheard of: in June 1991, *Nature* published an article its editors had received in the autumn of 1987 and delayed because of doubts about the completeness of the data.¹¹

How could we get into the business of publishing the work of someone found by three committees at the University of Pittsburgh and one OSI panel to have been guilty of something close to scientific misconduct?

I myself had no hand in any of the decisions reached, but I remind everyone that authorship requires those whose names are on the article to assume responsibility for it. Editors have found only too often that when, after publication, the data in, or even the integrity of, a study has been questioned, the study has become an orphan or, at any rate, only a distant relative. For example, in 1978, one group published two studies simultaneously, with entirely discrepant results, neither study citing the other.^{12,13} When challenged, they excused the inexcusable by saying that "it has been our policy not to discuss unpublished data in a published paper."¹⁴

It is for this reason that journals such as *JAMA* have become so insistent about authors facing up to their responsibilities by signing forms that lay them out. In the present instance, Cantekin and his coauthors have signed these forms, acknowledging that they take full responsibility for their article. We would not publish it unless they had done so. Editors, while they do their utmost to get careful review and to select and edit papers with love and attention, go out of their way to disclaim responsibility for the accuracy of the work they actually publish, as we do in the present case.¹⁵ We publish this article, as usual, without endorsing or guaranteeing its contents.¹⁶

Scientific Correctness

In order to function coherently, institutions have to have commonly accepted modes of operation, and it is accepted that the principal investigator, for the pains of taking scientific, legal, and monetary responsibility, has first dibs on the data. But the problem with this is that the institution is unlikely to decide a dispute about the matter on the basis of the quality of the science, but on the basis of institutional hierarchy. Having the name of the principal author on a manuscript certainly does not guarantee that it is scientifically valid, or even that it is more valid than the studies that any of the other workers might publish.

Ownership of the Data

Meetings arranged by the OSI on data ownership and sharing over the last 2 years have shown that no one has a clear idea about who owns data, let alone how to share them.^{17,18} We behave as if the principal investigators owned and controlled the data: they take scientific responsibility; they defend their data and their interpretation. However, who owns and has rights to data in collaborative projects is often undecided.¹⁷ And ownership by the investigator is fine until problems arise, and then the institution that administers the grant money is called upon to take responsibility. It is, therefore, understandable that the institutions then claim rights over the data, even if the administrators cannot answer for the quality of the science. Although there are good arguments for holding that data gained with public money are owned by the public, researchers are going to be hesitant about investing sweat and blood in obtaining data if their results are to be freely and immediately available to those who have invested neither. If the principal investigator has had his or her chance, however, data should, after a reasonable time, become accessible to the public. In the present instance, plenty of time had passed. Moreover, Cantekin was not simply a member of the public, some outsider, but was research director at the OMRC. He had put the sweat of his brow into the products of the OMRC. Surely, he had rights of publication, too? Given that he had made his disagreement with Bluestone and his colleagues abundantly clear in his letters of submittal, was he not being effectively denied publication, not on the basis of the quality of his work, but by institutional decree?

The Role of THE JOURNAL

All of this would be moot if we did not think that the article by Cantekin et al was worth publishing as a substantive contribution to the literature on therapy for an important and common condition, otitis media with effusion. Viewed in this light, we are publishing despite, rather than because of, the controversy. We are particularly sensitive to this issue for a number of reasons having to do with our commitment to improve editorial peer review.¹⁹ The present article reports that amoxicillin is ineffective: its performance was no better than that of placebo. We believe that investigators have an obligation to publish "negative" results in order to avoid "publication bias."^{20,21} Dickersin et al²² have shown that 95% of the time when no published article had come out of research, it was because the results had never been submitted to a journal. With this in mind, when we receive a good "negative" article, we are not going to turn it down lightly,

especially if a contradictory “positive” article such as that by Mandel et al⁷ already has been published and cited a number of times. The Agency for Health Care Policy Research is currently backing a large prospective trial to assess the medical effectiveness of therapies in otitis media. Although we are unlikely to know the results for some years, a meta-analysis of trials of therapy is now in progress (Tom Chalmers, MD, oral and written communications, 1991), and this should aid our thinking. It is obvious that unbiased meta-analysis depends on access to the results of *all* trials.

A journal must be an arena for all comers to fight it out. We at *JAMA* have made a well-publicized commitment to fairness. A major criticism of editorial peer review is that it rewards orthodoxy and silences dissent.²³ An editor should, as Tennyson observes, “Cleave ever to the sunnier side of doubt.”²⁴ Whether we do or not, Ruderfer²⁵ has pointed out that erroneous acceptance is self-correcting, but erroneous rejection is not.

Was Cantekin to Blame?

The final determination by the OSI has been that both of the protagonists bore some blame, but neither was convicted of wrongdoing. Neither will like this, but it seems fair. Cantekin did indeed act in an “uncollegial” manner, but perhaps his dissent was not given enough credence by his colleagues, and a characteristic of whistle-blowers is that, whether by nature or because they feel forced into it, their actions are anything but collegial. Indeed, whistle-blowing, which is what Cantekin evidently thought he was doing, is the ultimate uncollegial act, and one we always seem, as if by reflexive action, to punish.

But the verdicts about the submission of the *NEJM* article trouble me, as they troubled the lone dissenter on the final inquiry board at Pittsburgh, and the tone of Pittsburgh’s response to Cantekin raises doubts about fairness. They raise questions about the role of a university in encouraging dissent.

The Pittsburgh reports read as if drawn up by the prosecution. To an editor, the strangest aspect is the fact that Cantekin, before sending his manuscript to a journal, had circulated it to Bluestone and the others, and they had withdrawn their names from it, so they knew very well that this manuscript existed. Stranger still is the fact that though he made very full disclosure to the editor, this remarkable fact is dismissed, not merely as a mitigating circumstance, but as having any relevance at all. This is even more bizarre when one considers what Cantekin could possibly have hoped to gain by sending his manuscript to the same journal as Mandel et al, and then drawing the editor’s attention to this fact. A surer way of alerting everyone to the facts of the case could not have been employed. If he had simply wished to get published, he would have sent the manuscript to another journal without saying a word, and if he had wanted to “derail” the publication of the article by Mandel et al, he would not have drawn the editor’s attention to the controversy.

We were impressed that Cantekin told all the editors of the three journals that his was a competing manuscript; that when, in January 1988, he sent us the second revision, he included a copy of the charges brought against him by the university; that when Cantekin was found guilty after the first inquiry, he sent a copy of the findings to us; and that when he submitted the manuscript early this year, he en-

closed the OSI’s final report. None of this seemed to be the behavior of someone trying to get fraudulent work published by deceit—which is why I look at the findings of the Pittsburgh inquiries with some surprise. When assessing Cantekin’s *NEJM* submission, why did the inquiry panels dismiss the piece of evidence that I would find most strongly to support Cantekin? These panels had to assume that letters accompanying manuscripts are meaningless or unread. My guess is that the editor of the *NEJM* read the covering letter, and that it was as a result of reading it that he wrote to the institutions concerned. Obviously, we at *JAMA* believe that the covering letter (and accompanying reprint) fully informed us of the situation. Also, as editors, we felt free to publish Cantekin’s piece only after he had added appropriate citations: something we very frequently demand of authors.

There is, moreover, an *ad hominem* quality to the Pittsburgh response that is disturbing. Cantekin’s bosses at Pittsburgh, Drs Myers and Donaldson,³ in their letter to *JAMA* commenting on Cantekin’s article, go out of their way to note that the writers of the paper Cantekin presented at the Peer Review Congress were “a bioengineer, an economist, and a lawyer,” the implication being that such people were incapable of writing a credible paper. Editors, on the other hand, make great efforts to judge manuscripts on the quality of research rather than the status of the researcher. A better argument for “blinded” peer review (blinding the reviewer to the name, rank, qualifications, and institution of the author) would be hard to find. Later on, Myers and Donaldson³ write, “Indeed, Dr Cantekin is not a physician,” as if Cantekin had been trying to represent himself as such, which he has not done. We editors were surprised at this approach. The trouble about bringing a bioengineer to Pittsburgh and putting him in charge of research in a clinical center and promoting him all the way to full professor is that he remains a bioengineer, and arguments buttressed by his not being a physician not only ring hollow but are self-defeating.

It’s a nuisance to have people around who oppose the official view. But universities and journals, which, as has often been said, are universities without walls, have to tolerate, and, indeed, flourish in the presence of difficult, awkward, critical people like Cantekin. It’s our job to put up with, and encourage, uncomfortable uncollegial characters who have unusual, unpopular, and original views: that’s what academic freedom is. The price of sticking with the “official line” is Lysenkoism, and it would be interesting to know whether the faculty at Pittsburgh were as enthusiastic as the administration in prosecuting Cantekin.

The Consequences of Publishing Two Competing Articles

The traditions of scientific publication are not lightly discarded, and this untraditional approach is alarming both to scientists and to editors, both of whom naturally fear a breakdown in collegiality. Surely the team should be required to work out their differences before going public? How much of a disagreement merits an alternative article? Would publication of the Cantekin manuscript open the gates to a flood of manuscripts by dissenting coauthors? How many manuscripts based on the same data could how many coauthors submit?

For a partial answer, let us look at what already happens.

The submittal of two such manuscripts, by coworkers unable to agree on interpretation of their data, must be exceedingly rare. In 1990, *The Lancet* published an article in which the "Introduction," "Methods" and "Results" sections were followed by two "Commentaries" because the authors had been unable to agree on one interpretation.²⁶ There may be a huge oil field of dissenting manuscripts out there, ready to gush, but I doubt it. I therefore believe that such dual submissions are unlikely to increase suddenly. All the forces of team dynamics tend to get researchers to work things out, and if, as will happen occasionally, this is impossible, then freely acknowledging and airing the problem may go a long way toward solving it.

The International Committee of Medical Journal Editors tackled the question when they met in 1989. Indeed, their statement on "competing manuscripts based on the same study" could be called the Cantekin resolution.²⁷ Pointing out that editors should discourage competing manuscripts, they divide such submissions into two theoretical types. In one, there is disagreement about the facts: on what was actually done or observed. Here, peer review cannot help, and it's hard to imagine publishing either. Where disagreement is on the analysis and interpretation, as in the present case, peer review may assist in distinguishing which version should be published. The Committee suggests that one might be published later than the other, either as a letter to the editor or as a full article.

So accepting both manuscripts and leaving it to the reader to decide between them would have best served the cause of scientific openness. It would scarcely have brought the system to its knees, or started any dangerous and subversive trend, and it would have reflected the fact that scientific disagreements among coworkers are frequent, indeed, they are the stuff of science. It would surely have provoked a lively correspondence: in many ways the very best form of peer review.

Coda

During the time that the Cantekin affair has unfolded, many changes have taken place. Increased public and congressional awareness of misconduct has forced the setting up of government bodies like the OSIR (Office of Scientific Integrity Review) and OSI, and new rules have been promulgated that govern institutional conduct. These rules, and other issues such as data ownership and sharing, are being strenuously debated. But almost none of the machinery was in place when the parties in this dispute took up arms and when the University of Pittsburgh and the NIH were put in the position of trying to sort it out.

Whether or not Cantekin's attempt to get his version published was, in the words of the board that convicted him, "an attempt to derail publication of the official report," the bringing of charges against Cantekin did in fact derail *his* report, since it would otherwise have been accepted by *JAMA*. So after all these years and all these inquiries, so costly in time, money, and emotions, the public have yet to see the counter

view. Looking back, surely publication of this dissenting view would have been very greatly to the benefit of all parties. We are now publishing it so that our readers can decide for themselves.

Drummond Rennie, MD

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