

# Dishonesty in Medical Research

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**The President:** Good evening, ladies and gentlemen. We are in for another treat. Having had dinner this evening with our speaker, Dr Peter Wilmshurst, I can assure you that he is a man of many parts. He is a cardiologist at Shrewsbury and was formerly at St Thomas's. I think he has been irritated by the comments in the media about expert witnesses, because he said to me in an e-mail, "I will justify my ability to speak on this subject during the course of the talk." He is going to speak on misconduct in medical research or "Dishonesty in Medical Research". He is a member of the Committee on Publication Ethics and received an award from HealthWatch in London "for challenging misconduct in medical research". Peter, please give your talk; we would be most grateful.

**Dr Wilmshurst:** Thank you very much for asking me to speak about dishonesty in medical research. Research fraud is just one of the types of fraud we come across in medicine. It may involve falsification of data, falsification of approval from Research Ethics Committees, falsification of documentation relating to use of radioactive isotopes (such as ARSAC certificates), and even falsification of Clinical Trial Certificates by a pharmaceutical company. People who falsify their research often have a history of other types of dishonesty, including cheating in examinations, plagiarism, falsification of qualifications, financial fraud and falsification of audit data. Today I want to present to you examples of most of these types of dishonesty.

My main concern is not that some doctors and some researchers are dishonest, because in any profession there will be some dishonest people. My main concern is that within the medical profession there is a failure to deal with the misconduct and that is illustrated in the examples I will present.

We do not know how common research fraud is, but there is some data. In 1988, when he was the editor of the BMJ, Stephen Lock published a survey in which he asked academics in the UK about their experience of fraud in medical research (Lock 1988). Half were aware of cases of research fraud, but in only 8% of the cases was the fraudulent research retracted and only 3% of the fraudsters were dismissed. In 1995 a Scandinavian study reported that 22% of scientists surveyed were aware of research fraud (Bekkelund 1995). The Committee on Publication Ethics was founded in 1997. In the committee's first five annual reports it described over 160 cases of research misconduct which it had investigated.

First I should describe how I am qualified to talk on the subject. In 1982, I was a Research Registrar doing research on the drug amrinone, which was intended to be a treatment for heart failure. Sterling-Winthrop, the pharmaceutical company that made amrinone, hoped that it would be a positive inotropic agent (that is, increase the force of contraction of the heart) with few side effects. The results obtained by my colleagues and I showed that amrinone was not an inotropic agent and that it had a very high incidence of adverse events. When we informed Sterling-Winthrop of our findings we were asked by the company to remove certain of our patients from our analysis. The reasons given by the company for requesting the removal of these patients were spurious, but each patient was one whose measurements showed a slight reduction in contraction after they were given the drug. Removing those patients would have altered the statistics and would have resulted in an apparent increase in contractility with the drug when none existed. When we said we were obliged to publish our observations, we were threatened with litigation if we did.

Later that year I went to San Diego and I met Bob Slutsky. Bob Slutsky was one of the most prolific fraudsters in the history of cardiac research (Lock 1996). Many of his papers have been retracted. At his height, Slutsky was publishing a paper every ten days. When I visited San Diego it was apparent to me that most of his colleagues in the department and

many other people in the hospital probably knew or suspected that he was making up his data. Yet Slutsky was not exposed until four years later.

In 1986 I went to *The Guardian* newspaper to point out problems with research that I had come across (Erlichman 1986, Wilmshurst 2004). I turned to the press because I could not get any of the institutions in this country that I felt should have dealt with research misconduct to do so.

For the next ten years I tried unsuccessfully to get editors of journals interested in the subject. Then in 1996 Richard Smith invited me to give a seminar at the BMJ for editors of the BMJ Publishing Group. Richard Horton from *The Lancet* was there. At the start of the seminar I told them that I would be presenting cases of research misconduct that I believed were common knowledge within different medical specialities but where there had been no correction of the scientific record or punishment of the guilty. There was great scepticism about this claim before the seminar. I then presented 16 cases. People in the audience were able to confirm what I said about five of the cases. This confirmation had a dramatic effect. Immediately after the meeting Richard Smith and Richard Horton agreed to publish editorials in the *BMJ* and *The Lancet* calling for action on research fraud. They appeared two weeks later (Lancet editorial 1996, Smith 1996).

In 1997 COPE was founded and I was asked to sit on it. Since 1999 I have briefed the Chief Medical Officer twice and senior officials from the NHS Executive about the problem of research fraud. But the thing that strikes me is that when I speak to medical leaders about research fraud, it is clear to me they have got no idea what they should do about it. I have reported about 20 doctors to the General Medical Council (GMC) for research misconduct.

The first two doctors who appeared before the GMC were Banerjee and Professor Peters from King's College London (Wilmshurst 2002). Eighteen months after he had qualified as a doctor Banerjee had 49 publications. Apparently, nobody seemed to find it suspicious that such a junior doctor had this phenomenal number of publications. At that stage he was appointed to be a surgical SHO at Northwick Park Hospital. Dr Peters was working as a consultant biochemist at Northwick Park Hospital at the time. Banerjee wrote to Dr Peters to ask whether he could do some research in Peters' laboratory in his spare time. We know that a surgical SHO does not have much spare time. Researchers in the laboratory started to notice that Banerjee was producing data in a few weeks that they, working full-time, would take eighteen months to produce. Peters was warned of concerns about Banerjee. Members of the research staff were offered co-authorship of papers drafted by Banerjee, but refused the offers because they had no knowledge of the research reported. Later it was proved to be fabricated. Then Peters moved from Northwick Park to King's College London to become Professor of Clinical Biochemistry based at King's College Hospital. Many of the staff in his laboratory moved with him. Despite concerns expressed to Peters about Banerjee's honesty, Banerjee also moved to King's with Peters. Banerjee had concurrently a clinical attachment in the department of surgery at King's College Hospital: so he was part surgical registrar and part research fellow. He had a Medical Research Council grant and some other research grants.

At King's people also became concerned about the research Banerjee claimed to be doing. Banerjee claimed to have done experiments that required techniques he had not been taught. He claimed to have used equipment to which he had no access. Seven colleagues complained to Peters that Banerjee was making up data. Eventually Banerjee was caught out because he claimed to have used more of a particular radioactive isotope for an experiment than the department had purchased. As a result he admitted that he had made up data. At around the same time he was taken off clinical duties in the Department of Surgery at King's, because of concerns about his clinical skills.

King's held an investigation. Professor Harold Baum, a clinical biochemist and head of another faculty at King's College, investigated. Harold Baum's brother, Professor Michael Baum, was the head of the department of surgery in which Banerjee had his clinical attachment. Harold Baum reported back in 1991 that:

“Having carefully examined the documentary evidence which you sent me, I am totally satisfied that much of the research data reported by Dr Banerjee since 1988 is at best unreliable and in many cases spurious.”

So what happened? Much of the documentary evidence was never seen again. Whistle-blowers who complained about Banerjee were advised to keep quiet or their careers would suffer. King's did not tell the Medical Research Council or any of the other funders that Banerjee had not done the research for which they had given their grants. King's did not repay the grant money. Peters subsequently put his name as co-author on a paper that many people in the department said was falsified. Banerjee left in the usual way. He got a good reference and was promoted.

He also got for this research a Master of Surgery degree from the University of London, even though a person in Peters' department informed the University that the research was fabricated. That MS has not been retracted even though the research was later shown by the GMC to be fabricated. I know that the MS has not been retracted, because I went to the University of London on my way here today and checked. The failure to revoke his MS is despite the fact that after Banerjee appeared before the GMC, the University of London asked Professor Michael Farthing to check the MS and Professor Farthing confirmed that the data in the MS was largely identical to that which the GMC had determined was falsified.

Banerjee was also awarded a Hunterian Professorship for the falsified research and presented it during a Hunterian Lecture to the Royal College of Surgeons, England. Those are the most prestigious lectures at the Royal College of Surgeons. He gave the lecture though some senior Fellows of the College were aware that the data he was presenting was false.

After leaving King's, Banerjee moved on to the West Midlands surgical registrar rotation. He was not on the rotation long, because according to his Consultant he was found to be “the worst registrar we ever had”, and he was sacked. But he was immediately appointed to the surgical rotation in the Trent region. Banerjee got an MD from Nottingham University. Banerjee then got a consultant post in Halifax. He was suspended a couple of years later for financial dishonesty and concerns about his clinical skills.

Banerjee had two GMC hearings. Banerjee was nominated for Fellowship of the Royal College of Physicians in both London and Edinburgh at a time when he was suspended from his hospital, the Royal College of Surgeons of England was investigating his clinical incompetence, the police were investigating his financial dishonesty and he was awaiting his GMC hearings. I saw his name on the list of doctors nominated for the Fellowship of the Royal College of Physicians in London, because I am a Fellow of the London College. I telephoned the College and informed the Officers of my concerns about Banerjee. As a result the London College held off giving him the FRCP. Unfortunately nobody warned the Edinburgh College and Banerjee got the FRCP from Edinburgh in time for his GMC appearance. Banerjee was initially found guilty of serious professional misconduct for his research misconduct. Shortly afterwards Peters was found guilty of serious professional misconduct for failure to take appropriate action when Banerjee's misconduct was reported to him.

Banerjee's second appearance before the GMC was for misleading patients about NHS waiting lists. He lied to patients about the waiting times for surgery to induce people to go privately. Most shameful was the inflation of waiting times for procedures for patients suspected to have bowel cancer. He also performed unnecessary private operations. He incorrectly billed patients and their health insurers to increase the amounts he received. Banerjee was eventually removed from the Medical Register because I complained to the GMC about his misconduct.

In my opinion, the disgrace is that senior doctors and managers, who were far better informed about Banerjee's misconduct than I, were prepared to allow him to progress despite concerns about his clinical skills and honesty. We know that senior members of the profession did not stop him getting qualifications dishonestly. A professor put his name to research he knew to be falsified and others were prepared to see false research published. Is that an isolated case?

As I said earlier, when I worked on a drug called amrinone back in the early 1980s we were put under severe pressure in an attempt to stop us publishing our data (Erlichman 1986, Wilmshurst 2004).

Sterling-Winthrop, the company that made amrinone, prematurely stopped our other trials with amrinone. Then the company started attempts to discredit our data. Initially when I presented our data at a meeting a company representative would stand up and accuse me of fabricating the data. That was easy to counter. I would point out that I was an independent investigator with nothing to gain by making up negative data and that my accuser was a company employee. I would then ask the chairman to appoint someone to look at our data. Then Winthrop started to get eminent cardiologists to claim at meetings that they had attempted to replicate our studies and failed. They did this on a number of occasions, until 1984. In that year at the European Congress of Cardiology, I pointed out that a particular professor had repeatedly said for two years that he had failed to replicate our findings but that he had not published his observations, so people might doubt his honesty. He did not challenge me publicly again. Twenty years later there has been no publication of any failure to replicate our data. This convinced me that some opinion leaders could be paid by pharmaceutical companies to make false statements about drugs and research. I know that an American professor of cardiology, who was a consultant to the company, persuaded three other groups (in Arkansas, California and Ohio) not to publish their finding on amrinone. He did so by telling them that they alone were failing to show that amrinone was a positive inotropic agent. He told them that if they published, they would be embarrassed by their failure to confirm what everyone else could show. In fact their findings were consistent and confirmed what we demonstrated.

While this was going on I discovered that amrinone capsules had not got a Clinical Trial Certificate for use in the United Kingdom, even though the company said that it did. We had been working with amrinone at St Thomas's Hospital. Others at the National Heart Hospital, at Hillingdon Hospital, in Birmingham and at the Freeman Hospital in Newcastle also worked with amrinone, and all had been told that amrinone had a Clinical Trial Certificate. The company had clearly broken the law covered by the Medicines Act.

Soon after we published a paper on the side effects of amrinone (Wilmshurst and Webb-Peplow, 1983) I received a letter from a doctor at the Netherlands Committee for the Evaluation of Medicines, which is the equivalent of the UK Committee on the Safety of Medicine. He said he did not understand the paper we had just published because he had our clinical records cards and the side effects described in the paper were not recorded in the record cards. I had a copy of my clinical records cards and we compared those with the documents that had been supplied to the Netherlands Committee by Sterling-Winthrop. The clinical records cards submitted by Sterling-Winthrop to the Netherlands Committee had been falsified and the company had deleted data about side effects. For example we found that 50% of patients on oral amrinone for a week became thrombocytopenic.

It is useful to look at how we came to start work on amrinone. It appeared to be a promising drug. At that time there were only two treatments for heart failure – diuretics and digoxin. There were no ACE inhibitors and no vasodilator therapy. Then in 1978 the *New England Journal of Medicine* published a paper by Benotti and colleagues (Benotti *et al*, 1978). It was accompanied by an editorial by an eminent cardiologist, Professor Arnold Katz. The article caused a lot of interest and the price of Sterling-Winthrop shares increased dramatically. However the study was small and its authors made claims that were not supported by the data. To claim a pharmacological effect one must demonstrate a dose-response effect and the authors had not. There were only six patients in whom the authors measured contractility. I do not think that this study would have been published in the *New England Journal of Medicine* had it not been that one of the five authors was Eugene Braunwald. Braunwald was the Professor of Medicine and Cardiology at Harvard, a member of the editorial board of the *New England Journal of Medicine*, and a close personal friend of Dr Arnold Relman, the editor of the journal. The paper claimed that the five authors were all employed by Harvard Medical School. In fact two of them were full-time employees of Winthrop. Two others were paid consultants for the company (Wilmshurst 1997b). None of

these conflicts of interest were declared. In fact the New England Journal of Medicine's policy on conflicts of interest, which they vaunt, was published in the journal one month after I wrote to the Massachusetts Medical Society, which owns the New England Journal of Medicine, complaining that these authors, including a member of the Journal's Editorial Board, had not declared their conflicts of interest (Wilmshurst 1997b, Relman 1984). In response to my letter to *The Lancet* in 1997 Relman stated "We took no action in the 1978 because at that time we had no basis for insisting on disclosure" (Relman 1997).

News of the side effects of amrinone seeped out very gradually. As stated previously the price of the shares in Winthrop increased dramatically in the weeks after the paper by Benotti and colleagues appeared in the *New England Journal of Medicine*. In Los Angeles, California, another cardiologist, Dr Stanley Rubin had a patient with heart failure and, unfortunately for that patient, his wife was a stockbroker. She saw the dramatic increase in the price of Winthrop shares following the paper by Benotti and colleagues. She persuaded Rubin to get this *wonder drug*, amrinone, on a named patient basis for her husband and unfortunately he died very soon afterwards from the side effects of the drug, including thrombocytopenia and autoimmune phenomena. Rubin and some of his colleagues sent a report about these side effects to the *New England Journal of Medicine*. It was the first report of side effects with the drug (Rubin *et al*, 1979). They did not tell Sterling-Winthrop that they were submitting a report. Within two days of sending the report to the journal Rubin was under pressure from the company to retract the paper. Relman, the editor of the journal, had sent a copy of the report to Sterling-Winthrop and the company tried to get Rubin to retract the report. Eventually Rubin got his report published in the journal, because he threatened that unless his report was published he would go to the press and point out the collusion between the journal and Sterling-Winthrop (Wilmshurst 1997b, Relman 1997, Wilmshurst 1997c).

Soon after this, Sterling-Winthrop produced a congener of amrinone called milrinone. It was 15 times more potent than Amrinone. Research on milrinone was also undertaken in Braunwald's laboratory (Baim 1983). When the paper was submitted the journal sent it to two referees, one of who was Arnold Katz. Both Katz and the other referee recommended rejection. So Relman sent the paper to two further referees. They also recommended rejection. Then this so-called peer review journal published the paper, despite the fact that the referees expressed serious reservations about its publication (Wilmshurst 1997b). Relman rejected the allegations that I made in *The Lancet* (Relman 1997), but I provided *The Lancet* with documents to support my allegations (Wilmshurst 1997c).

In 1984 Sterling-Winthrop told the Food and Drug Administration in the USA that amrinone was unsafe because there had been over 1,400 life-threatening side effects in the first 1,200 patients given the drug. Sterling-Winthrop told the FDA that the company agreed to stop research on or marketing of amrinone or applying for product licences worldwide. Two years later I discovered that this drug, which was unsafe to have on a doctor's prescription in Europe or North America, could be bought over the counter in parts of Africa and Asia. I went to Oxfam to collect the evidence, because Oxfam had staff in all the relevant countries. Oxfam collected the evidence and it was presented to the World Health Assembly in Geneva in 1986. This embarrassed Sterling-Winthrop into withdrawing amrinone worldwide, two years after the company had promised to withdraw it.

In 1986 I also went to the *The Guardian* newspaper to report the marketing and research practices of Sterling-Winthrop. I was concerned that there had been no sanctions for breach of the Medicines Act with respect to lack of a Clinical Trials Certificate. I now know why that was, because Dr Trout, the senior Vice-President of Winthrop, told me. He bragged that he was going to tell the Health Minister that if Sterling-Winthrop was prosecuted for the breach of the Medicines Act the company would withdraw all drug manufacturing in this country and close a big manufacturing plant they had at Fawden near Newcastle-upon-Tyne. I went to the GMC, the Association of the British Pharmaceutical Industry and the Royal College of Physicians of London, which accommodates the Faculty of Pharmaceutical Medicine. None of these organisations would take any action against the company or doctors employed by the company. I went to medical journals, including the *BMJ*, *Lancet* and *Nature*. All of them believed the story I told but none of them was prepared to take on a multinational

pharmaceutical company. So I went to *The Guardian*. *The Guardian* and its lawyers were confident that with the documents I supplied, we would not be sued if they published the story. *The Guardian* published in 1986 (Erlichman, 1986) and we were not sued.

Around the same time, Dr John Darsee also worked in Braunwald's laboratory at Harvard. Darsee falsified many publications (Lock 1996, Wilmshurst 1997a). He was caught because his findings in a multicentre study did not accord with those found by others. The resulting inquiry discovered that Braunwald had been aware that Darsee was falsifying his data for many months prior to his exposure, but Braunwald had decided to let Darsee continue doing research (Broad 1982, Broad and Wade 1985). Stewart and Feder, working at the NIH (National Institutes of Health), looked at the research from Braunwald's laboratory and they reported major discrepancies in much of the data coming out of it (Stewart and Feder 1987). Braunwald responded in the same issue of the journal (Braunwald 1987). Stewart and Feder were reprimanded by NIH for investigating research fraud.

Darsee, working in Braunwald's department at Harvard, was the second most prolific fraudster in cardiology research. He was second only to Bob Slutsky, who worked in San Diego in the department that Braunwald had set up before he moved to Harvard.

In 1986 Dr Petersdorf, the head of the Medical School at the University of California, San Diego, wrote:

“A young faculty member ... was discovered to have submitted several papers containing fraudulent data to several reputable journals. Up to this shocking discovery he had not been suspected of malfeasance” (Petersdorf 1986)

However, five years earlier, in 1981, I had told a doctor at the London School of Tropical Medicine that I was visiting San Diego the following year. She had worked in San Diego and she told me that I would meet Slutsky and that everyone knew he made up his data. When I went to San Diego, it was clear that Slutsky made no secret of his research fraud – it seemed to me that everyone knew. He even told me: “I always knew Darsee was a crook. He's the only one who published more than me.” For at least five years it was no secret in his hospital that he was making up data; many colleagues knew and nobody did anything about it. Slutsky was caught because of the vigilance of an external assessor.

Nearer home, I reported Clive Handler to the GMC and he was found guilty of serious professional misconduct (Dyer 2002). His offence was not research fraud, but he embezzled charitable research funds at Northwick Park Hospital. He used charitable research funds to pay for hire of his private consulting rooms, to pay his Medical Defence Union and British Cardiac Society subscriptions, and to pay for social events. The technicians in the Cardiac Department at Northwick Park Hospital were very angry about this and they reported him to the hospital management. An investigation confirmed that Handler had embezzled thousands of pounds. We will never know exactly how much because the hospital reached a severance agreement with Handler that if he went quietly they would not tell the police or the GMC, they would destroy the documentation and they would let him continue to use the private facilities at the Hospital until he got set up in Harley Street (Dyer 2002). The Trust Board agreed this deal. The most senior doctor on the Trust Board at the time was its Medical Director, Professor Peter Richards. Richards should have known that embezzling was the sort of thing one ought to report to the GMC, because Richards was a member of the GMC. When Handler appeared before the Professional Conduct Committee of the GMC Richards was its Chairman. Richards had to stand down from the hearing and let someone else chair it, because of his conflict of interest (Anonymous 2002). After the finding of serious professional misconduct against Handler, Richards returned to chairing Professional Conduct Committee hearings. Can you imagine a similar situation in a criminal court, with a judge having to stand down from hearing a case because he had been implicated in the cover up of crimes and then, as happened to Richards, being permitted to going back to being a judge? The GMC's own solicitors and I asked that the GMC act against Richards. The GMC will not act against him and the GMC will not tell me its reasons. The GMC let Richards remain on the Professional Conduct Committee. In the case of Banerjee and Peters, Peters was found guilty of serious professional misconduct by the GMC because he had not taken action to expose Banerjee's

misconduct. Surely the behaviour of Richards was similar to that of Peters, because Richards had failed to report Handler's misconduct? The GMC seems to have special rules for protecting its own.

Professor Peter Collins at the Royal Brompton Hospital is someone else that I reported to the GMC. Collins had made false statements about having been awarded an MD degree in job applications. However, the thing that concerns me most is that Collins was promoted to be professor after the senior managers and governors at the Royal Brompton Hospital were made aware that he had made false statements about qualifications in successful applications for posts of Senior Registrar and Senior Lecturer at the Royal Brompton, and the post of Honorary Consultant Cardiologist at the Westminster Hospital. When the Westminster Hospital discovered this dishonesty they immediately terminated his contract, but Collins not only remained at the Royal Brompton, he was promoted to be a professor of cardiology. Collins' dishonesty went on for a number of years. He had been putting false qualifications on his letterheads and in medical directories. On discovering the deception by Collins, which was before he was promoted from Senior Lecturer to Professor, the management at the Royal Brompton Hospital sent a memo to every consultant in the hospital pointing out that they were not allowed to claim qualifications they had not been awarded. One wonders why a hospital would feel it necessary to do that unless there were concerns that Collins was not unique in this behaviour.

Another consultant cardiologist at the Royal Brompton complained and suggested that Collins should be sacked. The Chairman of the Board of Governors at the Royal Brompton, Sir Philip Otton, advised that consultant that his career might suffer unless he dropped the matter. Sir Philip Otton is a very senior judge. He is a member of the Judicial Committee of the Privy Council. He hears the appeals by doctors against the findings of the GMC. The GMC has decided that it will take no action against Collins. However the GMC's treatment of Collins differs markedly from treatment other doctors have received in recent times for claiming qualifications that they had not been awarded. Many have been erased or suspended from the Medical Register in recent years. Most of those treated that way had names that do not sound British. In fact most sound African or Asian.

One of my main research interests is in diving medicine and decompression illness. I am Chairman of the UK Sport Diving Medical Committee and I am a cardiac advisor to the Health and Safety Executive on diving medicine. So I was interested in the report in *The Lancet* in 1989 by Adkisson and colleagues in the Royal Navy. It described a radioactive isotope HMPAO brain scan technique for use in divers who had decompression illness. The authors claimed that the results of their technique always correlated with clinical findings. However I was immediately concerned about the report because I see many amateur divers who have had decompression illness in the UK so that they can be certified to return to diving. Around the time of the publication I saw divers who had had scans performed by the Royal Navy and they showed me letters from the Royal Navy doctors suggesting that the claims in the paper were inaccurate. For example one had a letter stating that although he was thought clinically to have non-neurological decompression illness his brain scan suggested neurological involvement. Clearly in his case there was no absolute correlation between his scan and clinical findings. Also a senior Royal Navy officer stated that they were picking up more cases of neurological decompression illness using this scanning technique, because it could pick up neurological involvement that was not detectable clinically. I also had concerns about whether ethics committee approval and ARSAC approval for use of the isotope had been obtained. I wrote to the Royal Navy in my capacity as Medical Adviser to the governing body for sport diving. The most senior doctor in the Royal Navy at the time, Surgeon Rear Admiral Revell, assured me that ethics and ARSAC approval had been obtained but he did not send me a copy of the certificates despite my request for these. I initially tried to get the *Lancet* to do something about my concerns six weeks after the paper was published, and again two years later, but the *Lancet* was not interested in pursuing the matter. Then in 1995 Richard Horton declared a policy whereby the *Lancet* would withdraw aegis from an article if the *Lancet* agreed that had the full facts been known at the time of publication the paper would not have been accepted (Horton 1995). To date there is no final decision on withdrawal

of aegis. I also complained to the GMC about the authors and two Admirals, Revell and Payne – Payne was Revell's successor. The GMC confirmed my fears that this paper did not have ethics committee approval or ARSAC approval for the injection of radioactive isotopes into people who were suffering an acute neurological event. So when Revell told me that ethics committee and ARSAC approvals were in place, it was untrue, though I cannot say what Revell had or had not been told about this when he wrote to me. The GMC has confirmed that there was no written consent. The authors will not produce their data for the *Lancet*, for me, my Committee or the GMC. When I initially complained about this research, Payne complained to the GMC about me, alleging that I was disparaging the doctors who were the authors of the paper. The GMC insisted they investigate me for disparagement before they investigated my allegations that the research was unethical and falsified. The MDU, which represented me, felt that this was strange. On the face of it the GMC was giving precedent to investigating the less serious charge of disparagement and we asked the GMC how they could investigate whether there had been disparagement without looking to see whether the allegations were true. I was exonerated and the GMC has found that much of what I alleged was true. The GMC will not rule on the issue of falsification of data, for the simple reason that the authors will not produce their original raw data for the GMC. I believe that the GMC is afraid to take on the Royal Navy. The Chief Medical Officer is not keen to do anything about this. I am still trying to get the *Lancet* to withdraw aegis from this paper.

Because of my experiences, I believe that dishonesty is common in medical research. It is an international problem. One may do research in one country and publish the findings in a journal in another country. It obviously wastes resources and endangers patients. There is active concealment of dishonesty by some colleagues and passive tolerance by others. It seems clear to me that senior officials do not know what to do about it.

I do not think that I have all the answers, but I think we need to establish the extent of the problem. We need to change the reasons that people do research. We need to train people to do research and to train people to supervise research. We need inspection of raw data, proper investigations of allegations of misconduct, real sanctions against the dishonest and proper protection for whistle-blowers. We also need help from the lawyers and law-makers to amend the libel laws. I publish lots of cardiac research that has implications for patient survival and no journal editor has ever asked me to prove that I got the result I claimed. I also have sent journals articles that might embarrass a physician and the journal's lawyers mull over my article for years before they decide whether we can or we cannot publish it.

Thank you very much. (Applause)

## Discussion

The President: Well, that was a most provocative talk. I think there may be scope for interaction with John Griffin.

Well, I know you have got to be off by quarter-past nine, but are you happy to take a few questions?

**Dr Wilmshurst:** Yes.

**The President:** Would you please, for the record, say who you are and what is your discipline?

**Dr Mansell:** I am Martin Mansell, I am a nephrologist, and of course I followed you from St Thomas's to Northwick Park. Can I ask you two questions? You were presumably doing your Research Fellow at Tommy's when the Amrinone work was going on?

**Dr Wilmshurst:** Yes.

**Dr Mansell:** Were you getting awful flak from the company, or were the consultants in charge of the research project?

**Dr Wilmshurst:** Mostly me. One of the consultants got some, but it was mostly me, because I was presenting the work, I was doing the work and I suppose I was the easier target.

**Dr Mansell:** Did they give you guidance as to how to handle the flak?

**Dr Wilmshurst:** No, not really. At one point I rang up the MDU and I spoke to one of their medical advisers. I asked what I should do about the way the company had stopped our

trials without consultation. The adviser said she would discuss the problem with colleagues and get back to me. She did not contact me again, but a few hours later a consultant physician at St Thomas's sought me out and advised me to let the matter drop, or it would be bad for both St Thomas's and the medical profession. The physician was not a cardiologist and I had not said anything to him about what was going on. I later discovered what happened was that the adviser at the MDU had asked the senior doctor at the MDU, Dr John Harman, for his advice. Dr Harman had worked at St Thomas's, so he rang Dr Desmond Croft, who was the senior physician at St Thomas's. Dr Croft then told another consultant, who tried to put pressure on me to drop the whole matter. So things were very difficult. I thought that I was not getting adequate support from seniors in my hospital and that even my defence organisation, the MDU, had let me down by breaching confidentiality and increased the pressure on me to conceal misconduct.

**Dr Mansell:** Can I follow with another question, because I am also the Deputy Editor of the Journal, which is going to publish what you have said tonight. You have been very direct in what you have said, and that's fine. Would I be right in thinking that you are saying "I dare you..." to some of the people that you have mentioned. I know that this is all in the public domain, I have read this, but it is going to appear in what we think is a respected journal read by a lot of lawyers and some doctors. Should I be worried about that, or should our President be worried about that?

**Dr Wilmshurst:** I think your lawyers should. Lawyers see things entirely differently to the rest of us. I thought I knew what the truth was. Then I got into research and I realised that the truth is what you could prove. Then I got involved with lawyers and I realised that the truth is what the lawyers of the insurer of the journal say that they are prepared to support in a court hearing.

**Dr Mansell:** I am sure my Editor will want to follow that up. (Laughter)

**Mrs Brahams:** Dr Wilmshurst, I am the Editor, Diana Brahams. Can I thank you very much for a very brave and provocative talk.

**The President:** Hear, hear!

**Mrs Brahams:** I was wondering whether you had any comfort from some of the remarks made by Dame Janet Smith today talking about the GMC.

**Dr Wilmshurst:** I only saw the newspaper headlines this evening.

**Mrs Brahams:** She said it is a rather cosy club...

**Dr Wilmshurst:** Yes.

**Mrs Brahams:** ...which looked after its own rather than patients and needed a great deal of change.

**Dr Wilmshurst:** Yes, I agree that the GMC is a cosy club.

**The President:** I think she said that it was putting the interests of doctors before the interests of patients.

**Dr Wilmshurst:** As I stated Professor Peter Collins obtained advancement by claiming to have an MD that he had not been awarded. The GMC did not even take him to the Preliminary Proceedings Committee, and they told me that what he had done was not the sort of thing that they would normally erase someone for. I looked at GMC verdicts a couple of years before and a couple of years after the GMC told me they would not take action against Collins. In that period there were six or eight doctors taken to the Professional Conduct Committee for claiming qualifications that they had not been awarded and some were struck off and some were suspended. So clearly they do take this offence seriously on some occasions. I do not know any of these people, but what was very clear about the names is that all the names of these people sound African or Asian to me.

**The President:** One last question. Sir John Skehel.

**Sir John Skehel:** I don't quite understand the role of Ethical Review Committees in such matters. I mean, does what you say mean that such committees can't be approached from outside, or does it mean that they have nothing to do with what goes on after they have given permission for it to start in the first place?

**Dr Wilmshurst:** I do not think they check. Perhaps they ought to check, but I do not know if they are qualified or have time to check what happens in research. I do not think that ethics

committees have the facilities or the will or the power to look at what goes on after they have approved it. Of course there are all sorts of ways of circumventing the need to get approval. For example there are British researchers who have done research in developing countries because they could not get approval to do the research in their own institution.

**The President:** Thank you very much, Peter. May I, on behalf of the Society, offer you a little token in appreciation of your courage and what you have said to us tonight, which I am sure is going to give us considerable food for thought.

**Dr Wilmshurst:** Thank you very much.  
(Applause)

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