The effects of the libel laws on science – a personal experience

Dr Peter Wilmshurst

Over the last three and a half years I have defended three defamation claims (for both libel and slander) in the High Court in England brought by NMT Medical, (NMT) a US medical device corporation. The claims ended recently when NMT went into liquidation. I still do not know how much defending the claims has cost me. I believe that I had to defend the claims to ensure that the results of the Migraine Interventional with STARFlex© Technology (MIST) Trial were published accurately and fully. To understand the legal cases one needs to understand some of the events in the trial. The trial was sponsored by NMT, it was performed in the UK and I was one of two co-principal investigators.

The first claim was issued soon after I spoke about the results of the MIST Trial at the Transcatheter Cardiovascular Therapeutics (TCT) conference in the USA in October 2007. Comments attributed to me were put in an article on a US cardiology website, called *heartwire* by medical journalist Shelley Wood. The website and the journalist were not sued. The second claim was for an amended version of the article, which remains on the website [1]. Shelley Wood had made a recording of what I said about the trial at TCT. Defending the claims was made difficult because the website editor, Larry Husten, refused to give me either a copy of the recording or a transcript of the words I had said about the trial. He claimed that what I had said was confidential and company policy did not allow him to share with me what I had said. Some may think it is strange that the same consideration for confidentiality did not prevent the website publishing part of what they claimed that I had said about the trial.

The Today Programme on Radio 4 broadcast an interview with me about the English libel laws on 27 November 2009. The interview was pre-recorded and checked by the BBC's lawyers to make sure that there was no risk of defamation. Nonetheless NMT issued a third claim against me in the High Court on 26 November 2010 in respect of the broadcast. Because there is a limit of one year on issuing claims for defamation that was the last possible day that the claim could be issued. NMT had a maximum of 4 months after the claim was issued in which to serve it. They served it at 10.20pm on 24 March 2011. The fact that NMT waited until the last possible moment to issue the claim and then to serve it does not suggest urgency on the part of NMT to

defend its reputation. NMT took no action against the BBC and did not attempt to have the interview removed from the BBC's website.

I believe that everything that has been done during the claims was designed to make the case long and complex, which increased legal costs and would have increased the chance of bullying me into an agreement that gagged me from expressing my concerns about the clinical trial. I do not believe that the claims were ever about NMT's reputation in this jurisdiction. In fact NMT's device was not used by many UK cardiologists and I believe that few if any of those would have seen the article on *heartwire* until their attention was drawn to it when news of NMT's claim against me became public knowledge.

Another reason that I believe that the purpose was to prevent me expressing my concerns about the MIST Trial is that for more than a year before the first claim was issued NMT and the company's lawyers threatened me by email and letter with an action for breach of confidentiality and threatened to get an injunction to prevent me speaking about the MIST Trial's results.

Because I was the principal cardiologist in the trial I knew that the results promulgated were incorrect and incomplete including those published in 2008 in the medical journal, *Circulation*.[2] Even though the steering committee had earlier agreed that I would be the first author of the paper, I rejected the offer to be an author of the paper in *Circulation*. So did another member of the steering committee, Dr Simon Nightingale. NMT had refused to give the steering committee full access to the data, but even with limited data it was clear that the paper contained errors and omissions.

I provided scientific evidence to *Circulation*. In 2009 *Circulation* published a correction of 700 words, a data supplement of 4 pages and an amended version of the paper.[3, 4, 5] Despite my scientific vindication, NMT continued the actions. One might think that the correction supported a defence of "justification" (the legal defence that what was said was true), but NMT's lawyers argued an innuendo meaning that by seeking a correction I accused the corporation of dishonesty.

NMT's legal claims went in tandem with attempts by the corporation to discredit me. For example it was reported that NMT claimed that I had lied when I had said that I was a co-principal investigator in the MIST trial. Commenting on that Shelley Wood wrote that numerous press releases on NMT's website referred to me as a co-principal investigator [1]. I did not sue NMT even though my lawyers advised that I had been libelled. I was faced with the virtual impossibility of enforcing any libel judgement in the USA. NMT were protected from the reach of the English defamation laws by US laws, but the corporation could use the English libel laws to make me a victim of libel tourism. Secure in

that knowledge NMT falsely accused me of such things as protocol violations, but when challenged on that by reporters NMT refused to specify the protocol violations.

There were other issues during the clinical trial that concern me. I discovered that some of the trial investigators, including my co-principal investigator, Dr Dowson, and another member of the trial steering committee had owned shares in NMT during the trial. This was despite the written assurance by Dr Dowson to the responsible Multicentre Research Ethics Committee (MREC) that neither he nor any other key investigator owned shares in NMT. After the trial was over I discovered that during the trial Dr Dowson had been under investigation by the General Medical Council (GMC) for misconduct in another industry sponsored multicentre migraine clinical trial in which Dr Dowson was the principal UK investigator. In March 2004 the responsible MREC closed that other trial down and reported Dr Dowson to the GMC. The GMC was informed that MREC "decided that it would not be appropriate for Dr Dowson to continue to act as chief investigator for the study in the United Kingdom." A few months later another MREC committee allowed Dr Dowson to be my co-principal investigator in the MIST Trial while the GMC investigation was in progress.

Dr Dowson joined the MIST Trial in August 2004 soon after Professor Peter Goadsby, who originally planned to be the principal headache specialist in the trial, resigned. I was not told that Dr Dowson was under investigation by the GMC, even though I was the co-principal investigator and principal cardiologist in the MIST Trial. In March 2006, the findings against Dr Dowson were found proved by the GMC and conditions were imposed on his registration,[6] but even at that point I was not told about the GMC investigation or hearing. I learned about the GMC findings in October 2006 from an individual unconnected with the trial. Dr Dowson's participation in the trial occurred despite the fact that the Clinical Trial Agreement explicitly stated that individuals were not allowed to be trial investigators if they were under investigation by a list of regulators, which included the GMC, or if data produced by the investigator in any previous study has been rejected because of concerns about its accuracy or because it was generated by fraud.

When the paper concerning the MIST Trial was published in *Circulation* I had a number of additional concerns. For example there was no mention of the fact that in some patients in the trial the STARFlex implant had come loose from the implantation site in the heart. One device lay free in the right atrium and another was carried by blood-flow to a pulmonary artery. These are serious, indeed potentially life-threatening, complications of the implantation procedure. That those serious adverse events occurred was stated

explicitly in the corrected version of the paper, but I am concerned that they were not revealed in the original version and that other things that should have been explicitly amended have not been corrected even though the editors of *Circulation* knew about them before the correction was published.

The published paper had 15 authors. None of the authors was on the committee that designed the trial but I was. There was no acknowledgement of the members of the trial design committee and I suspect that might have been to avoid acknowledgement of my contribution to the design of the MIST Trial. Neither was there any acknowledgement of the contribution of Dr Nightingale, who was also on the steering committee with me and like me was so concerned about the way that the results were presented that he also refused to be an author. Dr Nightingale and I had also done over 600 (over 30%) of all patient visits in the trial, we had written the first draft of the paper at the request of the steering committee, and we had helped with data analysis, but we got no acknowledgement, even when the paper was corrected. It is notable that some of the named authors did very few patient visits; none had a role on the trial design committee; and few were involved in trial administration, data analysis or correcting the drafts of the paper. One author's role was purely to do only 8 patient visits. I believe that it is unacceptable that *Circulation* has failed to deal properly with the issues of authorship and acknowledgement of contributions in the corrected version of the paper.

Bizarrely one doctor named as an author, Dr Rickards, died in May 2004,[7] six months before MREC gave approval for the trial to start in November 2004 and three months before Dr Dowson was recruited in August 2004. Dr Rickards was an eminent cardiologist and his name adds credibility to the trial, but he was not on the design committee and he died too early to have contributed to the research. Not only was he named as an "author" of the paper, he was also named as an author of a response to correspondence about the paper that was published in 2009 - 5 years after he died [8]. That response was published after I informed the editors of *Circulation* that Dr Rickards died in 2004. Apparently the editors of *Circulation* saw no obstacle to allowing Dr Rickards to be an "author" of a response he did not approve, in reply to correspondence that he had not read, that questioned a paper that he had not approved or seen, which dealt with research to which he had not contributed. It seems that *Circulation* has ignored the journal's published requirements for authorship and acknowledgement of contributions.

In the *Circulation* paper, the address of Dr Dowson, the first author is given as King's College Hospital. The hospital has stated that none of Dr Dowson's work in the trial was performed there. Dr Dowson's work

at that hospital is limited. It consists of him doing one headache clinic each week. Although Dr Dowson stated at TCT that he is a neurologist that is untrue. He is not on the GMC's specialist register and he is not a consultant. Neither is he on the general practice register. Most of Dr Dowson's work is in a private clinic in Guildford and it appears that all of his work in the MIST Trial was performed there. Obviously, stating that the first author's contribution was from a private clinic in a small town is less impressive than saying his contribution was from a major teaching hospital in the capital city. *Circulation* is aware of these facts but has not corrected Dr Dowson's attribution.

I believe that the corrected version of the paper still contains errors and omissions. Even in the corrected version of the paper *Circulation* has failed to report that Dr Dowson owned shares in NMT during the MIST Trial. The American Heart Association owns *Circulation* and the Association confirmed for me that they have a record that Dr Dowson owned NMT shares during the trial, but *Circulation* failed to declare that conflict of interest in the corrected version even though I pointed it out to the editor of the journal.

There are many other unusual things about the reporting of the MIST Trial. For example, when doing an internet search I discovered another paper about the trial with the authors named as "A J Dowson, P Wilmshurst, K W Muir, M Mullen and S Nightingale on behalf of the MIST Study investigators" [9]. Dr Nightingale and I had no knowledge of that paper.

The MIST Trial was a randomised, double blind, sham controlled study of the effect of closing a type of hole in the heart, called a persistent foramen ovale (PFO), with NMT's STARFlex© implant to see whether that relieved severe refractory migraine with aura. There was a good scientific basis for the study and observational reports of efficacy that made the investigators and MREC believe it was a worthwhile and ethical study. Patients with severe refractory migraine with aura and a large PFO were randomised under general anaesthetic to either PFO closure or a sham procedure. They were followed up for 6 months after the procedure by neurologists and headache specialists who, like the patients, were blind to treatment assignment. The primary endpoint of the trial was the number of patients in the groups who were free from migraine. There was no difference: 3 out of 74 randomised to implantation and 3 out of 73 randomised to sham intervention were migraine-free in the analysis period.

Despite the negative outcome from the trial NMT placed testimonials with the names and photographs of the three patients who had a STARFlex implant and who were free of migraine during the analysis period on a rotating banner on the corporation's website and in the corporations's annual report. NMT did not publish testimonials from

the three patients who were free of migraine after they had a sham procedure. NMT did not publish comments from those who had STARFlex implants and who were no better or worse, and two patients had intractable migraine after STARFlex implants.

An important question is how NMT came to make contact with the three patients who were free of migraine after STARFlex implants. The patient consent forms assured patients that their identities would be kept confidential to clinicians. NMT specifically pointed out during the trial that no company employee should know the identities of the patients. The patients were identified outside the treating hospitals only by an alphanumeric code. There was no way that NMT should have been able to identify these patients. I now know that each of these three patients was under the care during the trial of investigators who owned shares in NMT.

A testimonial from one of the three MIST Trial patients who was migraine-free after a STARFlex implant also appeared on the website of the Royal Brompton Hospital between mid-2006 and December 2010. Like the NMT website, the website of the Royal Brompton Hospital had a photograph and the name of the patient. The website said

> *"Our researchers investigated the relationship between migraine headaches and holes in the heart. Their study indicates that as many as 40 percent of patients could have their migraine symptoms significantly relieved through intervention to close the holes in their hearts. The MIST 1 (Migraine Intervention with STARFlex Technology) study brought together a significant number of partners, with the Royal Brompton & Harefield acting as a key cardiology centre……. Commenting on the launch of the trial, Dr Mike Mullen said "This is significant news for migraine sufferers. For the first time this study has shown that closing a PFO can have a substantial effect on reducing the symptoms for patients with severe migraine. The challenge now for headache doctors and cardiologists is to identify the characteristics of patients who can benefit from this treatment." Zoe Willows, a patient involved in the trial, suffered migraine with acute aura symptoms for over 22 years. "My doctors just kept on prescribing different pills and medication but nothing ever worked" she said. "I've now been completely cured and can live my life as a normal person. I encourage other migraine sufferers like me to go to their GPs and insist that they refer them to a specialist to test whether they too have a hole in their heart.""*

There was also a link from the Royal Brompton Hospital's website to a website sponsored by NMT.

It was unacceptable that NMT's website used selective testimonials to suggest that, contrary to the overall results of the MIST Trial, PFO closure with a STARFlex implant cured migraine. How much more unacceptable was it for the website of an NHS hospital to also misrepresent the results? I expressed concerns about the testimonials on NMT's website and the Royal Brompton Hospital's website to Dr Ben Goldacre. In December 2010 he wrote about the websites in his Bad Science column in the Guardian newspaper [10]. Only then did the Royal Brompton Hospital remove this misleading webpage.

My experience suggests that corporations can use the English defamation laws to misrepresent the results of clinical research. A corporation can propagate a misleading version and can use the defamation laws to bully those who object into remaining silent. I believe from speaking to other doctors in the UK that the fact that NMT sued me had the result that other clinicians with concerns about NMT's devices remained silent. I have been told that NMT threatened another doctor that he might be sued for libel and I have seen evidence that NMT discussed with their English lawyers the possibility of initiating claims against others. I believe that because of the resulting gagging of doctors with concerns some patients have had inappropriate procedures and some have been harmed as a result.

The law courts are not the best way to determine scientific truth. Few judges and even fewer juries have the training to weigh scientific evidence. An adversarial system is not the appropriate way, particularly when it pits an ordinary individual with limited financial resources against expensive barristers employed by corporations with more money. Truth should not be decided by those with greatest wealth using bullying and threats to make a scientist retract what he or she knows is true.

An example of the type of bullying tactics used was an email sent me by NMT's lawyer with a Claim Form sealed by the Court "by way of notice rather than service" at 17.09 on the last working day before Christmas 2007. It was sent to me as a non-lawyer without explanation. Because lawyers' offices had closed for Christmas ten minutes earlier, I was unable to get legal advice for two weeks. So for two weeks, I had no idea that the claim had no legal standing until served. It was served at the last permitted moment four months later. I am sure that the purpose in sending that form "by way of notice" at that time was to ruin Christmas for my family and me.

Elsewhere I have described my experience earlier in my career of being threatened with legal action by a pharmaceutical company in order to silence me [11]. We know that the English libel laws prevent journal editors publishing some articles that they would otherwise publish, cause others to remove valid data from websites and prevent publication of retractions of fraudulent research in case dishonest authors sue them claiming that the retraction was libellous. There are other examples of scientists being sued for libel for scientific presentations and research publications. This should be a concern for everyone with an interest in industry-related research, including all patients and consumers.

Some problems for scientists and doctors with the English libel laws are that:

1. Defamation cases are unique in English law by virtue of the fact that the onus of proof is on the defendant. This makes it difficult for a defendant to win even when one is in the right.
2. The costs of defending an action are considerably greater than the damages that might be awarded. Cost lawyers estimated that if my case had gone to trial the costs would be £3.5 million for each side, but the damages likely to be awarded if I lost was estimated at about £10,000. As a result the certainty of hundreds of thousands of pounds of costs rather than possible damages of tens of thousands of pounds are a deterrent to defending a good case.
3. Normally one has to pay legal costs as one goes along. If I had had to do that it would have meant that I should have been bankrupted long before the case got to court. The alternatives are to either fight as a litigant in person defending oneself in court or to get a lawyer to agree to a Conditional Fee Agreement (CFA - "no win, no fee"). Very few lawyers will act for defendants on a CFA because the odds are stacked against defendants in English defamation cases, because, as stated, the onus of proof is on the defendant. NMT's annual reports made it clear that the corporation was confident that I would run out of money and I would have to defend myself in

court against their expensive counsel. Obviously it is difficult for an individual to win a legal argument against a trained barrister. In that situation, had I won, NMT would not have had to pay me any legal costs because I would have run up no costs. Fortunately, Mark Lewis and Alastair Wilson QC agreed to act for me on CFAs because they considered the issues so important. They ran the risk of spending much time working on my case for 5 or 6 years until the case came to trial and of getting nothing if we lost. I am very grateful to them.

4. A further deterrent to defending a good case is that if one wins, the full costs are not recoverable. Typically only about two-thirds of costs are recoverable. If my case had gone to trial and I had won (as I expected I would) I would have got back about £2.5 million out of about £3.5 million spent. As a result I would have been bankrupt and homeless despite winning.
5. It was estimated that the trial would last 6 months. Because I would have to be in court, I would have to resign my job to fight the case.
6. If one wins there is no compensation for personal cost, such as time wasted and earnings lost by spending time dealing with the case.
7. The duration of legal proceedings is out of proportion to the importance of matters considered. In other European countries defamation trial have a much shorter duration and, as a result, costs are a fraction of costs in England. In a recent comparable case in France total costs for both sides combined were less than 10,000 Euros compared with an expected total of £7 million in NMT versus me, yet the amount of damages disputed was comparable (less than £10,000).[12] The reason for the excessive duration of defamation cases here is that judges spend an inordinate amount of time pondering issues such as the meaning of words. For example, in the case of the British Chiropractic Association versus Simon Singh senior judges spend considerably longer in deciding the meaning of the single word “bogus” used in Simon Singh’s article in the Guardian newspaper than the six days of deliberation by the jury in deciding which people Harold Shipman had murdered.
8. Libel tourism is permitted, so that wealthy foreign individuals or corporations are allowed to sue in England, even when they are themselves immune to actions brought against them here.

The result of all this is that wealthy individual and organisations can use the English defamation laws to prevent the truth being made public and therefore they can use those laws to prevent revelation of matters of public concern.

References

1. Wood S. (2007) Co-PI of MIST alleges data mismanagement, misinformation. Available from http://www.theheart.org/article/821779.do
2. Dowson A, Mullen MJ, Peatfield R, Muir K, Khan AA, Wells C, Lipscombe SL, Rees T, De Giovanni JV, Morrison WL, Hildick-Smith D, Elrington G, Hillis WS, Malik IS, Rickards A. (2008) Migraine intervention with STARFlex Technology (MIST) Trial: a prospective, multicenter, double-blind, sham- controlled trial to evaluate the effectiveness of patent foramen ovale closure with STARFlex septal repair implant to resolve refractory migraine headache. *Circulation* 117, pp.1397-1404.
3. Correction. (2009) *Circulation* 120, e 71-72. http://circ.ahajournals.org/content/120/9/e71.full
4. Migraine Intervention with STARFlex Technology (MIST) Trial Data Supplement (2009) *Circulation* available from http://circ.ahajournals.org/cgi/content/full/CIRCULATIONAHA.107.727271/DC1
5. Dowson A, Mullen MJ, Peatfield R, Muir K, Khan AA, Wells C, Lipscombe SL, Rees T, De Giovanni JV, Morrison WL, Hildick-Smith D, Elrington G, Hillis WS, Malik IS, Rickards A. (2009) Migraine intervention with STARFlex Technology (MIST) Trial: a prospective, multicenter, double-blind, sham- controlled trial to evaluate the effectiveness of patent foramen ovale closure with STARFlex septal repair implant to resolve refractory migraine headache. Latest version. *Circulation*, available from http://circ.ahajournals.org/content/117/11/1397.full
6. http://webcache.gmc-uk.org/minutesfiles/2063.html
7. Caroline Richmond. (2004) Obituary: Anthony Francis Rickards. *British Medical Journal* 329, p. 234.
8. Dowson A, Mullen MJ, Khan AA, Rickards A, Peatfield R, Muir K, Wells C, Lipscombe SL, Hildick-Smith D, Rees T, De Giovanni JV, Morrison WL, Elrington G, Hillis WS, Malik IS. (2009) Response to letter regarding "Migraine Intervention with STARFlex Technology (MIST) Trial. *Circulation* 119, e194.
9. Dowson A J, Wilmshurst P, Muir K W, Mullen M, Nightingale S on behalf of the MIST Study investigators. (2005) A prospective, multicentre, double-blind, placebo-controlled study to evaluated the efficacy of patent foramen ovale closure for the resolution of refractory migraine headache (the MIST study): prevalence and size of shunts. *Headache Care* 2, pp. 223-7.
10. Goldacre B. (2010) NMT are suing Dr Wilmshurst. So how trustworthy are this company? Let's look at their website….

Guardian 11th December 2010, available from http://www.badscience.net/2010/12/nmt-are-suing-dr-wilmshurst-so-how-trustworthy-are-they/

11. Wilmshurst, P. (2003) 'Obstacles to honesty in medical research', Acceptance speech, Health-Watch Award 2003, available from http://www.healthwatch-uk.org/awardwinners/peterwilmshurst.html
12. Benkimoun P. (2011) Paris court rejects drug company's case against journal. *British Medical Journal* 342, d1498.

Dr Peter Wilmshurst
Consultant Cardiologist, Royal Shrewsbury Hospital
Senior Lecturer in Medicine, University of Keele
peter.wilmshurst@tiscali.co.uk