Prometheus
Vol. 29, No. 1, March 2011, 67–71

Routledge
Taylor & Francis Group

PROPOSITION

The effects of the English libel laws on medicine and research – a personal view

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Dr Peter Wilmshurst is a consultant cardiologist. He is a leader in his field, and also a whistleblower, drawing attention to that which he believes to be wrong. He was presented with the HealthWatch Award 2003. Peter Wilmshurst has clashed with universities, editors, the medical establishment, and – perhaps inevitably – with the pharmaceutical industry. It is this last encounter that has taken him to court and that has made explicit and very public the relevance of the UK's libel laws to scientific research.

I was the co-principal investigator in the Migraine Intervention with STARFlex Technology (MIST) Trial (Dowson *et al.*, 2008, 2009). I spoke about the trial at a medical conference in the United States in October 2007 and some of my comments were published by a Canadian medical journalist in a paper on a US cardiology website. NMT Medical Inc., the medical device company that sponsored the trial, started legal proceedings against me in the English High Court claiming that I had libelled the company in England because the Internet paper was accessible in England (Gornall, 2010; Wilmshurst, 2010). So it should come as no surprise that I have serious concerns about the English libel laws. My opposition to the misuse of these laws goes back nearly 30 years and I had written that I believe they need amendment long before NMT Medical sued me (Wilmshurst, 1997, 2007).

Of course, I believe that individuals should be able to take action to protect their reputation, because one must be able to clear one's name when a false accusation is made. I want to explain why, based on my personal experience, I believe that the English libel laws are so unbalanced by an archaic premise that the reputations of wealthy individuals should be valued above the well being and lives of ordinary people, that the libel laws are a danger to the safety of all patients and the general public (including the wealthy individuals whose reputations are so valued).

Thirty years ago, I was a research registrar investigating the effects of the drug amrinone. It was hoped amrinone could be used to treat heart failure. My research suggested that it did not have the cardiac effects claimed and that it had severe adverse effects. As I described in a lecture to HealthWatch (Wilmshurst, 2003), I was offered money and received threats of legal action from Sterling-Winthrop, the manufacturer, to induce me to conceal my findings; attempts were made to prevent presentation of the research and to discredit it; false documentation was submitted to a European drug licensing authority; and trials of amrinone capsules in the United

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ISSN 0810-9028 print/ISSN 1470-1030 online

DOI: 10.1080/08109028.2011.570987
http://www.informaworld.com

Kingdom were illegal because they should not have been conducted without a clinical trial certificate (Erlichman, 1986).

A then senior executive of Sterling-Winthrop told me that the company would not be prosecuted for breaches of the Medicines Act, because they intended to tell Department of Health officials that, if prosecuted, they would close down pharmaceutical manufacturing in the UK. The company was not prosecuted. I could not persuade the Association of the British Pharmaceutical Industry to act against the company; nor would the General Medical Council (GMC) or the Faculty of Pharmaceutical Medicine investigate the doctors employed by the company who were involved in the trials. So I asked the *British Medical Journal* (*BMJ*), the *Lancet* and *Nature* to publicize what had happened. The editors of these journals did not dispute the facts, but each refused to publish, saying that the journal could not afford to run the risk of being sued for libel by a multinational pharmaceutical company.

It took nearly five years for my complaints to be rejected by all the official bodies in the UK that I believe should have dealt with them. None took action, but during that time, in 1984, the company told a hearing of the Food and Drugs Administration in the US that there had been over 1400 serious adverse events in 1200 patients given amrinone capsules. At that point, the company announced that it would cease clinical trials and applications for product licences worldwide. Officially, Sterling-Winthrop said that amrinone capsules were unsafe to take even on a doctor's prescription. Two years later, in 1986, I discovered that Sterling-Winthrop was still marketing amrinone capsules in parts of Africa and Asia (Erlichman, 1986) where it was being sold as an over-the-counter treatment for heart failure. I approached Oxfam, which had workers in the developing countries where this was happening. Oxfam collected receipts as evidence of purchase of amrinone capsules and this evidence was presented to the World Health Organisation. Sterling-Winthrop was finally embarrassed into withdrawing amrinone capsules worldwide in 1986 (Erlichman, 1986).

It was an Oxfam employee who put me in touch with James Erlichman, a *Guardian* reporter. Erlichman and the then editor, Peter Preston, were convinced by the hundreds of pages of documents I showed them. However, it took long discussion with the *Guardian*'s lawyers before the lawyers agreed that we could fight a libel action if necessary. The *Guardian* covered the story on three pages of one issue in November 1986 (Erlichman, 1986) and in follow-up stories in other issues. Sterling-Winthrop issued denials of the allegations but we were not sued. Over the next decade, I became increasingly concerned as other cases of research misconduct came to my attention. It was obvious that these issues needed to be raised, but editors of medical journals refused to publish any discussion of the issues because of fear of a libel action. That was the 'chilling effect'.

Eventually, Richard Smith, then editor of the *British Medical Journal*, asked me to give a closed seminar to editors of the *BMJ* publishing group and the *Lancet* in March 1996. He described this in his 'Editor's choice' column on 23 November 2002 (Smith, 2002).[1] In the seminar, I described a number of cases of misconduct known to me and known generally within individual medical specialties in the UK, but where no action had been taken to correct the scientific record or punish the guilty. Two weeks later, prompted by that seminar, the *BMJ* and the *Lancet* carried editorials calling for action on research misconduct (Smith, 1996; *Lancet*, 1996). In his *BMJ* editorial, Smith reported that a factor contributing to failure to report cases of research misconduct was 'England's repressive libel laws'.

A year later, the *Lancet* published an invited paper from me (Wilmshurst, 1997), which described how misconduct was concealed by doctors. Even though I did not name individuals in the paper, because of concerns about the possibility of a libel action, I was required to go through the paper with the *Lancet*'s editor, Richard Horton, showing him the documents that supported every statement made. I have published many scientific papers with implications for the safety and survival of patients, but no editor has before or since asked me to provide evidence for every statement I made in a scientific paper. Since then I have been often asked to provide proof when writing about misconduct by doctors.

After the *BMJ* seminar, it was also suggested that I again ask the GMC to consider cases where I believed that there had been misconduct. In a paper in the *BMJ* (Wilmshurst, 2002), I described the first two of those cases to come before the GMC, cases in which both doctors had been found guilty of serious professional misconduct.[2] As with the *Lancet* paper, I went through the text sentence by sentence with the editor. The *BMJ* spent thousands of pounds on legal fees (paid to a specialist defamation barrister), in checking supporting evidence and preparing the paper (Smith, 2006). Despite these checks, the *BMJ* spent a further £20,000 fending off accusations of libel after publication. Eventually, the insurers of the *BMJ* insisted that the paper and the accompanying 'Editor's choice' be removed from the journal's website to prevent the risk of further legal challenges. The paper has not been retracted because the *BMJ* and I stand by it, but because of the concerns about vulnerability to the multiple publication rule in the English libel laws, the paper can no longer be accessed via the Internet. The decision was based purely on financial risk assessment and one might argue that it is contrary to my right to free speech under Article 10 of the Human Rights Act.

Another of my papers (Wilmshurst, 2007) went through a similar process of legal review lasting two years with justification of every statement to the editor, the president of the society that owns the journal, and specialist defamation lawyers asked to review the paper before publication. The fact that medical journals check that statements that might lead to a libel action can be verified, but do not check claims in scientific papers which might affect the lives of patients suggests to me that medical journals are more concerned about their own financial risks from a libel suit than they are about the risks to patients posed by inaccurate scientific claims.

In fact, some journals have failed to retract papers that the editors know to be dishonest after investigations have demonstrated research fraud (Sox and Rennie, 2006). This is because retraction of a paper defames its authors and these editors would rather allow dishonest research to remain on the record than risk the possibility of a libel action. I know of a university that has failed to withdraw a higher medical degree after an independent inquiry showed that it had been awarded for research that the GMC had ruled was fraudulent. The thesis containing the fraudulent research remains in the university's catalogue because the university is afraid that withdrawal of either degree or thesis might result in a libel action.

Fear of being sued for libel is understandable. Libel actions are expensive, time consuming and unevenly balanced towards the claimant. Cases can run for years, as mine demonstrates. The legal costs of fighting a libel case are disproportionate because the costs are usually many times greater than the damages awarded and the victor never recovers his full costs. If a defendant loses a libel action, he may have to pay tens of thousands of pounds in damages to the claimant, but the bill for his own

and the claimant's legal costs may be millions. If he wins, a defendant will rarely recover more than 75% of his costs. So, even if the defendant wins, his unrecoverable costs may be several hundred thousand pounds. Therefore, if one is sued for libel, the expedient course is to apologize (even when one is in the right) and offer a relatively small sum as compensation to the claimant. The alternative of fighting a libel case can lead to financial ruin, even if one wins.[3]

I am also aware of other cases where the English libel laws have put patients at risk. In two separate cases where doctors were reported to the GMC for what I believe was serious misconduct, other doctors who had witnessed misconduct were deterred from providing a statement to the GMC because of fear of being sued for libel. In fact the doctors could not have been sued because testimony to the GMC is privileged (protected from legal action), but the threats were sufficient deterrents. In one case the accused doctor contacted the witness, a doctor with whom he had worked, and threatened to sue him for libel. The witness then denied having any knowledge of the alleged offence, though I have clear recollection of him telling me about it, and he refused to provide a statement, so the complaint did not proceed. Several years later the GMC was able to stand up similar charges against the doctor involving different patients. I believe that the delay may well have resulted in harm to some patients treated by the doctor in the interim. In the other case, the witness was the chair of a medical organization and expressed concern about a member. Later fear of a libel action prevented the chair providing testimony. Without that testimony, I believe that the accused doctor received more lenient treatment from the GMC than was warranted.

Over the years a number of potential whistle-blowers have asked me for advice. I have seen how they were mistreated and how some resorted to libel actions to clear their names and obtain some financial compensation. However, it is clear to me that the process is often detrimental to the public interest. Because of confidentiality agreements endorsed by the High Court, I cannot name those involved for fear of being in contempt of court. However, I know that some things concealed by the agreements include criminal and unethical acts by doctors, including an assault on a patient, falsification of medical records and fraudulent publication. I have seen documents that clearly show these occurred. In the case of fraudulent publication the editors of the journal have also seen the documents, but the order of the High Court means that this cannot be made public.

The confidentiality agreements sanctioned by the High Court also allowed concealment of the methods used by organizations in cover-up of misconduct, which in some cases includes the cost of inappropriate litigation. For example, one health authority (that I am forbidden to name) spent £2.5 million on legal fees alone in attempts to silence a whistle-blower and that cost does not include the money paid to the whistle-blower in the settlement or the cost of time spent over a number of years by the officials of the health authority in dealing with the matter. What concerns me most is that the settlement between health authority and whistle-blower, which was sanctioned by the High Court, amounted to an agreement to keep secret illegal activity by a senior doctor. To the best of my knowledge, because of my involvement in helping the whistle-blower, I am obliged by the agreement and order of the High Court to also keep the identity of those involved secret or face a charge of contempt of court.

It is clear to me that the English libel laws can be and are used to conceal serious misconduct in medicine and research.

Notes

1. The column is no longer on the *BMJ's* website, having been removed to prevent the journal being sued for libel under the multiple publication rule: the rule predates the Internet and means that the time limit for a claim runs from the date of publication. What this means is that the time limit to sue for libel over a paper on the Internet starts each time the web page is accessed.
2. This paper has not been retracted, but it has been removed from the *BMJ's* website for legal reasons.
3. When asked whether he had ever published anything he knew to be untrue, one editor replied 'only the apologies'.

References

Dowson, A., Mullen, M., Peatfield, R., Muir, K., Khan, A., Wells, C., Lipscombe, S., Rees, T., De Giovanni, J., Morrison, W., Hildick-Smith, D., Elrington, G., Hillis, W., Malik, I. and 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.1397–404. Data supplement available from http://circ.ahajournals.org/cgi/data/CIRCULATIONAHA.107.727271/DC1/1; clinical perspective available from http://circ.ahajournals.org/cgi/content/full/117/11/1397#response.

Dowson, A., Mullen, M., Peatfield, R., Muir, K., Khan, A., Wells, C., Lipscombe, S., Rees, T., De Giovanni, J., Morrison, W., Hildick-Smith, D., Elrington, G., Hillis, W., Malik, I. and Rickards, A. (2009) 'Correction', *Circulation,* 120, pp.e71–e72, available from http://circ.ahajournals.org/cgi/content/full/circulationaha;120/9/e71.

Erlichman, J. (1986) 'Drug firm "made threats". Company tested heart drug without DHSS clearance', *Guardian,*3 November, pp.1, 6.

Gornall, J. (2010) 'A very public break-up', *British Medical Journal,* 340, pp.180–83.

Lancet (1996) 'Dealing with deception', *Lancet,* 347, p.843.

Smith, R. (1996) 'Time to face up to research misconduct', *British Medical Journal,* 312, pp.789–90.

Smith, R. (2002) 'Editor's choice', *British Medical Journal,* 325, 23 November.

Smith, R. (2006) *The Trouble with Medical Journals,* Hodder, London.

Sox, H. and Rennie, D. (2006) 'Research misconduct, retraction, and cleansing the medical literature: lessons from the Poehlman case', *Annals of Internal Medicine,* 144, pp.609–13.

Wilmshurst, P. (1997) 'The code of silence', *Lancet,* 349, pp.567–69.

Wilmshurst, P. (2002) 'Institutional corruption in medicine', *British Medical Journal,* 325, pp.1232–35.

Wilmshurst, P. (2003) 'Obstacles to honesty in medical research', Acceptance speech, HealthWatch Award 2003, available from http://www.healthwatch-uk.org/awardwinners/peterwilmshurst.html [accessed November 2010].

Wilmshurst, P. (2007) 'Dishonesty in medical research', *Medico-Legal Journal,* 75, pp.3–12.

Wilmshurst, P. (2010) 'Peter Wilmshurst replies to Jonathan Gornall', *British Medical Journal,* 340, p.496.