

NEWS

Headache doctor found guilty of dishonesty in research misconduct case

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A headache specialist who jointly led a clinical trial that sparked a celebrated libel action was dishonest in signing a “materially false” statement in a clinical trial agreement and in not telling a research ethics committee that he had breached the research protocol of a previous trial, a UK regulatory panel has held.

The Medical Practitioners Tribunal Service panel found two charges of dishonesty proved against Andrew Dowson, who was joint principal investigator with the cardiologist Peter Wilmshurst on the Migraine Intervention with STARFlex Technology (MIST) trial. The case is seen as the most important to feature allegations of research misconduct by the General Medical Council since that of Andrew Wakefield, whose work resulted in an international scare over the measles, mumps, and rubella vaccine.¹

Having reached its conclusions on the facts, the panel will go on to consider whether Dowson’s fitness to practise is impaired and, if so, what sanction he should face. The hearing is scheduled to conclude by 19 February.

NMT Medical, the US manufacturer of the STARFlex device, sued Wilmshurst for defamation over comments he made about the accuracy of the trial results to a reporter at a US cardiology conference. He refused to back down and ran up large legal costs before the company went into liquidation.² The case helped lead to reform of English defamation law.

Wilmshurst reported several investigators on the MIST trial to the GMC, but Dowson, director of headache services at King’s College Hospital London, is the only one to face a full hearing.³

In 2003 Dowson was dismissed from the role of chief investigator in a Botox trial and was required to remove “erroneous data” from case reports after he was found to have breached the trial protocol. The North Yorkshire Multi-Centre Research Ethics Committee sent a report to the GMC stating that the breach of protocol made him unsuitable to remain a chief investigator.

In November 2004 the GMC notified him of the ethics committee’s complaint. In March 2006 a GMC panel found no dishonesty but held that his fitness to practise was impaired and

accepted undertakings from him, including an agreement to disclose the GMC’s findings to all research contractors.

Dowson signed a clinical trial agreement around 23 February 2005 between his company, Practical Solutions in Medicine, and NMT to provide his services. It included a declaration that he was “not involved in any regulatory or misconduct litigation or investigation . . . by the General Medical Council or other regulatory authorities.”

Dowson’s counsel argued that NMT, the only other party to the agreement, was fully aware of the admitted research misconduct in the Botox trial and that therefore no one was misled. But the panel said that he had “an overriding duty not to sign a patently false statement even in circumstances where there was little immediate risk of anyone being misled.”

The panel also found that, when applying to the West Midlands Multi-Centre Research Ethics Committee for ethical approval for the MIST trial in September 2004, Dowson failed to disclose the North Yorkshire ethics committee’s concerns about his role as chief investigator in the Botox trial. He had chosen not to reveal this to maximise his chances of getting approval for the MIST trial and his role as chief investigator, the panel said.

On several of the charges the panel found that Dowson had committed breaches of duty but was not dishonest. Several other charges were found not proved, including that he had failed to disclose a significant shareholding in NMT Medical.

He bought 3400 shares for £13 004.21 (€17 400; \$19 800) on 13 April 2005 and sold them on 30 June 2005 for £18 650.63. But the panel decided, in the absence of British guidance on what constitutes a significant shareholding, he was entitled to rely on the threshold of \$50 000 given in US federal regulations.

- 1 Dyer C. GMC lays out charges against headache doctor in research misconduct case. *BMJ* 2014;349:g6141
- 2 Dyer C. Libel case against Wilmshurst collapses as firm goes into liquidation. *BMJ* 2011;342:d2646.
- 3 Dyer C. GMC drops case against man accused of submitting incorrect data about heart device to medical journal. *BMJ* 2012;345:e7391.

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