



opinion
& debate

DAVID J. NUTT

The pharmaceutical industry and psychiatric research – a marriage for richer . . . ?

It is timely to review the relationship between the pharmaceutical industry and psychiatry, given the continuing move towards more evidence-based practice in medicine, as well as two recent government initiatives to improve the value of research in the National Health Service (NHS), especially research that is commercially driven.

Evidence-based medicine is a fact of current medical life, and in the field of psychiatry almost all the top-quality evidence we have on drug treatment comes from commercial trials sponsored by the pharmaceutical industry. Without that industry we would have no anti-psychotics, antidepressants, anxiolytics, anti-addiction drugs or mood stabilisers (with the possible exception of lithium). The Medical Research Council, NHS and other research funding bodies have never had – and will never have – the resources to conduct the necessary placebo-controlled trials required to prove clinical efficacy, nor will they invent new drugs. In the USA the situation is similar, although the much higher level of funding from the National Institutes of Health makes some small-scale, non-industry drug development possible. Even these are usually in partnership with the inventing pharmaceutical company, as in the case of buprenorphine or naltrexone for addiction. In countries where drug discovery and development were driven by state direction rather than the free market, such as the former USSR, few if any new treatments were discovered, despite a significant investment of government resources. Moreover, the quality of research (both preclinical and clinical) that the pharmaceutical industry conducts conforms to the highest level of quality control. Because their research is conducted under the direction of regulatory bodies such as the UK Committee on Safety of Medicines or the US Food and Drug Administration, it means that record-keeping and monitoring are of highest quality and are generally much better than that seen in other research in the NHS. Moreover, the regulatory thresholds for efficacy that drug treatments have to exceed in order to be licensed are exceedingly high. It is doubtful that any currently used psychological treatments could be 'licensed' if they had to be subjected to the same vigorous design and statistical criteria (i.e., multicentre, placebo controlled, intention-to-treat analysis, etc.).

The UK government has clearly accepted the pharmaceutical industry approach is desirable and is attempting to facilitate the UK's commercial ability to continue in this mode and remain internationally competitive by initiating some new ideas and procedures in NHS research. These have been outlined by the Pharmaceutical Industry Competitiveness Task Force (2001). The major reasons for these initiatives are that the UK pharmaceutical industry is the country's second biggest exporter,

employs several hundred thousand highly skilled people and is one of the few commercial and academic arenas in which the UK is unquestionably a world player.

Clinical trials directive

The first new initiative is the government's clinical trials directive which came into force in April 2004, making NHS trusts the research sponsors, so giving them central roles in the management and, more particularly, the delivery of quality research, especially clinical trials. This directive is designed to make NHS-sited clinical research much more effective and efficient, and has the main goal of improving the speed and quality of trials funded by the pharmaceutical industry as well as encouraging cross-trust collaboration in patient recruitment and retention in trials. Although this policy change was driven by the need to keep the UK at the forefront of commercially sponsored trials in cancer, it applies to all trials conducted in the NHS, and thus will have a major impact on research in psychiatry.

Implicit in the process is the assumption that the NHS is a major research resource for the UK that is not being optimally used at present. I believe the thinking behind this initiative is that research income from commercial trials should become a significant source of income to the NHS. Trials themselves bring a profit (in the form of overheads) to health trusts, and can be used for patient-related purposes. I predict that in the not-too-distant future trust funding from the government will be partly determined by the size and quality of patient cohorts entered into trials. Already such figures are used to determine the funding of acute medical trusts that host cancer networks. Moreover, the current review of NHS research and development may well decide that commercial clinical trial income should become a driver in resource allocation. Although this will not affect all psychiatry trusts it could have a big impact on those linked to academic centres if they do not take pharmaceutical industry research seriously.

Collaboration with industry

Because the major source of income for such trials will be the pharmaceutical industry, it is critical that trusts develop appropriate processes to facilitate what will become a necessary collaboration. It is likely that future governments of any political persuasion will consider such an income stream as a useful contribution to the funding of the NHS, so in psychiatry we will not serve ourselves or our patients well if we argue that we are somehow not



subject to the same financial imperatives as other medical specialisms.

The second initiative, Bioscience 2015, is related to the first, and may have developed from the same government think tank (Bioscience Innovation and Growth Team, 2003). This is now out for consultation and will further 'encourage' the commercialisation of NHS research in order to maximise income for patient benefit. Again, it is hard to see how any trust or medical discipline such as psychiatry can be excluded from this directive, since it is ethical to conduct controlled clinical trials in all psychiatric arenas, including learning disability and old age psychiatry.

The idea that psychiatry is for sale is a naïve one, seemingly based on a number of false beliefs: these include the idea that our discipline is different from others in medicine and that the pharmaceutical industry is out to exploit doctors and patients. I contend that psychiatric disorders are as amenable to controlled trials as other disorders, the effect sizes we see in psychiatry are as good as – if not better than – those in most other branches of medicine and that almost every patient who benefits from drug treatment owes a debt of gratitude to the pharmaceutical industry. Many patients and patient organisations support my perspective. Future patients' interests will be best served by a close and mature collaboration between the NHS and the pharmaceutical industry to maximise the value of research studies and the research potential of the NHS. The new

government directives, if embraced rather than resisted, will benefit patients and health care providers alike.

Declaration of interest

D.J.N. was employed by the pharmaceutical industry from 1988 to 1992 as director of the Reckitt & Colman Psychopharmacology Unit that he founded at Bristol University. Since then he has acted as a consultant to many companies involved in the discovery and development of drugs for psychiatry. He has conducted industry-funded clinical trials in the field of depression, insomnia, anxiety and addiction and has received own-investigator research grants from a number of companies.

References

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David J. Nutt Professor of Psychopharmacology and Head of the Department of Community Based Medicine, University of Bristol, Dorothy Hodgkin Building, Whitson Street, Bristol BS1 3NY, UK (tel: 0117 331 3178; fax: 0117 331 3180; e-mail: David.J.Nutt@bristol.ac.uk)