Check for updates

1 Robinson Research Institute, University of Adelaide

2 California State University, Northridge

Cite this as: *BMJ* 2022;376:o702
http://dx.doi.org/10.1136/bmj.o702
Published: 16 March 2022

The illusion of evidence based medicine

Evidence based medicine has been corrupted by corporate interests, failed regulation, and commercialisation of academia, argue these authors

Jon Jureidini, [1] Leemon B. McHenry[2]

The advent of evidence based medicine was a paradigm shift intended to provide a solid scientific foundation for medicine. The validity of this new paradigm, however, depends on reliable data from clinical trials, most of which are conducted by the pharmaceutical industry and reported in the names of senior academics. The release into the public domain of previously confidential pharmaceutical industry documents has given the medical community valuable insight into the degree to which industry sponsored clinical trials are misrepresented.[1-4] Until this problem is corrected, evidence based medicine will remain an illusion.

The philosophy of critical rationalism, advanced by the philosopher Karl Popper, famously advocated for the integrity of science and its role in an open, democratic society. A science of real integrity would be one in which practitioners are careful not to cling to cherished hypotheses and take seriously the outcome of the most stringent experiments.[5] This ideal is, however, threatened by corporations, in which financial interests trump the common good. Medicine is largely dominated by a small number of very large pharmaceutical companies that compete for market share, but are effectively united in their efforts to expanding that market. The short term stimulus to biomedical research because of privatisation has been celebrated by free market champions, but the unintended, long term consequences for medicine have been severe. Scientific progress is thwarted by the ownership of data and knowledge because industry suppresses negative trial results, fails to report adverse events, and does not share raw data with the academic research community. Patients die because of the adverse impact of commercial interests on the research agenda, universities, and regulators.

The pharmaceutical industry's responsibility to its shareholders means that priority must be given to their hierarchical power structures, product loyalty, and public relations propaganda over scientific integrity. Although universities have always been elite institutions prone to influence through endowments, they have long laid claim to being guardians of truth and the moral conscience of society. But in the face of inadequate government funding, they have adopted a neo-liberal market approach, actively seeking pharmaceutical funding on commercial terms. As a result, university departments become instruments of industry: through company control of the research agenda and ghostwriting of medical journal articles and continuing medical education, academics become agents for the promotion of commercial products.[6] When scandals involving industry-academe partnership are exposed in the mainstream media, trust in academic institutions is weakened and the vision of an open society is betrayed.

The corporate university also compromises the concept of academic leadership. Deans who reached their leadership positions by virtue of distinguished contributions to their disciplines have in places been replaced with fundraisers and academic managers, who are forced to demonstrate their profitability or show how they can attract corporate sponsors. In medicine, those who succeed in academia are likely to be key opinion leaders (KOLs in marketing parlance), whose careers can be advanced through the opportunities provided by industry. Potential KOLs are selected based on a complex array of profiling activities carried out by companies, for example, physicians are selected based on their influence on prescribing habits of other physicians.[7] KOLs are sought out by industry for this influence and for the prestige that their university affiliation brings to the branding of the company's products. As well paid members of pharmaceutical advisory boards and speakers' bureaus, KOLs present results of industry trials at medical conferences and in continuing medical education. Instead of acting as independent, disinterested scientists and critically evaluating a drug's performance, they become what marketing executives refer to as "product champions."

Ironically, industry sponsored KOLs appear to enjoy many of the advantages of academic freedom, supported as they are by their universities, the industry, and journal editors for expressing their views, even when those views are incongruent with the real evidence. While universities fail to correct misrepresentations of the science from such collaborations, critics of industry face rejections from journals, legal threats, and the potential destruction of their careers.[8] This uneven playing field is exactly what concerned Popper when he wrote about suppression and control of the means of science communication.[9] The preservation of institutions designed to further scientific objectivity and impartiality (i.e., public laboratories, independent scientific periodicals and congresses) is entirely at the mercy of political and commercial power; vested interest will always override the rationality of evidence.[10]

Regulators receive funding from industry and use industry funded and performed trials to approve drugs, without in most cases seeing the raw data. What confidence do we have in a system in which drug companies are permitted to "mark their own homework" rather than having their products tested

BMJ: first published as 10.1136/bmj.o702 on 16 March 2022. Downloaded from http://www.bmj.com/ on 19 March 2022 by guest. Protected by copyright.

by independent experts as part of a public regulatory system? Unconcerned governments and captured regulators are unlikely to initiate necessary change to remove research from industry altogether and clean up publishing models that depend on reprint revenue, advertising, and sponsorship revenue.

Our proposals for reforms include: liberation of regulators from drug company funding; taxation imposed on pharmaceutical companies to allow public funding of independent trials; and, perhaps most importantly, anonymised individual patient level trial data posted, along with study protocols, on suitably accessible websites so that third parties, self-nominated or commissioned by health technology agencies, could rigorously evaluate the methodology and trial results. With the necessary changes to trial consent forms, participants could require trialists to make the data freely available. The open and transparent publication of data are in keeping with our moral obligation to trial participants—real people who have been involved in risky treatment and have a right to expect that the results of their participation will be used in keeping with principles of scientific rigour. Industry concerns about privacy and intellectual property rights should not hold sway.

Competing interests: McHenry and Jureidini are joint authors of *The Illusion of Evidence-Based Medicine: Exposing the Crisis of Credibility in Clinical Research* (Adelaide: Wakefield Press, 2020). Both authors have been remunerated by Los Angeles law firm, Baum, Hedlund, Aristei and Goldman for a fraction of the work they have done in analysing and critiquing GlaxoSmithKline's paroxetine Study 329 and Forest Laboratories citalopram Study CIT-MD-18. They have no other competing interests to declare.

Provenance and peer review: Not commissioned, externally peer reviewed

1 Steinman MA, Bero LA, Chren MM, Landefeld CS. Narrative review: the promotion of gabapentin: an analysis of internal industry documents. *Ann Intern Med* 2006;145:284-93. doi: 10.7326/0003-4819-145-4-200608150-00008 pmid: 16908919

2 Mukherjee D, Nissen SE, Topol EJ. Risk of cardiovascular events associated with selective COX-2 inhibitors. *JAMA* 2001;286:954-9. doi: 10.1001/jama.286.8.954. pmid: 11509060

3 Doshi P. Pandemrix vaccine: why was the public not told of early warning signs?*BMJ* 2018;362:k3948doi: 10.1136/bmj.k3948.

4 Jureidini J, McHenry L, Mansfield P. Clinical trials and drug promotion: Selective reporting of Study 329. *Int J Risk Saf Med* 2008;20:73-81doi: 10.3233/JRS-2008-0426.

5 Popper K. *The Logic of Scientific Discovery.* Basic Books, 1959.

6 Bok D. *Universities in the Marketplace: The Commercialization of Higher Education.* Princeton University Press, 2003.

7 IntraMed. Criteria Used to Develop Influence Score. 2008. https://www.industrydocumentslibrary.ucsf.edu/drug/docs/#id=shbn0225

8 Schafer A. Biomedical conflicts of interest: A defense of the sequestration thesis—Learning from the cases of Nancy Olivieri and David Healy. Journal of Medical Ethics. 2004;30:8-24.

9 Popper K. *The Poverty of Historicism.* Routledge, 1961: 154-5.

10 Howick J. Exploring the asymmetrical relationship between the power of finance bias and evidence. *Perspect Biol Med* 2019;62:159-87. doi: 10.1353/pbm.2019.0009 pmid: 31031303

BMJ: first published as 10.1136/bmj.o702 on 16 March 2022. Downloaded from http://www.bmj.com/ on 19 March 2022 by guest. Protected by copyright.