Is it right for drug companies to carry out their own clinical trials?

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In *BMJ* today two experts debate whether the conflict of interest is unacceptable when drug companies carry out clinical trials on their own medicines.

Their views come as new guidance on the standards required for communicating company sponsored medical research is published.

Vincent Lawton, a healthcare consultant and non-executive director at the Medicines and Healthcare products Regulatory Agency in London, argues that having invested billions of pounds in medicine development, it is unrealistic to expect the drug industry to "surrender its intellectual property." He adds that taking away research from pharmaceutical companies will lead to delays, inefficiency and a lack of innovation.

Ben Goldacre, a doctor and writer from London disagrees and argues that "it is hard to see any justification" for allowing the current situation to continue.

Goldacre says that increasing evidence points to a conflict of interest for the drug industry which "results in bad evidence, which distorts medical decision-making, and harms patients."

One of the problems, argues Goldacre, is that the industry can choose which data to publish, and which to leave unavailable. He refers to the difficulties in getting clear information about the number of suicide attempts in industry trials of SSRI antidepressants or the number of heart

attacks in individuals taking the anti-inflammatory drug rofecoxib (Vioxx).

Goldacre concludes that the current situation "is dangerous and absurd" and that "doctors who are making treatment decisions need access to good quality trial data, presented transparently, and all of it, not just the positive findings that drug companies choose to share."

Vincent Lawton, however, believes that it is acceptable for the drug industry to make a profit and still undertake rigorous clinical trials that stand up to regulatory scrutiny.

He points out that, in January 2005, the industry made a commitment to increase the transparency of clinical trials by registering its trials in central, publicly accessible databases. Most major companies also publish trial results, whether positive or negative, on their own websites.

Lawton sums up by saying that it is unlikely that publicly sponsored academics would have the infrastructure to conduct all clinical trials on all new medicines, leading to regulatory approval.

An accompanying paper, also published on bmj.com today, sets out new guidance for communicating company sponsored medical research.

Written by the International Society for Medical Publication Professionals, the good publication practice (GPP2) guidelines have been updated in response to changes in the environment in which authors, presenters, and other contributors work together to communicate medical research.

They include guidance on defining the roles of authors, sponsors, and other contributors, recommendations about reimbursement, and confirmation of the role of professional medical writers, and apply to

peer reviewed journal articles and presentations at scientific conferences.

Lead author, Chris Graf says the guidelines "make recommendations that will help individuals and organisations maintain ethical practices and comply with current requirements when they contribute to the communication of medical research sponsored by companies."

Source: British Medical Journal (news : web)