BMJ

BMJ 2013;347:f5164 doi: 10.1136/bmj.f5164 (Published 20 August 2013)

LETTERS

OPEN DATA

EFPIA-PhRMA's principles for clinical trial data sharing have been misunderstood

Peter Doshi *postdoctoral fellow*

Johns Hopkins University, Baltimore, Maryland, USA

The recent joint statement of the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the Pharmaceutical Research and Manufacturers of America (PhRMA) of their principles for responsible sharing of clinical trial data[1] has been misunderstood in two important ways, exaggerating the perceived progressiveness of the principles.

Firstly, despite reports that all member drug companies have agreed to set up independent or external review panels to judge third party requests for clinical trial data,[1 2] the principles document calls only for review boards containing non-employee members. The principles do not prescribe how many non-employee members there should be or require that the non-employee members have no financial relationship with the company.

Secondly, despite the impression that industry is on the verge of opening up vast stores of data, the principles document is almost entirely focused on clinical trials of the future, declaring standards for sharing the results of trials of new drugs and new indications of old drugs. The document therefore provides no principles for sharing data from the tens of thousands of already completed industry trials that investigated the indications of drugs currently approved for use.

Even companies such as GlaxoSmithKline and Roche, both praised for having progressive new data sharing policies (which do extend to past trials), are committed only to providing controlled access to trials of products tested in approved indications and of terminated products.[3 4] Therefore access to patient level data from trials of so called off label uses of drugs is off the table. As Deborah Zarin, director of ClinicalTrials.gov, has recently pointed out, these practices may ultimately "perpetuate a dissemination bias by increasing the amount of information available for some trials while keeping other trial results inaccessible."[5]

Competing interests: PD has a UK National Institute for Health Research grant to carry out a Cochrane review of neuraminidase inhibitors (www.hta.ac.uk/2352) which used (and is using) clinical study reports obtained from the European Medicines Agency, GlaxoSmithKline, and Roche. PD received €1500 from the European Respiratory Society in support of his travel to the society's September 2012 annual congress, where he gave an invited talk on oseltamivir.

1 O'Dowd A. Drug industry pledge on access to trial data is met with scepticism. *BMJ* 2013;347:f4829. (30 July.)
2 Thomas K. Drug companies promise more data transparency. *New York Times* 2013 Jul 24. www.nytimes.com/2013/07/25/business/drug-companies-promise-more-data-transparency.html.
3 Roche. Roche global policy on sharing of clinical trials data.http://roche-trials.com/dataSharingPolicy.action.
4 Nisen P, Rockhold F. Access to patient-level data from GlaxoSmithKline clinical trials. *N Engl J Med* 2013;369:475-8.
5 Zarin DA. Participant-level data and the new frontier in trial transparency. *N Engl J Med* 2013;369:468-9.

Cite this as: *BMJ* 2013;347:f5164

pnd@jhu.edu