

Does industry sponsorship bias research findings?

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<u>A new study</u> reveals that the findings obtained from industry sponsored studies for widely prescribed cholesterol drugs are similar in magnitude as those in non-industry sources. <u>Huseyin Naci</u>, LSE Health research fellow and co-author of the study (pictured), explains further.

There is concern that the <u>vast majority of published medical research findings may be biased</u>. An important source of potential bias relates to the influence of pharmaceutical industry sponsorship of clinical studies. A growing share of biomedical research is sponsored by industry and the findings from industry-sponsored research are often the most influential.

There are clear financial and non-financial conflicts of interest with such research. Of greatest concern, pharmaceutical companies have a long history of delaying the publication of unfavourable clinical study reports, withholding data from patients and regulators, and cherry-picking the publication of favourable findings.

But is all research sponsored by the industry biased? Do conflicts of interest that intertwine industry sponsors and researchers influence the outcome of clinical studies? These are pressing questions that warrant urgent answers – especially when millions of people in the UK are receiving medications whose evidence base is predominantly industry-sponsored.

If there is sponsorship bias, industry-funded studies would produce systematically different findings compared with those obtained from identical (or at least comparable) studies funded by non-industry sources.

To explore this question, I collaborated with Professor Tony Ades and Dr Sofia Dias at the University of Bristol and evaluated the risk of industry sponsorship bias in the clinical studies of statins – the most frequently prescribed medicines in the UK. Our study was recently <u>published in the BMJ</u>.

Statins are a fascinating case study for exploring industry sponsorship bias. All six statins currently on the market are manufactured by competing pharmaceutical companies and over the years each company conducted head-to-head comparisons of their products against alternatives sponsored by other companies.

We wanted to see if a pharmaceutical sponsor favoured its own product in placebo controlled or active comparator trials, or the highest dose of its own drug in a study comparing multiple doses.

In <u>our paper</u> we exhaustively reviewed the clinical literature on the industry-sponsored and independent studies of statins and pooled data from over 250,000 individuals. Combing through the results of 183 clinical studies of statins where cholesterol-lowering effects were studied, we found no systematic difference between the results from industry sponsored and non-industry clinical studies of these widely popular drugs.

There are differences in the effectiveness of individual statins at different doses: statins at higher doses achieve greater cholesterol reductions from baseline than lower dose statins. When such dose differences are taken into account, there is no systematic difference between the results from industry sponsored and non-industry studies.

Still, our analysis confirms previous concerns that pharmaceutical companies almost exclusively sponsor clinical studies that have favourable conclusions for their products. Companies rarely compare their products

to non-pharmacological interventions. When they investigate the comparative effectiveness of their products to existing alternatives, many industry-sponsored studies use a lower dose of the competitor's drug.

Should we discount industry sponsored studies because they often include a lower dose of the competitor's drug? Not necessarily. Several clinical studies of statins funded by non-industry sources over the past 25 years included the same dose comparisons as those in industry sponsored studies. Indeed, the industry's research practices over the past quarter century yielded important information about the dose-comparative effects of different statins.

More importantly, the use of inferior comparators (that is, comparators at lower doses) may not mean that the study results themselves are biased. We found no evidence of dishonesty or inaccuracy – either qualitatively or quantitatively – in the conduct of industry sponsored studies.

Undoubtedly, the industry's research practices in comparing its products to inferior alternatives disproportionately contribute to an evidence base that is often inadequate to inform decisions in clinical practice and health policy. Our study highlights a key limitation of the industry sponsored evidence base on statins: there is still a lack of strong evidence on how different statins compare to each other in terms of clinically important outcomes. There are very few prospectively designed, direct head-to-head studies of different statins evaluating what really matters: their comparative mortality benefits. Regulatory agencies, institutional review board panel members, peer-reviewers, and academic journal editors have an important role in keeping pharmaceutical companies in check and ensuring that clinical studies of medications include appropriate and clinically meaningful comparators; present their findings in full; and avoid any "spin" that can be put on the conclusions of a study.

Further information

Naci H, Dias S, Ades AE (2014) <u>Industry sponsorship bias in research findings: a network meta-analysis of LDL cholesterol reduction in randomised trials of statins</u>, *British Medical Journal*, 349, g5741.

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