Charlotte Haug (born 1959), Dr. med. and master's degree in health services research from Stanford University. She has been editor-in-chief of the Journal of the Norwegian Medical Association since 2002.

Photo: Einar Nilsen

That virtually all clinical studies are commercially funded is a major problem for medicine. But we must not in addition halt studies aimed at checking the results.

Selling disease

In October 2013, Abramson et al. published a study in the British Medical Journal (BMJ) which showed that giving statins to people with low risk of cardiovascular disease neither reduced overall mortality nor the risk of serious disease; they also found that there was an approximately 18 % risk of adverse effects (1). Based on this conclusion, they believed it would be wrong to expand indications for statins, as a Cochrane report had recently recommended (2). Subsequent to the publication of the paper, there was a scientific discussion focused particularly on calculations of adverse-effect frequency, which led to the authors correcting their figures. The main finding – no effect on overall mortality, and thus greater risk than efficacy – remained standing.

Thus far everything was as normal: a paper had been submitted to a medical journal, quality-assured editorially and externally peer-reviewed, published, commented on and discussed in full openness. But that is not the whole story: in December 2013, Sir Rory Collins, Professor of Medicine and Epidemiology at the University of Oxford, went to see editor-in-chief Fiona Godlee of the BMJ and demanded that the article be retracted. When his request was not complied with, he went to the British media and accused the BMJ of scaremongering that would cost a great many lives (3). When that ploy also failed, he wrote Godlee a confidential letter. He refused repeatedly to take part in the scientific debate in the normal manner, i.e. openly in the columns of the BMJ (4).

In November 2013, Vigen et al. published a study in the Journal of the American Medical Association (JAMA) showing that testosterone therapy for men who underwent coronary angiography was associated with increased risk of mortality and adverse outcomes (5). Subsequent to publication, there was a scientific discussion of the calculations used in the study. The authors then corrected some figures and outcomes. The main finding – increased risk of adverse outcomes for men and unclear benefit of testosterone therapy – remained standing.

But that was not the whole story here, either: in March 2014 a group of doctors who disagreed with the conclusions in the JAMA article decided to form an ad hoc group called the Androgen Study Group. This group wrote to Howard Bauchner, editor-in-chief of the JAMA, urging him to retract the article. Instead of arguing in the usual scientific manner, openly and in the columns of the journal, they spread the letter the length and breadth of the US media. Abraham Morgentaler, the group's chairman, said in a press release (6): «This unprecedented action is a complete repudiation of the false information published by JAMA that has harmed public health, distorted medical science, and violated the trust between medical journals and the consumer.» At the date of writing (20 May 2014), the editor-in-chief of JAMA has no plans to retract the article.

What features do these two stories have in common? The most striking are the commercial interests involved. Cholesterol-lowering therapy with statins was for many years an almost continuous success story both medically and financially. In 2011, global sales of statins amounted to about NOK 120 billion ($ 20 billion). But expiring patents, combined with increasing numbers of reports of possible adverse effects, naturally threaten sales. One way of keeping sales up is to expand indications for statins – for example by applying them to lowering cholesterol levels in symptom-free adults. A study like the one published by Abramson et al. might then have a potentially very unfortunate impact on sales of the drugs. And Sir Rory Collins's role in all this? In addition to being a professor he also heads the Cholesterol Treatment Trialists' (CTT) Collaboration, a group which among other things summarises and re-analyses studies of cholesterol-lowering drugs – most of them funded by the pharmaceutical industry.

The story of the testosterone therapy is slightly different. While it is well documented that high cholesterol levels are not healthy and that cutting cholesterol levels is advantageous, it is extremely unclear whether «too low» a level of testosterone is actually a disease or how effective testosterone therapy is. Male hypogonadism should of course be treated, but where should we draw the line between normal ageing and pathology? It is easy to see how a small adjustment could open up a big market, as Schwartz & Woloshin so accurately describe in «how to sell a disease» (7). And Abraham Morgentaler's role in all this? He is the Director of Men's Health Boston, whose mission is to be «actively engaged in helping the medical community and public understand how to safely treat men with low testosterone levels». He is supported by among others AbbVie, which markets AndroGel (Testogel in Europe) – the most widely used testosterone therapy in the USA.

The remarkable thing about both these stories is also the bully-boy tactics employed against the editors. Instead of arguing openly and scientifically, colleagues are attempting through underhand means to have articles they dislike removed, by employing suppression techniques such as indirect threats, slander and ridicule. They should not succeed. We have big enough problems in medicine as it is, when virtually every clinical study of drugs and medical equipment is funded by the company that also has a direct interest in their use. This means that attempts to check and question results should be encouraged, and not that attempts should be made to stop them.

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