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**European Society for Statisticians in the Pharmaceutical Industry (EFSPI) challenges the distrust in statisticians working in the pharmaceutical industry**

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# European Society for Statisticians in the Pharmaceutical Industry (EFSPI) challenges the distrust in statisticians working in the pharmaceutical industry

**Merete Jørgensen, Bernhard Huitfeldt, Gerd Rosenkranz**

On behalf of the European Federation of Statisticians in the Pharmaceutical Industry (EFSPI, www.efspi.org) we would like to comment on the new Journal of the American Medical Association (JAMA) policy concerning conflicts of interest[1] and the role of statisticians in the publication of industry-sponsored clinical trials. Among other things, this policy requests a confirmation of the statistical analysis of such trials by an independent university-based statistician. Others have also given comments on this remarkable editorial, all with essentially the same critical messages[2,3,4].

We interpret the policy adopted by JAMA as a general distrust of the professionalism of many thousands of academics working in the pharmaceutical industry and in particular the statisticians. We define our primary role to ensure adequate study design, high data quality, appropriate statistical analysis and interpretation to support the conclusions from clinical trials. That is, to deliver solid scientific evidence for study reports, drug applications and publications.

Statisticians in the pharmaceutical industry are working in a highly regulated environment. The principles are described in several regulatory guidelines, primarily the International Conference on Harmonisation guideline E9 about statistical principles for clinical trials[5]. Furthermore, a protocol synopsis of all clinical drug trials is now made available in a public clinical trial registry, where the principal features related to the planned statistical analysis of the data are described. Clinical drug trial data are usually part of a regulatory submission for a new drug application and are assessed for statistical validity by regulatory authorities as part of the approval process. In the light of these circumstances it is not clear to us why the contributions by statisticians in the

pharmaceutical industry are singled out for this special scrutiny. The policy obviously lacks symmetry and consistency with regard to other skill types and sources of sponsorship. In our opinion the quality assessment of submitted manuscripts should be handled in the peer review process and we encourage the regular involvement of professional statisticians for this task.

The JAMA policy indicates a general lack of knowledge of the principles of the quality processes including data collection, data-checks and pre-defined statistical analysis plans for industry-sponsored clinical trials. We are convinced that the quality processes applied by industry competes favourably with the quality processes applied in academic medical research. We intend to follow up this letter with a publication describing this process in more detail.

**References:**

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