mistaken and does not portray accurately the roles, objectives and operations of CROs in the clinical research process. CROs work on a sponsor's behalf in a highly regulated environment to implement and manage a clinical trial according to the study protocol. They provide research services including consultation regarding study design, facilitation of the recruitment of investigators and study patients, assurance of patient protection and data integrity, and data analysis to maximize the quality of the research, and guidance through the complex regulatory environment. CROs do not sponsor clinical trials, do not own trial data, do not provide routine patient care and do not participate in agreements concerning publication rights and responsibilities, which are negotiated between sponsors and investigators. The CRO's contractual obligation is to ensure the integrity of data and compliance with US Food and Drug Administration and international regulations, not specific results. This enhances, not erodes, the quality and standards of clinical trials.

Both academic and community-based investigators participate in CRO-managed clinical investigations, and many of them participate in the development of study protocols. In CRO-managed studies the investigator is neither our employee nor our customer but rather an integral partner in the research process. The breadth of our research spectrum encourages us to seek the best and brightest physician-scientists across all clinical disciplines.

We maintain that CROs contribute to high-standard clinical research by working with — not competing with — clinical investigators in both academic medical centres and community-based clinics.

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Reference

1. Davidoff F, DeAngelis CD, Drazen JM, Nicholls MG, Hoey J, Højgaard L, et al. Sponsorship, authorship and accountability [editorial]. *CMAJ* 2001;165(6):786-8.

Academic researchers must have complete freedom to participate in and approve all aspects of industry-sponsored clinical trials, including any publication resulting from such a trial. We encourage all authors to abide by the new rules of the International Committee of Medical Journal Editors.[1]

That having been said, we must register our strong objection to the biased tone of the commentary, which slights the vital contributions of our industry to the clinical trial process. Throughout the commentary, the integrity of academic investigators is assumed, while the industry's integrity is questioned. The commentary ignores the fact that the trial sponsors usually do most of the actual work in clinical trials, including planning and designing the study, providing supplies, arranging contracts, and analyzing and interpreting the data; the sponsors sometimes also prepare manuscripts for publication. There are many well-respected, highly ethical and experienced clinicians working for industry who are not subject to the potential conflicts of interest arising from pressures that affect most academicians, such as the need to obtain grants and secure tenure.

Thus, although our industry supports the need to ensure the independence of researchers, the commentary is unnecessarily antagonistic, which weakens its impact. A more balanced approach would have recognized the essential roles that both industry and investigators play in developing safe and effective medicines for patients.

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Reference

1. Davidoff F, DeAngelis CD, Drazen JM, Nicholls MG, Hoey J, Højgaard L, et al. Sponsorship, authorship and accountability [editorial]. *CMAJ* 2001;165(6):786-8.

A group of academics puts forward a proposal "to protect the university's most precious commodity: intellectual integrity," specifically in the context of clinical research on drug effects[1]; and in an adjoining article a group of medical journal editors, in the same spirit, introduces new requirements for manuscripts submitted to biomedical journals.[2] In both initiatives, the aim is to manage the threat that the recent surge in industrial sponsorship of applied drug research is seen to pose to the integrity of such research, from study design all the way to its ultimate impact on the knowledge base of scientific medicine. The basis for the concerns is that the industrial sponsor has, fundamentally, a singularly pecuniary motive, with the pursuit of truth at best a means to commercial ends; and that there is published evidence of some industrial sponsors actually having sought to subvert the truth. Implicitly, the idea seems to be that in the absence of exogenous subversive influences, medical academics would exhibit the integrity that is expected of them, and that nothing really is taking away from the integrity expected of medical journal editors.

Let's be frank: threats to the integrity of the knowledge base of scientific medicine are mainly *intrinsic* to medical academia and medical journals. Ulterior motives are there, and so are