

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 a 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 slightes 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 sup-

ports 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 effects¹; 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

their related transgressions, only public attention tends not to be drawn to these, unsurprisingly. The main need is for initiatives to manage the intrinsic threats.

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References

1. Lewis S, Baird B, Evans RG, Ghali WA, Wright CJ, Gibson E, et al. Dancing with the porcupine: rules for governing the university-industry relationship [editorial]. *CMAJ* 2001;165(6):783-5.
2. 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.

Steven Lewis and colleagues have proposed a reasonable concept but, as is the wont of those who administer, they cannot refrain from trying to impose another layer of administration.¹ Surely, with their present administrative hierarchy our universities and, in particular, our ethical review committees are able to implement guidelines such as those proposed by Lewis and colleagues, should the universities choose to adopt them. I can see little need, except that of administrative aggrandizement, for some other overseeing body. I note that the authors have not failed to target the pharmaceutical industry as the body that should pay, thereby adding to the cost of bringing new therapeutic agents to patients.

Instead of a proposal that the universities and the pharmaceutical industry deal with individual transgressions, I see the usual administrative urge to make one size fit all. Given the litany of administrative failures to achieve the latter in other areas of medicine, we should be chary of allowing this proposal to proceed in an uncritical manner.

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Reference

1. Lewis S, Baird P, Evans RG, Ghali WA, Wright CJ, Gibson E, et al. Dancing with the porcupine: rules for governing the university-industry relationship [editorial]. *CMAJ* 2001;165(6):783-5.

Although we agree with the publication rules suggested by Frank Davidoff and his colleagues in the International Committee of Medical Journal Editors,¹ we think the implementation of the proposals of Steven Lewis and coauthors² would seriously impair the conduct in Canada of academically credible clinical research carried out in partnership with industry. The examples cited by Lewis and colleagues are all warnings to investigators that companies are primarily responsible to their stockholders, but only one, the Olivieri case, relates to a dispute over the publication of results.²

Our experience in coordinating over 120 national clinical trials in which pharmaceutical companies supplied drugs or financial support or both suggests strongly that such untenable situations can be avoided if the principles identified by Davidoff and colleagues are contractually protected. In all of our trials we, or a partner academic group, create and maintain the trial database, analyze the trial data according to protocol-specified plans and have the right to publish our conclusions. Our host university insists on preserving these academic rights. Furthermore, we are ultimately accountable for all of our studies, whether supported by industry or by competitive grants, to the National Cancer Institute of Canada, which periodically peer reviews the scientific quality of our program and the trials we conduct.

By focusing on a few justly disturbing cases and not examining alternative models, Lewis and colleagues failed to gather the data needed to make sound recommendations.² At a time when the major source of new therapeutic agents is the pharmaceutical industry, we need solutions that protect academic integrity but simultaneously allow Canadian trials to be developed and conducted quickly by qualified physician-investigators. The highly centralized and potentially bureaucratic system proposed by Lewis and colleagues might fulfill the former

requirement but will certainly not fulfill the latter.

We feel strongly that better approaches must be adopted if Canadian investigators are to be adequately protected in, but not excluded from, an important research endeavour. Our experience suggests that the key elements of such approaches should include accountability to an agency that represents the public interest and a clear understanding on the part of investigators and university contract officers of their rights and responsibilities. All of this can be achieved by educational initiatives and appropriate leadership from existing professional and funding bodies.

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