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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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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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 coauthors[2] 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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[Steven Lewis responds:]

Barry Koehler misunderstands the nature and purpose of our proposed oversight mechanisms.[1] It is actually less complicated and bureaucratic to standardize the principles and basic contractual mechanisms governing university–industry relations than to have a Babel of options confronting researchers, universities and industry. Administration of the rules would of course remain local, but there would be both accountability and appeal mechanisms to ensure consistency, transparency and disinterested adjudication of conflicts. It's a bit like medicare: the principles are established for all, but the operations are highly decentralized. As for costs, even a budget of $2 million per year for the oversight office would amount to less than a tenth of one percent of the industry's taxpayer-subsidized annual marketing expenditures. It is thus highly affordable without "adding to the cost of bringing new therapeutic agents to patients."

Joseph Pater and colleagues essentially maintain that the status quo works and that exceptions are truly anomalous. This view flies in the face of the literature we cited, documenting frequent and in some cases systematic conflicts of interest, bias and restraints on freedom to publish. That the editors of 12 of the world's leading medical journals — including *CMAJ* — have recently introduced publication policies to discourage this behaviour reflects widespread recognition that there is a serious and growing problem.[2]

Pater and colleagues place their faith in "educational initiatives and appropriate leadership from existing professional and funding bodies" and reject our more concrete proposals. This seems naive in view of the extraordinarily powerful economic pressures at work. Researchers, and their corporate sponsors, sometimes behave badly because it pays. If there is to be an effective speed limit one must post signs, pay to monitor behaviour and penalize transgressors. Nothing in our proposed rules should slow down trials; indeed, standardization should diminish the upfront time required to negotiate terms and conditions.

Olli Miettinen correctly reminds us that interactions with pharmaceutical companies are only one potential threat to scientific integrity, others being intrinsic to the academy itself. However, both the literature and the response by journal editors indicate that pharmaceutical companies are currently the large and growing threat.

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[Editors' note:]

Portions of this correspondence and a response from the International Committee of Medical Journal Editors have appeared in the *New England Journal of Medicine* (*N Engl J Med* 2002; 346(4):290-2).

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