

Community health programs in Canada

In view of the Walkerton calamity, the anthrax scare in the United States and the threat of chemical and biological warfare, I think we should look again at the education of physicians in the specialty of community (public) health.

When I joined the Toronto School of Hygiene in 1956 the program covered 10 subjects: chemistry in relation to hygiene and sanitation, epidemiology and biometrics, hospital administration, hygiene and preventive medicine, viral infections, experimental cytology, parasitology, physiological hygiene, public health administration and public health nutrition. At the time, the Diploma in Public Health program in microbiology was the best in the country.

When the Master of Health Sciences degree was established at the University of Toronto in 1979, training in microbiology disappeared. I submit that this was a mistake. Physicians who specialize in public health should be well acquainted with all agents of disease, be they biological, chemical, social or environmental. They should know about the effects of war, famine and natural disasters. Public health is not merely an exercise in statistics and administration.

The skeleton of a school of public health exists at the University of Toronto. A somewhat more complete program in public health is available at McGill University, which has departments of epidemiology and biostatistics, occupational health, human genetics, microbiology and immunology, nutrition and food, and social studies in medicine, a Centre for Studies in Aging, a Centre for Host Resistance and a Centre for Tropical Diseases. In Canada there is nothing like the Harvard School of Public Health or the London School of Hygiene and Tropical Medicine.

We need a broadly based graduate program in community health jointly supported by academe and the Royal College of Physicians and Surgeons of

Canada. Schools of graduate studies favour rather narrowly focused master's level programs, but that will not work for the specialization in question.

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Ethics and industry-sponsored research

As a retired research scientist in entomology and nutrition, I was delighted to hear that prestigious medical journals will not publish results of research financed by pharmaceutical companies if the researchers are not given complete academic independence.¹ Companies that withhold data unfavourable to their products, persuade scientists to include their names on ghost-written articles or make researchers sign contracts barring them from publishing their findings without company approval should be considered unscrupulous.

This policy, if followed, will be important in preserving scientific integrity and rekindling a feeling of pride among

scientists. I recall that many years ago our research director firmly believed that all or most of the scientific research conducted in Canada should be funded by government so that scientists could be independent of private funders. The "findings" of scientists employed by the tobacco industry about 45 years ago should serve as a warning of the potential dangers of privately funded research.

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Reference

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

We represent 7 of the largest contract research organizations (CROs) in the United States. We agree with the authors of the recent commentary on sponsorship of clinical trials¹ that all research must be conducted and reported objectively, dispassionately and with the highest levels of scientific accuracy and integrity.

The perception stated in the commentary of "head-to-head" competition between CROs and academic sites is

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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