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Clinical-trial registration

The continuing discussion on clinical-trial registration, as described in the article "Clinical-trial registration: a call for its implementation in Canada" (*Can Med Assoc J* 1993; 149: 1657-1658), by David Moher, might be more efficient if approached in terms of outcome. The creation of yet another bureaucracy to undertake such registration will not be an improvement.

Our community might be better served by a more efficient use of existing resources. For example, it has generally been difficult to establish continuing working relations among academic research communities, industry and government. Bill C-22, which amended the Patent Act and affected research into prescription drugs, has resulted in more collaborative undertakings through the initiatives of the Medical Research Council of Canada. Such strategies may stimulate new approaches to re-

search and development that do not require additional resources.

This cooperative approach has also extended into the drug approval process. Although still in its infancy a recent move to involve experts in the evaluation of new drug submissions may make the approval mechanism more transparent and open to expert opinion. The establishment of expert panels could be a next, logical step. Such panels would not only benefit the approval process but also improve communication between academia, industry and government. As well, they would facilitate the more complete dissemination of knowledge, including negative results from clinical trials. This dissemination is needed for economy of effort in future research and will save needless expenditure and exposure of clinical populations to risk.

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[The author responds:]

Drs. Lapierre and Mohr suggest that the development of a Canadian clinical-trial registry would create more bureaucracy and might not achieve the desired goal of compiling information about all trials conducted in Canada.

Developing a clinical-trial registry does incur costs, to employ a director, manager, computer programmer, computer communications specialist, data-entry clerk and part-time secretary. Once a registry is developed it must be maintained, which is very time-consuming. Estimates of the cost of developing and maintaining a clinical-trial registry

are \$30 000 to \$40 000 per year.¹ Costs could be kept to a minimum if the registry were located in a research facility that had personnel with expertise in clinical trials, computer programming, electronic communications and clinical-trial registries.

Collaborative relations between academia, industry and government are important and need to be fostered. However, these links alone may be inadequate to address the problems posed by publication bias. As well, they do not address the need for public access to information about clinical trials.

Publication bias is still a problem for peer-review granting agencies.² The World Health Organization has recommended that the pharmaceutical industry be more forthcoming about registering trials and making information about them available.³ Investigators should be encouraged to report their results, whether positive or negative: "negative" may simply mean that a statistical threshold was not reached, not that the trial had no importance.

In Canada a significant number of clinical trials are funded through agencies that receive their monies from federal and provincial taxes and voluntary contributions by members of society. However, there is no database accessible to the public that could provide information on what trials are being funded and conducted.

Information about all clinical trials exists within research ethics boards. Registering clinical trials during the process of approval by these boards could be, I believe, the most pragmatic approach. Investigators could complete a registry information form and then forward it to the Canadian clinical-trial registry office. To ensure that a form was