

EDITORIAL

On Salvaging the Pharmaceutical Sciences in Canada?

Only a decade ago the concept of a Canadian pharmaceutical industry was considered unattainable. It was a generally held belief that due to the high cost of research and development, only multinational pharmaceutical houses, the "big pharmas", were capable of introducing new drug entities. Since few major pharmaceutical research and development facilities had a significant presence in Canada, this country would necessarily be a small player in this major economic activity. Recent events, however, signify significant change to this landscape.

In the last few years several smaller companies have engaged in the initial development stage of many important and exciting drugs. These companies, often spin-offs from academic research centres, have been very cost effective in developing a concept into a viable reality. They are often the brain-child of scientists who, with the blessing of their institutions, attempt to commercialize creative ideas. There are several hundred such small ventures. Indeed, the Medical Research Council of Canada (MRC) informally predicts that as a consequence of newly available research funds the present numbers will double in a short time. This is good news. However, a major player in this rosy scenario has been ignored. Specifically, the skilled manpower required to fulfill the pharmaceutical R & D function.

The first stage in drug development is "discovery". For example, a scientist formulates a thought which, after intensive research activity, generates a molecule with pharmacological activity. The next step, "proof of concept", must demonstrate that the molecule indeed has desirable pharmacological properties in animal models. If validated, a potential drug is at hand. The discovery stage may be carried out in small laboratories, by many scientists, with a wide spectrum of specialties including chemistry, immunology, biochemistry and botany. A majority of Canadian pharmaceutical or biotech companies are at this discovery stage.

The next step is to produce a drug formulation for use in humans. This stage may be called "pharmaceutical R & D" and involves a series of detailed, regulated pre-clinical and clinical experiments. These will determine the most suitable product and establish its safety and efficacy prior to submission to appropriate regulatory agencies. Drug delivery, pharmacokinetics, toxicology, and clinical pharmacology are included in this stage. After regulatory approval the product is introduced into the marketplace with expectations of therapeutic benefit and profit. Unfortunately, the majority, and perhaps all, emerging Canadian pharmaceutical and biotech companies lack the expertise and the resources to accomplish the "pharmaceutical R & D" phase. The economic consequences of this short fall are immense. In order for a molecule to be developed into a drug product, small companies generally have little choice but to sell their patented concept to the "big pharmas". Unfortunately, Canada's contribution to the pool of "big pharmas" is small and we do not fully benefit from the labors of our scientists. Canada is not doing as well as it could in training the requisite number of pharmaceutical scientists, and the well-known brain drain usually siphons off the few that are. Sufficient manpower must become available if we are to reverse these events.

The principal sites for training pharmaceutical scientists have been, and still are, pharmacy graduate schools. Drastic cuts in research funding during the 90's has forced many schools to close excellent graduate program laboratories. Such closures are not exclusive to pharmacy but are a general event among biomedical research organizations.

The grave consequences of closures have only recently been realized at the national level. To rectify the problem, the federal government has, over the next several years, earmarked new funds for biomedical research with directed funding to be increased substantially to the real dollar value of 1991. These corrective measures are by no means sufficient to reverse the damage done. They do, however, suggest an end to a decade of neglect and

recognition of the economic consequences of a manpower shortage in biomedical research.

These new funds must be used with efficiency and accountability. The MRC has proposed a Canadian Institute of Health Research (CIHR), modeled on the US National Institute of Health (NIH), as a structure for distribution of research dollars among Canadian scientists. CIHR is divided into several disease or theme-based institutes to encourage networking and a collective approach to solving health problems. The investigator will submit a research grant proposal to an institute of choice after which it will be evaluated by an appropriate cross-institutes peer-review committee. At present there is no specific institute designated to the pharmaceutical sciences. It is anticipated that this entire "discipline" will be absorbed by the various theme-based institutes. Pharmaceutical scientists have not historically had a significant presence in the MRC infrastructure. Their small numbers is one explanation. Regrettably, the CIHR framework continues to minimize their importance despite the obvious rapidly changing pharmaceutical industry landscape.

The economic drain will continue unless viable alternative approaches are implemented to promote activities in the pharmaceutical sciences. This may include formation of a pharmaceutical sciences institute within CIHR, establishing a virtual pharmaceutical sciences university to promote borderless growth of the field, and earmarking special funds to encourage training of desperately needed pharmaceutical scientists.

Revitalizing the fading embers of pharmaceutical science in Canada is achievable but we must first acknowledge the roots of the problem. Are the decision makers listening?

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