Does family medicine have a professional obligation to play a leading role in pharmaceutical industry–sponsored drug research?

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YES

A recent report by the Health Council of Canada[1] has suggested that the number of prescriptions for common drugs is increasing and that family physicians are doing most of the prescribing. In fact, drug costs represent the second-highest spending area in the Canadian health care system,[2] an issue that has received considerable focus in the 2003 First Ministers' Accord on Health Care Renewal and the 2004 10-year plan to strengthen health care.[2] Because family physicians fuel the economic engine of the pharmaceutical industry and drug costs in general, it is relevant to ask whether family medicine has a professional obligation to play a substantial role in the drug development process—in particular, play a leading role in pharmaceutical industry–sponsored drug research that is relevant to primary care. Without such a mandate, the discipline of family medicine cannot be expected to contribute directly to the development of "real world" evidence-based management guidelines and drug surveillance systems at a time when the management of complex chronic conditions shifts into the community setting.

Among health services researchers[3] and policy makers,[4] the relationship between physicians and the pharmaceutical industry has become a primary topic of concern on a number of fronts. There is a robust body of evidence suggesting that physicians' interactions with pharmaceutical sales representatives can influence clinical decision making in a manner that might not be in the best interests of the patients; for example, the use of expensive treatments rather than less costly alternatives with comparable therapeutic efficacy.[5] Furthermore, there is a concern that marketing common drugs is to a great extent driven by misleading information. In 2002, a US congressional inquiry reported that from August 1997 to August 2002 the Food and Drug Administration issued 88 letters accusing drug companies of advertising violations.[6] Finally, there are reports suggesting that systematic bias in drug studies favours products manufactured by the company funding the research.[7] The latter discussion highlights the importance of implementing meaningful "checks and balances" in health care systems within which pharmaceutical organizations influence drug development and promotion at many levels. The primary care environment is well-suited to achieve such goals if drug research and pharmacoeconomic oversight are identified as priorities.

Accepting responsibility

The 4 principles of family medicine[8] include that "family physicians accept their responsibility in the health care system for wise stewardship of scarce resources" and that the family physician is a resource to a defined practice population and has "the ability to evaluate new information and its relevance to the practice." The limited direct role of family medicine in drug research and guideline development makes fulfilling some of its principles quite difficult if not impossible. The lack of a leading role in pharmaceutical industry–sponsored drug research also prevents family medicine from implementing critical oversight strategies that are needed in order to improve efficiencies related to drug prescribing in the primary care setting. Without the substantial involvement of family medicine researchers in this area, we risk letting drug companies choose the message and the messengers to provide education about pharmacotherapeutic strategies destined for adoption in primary care.

Recent data[9] suggest that family medicine residency programs limit residents' interactions with pharmaceutical companies, while some programs exclude any kind of association with the pharmaceutical industry at all. However, it is reported that approximately two-thirds of physicians receive drug samples from pharmaceutical industry representatives.[10] This behaviour highlights a glaring disconnect between the low level of trust for pharmaceutical industry representatives compared with the products they promote. Because many drug studies reported in national and international management guidelines are not carried out in the primary care setting and are funded by the pharmaceutical industry, it is not clear how the exclusionary tactics toward the pharmaceutical industry allow physicians to make more informed decisions when prescribing medications or trying out drug samples. Our attempts to soothe ethical and moral anxieties related to interactions with the pharmaceutical industry should not prevent us from forging collaborations that might be

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in the best interests of our patients. Family medicine is burdened with the task of balancing its role as a major driver of drug costs with its limited role in establishing best practices related to pharmacotherapy use in primary care, including adverse event monitoring.

Quality control

Quality innovation in family medicine should promote the development of practice-based research networks that include a vision for developing core capabilities in conducting clinical efficacy and effectiveness trials in collaboration with the pharmaceutical industry. Such a relationship should include an understanding that comparative effectiveness research is critical to the development of management strategies that are safe and cost effective at the primary care level. I support the notion that as family physicians we have an ethical duty to participate in clinical effectiveness trials of new medications destined for consumption in primary care.[11] I believe that family medicine should also play a leading role in clinical efficiency trials for new medications, as this strategy could serve to provide valuable insight into the design and conduct of appropriate clinical effectiveness trials in the community setting.

The barriers that limit the participation of physicians in randomized controlled trials are well documented[12] but can be overcome. As the discipline of pharmacoeconomics continues to emerge as an important fiscal priority, the need for best practice oversight at the primary care level will continue to escalate. Without a meaningful role in pharmaceutical industry–sponsored drug research, family medicine runs the risk of being a primary accomplice to broadening and costly care gaps that threaten to overwhelm public health services.

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Competing interests

Dr D'Urzo has received research, consulting, and lecturing fees from GlaxoSmithKline, Sepracor, Schering-Plough, Altana, Methapharm, AstraZeneca, Nycomed, ONO Pharmaceutical Group, Merck Canada, Forest Laboratories, Boehringer Ingelheim (Canada) Ltd, Pfizer Canada, SkyePharma, and KOS Pharmaceuticals.

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CLOSING ARGUMENTS

- As primary drivers of drug prescriptions and costs, family physicians should play a leading role in pharmaceutical industry–sponsored drug studies.
- Without a meaningful oversight role in the drug research process, family physicians might be primary accomplices to broadening care gaps.
- Practice-based research networks should promote core mandates to develop productive and collaborative relationships with the pharmaceutical industry that include participation in efficacy, effectiveness, and comparative effectiveness drug trials.

The parties in this debate refute each other's arguments in rebuttals available at **www.cfp.ca.** Join the discussion by clicking on **Rapid Responses.**