

FOR THE RECORD

Failed oversight

The United States Food and Drug Administration's process for approving high-risk class III medical devices is outdated and fails to ensure the safety and effectiveness of such products, according to a report by the highly respected US Government Accountability Office, (www.gao.gov/new.items/d09190.pdf).

The report indicated that since 2003, the FDA allowed 24 different types of class III devices to be cleared as if they were class I and class II devices, such as electrocardiographs, which manufacturers can bring to market without having to provide clinical evidence that they are safe for use.

The 24 included "certain types of hip joints, implanted blood access devices, pedicle screws for certain types of spinal surgeries, [and] dental implants."

No more freebies

The United Kingdom's Royal College of Physicians has joined the growing chorus calling for an end to the "culture" of doctors receiving freebies from the pharmaceutical industry (*CMAJ* 2008;178[13]:1651-2 and *CMAJ* 2008;179[3]:225-6).

A "decoupling" of pharmaceutical industry funding and continuing medical education programs is among the solutions recommended in a College working group report, *Innovating for health: Patients, physicians, the pharmaceutical industry and the NHS*, released in February (www.rcplondon.ac.uk/pubs/contents/7673804-76c5-4ab3-89a0-92d44e45edc3.pdf).

With industry having planted "deep roots" in, and funding half of, postgraduate medical education, there is concern that continuing professional development programs are little more than a form of drug promotion, argued the working group in the report.

To redress that, "new ways should be found to reduce the reliance of postgraduate medical education on sponsorship by pharmaceutical companies and

the wider biomedical industry." Alternative sources of funding, such as the royal colleges or the federal health ministry, should be sought.

The report also calls for new measures to provide independent assessments of the effectiveness of different prescription drugs, as well as a more principled approach by doctors with respect to receiving payments, gifts, honoraria or hospitality from industry.

Stalled strategy

The much-ballyhooed promise that the National Pharmaceuticals Strategy would reduce the financial burden that prescription medications placed on Canadians was essentially abandoned with the election of Conservative Prime Minister Stephen Harper in 2006, the Health Council of Canada says.

In a progress report on the 2004 strategy — a 9-point action plan to provide more affordable access to drugs that was reached as part of the 2004 intergovernmental Health Accord — the

Health Council bluntly noted the strategy was derailed when the Conservatives were elected.

Progress was being made "but then governments changed, and progress slowed," the Council stated in *A Status Report on the National Pharmaceuticals Strategy: A Prescription Unfilled* (www.healthcouncilcanada.ca).

Perhaps the most progress was made on the development of a common national drug formulary. But even then, once the provinces and territories reached the point that roughly 90% of drugs were commonly covered, they indicated that "a common national formulary is no longer needed."

The Health Council wasn't amused. "This would mean that 10% of medications, which may include newer and/or more expensive medications, are inconsistently offered across the country. Canadians need to know what these medications are, as well as the government's plans to close that 10% gap." — Wayne Kondro, *CMAJ*

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Dr. Jorge Enrique Zamora

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