



The Pharmaceutical
Advertising Advisory Board
REVIEW
By Ray Chepesiuk, Commissioner

If you had the choice...

Would you prefer the Canadian or U.S. drug advertising regulatory system? In February 2002, I attended a Drug Information Association-sponsored conference called "Marketing of Pharmaceuticals: How to be Aggressive and in Compliance." The speakers were current staff members of the Food and Drug Administration (FDA), former FDA staffers currently in the industry or consulting, pharmaceutical industry personnel and consultant lawyers. The main concepts of the conference were to give an update on FDA enforcement activities and to help people understand where the lines of advertising regulation stand.

Over 300 people involved in the international pharmaceutical industry attended the conference. I was there to learn about innovative marketing tactics (something U.S. pharmaceutical companies are famous for) and how the FDA Division of Drug Marketing, Advertising and Communications (DDMAC) attempts to control them. Having already attended a few of these conferences, I know that the regulating principles of drug advertising for health professionals do not differ significantly between Canada and the U.S., though there are, of course, major differences between the two countries regarding the promotion of prescription drugs to the general public (DTCARx). In the U.S. there have been political challenges to the maintenance of the current DTCARx system and it may face changes in the not-too-distant future. The FDA has commissioned studies to assess the value of DTCARx to the health-care system, and they are also closely monitoring the opinion of the American public.

One major factor that may affect future drug advertising regulations in the U.S. will be the appointment of a new head of the FDA. There is currently a short-

list of four candidates and a decision is expected to be made soon.

Staffing also affects the government's ability to efficiently enforce regulations. Both DDMAC and the Center for Biologics Evaluation and Research (CBER) are currently understaffed in their effort to effectively control drug advertising in the U.S. Here at the PAAB, we have augmented our staff to meet our turn-around time for the first review, while maintaining the quality of our service and our commitment to the industry.

Other major issues in the U.S. include drug pricing, Medicare reform, Medicaid and the Prescription Drug Users Fee Act. In Canada, we have been through these issues several times before.

Finally, there has been an air of uncertainty in the U.S. ever since the Washington Legal Foundation case regulation ruling. This case set a precedent for off-label promotion and the right of drug companies to disseminate published study material. One lawyer reminded the audience that, although the ruling stated that DDMAC could not stop a company from distributing a published paper about an off-label use, DDMAC could still prosecute on the grounds that the material is false and/or misleading if it is not based on good science.

In Canada, there is no uncertainty. The PAAB believes that pharmaceutical companies should distribute only information that is based on strong evidence, and the law states the information must be consistent with the product monograph approved by Health Canada.

The ethics of medical product marketing is a contentious issue in the U.S. The press and public are associating the high cost of prescription drugs with promotional spending. There has been no shortage of articles written in major U.S. newspapers and maga-

zines about the money that went into DTCARx. Other reports have addressed the alleged “wining and dining” of doctors in order to “buy” their prescribing loyalty, the funding of CME, pseudo-consulting by doctors, how scientific articles get published, and the activities of Medical Science Liaison personnel.

U.S. pharmaceutical companies are taking these issues seriously. Many of them have added a “Health Care Compliance Officer” to help keep the company onside with respect to regulations and ethics. And, of all things, there have been calls for the industry to self-regulate marketing practices! In Canada, self-regulation is well-entrenched — you might say we are even light-years ahead of the U.S. The PAAB and Rx&D have actively enforced their codes with respect to many of these problems.

A review of the FDA enforcement letters show that “fair balance” is a major concern in drug advertising. As in the U.S., the PAAB has been battling for Canadian pharmaceutical companies to respect this principle of fair balance.

Liability is a related issue with respect to communications about drug products. There have been some large settlements in the U.S. regarding improper labelling and claims. Why is it so difficult for Canadians to grasp that concept? The pharmaceutical industry has been very combative with the PAAB during submission reviews, so in some ways we can learn from our American neighbours, and they can learn from us — especially about self-regulation of promotional activities.

Overall, I believe we have a very good system to regulate drug advertising to health professionals here

Before



After



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