

Promoting Pharmaceuticals— The Changing Landscape



The Pharmaceutical Advertising
Advisory Board

REVIEW

Ray Chepesiuk,
Commissioner

The year 2006 marks the 30th anniversary of PAAB since its incorporation as a federally chartered, non-profit association.

Since its inception, there have been major changes in the pharmaceutical industry and society as a whole. I have been with the PAAB for 20 years and the most striking observation I have made is the change in attitude of many pharmaceutical marketers regarding ethical promotion. People now see the value of what the PAAB has been espousing through the standards in the Code of Advertising Acceptance.

The PAAB Commissioner has been a voice of moderation, begging two polarized factions, the industry and its critics, to come together for the good of patient care. Presently, more industry people talk to me at social events than in the past. As the great American song writer, Bob Dylan wrote, "The times they are a-changin'." They acknowledge that what the PAAB has been delivering works towards the best interests of the industry and the patients. The industry is not always right and neither are the critics. The PAAB strives for a balanced approach.

We appear to be living in interesting times regarding public perception. Ideology abounds and society has been rapidly evolving towards a state of conflict.

In Canada, healthcare has evolved to being an undeniable right of every citizen, and this appears to be happening, even if at a slower rate, in the US. As a result, the pharmaceutical industry is under more scrutiny than ever before. One could argue that drugs and drug companies are not as close to the heart or emotional strings of patients as are doctors, nurses and hospital staff. Therefore, the pharmaceutical

industry is an easy target, free of the encumbrance of personal attachment.

Just what has been happening lately?

In recent months, there has been a couple of polarizing events involving direct-to-consumer (DTC) advertising of prescription drugs.

1. The Canadian government is facing a lawsuit which began in December 2005. Canwest Global Communications Corporation filed an application with the Ontario Superior Court asking it to strike down the current federal statute and regulations restricting DTC advertising of prescription medicines, on the basis that they constitute a violation of section 2(b) of the Canadian Charter of Rights and Freedoms that guarantees freedom of expression.

2. In January 2006, the Health Council of Canada released a report entitled *What are the Public Health Implications? Direct-to-Consumer Advertising of Prescription Drugs in Canada*. While the report did call for a complete ban of prescription drug advertising to the public and a reformation of the advertising to health professionals by the healthcare products industry, there was nothing new in that report. Unfortunately for the sponsors, the report contained inaccuracies, omissions and misrepresentations.

In my opinion, the report could have been a lot more useful if objectivity had prevailed. It was a simplistic observation of a rather complex subject. It was based on opinion and not evidence and would be in violation of the PAAB Code of Advertising Acceptance.

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At the time of writing this article, I had not heard a lot of feedback regarding the impact of these two events. However, the government of Canada has to respond to the lawsuit in a prescribed time frame. Realistically, any legal settlement of that suit would probably not come anytime soon.

Did you see the January 2006 JAMA article?

The January 2006 JAMA article is entitled *Health Industry Practices That Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers*. The authors conclude that “more stringent regulation is necessary, including the elimination or modification of common practices related to small gifts, pharmaceutical samples, continuing medical education, funds for physician travel, speakers bureaus, ghostwriting, consulting and research contracts.”

The ever-changing marketplace does not leave us a lot of time to celebrate 30 years of PAAB success!

This article is interesting and refreshing because it is the doctors who are saying they should restrict what they receive. I have always thought that you cannot hand something to someone who isn't looking for a handout. This follows the implementation of, and several revisions to the US PhRMA Code of Conduct, regarding what the members of that association can do ethically with respect to marketing practices. PhRMA has actually proposed guidelines for the DTC advertising of prescription drugs and those guidelines are similar to the PAAB Code with respect to providing a fair balance of safety information in the advertisement. PhRMA has agreed that safety information should be thorough and presented in a manner that is easy to receive and understand.

The US pharmaceutical industry is reeling from the knowledge that there are over 150 *qui tam* action lawsuits under seal. These are the result of the famous whistle-blower clause they have in American law. Keep in mind that these cases date back at least three years. They do not reflect current attitudes and activity. The US industry has made an

effort to clean up its act. Last November I was present at a conference attended by 400 compliance officers in the US. The prevailing theme was that due to severe financial consequences, they could not do what they had been doing five years ago. Thirteen companies had been hit with fines for millions of dollars and people cautioned others not to be so smug because their company's name was not on the list; they could be on the Department of Justice's hit list of more than 150 cases.

I don't believe we in Canada need to wait for a whistle-blower act to be imposed. Nor do we need to wait to see what the federal Legislative Renewal brings. We all know what the right thing to do is and we have checks and balances through enforced codes to keep it that way, which unfortunately for the US, did not exist. Let's make our system of self-regulation work!

Perhaps the US needs a PAAB!

The PAAB Code is a dynamic document that changes with the times. We are seeing marketing practices that are a hybrid of activities. Although we had implemented a cover-to-cover review and revision of the PAAB Code in 2005, perhaps it will need future adjustment to reflect the changing marketplace. For the year 2006, PAAB has been asked to participate in several external advisory committees which involve internet activities, physician-industry relationships, CHE, patient information and promotion related to a specific disease. We frequently get questions about the DTC advertising of prescription drugs. We are aware of a trend involving academic or medical institutions or groups being funded through pharmaceutical company sponsorship to help produce newsletters and reports that disseminate off-label and comparative advantage claims. The reports look like “advertising,” but are called CME, funded by “an unrestricted educational grant.” The US Congress is investigating similar funding activities as they are deemed unethical and in some cases, fraudulent. The PAAB mandate extends to healthcare product companies and not to physicians and academic institutions. I have asked the PAAB members to conduct strategic planning later this year to address the ever-changing marketplace.

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