

## Purdue Pharma

Advancing Healthcare Through Research, Education and Pharmaceutical Innovation

Talking with John H. Stewart, Executive Vice-President and General Manager, Purdue Pharma Canada.

your career to date leading to your appointment as Executive Vice-President and General Manager of Purdue

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Following the completion of my graduate studies in microbiology and immunology, I began my 31-year career with Purdue as a sales representative. During my time with the company, I have also held positions of direct responsibility for clinical research, product development and regulatory affairs. I was appointed Vice-President of Scientific Affairs in 1986 and Executive Vice-President and General Manager in 1989. In addition to direct responsibilities for Canada, I also have regional responsibility for operations in Australia and New Zealand.

Can you give us a brief overview of Purdue Pharma's history as a corporate entity?



Purdue Frederick, as we were originally known, began its Canadian operations in Montréal in 1956. Canada was the first international affiliate of Purdue Pharma, a privately held, multinational corporation which operates under different banners worldwide: Purdue in the US, Napp in the UK and Mundipharma in 18 other countries. In 1958, the company moved from Montréal to Toronto and relocated to its present headquarters in Pickering, Ontario in 1990. Purdue is one of a limited number of pharmaceutical companies that has continued to maintain a fully integrated R&D formulation laboratory, drug development function and manufacturing capability in Canada. This year, Purdue is celebrating its 50th anniversary.

Dr. Kris Krishnamurthy, Director, Research and Development, in the Purdue Drug Formulation Laboratory

What are the current therapeutic focuses of Purdue in Canada and what does each focus contribute to the overall business? Is it similar on an international scale?

In product development, we have focused our efforts on the relief of pain, respiratory and inflammatory diseases, gastrointestinal conditions and the prevention and treatment of infection. The majority of our current business is in analgesic medicines for the management of chronic pain, including cancer pain. Purdue's UK Associate, Napp Laboratories, originally developed the Contin controlled-release delivery system, a novel technology that provides for close control over the amount of drugs released to the bloodstream. The system benefits patients by providing improved efficiency while also reducing the number of doses they need to take every day. The therapeutic profile among the Purdue family of companies in Canada and worldwide is relatively similar.

## What goals have you set for Purdue over the next few years?

We have specific plans to expand and diversify our product line through the addition of multiple new product offerings. These will cover a broader range of pain severities and include expanded dosage forms, which will better meet individual patient needs. In the coming year we plan to launch Uromax® for urinary incontinence and Biphentin® that will be used to treat Attention Deficit Hyperactivity Disorder (ADHD). These products will represent meaningful therapeutic advances in their respective categories and they are also "home grown", that is, the formulations were fully developed within Purdue Canada's R&D laboratory. In fact, Canada will be the first country among the Purdue/ Mundipharma/Napp group of companies where these specific formulations will be marketed. We are all proud of these achievements because they demonstrate that the Canadian organization is fully capable of identifying, developing and registering new product opportunities.

Another goal is to enhance our sales and marketing interactions with healthcare professionals. We plan to ensure that our marketing and CME activities deliver the information and support materials needed to achieve appropriate utilization of all of our products. Everything we do as a company is directed toward achieving patient-specific healthcare outcomes. Purdue currently does a good job communicating with health professionals, but a challenge is to find more effective ways of getting information to patients while operating within the constraints imposed by regulatory bodies.

What major initiatives has Purdue undertaken corporately and therapeutically? What is planned for the future?

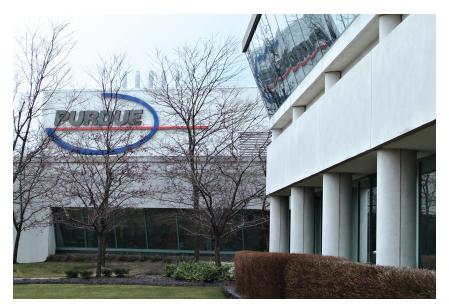
Purdue is a leader in pain research and patient support programs. Under-treated pain is of epidemic proportions in Canada. According to the Canadian Pain Society, persistent chronic pain affects 20% to 30% of Canadians—with an estimated \$6 billion annual cost to our economy in terms of disability leave, hospital stays and physician visits. In response, we are making good progress towards expansion and diversification of our analgesics line and we will also continue to work closely with the pain management community to increase awareness of pain and improve access to treatment. Some of our specific initiatives in this area include the establishment of the website, www.painCare.ca and the publication of textbooks on the management of cancer and non-cancer pain. Over 170,000 of these books have been distributed to healthcare professionals over the past 10 years.

Corporately, Purdue plans to get involved with appropriate partners to help raise awareness about the dangers of prescription drug abuse. Opioids are one of several types of controlled substances with the potential to be abused and we have to come up with a way to help fight this problem, without hurting the patients who legitimately need these medicines. Currently, Purdue supports an extensive education program on optimal pain management for healthcare professionals. As well, we continue to build our law enforcement liaison group, conducting seminars and distributing a product ID brochure, which enables police officers to quickly identify any of the most commonly prescribed opioid-containing products. Over 10,000 copies of this brochure are being used by law enforcement agencies across Canada.

In an era of joint ventures and co-promotion agreements, why has Purdue not taken this route to date and will future opportunities be considered? In fact, corporately and at the international level, Purdue is involved in a number of joint ventures in countries such as India, China and Japan. Last year, Purdue Pharma announced a licensing and distribution agreement with Labopharm in Laval, Québec for a once-daily formulation of the analgesic, tramadol. Purdue will have the exclusive rights to market, sell and distribute Labopharm's product in the US. In Canada, we have been actively and selectively pursuing in-licensing and product acquisitions in new therapeutic areas. The opportunity has to be right for both Purdue and the potential partner and must not come at the expense of our current product portfolio, which is still experiencing strong growth.



Standing left to right: George Vautour, Director, Analgesic Product Group; Randy Steffan, Director, Corporate Affairs and Communications; Kathryn Raymond, Director, Healthcare Education; John Stewart, Executive Vice-President and General Manager; Chris Kostka, Vice-President, Sales; Kim Horrill, Manager, Regional Development Programs; Bill Jeffery, Vice-President, Marketing; Alex Chan, Director, New Product Planning and OTC's.



Located in Pickering, Ontario, Purdue's impressive Canadian facility houses administration, research, manufacturing and sales support functions.

Can you give us an indication of where your research and new product activity is directed and the timeline for the introduction of new products in the Canadian market? Our top research priority is the development of abuse-resistant analgesic medicines that provide pain relief to patients, but are unattractive to potential abusers. Prescription drug abuse is a serious public health problem and our controlled-release formulation of oxycodone, OxyContin®, has become a target for abuse in some communities. The intent of one of our development projects is to cancel out the effects of the oxycodone content if the tablet is crushed, chewed or snorted. This is a very complex science and it will be some time before such an abuse-resistant opioid analgesic is perfected. In the meantime, Purdue will continue to work collaboratively with the medical community, law enforcement agencies and regulatory authorities to curb illegal diversion of all opioid-containing medicines.

You have been very active with Rx&D throughout your career. What impact will the new Rx&D Code of Conduct have on the way pharmaceutical companies conduct their business in Canada?

Yes, I am a past-chair of Rx&D's Board of Directors. During my many years on the Rx&D Board, I served as Chair of Rx&D's Patented Medicines Prices Review Board Committee (PMPRB), Health Canada Committee and National Political Action Committee (NPAP). I am currently Chair of Rx&D's newly formed Policy Committee. In addition to Rx&D activities, I have also represented the industry on the National Advisory Council on Pharmaceutical Research, the Treasury Board's Advisory Group on Cost Recovery/User Fees and the Advisory Committee to the Ontario Drug Programs Reform Secretariat.

I am confident that Rx&D's new *Code of Conduct* demonstrates that our industry is very serious about its business practices. Although polling data shows that 57% of Canadians have a positive view of the research-based pharmaceutical industry (Rx&D-Veraxis Fall 2005), a climate of distrust still exists, largely promoted by the industry's detractors and is based on

inaccurate perceptions of the ways in which drugs are marketed to physicians. The *Code* establishes general principles for ongoing interactions with healthcare professionals and places responsibility on individual companies to establish policies and specific conduct guidelines for CME events and hospitality. I am a great believer in having clear standards of ethical conduct. Not only is it the right thing to do, but employees take great pride in being part of a company and industry that is highly ethical.

What are the major issues that currently impact Purdue and the pharmaceutical industry? What issues do you foresee in the future?

The single most important issue the pharmaceutical industry faces is a lack of recognition for the value of medicines within the overall healthcare system. Modern medicines have been responsible for many of the significant healthcare gains in the latter half of the 20th century. These include the introduction of drugs which have transformed HIV/AIDS into a manageable disease, cholesterol-lowering drugs which can prevent heart disease by reducing expensive surgeries and hospitalizations, and recent breakthroughs in targeted therapies for breast cancer, which have shown great promise in increasing survival time.

If you look at pharmaceutical company pipelines, there are many more potential advances in areas such as arthritis, cancer and neurological disorders. What is frustrating for those of us who work so diligently to develop and bring these medicines to market is the current preoccupation with cost containment—a preoccupation at the very real expense of lost therapeutic benefit. Initiatives like the National Pharmaceutical Strategy and Common Drug Review are troubling because they primarily represent additional roadblocks which further delay a patient's access to new medicines. These initiatives will also stifle innovation by reducing the incentive for research.

Our healthcare system would be better served if the current rhetoric was redirected to find ways whereby we can maximize the efficiency that patients get from the existing dollars spent on drug therapy. For example, we know that adherence or compliance as it was formerly known, is not optimal. There is a lot of wasted drug therapy, needless drug interactions and the underutilization of proven therapies. We should be focusing public policy on how to improve the use of drug therapy, not on how to further reduce the number of drugs covered by publicly funded insurance programs. Purdue is very interested in supporting academic studies which demonstrate the significant gains that could be achieved by such an approach.