Rx&D

...“An Amazing and Exciting Story”

Talking with Russell Williams, President, Rx&D

Please review your career path leading to your current position as President of Rx&D.

Throughout my career, I have been active in community service and the public service, including Director General of the Canadian Human Rights Foundation and, for a brief time, Director General of the Brant Regional Health Council in Ontario.

In 1986, I entered municipal politics and served as a councillor for Beaconsfield, Quebec. Three years later, I entered Quebec provincial politics as the MNA for Nelligan. I was to serve in this capacity for nearly 15 years.

During this time, I was very involved in health care and economic policy development. I was the parliamentary assistant for two ministers of health and became involved in patient access issues and effective health-care planning.

There were a number of research-based pharmaceutical companies in my riding and I was honoured to work with them and community groups on issues such as patient access and the role the pharmaceutical industry plays in Quebec as a key contributor to the province’s economy and community as a whole.

One of my accomplishments, of which I am quite proud, was the establishment of a unique pharmaceutical pricing policy that encourages health research and development.

Please outline the make-up of the Rx&D board and the respective chairs.

The following charts list the members of the Rx&D Executive Committee and Directors of the Board of Directors (Tables 1&2). Company positions and chair responsibilities are outlined in Figure 1, page 15.

Table 1 Rx&D - Board of Directors Executive Committee/Directors

Mr. Paul Lucas, Chairman of the Board
President & CEO, GlaxoSmithKline Inc.

Mr. Philip Blake, First Vice-Chair
President & CEO, Bayer Inc.

Mr. Michael Cloutier, Second Vice-Chair
President & CEO, AstraZeneca

Mr. Ronnie Miller, Treasurer
President & CEO, Hoffmann-La Roche Limited

Mr. Jean-Michel Halfon, Immediate Past-Chair
President & CEO, Pfizer Canada Inc

Mr. Gilles Gagnon, Executive Committee member representing Biopharmaceutical Members
President & CEO, AEterna Zentaris Inc.

Mr. Russell Williams, President
Canada's Research-Based Pharmaceutical Companies (Rx&D)

Table 2 Rx&D - Board of Directors Directors

Dr. Philippe Calais
President, Neurochem Inc.

Mr. Jeff Davis
General Manager, Procter & Gamble Pharmaceuticals Canada Inc.

Mr. Rajiv De Silva
President, Novartis Pharmaceuticals Canada Inc.

Mr. Jonathan Goodman
President & CEO, Paladin Labs Inc.

Mr. André Marcheterre
President, Merck Frosst Canada Ltd.

Mrs. Diane McDougall
Executive Director & General Manager, Merck Frosst-Schering Pharma Partnership

Mr. David Ricks
President & General Manager, Eli Lilly Canada Inc.

Ms. Judy Robertson
President & General Manager, Bristol-Myers Squibb Canada Inc.

Mr. Jérôme Silvestre
President & CEO, sanofi-aventis Canada

Mr. John Stewart
Executive Vice-President & General Manager, Purdue Pharma

Mr. John Suk
President & CEO, ALTANA Pharma Inc.

Dr. Roland Turck
President & General Manager, Berlex Canada Inc.

Mr. Arnout Ploos van Amstel
President & Managing Director, Wyeth Pharmaceuticals

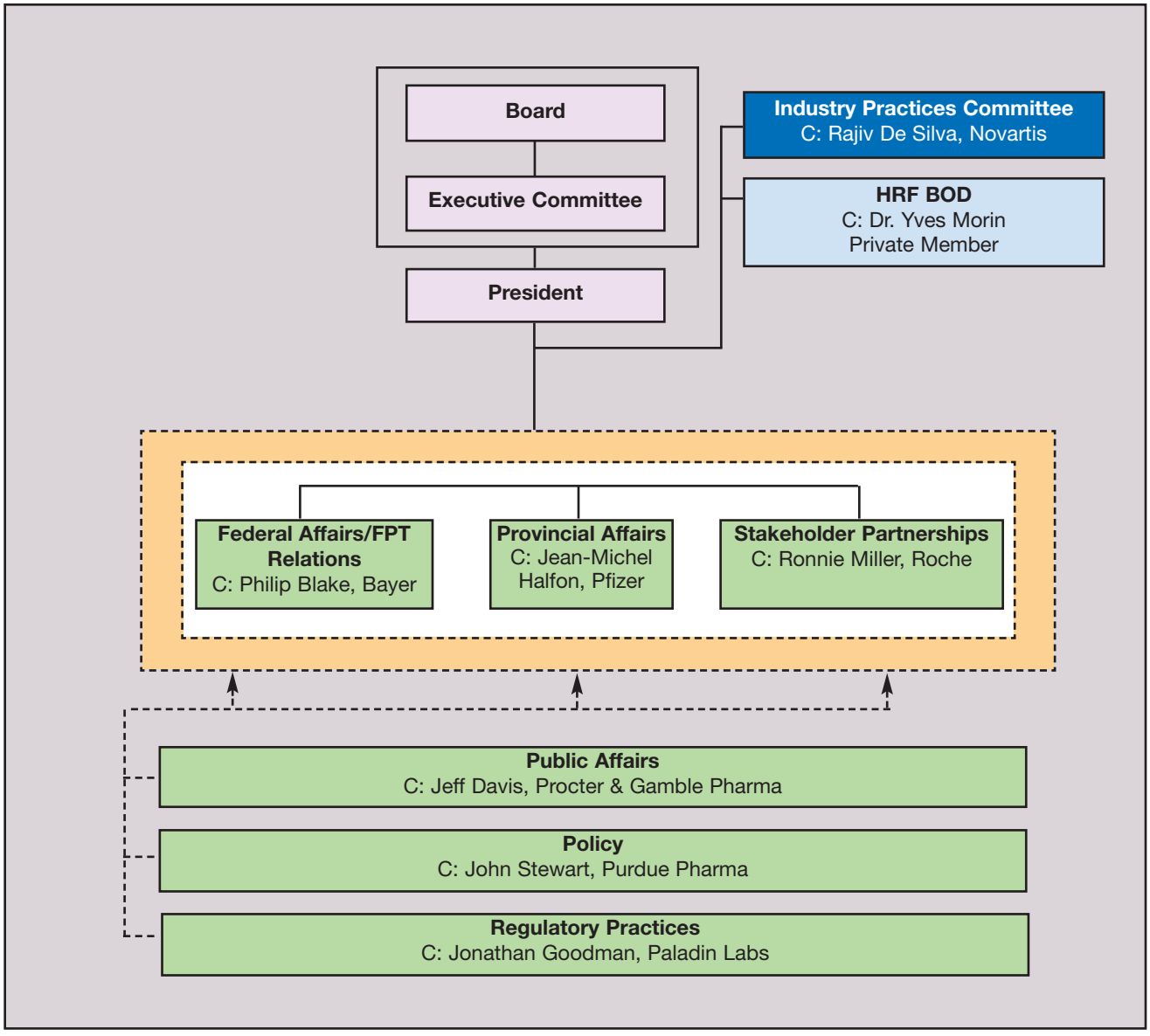

Figure 1 Rx&D Positions and Chair Responsibilities

What objectives have you set for yourself and the association in the short and long term?

The primary objective is to ensure that Rx&D is respected as a health-care partner. Secondly, that the research-based pharmaceutical community is fully recognized as an integral part of Canada's economic development and part of our country's global strategy to attract R&D investments to Canada.

The association has developed an innovation agenda we believe, if shared by governments, will create a better investment environment in Canada. In this regard, we have been working with all levels of government to illustrate how the agenda of patients' health and the wealth of the country can coexist and be mutually supportive, resulting in an improved and sustained health-care system.

What are the major impediments to the success of the pharmaceutical industry in Canada?

I believe it is important to state what factors help make for a successful research-based pharmaceutical industry. These include:

- improved drug approval times by Health Canada;
- increased patient access to new medicines in a timely and equitable fashion;
- a globally competitive investment climate to attract research and development dollars;
- an enhanced intellectual property protection that includes patent term restoration for time lost in the drug approval process and internationally competitive data protection for new drug submissions; and
- a world-class pricing policy that includes the risks and benefits of medicines.

Russell Williams, President of Rx&D, is surrounded by his executive team.

Front row (from left to right): Walter Robinson, Vice-President, Provincial Affairs; Russell Williams, President, *Canada's Research-Based Pharmaceutical Companies* (Rx&D); Declan Hamill, General Counsel.

Back row (from left to right): Mark Ferdinand, Vice-President, Policy, Research, Regulatory and Scientific Affairs; Jacques Lefebvre, Vice-President, Strategic Affairs and Communications; Brigitte Nolet, Vice-President, Federal Government Affairs/ FPT Relations; Darren Praznik, Vice-President, Stakeholders & Partnerships.

You've referred to the need and importance of a national innovation strategy for Canada; can you outline what components need to be included?

Innovation is our community's *raison d'être*. It is also the key to Canada's continued economic success. In our global economy, knowledge provides competitive advantage, increasingly drives new products and services, helps make our production methods and processes more efficient and effective, and drives increased, knowledge-based high-quality jobs.

Rx&D's innovation agenda creates a balance between the agendas of health and wealth. Components include:

- timely and equitable access to new medicines in the provinces and territories;
- addressing cross-border trade to ensure that medicines approved for use by Canadian patients remain in Canada;
- the establishment of a federal pricing policy model that considers innovation when setting prices of new medicines;
- improving drug review and approval times by having Health Canada meet international standards; and
- globally competitive data protection as part of an effective and competitive intellectual property protection policy. Current proposed regulatory changes in this area will increase data protection for new pharmaceuticals to eight years, as well as provide an additional six months of data protection if paediatric research is undertaken on these medicines.

Each of these elements provides governments and policy makers with the tools to help effect change and create a climate that encourages and strengthens life sciences R&D investment in Canada.

R&D investment in Canada has been slipping in recent years. Does this open the door for greater government intervention in the patents issue, limiting market access, *etc.*?

Rx&D member companies invested over 10% of sales from 1993 to 2001, reaching a high of 12.9%. The Canadian environment has not kept globally competitive and therefore it has been difficult to maintain this level recently.

The innovation agenda we have proposed to the federal and provincial/territorial levels of government is but one way we believe governments can put Canada on track to achieve international competitiveness, resulting in new and increased innovation by the life sciences sector.

We are making progress. Rx&D and our stakeholders have played an important role in having governments recognize the importance of innovation to the health and well-being of our citizens, our economy and productivity.

In Ontario, for example, the premier recently created and now heads up the ministry of research and innovation. As a result, innovation and the importance of the life sciences sector to the province's economy have advanced considerably on the government's economic agenda.

Likewise, Quebec has introduced a new *politique du médicament* or drug policy that recognizes innovation and patient health outcomes in its four policy principles:

- accessibility to new medicines;
- fair and reasonable price for prescription medicines;
- optimal use of prescription medicines; and
- maintaining a dynamic pharmaceutical industry in Quebec.

It takes vision by governments to understand that through partnerships much can be realized. Life sciences innovation is critical to Canada's economic and health-care well-being. Working together in partnership is a "win-win" situation for governments, stakeholders and Canada as a whole.

Rx&D member companies are proud of our mandatory *Code of Conduct* and our commitment to the high standards of ethics in our ongoing business relationships with Canada's health-care professionals.

Much has been discussed of the Rx&D *Code of Conduct*. Is the *Code* working within the industry, and has it been well received externally by all your stakeholders?

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As a living document, the *Code* has undergone several improvements since its genesis in 1988. The latest improvements to the *Code* include:

- eleven guiding principles that member companies must adhere to in their ongoing interactions with health-care professionals. The guiding principles are supported by:
- an effective enforcement mechanism;
- an enhanced section on *Code* violations. For a company that has five or more violations in one calendar year or has two successive years with at least three violations in each year, the Rx&D Executive Committee will place the company on a 12-month probationary period;
- If the company is found to be in violation of the *Code of Conduct* during its probationary period, the Board of Directors will determine if the violation is just cause to have the company expelled from Rx&D; and
- an Industry Practices Review Committee (IPRC) to adjudicate a reported *Code* infraction or infractions by a member company. The Committee is composed of experts including industry legal counsel, regulatory and marketing representatives and two external health-care professionals (physician and pharmacist).

These new improvements and others took effect January 1, 2006, and were made in consultation with a number of key stakeholders including the Ontario and Quebec pharmacists association, the Canadian Medical Association (CMA), and the College of Family Physicians of Canada (CFPC).

Can you comment on the PMPRB's desire to increase its mandate beyond monitoring R&D investment and reviewing the prices of patented medicines?

When it was created 18 years ago, the Patented Medicines Prices Review Board (PMPRB) was supposed to balance the prevention of excessive pricing by patentees and the encouragement of research and development in Canada. We believe that balance is out-of-sync. Given the discussion papers released in the spring of 2005, I believe they are losing sight of their original mandate. Also, I have serious reservations regarding the ongoing efficacy of the PMPRB—specifically how its activities foster innovation. I think Canada should seriously review the effectiveness of the PMPRB within its prosperity agenda.

It is essential in our democracy that bodies, like the PMPRB, CDR/NPS, are accountable to legislators and the Canadian public. Whether it is the PMPRB, the Common Drug Review (CDR) or a National Pharmaceutical Strategy (NPS), what seems to be developing is an unaccountable agenda that is silo-focused and short-sighted in its limited focus, without appreciating the effect on the health-care system, health outcomes for Canadian patients and economic development costs.

In the long run, this agenda, if left unbalanced, will cause serious harm to the Canadian health-care system by impeding patient access to innovative medicines. Furthermore, I want our research-based pharmaceutical community to be involved, so they can continue discovering new life-saving and improved medicines in Canada with an environment that encourages health innovation.

It is time to make an objective evaluation of the PMPRB and ask ourselves whether it has fulfilled its original legislative mandate. By its own review, prices of patented medicines have declined or remained relatively unchanged for each of the last 12 years. This overall evaluation also applies to the CDR and NPS to ensure they truly respond to all the needs of Canadians.

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As we begin a new year, do you have a final message for your constituents at the CEO level, as well as the front-line sales and marketing personnel?

We play an important role in advancing patient care, our health-care system and our economy. In conjunction with our innovation agenda, ours is an industry that positively impacts the health and well-being of Canadians everywhere. It is an amazing and exciting story. It is our responsibility to ensure that this story is told and understood.

However, we are at a crossroads. We have an opportunity to build partnerships that will protect what we have now as well as build for the future.

The year 2006 will be important for our community as we talk to and with all our stakeholders, including all governments, on issues that impact our community, the health and well-being of Canadians and our own prosperity. CPM

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