BY KIM RIBBINK

SENSE & SENSIBILITY

With a wide and deep understanding of the inner sanctum of numerous departments in the life sciences, *Pamela Williamson Joyce* has been able to bring both inventiveness and clear-headed thinking to Serono's regulatory practice, helping the company to bring many new products to market.

The path to drug approval is a long and complex one, but Pamela Williamson Joyce brings a level of energy and commitment that is infectious to those around her and encourages visionary thinking to overcome challenges.

At the same time, Ms. Joyce, Serono's VP of regulatory affairs and quality assurance, measures her enthusiasm with a healthy dose of common sense aimed at ensuring that clear and objective goals are set and followed.

"With a lot of focus these days on profit, which is of course important, and so many areas of the business being heavily regulated, it's important to take a step back and do a reality check every once in a while to ensure that the path we're taking makes sense and that we don't make the means the end," Ms. Joyce says.

Her level-headed disposition has helped to bring extraordinary results to Serono during the 20 plus years she has spent at the company, including overseeing nine NDA/BLA approvals. She has built teams of dedicated, knowledgeable professionals who have been central to the company's growth.

Serono, a global biotechnology company, focuses on four core therapeutic areas: reproductive health, where the company has long been a leader; neurology; growth and metabolism treatments for HIV-associated wasting and growth deficiencies; and dermatology.

Serono has more than 30 ongoing projects in the development pipeline, including recombinant proteins and small molecules. The projects span the company's existing therapeutic areas, as well as niches within new therapeutic areas, such as inflammatory and autoimmune diseases and oncology.

Serono's fast-paced, energetic, and innovative approach to drug development is a perfect fit for Ms. Joyce.

"I like to work in positions where I believe that what I'm doing has an impact, and because the company allows people to become personally engaged and take some risk, we actually have an opportunity to see the impact that we're having on the business; it's invigorating," she says.

PAMELA WILLIAMSON JOYCE

Finding a Niche

After completing a degree in psychology, Ms. Joyce accepted a job with a medical equipment and blood processing equipment company, Haemonetics Corp., which gave her a good grounding in the medical industry.

A year later, the young professional was approached by a recruiter for a job at Serono; since then, she hasn't looked back.

"Coincidentally, the same recruiter who approached me to consider the position at Haemonetics also approached me to consider this position at Serono," Ms. Joyce says.

When she joined Serono, the company focused predominantly on reproductive health and fertility, though it also had a diagnostics division, which Ms. Joyce says made it a logical segue from the blood-processing equipment she had been working with at Haemonetics.

Since then, Serono has vastly expanded its therapeutic field and has also extended into biotechnology.

"When people have difficulty conceiving a child, Serono has been the first company that comes to mind because the company has been a real innovator in the field," Ms. Joyce says. "Although Serono is still the clear leader in the area of reproductive health and fertility, it has expanded into neurology, metabolic endocrinology, and is investing heavily in the area of oncology."

Even after 20 years, Ms. Joyce remains excited by the company and its core philosophies.

"Serono demonstrates a very strong commitment to its patients," she says. "It's never been a me-too company; it has always been at the forefront of trying to bring innovative, patient-friendly services to the market, in addition to providing high-quality products."

Consistent with Serono's mission, most of the products in the pipeline are intended to target unmet medical needs.

"Although there may be some products already on the market to treat these conditions, they may not be fully effective for every member of the specific patient populations or they may have significant side effects," Ms. Joyce says. "So it's exciting to see products being developed that are even more efficacious and at the same time safer than the ones that already exist."

Collaboration with biotechnology and pharmaceutical companies, as well as leading

The Regulatory Landscape

PHARMACEUTICAL INDUSTRY LEADERS IN THE REGULATORY FIELD FACE MANY CHALLENGES, AS WELL AS OPPORTUNITIES, IN TODAY'S DEMANDING ENVIRONMENT.

For Pamela Williamson Joyce, VP of regulatory affairs and quality assurance at Serono, what makes the industry both inspiring and fraught is the rapid advancement and development of the science.

"For example, the industry is more and more becoming focused on patient-specific therapeutic solutions to various types of diseases and conditions," she says. "So the entire area, for example, of pharmacogenomics is one that holds a lot of promise and excitement for anyone working within the industry."

At the same time, advancements in science present far greater challenges because they require new ways of studying and evaluating drugs that are much more complicated than those previously seen. This is made harder by some upheaval within the FDA, particularly at the top.

"Over the past four years, the slot of an FDA commissioner has been vacant more frequently than it has been filled," Ms. Joyce says. "I'm sure it's very challenging for the various reviewers and members of the FDA to move forward with their initiatives when policy issues may take longer to address than they would otherwise if there were a full-time, permanent FDA commissioner in place for longer than a few months."

The innovations of biotechnology have not only produced a variety of novel drugs, but have introduced additional challenges and hurdles to drug-approval processes, Ms. Joyce notes.

"The more sophisticated the products become, the more important it is that issues of risk-benefit and drug safety are addressed," she says. "The importance of drug safety is a subject that has received heightened interest and heightened awareness, particularly during the last year. And it's an important balance that needs to be struck, because there are no drugs that are guaranteed to be 100% safe, whether it's a unique and complex drug that's being introduced for the first time, or a drug that is available over the counter."

According to Ms. Joyce, it is important to gain as much information as possible to make a decision and to ensure that companies and physicians and patients understand that the potential benefit for the drug, in terms of efficacy, also has with it a certain amount of potential side effects.

"It's a balance that's always very difficult to strike, because we all want to believe that if we're taking a drug that is prescribed by our physician and approved by the FDA that it must be 100% safe, but that's never the case and never can be the case," she says.

One big change in the regulatory environment is increased efforts by global compliance authorities to take a more harmonized approach to the regulatory process.

"In the past, when there was a unified approach used by the various health authorities, it wouldn't be uncommon for companies to have to have multiple development programs and redundant studies ongoing to meet subtle differences in what the health authorities required," Ms. Joyce says. "Having greater visibility of what health authorities require — not just the FDA, but the EMEA and others — allows us to take a more holistic approach and gain efficiencies and have fewer surprises when it comes time to actually make a filing."

academic institutions, is also integral to efforts to discover and develop products to meet patients' needs. The company continues to expand its therapeutic areas and its pipeline.

According to Ms. Joyce, the fact that Serono is a global company is also a big draw because it provides visibility to different cultures and allows her to hone her skills to meet the various regulatory requirements for the different governing bodies for the approval of new products.

"In my position, having this broad perspective enables me to provide input into our clinical-development programs early on," she says. "This gives me not just an understanding of what the FDA may require to register a new product, but also ensures the most efficient uses of the company's resources."

A Broad Perspective

Over the course of her career, Ms. Joyce has held a wide variety of positions at Serono, giving her a detailed overview of the various departments and operations within the company. These opportunities, she says, have been priceless.

"Very few companies allow moves across functions the way Serono has," she says. "It has given me a first-hand view of the challenges of the different areas of the business. For example, I worked in sales and marketing and was actually able to go out in the field and experience what sales representatives deal with day in and day out as they interact with different physicians."

She spent the early part of her career in manufacturing operations, and she managed all material control functions to support the development and manufacture of ethical pharmaceuticals, *in vitro* diagnostic kits, and instrumentation.

"I really had an opportunity to see from the ground up how these products are developed and manufactured, what the challenges are, and how important it is to ensure that the quality of the product remains as close to the gold standard as possible, and how that impacts other areas of the business," she says.

It was at a time, Ms. Joyce notes, when few women worked in that end of the business, but she says this was never an impediment to her being able to do her job effectively, and in fact she enjoyed extensive support from her male colleagues.

"I would say most, if not all, of the individuals I worked with and for were very supportive and open minded," she says. "So although I was in the minority in terms of the gender balance, it didn't really impact the interactions with my fellow colleagues; it was a difference but it wasn't a hindrance."

Today, many women at Serono enjoy senior positions. Ms. Joyce says in addition to herself, Renee Connolly, Serono's VP of corporate communications, is also on the senior management team, and even further across the organization there are many VPs and director positions that are held by women.

"So the gender bias has really been reduced," she says. "For example, both the VPs of sales and of marketing in two of our three therapeutic areas are women."

Because Serono was a small company when Ms. Joyce joined in 1983, she was given considerable flexibility in career development and input into the company's operations.

"When opportunities arose in how to expand the business, I was allowed to engage in those discussions," she says.

Those opportunities led to many successes for Serono and for Ms. Joyce's career.

"I helped oversee a technology transfer of a recombinant growth hormone for the treatment of patients with AIDS wasting from our Swiss manufacturing facilities to a manufacturing facility here in the United States," she says. "It was quite complicated, but in the end it resulted with the company being able to receive approval from the FDA for a treatment IND, which provided access to the product to patients in need in advance of the full approval."

In each position she says her psychology degree has been helpful in enabling her to understand a variety of different points of view and work more effectively with different indi-

Research at All Levels

IN AN EXCLUSIVE INTERVIEW WITH PHARMAVOICE, PAMELA WILLIAMSON JOYCE, VP OF REGULATORY AFFAIRS AND QUALITY ASSURANCE AT SERONO, TALKS ABOUT WHAT AND WHO INSPIRES HER, THE IMPORTANCE OF COLLABORATION, AND THE ISSUES THAT MOST CONCERN HER.

WHAT MOST INSPIRES YOU ABOUT THE LIFE SCIENCES?

What excites me is the fact that studies at the research level continually turn out new things. The company recently identified 80 genes that are involved in the neurodegenerative pathways of multiple sclerosis, which offers the promise of change and hope and new therapies for the future; it's always evolving and there's always more to know and more to learn. I'm always very impressed with the many different scientists who I have had the opportunity to work with and also the many different clinicians who treat the various patients and how these early discoveries have the potential to evolve over years with the hard work of many people into something that can actually provide a true meaningful clinical benefit to the patient.

WHAT DO YOU PERCEIVE TO BE THE BIGGEST THREATS TO THE INDUSTRY AND HOW CAN LEADERS SUCH AS YOURSELF ACT TO OVERCOME THOSE DIFFICULTIES?

There is, unfortunately, a growing misconception within the public of the biotechnology and pharmaceutical industry as a whole. And it's important for us to get the messages out about how difficult it is to bring new products to the market, how challenging it is, how few of the early leads ever make it through the entire process into the market, and how expensive it is to do so. On the one hand, we all want to keep the price of drugs as reasonable as possible, but it takes a significant amount of investment, infrastructure, resources, and commitment over many, many years to bring these drugs to market and in the end it's important that we educate everyone about the hurdles and challenges that exist.

YOU ARE INVOLVED IN A NUMBER OF PROFESSIONAL ORGANIZATIONS. HOW DOES INVOLVEMENT IN SUCH PROFESSIONAL GROUPS AID YOU PROFESSIONALLY?

Bringing together groups that have a common

viduals in different functions and at different levels of the organization.

"Probably most important, it has enabled me to gain an understanding about where people are coming from so I can address their specific needs," she says. "This is particularly relevant in terms of group dynamics because while we like to believe people in various functions attempt to move toward the same objective and the same goal, it's not always possible for people to let go of their individual stakes. Understanding this dynamic is valuable in trying to get people on the same page and to reach a common goal, sometimes when there are competing objectives."

Guiding the Team

In 1998, Ms. Joyce joined the regulatory-affairs team, first as executive director, regulatory affairs, of metabolic endocrinology and then executive director of regulatory affairs and operations, before being promoted in 2000 to her current position of VP of regulatory affairs and quality assurance.

"One of the things I focus on is trying to optimize the time that it takes to move new products through the pipeline," she says. "For me, it's critical to have visibility early on, understand what type of product it is, what the mechanism of action is, what the patient population target would be, and what the potential regulatory hurdles could be. That makes it possible to have effective discussions with the FDA and negotiate a path forward that brings these products to the market and to the patients as soon as possible."

Regulatory is a highly fraught and complex area for the industry, but it's one that Ms. Joyce thrives in.

For example, direct-to-consumer advertising can be a double-edged sword because while there is indisputable value in allowing both physicians and patients to have access to information about new products that are brought to market, there is a clear need for balance to ensure that the information is factual and that safety information is clear. But Ms. Joyce sees this as a creative opportunity rather than a regulatory headache.

"It's a very interesting, evolving, and creative end to the business," she says. "And because the people who work with me in regulatory tend to really enjoy challenges, it makes it fun to work with marketing on trying to get the important messages out, but in a manner that's responsible to the public."

With responsibility for overseeing the regulatory aspects of product development through commercialization, Ms. Joyce has a long list of achievements to her name. She is particularly proud of the work she and her team undertook to achieve approval for three drugs during the past three years.

"Our multiple sclerosis product Rebif, which was approved in 2002, set a precedent because it was the first and only time that a company had received approval of a product based on clinical superiority as demonstrated in a head-to-head trial at a time when a competitor product held orphan exclusivity," she says.

A couple of years later, two other products that Ms. Joyce and her team worked on received approval: Zorbtive, which is indicated for the treatment of short bowel syndrome in patients receiving specialized nutritional support; and Luveris, which is indicated for the treatment of infertile hypogonadotropic hypogonadal women with profound LH deficiency.

"The reason I'm particularly proud of those two achievements is that they involved a cross-functional approach within the company working on FDA advisory committees," Ms. Joyce says. "These two products are both for treatments of rare diseases, and both hold an orphan drug designation. It demonstrates the company's commitment to following through on long clinical-development programs and registration for these very small patient populations."

Her innovative approach to overcoming challenges has meant Ms. Joyce has sought to ensure Serono stays on the cutting edge of technology, particularly in the regulatory field. One of the biggest changes Ms. Joyce has overseen is the way Serono submits applications to the FDA.

"We moved a few years ago to e-submission of all our applications," she says. "In the past, we had literally truck loads of papers being carted off to the FDA, which was rather unwieldy. But we can now put it all on CDs, which makes it much more efficient."

The VP of regulatory affairs position has evolved since Ms. Joyce's appointment, and today she spends much of her time on health-

interest enhances collaboration and allows us to bring a much stronger message across, whether it's one we want to deliver to the public or to the FDA or to some other segment within the government. It also allows for cross-fertilization of ideas and experiences. We have an opportunity to impact health policies as they evolve and unless opinions are shared based on experiences, there really isn't an opportunity to effect change.

CAN YOU TALK ABOUT THE INDIVIDUALS WHO HAVE INSPIRED YOU AND LED YOU TO WHERE YOU ARE TODAY?

There have been two people who have been a significant influence on me. The first is my father; from the very beginning he always encouraged me and sent a clear message that anything is possible if you work hard enough and do it with the right motivation and intent.

Within the industry, Jean-Pierre Verhassel, who recently retired, was an important influence on my outlook. He held a number of senior-level positions in Serono and lived both in Switzerland and the United States for various periods of time, and he moved across functions. When I first met him, it was back in the days when we had a diagnostics organization and he headed that up, and subsequently he moved to head up worldwide manufacturing, worldwide sales and marketing, and also served a term in the United States as president of Serono Inc. And he set a wonderful example about being a risk-taker, introducing an element of common sense into management, and being very clear about setting goals to avoid becoming sidetracked. He influenced how I view the company and what needs to be done to make the company successful and ensure the employee base is cared for and supported.

WHAT IS THE ONE ISSUE, BE IN THE INDUSTRY OR IN THE WORLD AT LARGE, THAT MOST CONCERNS YOU?

There are so many challenges; it's very difficult to identify just one. But I think I would say the issue of education is of concern and ensuring that children get a robust, high-quality education early on and a lot of support in their educational development. These are the people who are going to be influencing what happens in the country and the world and what happens to people who preceded them. The future is going to be in their hands and if they don't get a good, strong education, founded in ethics and morals, then how they evolve could be suboptimum. They're tomorrow's leaders, and I think that education is key. And it doesn't matter whether it's an education in math or sciences or psychology or some other area; a quality education makes for a better, well-rounded person.

I really try my best NOT TO PREACH ABOUT THINGS that I'm not willing to practice myself, and I think THAT GOES A LONG WAY TOWARD OTHERS BEING WILLING to trust and become engaged and put out the extra effort that it takes sometimes to reach very difficult objectives.

policy issues and interacting with people at various levels of the FDA, as well as the U.S. trade associations, including the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Industry Organization (BIO), to ensure that the interests of patients and the industry are represented.

Two issues that have been central to health-policy debates of late are importation of drugs from Canada and the subject of follow-on protein products, or generic biologics.

"There are some misperceptions among the general public about drug importation and the distribution channel," Ms. Joyce says. "The reality is that a significant amount of counterfeit drugs come across our borders through the Internet. If importation is something that is deemed to be in the best interest of the American populace there needs to be adequate budgets and controls put in place to ensure that the authority of the FDA isn't undermined and that patients don't inadvertently receive products that are not of the same specifications that are approved in the United States."

Ms. Joyce says with regard to generic biologics it is important to ensure that the same level of quality that existed when these products were approved by the FDA on behalf of the innovator company is maintained.

"There is a need for robust clinical trials in humans when a sponsor wants to introduce a follow-on product to the market," she says.

To ensure her staff members are well-positioned to tackle the issues that arise, Ms. Joyce employs a management technique called situational leadership.

"The goal is to heighten awareness to different types of people to be able to adapt your style to accommodate the skill sets of the people on particular teams, or differences in opinions, or where they are in terms of their own evolution on the curve," she says. "Also, because people on teams come from their own individual functions within an organization, it is sometimes easy to slip into a comfort zone that is specific to their own silo. It's extremely important to be able to bring a group of people together and get them working toward a common goal."

A critical part of leading a team, Ms. Joyce believes, is to walk the talk.

"I try my best not to preach about things that I'm not willing to practice myself, and I think that goes a long way toward others being willing to trust and become engaged and put in the extra effort that it takes sometimes to reach very difficult objectives," she says.

In the long run, her hope is that she will have set an example that, despite obstacles, it is always possible to come up with creative ways to reach objectives.

"Even when things are at their most difficult, if you put your mind to it and don't give up, anything is achievable," she says.✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

Staying the Distance

PAMELA WILLIAMSON JOYCE — RESUME

2000 – PRESENT. VP, Regulatory Affairs and Quality Assurance, Serono Inc., Rockland, Mass.

1999 – 2000. Executive Director, Regulatory Affairs and Operations, Serono Inc., Rockland, Mass.

1998 – 1999. Executive Director, Regulatory Affairs, Metabolic Endocrinology, Serono Inc., Rockland, Mass.

1995 – 1998. Executive Director, Operations Logistics, Ares-Serono Inc., Boston

1992 – 1995. Director, Operations Logistics, Ares-Serono Inc., Boston

1991 – 1992. Director, Materials Management, Ares-Serono Inc., Boston

1989 – 1991. Director, Sales Systems and Services, Ares-Serono Inc., Boston

1987 – 1989. Corporate Project Manager, Ares-Serono Inc., Boston

1987 – 1987. Materials Control Manager, Ares-Serono Inc., Boston

1986 – 1987. Manager, Inventory Control, Ares-Serono Inc., Boston

1983 – 1986. Supervisor, Inventory Control and Purchasing, Ares-Serono Inc., Randolph, Mass.

1981 – 1983. Materials Analyst, Haemonetics Corp., Braintree, Mass.

EDUCATION

1988. Master of Business Administration, Northeastern University, Boston

1981. Bachelor of Arts, psychology, cum laude, Skidmore College, Saratoga Springs, N.Y.

PROFESSIONAL AFFILIATIONS

Pharmaceutical Research and Manufacturers of America

Biotechnology Industry Organization

Massachusetts Biotechnology Council

Food and Drug Law Institute

Drug Information Association

Regulatory Affairs Professionals Society, Regulatory Affairs Certified