

WOMEN'S BUSINESS

BOSTON

Covering Massachusetts, New Hampshire and Rhode Island

April 2006

THE PROFESSIONAL AND BUSINESS WOMAN'S JOURNAL

COVER

Alison Lawton's Rx Is Global Vision, Regulation, Distribution

By Helen Graves

For Alison Lawton, senior vice president of global regulatory affairs, corporate quality systems and policy programs at Genzyme, advancing new medicine is a matter of: Think globally and act globally.

From advising on clinical test design at Genzyme to helping shape public policy in the U.S. and abroad, Lawton brings her big-picture perspective to responsibly delivering therapies to those suffering with debilitating disease no matter where they live.

The new order of drug development, especially with the breakthrough understanding of the human genome, requires new thinking and legislating in terms of quality, safety, urgency and accessibility the world over.

It's old hat for Lawton, who's infused the international perspective since her 1991 start at Genzyme, but something that's fresh on her mind as she constantly looks for new opportunities to improve health care outcomes.

"Over the years, what has been important to me is looking at how we establish efficient processes and how we update those processes so they're compliant and continually improving as we manage from a global perspective," she says.

Today, Lawton oversees 150 people in Cambridge and 22 locations around the globe. She's responsible for overseeing the approval of new treatments from any of 105 regulatory agencies worldwide, maintaining those approvals in their markets, continuing to study and report on commercialized products and, in the process, mobilizing industry and governments around setting and sustaining ethical standards and guide-



Alison Lawton has shaped regulatory affairs at Genzyme for the past 14 years.

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lines.

Genzyme (Nasdaq: GENZ) develops and markets advanced technologies for rare inherited disorders, kidney disease, orthopedics, transplant and immune disease, cancer and diagnostic testing. The \$2.7 billion biotech employs more than 8,000 and distributes more than a dozen products globally. To date, none of its products have been rejected by the FDA.

Native to the U.K., Lawton transferred her pharmaceutical background to biotech when she moved here for her husband's job. After a summer off, she was ready to return to work, hoping to make a difference in patients' lives.

Early on, Lawton had pursued a University of London degree in pharmacology, interested in how drugs work. She worked at then Parke-Davis, now Pfizer, for eight years in its U.K. office seeking out approvals in Europe, the Middle East, Africa and other international regions for what she calls "me-too products."

The prospect of helping bring first-time therapeutics to patients was exciting, Lawton says. Genzyme had just received USFDA approval for its first therapy, Ceredase. Relieving or reversing the symptoms of Gaucher disease, it targeted a primarily Jewish population, so approval in Israel and Europe next was tantamount.

"It was a new technology approach to a disease that didn't have any therapy at all for these patients, and so that was a huge interest to me," Lawton says.

She was the third person to join Genzyme's regulatory affairs department, and the only one with international experience. Her immediate challenge was: "How do you do product development for these new breakthrough therapies more from a

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By applying a broader focus to testing, manufacturing, marketing and distributing right from the very first indications of promise in a new therapy has been Lawton's answer over the years. It's providing advice on what kind of pre-clinical studies to conduct, or how to manufacture to standard, or reporting new information, or bringing in the business side at the get-go – all in keeping with a specific authority's regulations and with an eye on common global compliance.

As Genzyme grew from one treatment to multiple products and platforms, Lawton was the one to drive and shape regulatory affairs around managing the complexity of global development and supply.

It's a responsibility of incredible magnitude. Take Myozyme, the first treatment for a degenerative muscle disorder that can be fatal in infants and adults alike. Its FDA and European application was 77,000 pages long and included years of data pertinent to efficacy and compliance. Approval in both regions was imminent at the time of the interview.

For Genzyme's first product, Lawton still oversees hundreds of submissions annually, whether updating manufacturing, reporting on safety, changing labeling or noting new therapy applications.

The work takes good technical and people skills internally and externally in order to build and maintain relationships that reflect integrity and respect. "Communication, negotiation and facilitation are all very important roles for our regulatory folks," Lawton says.

Having people placed around the globe, she points out, provides "the regulatory intelligence we need to make sure we're up to date and reacting efficiently in real time, that we're not missing something that we're required to do and understanding where we need to be proactive."

About five years ago, Lawton established corporate quality systems, the auditing group she leads to ensure compliance and quality country to country. Last year, she added global policy programs to her role to create, out of regional differences, a single

corporate philosophy and approach. This year, she is spending a good amount of her time looking at how to facilitate policy across the different business units in all the different countries.

Taking on global policy is nothing new for Lawton. She served two terms on FDA committees discussing the ethical questions new gene and cell technologies pose as well as reviewing specific products and therapies. She's currently active in industry organizations, serving on regulatory affairs committees and lending her expertise to policy issues.

Recently she chaired the board of the global Regulatory Affairs Profession Society, where she helped launch a professional code of conduct and the development of a competency model for the regulatory affairs professional ladder.

As part of her work at Genzyme, Lawton is an activist for orphan drug legislation and urging governments to provide incentives for developing therapies that target small populations. "We've actually been very influential in building from the U.S. to other regions an understanding of whether this is something they should be introducing," she says.

Going forward, Lawton believes that the industry and regulators must work together to think through the development paradigm for personalized medicine, the possibility presented by human genome breakthroughs. "Bringing those therapies to individual patients will be a very different approach to how we do drug development than how we approach it now," she says.

Continuing with gene therapy and its potential for a cure, renewing consumer confidence in the wake of drugs pulled off the shelf and figuring out how to make expensive therapies accessible to those in need are other areas Lawton sees as challenges for the near future.

Lawton herself has plenty of challenge to keep her going – which is just how she likes it.

Genzyme is currently conducting a late-stage clinical trial for Tolevamer, a product that will help fight a potentially fatal bacterial

infection common in hospitalized patients. Another product, Campath, is about to be taken into a pivotal trial for multiple sclerosis.

"We have so many exciting things in our development pipeline, and we have a responsibility to make sure we're effective in bringing those things through to the patients," Lawton says. "I know I will continue to get new opportunities and new growth as the company continues to expand, that I'll see other things that need to be done from a global perspective."

Work, Family, Humor

Alison Lawton considers herself living proof that women don't have to choose between career and family. "It's a really important point and a message to women that you can do both," she says.

Lawton has shaped the global perspective in regulatory affairs at Genzyme over the past 14 years. Her two boys are 11 and 13.

"So I've gone from 'without children' to going through the whole process of their growing up while expanding my career at Genzyme," she says.

What it particularly takes is setting strict guidelines on when to leave for the day, Lawton says.

"I know I could work at Genzyme 24 hours a day, seven days a week, because that's how I am. One thing I've learned, I will never get through the pile of things that I have to do, so I have to make sure I work on what's important and what's urgent. Things that aren't will get to that point, or they'll drop off because they never were important."

Don't think that Lawton's a drudge, however.

"Honestly, you have to have a sense of humor," she says. "If I didn't have that, I don't know how I would survive."