

INTENTLY FOCUSED

Demonstrating the power of combining scientific curiosity with product safety.

By David Schoonmaker

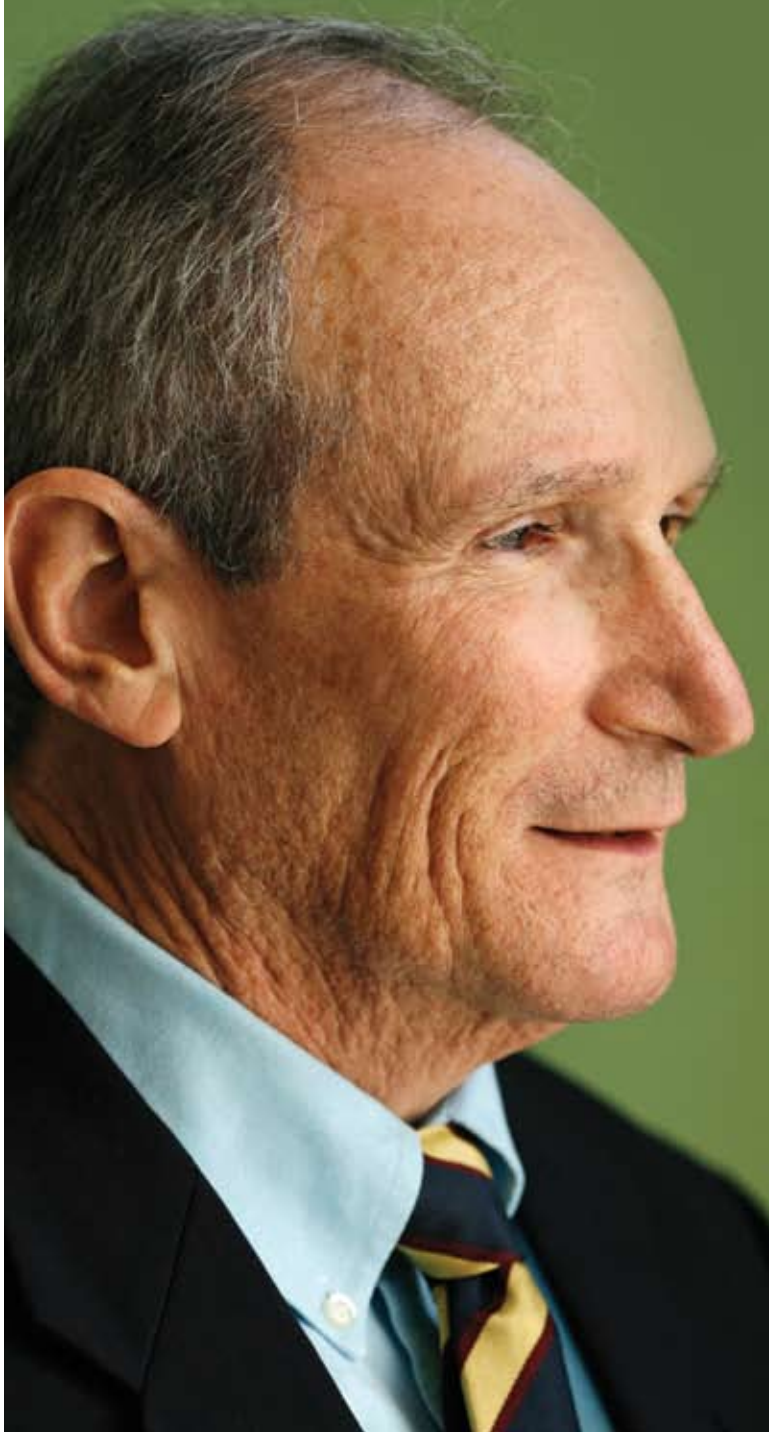
Stephen R. Petteway, Jr, regularly asks himself, “If I were a patient, what would I want to see in my products?” Unmet patient needs are his primary motivator, and he encourages the same attitude among the roughly 330 scientists, engineers, and technicians he directs at Talecris Biotherapeutics’ plant in Clayton, NC, as well as its research and testing laboratories in Raleigh and Research Triangle Park. With more than 25 years in the pharmaceutical business, the last 11 of them with Bayer and Talecris, he brings a wealth of knowledge and experience to developing protein therapies, and moving them out of the lab and safely into the clinic as quickly as possible.

Known in the scientific community for pioneering work on HIV and pathogen safety in blood plasma-based medicines, Petteway is the senior vice president of R&D at Talecris and has been chairperson of the Plasma Protein Therapies Association’s plasma-safety steering committee and industry representative for the transmissible spongiform encephalopathies (TSE) advisory committee of the Food & Drug Administration (FDA). He also served as an associate editor of the *Journal of Clinical Microbiology* from 1987 to 2000. Not surprisingly, he sees an intense, priority focus on product safety as the heart of his organizing philosophy.

DETAILS IN DEVELOPMENT

Because Talecris is vertically integrated, product safety spans a huge space in both distance and time: screening the donors at Talecris Plasma Collection Centers around the United States, testing samples of the collected blood plasma before the units leave the centers, cross checking when the plasma is stored, rigorous purity procedures during fractionation, clean-room sterility during packaging, and monitoring the patient community. It’s no coincidence that Talecris is the only plasma fractionator to perform in-house testing for hepatitis C, hepatitis B, and HIV using FDA-licensed protocols.

Petteway is responsible for four different research and development facilities. At the company’s Research Triangle Park laboratory, some research and a great deal of development take place. For example, scale models of the production equipment used in Clayton can test



processes for deactivation of viruses. Petteway and his team can then know, without question, that their procedures effectively remove, for example, H5N1 (bird flu) virus and prions, thought to be the source of TSE. About 85 workers test blood-plasma samples – 10,000 of them per day – at the Raleigh Testing Lab. Talecris also maintains a laboratory on the Centennial campus of North Carolina State University, which specializes in bioanalytics. In Clayton a team of scientists work hand in hand with operations to enhance process development, process technology, and process optimization.

While generally phrased R&D, Petteway openly says that he and his team “do a lot more D than R. Unlike many pharmaceutical companies, we don’t have a drug-discovery department. Instead, we look for partners who have expertise at developing new protein-based therapeutics but don’t have the capability to produce those medications and bring them to market. That’s where we excel.” He estimates that roughly only 15% of their work involves seeking new therapies; the rest goes to developing and improving processes for producing and delivering them.

One of the hallmarks of personnel management at Talecris is to encourage people to move laterally within the company. “We’re still small enough but just large enough that people can, if given the opportunity, learn how the entire operation works. By moving between departments, they can better understand the problems that others face.” Petteway encourages scientists

“cited” researcher by Thomson Scientific’s Institute for Scientific Information. Petteway also encourages his colleagues at Talecris to publish their research in peer-reviewed journals and to participate in scientific and patient-association conferences. He thrives on an intellectually stimulating environment and works to create that atmosphere among his coworkers.

Petteway became a Tarheel in 1993, when he became cofounder, vice president of R&D, chief scientific officer, and a board member of the Durham-based pharmaceutical company, Trimeris. He joined Bayer in 1995 as principal staff scientist and department head and became vice president of R&D in 2002. Over the years, he’s seen major changes in the Triangle. “Back in the 1990s, it wasn’t always easy to attract major talent from out of state. It wasn’t well known. Today, though, people recognize the rich intellectual environment and quality of life here, and welcome joining the community.”

But North Carolina itself has also proven to be a rich source of human capital for Talecris. “The University of North Carolina system produces some excellent folks. The satellites especially have fine biology and chemistry programs that have provided us with many skilled people,” Petteway says.

A key product being developed under his watch is Plasmin, a thrombolytic agent that is applied locally, offering the potential for less risk of unwanted bleeding than with systemic drugs. Using recombinant

“Petteway encourages scientists in research and development to cross into the plant to see their innovations brought to fruition.”

in research and development to cross into the plant to see their innovations brought to fruition. Likewise, he seeks opportunities for his coworkers to meet with patients whenever possible. “People come to Talecris for more than a paycheck. They are committed to a larger mission, and knowing the people who benefit from their work is very motivating.”

CAROLINA ATTRACTIONS

Petteway earned his PhD in molecular biology from the University of Alabama at Birmingham Medical Center, and he maintains a link to academia through an adjunct professorship at Duke University Medical Center in Durham. He has been an author on more than 120 publications, earning him the rank of “highly

techniques, Talecris developed rPlasmin, which was licensed by Bausch & Lomb in August 2006. The company has an exclusive worldwide license for the development of ocular products based on this Talecris innovation. Recombinant techniques are particularly attractive for companies developing blood plasma-based therapies, because the industry is growing at a rate of about eight percent per year, and the supply of plasma to fuel this growth is limited.

Talecris would welcome more innovations in recombinant production of protein-based medications. Yet, Petteway maintains his focus on the company’s core strength: bringing blood-plasma therapeutics to the marketplace quickly, efficiently, and with a constant and intense focus on safety. ■