

Assessing what happens in the real world, Epidemiologists provide compass for pharmaceutical research



Dr. Alice White

BEFORE PHARMACEUTICAL COMPANIES DECIDE WHERE TO FOCUS RESEARCH, THEY WANT TO KNOW WHAT THE UNMET NEEDS ARE. THEY WANT TO KNOW ABOUT THE DISEASES — AND THE PATIENTS — THEY HOPE TO TREAT.

That's where pharmaceutical epidemiologists like Dr. Alice White come in. White, who has a doctorate in epidemiology from Carolina's School of Public Health, is vice president of Worldwide Epidemiology at GlaxoSmithKline (GSK). She leads a team of about 70 GSK epidemiologists and data analysts in North Carolina, Pennsylvania, London, Brazil, Japan and Singapore.

"My department is about diseases, not drugs," she says. "We help the company and industry understand diseases at the population level. When they're making decisions about drug discovery and development, they need to know who the patients are and how the disease is affecting them."

She didn't start off planning to be a scholar with global executive responsibilities. In fact, White left college and moved with her husband to Pinehurst, N.C., to raise horses. But by 1977, she found herself a single mother working as a secretary. She was challenged

financially but not intellectually. Determined to improve her situation, she applied to UNC and moved to Carrboro to complete work on her bachelor's degree in psychology. Later, she enrolled in the School of Public Health to study epidemiology and became an assistant professor after graduation.

In 1990, she joined Burroughs Wellcome (now GSK), focusing on the epidemiology of HIV infection.

Today, White and other GSK epidemiologists assess the spread and characteristics of obesity, Type II diabetes, cancers and psychiatric diseases around the world, as well as autoimmune diseases like rheumatoid arthritis and lupus.

"We start there, studying the disease in the real world," she says, "but epidemiologists are now involved in so many levels of the process."

Once, the primary role of pharmaceutical epidemiologists was to assess how medicines were being used after they were out in the market, she says.

Clinical trials measure use in a very controlled population, but once medicines are available in the "real world," epidemiologists

track how they are used, by whom and with what results, she explains. "Epidemiologists apply methods to the data available and look at the *risks* associated with use of the drug," she adds. "It goes deeper and broader than what you learn just from spontaneous (side effect) reports."

This role is still critical, but the role of epidemiologists is expanding, she says. While GSK and most other major pharmaceutical companies are downsizing, her department has expanded from 20 people in 2000 to 75 now.

"The biggest challenge we're facing today," she says, "is the appropriate use of patient data. So much is available now, with electronic medical records and other computer-based ways of collecting data. But we have to look at quality control and standardized approaches to make sense of the data — to make it really meaningful."

White was instrumental in GSK's \$3 million gift to the School of Public Health in 2003 to establish the UNC-GSK Center for Excellence in Pharmacoepidemiology and Public Health (see page 60).

"The key is understanding diseases," she says. "Epidemiology is about populations — about public health — much more than just about medicines. It's a foundation GSK recognizes is critical to the process." ■

— BY RAMONA DUBOSE

Dr. Alice White is vice president of Worldwide Epidemiology at GlaxoSmithKline. She holds a doctorate in epidemiology from Carolina.