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

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. “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 real world, “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.”

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.

As the world becomes more of a global community, it’s the relationship building that we do in our work that will enable the countries to form teams in responding to a major pandemic.

It doesn’t hurt that Cáceres knows Central America well; his parents emigrated from Honduras two months before he was born. He visited there often as a child and still has extended family there.

Cáceres also knows what it’s like for epidemiologists learning to work in the field. From 1995 to 1997, he served as a member of the CDC’s Epidemic Intelligence Service, on which the FETP is modeled. Cáceres was part of a group that traced a South Carolina public health outbreak of Cyclospora (a pathogen that causes diarrheal illness) to raspberries imported from Guatemala. He ended up traveling to Guatemala to find the source of the outbreak and talking with farmers who were understandably skeptical.

In addition, over several years, Cáceres applied his team-building approach to eradicating polio. “He has contributed greatly to polio eradication by taking leadership in the research area,” says Roland Sutter, director of research and product development for polio eradication at the World Health Organization. Sutter points to Cáceres’ perseverance and diplomacy in implementing a study of inactivated polio vaccine (IPV) in Cuba.

Unlike other developing countries, Cuba has eradicated polio and doesn’t routinely give the oral vaccine, which is made of an attenuated live virus. That made Cuba a perfect testing ground to find out if the alternative, IPV, will really be effective once polio is eradicated and the oral vaccine phased out. “We were able to show the IPV worked in the polio-free environment,” Cáceres says. The Cuba IPV study was published in 2007 in the New England Journal of Medicine.

For Cáceres, the partnerships he forms in every aspect of his work aren’t just about whomever is in charge, and continually builds bridges between the CDC, the FETP offices in each country, and the ministries of health in Central America.

Cáceres brings his ability to see issues from many different perspectives to his job. “There’s no doubt that the CDC is a leader in epidemiology and public health, but we also have a lot to learn from the other countries,” Cáceres says. “There’s a lot of give-and-take and back-and-forth, constant interaction and problem-solving.”

As the world becomes more of a global community, it’s the relationship building that we do in our work that will enable the countries to form teams in responding to a major pandemic.

Dr. Victor Cáceres gives an oral polio vaccine to a young girl in the Dominican Republic as part of a response to an outbreak of polio in that country in 2000.

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

Dr. Augusto Lopez, a medical epidemiologist and regional advisor in FETP who has worked with Cáceres for about three years, says the six countries in which FETP operates often experience changes in government leadership. Through it all, Lopez says that Cáceres maintains a clear vision that he conveys to