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Landmark drug study set to begin

By SARAH AVERY; STAFF WRITER

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Dr. Jeffrey Lieberman

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CHAPEL HILL -- Dr. Jeffrey Lieberman was in his element Friday morning.

Sitting at the center of the speaker's table, facing a crowd of fellow mental health professionals that he had worked to assemble from 80 sites in 32 states, Lieberman had before him an audacious task.

Four hundred people were there to learn what he and his team at the University of North Carolina at Chapel Hill had designed as the methods for conducting the largest clinical trial ever attempted in the mental health field.

It will cost \$42 million, and it will require the enlistment of 1,500 schizophrenia patients and 500 sufferers of Alzheimer's disease from across the country to help answer a critical question: Are new anti-psychotic drugs better than the old ones?

"This is the biggest thing anybody's ever done in psychiatric treatment," said Lieberman, professor of psychiatry, pharmacology and radiology. "This is a tremendous opportunity."

The university last year won the contract to conduct the trial, which is sponsored by the National Institute of Mental Health. UNC's team is led by Lieberman and Dr. C.E. Davis, chairman of biostatistics at the university's School of Public Health.

Since the grant was awarded, the group has been recruiting research sites and developing the methodology for the study. After this weekend's training session at the Sheraton, some of the sites will be able to begin enlisting schizophrenia patients as early as next month, and Alzheimer's patients in January.

Six sites in North Carolina are participating, including UNC and Duke University, Dorothea Dix Hospital in Raleigh, John Umstead Hospital in Butner, Carolina Health Systems in Charlotte and Wake Forest University in Winston-Salem.

Barry Lebowitz, chief of the adult and geriatric treatment branch with the National Institute of Health, said the scope of the trial is necessary because the questions of treatment are so critical - not only to patients, but to

health policy makers as well.

"We want patients, their families, their doctors and the policy makers and planners to have the most up-to-date information on what the comparative value of these medications are," he said.

Currently, the new anti-psychotic drugs represent 60 percent of prescriptions. But they are 10 to 15 times more expensive than the old drugs, and some insurers require that the old medications be proven ineffective before they'll pay for the new ones.

The study will clarify the issue. If the new drugs are found to be better, more people will get treated sooner. If the drugs are found to be of little benefit, they won't be prescribed, and the health system will be spared the costs.

For Lieberman, the trial will benefit patients, one way or another.

"It is really a heart-rendering, tragic experience to spend any time in a mental hospital and be around people who are shells of their former selves," Lieberman said.

Lieberman, who came to UNC five years ago from the Albert Einstein College of Medicine in New York, said he entered the field of psychiatry in the early 1970s, when anti-psychotic drugs were just starting to be used.

The early drugs, such as Haldol and Thorazine, represented revolutions in the treatment of psychosis, because, for the first time, they quieted hallucinations and delusions. But they also tended to induce nausea, dry mouth, shakiness, spasms and seizures, among other things. Those side effects prompted many users to quit taking the medicine, so that the hallucinations and delusions inevitably returned.

Throughout the early 1990s, drug companies unveiled several new anti-psychotic drugs that not only appeared to treat the delusional aspects of schizophrenia and Alzheimer's but also some degree of the social withdrawal, memory loss and mood swings.

Lieberman said he thinks the new medicines offer promise, and he is encouraged by the anecdotal evidence in patients he has treated. But, he said, the trial he is leading will offer a definitive comparison.

"We will have the answer," he said.

Caption:
photo

Dr. Jeffrey Lieberman of the University of North Carolina at Chapel Hill fields questions during a training session for a massive \$42 million trial of new anti-psychotic drugs.

Staff photo by John Rottet

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