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NIH Contract Is Set to Study Antipsychotics

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Abstract:

A pair of researchers from the University of North Carolina at Chapel Hill will investigate the effectiveness of a new class of antipsychotic drugs under one of the largest National Institutes of Health awards ever made.

The \$42.1 million contract, spread over five years, is expected to be announced today by the National Institute of Mental Health, a unit of the NIH, the nation's premiere medical-research agency. The contract is the largest ever awarded by the unit and ranks among the largest ever awarded by the entire NIH, according to university and agency officials.

The research, which will be conducted at 50 clinical sites around the country, is designed to test the effectiveness and safety of a relatively new class of antipsychotic drugs referred to as atypicals. The drugs are on the market -- including Novartis AG's Clozaril, Johnson & Johnson's Risperdal, Eli Lilly & Co.'s Zyprexa and AstraZeneca PLC's Seroquel -- and have turned into major sellers.

Full Text:

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WASHINGTON -- A pair of researchers from the University of North Carolina at Chapel Hill will investigate the effectiveness of a new class of antipsychotic drugs under one of the largest National Institutes of Health awards ever made.

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The federal research agency is stepping in where drug-company-sponsored studies often leave off: examining the comparative, economic and quality-of-life effects of the drugs to help doctors make better prescribing choices.

Steven Hyman, director of the mental-health institute, said the study on antipsychotics is one of a handful his agency is funding to test the long-term effectiveness of drugs already on the market -- and thus add to the scientific knowledge usually supplied by drug makers themselves. Another major NIH contract on antidepressants is expected to be awarded during the next few weeks, he said.

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effectiveness and safety of a relatively new class of antipsychotic drugs referred to as atypicals. The drugs are on the market -- including Novartis AG's Clozaril, Johnson & Johnson's Risperdal, Eli Lilly & Co.'s Zyprexa and AstraZeneca PLC's Seroquel -- and have turned into major sellers.

The drugs -- chemically known as clozapine, risperidone, olanzapine and quetiapine -- differ from older drugs because they act on multiple cell-receptor sites in the brain, rather than one. They also aren't burdened by what researchers say is the "incredibly high side-effects rate" in the older drugs, which caused potentially serious neurological effects in a large percentage of patients who took them.

Even so, the new drugs cost much more than previous generations of antipsychotics: more than 10 times as much, according to the North Carolina researchers. The drugs are used in the treatment of people with schizophrenia and those with psychotic and disruptive behaviors associated with Alzheimer's disease.

"These drugs appear to be more effective and much safer than the older drugs, but the question is, 'Does this justify the increased cost?' " asked Jeffrey A. Lieberman, a professor of psychiatry, pharmacology and radiology at the University of North Carolina at Chapel Hill School of Medicine. He and C.E. Davis, a professor of biostatistics at the university's School of Public Health, are the project's principal investigators.

Several other universities will participate in the study, which will enroll 1,000 patients with schizophrenia and as many as 500 Alzheimer's patients.

While the drugs appear to be more effective than earlier generations of antipsychotic drugs, that effectiveness is far from universal. In addition, the new class of drugs can bring some significant side effects, such as the potential for large weight gain, lethargy and constipation.

While the drugs' safety and efficacy was tested in order to win federal approval, the new research will seek to build on that base of knowledge and explore how the drugs affect patients' quality of life and ability to work.

Credit: Staff Reporter of The Wall Street Journal

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