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Romanian Drug GH3 Being Tested at Duke

For the past 20 years, thousands of elderly patients from Europe, Asia, Africa and the United States have flocked to clinics in Bucharest and Constanza, a resort city on the Black Sea, to receive treatments with a controversial Romanian "youth drug" — Gerovital H3.

Now researchers at Duke are conducting one of the first double-blind clinical trials of Gerovital (GH3) in the United States to determine whether it is effective in treating mental depression among the aged.

The study is designed specifically to test the drug for mild to moderate depression, even though Romanian scientists have claimed that it can overcome the effects of everything from arthritis and angina pectoris to senility.

The principal investigator on the project is Dr. William W. K. Zung, professor of psychiatry, who is widely known for his research on depression.

Last June Zung visited Professor Ana Aslan, director of the Geriatrics Institute in Bucharest and developer of GH3 therapy, to see how the drug is used there.

Dr. Aslan sparked a stir throughout the world in 1956 when she reported in a German medical journal on the phenomenal improvement in the psychic, physiological and social functioning of 189 elderly patients who had undergone GH3 therapy during a 10-year period.

Other investigators throughout the world have tried to duplicate her findings, but the results have been equivocal, and the therapy has come under sharp criticism.

Car Pool Stations Established Here

To assist people in working out car pooling arrangements more easily, four car pool sub-stations will be operated during the coming week at various spots throughout the campus.

At the medical center, the location will be in the first-floor corridor outside the Personnel Office (Yellow Zone). That's the same location where a Durham County map, dividing the county into car pool zones, has been mounted.

A representative from the Parking and Traffic Office will man a desk there next Monday-Friday (Feb. 18-22) from 8 a.m.-5 p.m.

Car Pool Information Forms were distributed last week by payroll clerks. Copies also are available at the Personnel Office, at the medical center's Parking and Traffic Office in 350 Bell Building and at the main campus Traffic Office at 2010 Campus Drive.

Those forms are to be completed by anyone interested in car pooling, and mailed to the 2010 Campus Drive office.

Copies of all completed forms will be distributed to the car pool sub-stations for use next week in helping people match up for rides.

One of Dr. Aslan's replies to this criticism has been that other researchers have not used the Romanian product GH3 but have substituted some other form of procaine or Novocain.

The study now being conducted at Duke uses the Romanian drug GH3 supplied by Rom-Amer Pharmaceuticals, Ltd. The Food and Drug Administration last May authorized Rom-Amer to conduct clinical trials of the drug in the U.S. under an Investigational New Drug application.

In the Duke study, patients receive either GH3, or a known antidepressant called imipramine or a supportive medication. The study is designed so that at some time during his two-month participation, each patient will have received a full course on GH3.

This is a double-blind study, which means neither the doctor nor the patient knows until it is all over what drug the patient is taking during which part of the study. Zung said some patients have already entered the study, and he plans to eventually include at least 60 patients.

Zung said no drug has ever before been thoroughly and specifically tested for depression in elderly patients. Antidepressants such as imipramine have been tested in other age groups and found effective, but they cause side effects such as dizziness and hypotension (low blood pressure) which can be especially dangerous in the elderly.

One of the benefits claimed for GH3 is that it has almost no known side effects, Zung said.

Investigators claim that the scientific rationale for the reported benefits of GH3 therapy is that the drug is an effective monamine oxidase (MAO) inhibitor. MAO is an enzyme which is widely distributed in the body, especially in the central nervous system.

Various studies have related high levels of this enzyme to depression and other psychiatric disorders. Other researchers have reported a direct correlation between aging and increased MAO activity.

It has been speculated that the lack of side effects is due to the fact that GH3 is a reversible MAO inhibitor, while most antidepressants such as imipramine are irreversible.

Zung said patients taking part in the study are 60 years of age and over and have clinical diagnoses of mild or moderate depression. Four Duke psychiatrists are serving as the clinical team for the project — Dr. Daniel T. Gianturco, Dr. Eric Pfeiffer, Dr. H. Shan Wang and Dr. Alan D. Whanger.

These four psychiatrists are responsible for the primary care of the patients during the study. An evaluation team made up of Dr. Steven Potkin, Dr. Peter Bridge and JoAnn Perry is responsible for testing the patients before, during and after the study using a battery of rating scales and inventories to determine any changes in the patients' conditions.



ROMANIAN RESEARCHER—Duke psychiatrist Dr. William W. K. Zung is shown with Dr. Ana Aslan during a visit to her Geriatrics Institute in Bucharest last summer. Dr. Aslan, developer of Gerovital H3, spoke here yesterday at Department of Psychiatry Grand Rounds. Zung is conducting clinical trials on the effectiveness of her drug in treating mental depression in the aged.

Personnel Paragraphs

Questions from readers are encouraged. If you have a question, send it to:

*Personnel Paragraphs
Box 3017*

All inquiries must be signed, but you may request that your name not be used if your letter is published. All questions will be answered or referred to an appropriate source, but only questions of wide, general interest will be published. "Personnel Paragraphs" is your column, so let us hear from you.

BENEFITS

The Personnel Policy Manual for Bi-Weekly Employees lists 19 benefits. They are: Holidays, Vacation, Sick Leave, Jury Duty, Voting Time, Funeral Leave, Military Leave, Retirement, Maternity Leave, Hospital Insurance, Life Insurance, Long Term Disability, Unemployment Compensation, Workmen's Compensation, Social Security, Continuous Service Credit, Educational Assistance, Survivor's Benefits, and Travel Accident Insurance.

"Personnel Paragraphs" will discuss each of these benefits in future articles and encourages readers to write in any questions they may have about them.

HOSPITAL INSURANCE

Permanent employees who regularly work 20 or more hours per week are eligible to participate in the Blue Cross-Blue Shield Group Plan. The university pays a portion of the premium for employees who regularly work 30 or more hours. There are three coverage plans: Individual, Parent and Child, and

Family. Maternity benefits are provided only under the Family Plan. Descriptive literature and information on rates is available at the Personnel Office.

Employees may enroll in the Hospital Insurance Plan at anytime, but employees who do not enroll within 31 days of their employment date will be subject to a 24-month waiting period on pre-existing conditions.

The plan would then cover illness or injury which occurs after the effective date of coverage, but would not cover treatment of conditions which existed prior to sign-up.

The final determination of pre-existing conditions lies with a panel of physicians who advise Blue Cross-Blue Shield on these matters. Employees who sign up for insurance within 31 days of employment date or eligibility date are not subject to this waiting period. There is, however, a 270-day waiting period for maternity benefits on all enrollments.

NEW BLUE CROSS-BLUE SHIELD BENEFIT

Unmarried dependent children are removed from certificate of coverage upon reaching age 19, according to the Group Plan with Parent and Child or Family coverage. Blue Cross has issued a new endorsement which provides that mentally retarded and physically handicapped children may now be continued on the certificate of coverage beyond age 19.

Employees with dependent coverage will receive materials explaining the new benefit and a form to apply for coverage. The monthly premium will not change.