

ACCELERATING SCIENCE — ADVANCING MEDICINE

In January 2011, The U.S. Food and Drug Administration (FDA) held a meeting of the Neurological Devices Advisory Panel to decide how to classify Electroconvulsive Therapy (ECT) devices, a decision that could determine the future of ECT in the United States.

The open public presentations and deliberations among the panel members revealed sharp differences of opinion about both the effectiveness and safety of ECT. Although ECT has long been controversial, refinements in the procedure that have enhanced safety (e.g., muscle relaxants and anesthesia, both introduced by the mid-1950s) seemed to put terrifying and inaccurate Hollywood depictions of ECT behind us. To most psychiatrists, who embrace ECT as the gold standard for treating severe depression (and other serious disorders), doubts about a favorable risk-benefit ratio has come as a surprise. Not because of the mixed public reception (which is not surprising), rather because our colleagues in neurology, neuropsychology, biostatistics, and in the FDA itself are expressing reservations about the safety and effectiveness of ECT as currently practiced.

As a member of that FDA panel, I had a front-row seat to the debate. Although no formal vote was taken, more than half the members recommended that ECT devices remain in Class III, the highest risk category. If FDA follows this recommendation, then ECT devices may require premarket approval (PMA) applications in the same fashion as devices first requesting to be marketed. The FDA could require a large, randomized clinical trial with a sham control for each indication for use. It is feared that the cost of such trials could prove prohibitive to the two small companies that manufacture ECT devices. There are additional concerns about whether a sham-controlled study would be ethical or feasible in conditions such as severe depression where risk of suicide is high. If the manufacturers do not submit an acceptable application within 30 months of the issuance of the PMA requirements, the devices could be pulled from the market.



Wayne K. Goodman, Chair of the Department of Psychiatry and the Esther and Joseph Klingenstein Professor of Psychiatry at The Mount Sinai Medical Center

If this happens, thousands of patients with severe psychiatric disorders will be denied ECT without any new, more suitable treatments in its place. Let us hope that a more workable solution is found.

W. K. Goodman, "Electroconvulsive therapy in the spotlight." *The New England Journal of Medicine* 2011; May 12; 364(19):1785-7.

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RESEARCH FRONTIERS

Understanding Performance-Enhancing Drugs



Thomas Hildebrandt, PhD

Mount Sinai's Appearance and Performance-Enhancing Drug (APED) Program, created by Thomas Hildebrandt, PhD, Assistant Professor of Psychiatry, is a specialized research program that aims to understand the clinical science of such drugs, and the benefits and consequences of their use. To date, little is known about the psychiatric effects of APEDs.

APEDs are legal and illegal drugs such as anabolic-androgenic steroids, thyroid hormones, and stimulants. Typically, these drugs are used to improve an individual's outward appearance by increasing lean muscle mass or reducing body fat. Recently, Dr. Hildebrandt and his

colleagues developed and validated the first assessment tool for people who take APEDs, and they are close to completing the first longitudinal study of APED use.

"There remains a great deal of variability in psychiatric responses to APEDs," explains Dr. Hildebrandt. "We are on the cutting edge of being able to discern what it is about APEDs, and the people who use them, that increases the risk of developing psychiatric disturbances such as aggression, impulsivity, or body image problems such as muscle dysmorphia."

One of the goals of the program is to identify what causes such varied responses. Preliminary results show that steroid metabolism may increase the risk for aggression among some anabolic steroid users. The conversion of certain synthetic androgens into estrogens may explain why some men become more aggressive when using steroids.

■ EDUCATION

Residency Education for Specialized Care

Mount Sinai's Department of Psychiatry has many excellent educational programs. They include a core, four-year residency program—the largest



Ronald Rieder, MD

in the country with 53 residents; accredited post-residency training in many psychiatric subspecialties, such as Child and Adolescent Psychiatry, Geriatric Psychiatry, and Addiction Psychiatry; a first-of-its-kind fellowship in Hospitalist Psychiatry; and post-residency research fellowships. The department is also involved in many areas of the Mount Sinai medical student curriculum, including teaching both pre-clinical neurobiology and clinical psychiatry.

In his approach to education, Ronald Rieder, MD, Professor of Psychiatry, Vice Chair for Education in the Department of Psychiatry, and Director of Residency Education, has been guided by the department's increasing focus on the Centers of Excellence that provide specialized care for a broad range of psychiatric disorders.

"Mount Sinai serves as the referral hospital for patients with complex and difficult-to-treat psychiatric illnesses throughout the New York

metropolitan area, and beyond. Our specialists are developing a new understanding and administering new treatments for major conditions including Depressive Disorders, Obsessive Compulsive Disorder (OCD), Attention Deficit Hyperactivity Disorder, Autism, and Alzheimer's disease," says Dr. Rieder. "We encourage students in our residency program to think about the kinds of patients they find most compelling, and in what they would like to specialize."

Residents in psychiatry have time to develop an expertise in the diagnosis and treatment of a specific area of psychiatric illness under expert supervision. For example, in Mount Sinai's OCD Center of Excellence, Wayne K. Goodman, MD, Professor and Chair of the Department of Psychiatry, combines biologic treatments including various medications and Deep Brain Stimulation, with psychotherapeutic treatments such as Cognitive Behavioral Therapy.

■ CLINICAL PROGRAMS

Researching the High Suicide Risk in Veterans

These are startling statistics: Every day, 18 veterans commit suicide, and nearly 20 percent of all suicides in the United States are veterans. At Mount Sinai, Marianne Goodman, MD, Associate Professor of Psychiatry, and Antonia S. New, MD, Associate Professor of Psychiatry—two leading experts in borderline personality disorder—are conducting cutting-edge research to address this pressing issue in young servicemen and servicewomen returning from Iraq and Afghanistan.

As part of the James J. Peters Veterans Affairs (JJPVA) Suicide Research Program, Drs. Marianne Goodman and Antonia New are studying the high rate of suicidal behavior in young veterans. They are exploring several factors such as exposure to combat, difficulties with social relationships, and other underlying vulnerabilities that might make them susceptible to emotional difficulties when they return from service.

Both doctors are also testing new psychotherapeutic treatments that may help prevent suicide. Building on Mount Sinai's award-winning JJPVA Clinical Dialectical Behavioral Therapy (DBT) Program, directed by Wayne K. Goodman, MD, Professor and Chair of Psychiatry, the researchers are investigating the efficacy of DBT in veterans at high risk for suicide. DBT is a form of psychotherapy that has been shown to reduce suicidal behavior in borderline personality disorder, but it has not been studied yet

in veterans. Recently, Drs. Marianne Goodman and Antonia New set up the first randomized clinical trial in veterans, which is being funded by the U.S. Department of Defense.

The JJPVA Suicide Research Program is also involved in developing new forms of psychotherapy that may be used more broadly throughout the Veterans Administration health system to help suicidal veterans. Drs. Marianne Goodman and Antonia New are working with Erin Hazlett, PhD, Associate Professor of Psychiatry, to explore potential genetic and physiological biomarkers and cognitive measures for vulnerability to suicidal behavior and responsiveness to treatment.



Marianne Goodman, MD



Antonia S. New, MD