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Seven Emmes Employees Recognized in Lancet Study Comparing Two Opioid Treatments

NIDA-Funded Study is the Largest of its Kind

Rockville, MD – December 20, 2017 – The Emmes Corporation today announced its participation in a three-year study testing the results of two different opioid treatment medications. The <u>research</u>, published in one of the world's oldest and best known medical journals, concluded that for those able to begin treatment, both drugs are nearly equal in their safety and effectiveness. The National Institute on Drug Abuse (NIDA) funded the research.

In addition to providing data management and statistical support, Emmes served as the clinical coordinating center. This involved protocol development, pharmacovigilance, quality assurance, safety monitoring and regulatory support. The clinical trial occurred between 2014 to 2017 at eight community treatment programs across the U.S. A total of 570 patients participated, with each group followed for a 24-week period.

This is the first U.S. study providing comparative data on the two opioid treatment medications. A similar study, conducted in Norway, included far fewer patients who were required to complete detoxification and occurred over a shorter time period.

"Opioid addiction has emerged as one of the most critical public health issues," said Dr. Anne Lindblad, Emmes president and chief executive officer. "The U.S. needs to continue to invest in education and prevention – to try to reduce opioid addiction in the first place. This and other studies being conducted now by our team at Emmes address a related concern: how to treat

people already addicted and reduce the chances of relapse."

The opioid study, characterized by the New York Times as "long awaited," compared the most commonly prescribed opioid treatment medication, buprenorphine-naloxone (known as Suboxone) with extended-release naltrexone (known as Vivitrol). Suboxone is a partial agonist, which still activates opioid receptors, but less strongly, so that cravings and withdrawal symptoms are reduced. Vivitrol is an antagonist, which blocks the activation of opioid receptors and thus the feeling of euphoria. Patients who take Vivitrol must totally detoxify before starting treatment. The study found that Vivitrol patients who are able to overcome this "detox hurdle" have similar results to those taking Suboxone. The study considered factors such as cravings, adverse effects and relapse rates.

"The detox hurdle and other differences in characteristics and clinical management of the two treatments posed some challenges during the study design phase," noted Dr. Jeanine May, one of the Emmes co-authors. "However, the study's lead investigators valued and trusted each member's expertise, and this helped ensure a well-designed and executed trial. John Rotrosen, the lead investigator, deserves credit for his collaborative leadership."

Dr. Rotrosen, professor in the Department of Psychiatry at NYU School of Medicine, served as the senior author of the Lancet article. He was joined by Joshua D. Lee, MD, MSc, associate professor in the Departments of Medicine and Population Health at NYU School of Medicine, who was lead author. The team members cited in The Lancet article included a number of physicians and researchers at medical centers and treatment facilities across the U.S.

Seven Emmes employees were listed as co-authors: Jacquie King, MS; Robert Lindblad, MD; Abigail G Matthews, PhD; Jeanine May, PhD; Dagmar Salazar, MS; Dikla Shmueli-Blumberg, PhD; and Don Stablein, PhD.

About Emmes

We collaborate with our clients to produce valued, trusted scientific research. Our team members at Emmes are passionate about making a difference in the quality of human health, and we have supported more than a thousand studies across a diverse range of diseases since our formation in 1977. Our research is contributing to a healthier world. For more information, visit the Emmes website at www.emmes.com.