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Emory Announces Actions Following Investigation

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Emory University issued the following news release:

Emory University has conducted an investigation into allegations of **conflicts of interest** involving Dr. **Charles Nemeroff**, the long-time chair of the Department of Psychiatry and Behavioral Sciences at the Emory University School of Medicine. Based on the results of that investigation, Dr. Nemeroff has agreed to step down from the departmental leadership post he held for 17 years and to follow new restrictions on his outside activities.

Additionally, Emory will not submit any NIH or other sponsored grant or contract requests in which he is listed as an investigator or has any other role for a period of at least two years. He will remain in the Department as a professor and will focus on clinical care, teaching and other academic pursuits.

Senator Charles Grassley (R-Iowa) alleged earlier this year that Dr. Nemeroff had been paid substantial sums over seven years in outside income by pharmaceutical companies without reporting it to Emory as required by NIH and Emory University conflict of interest (COI) regulations and policies, and that some of these payments were provided primarily to deliver talks promoting the sales of particular drugs.

An internal investigation conducted by Emory has focused on payments from GlaxoSmithKline (GSK), because it was the largest single payer to Dr. Nemeroff, and it cooperated with Emory in making a complete set of records available for Emory's independent examination. The Emory investigation showed that Dr. Nemeroff received more than \$800,000 in income from GSK for presentations that he did not report to Emory. This represented payments for more than 250 speaking engagements in the period between January 2000 and January 2006.

Though Dr. Nemeroff viewed these talks as educational lectures not subject to disclosure, Emory policies required otherwise. The investigation determined that Dr. Nemeroff should have abided by the policies and/or sought clarification if, as he later stated, he believed the policies and regulations were ambiguous.

Following the investigation, the University and Dr. Nemeroff have additionally agreed that he will seek review and approval by the dean's office of any and all outside compensated engagements before he accepts them, and will report any and all outside compensation. He will be limited to accepting payment for ACCME-accredited speaking engagements sponsored by academic institutions or professional societies.

The University's investigation, to date, has found no evidence that Dr. Nemeroff's outside speaking activities affected clinical care for patients or persons enrolled in clinical trials, and no evidence that his activities biased scientific research in which he was engaged. Dr. Nemeroff has contended that his lectures were not product-specific but were limited to general medical topics such as depression and bipolar disorder. A review to date, based on his speaker slides and on interviews with attendees at presentations, supports that

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contention.

An internationally recognized leader in psychiatric research, education and clinical practice, Dr. Nemeroff has made fundamental contributions to the understanding and treatment of depression and other mood and anxiety disorders over many years. Since his recruitment to Emory, he is credited with building a department that is one of the most distinguished in the nation.

While recognizing Dr. Nemeroff's contributions, School of Medicine Dean Thomas J. Lawley stated, "As a Department Chair, particularly one who had been under heightened scrutiny, Dr. Nemeroff should have reported the payments from GSK and other companies, and the fact that he did not has resulted in these actions being taken." Dean Lawley continued, "We hold our Department Chairs to high standards at Emory because they are institutional representatives as well as professional role models for other faculty and students."

Dr. Nemeroff said he had long believed that all outside speaking activities, even those sponsored by for-profit companies such as GSK, were exempted from the University's COI disclosure requirements under provisions that apply to educational lectures and seminars. "I regret the failure of full disclosure on my part that has led to the current situation," he said. "I believe that I was acting in good faith to comply with the rules as I understood them to be in effect at the time. I pledge to continue my cooperation in working with Emory to clarify and strengthen our current system of disclosure here and throughout academic medicine."

Dr. Fred Sanfilippo, Emory's Executive Vice President for Health Affairs, noted that "universities traditionally depend on the integrity and voluntary cooperation of our faculty to meet the public trust to which we all strive."

"To strengthen this approach, we strongly support the public reporting by pharmaceutical and medical device companies of all payments to academic physicians and researchers," he said. "With access to a common set of data, medical schools, lawmakers, and most importantly the general public will have the transparency needed to ensure objectivity and accountability in biomedical research, clinical practice, and educational activities."

In October, Emory created a new University-wide central office to oversee administration and enforcement of conflict of interest (COI) policies for sponsored research. In November, President James W. Wagner appointed an advisory commission to review Emory's management of potential conflicts of interest by faculty and staff members engaged in research and other professional activities. Paul Root Wolpe, director of Emory's Center for Ethics and a nationally recognized authority on biomedical research ethics, is chairing the commission.

See <http://www.emory.edu/home/news/special/conflict-of-interest-research.html> for all previous University statements and announcements.

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