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For Immediate Release:

October 25, 2005

Release No. 05-62

APA Tells FDA of Need for Separate Acute and Maintenance Medication Treatment Studies

Arlington, Va. – In testimony to the U.S. Food and Drug Administration (FDA) today, the American Psychiatric Association (APA) addressed “correctable shortcomings” in the current drug approval and post-marketing monitoring process, while cautioning against collapsing requirements for separate acute and maintenance studies into a single phase-III process.

APA Research Director Darrel A. Regier, M.D., M.P.H., who testified on behalf of APA, told the FDA’s Psychopharmacologic Drugs Advisory Committee of the APA’s concerns regarding inadequate post-market monitoring. He also stressed the need for National Institute of Mental Health (NIMH)-supported long-term studies of the effectiveness of treatments that involve patients seen in routine clinical practice settings.

He told the FDA panel that the most important improvements are those that would directly aid physicians and patients:

- A comprehensive registry for all clinical trials conducted in the United States – a registry that should be set up by the federal government and be free and open to the public.
- Studies that have appropriate endpoint measures so as to ensure a meaningful systematic assessment of the drug in question.
- An improved adverse events reporting system.
- Long-term studies of medications, a portion of which could be facilitated by “partnerships with large managed health care plans that maintain extensive databases on prescribing patterns and patient outcomes.”
- And more NIMH-supported, head-to-head comparisons of medications and psychosocial interventions to help identify the effectiveness of the available treatments.

“As we work together to examine additional solutions that I have suggested here, we must be aware that failure to understand the most appropriate, cost-effective, and clinically useful roles of the FDA, the NIH [National Institutes of Health], the pharmaceutical industry, patient groups, and clinicians in large and smaller practices could easily compound today’s problems,” said Dr. Regier.

The full text of Dr. Regier’s testimony is available at:

http://www.psych.org/news_room/press_releases/FDA-PDAC_10-25-05_final_statement.pdf

About the American Psychiatric Association:

The American Psychiatric Association is a national medical specialty society whose more than 36,000 physician members specialize in diagnosis, treatment, prevention and research of mental illnesses including substance use disorders. Visit the APA at www.psych.org and www.healthyminds.org.