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FDA and NIH announce joint study on tobacco use and risk perceptions

Landmark collaboration is the first since the passing of the 2009 Tobacco Control Act

The U.S. Food and Drug Administration and the National Institutes of Health today announced a joint, large-scale, national study of tobacco users to monitor and assess the behavioral and health impacts of new government tobacco regulations.

The initiative, called the Tobacco Control Act National Longitudinal Study of Tobacco Users, is the first large-scale NIH/FDA collaboration on tobacco regulatory research since Congress granted FDA the authority to regulate tobacco products in the Family Smoking Prevention and Tobacco Control Act of 2009.

Scientific experts at NIH's National Institute on Drug Abuse and the FDA's Center for Tobacco Products will coordinate the effort.

“The launch of this study signals a major milestone in addressing one of the most significant public health burdens of the 21st century,” said FDA Commissioner Margaret A. Hamburg. “The results will strengthen FDA’s ability to fulfill our mission to make tobacco-related death and disease part of America’s past and will further guide us in targeting the most effective actions to decrease the huge toll of tobacco use on our nation’s health.”

Investigators will follow more than 40,000 users of tobacco-product and those at risk for tobacco use ages 12 and older. They will examine what makes people susceptible to tobacco use; evaluate use patterns and resulting health problems; study patterns of tobacco cessation and relapse in the era of tobacco regulation; evaluate the effects of regulatory changes on risk perceptions and other tobacco-related attitudes; and assess differences in attitudes, behaviors and key health outcomes in racial-ethnic, gender, and age subgroups.

“We are pleased to collaborate with the FDA on this study that may provide us with a better understanding of the impact of product regulation on tobacco prevention and cessation,” said NIH Director Francis S. Collins, M.D., Ph.D.

Westat, in Rockville, Md., was awarded the research contract in a competitive solicitation process. Study findings will help the FDA assess the impact of the Tobacco Control Act and will inform the agency about how to best use its tobacco regulatory authorities, such as making decisions about marketing of products, setting product standards, and communicating the risks from tobacco use to protect the public health.

While smoking rates have dropped significantly since their peak in the 1960s, nearly 70 million Americans ages 12 and older were current users of tobacco products in 2010. As a result, death and disease caused by tobacco use is still a tremendous public health burden. Tobacco use is the leading preventable cause of disease, disability, and death in the United States. Cigarette smoking results in more than 443,000 premature deaths in the United States each year – more than alcohol, illegal drug use, homicide, suicide, car accidents, and AIDS combined.

For more information:

- NIH and FDA Announce Collaborative Initiative to Fast-track Innovations to the Public <http://www.nih.gov/news/health/feb2010/od-24.htm>
- The Family Smoking Prevention and Tobacco Control Act <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm246129.htm>
- NIH: Information on Tobacco Addiction <http://www.nida.nih.gov/DrugPages/Nicotine.html>

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The National Institute on Drug Abuse is a component of the National Institutes of Health, U.S. Department of Health and Human Services. NIDA supports most of the world's research on the health aspects of drug abuse and addiction. The Institute carries out a large variety of programs to inform policy and improve practice. Fact sheets on the health effects of drugs of abuse and information on NIDA research and other activities can be found at www.drugabuse.gov. To order publications in English or Spanish, call NIDA's DrugPubs research dissemination center at 1-877-NIDA-NIH or 240-645-0228 (TDD) or fax or email requests to 240-645-0227 or drugpubs@nida.nih.gov. Online ordering is available at <http://drugpubs.drugabuse.gov>. NIDA's media guide can be found at <http://drugabuse.gov/mediaguide/>.

About the National Institutes of Health (NIH): NIH, the nation's medical research agency, includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. NIH is the primary federal agency conducting and supporting basic, clinical, and translational medical research, and is investigating the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit www.nih.gov.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.