UNIVERSITY OF MARYLAND

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UMD to Lead Cutting Edge Research on Tobacco and Public Health

Researchers awarded nearly $19 million from NIH, FDA to inform FDA tobacco regulatory activities

COLLEGE PARK, Md. – The University of Maryland (UMD) will launch a new research center focused on the study of a wide range of tobacco products and their impact on public health with approximately $19 million awarded to the university from the U.S. Food and Drug Administration (FDA) and the National Institutes of Health (NIH). The University of Maryland Tobacco Center of Regulatory Science (UMD TCORS) is one of 14 centers nationwide that are being created as part of a new federally-funded program that will provide the critical science base needed for the FDA to effectively regulate tobacco and protect public health.

Despite decades of work to reduce tobacco use in the United States, it continues to be the leading cause of preventable death and disease. New and highly engineered formulations of cigarettes and smokeless tobacco products are flooding the market, with disturbing increases in their use by youth. The UMD TCORS will focus its efforts on these hard to regulate and not yet well-understood products and provide information about how variations between products and brands affect exposure to toxins, health outcomes, addiction potential and the ability to quit successfully. The UMD-led team of experts in epidemiology, behavioral health, biostatistics, microbiology, toxicology, computer science and genomics is uniquely positioned to address these questions and rapidly provide relevant data to federal health agencies.

"Tobacco companies manipulate products to make them more appealing and are always changing formulations," explained Dr. Pamela I. Clark, director of the new UMD TCORS and a research professor in the UMD School of Public Health. "Our center will test new and modified tobacco products using innovative approaches that examine health risks from the molecular to the whole human level."

Dr. Clark's broad experience and leadership in transdisciplinary tobacco control research, including human laboratory studies of alternative nicotine/tobacco products such as hookah, electronic nicotine delivery devices and smokeless tobacco (snus), is complemented by the expertise of Dr. Sydney Gordon, who will co-direct the UMD TCORS. Dr. Gordon, a physical chemist with Battelle (a nonprofit research and development organization) and long-time collaborator of Dr. Clark's, is a recognized pioneer in the field of exhaled breath analysis whose techniques measure a wide variety of toxins in tobacco products such as combustible and electronic cigarettes, little cigars, waterpipe, and smokeless tobacco.

In addition to nine research experts from UMD and several from Battelle, the TCORS team includes two genomics scientists from the University of Maryland, Baltimore School of Medicine; and a neuroscientist from George Mason University.

"The University of Maryland School of Public Health's expertise has positioned us to make significant contributions to reducing the burden of preventable disease caused by tobacco use," said Dr. Jane E. Clark, dean of the UMD School of Public Health. "With our strategic collaborations across the College Park campus, and with the School of Medicine in Baltimore, Battelle, and George Mason, we are armed with tools to tackle this complex public health challenge."

The UMD TCORS will include three major research studies focused on new and manipulated tobacco products:

1) Toxicity testing through measurement of exposure to harmful and potentially harmful constituents (HPHCs) (led by Battelle's Dr. Courtney Granville);
2) Characterizing consumer acceptance and the likelihood that a person will use/become addicted to the product (led by UMD's Dr. Pamela Clark); and
3) Exploring the bacterial communities present in tobacco and the role they may play in the development of infectious and chronic diseases among tobacco users (co-led by Dr. Amy R. Sapkota, in the UMD School of Public Health's Maryland Institute for Applied Environmental Health and Dr. Emmanuel F. Mongodin, in the University of Maryland School of Medicine's Institute for Genome Sciences).

The third study explores the health risks of tobacco using new tools not usually applied to tobacco control research. Dr. Sapkota and Dr. Mongodin will partner to apply advanced DNA and RNA sequencing technologies to determine the range of potentially harmful bacteria present in the tobacco products (their bacterial microbiome) and in the mouths of tobacco users (the oral microbiome). One goal is to determine how these bacterial communities may influence the production of cancer-causing compounds in tobacco products and impact the health of tobacco users.

Expertise from biostatisticians in the School of Public Health (Dr. Mei-Ling Ting Lee and Dr. Raul Cruz-Cano) and computer scientists in the University of Maryland Institute for Advanced Computer Studies (Dr. Amitabh Varshney, UMIACS director, and Dr. Mihai Pop) will provide for the safe and rapid cleaning, analysis, storage and availability of the vast amounts of genomic and other data collected from the projects. A secure, interactive database will make

findings available to all project personnel, other TCORS and officials from the FDA Center for Tobacco Products and the NIH.

Another important component of the center will be to provide young investigators with training opportunities to ensure the development of the next generation of tobacco regulatory scientists. UMD's proximity to the FDA, NIH, and other federal agencies will allow these researchers to train with scientific leaders in a variety of settings.

"The University of Maryland is one of the world's leading research universities dedicated to applying science for the good of the people," said Dr. Patrick O'Shea, vice president of research and chief research officer. "This center is an excellent example of the power that transdisciplinary expertise brings to the fight, enabled by our joint efforts with the University of Maryland, Baltimore School of Medicine, Battelle, and partnerships with the NIH and FDA."

About the P50 Tobacco Centers of Regulatory Science (TCORS)

The Tobacco Regulatory Science Program, located in the NIH Office of Disease Prevention, coordinates the trans-NIH collaborative effort with the Food and Drug Administration (FDA) Center for Tobacco Products to conduct research that is needed to ensure that U.S. tobacco regulatory actions and activities are based on sound and relevant scientific evidence. The P50 Tobacco Centers of Regulatory Science (TCORS) are the centerpiece of this NIH-FDA collaboration. Using designated funds from FDA, TCORS will be coordinated by NIH's Office of Disease Prevention, directed by David M. Murray, Ph.D., and administered by three NIH institutes—the National Cancer Institute, the National Institute on Drug Abuse, and the National Heart, Lung and Blood Institute. The TCORS program brings together investigators from across the country to aid in the development and evaluation of tobacco product regulations. Each TCORS application identified a targeted research goal. Taken together, the TCORS sites will increase knowledge across the full spectrum of basic and applied research on tobacco and addiction. The program also provides young investigators with training opportunities to ensure the development of the next generation of tobacco regulatory scientists.

About the University of Maryland

The University of Maryland is the state's flagship university and one of the nation's preeminent public research universities. A global leader in research, entrepreneurship and innovation, Maryland is ranked No. 21 among public universities by *U.S. News & World Report* and No. 14 among public universities by *Forbes*. The Institute of Higher Education, which ranks the world's top universities based on research, puts Maryland at No. 38 in the world, No. 29 nationally and

No. 13 among U.S. public research institutions. The university is also one of the top 10 highest-rated D.C.-area employers, according to Glassdoor.com. Its faculty includes three Nobel laureates, two Pulitzer Prize winners, 49 members of the national academies and scores of Fulbright scholars. The university is recognized for its diversity, with underrepresented students comprising one-third of the student population.

For more information:

FDA: Center for Tobacco Products www.fda.gov/TobaccoProducts

Tobacco Centers of Regulatory Science (TCORS): http://prevention.nih.gov/tobacco/tcors.aspx

NIH: Office of Disease Prevention http://prevention.nih.gov/default.aspx

NIH: Tobacco Regulatory Science Program http://prevention.nih.gov/tobacco/default.aspx