

CRITICAL ENVIRONMENTS TODAY

INSIDE THIS ISSUE:

<i>Study Moves Closer to Improved Therapies</i>	1
<i>EPA Water Conservation</i>	2
<i>ISPE Courses</i>	2
<i>NIAID to Establish Flu Research Centers</i>	3, 4
<i>About Salus</i>	4
<i>Contact Us</i>	4

OF SPECIAL INTEREST

- Study suggests genetic link for those who successfully quit smoking
- NIAID awards \$161 million for influenza research and surveillance

NIDA STUDY IDENTIFIES GENES THAT MAY HELP SOME PEOPLE ABSTAIN FROM SMOKING



George Uhl, M.D., Ph.D.

Scientists supported by the National Institute on Drug Abuse (NIDA), part of the National Institutes of Health, have for the first time identified genes that might increase a person's ability to abstain from smoking. The breakthrough research was conducted by Dr. George Uhl at NIDA's Intramural Research Program and a team led by Dr. Jed Rose at the Center for Nicotine and Smoking Cessation Research at Duke University Medical Center.

"This research marks the first time we've been able to identify genes involved in the ability to quit smoking," says NIDA Director Dr. Nora D. Volkow. "It marks a movement from identifying the genetics of addiction vulnerability to identifying the genetic basis of successful abstinence. This knowledge could impact the success rate of cessation programs by helping health care providers choose the most appropriate treatment based on individual differences."

Dr. George Uhl and his colleagues performed a genome wide analysis on the DNA of two types of nicotine dependent individuals, one that was able to successfully quit the cigarette smoking behavior and one that was not.

"We identified 221 genes that distinguished successful quitters from those who were unsuccessful," says Dr. Uhl. "We know the functions of about 187 of these genes, but 34 have functions that are unknown at present. We also found that at least 62 of the genes that we had previously identified as playing roles in dependence to other drugs also contribute to nicotine dependence."

Genes that harbor variants that contribute to both success in quitting smoking and in vulnerability to become dependent on multiple substances include cadherin 13 (a molecule involved in cell adhesion, which governs how cells recognize and connect to their neighbors) and a cyclic G-dependent protein kinase gene (that plays a key role in normal brain development). In addition to genes implicated in intracellular signaling and intercellular interactions, a number of genes involved in other processes have also been identified. While many of the genes identified through this effort make sense because of their role in supporting new neural connections in the brain, more research is now needed to understand the actual mechanisms through which they may increase or reduce the rates of successful quitting.

Dr. Uhl says he and his colleagues have replicated this research in another sample, as he reported at the February 2007 meeting of the Society for Research on Nicotine and Tobacco.

"These findings provide ample justification for continuing the search for even more genetic variants associated with smoking cessation success," says Dr. Volkow. "We soon may be able to make use of this information to match treatments with the smokers most likely to benefit from them."



NSF GAINS APPROVAL AS PRODUCT CERTIFIER FOR EPA'S NEW WATERSENSESM PROGRAM

"...the average household adopting water-efficient products...could save enough water to supply a year's worth of drinking water to 150 of its neighbors."



March 20, 2007. Ann Arbor, MI-

NSF International announced its participation in a new certification program designed to verify the water efficiency and performance of high-efficiency toilets, which can save up to 900 billion gallons of water each year, according to the U.S. Environmental Protection Agency (EPA). The effort is a key part of EPA's new WaterSenseSM program, which recently approved NSF's participation in the program as an independent, product certification organization.

The EPA launched the WaterSenseSM program in 2006 to focus on high-efficiency products and services designed to conserve water, one of our most precious natural resources. This voluntary labeling program is available to all companies that partner with EPA and manufacture, sell or distribute household plumbing fixtures.



NSF has been approved to certify high-efficiency toilets to the WaterSenseSM specification as an EPA-Licensed Certification Body. The certification process will consist of product testing, including testing that ensures high-efficiency toilets consume no more than 1.28 gallons per flush (gpf) while successfully meeting all required performance testing.

WaterSenseSM makes it easier to identify water-efficient products and practices. By choosing products designated with the WaterSenseSM label, consumers will be saving water for future use. According to the EPA, the average household adopting water-efficient products and practices could save enough water to supply a year's worth of drinking water to 150 of its neighbors.

Certified products will be included on an EPA product registry and will bear the WaterSenseSM label. In addition to authorizing the use of the label and providing the artwork, NSF will list all of its certified products on its website at www.nsf.org. Ongoing annual inspections will ensure continued compliance. A more detailed list of requirements can be found at: www.epa.gov/watersense/docs/spec_het508.pdf.

"EPA's WaterSenseSM program is the ideal complement to NSF's overall sustainability initiatives," said NSF Vice President Bob Ferguson. "While providing new services for our clients, we will also help to conserve water and protect the environment for future generations."

During the initial phase of the WaterSenseSM program, the EPA is focusing on high-efficiency toilets. The program is expected to expand to include requirements for high-efficiency bathroom sink faucets. The EPA is accepting public comments on its draft specification for high-efficiency bathroom faucets until March 23, 2007; proposed requirements can be found at: www.epa.gov/watersense/partners/specs/faucet_background.htm. Future plans to expand the WaterSenseSM program may include requirements for showerheads, irrigation control equipment and other commercial equipment.



ISPE TO OFFER CLASSROOM TRAINING IN PHILADELPHIA

From April 16-19, ISPE is offering courses at the Hilton Philadelphia on such topics as Part 11 compliance, GMP fundamentals, basic principles of commissioning and qualification, GMP auditing, HVAC for pharmaceutical facilities and more. To read more about the training or to register online, go to www.ispe.org and select the Education and Training link.

NIAID EXPANDS CAPABILITY FOR INFLUENZA RESEARCH AND SURVEILLANCE

The National Institute of Allergy and Infectious Diseases will award \$23 million per year for seven years to six new centers that will work to bolster flu research and surveillance, the National Institutes of Health announced on April 2. Collectively, the centers will expand NIAID's influenza surveillance program internationally and in the United States, and will bolster influenza research in key areas, including understanding how the virus causes disease and how the human immune system responds to infection with the virus. The goal of the newly created centers is to provide the federal government with important information to inform public health strategies for controlling and lessening the impact of seasonal influenza as well as an influenza pandemic.

"The threat of an influenza pandemic is a major source of concern for the public health community," says NIAID Director Anthony S. Fauci, M.D. "The new NIAID Centers of Excellence for Influenza Research and Surveillance will help expand the federal government's existing international and domestic influenza surveillance efforts, further our understanding of influenza viruses, and generate the information and tools necessary to better prepare and respond to a pandemic situation."

The new awards build upon an ongoing program led by St. Jude Children's Research Hospital in Memphis, TN, initiated by NIAID after the

1997 Hong Kong outbreak of highly pathogenic avian influenza in humans. Under this program, researchers conducted surveillance of influenza viruses in aquatic birds and live bird markets in Hong Kong, which helped shed light on the natural history of flu viruses. Further, scientists conducted training courses in animal influenza surveillance, developed diagnostic tools to detect animal flu viruses, and generated viruses suitable for use in developing human influenza vaccines.

NIAID is expanding the surveillance and research program to now include six Centers of Excellence for Influenza Research and Surveillance. Their work will include determining the prevalence of avian influenza in animals that routinely come into close contact with people; understanding how flu viruses evolve, adapt and transmit infection; and identifying immunological factors that can determine whether a flu virus causes only mild illness or death. Additionally, some centers will monitor for international and domestic cases of animal and human influenza to rapidly detect and characterize viruses that may have pandemic potential and to create vaccine candidates targeted to those viruses. Ultimately, these studies will lay the groundwork for developing new and improved control measures for emerging and reemerging flu viruses.

Summaries of the six NIAID Centers of Excellence for Influenza Research and

Surveillance awards are provided below:

St. Jude Children's Research Hospital, Memphis (principal investigator — Dr. Robert Webster) Research activities will involve evaluating antiviral drug regimens and factors that drive drug resistance; identifying viral markers that may indicate how a virus becomes deadly, adapts and transmits infection; uncovering immune system mechanisms that protect against the H5N1 avian flu virus; and identifying the factors that make animals and people susceptible to flu virus infection. In addition, St. Jude will expand its animal surveillance to more than a dozen countries and multiple U.S. states. St. Jude also will monitor pediatric populations for flu activity and maintain a surveillance component to monitor for evidence of the reemergence of the severe acute respiratory syndrome (SARS). Additionally, the researchers will explore strategies for controlling influenza outbreaks in agricultural settings.

University of California at Los Angeles (principal investigator — Dr. Scott Layne) UCLA investigators will monitor animal influenza internationally and in the states of Alaska, Washington and California. They also will maintain a high-throughput laboratory network capable of providing real-time information about circulating influenza virus strains and antiviral drug resistance—information that will be most critical during the early stages of an influenza pandemic.



"The threat of an influenza pandemic is a major source of concern for the public health community."



Salus, Inc.

115 E Commercial
Wood Dale, IL 60191
phone: 630.694.0014
fax: 847.556.0613

Billing Address:
103 N Donald Avenue
Arlington Heights, IL 60004

Visit us online at
www.salustech.net

For information on the professional services that Salus offers, call:

Validation
Luis Solarte—847.344.4939
luis.solarte@salustech.net

Building Controls, Commissioning,
Assessment and Remediation
Mike Kosinski—847.344.4542
michael.kosinski@salustech.net
Ed Kaminski—847.354.0140
edward.kaminski@salustech.net

Environmental Certification
Bud Williams—847.344.1648
bud.williams@salustech.net
Pete Skees—847.344.2639
pete.skees@salustech.net

Test and Balance
Jackie Squires—847.376.0701
jackie.squires@salustech.net
Dennis MacDonald—847.354.0145
dennis.macdonald@salustech.net

About Salus

Within the industry, the Salus model is unique. Each of its four components—validation, certification, test and balance and assessment/remediation—is client-critical and stands on its own, yet in combination they create measurable cost and time-to-market advantages. We offer custom packages—monthly, semi-annual or annual—that combine whichever services your facility needs to keep it running safely and efficiently. Our team of critical environment experts is available to evaluate your facility's needs and prepare a cost-effective service plan.

Salus provides professional services to academic institutions and the pharmaceutical, biological and medical device industries. Our company is dedicated to providing outstanding customer service while building a reputation for quality and value.

To learn how Salus can assist your organization, contact one of our team members today.

Safeguarding Your Environment...And Your Investment

NIAID EXPANDS CAPABILITY FOR INFLUENZA RESEARCH AND SURVEILLANCE

(CON'T FROM PAGE 3)

University of Minnesota, Minneapolis (principal investigator — Dr. Marguerite Pappaiaonou)

These researchers will conduct international and domestic animal flu surveillance covering all major domestic flight paths of migratory birds. This center also will carry out a human influenza surveillance study in Thailand and will monitor U.S. agricultural workers who work with swine.

Emory University, Atlanta (principal investigator — Dr. Richard Compans) This center will conduct studies to determine how influenza viruses adapt to new hosts and are transmitted between different hosts, and analyze human immune responses to influenza vaccination and infection. The researchers will examine how human genes might be silenced to decrease or eliminate flu infections; identify new targets for antiviral medicines; and evaluate flu transmission between patients and physicians in the hospital emergency room setting. Emory will also offer a training program for postdoctoral fellows and veterinarians interested in influenza and other research performed in a biosafety level 3 laboratory.

Mount Sinai School of Medicine, New York City (principal investigator — Dr. Adolfo Garcia-Sastre) These researchers will conduct molecular studies to identify influenza virus genes associated with the development of disease, the adaptability of flu viruses in birds and mammals, and the transmission of flu viruses between different hosts.

University of Rochester, Rochester, NY (principal investigator — Dr. John Treanor) Dr. Treanor and his colleagues will establish a human surveillance system that will monitor selected communities in New York for seasonal flu virus infections, and will study the effectiveness of annual immunization programs using inactivated or weakened (live, attenuated) flu virus vaccines. The Rochester center also will perform clinical immunological studies to better define human immune responses to influenza vaccination and infection. Additionally, the center will study how flu viruses adapt to new species of animals.

All of the research findings generated by the NIAID Centers of Excellence for Influenza Research and Surveillance will be used to support and bolster the pandemic influenza preparedness and response efforts of the U.S. Department of Health and Human Services (HHS). NIH is an agency of the HHS.