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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES • National Institutes of Health • National Institute on Alcohol Abuse and Alcoholism

### **FEATURE**

## NIAAA FOSTERS INNOVATION THROUGH ITS SMALL BUSINESS RESEARCH PROGRAM



The Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) program supports the development and commercialization of

innovative tools, technologies, and strategies. The <u>National Institute on Alcohol Abuse and Alcoholism (NIAAA) SBIR/STTR program</u> aims to improve the diagnosis, prevention, and treatment of—as well as recovery from—alcohol-related problems. The SBIR/STTR program enhances NIAAA's research portfolio across the spectrum of basic, translational, and clinical research. This portfolio includes research on medications development, alcohol biosensors, screening and diagnostic tools, educational resources, mobile apps, and more.

"Established by Congress as a federal-wide effort, the SBIR/STTR program is an important component of the NIAAA research portfolio, with set-aside funds to advance innovative solutions out of the laboratory into mainstream use," reflects NIAAA Director George F. Koob, Ph.D.

### What Makes the SBIR/STTR Program Unique?

The SBIR/STTR program is also known as America's Seed Fund. It provides support to early-stage small businesses to meet the nation's research and development needs in a manner that stimulates innovation, encourages entrepreneurship, and contributes to the national economy. In turn, those research and development efforts increase the likelihood that publicly supported private-sector research gains will be commercialized for the benefit of the American people.

"The SBIR/STTR program provides an incentive for researchers who have innovative ideas and have completed successful R01 grants to try

### IN THIS ISSUE

### **FEATURE**



1 NIAAA Fosters Innovation Through Its Small Business Research Program

### **SPOTLIGHT**



3 New Resource: "Short Takes" Video Series Enhances Understanding About Alcohol Terms



4 NIAAA Expands Outreach to Diverse Audiences With New Factsheet Translations

### **NOTEWORTHY**



5 Litten Appointed as Director of NIAAA Division of Treatment and Recovery



6 New From NIAAA: An Updated Rethinking Drinking Booklet and Website

### FIVE QUESTIONS WITH...



7 David Lovinger, Ph.D., Acting Scientific Director, Division of Intramural Clinical and Biological Research, and Chief of the Laboratory for Integrative Neuroscience, NIAAA



out being an entrepreneur. It de-risks the transition from academia to small business ownership," adds Megan Ryan, M.B.A., who has served as NIAAA's SBIR/STTR Program Coordinator since 2016.

Prioritizing project support is essential for early-stage small business viability. Throughout the years, small businesses have leveraged the support provided through the SBIR/STTR program to advance products that show promise but are deemed a lower priority given limited resources.

An example is the development of Vivitrol, a long-acting, injectable form of naltrexone that received U.S. Food and Drug Administration (FDA) approval for alcohol use disorder (AUD) treatment in 2006. Alkermes, at the time a small business biopharmaceutical company specializing in drug delivery technology, was awarded an NIAAA SBIR contract in 2000 to conduct proof-of-concept and efficacy clinical trials of Vivitrol. The SBIR award effectively took the risk out of development and helped Alkermes leverage the award to raise additional financial support and conduct larger clinical trials, ultimately providing the data needed for FDA approval.

### Increasing the Visibility of the NIAAA SBIR/STTR Program

In recent years, NIAAA has focused on enhancing its SBIR/STTR portfolio. This effort has largely focused on raising awareness of NIAAA's SBIR/STTR program and educating entrepreneurs on how to apply for an NIAAA SBIR/STTR award.

To accomplish this, Ms. Ryan teamed up with a marketing company that specializes in science and healthcare to expand NIAAA's outreach about its SBIR/STTR program. Together, they developed new outreach materials, expanded the NIAAA SBIR/STTR website, and held informational webinars with small business incubators and "state bios." State bios are organizations that bring together a state's bioscience companies, universities, research institutions, and others dedicated to advancing life science research and commercialization. These efforts contributed to a 33 percent increase in the total number of SBIR/STTR applications received by NIAAA within a year. Despite research setbacks common in the COVID-19 pandemic, NIAAA has continued to receive an increased number of SBIR/STTR applications.

"These results demonstrate the importance of outreach to potential applicants, which will remain a focus of NIAAA's SBIR/STTR program moving forward," says Jenica Patterson, Ph.D., NIAAA's incoming SBIR/STTR Program Coordinator.

### **NIAAA SBIR/STTR Program Priority Highlights**

One of the program priorities of the NIAAA SBIR/STTR program is developing wearable biosensors to detect the amount of alcohol an individual has consumed. Researchers are using innovative techniques to improve the accuracy of the devices as well as their wearability. This work will allow researchers to better measure alcohol consumption in clinical research studies and treatment settings.

Another priority is the development of new medications to treat alcohol-related consequences and conditions, such as AUD, alcohol-associated organ damage (AAOD), alcohol withdrawal, and alcohol overdose. An example of an NIAAA-supported SBIR project, led by Felix Moser, Ph.D., at Synlife Bio, is the development of a novel therapeutic injection to counteract alcohol overdose. Billions of dollars are spent annually to treat alcohol overdose cases, many of which result in death—yet there are no FDA-approved pharmacological treatments. NIAAA's commitment to developing new medications is emphasized by a recent SBIR/STTR funding announcement, and is an important step in bridging the gap between basic research and clinical trials.



Improving diagnostics for AAOD is another area of interest for NIAAA's SBIR/STTR program. For example, InLighta BioSciences, a company started by Jenny Yang, Ph.D., has developed a novel contrast agent for magnetic resonance imaging (MRI) that significantly improves diagnostic ability for conditions such as liver disease. Unlike traditional contrast agents, this agent is non-toxic and can detect early stages of disease. From the beginning, this technology was poised to provide a non-invasive early diagnostic tool for liver disease—a disease in which alcohol misuse is a major risk factor. In the United States, nearly half of liver disease deaths are associated with alcohol misuse.

NIAAA's SBIR/STTR program also supports the development of alcohol prevention programs, educational services, behavioral treatment programs, and digital health technologies. In <u>one ongoing NIAAA-supported clinical trial</u>, DynamiCare Health is testing a smartphone-based digital coaching program to support accessible and affordable long-term recovery from AUD. The program is based on behavioral techniques such as contingency management, recovery coaching, and cognitive behavioral therapy.

### Learn More

For more information about the NIAAA SBIR/STTR program, visit the NIAAA SBIR/STTR website.

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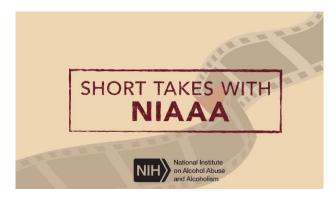
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### **SPOTLIGHT**

## NEW RESOURCE: "SHORT TAKES" VIDEO SERIES ENHANCES UNDERSTANDING ABOUT ALCOHOL TERMS

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) has launched a new video series called "Short Takes with NIAAA." Featuring commentary by NIAAA experts, this series consists of social media-friendly, 60-second videos explaining commonly used—but often misunderstood—alcohol terms.

The first installment of Short Takes provides concise, plain-language explanations of the following topics:



- Alcohol overdose (also available in Spanish)
- Alcohol use disorder
- Binge drinking
- Blackouts

We hope that our grantees, friends, and partners will share these accessible videos through their own social media channels. Stay tuned as we continue to add new videos to this series, which is designed to be helpful to both the general public and healthcare providers.

### **SPOTLIGHT**

## NIAAA EXPANDS OUTREACH TO DIVERSE AUDIENCES WITH NEW FACTSHEET TRANSLATIONS

Providing information in multiple languages can help extend the reach of the National Institute on Alcohol Abuse and Alcoholism's (NIAAA) resources.

Many visitors to NIAAA's website come from countries where languages such as Spanish, Tagalog, Japanese, and Chinese are spoken. In addition,

Executive Order 13166, issued in 2000, called for all federal agencies to provide individuals with limited English proficiency meaningful access to their services. NIH and the Census Bureau have identified certain languages as being of greatest need.



In support of these policies and to expand access to educational materials to a broader audience, NIAAA now offers some of its popular evidence-based factsheets on alcohol and health—including <u>Alcohol Use Disorder: A Comparison Between DSM-IV and DSM-5</u>, <u>Hangovers</u>, <u>Interrupted Memories: Alcohol-Induced Blackouts</u>, <u>Understanding Alcohol Use Disorder</u>, and <u>Understanding the Dangers of Alcohol Overdose</u>—in the following languages:

- Amharic
- Arabic
- Chinese (simplified)
- Chinese (traditional)
- Farsi
- French
- Haitian Creole
- Italian

- Japanese
- Korean
- Polish
- Portuguese
- Russian
- Spanish
- Tagalog
- Vietnamese

Visit the NIAAA website to find these and other free resources, and please share them with your networks.

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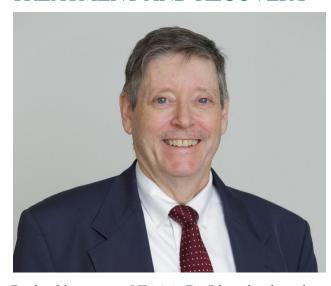
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### **NOTEWORTHY**

## LITTEN APPOINTED AS DIRECTOR OF NIAAA DIVISION OF TREATMENT AND RECOVERY



Raye Z. Litten, Ph.D., has been appointed Director of the Division of Treatment and Recovery (DTR) at the National Institute on Alcohol Abuse and Alcoholism (NIAAA). Dr. Litten joined NIAAA in 1989 and previously served as Associate Director of the Division of Treatment and Recovery Research, Acting Director of the Division of Medications Development, and Acting Director of the Division of Treatment and Recovery Research.

As DTR Director, Dr. Litten leads a broad program of extramural clinical research that focuses on improving treatments for alcohol use disorder (AUD), increasing the use and uptake of such treatments in real-world settings, and understanding the process of recovery from AUD.

During his tenure at NIAAA, Dr. Litten has been instrumental in expanding NIAAA's medications development research program. He helped establish the NIAAA Clinical Investigations Group, a network of clinical sites that conducts proof-of-concept, Phase II clinical trials of promising AUD medications. He also was key in establishing NIAAA's human laboratory program to efficiently screen compounds for safety and effectiveness prior to clinical trial testing, helping to overcome the "valleys of death" in medications development. Dr. Litten has also worked to promote the combined use of behavioral and medication treatments and to strengthen NIAAA's biomarkers and health services research portfolios. Currently, he oversees the development of a new educational resource titled "The Healthcare Professional's Core Resource on Alcohol" to help them better recognize the effects of alcohol in their patients and deliver improved care for those whose drinking may be affecting their health.

Dr. Litten says, "I am grateful for this opportunity to continue to play an active role in this vital part of NIAAA's portfolio of research and research translation. In addition to our ongoing efforts to create evidence-based treatment resources for people with AUD and the clinicians who care for them, DTR staff and other NIAAA scientists have unveiled a universal definition of recovery that can be used across research studies, and as a tool for clinicians. The new recovery definition will enable us to compare findings, identify which behavioral and



pharmacological treatments have long-term efficacies and for whom, and invest resources into those treatments that will truly make a difference. We also are working to understand the different phases of recovery—such as short, medium, and long term—and how they relate to the likelihood of returning to heavy drinking."

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### **NOTEWORTHY**

## NEW FROM NIAAA: AN UPDATED RETHINKING DRINKING BOOKLET AND WEBSITE



According to the 2019 National Survey on Drug Use and Health, more than half of Americans ages 18 and older reported drinking alcohol in the past month, and about a quarter of this same group reported past-month binge drinking. To help adults who drink alcohol to better understand their relationship with alcohol, the National Institute on Alcohol Abuse and Alcoholism (NIAAA) recently published a major update and redesign of its popular booklet and website, *Rethinking Drinking:* Alcohol and Your Health.

"Rethinking Drinking was first issued in 2009 and has been NIAAA's most popular resource. This updated edition of Rethinking Drinking continues to provide evidence-based information about alcohol misuse and offers a modern new look," says NIAAA Director George F. Koob, Ph.D. "We hope that this resource continues to empower people to be mindful of—and to take charge of—their drinking patterns."

The newly redesigned and updated booklet is available in both English and Spanish and provides information on:

- What counts as a "standard drink" (also known as an alcoholic drink-equivalent) and how many drinks are in common containers
- Recommendations about drinking in the U.S. Dietary Guidelines for Americans
- Short- and long-term consequences of alcohol misuse
- Signs and symptoms of alcohol use disorder
- Tips on how to assess your drinking pattern
- Strategies and tools for cutting down or quitting drinking
- Options and resources for peer, professional, and social support for cutting back on or quitting drinking

The booklet can be downloaded as a PDF from the main NIAAA website, and print copies of the 20-page booklet are available to order in English or Spanish.





For more information, readers can visit NIAAA's <u>Rethinking Drinking website</u>. In addition to the above topics, the website has special features such as:

- <u>Calculators</u> that estimate the number of "standard drinks" in an alcohol-containing beverage, calorie content of drinks, alcohol spending, and blood alcohol concentration
- Activities on handling urges to drink and building skills in refusing drinks
- Practical tips on overcoming a drinking episode when the goal is to quit

While Rethinking Drinking is a great tool for anyone to use to examine their relationship with alcohol, NIAAA offers additional resources specifically for people who would like to learn more about options for alcohol treatment for themselves or loved ones, including the <a href="NIAAA Alcohol Treatment Navigator">NIAAA Alcohol Treatment Navigator</a>® website and the Treatment for Alcohol Problems: Finding and Getting Help <a href="booklet">booklet</a>.

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### **FIVE QUESTIONS WITH...**

### DAVID LOVINGER, PH.D.

Acting Scientific Director, Division of Intramural Clinical and Biological Research, and Chief of the Laboratory for Integrative Neuroscience, National Institute on Alcohol Abuse and Alcoholism (NIAAA)



1 Your neuroscientific research spotlights fundamental biological processes—molecules, cells, and neurocircuits. What led you to this field, and how would you describe the importance of such basic science in helping us to understand alcohol's effects on health?

I have cultivated an interest in the neurobiological basis of behavior since my undergraduate days. My work on synaptic plasticity related to learning and memory led me to examine acute alcohol effects on the function of synaptic molecules involved in plasticity. Synaptic plasticity refers to the broad range of changes that occur in the strength of connections between neurons. Intriguing findings stimulated me to

expand this research program to examine chronic alcohol effects on synaptic function and assess how these synaptic changes alter learning, memory, and alcohol-related behaviors involving neural circuits that we were studying in other contexts. With the help of outstanding colleagues at NIAAA and throughout the field, our laboratory is now able to address these questions at the molecular, cellular, circuit, and behavioral levels.

Basic research in the Division of Intramural Clinical and Biological Research (DICBR) has always been at the forefront of research on the biomedical effects of alcohol. From the early development of animal models, and through pioneering metabolic studies, DICBR has provided ideas and resources that stimulate research throughout

and beyond the alcohol research field. Recent work in neurogenetics, alcohol-induced organ damage, and neuroscience carry on this tradition, including wide adoption of techniques and models developed in DICBR. The increased cross-talk between the basic laboratories and our outstanding clinical research group is now providing candidate therapies to treat the many facets of alcohol use disorder.

2 Among your recent publications is the intriguingly named paper, "A Circuit-Based Information Approach to Substance Abuse Research." Can you elaborate on that approach and its importance to the field?

As neurobiological research has expanded, it is clear that there is much to be learned about neural circuit/systems functions. Past research, including our own, focused on molecules, cells, and single brain regions. At the same time, research in this area is often driven by concepts from experimental psychology with efforts to model human behavior. We propose that these lines of research can be more mutually informative by better understanding circuit function and relationships to behavior, effects of drugs on these circuits, and reduced emphasis on finding which of the many imperfect animal models of human substance use disorders is the "best."

3 Scientists rely on access to special technology and often require close collaboration with colleagues. How have you and your fellow investigators at NIAAA been able to adjust to conducting research and working together during the COVID-19 pandemic?

I need to praise the members of the Laboratory for Integrative Neuroscience (LIN) for their exceptional dedication, organization, and attention to safety during these unusually difficult times. From the beginning of the pandemic, the resourceful members of LIN adopted web-meeting and team chat platforms to facilitate communication and maintain morale. During the full shutdown and maximum telework, we all worked on tasks achievable from home, such as analyzing data and writing papers. With the limited return to work, laboratory members organized shifts, allowing all projects to move forward while still meeting physical distancing requirements. The result was outstanding productivity and publications, not to mention that two postdocs obtained tenure-track positions, all while preventing a COVID-19 outbreak among the team members.

4 As a laboratory chief, you've made it a priority to mentor the next wave of young investigators. In what ways do you find NIAAA's intramural program to be especially suited to serve as a training ground for alcohol researchers of the future?

Good mentoring ensures scientific progress, paving the way for future discovery. Thus, it is one of the most important aspects of a scientist's career. I have been extremely fortunate to work with exceptional young scientists at the postbaccalaureate, graduate, postdoctoral, and early faculty levels. One thing I have learned is that mentoring is a bi-directional interaction. I learn so much from young scientists and hopefully can give back valuable training and career advice in return. The intramural program has the advantage of allowing a great deal of independence in choice of research topics, combined with outstanding resources.

### 5 Can you share some of your favorite things to do when you're away from your laboratory?

When I'm not at work, I love to escape. Pre- (and, I hope, post-) pandemic, this included travel to new and exciting places like Costa Rica. To me, there is nothing more enriching than seeing a new city or hiking in a beautiful natural setting where I can look for new plants and animals—especially birds, thanks to advice from my colleagues. I also can't resist swimming in any new pool, lake, sea, or ocean when the weather permits. When I can't escape physically, I dive into a good novel or movie, with science fiction being one of my favorite genres.

### **ABOUT US**

NIAAA Spectrum is NIAAA's webzine. With engaging feature articles, short news updates, and colorful graphics, NIAAA Spectrum offers accessible and relevant information on NIAAA and the alcohol research field.

### **CONTACT US**

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