ALCOHOL AND SUBSTANCE USE DISORDERS RESEARCH PROGRAM



MISSION: To identify, evaluate and advance pharmacotherapeutics for alcohol, opioid and other substance use disorders, with an emphasis on other co-occurring mental health conditions, to maximize the functioning and quality of life for Service Members, their Families, Veterans and the American public

Congressional Appropriations FY10-FY19, FY21-FY24: \$60.1M total



"ASUDRP is a pivotal program, uniting experts to confront the problem of alcohol and substance use disorders intertwined

with PTSD, impacting military personnel and Veterans. As a Programmatic Panel member, I was privileged to read grant proposals, witnessed firsthand the innovative solutions and collaborations and actively shaped the program's trajectory. The program contributes to identifying breakthrough projects that include preclinical studies of lead compounds and clinical trials evaluating promising pharmacotherapies for AUD or SUD and PTSD comorbidities. With every grant awarded, ASUDRP propels us closer to combating addiction and trauma more effectively, curbing the opioid crisis and enhancing lives."

Jana Drgonova, Ph.D., National Institute on Drug Abuse, FY19-FY24 Programmatic Panel Member



SCOPE OF THE PROBLEM

In 2022, deaths from drug overdoses exceeded **109,000**¹





Nearly **80,000** deaths associated with opioid use in a single year²

Fentanyl overdose is the **leading cause of death** for Americans age 18-45³



RELEVANCE TO MILITARY HEALTH

Disease prevalence in Veterans:4

- 32% with lifetime alcohol use disorder
- 20% with substance use disorder
- Nearly 15,000 Service Members survived opioid overdoses between 2017 and 2022⁵
- Alcohol and substance use disorders often co-occur with PTSD and increase risk of suicide⁶

PROGRAM PRIORITIES

Treat alcohol and other substance use disorders and improve treatment adherence, prevent relapse, and reduce risk of misuse, particularly among individuals with cooccurring PTSD, TBI, and/or other mental health conditions

- New treatment targets
- Novel medications
- Re-purposed medications
- Vaccines and other immunotherapies
- Drug-drug combinations
- More potent, longer-acting formulations to counteract opioid, including fentanyl and its analogs, overdose
- ¹ https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm
- ² https://blogs.cdc.gov/nchs/2023/05/18/7365/
- ³ https://www.getsmartaboutdrugs.gov/media/dea-administrator-record-fentanyl-overdose-deaths
- ⁴ Lan CW et al. Am J Addict 25, no. 1, 2016:7-24
- https://www.markey.senate.gov/imo/media/doc/dod_response_to_senator_markey_ colleagues_september_2022_letterpdf.pdf/
- $^{\rm 6}\ https://www.ptsd.va.gov/understand/related/substance_abuse_vet.asp$



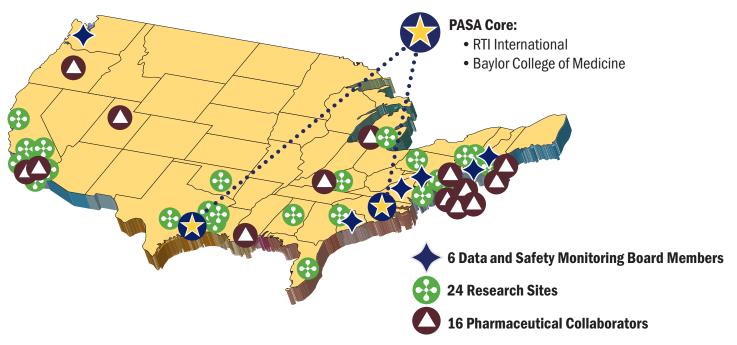






PASA Consortium - Engaging the Community

The ASUDRP funds the Pharmacotherapies for Alcohol and Substance Use Disorders Alliance consortium.



PASA Planned and Ongoing Research

- **DeepBiomarker2:** Deep learning and data mining of electronic medical records to identify patients with PTSD and alcohol use disorder at risk for poor clinical outcomes
- **Suvorexant:** A clinical trial of an FDA-approved sleep medication to improve sleep and mitigate symptoms of alcohol use disorder and PTSD
- **Lofexidine and buprenorphine:** A clinical trial of the combination drug therapy to improve outcomes and reduce PTSD symptoms and opioid use relapse

RESEARCH BREAKTHROUGHS — MAKING A DIFFERENCE

Transitions to Industry



Preclinical data supported further development of ASP8062

Prelinincal data suggested CERC-501 may be useful in treating PTSD

Astellas pursued ASP8062 as a potential treatment for alcohol use disorder

Janssen Pharmaceuticals procured rights to CERC-501 from Cerecor for further development as a treatment for major depressive disorder

Fentanyl Vaccine Development



Preclinical data demonstrated efficacy of the anti-fentanyl vaccine alone and in combination with buprenorphine

Supported future clinical development of the vaccine for opioid use disorder in combination with current FDA-approved treatments

Provisional patent application submitted for anti-fentanyl vaccine