



ASAM American Society of
Addiction Medicine

OFFICERS

President

Kelly J. Clark, MD, MBA, DFAPA, DFASAM

President-Elect

Paul H. Earley, MD, DFASAM

Vice President

Margaret Jarvis, MD, DFASAM

Secretary

Yngvild Olsen, MD, MPH, DFASAM

Treasurer

Brian Hurley, MD, MBA, FASAM

Immediate Past President

R. Jeffrey Goldsmith, MD, DLFAPA, DFASAM

BOARD OF DIRECTORS

Directors-at-Large

Anthony Albanese, MD, DFASAM

Marc Galanter, MD, DFASAM

William F. Haning, III, MD, DFAPA, DFASAM

Petros Levounis, MD, MA, DFASAM

John C. Tanner, DO, DFASAM

Itai Danovitch, MD, MBA, FAPA, DFASAM

Regional Directors

Region I Director

Jeff Selzer, MD, DFASAM

Region II Director

Murtuza Ghadiali, MD

Region III Director

Kenneth Freedman, MD, MS, MBA, FACP, AGAF, DFASAM

Region IV Director

Michael Shore, MD, DFASAM, DLFAPA

Region V Director

Anika Alvanzo, MD, MS, FACP, FASAM

Region VI Director

Gavin Bart, MD, PhD, DFASAM

Region VII Director

A. Kenison Roy, III, MD, DLFAPA, DFASAM

Region VIII Director

Miriam Komaromy, MD, FACP, DFASAM

Region IX Director

Peter Selby, MBBS, CCFP, FCFP, MHSc, DFASAM

Region X Director

Scott Teitelbaum, MD, DFASAM

Ex-Officio

Joseph M. Garbely DO, DFASAM

Stuart Gitlow, MD, MPH, MBA, DFAPA, DFASAM

Randolph P. Holmes, MD, FASAM

Michelle Lofwall, MD, FASAM

Penny S. Mills, MBA

Aleksandra Zgierska, MD, PhD

FOUNDING PRESIDENT

Ruth Fox, MD

1895-1989

March 14, 2019

Scott Gottlieb, MD

Commissioner

US Food and Drug Administration

10903 New Hampshire Avenue

Silver Spring, MD 20993

Janet Woodcock, MD

Director

Center for Drug Evaluation and Research

US Food and Drug Administration

10001 New Hampshire Avenue

Hillandale Building, 4th Floor

Silver Spring, MD 20993

Dear Commissioner Gottlieb and Dr. Woodcock,

On behalf of the American Society of Addiction Medicine (ASAM), a national medical specialty society representing more than 6,200 physicians and associated health professionals who specialize in the prevention and treatment of addiction, I am writing to you regarding the need for more medication treatment options for patients with substance use disorder (SUD). Foremost to ASAM's mission is increasing access to and improving the quality of addiction treatment. Patients with SUD, like all patients, should have available to them a robust and varied array of treatment options as no one treatment modality is appropriate or therapeutic for everyone.

Addiction is a complex condition. Clinicians and their patients need access to multiple, nuanced treatment options to meet their unique needs and circumstances. Access to multiple formulations and dosages expands the number of available effective and safe treatment options for SUD.

Therefore, as the FDA considers applications for new products to treat SUD, ASAM hopes that the FDA takes into consideration the need for access to multiple treatment options for clinicians and their patients. Expanding access to safe and effective treatment options for SUD can help advance efforts to address the nation's opioid overdose epidemic. Please contact Kelly Corredor, Senior Director of Advocacy and Government Relations at kcorredor@asam.org or (301) 547-4111 if you have any questions or would like to discuss this issue further. Thank you for your time and consideration of ASAM's concerns.

11400 Rockville Pike, Suite 200, Rockville, MD 20852

Phone: 301.656.3920 | Fax: 301.656.3815

www.ASAM.org

Sincerely,

A handwritten signature in black ink that reads "Kelly J. Clark". The signature is written in a cursive style with a large, stylized "K" and "C".

Kelly Clark, MD, MBA, DFASAM
President, American Society of Addiction Medicine