



American Society of Addiction Medicine

4601 NORTH PARK AVENUE • UPPER ARCADE SUITE 101 • CHEVY CHASE, MD 20815-4520
TREAT ADDICTION • SAVE LIVES

OFFICERS

Acting President

Stuart Gitlow, MD, MPH, MBA, FAPA

Secretary

Herbert L. Malinoff, MD, FACP, FASAM

Treasurer

Lori Karan, MD, FACP, FASAM

Immediate Past President

Louis E. Baxter, Sr., MD, FASAM

BOARD OF DIRECTORS

Directors-at-Large

Paul H. Earley, MD, FASAM

Mark Kraus, MD, FASAM

Petros Levounis, MD, MA, FASAM

Judith A. Martin, MD

A. Kenison Roy, MD, FASAM

John C. Tanner, DO, FASAM

Regional Directors

Region I

Marc Galanter, MD, FASAM

Region II

David Pating, MD

Region III

John P. Femino, MD, FASAM

Region IV

Mark P. Schwartz, MD, FASAM

Region V

J. Ramsay Farah, MD, MPH, FAAP,
FACMP, FASAM

Region VI

Dora D. Dixie, MD

Region VII

John Epling, Jr., MD, FASAM

Region VIII

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

Region IX

Raju Hajela, MD, MPH, FASAM

Region X

Richard Graves Soper, MD, JD, MS, FASAM

Ex-Officio

Gavin Bart, MD, FASAM

Kelly Clark, MD, MBA

Brian Hurley, MD, MBA

Ilse R. Levin, DO

Surita Rao, MD

Scott Teitelbaum, MD

Penelope P. Ziegler, MD, FASAM

Penny S. Mills, MBA, EVP/CEO

FOUNDING PRESIDENT

Ruth Fox, MD

1895-1989

March 13, 2013

Margaret A. Hamburg, MD
Commissioner
US Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Docket No. FDA-2013-N-0001

Dear Dr. Hamburg,

The American Society of Addiction Medicine (ASAM) is pleased to have the opportunity to comment on the new drug application (NDA) 204442, PROBUPHINE (buprenorphine hydrochloride and ethylene vinyl acetate) subdermal implant, submitted by Titan Pharmaceuticals, Inc.¹

Foremost to ASAM's mission is a goal to increase access to and improve the quality of addiction treatment. The introduction of novel addiction pharmacotherapies supports this goal. Addiction patients, 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.

Probuphine has been shown to be safe and effective for the treatment of opioid dependence. It may be particularly beneficial for rural patients who have limited access to other opioid maintenance treatment options and for patients concerned about accidental pediatric exposure to prescription drugs. Like all medication-assisted opioid therapies, treatment with Probuphine should include regular counseling and ongoing monitoring for relapse, drug interactions and overdose risk. Furthermore, Probuphine providers should be knowledgeable about addiction treatment and be adept at safely implanting the device.

ASAM supports the development and manufacturing of drugs that aid in the treatment of addiction and applauds the efforts of manufacturers to minimize the risks of diversion, accidental exposure and/or overdose attributed to potentially addictive pharmaceuticals. Both are necessary to improve the care of people with addiction and to advance the field of treatment but, independent of similar efforts to advance prevention, education and recovery support services, not sufficient to fully address the causes and consequences of addiction.

ASAM looks forward to a continued collaboration with your agency and all of our pharmaceutical, prevention and treatment partners to promote advances in and increased access to alcohol and drug addiction treatment. Again, ASAM thanks the FDA for the opportunity to share our comments with the Psychopharmacologic Drugs Advisory Committee.

Sincerely,

A handwritten signature in black ink, appearing to read "Stuart Gitlow MD". The signature is fluid and cursive, with a large initial "S" and "G".

Stuart Gitlow, MD, MBA, MPH, FAPA

Acting President, American Society of Addiction Medicine

ⁱ Disclosure Statement: The American Society of Addiction Medicine has received unrestricted grants from Titan Pharmaceuticals, Inc., and from Braeburn Pharmaceuticals.