

September 14, 2016

U.S. Food and Drug Administration
Advisory Committees on Psychopharmacologic Drugs and Drug Safety and Risk Management
10903 New Hampshire Avenue
Silver Spring, MD 20993

**RE: Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the
Drug Safety and Risk Management Advisory Committee**

Dear Committee Members:

The National Council for Behavioral Health appreciates the opportunity to provide commentary on the labeling of prescription drugs that treat tobacco addiction. As an association representing more than 3,000 community-based behavioral health organizations that serve 10 million patients annually, the National Council strongly supports evidence based approaches to eliminating tobacco consumption by people living with behavioral health conditions and substance use disorders. We agree with the growing body of research which concludes that pharmacological interventions paired with behavioral health services are efficacious, and improve the likelihood of long-term tobacco abstinence. The National Council has long advocated for policies that maximize access to effective behavioral health, pharmacological, and medication-assisted treatment interventions. The National Council is also doing work to support tobacco cessation in states, tribes, and provider organizations across the country. To this end, we support the removal of the Food and Drug Administration's black box warning label on varenicline as it serves as an unwarranted barrier to treatment.

The National Council's position on this topic is informed by robust evidence indicating varenicline's effectiveness, and the fact that people living with mental health conditions and substance use disorders (SUD) are more likely to consume tobacco. Key considerations include:

People living with mental health conditions and SUD often experience shorter than average lifespans.

Research^{1, 2, 3} indicates that mental health conditions correlate with an increased risk of all-cause mortality compared with the general population, with people living with SUD experiencing a mortality risk that can contribute to a 10 to 20 year reduction in life expectancy.⁴ These disparate outcomes in mortality are likely exacerbated by tobacco consumption.

People living with mental health and substance use disorders are more likely to consume tobacco

The Substance Abuse and Mental Health Service Administration (SAMHSA) and the Center for Disease Control and Prevention (CDC) report that people living with mental health and SUD are

more likely to consume tobacco products.^{4,5} Of note, while people living with mental health conditions represent nearly a quarter of the overall adult population, they consume nearly 40% of all cigarettes.^{5,6} This correlation also holds true for more recent tobacco related products—a 2016 study that sampled smokers seeking mental health and/or substance use services at a VA hospital in Connecticut revealed that over 30% used electronic cigarettes.⁷

Adverse neuropsychiatric effects from the use of varenicline are very rare

Peer reviewed analyses indicate that when a mental health disorder is already present, varenicline has not been shown to exacerbate neuropsychiatric symptoms. Furthermore researchers have found that people without mental health conditions experience moderate to severe side effects significantly less often than those ingesting transdermal nicotine replacement therapy.¹²

When varenicline is used as prescribed, there is no evidence of increased risk of suicide, attempted suicide, suicidal ideation, depression or death.

In fact, studies show that pairing varenicline with behavioral health and/or other pharmacological interventions can reduce the likelihood of already rare adverse neuropsychiatric reactions among people that have a history of attempted suicide, suicidal ideation or depression.¹³

Eliminating tobacco consumption among behavioral health clients, staff, and practice settings requires the sensible deployment of all effective tools. Accordingly, the National Council urges the removal of the FDA’s black box warning for varenicline. Additional details are included as an addendum to this written testimony. Please contact Shelina Foderingham at (202) 684-3740, or ShelinaF@thenationalcouncil.org if you have any questions regarding this commentary.

Works Cited

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