

**The SKY Youth Biopsychosocial Program for Youth Empowerment:
Applications for Adjunctive Treatment for Youth Nicotine Addiction and Prevention**

Statement for FDA Hearing:

Eliminating Youth Electronic Cigarette and Other Tobacco Product Use: The Role for Drug Therapies – January 18, 2019

Synopsis:

The success of drug therapies for the treatment of adolescent nicotine addiction and for prevention may be improved by addressing the unique needs of this population. Current literature indicates the significance of multi-directional interactions between biology, psychology and social behavior in adolescents. Thus, providing behavioral strategies that effectively address such bio-psycho-social factors of adolescent addiction, as adjuvants to drug therapies, holds great potential for improving treatment outcomes.

Bio-psycho-social factors related to maintenance of addiction include withdrawal symptoms and stress-induced relapse. Those affecting risks for initiation of drug use include anxiety, depression, difficulty in regulating emotions, and social isolation. The SKY Youth Program has been extensively used to address these bio-psycho-social factors in more than 100,000 adolescents across the USA. It offers standardized tools to address these factors by: (1) teaching breathing techniques empirically demonstrated to significantly reduce the stress response (thereby reducing withdrawal symptom intensity, anxiety, and impulsivity), enabling healthy prefrontal cortex function for effective decision making, (2) empowering youth with skills to think independently and build resiliency, and (3) creating a supportive community among youth, fostering a sense of belongingness, shown to be more effective than ‘targeted programs’ that primarily focus on individual problem behaviors. Over all, this multi-faceted program offers an innovative, effective adjuvant to drug therapy by addressing the specific bio-psycho-social factors that affect youth.

Relevance of bio-psycho-social programs for factors driving youth e-cigarette use

In addressing youth, it is imperative to attend to the unique features of youth drug use related to the developing brain and their social-emotional status. The brain circuitry important for decision making, including the prefrontal cortex, is not yet fully mature in adolescents, often leading to impaired judgment. In addition, hormonal changes can lead to fluctuations in mood and emotional states that may confer vulnerability to substance use. Moreover, the influence of peers and other social pressures may result in an increase of stress, which impairs prefrontal cortex function and execution of resistance skills. A multipronged approach that addresses both the biological status of youth and these socio-emotional factors is critical for both treatment and prevention.

The inability to effectively manage stress increases the odds of a teen seeking temporary relief via drug/tobacco use. Unmanaged stress can also lead to development of a host of mental and physical health issues such as anxiety, depression, social isolation, aggression, and stress related illness. Bio-psycho-social programs are highly effective for prevention of harmful coping strategies such as tobacco/drug use because they provide tools for reducing stress and increasing resiliency. The SKY Youth Program integrates a fun, experiential, social-emotional learning curriculum with evidence based, breath-based practices. This provides a highly effective suite of tools for reducing stress and negative emotions. Specifically, the Program achieves this by:

- Providing simple tools documented to elicit deep relaxation (e.g., breathing techniques that balance autonomic nervous system function by increasing parasympathetic tone).
- Reducing the stress response/sympathetic drive that arises during drug withdrawal, thereby increasing the duration of abstinence during this challenging period.
- Addressing social-emotional protective factors for tobacco-use cessation/prevention. These include: emotion regulation, resilience and resistance skills, and social-emotional learning (SEL) skills.

Even the best-formulated resilience skills (i.e., resisting peer pressure) can be weakened when emotions are intensified. The practices taught in the SKY Youth Program foster responsiveness vs. reactivity by supporting healthy functioning of the prefrontal cortex, which supports constructive decision making. Moreover, since smoking cessation programs are much more likely to be successful when the smoker is motivated to quit, socio-emotional factors that drive motivation must be addressed in conjunction with drug therapies to ensure overall treatment success.

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