

FDA Broad Agency Announcement - Facilitate Development of Drug Therapies for Youth Tobacco Cessation

BAA Solicitation Number [FDABAA-18-00123N](#)

2.6 Facilitate Development of Drug Therapies for Youth Tobacco Cessation

Despite major progress over the past half-century, tobacco use remains the leading cause of preventable disease and death in the United States, with at least 480,000 people dying prematurely each year from diseases caused by cigarette smoking or secondhand smoke exposure.¹ Nearly all tobacco product use begins during youth and young adulthood.² While the current use of any tobacco product among U.S. middle and high school students has decreased from 2011-2017, there has been an alarming increase in e-cigarette use over this time. In fact, since 2014, e-cigarettes have been the most commonly used tobacco products among youth, used by 1.73 million (11.7%) high school students and 390,000 (3.3%) middle school students in 2017.³ Youth e-cigarette use raises a number of health concerns including risk of addiction to nicotine early on in life, potential harm to the developing adolescent brain, and exposure to chemicals including carbonyl compounds and volatile organic compounds known to have adverse health effects; the full range of possible health effects is not yet completely understood.⁴

In addition to the prevention of initiation, which will be the cornerstone of any successful effort to curb youth tobacco use, FDA is also exploring additional approaches to address this public health issue. One such approach may be the development of drug therapies, as part of multimodal treatment strategies including

¹ US Department of Health and Human Services. *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General*. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, 2014.

² Ibid.

³ Wang TW, Gentzke A, Sharapova S, et al. Tobacco Product Use Among Middle and High School Students — United States, 2011–2017. *MMWR Morb Mortal Wkly Rep*. 2018;67:629–633. In this study participants were asked about their use of the following tobacco products: cigarettes, cigars, smokeless tobacco, e-cigarettes, hookah, pipe tobacco, and bidis (small imported cigarettes wrapped in a leaf).

⁴ US Department of Health and Human Services. *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.

behavioral interventions, to support youth tobacco cessation. To date, research on youth tobacco cessation has been limited and focused on smoking (i.e., combustible products) cessation. FDA is interested in the topic areas described below. Of note, we believe that many of these issues will need to be addressed uniquely based on the type of tobacco product being used (e.g., combustible cigarette, e-cigarette, smokeless tobacco). Submissions should indicate what type of tobacco products will be addressed by the research and justification for any evaluation that combines multiple type of tobacco products.

2.6.1 The development of data or methods to evaluate the factors driving initiation and continuation of tobacco use among youth, as well as youth attitudes towards tobacco cessation.

2.6.2 The development of data or methods to identify youth tobacco users who may benefit from treatment with drugs intended for cessation. Factors to consider include age (older vs. younger adolescent), patterns of use (duration and frequency of use), clinical features (level of addiction, presence/absence of comorbidities including psychiatric disease), and type of tobacco product.

2.6.3 Identification and analysis of scientific, clinical, and societal factors that could either encourage or impede the conduct of clinical trials evaluating drugs intended for youth tobacco cessation. Evaluation of approaches that could be used to overcome identified barriers and encourage research.

2.6.4 The development of methods and study designs appropriate for the evaluation of drug therapies for youth tobacco cessation. Factors to consider include the identification of informative endpoints and the development assessment tools to evaluate these endpoints.

2.6.5 The development of data or approaches to support the use of extrapolation of data from approved smoking cessation therapies for adults to youth tobacco cessation.