



AMERICAN
PSYCHOLOGICAL
ASSOCIATION



May 20, 2019

RE: Youth Tobacco Cessation: Science and Treatment Strategies

(84 FR 12619; Docket No. FDA-2019-N-1107)

To Whom It May Concern:

Tobacco use and addiction, primarily in the form of cigarettes, continues to kill nearly a half million people in the United States every year. The College on Problems of Drug Dependence (CPDD), the American Psychological Association (APA) and the Society for Research on Nicotine and Tobacco (SRNT) support the conclusions of the 50th Anniversary Surgeon General's report that more needs to be done to turn the tide of this epidemic of death and disease. That includes accelerated research and implementation of evidence-based tobacco use prevention efforts and ensuring that all tobacco users have access to evidence-based treatments regardless of financial means, ethnic status and age, and recognition of the continuum of risk which places cigarettes and other combustible tobacco products as the most harmful form of tobacco use.

CPDD, APA and SRNT support FDA's efforts as espoused by then Commissioner Gottlieb and Center for Tobacco Products Director Zeller in their 2017 New England Journal of Medicine commentary which summarized FDA's course as follows: "The agency's new tobacco strategy has two primary parts: reducing the addictiveness of combustible cigarettes while recognizing and clarifying the role that potentially less harmful tobacco products could play in improving public health. We must also work toward a greater role for medicinal nicotine and other therapeutic products in helping smokers to quit and remain nonsmokers." ([Gottlieb and Zeller, 2017](#))

Unfortunately, tobacco control and policy efforts for youth focus almost exclusively on prevention only, whereas tobacco control efforts for adults also include treatment, and increasingly harm reduction. This bifurcated approach flies in the face of the [1994 Surgeon General's Report](#) and [1994 Institute of Medicine Report](#) which both concluded that not only does the vast majority of cigarette smoking begin before the age of 18, but by the age of 18 most cigarette smoking youth have already become dependent. That implies that they should be treated as seriously as adults for tobacco use disorder. Yet the vast majority of smoking and other tobacco use cessation research has focused on adults. In fact, over-the-counter smoking cessation nicotine replacement therapies (NRT) are labeled for sale only to persons 18 years of age or older. That labeling was not intended to prevent use by persons under age 18 and includes the following: "If you are under age 18, ask your doctor before use."

The few existing pharmacological studies conducted in youth have not been found effective for tobacco use cessation under the conditions studied. But the dearth of research makes it difficult to determine the most effective methods for smoking cessation intervention in youth, whether the treatment be pharmacological,

psychosocial, or a combination of both. Of even greater concern is the lack of knowledge about how to treat youth electronic cigarette users.

CPDD, APA and SRNT believe it is critical to intervene with young people who begin to smoke cigarettes and use other forms of tobacco products before they reach adulthood by which time the addiction has become overpowering for many of them. There have been many advances in the science of tobacco use, dependence and cessation, but unfortunately most of the youth-focused science is focused on prevention of tobacco use rather than treatment for those who have become dependent and desire to quit.

CPDD, APA and SRNT support rapidly accelerated research on several key areas:

1. Identify ways to achieve and maintain tobacco abstinence in youth.
2. Achieve a better understanding of the pattern of youth use of other tobacco products, including electronic cigarettes, considering the psychosocial factors and pharmacological factors and product characteristics that facilitate their uptake and continued use.
3. Achieve a better understanding of what motivates a quit attempt in youth and how to stimulate this motivation.
4. Develop innovative and appealing treatments that involve both novel psychosocial and pharmacological interventions. Because youth would be the focus of such research, clear guidelines for participation should be established with the input of experts and ethicists involved in human research with non-adult populations.
5. When effective treatments are established for youth, it will be critical to conduct additional research on the best means of communicating the benefits of treatment(s) that don't undermine prevention programs.
6. The absence of strong evidence that treatments that work for adults work for adolescents does not mean that heavily dependent young people should not be treated with the same evidence-based medicines (e.g., NRT and varenicline). Young people merit special attention and the decision to recommend such medicine should be made on an individual basis. We recommend consideration of the discussion of these issues by the [American Academy of Pediatrics](#).

Even with accelerated programming, CPDD, APA and SRNT recognize that it may be several years before the recommended research would come to fruition. In the meantime, CPDD, APA and SRNT encourage FDA to continue the implementation of its Youth Tobacco Prevention Plan and its expansion of "The Real Cost" campaign. CPDD, APA and SRNT stand ready to work with FDA, NIDA and other federal agencies to develop new research as quickly as possible. Thank you for the opportunity to express our support for this important topic.

Respectfully,



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