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September 12, 2025

Martin Makary, M.D., M.P.H.
Commissioner
Food and Drug Administration
Attn: Dockets Management Staff (HFA-305)
5630 Fishers Lane, Room 10601
Rockville, MD 20852

**RE: Agency Information Collection Activities; Proposed
Collection; Comment Request; The Real Cost Campaign
Outcomes Evaluation Study: Cohort 3
Docket No. FDA-2025-N-1600**

Dear Dr. Makary,

Truth Initiative appreciates the opportunity to comment on “The Real Cost” Campaign Outcomes Evaluation Study: Cohort 3. Truth Initiative supports the FDA’s implementation of the Evaluation of FDA’s Public Education Campaign on Teen Tobacco (ExPECTT) Cohort 3 study. An evaluation of “The Real Cost” campaign will demonstrate its tremendous positive impact and provide insights that strengthen the campaign’s ability to educate young people and prevent tobacco product initiation. Truth Initiative urges the FDA to recognize the enormous public health value of “The Real Cost” campaign and to allocate appropriate funding and resources to support its continued role in reducing youth tobacco use.

Truth Initiative is a national nonprofit public health organization committed to a future where commercial tobacco and nicotine addiction are a thing of the past. Our mission is to prevent youth and young adult nicotine addiction and empower quitting for people of all ages. Both Truth Initiative and the FDA are committed to advancing youth tobacco prevention through our respective public education campaigns. Our proven-effective, nationally recognized truth® campaign has prevented millions of young people from smoking. truth®, targeted towards young adults ages 18 to 24, complements “The Real Cost” campaign’s focus on educating youth ages 12 to 17. By coordinating our efforts and tailoring our messages to distinct population segments, truth® and the FDA have maximized our collective impact, contributing to a dramatic decline in youth tobacco use.

The use of tobacco and nicotine products among youth is a significant public health crisis with profound impacts on youth well-



being. The tobacco industry has historically aggressively targeted young people in their marketing strategies,¹ identifying young adult smokers as ‘replacement smokers’ and youth as ‘learners’ in industry documents.^{2,3} In 2024, nearly 1 of every 59 high school students reported that they had smoked cigarettes in the past 30 days.⁴ E-cigarettes are currently the most commonly used tobacco product by U.S. youth, with 1.63 million youth reporting use of e-cigarettes in 2024. Additionally, of those youth who reported use of e-cigarettes, nearly 40% of them report vaping frequently – a clear sign of growing nicotine dependence.⁵ E-cigarette use exposes youth to harmful chemicals, including nicotine, which is highly addictive and poses dangers to adolescent brain development, negatively affecting memory, attention levels, and ability to learn.^{6,7} E-cigarette products also expose youth to synthetic or toxic chemicals and metals, some of which have been linked with developmental issues, lung disease, and cancer.⁸

Tobacco use is the leading preventable cause of chronic diseases including heart disease, stroke, cancer, respiratory diseases, and high blood pressure.^{9,10} In 2015, more than 16 million people in the United States lived with at least one serious illness or disease caused by smoking.^{11,12} Because tobacco product use is started and established primarily during adolescence,¹³ preventing the use of tobacco products by youth and adolescents is essential to averting a chronic disease crisis.

In order to combat the use of tobacco products by youth, the FDA launched “The Real Cost” campaign in 2014.¹⁴ The campaign is designed to prevent the initiation of cigarette smoking among youth aged 12 to 17 years who have never smoked but are susceptible to smoking and to discourage further smoking among youth who have experimented with smoking in the past.¹⁵ To address the rapid increase in e-cigarette use among youth observed between 2013 to 2017, FDA expanded its messaging in 2018 to educate youth about the harms of e-cigarette use.¹⁴

“The Real Cost” campaign has been highly successful in educating youth and preventing tobacco use initiation. It has influenced key outcomes, including awareness of campaign messages, targeted beliefs, and tobacco-related behaviors. In 2023, about 67% of youth reported seeing at least one e-cigarette ad from the campaign, and exposure was linked to stronger perceptions of the harms of tobacco and e-cigarettes.^{14,16} The Real Cost has been instrumental in reversing the trajectory of youth vaping, driving rates down from a peak of 5.4 million in 2019 to about 1.6 million today—back to levels seen before the epidemic emerged.^{5,17} The campaign has also prevented hundreds of thousands of adolescents from starting to smoke, including an estimated 444,252 youth aged 11–18 from initiating e-cigarettes between 2023 and 2024.^{18,19}

“The Real Cost” has also proven exceptionally cost-effective. Between 2014 and 2016, it prevented 175,941 youth from becoming established smokers, saving more than \$31 billion in health-related costs. Overall, the campaign generated \$180 in savings for every dollar of the nearly \$250 million invested in its first two years.²⁰



Evaluating the program through the ExPECTT Cohort 3 study will enable the FDA to identify opportunities for improvement, making the program even more effective in addressing the evolving landscape of tobacco products. Regular and rigorous assessment is crucial to maintaining the ongoing success of “The Real Cost,” ensuring its positive outcomes for at-risk youth are sustained and strengthened. The evaluation process allows “The Real Cost” to ensure that its mission of educating youth ages 12 to 17 about the dangers of tobacco use is being achieved.

It is critical that the ExPECTT Cohort 3 study evaluate “The Real Cost” campaign’s effectiveness in reaching communities that have been historically targeted by the tobacco industry. The tobacco industry has a long history of targeting both the Black community and American Indians and Alaska Natives through predatory marketing,^{21,22} which has had serious consequences for these populations. While approximately 11.5% of all U.S. adults are current smokers, tobacco product use is substantially higher among American Indian/Alaska Native and Black adults, with nearly one in five individuals in these groups reporting current use of tobacco products. Among youth, American Indian and Alaska Native high schoolers have the highest prevalence of any tobacco use (21.1%) and e-cigarette use (15.5%) compared to the overall high school population (9.3% for any tobacco use and 7.7% for e-cigarettes).⁵ In order to ensure that “The Real Cost” is fulfilling its mission of educating and preventing initiation by at-risk youth, it is critical that ExPECTT Cohort 3 evaluate the “The Real Cost” campaign’s reach into these most at-risk communities that are targeted by the tobacco industry.

Similarly, the ExPECTT study must include questions related to gender in its information collection in order to evaluate whether “The Real Cost” campaign is effectively educating and preventing initiation among the most at-risk youth. The LGBTQ+ community is one of the most at-risk communities for using tobacco products. Because of stress due to social stigma and discrimination, peer pressure, aggressive marketing by the tobacco industry, and limited access to effective tobacco treatment, the LGBTQ+ community experiences disproportionately high tobacco use rates.^{23,24} Youth identifying with any sexual minority identity have 3-4 times the risk of using cigarettes, e-cigarettes, and smokeless tobacco compared to heterosexual youth,²⁵ and prevalence of tobacco use for transgender youth is about 2-3 times that of cisgender youth.^{26,27} Adolescent onset of nicotine/tobacco use is associated with greater risk of chronic, persistent, and dependent patterns of nicotine/tobacco use into adulthood,²⁸ and sexual and gender minority youth are more likely to transition to regular and frequent tobacco use in adulthood.²⁹⁻³¹ Because of the increased risk to the LGBTQ+ community of lifelong tobacco use and potential for subsequent chronic disease, it is imperative that “The Real Cost” campaign incorporate interventions and materials that specifically target this at-risk community and that analysis of the campaign specifically include questions that help measure success among this population.

Thank you for the opportunity to submit comment on the “The Real Cost” Campaign Outcomes Evaluation Study: Cohort 3. Please do not hesitate to contact Stacey Gagolian,



Senior Vice President of Public Policy at sgagosian@truthinitiative.org, should you need more information or have questions about this submission.

Sincerely,

A handwritten signature in black ink that reads "Kathy Crosby".

Kathy Crosby
CEO and President



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