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Title of Initiative: Novel and innovative commercial tobacco cessation interventions in populations that experience health disparities.

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Objective: This initiative will support novel and innovative intervention research to reduce tobacco cessation disparities.

Background: Commercial tobacco smoking is one of the leading preventable causes of death in the United States. While the smoking prevalence based on national estimates has decreased significantly over the past 50 years, smoking has become increasingly concentrated in populations that experience a range of tobacco-related diseases and conditions and use. For example, in 2021, the combustible tobacco use prevalence was 14.5% overall, with higher estimates among people who report low household income (20.6%), live in rural (20.1%) vs. urban areas (13.6%), and who identify as lesbian, gay or bisexual (18.8%). The combustible tobacco use prevalence by race and ethnicity are as follows: Black or African American, 16.4%; White, 15.9%; Asian, 7.0%; Hispanic or Latino, 9.9%; and other racial or ethnic group, 18.0%. The combustible tobacco use prevalence was even higher for Native Hawaiian and Pacific Islanders (26.5%, reported in 2018), as well as American Indians and Alaska Natives (29.3%, reported in 2020). Among U.S. adults who smoke, 28.8% report menthol cigarette use, which varies significantly by race or ethnicity; Black or African American adults have the highest prevalence of menthol cigarette use (73%) compared with White adults (21.5%) and Mexican American adults (19.2%). Among individuals who report any tobacco smoking, the proportion of non-daily use has risen from 19.2% in 2005 to 25.0% in 2018.

The tobacco use prevalence reflects a myriad of structural factors, including lack of access to evidence-based and culturally specific tobacco cessation interventions, lack of insurance coverage for treatment, and lack of provider intervention/counseling/offer of support to quit. Moreover, there are also disparities related to smoking cessation. For example, the quit ratio among persons who ever smoked is lowest among Black or African American adults (53.7% vs. White adults 67.9%, and Asian adults 70%). Hispanic or Latino people are less likely to receive clinician advice to quit smoking relative to White people and interventions addressing the culturally specific needs of Native Hawaiian or Pacific Islander adults who wish to quit smoking are scarce. Finally, despite the increase in non-daily smoking, this group is often excluded from clinical

trials, and there is a lack of evidence-based interventions targeting people who report non-daily smoking.

There are well-established tobacco cessation interventions, such as behavioral counseling and U.S. Food and Drug Administration-approved pharmacotherapies. When used in combination, these interventions double the odds of long-term smoking cessation. However, delivery of these interventions to the populations with the greatest burden of tobacco use and those that report non-daily smoking remains relatively limited. There is a significant need to increase the reach and improve the effectiveness, delivery, and engagement of evidence-based interventions (focusing on treating the whole person), particularly those that provide a comprehensive approach to reducing tobacco use disparities and improving health outcomes. Furthermore, existing approaches to increase and sustain high reach, engagement, and intervention/treatment completion may need culturally specific strategies to address unique factors among populations with health disparities from systems levels to individual levels. Other important considerations include but are not limited to adverse social determinants of health, comorbid physical and mental health conditions, co-use of tobacco with other substances, nondaily/intermittent tobacco use patterns, and discrimination-induced stress.

There is also an urgent need for novel and innovative tobacco cessation interventions. Traditional methods may fall short in reaching diverse populations and maintaining long-term engagement. Emerging technologies and data science offer promising avenues to enhance these efforts. For instance, technology-based solutions such as mobile health apps, digital therapeutics, and wearable devices can provide personalized, real-time support and resources to make cessation programs more accessible and adaptable to individual needs. Artificial intelligence (AI) and machine learning (ML) can further refine these interventions by analyzing vast datasets to predict relapse risks, customize treatment plans, and identify populations needing more effective assistance. Integrating these advanced tools could revolutionize tobacco cessation interventions by providing targeted, scalable solutions that address both physiological, behavioral, and contextual factors, ultimately improving outcomes and reducing tobacco-related disparities.

This concept directly builds on the recent U.S. Department of Health and Human Services Smoking Cessation Framework objectives to reduce smoking and cessation-related disparities. It also addresses the White House Office of Science and Technology Policy's Prevention & Screening Task Force and Cancer Moonshot goals to increase smoking cessation rates and expand the use of effective cancer prevention approaches and their implementation. In alignment with this charge, the *NIMHD Strategic Plan goal 3 on "developing and testing interventions to reduce health disparities"* research calls for the exploration of innovative and improved approaches to reach and engage populations that experience health disparities. In addition, innovative dissemination and

implementation, as well as community-engaged models to improve utilization and participation with evidence-based interventions are needed. This may involve adapting communication strategies/campaigns, intervention delivery, and wraparound support to address social needs and other social determinants of health. Current NIH research efforts relevant to tobacco showed that very few awards focused on the evaluation of smoking cessation interventions, and none focused on novel strategies to address health disparities in populations disproportionately impacted by tobacco-related diseases or with known cessation disparities, including people who smoke intermittently or non-daily and those who co-use tobacco and other substances or evidence-based linkage models of care delivery treating the whole person.

Description of Initiative: This initiative seeks to stimulate novel and innovative intervention research to reduce tobacco cessation disparities among NIH-designated populations that experience health disparities. The area of focus will include the cessation of combustible tobacco products, including people who report non-daily smoking.

Research Priorities: Areas of interest include but are not limited to:

- Developing, implementing, and evaluating innovative interventions to help people who smoke tobacco products successfully quit, including non-daily smoking.
- Studies that use data science approaches, including AI/ML, to customize treatment plans, deliver just-in-time interventions more effectively, and predict relapse risks for the populations of interest.
- Studies that test evidence-based linkage models of care delivery via different platforms (e.g., telemedicine, mobile units, community organizations) to facilitate tobacco cessation interventions. Of interest are studies that engage community-based clinics, such as federally qualified health centers and/or community-based organizations to test intervention effects and sustainability and treating the whole person.
- Developing novel or adapting existing interventions to address the needs of populations experiencing health disparities, such as the prevalence of co-morbid physical and mental health conditions, menthol tobacco smoking, co-use of tobacco with other substances, and discrimination-induced stress.
- Studies investigating the effectiveness of digital and mobile health interventions, such as apps, telehealth, and wearables in reaching underserved populations and improving cessation rates are of interest.
- Leveraging existing large datasets to evaluate tobacco-related disparities. This may include examining the cost-effectiveness of tobacco cessation, quitting attempts, and professional services used in unique populations and/or settings.

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- Identifying and/or addressing the impact of national and local policies on populations that experience health disparities. This may include studies to understand the impact of novel or existing policies (e.g., smoking bans, advertising bans, tobacco taxes, health warnings, and banning sale of cigarettes in pharmacies) on combustible tobacco cessation efforts.

