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July 30, 2023

Office of the Assistant Secretary for Health
Office of the Secretary
Department of Health and Human Services
200 Independence Avenue, S.W. Washington, D.C. 20201

Submitted to: HHSSmokingCessationFramework2023@hhs.gov

RE: Document Number 2023-13928, Request for Information: Draft HHS 2023 Framework to Support and Accelerate Smoking Cessation

To Whom It May Concern:

On behalf of the American Association for Cancer Research's (AACR) more than 54,000 members consisting of laboratory researchers, physician-scientists, other health professionals, and patient advocates who constitute our national and international membership, we thank the Department of Health and Human Services (HHS) for the opportunity to provide information regarding the Draft HHS 2023 Framework to Support and Accelerate Smoking Cessation.

Despite decades of decreasing tobacco use across populations, cigarette smoking remains the leading preventable cause of premature disease and death. Annually, active and secondhand smoking is estimated to cause over 480,000 deaths in the United States (1,2). Tobacco use also has a profound impact on cancer incidence and mortality as it is attributed to 20 percent of all cancers diagnosed in the United States and nearly 30 percent of cancer deaths each year (3). To curtail the persistent burden of tobacco-related illness, implementation of evidence-based policies and programs to treat tobacco use are of the utmost importance. There are considerable benefits associated with smoking cessation including: improved cardiovascular and lung function, decreased risk for heart disease, and decreased risk for cancers across multiple organ systems (4). It is alarming, in light of increased awareness of the harms of tobacco use, that disparities remain in the offering of tobacco cessation assistance and treatment (5,6). The Draft HHS 2023 Framework to Support and Accelerate Smoking Cessation seeks to ensure access to comprehensive, data-driven cessation treatments that will benefit all populations. We appreciate the opportunity to comment on this Framework as this would provide the foundation necessary to support equity in tobacco cessation treatment access, thus meeting the Cancer Moonshot goal of ending cancer as we know it.

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Responses to Solicited Questions:

1. **Are the proposed goals appropriate and relevant for addressing the needs of populations disparately affected by smoking?**

AACR Finds the Proposed Goals Appropriate and Relevant for Addressing the Needs of Populations Disparately Affected by Smoking.

Tobacco use is known to cause at least 18 different cancers and is the top preventable cause of cancer and cancer-related deaths (7). Over the last 60 years, the national cigarette smoking rate decreased considerably from approximately 40 percent to 11.5 percent as a result of smoke-free laws, tobacco taxes, advertising restrictions, evidence-based smoking cessation programs, and awareness campaigns (8). However, disparities remain in successful tobacco cessation across medically underserved groups for many reasons, including predatory marketing by the tobacco industry (e.g., menthol and other flavored cigarettes), inconsistent insurance coverage for tobacco cessation therapies, and variability in the clinical advice received related to tobacco cessation.

2. **Do the broad strategies capture the key components and aspects needed to drive progress toward increasing cessation?**

AACR Encourages Further Development of The Framework Strategies to Drive Progress Toward Increasing Tobacco Cessation.

Most people who use tobacco products do so because they are addicted to nicotine, the major addictive component in tobacco. Although most users express a desire to reduce their use or stop entirely, overcoming nicotine addiction is incredibly difficult. Tobacco use in any form is one of the strongest threats to public health. Therefore, coordinated efforts are needed to enforce existing tobacco policies while ensuring equitable access to pharmacological interventions and behavioral therapy.

Following the passage of the Family Smoking Prevention and Tobacco Control Act of 2009 (TCA), the U.S. Food and Drug Administration (FDA) was given the authority to regulate tobacco product manufacturing, marketing, and distribution; including reducing nicotine in tobacco products except to zero. AACR and other public health-focused organizations have consistently urged FDA to set maximum nicotine concentrations to 0.4 milligrams of nicotine per gram of tobacco (9) and prohibit menthol cigarettes (10). In 2022, FDA responded by announcing plans to develop a proposed standard to establish maximum nicotine levels to reduce addictiveness in cigarettes and other selected combusted tobacco products (11). Reducing levels of nicotine to very low levels in combustible cigarettes have been shown to aid in reducing nicotine dependence and tobacco consumption (12–15) and is projected to avert 8.5 million

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tobacco smoking related deaths by 2100 (16). Additionally, FDA published a draft product standard to prohibit the manufacturing, distribution, or sale of menthol cigarettes (17). Several studies suggest that between 25 and 64 percent of adults who smoke menthol cigarettes would stop if menthol cigarettes were not available (18). Additionally, it is estimated that a federal menthol ban could save 654,000 lives within 40 years, which includes 255,000 African American lives saved (19). While the TCA prohibited flavored cigarettes, it exempted other tobacco products like flavored little cigars and cigarillos. Two thirds of adults who currently use these products have smoked cigars with flavors other than tobacco and African American and Hispanic adults are more than twice as likely as non-Hispanic White adults to smoke little cigars or cigarillos (20). To address these trends, FDA also proposed a draft product standard in May 2022 banning the manufacturing, distribution, or sale of flavored cigars (21). This policy is estimated to prevent 112,000 youth and young adults from initiating cigar smoking every year, and therefore decrease premature deaths from cigar smoking by 21 percent (22). AACR strongly supports tobacco product standards that reduce nicotine in cigarettes and cigarette-like products (e.g. little cigars, cigarillos) or other selected combusted tobacco products to minimally addictive levels, prohibits menthol flavored cigarettes, and any amount of natural or synthetic cooling agents, and flavored cigars (23,24). Thus, formally proposing a nicotine product standard, finalizing and implementing the proposed rules on menthol cigarettes and flavored cigars would greatly support the strategies to decrease tobacco cessation disparities described in the Draft Framework.

3. Are there additional goals or broad strategies that should be included in the Framework?

AACR Encourages Further Support for Community Services That Will Benefit Those at Greatest Need.

Smoking causes 78 percent of all lung cancer deaths among women with an estimated 59,910 women dying in 2023 alone (25,26). For adolescent and adult women of childbearing age, AACR encourages adding strategies to the Framework that increase access to tobacco cessation services including, especially for girls and women of childbearing age.

Additional contributing factors that perpetuate tobacco cessation disparities are income and insurance status. Concurrent with setting maximum nicotine concentrations to proposed minimally addictive nicotine levels and banning menthol cigarettes and flavored cigars, it would be important to increase evidence-based smoking cessation resources and programs to support cessation attempts across all populations. When considering income demographics, 26 percent of people with annual incomes less than $35,000 use tobacco products compared to 14 percent of people with annual incomes greater than $100,000 (27). Tobacco product use among adults that were either uninsured or Medicaid enrollees reach close to 30 percent compared to16 percent of adults with private insurance (28). People that are uninsured or publicly insured overwhelmingly

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receive their primary care at Federally Qualified Health Centers (FQHC), which are community-based health care providers that receive federal funds to service medically underserved communities. Expanding the capacity of FQHCs provides an opportunity for targeted tobacco cessation services across populations with high tobacco use rates (29).

In alignment with increasing access to high quality, comprehensive cessation treatment, it is imperative to improve coverage for tobacco cessation treatment across Medicare, Medicaid, and private insurance. AACR and partner organizations encourage additional guidance for insurers to cover all FDA-approved medications/pharmacotherapies and all three forms of counseling, including individual, group, and telephone counseling without cost-sharing, pre-authorization, or other barriers to access.

4. What targeted actions should HHS (Department-wide or within a specific HHS agency) take to advance these goals and strategies?

AACR Encourages the Center for Drug Evaluation and Research to Proactively Support Instructions for the Most Effective Use of Nicotine Replacement Therapy and Access to Non-Nicotine Replacement Therapy Medications.

One of the most important steps that can be taken by a person that uses tobacco products, regardless of age, is to quit smoking. In 2015, nearly 70 percent of adults in the United States that smoked expressed that they wanted to quit (30). In 2018, almost 55 percent of adults that smoked made quit attempts in the past year but only 8 percent were successful in quitting for 6-12 months (27). Quit rates increase when clinicians and health care providers are able to consistently identify and treat tobacco use in their patients (31). Currently, there are seven FDA approved cessation medications, five forms are nicotine replacement therapy (NRT), and two forms are non- nicotine replacement therapy (non-NRT). The patch, gum, and lozenge are the only NRTs available without a prescription. To increase access to cessation medications and therapies, AACR encourages the Center for Drug Evaluation and Research (CDER) to proactively convene a process to efficiently assure that all smoking cessation medications are labelled to reflect the best scientific evidence for use and assess whether any existing prescription smoking cessation medications can be used safely and effectively over-the-counter. It is paramount that CDER utilizes existing authorities to encourage the development of additional cessation medications for both adults and children.

The likelihood of successfully quitting further increases when cessation medications and NRTs are used in combination with behavioral counseling (32). In 2004, the National Tobacco Cessation Quitline Network was established with the goal to provide cessation services to people in all states and territories. During 2019, the National Tobacco Cessation Quitline Network received its ten millionth call (33). State quitlines, which are modeled after the National Tobacco Cessation Quitline Network, are also effective as they deliver evidence-based smoking treatment

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by trained counselors that coordinate the provision of FDA approved pharmacotherapy. AACR and partnering organizations strongly encourage that HHS provides support assuring all states can offer the maximum level of quitline support for all populations, including those that have been medically underserved. Improving and expanding the quitline effectiveness and impact could include providing all quitlines a minimum of 48 weeks of FDA-approved smoking cessation medications, either varenicline or combined NRT, at no cost to the caller. Offering the most effective use of nicotine replacement therapy that is available, along with behavioral support, should be a top priority.

5. What metrics and benchmarks should be included to ensure that the Framework drives progress?

AACR Encourages the Promotion of Research to Develop Additional Cessation Approaches for Youth and Adults

Increased research on accelerating smoking cessation, particularly using real-world community driven data, is key to eliminating disparities in tobacco cessation. Collaboration across HHS, including implementing Funding Opportunity Announcements that support high potential projects that can inform policy development at the local, state and federal level are critical. Moreover, NIH funding mechanisms could be modified to support large sample size Phase III investigations to get key results relatively quickly and support regulatory submissions in the absence of industry funded programs. It is crucial to move new results into practice more quickly.

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Concluding Remarks

AACR supports the goals and strategies highlighted in the Draft HHS 2023 Framework to Support and Accelerate Smoking Cessation. The AACR encourages collaborative, culturally aware efforts to address the tobacco cessation needs of medically underserved populations. These comments are based on careful discussion and evaluation by the AACR's AACR Tobacco Products and Cancer Subcommittee (roster attached) and are approved by the AACR's CEO, Chair of the Tobacco Products and Cancer Subcommittee, and Chair of the Science Policy and Government Affairs Committee. If the AACR can provide any additional information or assistance to HHS, please do not hesitate to contact Calais Prince, PhD, Associate Director of Science and Health Policy at calais.prince@aacr.org.

Thank you again for the opportunity to comment on this important issue.

Sincerely,

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