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US Department of Health and Human Services

Via: HHSSmokingCessationFramework2023@hhs.gov

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Dear Ms. Boateng

Request for Information: Draft HHS 2023 Framework to Support and Accelerate Smoking Cessation

We are responding to the request for comment on the Department of Health and Human Services proposed smoking cessation framework.[1] We have read and support the response made by David Abrams and others. We wish to add a further comment in response to three questions posed in the request for comment.

Summary

it is far harder to quit *nicotine* completely than to switch between different ways of taking nicotine because nicotine is the principal dependence-forming agent in tobacco products. The key breakthrough in *smoking* cessation will come from decoupling smoking cessation from a requirement to also quit nicotine. Smoking cessation without nicotine cessation will deliver almost all the health and welfare benefits for individuals but will also increase success rates and extend the reach to many more smokers. The key to achieving this is to recognize a consumer-based model of switching between high- and low-risk nicotine products *alongside* a medicalized model of treating smoking as a substance use disorder and attempting to achieve abstinence from smoking and nicotine. Success or otherwise of the consumer model depends on the communications, regulatory, fiscal, and innovation environment, and the knowledge and conduct of healthcare and public health professionals.

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

The goals are incomplete as specified; they should stress overall outcomes and recognize the negative welfare impact of some tobacco control policies. The goals should highlight the imperative outcome of reducing disease, premature death, and other negative welfare impacts of smoking. It is essential to acknowledge that *tobacco control policies* purposefully place burdens on people who smoke, such as regressive taxation, social restrictions, and stigma ("denormalization"), to incentivize smoking cessation. For people who continue to smoke, disproportionately represented in groups with various forms of

[1] Department of Health and Human Services, Request for Information: Draft HHS 2023 Framework To Support and Accelerate Smoking Cessation, June 30, 2023. 88 FR 42377

disadvantage, these policies impose welfare burdens in addition to the health burdens of smoking itself. This framing establishes an ethical imperative to promote smoking cessation as rapidly and widely as possible, using whatever respectful means are the most effective in reducing the overall health, well-being, and welfare burden of smoking.

This philosophy is known as *tobacco harm reduction*. It is an extension of the broad concept of harm reduction widely employed in other areas of public health, such as control of the harms of HIV, teenage pregnancy, and illicit drugs.

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

***No*, the broad strategies as described are necessary but not sufficient and overlook the most promising game-changing strategy**. The broad strategies listed for comment do not engage with critical insights that could dramatically increase smoking cessation, including among those who struggle hardest to quit. We set out our reasoning below:

i. **Nicotine demand is more robust than any particular way of taking it.** The demand for nicotine is more resilient and inelastic than the demand for any specific method to deliver it, such as cigarette smoking. This is why nicotine is often referred to as 'addictive' or dependence-forming. A subset of the population likely experiences real or perceived hedonistic, functional, or therapeutic rewards from using nicotine, and these form the basis of reinforcement.

ii. **Nicotine cessation is not necessary to achieve major health gains from smoking cessation.** Nicotine is not directly responsible for most of the adverse health, well-being, and welfare impacts of smoking. These are caused by inhaling products of combustion of tobacco leaf. This should be uncontroversial. As a recreational drug, nicotine is comparatively benign: it does not lead to overdose, intoxication, violence, vulnerability, family breakdown, or loss of employment.

iii. **Making nicotine cessation a requirement for smoking cessation makes smoking cessation more difficult**. Health professionals have traditionally coupled *smoking* cessation with *nicotine* cessation and achieving *abstinence*. By making smoking cessation contingent on nicotine cessation, we have made it far more difficult than it needs to be, as nicotine withdrawal and craving must also be overcome. Even with a range of therapies designed to mitigate the effects of nicotine dependence, the smoking cessation success rate is low. The efficacy of these treatments in the field rather than in clinical trials is in doubt, and the reach of these treatments and strategies is limited to a small proportion of smokers already motivated to quit and, therefore, ready to seek out support. The public health impact is a function of real-world efficacy *and* reach (the number of people willing or able to try the strategy).

iv. **It is increasingly possible to decouple smoking cessation and nicotine cessation**. This is where the major breakthroughs in smoking cessation will be found. Quitting smoking without quitting nicotine will make smoking cessation success more likely, more widespread in the population, and make the end of the epidemic of smoking-related disease more imminent. This strategy also

offers the prospect of engaging smokers with minimal motivation or no intention of quitting smoking *because they like or need to use nicotine*. Such smokers have become known as 'accidental quitters.'

v. **Quitting smoking without quitting nicotine addresses nearly all the risks associated with tobacco and nicotine use**. Smoking cessation addresses almost all the risks of disease and premature death and significantly improves welfare (fitness, etc.). It also eliminates policy-induced harms from tobacco control measures that have been justified by the harms arising from smoking, at least to the extent that such policies are applied to cigarette smoking only and not indiscriminately applied to all forms of nicotine use.

vi. **Quitting smoking without quitting nicotine does not foreclose a later attempt to quit nicotine**. A two-stage pathway with smoking cessation followed later by nicotine cessation may make an easier, more viable pathway to abstinence, particularly given that some non-nicotine reinforcing agents, such as MAOIs, in cigarette smoke may not be present in smoke-free products. There is some evidence that this pathway is common. Even if complete abstinence is ultimately unattainable or unwanted, the first step, *smoking cessation*, will have achieved nearly all the public health and welfare gains associated with abstinence.

The HHS smoking cessation strategy should recognize that there are essentially two models of smoking cessation:

1) **A medicalized approach**, in which the user is conceptualized as a patient with a substance-use disorder, undergoes rapid cessation and is treated with medications and talking therapies to build motivation and overcome craving and withdrawal. They may remain abstinent, ideally permanently, but will often relapse to smoking as the months pass.

2) **A consumer approach**, in which a person who smokes will switch to a different type of nicotine product on their own initiative and at their own expense. Their intention is to use nicotine *differently* and in a way that harms them less but may be experienced as just as pleasurable or more. They may move gradually through 'dual use' to exclusive non-combustible use. Even if these pathways to smoking cessation are a by-product of consumer nicotine-seeking behavior, they still count as smoking cessation from a public health and welfare perspective.

A national strategy for smoking cessation should recognize, endorse, and encourage both approaches. However, it should also acknowledge that they are conceptually very different and, from the users' perspective, involve entirely different motivations and intentions. But that is why, taken together, they are likely to reach a far larger share of the at-risk population.

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

***Yes*. The critical game-changer for smoking cessation is the effective promotion of tobacco harm reduction for smoking cessation**. The most promising new direction is the consumer-based tobacco harm reduction model discussed above. The effectiveness of tobacco harm reduction is not primarily a

function of the low-risk products that must displace cigarettes (vapes, heated or smokeless tobacco, oral nicotine, etc.) but an emergent characteristic of the system of behavioral influences on smoking behavior. These influences include:

- **Communications**. The truthful communication of risks and benefits and the encouragement of public bodies such as the CDC, the Surgeon General, and the FDA is essential both to build and earn public trust. At present, the American public is highly misinformed about the relative risks of different tobacco and nicotine products and about the role of nicotine in smoking-related disease. Much risk communication targeting youth is misleading and far adrift from science. It may be contaminating adult risk perceptions and degrading trust.

- **Regulation**. A coherent risk-proportionate approach to regulating combustible and much lower-risk non-combustible nicotine products is necessary and possible. The regulatory regime is currently *anti-proportionate*; easy on the incumbent 3,000 cigarette products in widespread circulation but extremely hostile to low-risk smoke-free entrants to the market.

- **Innovation**. The barriers to entry of new forms of low-risk nicotine products are exceedingly high, expensive, and time-consuming. The most modern, safe, and effective products available in most jurisdictions in the world are denied to Americans through the FDA's interpretation and execution of its duties under the Tobacco Control Act.

- **Fiscal**. A coherent, risk proportionate approach to tobacco and nicotine taxation. The fiscal regime should encourage migration from high-risk to low-risk nicotine products and never be a barrier.

- **Professional conduct**. The conduct and beliefs of health professionals and frontline practitioners should be grounded in sound science and a problem-solving concern for health and welfare improvements. Pragmatic professionals concerned with health should endorse tobacco harm reduction and encourage the most entrenched smokers to give it a try.

The Department of Health and Human Services is well placed to function as a coordinator and "ringmaster" for a multi-stranded population-based framework for smoking cessation that incorporates both the medicalized and consumer models of smoking cessation.

We hope these comments are of value as the Department finalizes this important life-saving framework.

Yours sincerely,

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