

Edition 61 – Bringing Health Equity to the Forefront of Tobacco Product Regulation - HPHR Journal

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Citation

Bringing Health Equity to the Forefront of Tobacco Product Regulation. HPHR. 2022;61. DOI: 10.54111/0001/III2

Bringing Health Equity to the Forefront of Tobacco Product Regulation

Over the last 55 years, cigarette smoking rates in the U.S. have declined considerably among adults, reaching the lowest level ever recorded (<u>12.5 percent</u>) in 2020. This represents one of the greatest public health achievements of the past century, resulting in millions of lives saved. Similarly, cigarette smoking has declined considerably among U.S. youth, with rates peaking in the mid-1990s and declining steadily ever since. However, among persons who smoke, progress hasn't been experienced equitably. Smoking disproportionately affects communities including, but not limited to, certain racial and ethnic populations, low-income populations, people living with mental health conditions, and LGBTQI+ individuals.

The tobacco product landscape has also diversified, particularly in recent years, to include a variety of combustible and non-combustible products. There is no safe tobacco product; however, products do exist on a continuum of risk, with combustible products being responsible for the overwhelming burden of disease and death from tobacco use. Within the U.S., patterns of tobacco product use vary across product types and population groups; for example, by race/ethnicity, e-cigarette use is highest among White youth, while cigar use is highest among Black youth.

Having recently taken on the role of <u>Director of the FDA's Center for Tobacco Products (CTP)</u> after working in tobacco control science for the better part of the past two decades, I recognize that we are in a pivotal time. In the 13 years since the landmark <u>Tobacco Control Act</u> (<u>TCA</u>) was signed into law, CTP has done significant work to effectively research, regulate, and educate in a complex and rapidly changing tobacco product landscape.

We also have a tremendous opportunity to create meaningful change for populations that have been <u>disproportionately affected by</u> <u>tobacco use</u>. The FDA is uniquely positioned to address tobacco-related health disparities in several impactful ways, now and in the coming years, so that tobacco-related disease and death are a part of America's past, not America's future, *for all populations*.

We're specifically addressing tobacco-related disparities through four key areas: tobacco product regulation, public health education and communication, sound science, and strategic relationships.

A Population-Based Approach to Health: The Importance of Tobacco Product Regulation

Many of our regulatory actions are aimed at reducing tobacco-related health disparities.

For example, in 2021, the FDA issued a final rule on the content, format, and review of Premarket Tobacco Product Applications (PMTA). A PMTA is a type of application for any new tobacco product seeking an FDA marketing order. The rule ensures that applicants address the potential effects of permitting the marketing of a new tobacco product to vulnerable populations to assess the potential

effects on such groups as part of the FDA's assessment of the effect on the population as a whole. The PMTA rule defines 'vulnerable populations' to mean groups that are susceptible to tobacco product risk and harm due to disproportionate rates of tobacco product initiation, use, burden of tobacco-related diseases, or decreased cessation.

The FDA had also issued a <u>final rule that requires new health warnings for cigarette packages and advertisements</u>. The FDA undertook a science-based approach to develop and evaluate the new cigarette health warnings. The 11 finalized cigarette health warnings represent the most significant change to cigarette labels in more than 35 years and will considerably increase public awareness of lesser-known, but serious negative health consequences of cigarette smoking. Some groups that disproportionately suffer from the harms of smoking, such as those with lower education levels and non-English speaking groups, have less knowledge about the negative harms of smoking and have lower health literacy. The collective scientific evidence demonstrates that pictorial cigarette warnings, such as the required warnings in the final rule, are effective across diverse populations and will help reduce disparities.

More recently, our proposed <u>menthol cigarette and flavored cigar rules</u> would help address longstanding health disparities related to smoking menthol cigarettes and flavored cigar products. The TCA had previously prohibited all characterizing flavors, excluding menthol, in cigarettes.

Included among those who are more likely to smoke menthol cigarettes are Black Americans, other racial and ethnic minority groups, youth and young adults, female adults, persons with less than a high school diploma, and individuals who identify as lesbian, gay, or bisexual. Scientific evidence indicates that <u>menthol cigarettes</u> have historically been and continue to be disproportionately marketed in underserved communities. For example, nearly 85 percent of all non-Hispanic Black adults who smoke use menthol cigarettes, compared to 30 percent of non-Hispanic White adults who smoke.

Addressing how these products affect populations at disproportionately higher risk for tobacco product use would yield significant population level public health impacts. Published modeling studies estimate that if menthol cigarettes were no longer available in the U.S., we could see a 15 percent reduction in smoking overall within these same 40 years; it would also avoid 324,000 to 654,000 smoking attributable deaths over the course of 40 years, 92,000 to 238,000 of those among Black Americans.

Prohibiting characterizing flavors, other than tobacco flavor, in cigars would reduce the appeal of cigars, particularly to youth and young adults. This would decrease the likelihood of experimentation, development of nicotine dependence, and progression to regular use. More than half of youth who smoke cigars, including little cigars and cigarillos, use flavored cigars (around 550,000 youth). Additionally, use of flavored cigars, including flavored little cigars and cigarillos, is <u>especially</u> common among Black, Asian, and Hispanic youth when compared to their White peers as well as young adults who identify as lesbian, gay, or bisexual when compared to their heterosexual peers.

The FDA is developing a proposed product standard that would establish a maximum nicotine level to <u>reduce the addictiveness of</u> <u>cigarettes</u> and certain other combusted tobacco products, which would also have profound health equity implications. The proposed rule would reduce tobacco related disease and death by promoting cessation and preventing initiation, potentially saving millions of lives and keeping the next generation from becoming hooked.

The Language We Use Matters: Public Health Education and Communication

Clear, transparent, and timely communication is vital to advance health equity. We're living in a time in which people receive communication and information in a variety of ways, and we must leverage the full diversity of those mechanisms to reach key populations, particularly youth and young adults at high risk for tobacco product use, and those who are disproportionately impacted by the negative health consequences of tobacco products.

Rooted in science, the FDA's <u>tobacco public education campaigns</u> are critical to our public health mission. From the foundation, we've developed a suite of tailored, evidence-based campaigns that have adapted and evolved over time based upon unique messaging needs for populations disproportionately impacted by tobacco use.

Through meaningful consideration of health equity, we've implemented: "<u>Fresh Empire</u>" cigarette use prevention campaign (reaching African American, Hispanic, and Asian American/Pacific Islander youth), "<u>This Free Life</u>" cigarette use prevention campaign (reaching LGBTQI+ young adults), "<u>The Real Cost</u>" smokeless tobacco use prevention campaign (reaching rural male youth), and "<u>Every Try</u> <u>Counts</u>" campaign (reaching adults in 35 U.S. counties with high smoking rates to encourage them to quit).

Our award-winning public education campaign, "<u>The Real Cost</u>," continues to prevent youth from starting and continuing to use tobacco products. In its first two years, <u>research showed "The Real Cost</u>" prevented up to 587,000 youth ages 11 to 19 from initiating smoking, half of whom might have gone on to become established adult smokers. Since then, we've been researching and implementing creative ways to find and reach teens most at-risk for tobacco product use to help close the gap on the remaining populations disproportionately impacted by tobacco product use within this demographic.

This year, we launched "<u>Next Legends</u>" – a new youth e-cigarette use prevention campaign that aims to educate American Indian and Alaska Native (AI/AN) youth about the harms of vaping. Native youth are more susceptible to tobacco product use than their non-Native peers, and they demonstrate disproportionately high experimentation and current use of e-cigarettes. This campaign includes unique branding and tailored messaging specifically designed for AI/AN youth.

The terminology we use matters as well. In accordance with our commitment to diversity, equity, inclusion, and accessibility, we've updated the term <u>"grandfathered tobacco product"</u> to <u>"pre-existing tobacco product"</u> to more clearly and appropriately describe these products. The term "grandfathered" – when used to describe someone or something exempt from a new law or regulation – has its roots in 19th century racist voting laws.

What Gets Measured Gets Done: Sound Science to Achieve Health Equity

Science is central to informing tobacco regulatory decision making. As a scientist by training, I'm particularly attuned to the vital importance of ensuring we gather and use the best scientific evidence available, as well as sharing our findings and collaborating with the scientific community to collectively advance health equity.

We ground ourselves in the best science by making sure that we embed health equity into each step of the research process. One example of this is taking health equity into account when creating our core set of demographic measures for studies used to develop and evaluate public health education campaigns. As part of our latest effort to update these measures to reflect the most up-to-date data on populations of interest, we've expanded answer choices for gender identity and sexual orientation along with improved measures for socioeconomic status.

We've also expanded questions in our routine population-based surveys. For example, the <u>Population Assessment of Tobacco and Health</u> (<u>PATH</u>) <u>Study</u> revised and expanded its sexual orientation and gender identity questions to align with the National Academies of Sciences, Engineering and Medicine's 2022 recommendations for measuring gender identity and sexual orientation. These changes will be implemented beginning with Wave 7.5 data collection, which is planned for 2023 and will survey youth and young adults.

As noted, our public health education campaigns are aimed at addressing tobacco-related health disparities in populations disproportionately affected by tobacco product use. Before we embark on those campaigns, we first conduct extensive qualitative and quantitative formative research to establish messages that are evidence-based and authentic with the communities we are trying to reach.

Two examples of this are the research we did leading up to the launch of our "Next Legends" and "The Real Cost" smokeless campaigns. For our "Next Legends" youth e-cigarette use prevention campaign, we worked with a Native-owned agency with over 20 years of experience working with AI/AN tribes and communities and convened a meeting of 14 subject matter experts (community leaders, tribal elders, and Native teens) to advise on areas of cultural sensitivity and receptivity. For our "The Real Cost" smokeless tobacco use prevention campaign, we conducted ethnographic research with rural male adolescents, who bear the disproportionate burden of smokeless tobacco product use, to better understand their lives before we began developing campaign messages.

This research helped us craft public health education campaigns that spoke authentically to the intended audiences and reflected an understanding of key cultural aspects and community norms. By doing so, we were able to better reach disproportionately affected populations with critical messages they needed to help reduce tobacco-related health disparities.

We're also working diligently to ensure tobacco-related disparities are explored in scientific reporting. Since 2011, the FDA has supported 448 CTP-funded publications to address tobacco disparities. These publications resulted from CTP-funded projects including grants administered by NIH; contracts; interagency agreements and other partnerships; and internal CTP staff research.

It Takes a Village: Fostering Strategic Relationships

It's critical to cultivate and sustain relationships – both within and outside the FDA – to best achieve our mission and advance health equity. We strive to engage with a wide array of stakeholders, including those that work with and represent individuals and communities who are disproportionately impacted by tobacco use, to facilitate an open exchange of opinion from diverse groups. This outreach includes holding consultation with federally recognized tribes on proposed rules.

We've co-sponsored the Society for Public Health Education (SOPHE) <u>Tobacco and Health Equity Focus Issue</u> with FDA's Office of Minority Health and Health Equity. We also work across HHS and at the interagency level to advance health equity, including participating in the <u>Healthy People 2030 LGBT Health Workgroup</u>, <u>Healthy People 2030 Social Determinants of Health Workgroup</u>, and HHS LGBTQI+ Coordinating Committee, Research and Data Subcommittee. Through the rulemaking process, we have also engaged with key stakeholders in the development of proposed product standards, including those related to menthol cigarettes and flavored cigars.

In March of this year, we launched a new suite of <u>cigarette cessation education posters</u> for adults who use tobacco products and public health stakeholders. The posters feature positive, motivational cessation education messages and are tailored for a range of audiences, including LGBTQI+ individuals and young adults who smoke. In collaboration with our partner, the National Alliance for Hispanic Health, several of the <u>posters were culturally tailored and trans-created in Spanish</u>. In fact, we make many of our <u>materials accessible to Spanish-language audiences</u>.

As part of the education posters and other smoking cessation messaging efforts, we direct audiences interested in quitting smoking to <u>EveryTryCounts.gov</u>, developed in collaboration with the National Cancer Institute. We recognize the importance of ensuring broad and equitable access to all the tools and resources that can help those who smoke to quit. Through this invaluable collaboration, we're able to provide quitting tips, cessation text messaging programs, and online cessation counseling in both English and Spanish.

We are committed to fostering relationships with stakeholders directly. By building these partnerships, we can extend our reach to communities that may not see our messages through traditional communications avenues. As we work to reduce tobacco-related health disparities, we will leverage existing relationships to build new ones in order to expand our interactions with and engage the broadest range of stakeholders who can help us to gain insight on and reach populations at high risk for tobacco use.

Continuing to Advance Health Equity Moving Forward

Reducing tobacco-related health disparities has been a foundational component of CTP's policies and programs as part of our mission to protect and advance public health by helping to reduce harm from tobacco products. However, there's more that can be done, and it's time to swing the spotlight onto these actions and intensify our efforts to address tobacco-related health disparities. Toward that end, we've recently announced the addition of the position of Senior Advisor for Health Equity to CTP's leadership team to help lead our center's work in this area.

As we move forward, we encourage you to join us as we bring health equity to the forefront of tobacco product regulation and public health education. For example, if you're a public health professional looking to help reduce tobacco-related health disparities, we have free resources in our <u>Tobacco Education Resource Library</u> that can assist you. Likewise, our new <u>Vaping Prevention and Education</u> <u>Resource Center</u> provides science-based, standards-mapped materials that public health educators can use to help teens understand the dangers associated with vaping and nicotine addiction.

We also invite you to subscribe to our emails and follow our progress to advance health equity.

About the Author



Brian A. King, PhD, MPH (he/him/his)

Dr. Brian King was appointed Director of the Food and Drug Administration's Center for Tobacco Products (CTP) in July 2022. In this position, Dr. King is responsible for assuring that CTP accomplishes its public health goals and for operationalizing the Center's vision and mission as it implements the Family Smoking Prevention and Tobacco Control Act.

Dr. King has worked for nearly two decades to provide sound scientific evidence to inform tobacco control policy and to effectively communicate this information to key stakeholders, including decision makers, the media, and the general public. Prior to joining FDA, he served as the Deputy Director for Research Translation in CDC's Office on Smoking and Health, and more recently as the Executive Editor of CDC's Morbidity and Mortality Weekly Report Series. He has authored more than 200 scientific journal articles related to

tobacco prevention and control, served as Senior Associate Editor for multiple U.S. Surgeon General's Reports on tobacco, and was lead author of CDC's 2014 evidence-based guide, "Best Practices for Comprehensive Tobacco Control Programs."

Dr. King holds a Ph.D. and a M.P.H. in epidemiology from the State University of New York at Buffalo.