ADVANCING RACIAL EQUITY AND SOCIAL JUSTICE FOR BLACK COMMUNITIES IN UNITED STATES TOBACCO CONTROL POLICY

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Abbreviations
U.S. – United States; FDA – U.S. Food and Drug Administration

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ABSTRACT

The United States (U.S.) Food and Drug Administration (FDA) applies the Population Health Standard in tobacco product review processes by weighing anticipated health benefits against risks associated with a given commercial tobacco product at the population level. However, systemic racism (i.e., discriminatory policies and practices) contributes to an inequitable distribution of tobacco-related health benefits and risks between white and Black/African Americans at the population level. Therefore, Black-centered, anti-racist data standards for tobacco product review processes are needed to achieve racial equity and social justice in U.S. tobacco control policy. Regardless of whether FDA implements such data standards, non-industry tobacco scientists should prioritize producing and disseminating Black-centered data relevant to FDA's regulatory authority. We describe how systemic racism contributes to disparities in tobacco-related outcomes and why these disparities are relevant for population-level risk assessments, then discuss four possible options for Black-centered data standards relevant to tobacco product review processes.

WHAT THIS PAPER ADDS

- Existing standards for tobacco product review processes weigh anticipated health benefits against risks at the population level, but tobacco-related racial disparities driven by underlying social and economic inequities that are rooted in systemic racism create an unbalanced status quo. On March 4, 2021, the United States Food and Drug Administration released a funding opportunity announcement calling for research to establish data standards for ongoing tobacco product review processes, and such data standards could be leveraged to advance racial equity in tobacco control policy.

- Through a Black-centered lens, we summarize existing evidence of the many complex factors that contribute to tobacco-related racial disparities, describe how these contributing factors are relevant to existing criteria for reviewing tobacco product applications, and highlight opportunities for future research seeking to inform data standards for tobacco product review processes.

BACKGROUND

In 2009, the Family Smoking Prevention and Tobacco Control Act extended the United States (U.S.) Food and Drug Administration's (FDA) regulatory authority over pharmaceutical drugs to include the manufacture, distribution, and marketing of commercial tobacco products,[1] including e-cigarettes and cigars as of 2016.[2] Consequently, FDA is responsible for tobacco product review processes, including premarket and modified risk tobacco product applications. The "safe and effective" evaluation criteria employed by FDA for pharmaceutical drugs are irrelevant when evaluating tobacco products. Instead, the focus shifts to minimizing harm at the population level. As such, tobacco product review processes apply a set of three criteria – together referred to as the "Population Health Standard" – to estimate the likely net public health impact of a given tobacco product given the current status quo: a) Risks and benefits to the population as a whole, including users and nonusers of tobacco products, b) Increased or decreased likelihood that existing users of tobacco products will stop using such products, and c) Increased or decreased likelihood that nonusers will start using tobacco products.[3]

In *theory*, the Population Health Standard makes sense – data on population-level benefits are weighed against data on population-level risks (e.g., likelihood of cessation among all tobacco users versus likelihood of initiation among all nonusers in the U.S. population) and the balance of evidence must lean in favor of anticipated public health benefits rather than risks for any given tobacco product. This is problematic in *practice* given an overwhelming body of evidence demonstrating that systemic racism creates an unbalanced status quo in the U.S.[4–6] Decades of discriminatory policies and practices in the U.S. result in unequal access to healthcare, residential segregation, mass incarceration, and police brutality, which greatly impact population health and contribute

to racial disparities in tobacco use and tobacco-related health outcomes,[5–7] [8] but systemic racism is not explicitly considered in current data standards for tobacco product review processes. Without anti-racist data standards, the default outcomes of tobacco regulatory decision making based on the Population Health Standard as is disproportionately value white Americans and devalue Black Americans—a group that has experienced a long and well-documented history of systemic racism in the U.S. To achieve equity in tobacco control, assessments of population-level risks must consider that the baseline level of risk is not equal across the population.

On March 4, 2021, FDA released a funding opportunity announcement calling for research to establish data standards for ongoing tobacco product review processes.[9] This announcement may encourage tobacco scientists to develop study aims relevant to informing such standards, thus, creating opportunities to establish evidence-based, systemically anti-racist data standards. We describe how systemic racism contributes to disparities in tobacco-related outcomes and why these disparities are relevant for population-level risk assessments, then discuss four possible Black-centered data reporting requirements that could be formally imposed on manufacturers submitting tobacco product applications (herein referred to as “firms”) and informally adopted among non-industry tobacco scientists.

TOBACCO-RELATED RACIAL DISPARITIES AND THE POPULATION HEALTH STANDARD

Existing evidence demonstrates that tobacco-related racial disparities between white and Black Americans are relevant to all three of the Population Health Standard criteria (a-c):

a) Risks and benefits to the population as a whole, including users and nonusers

In the context of the Population Health Standard, "risks" may include both direct effects (e.g., cardiovascular disease, nicotine dependence) and indirect effects (e.g., secondhand smoke exposure) associated with a tobacco product.[3] Reviews of population-level public health interventions have found that individuals who were formerly at lower risk for adverse health outcomes prior to program implementation derived more benefits compared to those who were formerly at greater risk.[10] This suggests that Black Americans – who are at greater risk for nearly every major tobacco-related disease relative to whites[11] – would likely receive fewer benefits from population-level approaches to regulating tobacco products. Direct and indirect risks related to tobacco use are further exacerbated by systemic and experienced racism in healthcare settings. Black Americans experience poorer quality healthcare compared to whites due to the impact of racial residential segregation on access to healthcare,[7,12] as well as implicit bias among health care providers,[13] which translates to poorer tobacco-related disease outcomes. On an interpersonal level, psychosocial distress caused by experienced race-based discrimination in healthcare, employment, education, housing, and a wide range of other structural domains cumulatively increases the likelihood of tobacco use and cardiovascular disease across the life course.[12,14]

Health risks associated with combustible tobacco use are greater among Black users and nonusers compared to whites. Although Black smokers consume fewer cigarettes per day compared to whites, Black smokers have a greater risk of lung cancer and cardiovascular disease,[15] and they are more likely to die prematurely from tobacco-related disease compared to whites of the same age.[16] Further contradictory to what we would expect given lower cigarette consumption among Black smokers relative to

whites, the prevalence of secondhand smoke exposure among Black youth is substantially greater compared to their white peers (66% vs. 38%, respectively).[17] The disproportionate health burden of secondhand smoke exposure spans across the life course, beginning in utero, and contributes to racial disparities in tobacco-related morbidity and mortality.[18] Smoking cessation is essential for reducing health risks associated with secondhand smoke exposure, but Black smokers experience poorer cessation outcomes compared to whites.[19]

The unbalanced baseline level of risk between white and Black Americans is also driven by the complex power differentials between the tobacco industry and Black communities that have compounded over decades. “The tobacco industry regards African Americans as a group with particular historic, social, and economic vulnerabilities,”[20] and, over the past several decades, sought to gain trust and maintain a favorable public image among Black communities by building connections with nearly every Black leadership organization in the U.S. For example, under the guise of generosity, the industry made significant donations to civil rights organizations that had difficulty securing funding from other sources; however, the industry seemingly viewed such “donations” as seed funding for future profits generated from Black tobacco users. Review of internal tobacco industry documents found that their motivations for performative activism were to increase tobacco use among Black Americans and gain public support (or lack of public protest) for industry policy positions.[20] Risk assessments must consider how the tobacco industry has disproportionately influenced the environments where Black tobacco users and nonusers perceive tobacco products and make decisions about tobacco use.

b) Increased or decreased likelihood that existing users of tobacco products will stop using such products

Although Black smokers make more quit attempts compared to white smokers,[19] Black smokers have lower cessation rates.[21] These trends defy logic yet are unsurprising when considered in the context of systemic racism. Black smokers are less likely to utilize evidence-based cessation pharmacotherapies while making a quit attempt, largely due to mistrust of the pharmaceutical industry, disbelief about efficacy, and fear that is rooted in direct public health harm from U.S. governmental agencies (e.g., police violence, Tuskegee syphilis experiment).[22–24] Healthcare providers could play a key role in addressing these concerns, but Black smokers are less likely than white smokers to have insurance coverage or receive smoking cessation support in healthcare settings.[25,26] Moreover, at the interpersonal level, Black smokers are more likely to experience race-based discrimination than whites, which is positively associated with tobacco use and negatively associated with tobacco cessation.[27,28]

The disproportionate burden of low cessation rates is inherently linked to both race and certain product characteristics, such as mentholated tobacco and flavored small cigars. Menthol cigarettes are more difficult to quit than non-menthol cigarettes,[29] and Black smokers are more likely to use menthols than white smokers (85% vs. 29%, respectively).[30,31] Additionally, Black tobacco users are more likely than whites to smoke flavored small cigars, which are associated with decreased quit intentions and increased nicotine dependence.[32] Cigars are commonly sold as singles for prices less than $1 (compared to cigarettes that can only be sold in packages of 20) and are more accessible in predominantly Black neighborhoods,[33,34] illustrating how regulations related to specific product characteristics (e.g., minimum pack sizes for small cigars) could play a key role in advancing health equity.

c) Increased or decreased likelihood that nonusers will start using tobacco products

Any nicotine exposure in nonusers is harmful to health, particularly during adolescence and young adulthood due to increased neural plasticity that increases the risk of developing nicotine dependence.[35] Psychological and physiological dependence on nicotine sustains tobacco use, indirectly contributing to tobacco-related morbidity and mortality.[35] As described above (b), Black tobacco users have poorer cessation rates than whites, thus, preventing initiation among Black nonusers is critical. Among the overall population, those who initiate tobacco use later in life have a decreased risk of premature mortality relative to those who initiate at a younger age, and, on average, Black users initiate tobacco use later in life compared to whites.[36] In theory, the observed later age of initiation among Black users should be associated with decreased risk of tobacco-related disease, but this is not observed in practice; stratified analyses have found that the decreased risk of premature mortality associated with later age of tobacco initiation is only significant among white users – no differential effects by age of initiation have been observed among Black users.[36] This highlights a significant limitation of study results that are not reported stratified by race.

Exposure to tobacco advertisements is a key driver of initiation among nonusers,[1] and race-based tobacco marketing strategies contribute to observed disparities in tobacco initiation.[17,31,37] The tobacco industry has a documented history of gathering extensive racial data on tobacco use patterns and collecting psychographic profiles among residents in neighborhoods with high concentrations of Black residents to pervasively market their products to this population.[38] Redlining and the subsequent impact of racial residential segregation facilitated such targeted marketing practices.[8]

Formerly redlined neighborhoods with high concentrations of low-income and Black residents have a greater density of tobacco retailers and advertisements,[8] particularly for combustible tobacco products.[33,34,39] Race-based marketing played a significant role in the disproportionate use of menthol cigarettes among Black (vs. white) smokers,[30,31] indirectly contributing to racial disparities in tobacco-related outcomes. Because menthol cigarettes facilitate smoking initiation,[29] the disproportionate use of menthol cigarettes among Black smokers translates to a disproportionate risk of initiation (and subsequent sustained use via disproportionate risk of nicotine dependence)[29] compared to whites.[30] Although FDA has recently announced its intent to ban menthol as a characterizing flavor in cigarettes and cigars, race-based marketing practices for other products with various characteristics could further contribute to health inequities and racial disparities in product initiation.

BLACK-CENTERED DATA STANDARDS

While the tobacco industry bears responsibility for racial disparities in tobacco use and tobacco-related morbidity and mortality, tobacco control policies to date have done little to rectify the consequences of the industry's actions. Tobacco-related outcomes among white users and nonusers have been systemically prioritized and centralized in tobacco policy decision making, resulting in a limited knowledge base on differential impacts by race from which to develop anti-racist tobacco control policies. Given the status quo of racial inequity in the U.S., regulatory action should seek to address racial inequities, and this approach requires Black-centered data.

First, FDA could require that firms report primary research findings stratified by race to identify anticipated racial differences in net population harm associated with the product under review. Although race is a social construct with no genetic or biological

basis,[5,6] race indicator variables are necessary to capture the effects of systemic racism on tobacco use and inform evidence-based, anti-racist tobacco control policies.[4] Unstratified estimates may preclude the ability to detect critical racial differences in tobacco-related health outcomes.

Second, FDA could require analytic samples with representative proportions of Black/African American research participants. Per the 2020 U.S. Census, approximately 13% of the U.S. population identifies as Black or African American, therefore, samples with fewer than 13% Black participants do not reflect the U.S. population. Data that are reasonably sampled and modeled to represent the U.S. population may yield more accurate assessments of anticipated public health benefits and risks.

Third, data standards could require direct comparisons of certain product characteristics by race, including menthol products and cigar pack sizes. Considering the already disproportionate prevalence of combustible tobacco product use among Black smokers, studies that directly compare product characteristics known to drive these disparities are needed to inform policies that will balance the status quo, rather than maintain – or potentially exacerbate – the unbalanced distribution of risks associated with combustible product use.

Fourth, although firms are already required to submit example marketing strategies, FDA could further require that firms include the specific populations(s) that they intend to target, as well as an assessment of other populations that could potentially be exposed and impacted by such strategies – whether intentional or not. As described above (c), exposure to tobacco advertisements is a key driver of initiation among nonusers, and Black Americans are exposed to a greater volume of tobacco advertisements.[33,34,39]

Potential data standards described here could provide FDA with information needed to make anti-racist regulatory decisions; however, tobacco firms could also exploit such standards for their benefit. The tobacco industry already engages in racial data gathering,[38] thus, legally requiring that firms report racial data may exacerbate the impact of these harmful practices under the guise of regulatory compliance. Any data standards that are implemented should be evidence-based and demonstrated to have worked well in practice; partnering with the Black community while developing anti-racist data standards may reduce the likelihood of unintended consequences. Although this paper focused specifically on comparisons between white and Black Americans, the fundamental argument can be extended to other tobacco-related disparities, including disparities among Hispanic/Latinx and Indigenous populations, individuals with mental health conditions, and sexual and gender minorities. Black-centered evaluations of federal, state, and local tobacco control policies beyond tobacco product review processes described in this paper are also needed.

CONCLUSION

Systemic racism contributes to disparities in tobacco use and tobacco-related morbidity and mortality between white and Black Americans. To achieve racial equity and social justice in tobacco control policy, Black-centered data are needed, and data standards for tobacco product review processes could be leveraged to meet this need. Regardless of such standards, non-industry research provides another layer of data for FDA to reference during regulatory decision making. Non-industry tobacco scientists should prioritize producing and disseminating Black-centered data relevant to FDA's regulatory authority over tobacco products.

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Ms. Sam Cwalina developed the concept, synthesized available data, wrote and edited the manuscript, and approved the manuscript as submitted. Dr. Ugonna Ihenacho synthesized available data, wrote and edited the manuscript, and approved the manuscript as submitted. Dr. Joshua Barker synthesized available data, wrote and edited the manuscript, and approved the manuscript as submitted. Dr. Sabrina L. Smiley synthesized available data, contributed to writing and editing the manuscript, and approved the manuscript as submitted. Dr. Mary Ann Pentz acquired funding support, provided supervision, contributed to concept development, writing and editing, and approved the manuscript as submitted. Dr. Heather Wipfli developed the concept, synthesized available data, provided supervision, contributed to writing and editing the manuscript, and approved the manuscript as submitted.

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