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EDITORIAL

The lingering question of menthol in cigarettes

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Abstract Tobacco use is the single most important preventable cause of cancer-related deaths in the USA and many parts of the world. There is growing evidence that menthol cigarettes are starter tobacco products for children, adolescents, and young adults. Accumulating research also suggests that smoking menthol cigarettes reinforces nicotine dependence, impedes cessation, and promotes relapse. However, menthol cigarettes are exempt from the US Food and Drug Administration ban on flavored cigarettes due, in part, to the lack of empirical evidence describing the health consequences of smoking menthol cigarettes relative to regular cigarettes. Determining the biological effects of menthol cigarette smoke relative to regular cigarette smoke can clarify the health risks associated with the use of respective products and assist regulatory agencies in making scientifically based decisions on the development and evaluation of regulations on tobacco products to protect public health and to reduce tobacco use by minors. We highlight the inherent shortcomings of the conventional epidemiologic, clinical, and laboratory research on menthol cigarettes that have contributed to the ongoing debate on the public health impact of menthol in cigarettes. In addition, we provide perspectives on how future investigations exploiting state-of-the-art biomarkers of exposure and disease states can help answer the lingering question of menthol in cigarettes.

Keywords Cancer · FDA · Health risk · Tobacco products · Smoke

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With the enactment of the Family Smoking Prevention and Tobacco Control Act (FSPTCA) in 2009, the US Food and Drug Administration (FDA) was granted authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health and to reduce tobacco use by minors [1]. In 2011, the Tobacco Products Scientific Advisory Committee (TPSAC) reported to the FDA that "menthol cigarettes damage public health," and recommended that "removal of menthol cigarettes would benefit public health in the USA" [2]. The TPSAC report has been substantiated by ample research, suggesting that smoking menthol cigarettes is a "gateway" to using other tobacco products, especially during childhood and early adulthood, increases nicotine addiction, deters quitting, and promotes relapse [3, 4]. Because smoking is our nation's leading cause of preventable death [5, 6], any ingredient that may encourage people to take up this deadly habit or reinforce this lethal addiction should be considered a significant public health concern. However, the FDA has not yet taken regulatory steps, including imposing a ban on menthol cigarettes despite banning all the other flavored cigarettes from the US market [1]. This lack of action may, in part, be due to the absence of empirical evidence describing the health consequences of smoking menthol cigarettes relative to regular cigarettes [7, 8]. Finding scientific underpinnings for the adverse health effects of smoking menthol cigarettes relative to regular cigarettes is of significance because it can help advance the FDA's mission of developing and evaluating regulations on tobacco products to protect the public's health and to reduce tobacco use by minors [1].

Menthol ($C_{10}H_{19}OH$), a monocyclic terpene alcohol derived from both natural and synthetic sources, is used as a flavoring agent in cigarettes and other consumer products [9–11]. Menthol cigarettes are manufactured by spraying

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this additive on tobacco, applying it to the packaging foil, or introducing it into the filter [12]. Menthol cigarettes account for a substantial portion of market share in the USA and many parts of the world; current market shares for mentholated brands include 26 % in the USA, 60 % in the Philippines, 35–40 % in Cameroon, 26 % in Hong Kong, 22 % in Singapore, and 5–10 % in other countries surveyed [13, 14]. Menthol cigarettes are disproportionally used by certain segments of the population [15]. In the USA, youths, women, and communities of color, particularly, African-Americans, Hispanics, and other racial and ethnic minorities of low income, are preferential users of menthol cigarettes [15–17]. The disparate use of menthol cigarettes by smokers of different gender, race, or ethnicity is thought to contribute, at least, partly to the uneven distribution of tobacco-attributable diseases across populations [18–22]. In support of this theory, over 70 % of African-Americans smoke menthol cigarettes as compared to 30 % of Whites [13, 23, 24], which is consistent with the higher incidence and mortality rates of lung cancer (36 and 31 %, respectively) in African-American men than in White counterparts [20, 25]. Also, the death rates from cerebrovascular disease, for which smoking is a major risk factor, are nearly twice as high among African-American men and women as those among White counterparts [21].

However, epidemiologic studies have not unequivocally linked menthol cigarette use as compared to regular cigarette smoking to the disparate burdens of tobacco-attributable diseases in different (sub-) populations [26–28]. Notwithstanding this, epidemiologic tools are too blunt to detect an augmented risk due to the presence of menthol in cigarettes, considering the overwhelming harm associated with smoking any type of tobacco cigarette [29, 30]. Additionally, epidemiologic studies are limited by real-world smoking patterns and the difficulties of identifying smokers who "exclusively" use menthol cigarettes for a long enough period of time to allow meaningful comparisons with non-menthol cigarette smokers [3]. Given the above limitations of the epidemiologic studies [29, 31, 32], it seems unlikely that conventional epidemiologic approaches would unambiguously tie menthol cigarette use to elevated risks of tobacco-related diseases across diverse populations [3, 4].

Likewise, clinical and basic laboratory research is yet to provide compelling empirical evidence that menthol cigarette use indeed causes greater or more severe biological consequences than regular cigarette smoking [4]. For example, clinical investigations of smoke-exposure biomarkers (e.g., serum cotinine or carbon monoxide) or smoking topography (e.g., puff frequency or puff volume) in menthol and non-menthol cigarette smokers have shown inconsistent results, with some reporting higher, some lower, and some comparable levels of the measured biomarkers/indices in the two smoking groups [3, 4]. Similarly, basic laboratory research on the biological effects of menthol and regular cigarette smoke has produced mixed results [4]. Whereas smoke inhalation experiments in rodents have indicated inconsistent tumorigenic effects for menthol cigarettes relative to regular cigarettes [33, 34], in vitro cell culture experiments have shown that menthol increases the permeation of tobacco carcinogen nitrosonornicotine and nicotine across mucous membranes and inhibits cell proliferation, and/or induces cytotoxicity [3, 4]. However, tobacco-industry-associated research has contended that menthol and regular cigarette smoke have similar levels of cytotoxicity in short-term bioassays [35]. Conversely, smoke chemistry studies have shown that the chemical composition of mainstream smoke of selected menthol cigarettes is different from that of non-menthol cigarettes [36]. Also, chemical analysis of the mainstream smoke of mentholated and regular cigarettes has revealed that menthol increases the yield of total particulate matter, onto which tobacco carcinogens, such as polycyclic aromatic hydrocarbons, and tobacco-specific nitrosamines, are deposited [37]. It is suggested that menthol may also retard nicotine metabolism and interfere with activation or detoxification of smoke toxicants, thus prolonging the existence of addictive, toxic, and/or carcinogenic compounds in the body [4, 38–41]. Furthermore, it is hypothesized that introducing a single agent, such as menthol, to tobacco may cause additional formation of a number of toxic and/or carcinogenic compounds in the smoke, which would not have emerged had menthol not been present [42]. Future clinical studies and basic laboratory research are expected to exploit cutting-edge technologies for biomarker discovery, which will enable robust comparisons of the biological effects of menthol and regular cigarette smoking. It is anticipated that these investigations will monitor state-of-the-art biochemical, cellular, or molecular markers in well-defined populations of menthol and non-menthol cigarette smokers, and also in validated model systems in vitro/in vivo.

Over the past decade, observational studies and clinical trials have increasingly investigated the effects of menthol on smoking initiation, addiction, and cessation [43]. The growing body of evidence supports that the minty and candy-like flavor, aroma, and topical cooling and anesthetic properties of menthol make mentholated cigarettes preferable to those who struggle to overcome their aversion to certain sensations of smoking, such as harshness, throat and chest irritation, and stale aftertaste [44–46]. By easing the discomfort associated with smoking and smoothening the smoking experience, menthol cigarettes may serve as a starter product for youth and young adults, thus helping facilitate the transition from experimentation to regular smoking and addiction [12, 47–49]. Furthermore, menthol

cigarettes are increasingly shown to promote nicotine dependence and adversely impact smoking cessation, especially among sub-populations of smokers, e.g., African-Americans or women [3, 29, 43, 50, 51]. Recent nationally representative studies in the USA and Canada [49, 51–60] have confirmed earlier reports [61–69] that menthol cigarette use is associated with increased nicotine addiction and reduced cessation success. Other studies, however, failed to demonstrate a significant difference in cessation-related outcomes between menthol and non-menthol cigarette smokers [26, 70–74]. The latter studies, however, have been criticized for not using sensitive and robust indicators of cessation, e.g., longitudinal abstinence trajectories [43, 51, 75]. In addition, these studies may have been underpowered to detect the effects of menthol, especially, within sub-populations of menthol and non-menthol cigarette smokers [51, 59]. Altogether, the emerging picture from the majority of the initial investigations and the most recent large-scale studies is that menthol is associated with smoking initiation in children and young adults and a heightened risk of cessation failure among habitual smokers [7, 13, 50].

Within the framework of the FSPTCA, the FDA and National Institutes of Health have formed an interagency partnership to foster research relevant to tobacco regulatory science. Multiple research priorities have been identified, including the impact of tobacco product characteristics, e.g., ingredients, constituents, components, additives, such as flavors, and labeling and marketing, on the initiation, especially among youth and other vulnerable populations, as well as the use (including transition to other tobacco products and multiple use), perceptions, dependence, and toxicity of the conventional and new tobacco products (https://prevention.nih.gov/tobacco-regulatory-science-program/research-priorities). The ongoing research and future investigations on these topics are expected to provide a compelling weight of evidence that can be used to inform the general public, scientific community, and regulatory authorities of the health risks/benefits associated with the use of various tobacco products, including menthol cigarettes. Not only this information will help generate further interests for scientists in the field of tobacco research, but it will also assist the regulatory agencies in developing and evaluating regulations on tobacco products to protect the public's health and to reduce tobacco use by impressionable teens and other vulnerable groups. The hope is that the studies supported by the FDA/NIH initiative will address the outstanding questions regarding the issue of menthol in cigarettes once and for all.

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Conflict of interest All the authors declare no conflict of interest.

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