ABSTRACT

Title of Dissertation: MENTHOL TOBACCO SALES RESTRICTIONS AT THE LOCAL LEVEL: COMMUNITY PERCEPTIONS, LESSONS LEARNED, AND POLICY EVALUATION

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Menthol cigarettes are a significant public health concern. While sales of regular cigarettes have declined in recent years, menthol cigarette sales are increasing. Known for their minty taste and cooling effects, menthol cigarettes are a starter product for youth. The tobacco industry has a long history of predatory marketing to African Americans, who are more likely to smoke menthol cigarettes, have lower quit rates, and experience higher tobacco-related mortality than white smokers. Because flavored cigarettes are appealing to youth, the 2009 Tobacco Control Act banned the sale of flavored cigarettes; however, menthol was exempted. Due to federal inaction on menthol, localities are enacting restrictions to address this social justice issue.

In 2017, Minneapolis, Minnesota was among the first U.S. jurisdictions to restrict menthol sales to tobacco shops and liquor stores. Grounded in the Social

Ecological Model, this dissertation utilized multiple methods to increase our understanding of the experience and impact of the Minneapolis menthol policy.

Study 1 examined African American adult smoker perceptions and found that many menthol smokers perceived menthol to be as harmful or more harmful than non-menthol cigarettes and emphasized the role of tobacco industry targeting to African American communities and youth. Participants also indicated mixed support for menthol policy restrictions.

Study 2 identified key factors that led to policy passage and included an in-depth assessment of critical steps in policy-making from policy formulation through adoption. The active engagement of youth and support of members of communities most impacted by menthol tobacco-related disparities were identified as critical to the policy's successful adoption.

Study 3 evaluated the impact of the menthol policy on the retail environment and found reduced menthol availability and decreased menthol marketing at the point-of-sale two months following policy implementation. Unintended consequences of the policy were also observed; two tobacco shops were added to convenience stores and continued to sell menthol tobacco.

Results from these studies provide critical insights from several phases of the policy process. Findings can inform other jurisdictions around the country interested in pursuing menthol restrictions to reduce the burden of tobacco use and advance health equity for priority populations.

MENTHOL TOBACCO SALES RESTRICTIONS AT THE LOCAL LEVEL: COMMUNITY PERCEPTIONS, LESSONS LEARNED, AND POLICY EVALUATION

by

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Dedication

This dissertation is dedicated to my parents, Joaquim and Blanche D'Silva, who made innumerable sacrifices, instilled in me the value of hard work, and provided love and encouragement throughout my academic journey across oceans and continents.

Amchea Purvozachim Sopnam Sarkim Zallim!

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Chapter 1: Introduction

1.1 Background

Tobacco[1] use remains the leading cause of preventable mortality globally and is projected to lead to one billion deaths in the 21st Century (World Health Organization, 2011). Menthol cigarettes, which make up over one-third of the cigarette market in the U.S. (Federal Trade Commission, 2018), have been linked to increased initiation among youth, increased addiction and decreased quitting (Tobacco Products Scientific Advisory Committee, 2011). The tobacco industry has a long history of predatory marketing to African Americans (Gardiner, 2004), who are four times more likely to smoke menthol cigarettes (Villanti, Johnson, et al., 2017) and are more likely to die from tobacco-related diseases than white smokers (American Lung Association, 2010). These tobacco-related disparities highlight the need for interventions to curtail the use of menthol cigarettes. Restricting the sale of menthol tobacco products is one policy-level approach that has the potential to have a greater impact on reducing the burden of smoking among African Americans. Yet, little published evidence exists for this promising pro-equity policy strategy.

Tobacco policy-level interventions seek to create health-promoting environments by addressing the underlying social determinants of health. The World

[1]*Tobacco* in this document refers specifically to the use of commercial tobacco products. Commercial tobacco is used to differentiate cigarette smoking and other tobacco use from the sacred and traditional use of tobacco by American Indians and other groups (Boudreau et al., 2016).

Health Organization (WHO) defines social determinants as "the circumstances in which people grow, live, work and age, and the systems put in place to deal with illness. These conditions in which people live and die are, in turn, shaped by political, social and economic forces, and are characterized by the unequal distribution of power, income, goods, and services; unequal access to healthcare, schools, and education; and conditions in work and leisure settings, homes, communities, towns, or cities" (WHO Commission on Social Determinants of Health & World Health Organization, 2008). By reducing access to menthol tobacco products at the point-of-sale, local menthol sales restrictions have the potential to change the physical and social environments that impact tobacco use behaviors, and thereby contribute to reducing tobacco-related disease (Garrett, Dube, Babb, & McAfee, 2015; National Cancer Institute, 2017).

1.2 Conceptual Framework

This dissertation is grounded in the Social Ecological Model, which provides a framework to assess and impact multi-level determinants of health (Bronfenbrenner, 1992; McLeroy, Bibeau, Steckler, & Glanz, 1988). Figure 1.1 depicts five levels of influence, including the individual, interpersonal, organizational, community, and policy levels, with associated concepts aligned with each study.

The Social Ecological Model emphasizes the dynamic relationship among behaviors, socio-political structures and health outcomes. This systems approach moves beyond individual-level determinants of behavior and underscores the synergistic impact of implementing multi-faceted interventions directed at addressing tobacco use (Corbett, 2001). At the highest level of influence, policies such as the

Minneapolis menthol restriction can impact the environments within which individual behaviors occur. Thus, policy-level interventions can foster health-promoting environments that reduce tobacco industry influence.

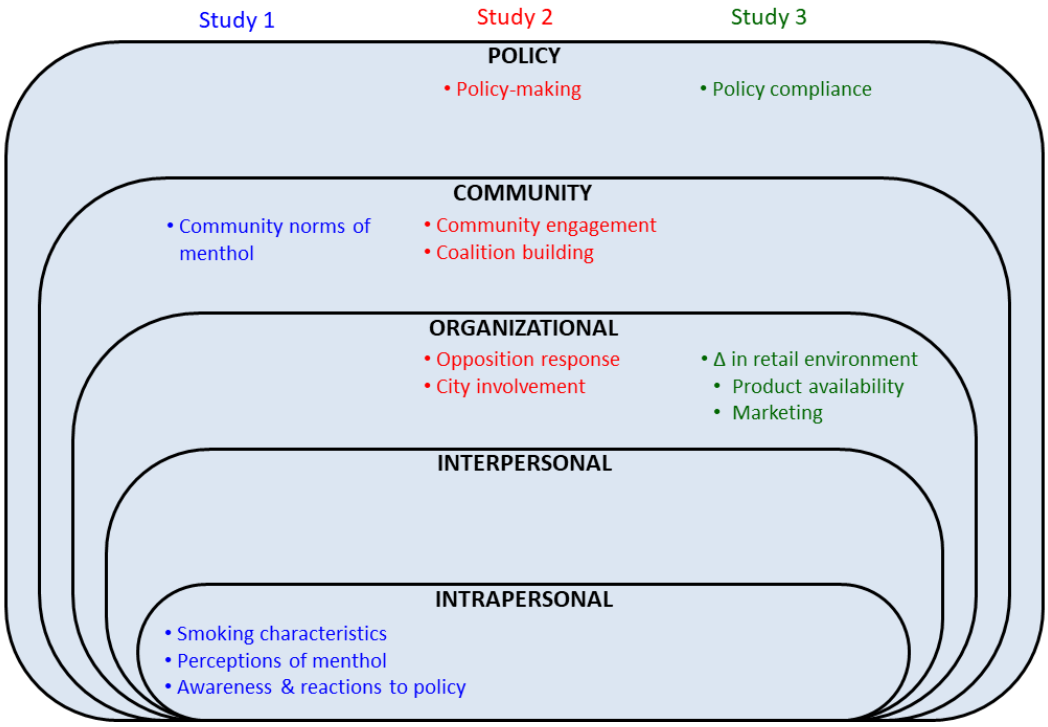

Figure 1.1 Conceptual Framework Grounded in the Social Ecological Model

Study 1 focuses on individual-level factors including smokers' characteristics, perceptions of harm related to menthol vs. non-menthol cigarettes, awareness of and reactions to potential policy options, as well as community norms regarding whether menthol is viewed as a problem in the community. With its focus on the policy change process, Study 2 addresses how menthol was identified as a policy priority and the overall story of policy passage from formation to adoption. It also includes community-level factors, such as community engagement and coalition building, as well as strategies led by change agents from affected communities and key

stakeholders. At the organizational level, key organizations who were involved in facilitating as well as opposing the proposed policy changes will be identified. Finally, Study 3 addresses compliance with the policy and measures changes at the organizational level by focusing on the tobacco retail environment.

1.3 Purpose of the Study

The Centers for Disease Control and Prevention (CDC) recommends interventions at the policy level as part of a comprehensive tobacco control strategy to reduce secondhand smoke exposure, promote cessation, and prevent initiation (Centers for Disease Control and Prevention, 2014). Policy interventions, such as increasing the price of tobacco products and creating smoke-free environments in public places, have largely been responsible for the decrease in overall smoking rates in recent decades (U.S. Department of Health and Human Services, 2014). These policies, which take a population-based approach to addressing tobacco use, have the potential to reach large segments of the population. However, the higher rates of smoking among some priority populations (Jamal, 2018) suggest that known population-level tobacco control strategies may not have equally benefited all segments of the population. As the retail environment continues to provide the tobacco industry with virtually unfettered opportunities to market and sell tobacco products, the need for efforts focused on reducing tobacco industry influence at the point-of-sale is evident (Ribisl et al., 2017). Accordingly, policies that prohibit the sale of menthol products can promote health equity by counteracting unhealthy retail environments that are pervasive in priority population communities (Centers for Disease Control and Prevention, 2016).

In 2017, Minneapolis, Minnesota was among the first cities in the U.S. to regulate the sales of menthol tobacco products. The policy went into effect on August 1, 2018, restricts the sale of menthol, mint, and wintergreen flavored tobacco products to tobacco shops and liquor stores.

According to the WHO (World Health Organization, 2005), there are five key phases in health policy-making including:

- Phase 1 – Problem Identification: Issues are clearly defined and framed within a political context;
- Phase 2 – Policy Formulation: Solutions to address the problem are identified and revised in an iterative process;
- Phase 3 – Policy Adoption: Governing entity's formal approval of the policy;
- Phase 4 – Policy Implementation: Enforcement and other actions whereby the policy is put into place; and
- Phase 5 – Policy Evaluation: Assessment of intended and unintended outcomes associated with policy implementation.

The overarching purpose of this dissertation was to gain an in-depth understanding of community perceptions (phase 1), identify lessons learned from the policy process (phases 1 - 3), and evaluate the impact of the Minneapolis menthol policy in the retail environment (phase 5).

1.4 Research Question, Specific Aims & Hypotheses

The overarching research question for this dissertation research was: "What is the experience and impact of the Minneapolis menthol policy?"

Aim 1: To identify African American adult smoker perceptions of menthol cigarettes and menthol policy.

Aim 2: To identify key factors that led to successful passage of the Minneapolis menthol policy.

Aim 3: To evaluate the impact of the menthol policy on the retail environment.

Hypothesis 3A: Intervention stores in Minneapolis have a significant decline in the *availability* of menthol tobacco products post-policy implementation compared to Brooklyn Park, the comparison city.

Hypothesis 3B: Intervention stores in Minneapolis have a significant decline in the *marketing* of menthol tobacco products post-policy implementation compared to Brooklyn Park, the comparison city.

Hypothesis 3C: Intervention stores in Minneapolis have a significant decline in the *availability* of menthol tobacco products post-policy implementation compared to tobacco shops and liquor stores, who are exempt from this policy restriction.

Rationale: Previous research evaluating point-of-sale restrictions demonstrated a significant decline in flavored (non-menthol) tobacco product availability following policy implementation (Farley & Johns,

2017). The majority (95%) of tobacco retail stores display tobacco marketing materials in the interior and exterior of the store (Ribisl et al., 2017). Therefore, we hypothesized that the removal of menthol tobacco from shelves results in a reduction of menthol tobacco marketing.

1.5 Public Health Implications

Since the 1960s, a body of evidence has detailed the detrimental effects of smoking and secondhand smoke exposure (U.S. Department of Health and Human Services, 2014). The 2014 Surgeon's General report detailed how smoking impacts nearly every organ in the body and causes cancer, cardiovascular, and pulmonary disease (U.S. Department of Health and Human Services, 2014). Tobacco-related disease is linked to over 6,300 Minnesotan deaths annually, causing more deaths than alcohol, murder, car crashes, AIDS, illegal drugs, and suicide combined (Blue Cross and Blue Shield of Minnesota, 2017). Smoking also costs the state $3.19 billion in direct health care costs annually (Blue Cross and Blue Shield of Minnesota, 2017). Despite significant progress in the reduction of overall smoking rates in Minnesota, priority populations continue to be disproportionately impacted by tobacco use (Boyle, D'Silva, Stanton, Carusi, & Tang, 2017). The widening gap in smoking prevalence highlights the urgent need for strategies to reduce tobacco use in populations most impacted by tobacco disparities (Boyle et al., 2017).

The objective of this research is to enhance our understanding of a point-of-sale strategy to restrict the availability of menthol tobacco products at the local level.

The results from these studies collectively have the potential to significantly impact policy and public health practice. For example, findings from the African American smoker interviews (study 1) provide insights into consumer perceptions and can inform messaging and community education campaigns on the harms of menthol tobacco products. These community perspectives will also be critical in informing community-engaged and community-led menthol policy-making efforts.

Lessons learned from the case study of the policy passage process (study 2) can help inform other jurisdictions around the country that may be pursuing menthol sales restrictions. The case study highlights industry and other opposition tactics that can be informative to policy-makers and advocates in crafting counter-arguments. Successes and challenges encountered during the policy change process can inform local advocates and policy-makers in ongoing local efforts to restrict tobacco use (e.g. Tobacco 21, which seeks to increase the minimum legal tobacco sales age from 18 to 21).

Finally, the retailer assessments (study 3) provide timely, real-world information about the primary (change in availability of menthol tobacco) and secondary (change in marketing of menthol tobacco) impacts of policy implementation in the retail environment. Study 3 findings can inform city staff who are charged with educating retailers and monitoring compliance over the long-term. If the policy does not have its intended effect, findings may provide evidence for removing exemptions or enacting additional restrictions, including restrictions at the state level, to mitigate any negative unintended consequences of the policy. Lastly, findings from all three studies will be of interest to the Food and Drug Administration

Center for Tobacco Products, which has authority over tobacco products and relies on scientific evidence in its regulatory decision-making.

1.6 Definitions of Terms

Established Smoker: For study 1, participants with daily cigarette use for five years or more were defined as established smokers.

Intervention Stores: Convenience stores, grocery stores, pharmacies and other tobacco retail stores that are subject to the menthol sales restriction.

Menthol Ban: The FDA has the authority to prohibit menthol tobacco products under its authority to regulate tobacco products at the federal level.

Menthol Sales Restriction: Local governments have the authority to restrict the sale of menthol tobacco products within their jurisdictions.

Non-Intervention Stores: Tobacco shops and liquor stores that are exempt from the menthol sales restriction.

Priority Populations: Subgroups of the population who have higher prevalence of tobacco use; are disproportionately impacted by tobacco-related disease; are less likely to use tobacco cessation services; and/or are targeted by the tobacco industry. Priority populations include, but are not limited to, African Americans and other

racial and ethnic subgroups, LGBTQ populations as well as individuals with low income and low education attainment.

Tobacco: Any product containing nicotine or tobacco including cigars, little cigars, cigarillos, smokeless tobacco, hookah, and e-cigarettes.

Tobacco Control Act: The Family Smoking Prevention and Tobacco Control Act was signed into law by President Obama in 2009. It established the regulatory authority of the FDA over tobacco products. The Tobacco Control Act also banned the use of fruit-, candy-, and other-flavored cigarettes but exempted menthol cigarettes.

Tobacco shop: An adult-only tobacco products shop is a retail establishment with an entrance door opening directly to the outside that derives at least 90% of its gross revenue from the sale of tobacco products and does not permit minors. Tobacco shops were exempted from the Minneapolis menthol sales restriction.

Chapter 2: Literature Review

2.1 Background on Menthol Cigarettes

In 2016, menthol cigarettes made up 35% of the cigarette market in the U.S. (Federal Trade Commission, 2018). Since 1963, the domestic market share of menthol cigarettes has ranged from 16% (1963) to 35% (2016), with Newport and Marlboro menthol cigarettes leading the market (Federal Trade Commission, 2018; Giovino et al., 2013). Menthol is also added to over 90% of all cigarettes, including those not labeled as menthol (Giovino et al., 2004). Even though menthol is the only flavored cigarette currently available, menthol is also pervasive in other tobacco products. Kuiper et al. (2017) examined Nielsen tobacco sales data and found that 19.4% of little cigars, 57.0% of moist snuff, and 88.5% of snus tobacco sales in 2015 were menthol-flavored.

The characterizing flavor of menthol, which is derived from the peppermint plant or can be synthetically produced, provides a minty taste and cooling sensation (World Health Organization, 2016). These sensory characteristics reduce the harsh taste of tobacco smoke and throat irritation associated with smoking regular (non-menthol) cigarettes (Kreslake, Wayne, & Connolly, 2008; Lawrence, Cadman, & Hoffman, 2011). Menthol is more than just a flavoring or additive; tobacco industry documents research revealed that menthol levels were manipulated in cigarettes to increase their appeal, thereby facilitating smoking uptake among new users (Klausner, 2011; Kreslake et al., 2008). Further, menthol increases respiratory airflow, which enables users to inhale deeper and increases exposure to toxins

(Lawrence et al., 2011). These mechanisms are hypothesized to lead to poorer long-term health consequences for menthol smokers than non-menthol smokers (Alexander et al., 2016; Lawrence et al., 2011).

2.2 Prevalence and Correlates of Menthol Cigarette Use

Menthol cigarettes are a known starter product for youth. The majority of tobacco users begin smoking in adolescence and with menthol cigarettes (Villanti, Collins, Niaura, Gagosian, & Abrams, 2017). There are over 20 million menthol smokers in the U.S. (Substance Abuse and Mental Health Services Administration, 20013). From 2004 to 2014, the use of non-menthol cigarettes by youth declined while the use of menthol cigarettes remained constant among adolescents and increased among young adults (Villanti et al., 2016). According to the 2013-2014 Population Assessment of Tobacco and Health study, 59.5% of current youth (aged 12-17) smokers used menthol cigarettes compared to 37.1% of adult smokers (Villanti, Johnson, et al., 2017). In Minnesota, 34.1% of teen smokers report smoking menthol cigarettes compared to 25.1% of adult smokers (D'Silva, Amato, & Boyle, 2015; Minnesota Department of Health, 2018).

African Americans are more likely to smoke menthol cigarettes compared to other racial/ethnic groups. Nationally, 88% of African American smokers use menthols, compared to 29% of white smokers (Villanti et al., 2016). In Minnesota, 79% of African American adult smokers use menthol cigarettes compared to 23% of white smokers (D'Silva et al., 2015). Evidence indicates that menthol smoking may contribute to disparities in tobacco-related mortality (Alexander et al., 2016). African-American men are more likely to die of lung cancer than white men despite

consuming fewer cigarettes per day and initiating smoking at an older age (American Lung Association, 2010).

Beyond racial/ethnic differences in the prevalence of menthol smoking, individuals with low socioeconomic status, women, and sexual and gender minorities are more likely to be menthol smokers than their counterparts (Fallin, Goodin, & King, 2015; Lawrence et al., 2010). Menthol smokers are more likely to use flavored little cigars and cigarillos compared to non-menthol smokers (Sterling, Fryer, Pagano, Jones, & Fagan, 2016).

2.3 Rationale for Menthol Restrictions

Because flavors in cigarettes are appealing to youth, the 2009 Tobacco Control Act banned the sale of fruit and candy-flavored cigarettes; however, menthol was exempted (Center for Tobacco Products, 2009). Specifically, the law bans "an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke" (Center for Tobacco Products, 2009). The law also does not apply to non-cigarette tobacco products such as little cigars and e-cigarettes, which have gained popularity in recent years (Singh, 2016).

While the flavored cigarette ban was effective in reducing adolescent tobacco use overall, evidence indicates that adolescent smokers switched to other flavored tobacco products, including menthol cigarettes, that are still available in the marketplace (Courtemanche, Palmer, & Pesko, 2017). Analysis of National Youth Tobacco Survey data indicate that among adolescents, the probability of being a

menthol (vs. non-menthol) smoker increased 45% following implementation of the Tobacco Control Act (Courtemanche et al., 2017).

To address the issue of menthol, the FDA was charged with convening the Tobacco Products Scientific Advisory Committee (TPSAC) to review the available evidence on the impact of menthol in cigarettes. In 2011, the TPSAC concluded that a ban on menthol would benefit public health (Tobacco Products Scientific Advisory Committee, 2011). Following the TPSAC report, the FDA undertook an independent review of the science and in 2013 concluded that "menthol cigarettes pose a public health risk above that seen with non-menthol cigarettes" (U.S. Food and Drug Administration, 2013). These conclusions were based on a body of evidence that link menthol in cigarettes to increased initiation, greater addiction, and decreased cessation (Tobacco Products Scientific Advisory Committee, 2011).

2.3.1 Menthol and Initiation

Menthol cigarettes are associated with increased initiation and progression to regular smoking among young people (Tobacco Products Scientific Advisory Committee, 2011). The minty flavor and cooling sensation of menthol makes cigarette smoking more palatable for first-time users. Research shows that the tobacco industry manipulated menthol levels to attract and retain youth smokers (Klausner, 2011). Evidence indicates that younger smokers use menthol cigarettes at higher rates than older, established smokers (Villanti, Johnson, et al., 2017).

2.3.2 Menthol and Addiction

The TPSAC concluded that menthol cigarettes were associated with increased likelihood and degree of addiction among youth. Menthol smokers are more likely to smoke within five minutes of waking, indicating greater nicotine dependence (Tobacco Products Scientific Advisory Committee, 2011). There are several possible biological mechanisms that explain the role of menthol (Wickham, 2015). Among African Americans, it is hypothesized that sensitivity to the taste of nicotine may influence nicotine dependence (Alexander et al., 2016; Mangold, Payne, Ma, Chen, & Li, 2008). Menthol can also serve as a sensory cue that reinforces nicotine and alter nicotine metabolism, thereby contributing to continued addiction (Wickham, 2015).

2.3.3 Menthol and Cessation

Menthol smokers are less likely to successfully quit smoking (Tobacco Products Scientific Advisory Committee, 2011). Studies have shown that menthol smokers are more likely to make quit attempts but are less successful in quitting, even when using cessation aids (Levy, Blackman, et al., 2011; Okuyemi, Faseru, Sanderson, Bronars, & Ahluwalia, 2007; Smith, Fiore, & Baker, 2014). The lower quit rates among African American smokers suggests a possible explanation for increased tobacco-related disease and mortality among African Americans (Alexander et al., 2016).

2.3.4 Menthol as a Social Justice Issue

The tobacco industry has a long history of predatory marketing of menthol cigarettes to racial/ethnic minority communities (Cruz, Wright, & Crawford, 2010). Several studies illustrate how menthol cigarettes have historically been and continue

to be targeted to African American communities (Gardiner, 2004; Yerger & Malone, 2002; Yerger, Przewoznik, & Malone, 2007). The tobacco industry targeted low-income African American residents with marketing and promotions designed to specifically appeal to them and provided funding and other resources to African American community leaders to promote goodwill and buy-in (Yerger & Malone, 2002; Yerger et al., 2007). Research shows that menthol advertising and price promotions are more prevalent in low-income and African American neighborhoods (Henriksen, Schleicher, Dauphinee, & Fortmann, 2012; Seidenberg, Caughey, Rees, & Connolly, 2010). Newport cigarettes are cheaper in neighborhoods with a higher proportion of African American students (Henriksen et al., 2012; Lee, Henriksen, Rose, Moreland-Russell, & Ribisl, 2015). The insidious targeting of the tobacco industry towards African American communities highlights the need for a social justice approach to address tobacco-related disparities (Healton & Nelson, 2004).

2.4 Perceptions of Menthol Cigarettes and Attitudes toward Menthol Policy

2.4.1 Perceptions of Menthol Cigarettes

Although tobacco industry research has documented how menthol cigarettes have historically been marketed as refreshing, cool, and smooth, less is known about present-day consumers' perceptions (Anderson, 2011; Kreslake et al., 2008; Rising & Alexander, 2011). Previous studies of African American adult smokers found that menthol cigarettes were perceived as "healthier" alternatives and were therefore less harmful than non-menthol cigarettes (Richter, Beistle, Pederson, & O'Hegarty, 2008; Unger, Allen, Leonard, Wenten, & Cruz, 2010). In 2005, Richter et al. (2008) conducted small group discussions with African American smokers aged 45-64 in

Georgia and asked participants about the relative harm of menthol versus non-menthol cigarettes. Some participants described non-menthol cigarettes as harsh and attributed fewer health effects to smoking menthol cigarettes (Richter et al., 2008). However, other participants noted the harm of menthol cigarettes, including the use of fiberglass in menthol cigarette filters. In 2006, Unger et al. (2010) surveyed black adult smokers in Los Angeles County and found that menthol smokers were more likely to endorse medicinal effects of menthol cigarettes, including their use for a sore throat or to loosen up a stuffy nose. These perceptions correspond with marketing messages prevalent in the 1950s and 1960s (Unger et al., 2010). These messages are in stark contrast to the modern marketing strategies for menthol products that depict urban culture and focus on non-health related themes of sociability (Cruz et al., 2010; Richardson et al., 2015).

Interestingly, findings from more recent studies of smoker perceptions are less consistent. An examination of data from Wave 1 of the Population Assessment of Tobacco and Health study found that African American menthol smokers were more likely than African American non-menthol smokers to perceive their cigarette brand to be more harmful compared to other cigarette brands (Cohn et al., 2017). A recent focus group study by Wackowski et al. (2014) found that black young adult smokers did not perceive menthol cigarettes as different in risk relative to non-menthol cigarettes. They did, however, note that menthol cigarettes were less harsh and easier to inhale, which may contribute to perceptions of reduced harm when initiating smoking. These findings suggest that perceptions of harm may change as individuals progress from experimenters to established smokers and as industry marketing

strategies evolve over time. Study 1 fills a gap in the literature by assessing perceptions of harm among established adult smokers as well as extends previous work by examining the extent to which smokers view menthol as a problem in their community, which sheds light on community-level factors.

2.4.2 Attitudes toward Policy

We are unaware of any studies that address African American smokers' attitudes toward local policy options on menthol; however, a few studies have addressed regulation of menthol cigarettes at the federal level. A 2009 national survey of adults found that the majority of black respondents supported a national ban on menthol, including over half (53%) of black smokers (Winickoff et al., 2011). African American menthol smokers in Minnesota were 2.5 times more likely to indicate an intention to quit compared to white menthol smokers (D'Silva et al., 2015). In their focus group study, Wackowski et al. (2014) found very low awareness of the potential for FDA to ban menthol cigarettes. Black participants noted that a ban on menthol may prompt them to quit because they would be unlikely to switch to non-menthol cigarettes. Other participants noted that they may switch to other tobacco products, including cigarillos and e-cigarettes. Some participants expressed anger at the idea because they felt they were being unfairly targeted and were unsure why menthol cigarettes were singled out. It is unknown how African American smokers will react to menthol sales restrictions because it is unlike a federal ban on menthol cigarettes. Therefore, it is important to assess African American smokers' reactions to local policy options in order to fill an important gap in the literature (study 1).

2.5 Menthol Regulation

2.5.1 Local Jurisdiction on Menthol Cigarettes

While the FDA continues to deliberate regulatory action, local governments are moving ahead with restrictions to address menthol cigarettes. Despite the federal government's authority to set product standards and ban menthol, the language of the Tobacco Control Act does not preempt state and local governments to restrict the sale of menthol tobacco products within their jurisdictions (Lester & Gagosian, 2017). Preemption occurs when the authority of the federal government limits the authority of state and local governments to enact tobacco control legislation. To date, no states have passed restrictions on menthol.

A few cities and counties have taken various types of regulatory action of menthol cigarettes. These sales restrictions fall into three major categories: buffer zones, policies with retailer exemptions, and full bans. In 2014, Chicago became the first city to restrict the sale of menthol tobacco products within 500 feet of all schools. Policy implementation was delayed until July 2016 due to legal challenges and the ordinance was subsequently rolled back with the buffer zone restrictions only applying to high schools. According to the Tobacco Control Legal Consortium (Tobacco Control Legal Consortium, 2017), other cities that have enacted buffer zone restrictions include Hayward, CA, Berkeley, CA, and unincorporated parts of Contra Costa County, CA. Jurisdictions that have passed full bans include Oakland, CA, Palo Alto, CA, San Francisco, CA, unincorporated parts of Yolo County, CA, El Cerrito, CA, and West Hollywood, CA. The Minneapolis policy falls into the retailer exemption category, which exempts exclusive tobacco shops or other types of retail

stores. Other jurisdictions that have enacted these types of menthol restrictions with exemptions include Santa Clara County, CA, Los Gatos, CA, Duluth, MN, and Saint Paul, MN.

On a local note, the city of Baltimore considered pursuing a buffer zone restriction on menthol cigarettes in 2015 (Cohn, 2015). However, advocacy efforts stalled due to concerns regarding preemption by the state that were prompted by a previous case in the Court of Appeals. It is unlikely that there will be any local menthol efforts within the state of Maryland unless the state passes legislation that confirms the authority of local jurisdictions to enact and enforce local tobacco control legislation. A previous attempt at such legislation failed in 2016 (Waldstreicher et al., 2016)

2.5.2 Minneapolis Menthol Restriction

In 2015, the City Council amended Title 13 Tobacco, Chapter 281 of the Minneapolis Code of Ordinances relating to Licenses and Business Regulations: Tobacco Dealers to restrict the sale of flavored tobacco products, including e-cigarettes, but exempted menthol, mint, and wintergreen flavored tobacco products. Two years later, following a robust community engagement process and educational campaign, the Minneapolis City Council voted 10-2 to eliminate the menthol exemption on August 4, 2017. The specific language of the ordinance indicates that sales of tobacco products with the taste or aroma of menthol, mint and wintergreen "that is distinguishable by an ordinary consumer" are restricted to tobacco products shops and certain liquor stores. An adult-only tobacco products shop (tobacco shop) is defined as a "retail establishment with an entrance door opening directly to the

outside that derives at least 90% of its gross revenue from the sale of tobacco products" and does not permit individuals under the age of 18 (this was increased to 21 in 2018). The liquor store exemption applies to those stores that do not permit entrance to individuals under the age of 21 unless accompanied by a parent or guardian.

2.5.3 Minneapolis Policy Implementation

The Minneapolis menthol restriction took effect on August 1, 2018, following a yearlong implementation delay. The Minneapolis Health Department is charged with notifying all retailers with tobacco licenses of the menthol restrictions. The Minneapolis Business Licensing division is responsible for retailer compliance. Ordinance violations are subject to the following penalty structure: administrative citations ($200 for the first offense and doubling thereafter), or misdemeanor criminal prosecution. Repeated retailer offenses are subject to license suspension, revocation, nonrenewal or other adverse license action.

According to the Minneapolis Health Department, the purpose of the policy was to "prevent youth tobacco use, lifelong addiction to nicotine, the negative health effects of tobacco use and the tobacco-related health disparities between white populations and people of color" (Minneapolis Health Department, 2017). The policy was intended to reduce the availability of menthol products from 318 retail stores to 25 tobacco shops (Minneapolis Health Department, 2017). During the policy-making process, a liquor store exemption was introduced.

2.5.4 Evaluations of Point-of-Sale Restrictions

While little is known about the impact of menthol sales restrictions in the U.S., evidence from the evaluation of non-menthol flavored tobacco sales restrictions and jurisdictions outside the U.S. shows that they can be effective in reducing sales and tobacco use. Evaluation of the 2010 NYC restriction on flavored tobacco products (excluding menthol) found significant declines in the odds of ever trying flavored tobacco products or using any type of tobacco product among teens between 2010 and 2013 (Farley & Johns, 2017). The sales of flavored tobacco products also decreased overall (Farley & Johns, 2017; Rogers et al., 2017). However, these studies also found evidence that the NYC policy was not fully implemented as intended. For example, flavored cigars continued to be pervasive in the marketplace.

Farley et al. (2017) also found that the tobacco industry repackaged tobacco products with ambiguous product names (such as Show "TaTa" cigarillos and Rock 'n' Roll "Blue" cigars). Although these products were found to contain flavor chemicals, they were not packaged as such. Similarly, evaluation of a ban on menthol cigarettes in Canada found that the industry replaced products previously labeled as menthol with the word "green" (Brown et al., 2017). These studies suggest it is important not only to assess compliance with policies but to monitor unintended consequences and potential tobacco industry tactics to circumvent restrictions following policy-implementation.

Although the Minneapolis menthol restriction applies only to the sales of tobacco products, it is plausible that marketing of tobacco products may also be impacted. Previous research has demonstrated how greater levels of advertising and

promotions are associated with greater susceptibility to smoke and increased smoking initiation among youth (Paynter & Edwards, 2009; Slater, Chaloupka, Wakefield, Johnston, & O'Malley, 2007). Therefore, the retailer assessments in study 3 will measure changes in the availability of menthol products along with promotions and advertising of menthol tobacco products.

2.6 Conclusion

Federal inaction on menthol, despite being supported by several independent reviews of the literature (Tobacco Products Scientific Advisory Committee, 2011; U.S. Food and Drug Administration, 2013; World Health Organization, 2016), has compelled local jurisdictions to take action on menthol. Such efforts to reduce access to menthol tobacco products at the point-of-sale have the potential to ameliorate tobacco-related disparities, particularly among African American communities. Results from the studies will provide critical insights from multiple perspectives during each phase of the policy process. Findings can inform other jurisdictions around the country interested in pursuing menthol restrictions to reduce the burden of tobacco use and advance health equity.

Chapter 3: Exploring African American Smokers' Perspectives on Menthol Cigarettes and Reactions to Local Menthol Policy (Study 1 Manuscript)

3.1 Introduction

Menthol cigarettes, which make up over one third of the cigarette market in the U.S. (Federal Trade Commission, 2018), have been linked to increased initiation among youth, higher levels of addiction and decreased quitting, especially among African Americans (Tobacco Products Scientific Advisory Committee, 2011; U.S. Food and Drug Administration, 2013). Tobacco industry documents demonstrate how menthol levels in cigarettes were manipulated to increase their appeal, thereby facilitating smoking uptake among new users (Klausner, 2011; Kreslake et al., 2008). Nationally, 88% of African American adult smokers use menthol cigarettes, compared to 29% of white smokers (Villanti et al., 2016). These high rates of menthol smoking have been hypothesized as a contributing factor to the disproportionate burden of tobacco-related morbidity and mortality among African Americans (Alexander et al., 2016). For example, African-American men are more likely to die of lung cancer than white men despite consuming fewer cigarettes per day and initiating smoking at an older age (American Lung Association, 2010; Fagan, Moolchan, Lawrence, Fernander, & Ponder, 2007).

Several studies illustrate how menthol cigarettes are specifically marketed to African American communities with targeted promotions (Gardiner, 2004; Yerger &

Malone, 2002; Yerger et al., 2007). The tobacco industry also targeted low-income African American residents with marketing and promotions designed to specifically appeal to them and provided funding and other resources to African American community leaders to promote goodwill and buy-in (Yerger & Malone, 2002; Yerger et al., 2007). As noted by Gardiner (2004), the "African Americanization" of the menthol cigarette dates back to the tobacco industry's targeted focus on this community since at least the 1940s. Early marketing messages focused on the medicinal properties of menthol and were followed by ads featuring black models and spokespersons who touted menthol as refreshing, cool, and smooth (Anderson, 2011; Kreslake et al., 2008; Rising & Alexander, 2011; Unger et al., 2010). These messages likely translated to misperceptions of menthol cigarettes as less harmful relative to non-menthol cigarettes. Early studies examining African American adult smoker perceptions found that menthol cigarettes were perceived as "healthier" alternatives with fewer health effects (Richter et al., 2008; Unger et al., 2010).

While older adults may have been exposed to these early marketing messages that conveyed reduced harm, more recent studies of smoker perceptions suggest that perceptions may have evolved, particularly as more modern menthol marketing focuses on themes of sociability and sexuality instead of health (Cruz et al., 2010; Richardson et al., 2015). Examining 2013-2014 national data from the Population Assessment of Tobacco and Health (PATH) study Cohn et al. (2017) found that African American menthol smokers were more likely than African American non-menthol smokers to perceive their cigarette brand as more harmful compared to other cigarette brands. Another focus group study with young adult black smokers reported

that menthol cigarettes were not perceived as different in risk relative to non-menthol cigarettes (Wackowski et al., 2014). Consequently, there may be a generational shift in how menthol is now perceived, prompting a need to further explore these changing perceptions and to uncover what influences contemporary adult African American smokers' perception of the relative harm of menthol compared to non-menthol cigarettes.

Menthol cigarettes remain widely available despite a body of evidence that supports their removal from the marketplace to benefit public health (Villanti, Collins, et al., 2017). While the 2009 Family Smoking Prevention and Tobacco Control Act (TCA) banned the sale of other flavored cigarettes because of their appeal to youth, menthol cigarettes were exempted (Center for Tobacco Products, 2009). The U.S. Food and Drug Administration (FDA) has the authority to ban menthol, a regulatory action that has the potential to save more than 300,000 lives, approximately a third of which would be in the African American community (Levy, Pearson, et al., 2011).

Studies that have examined smoker perspectives on the regulation of menthol cigarettes found that African American smokers are supportive of federal regulation and report intentions to quit if menthol is banned (D'Silva et al., 2015; Wackowski et al., 2014; Winickoff et al., 2011). However, less is known about what shapes these intentions and how African American smokers may react differently to partial local restrictions, where the availability of menthol cigarettes is reduced but not completely eliminated. Unlike a complete FDA ban on menthol, localities are limited to pursuing sales restrictions within their jurisdictions (Lester & Gagosian, 2017). For example, in

2017 the cities of Minneapolis and St. Paul, Minnesota passed local ordinances restricting the sale of menthol cigarettes to adult-only tobacco shops and liquor stores. With growing momentum on local menthol sales restrictions across the U.S. (Glantz & Gardiner, 2018), it is imperative to understand the perspectives of those most likely to be affected by these policies, especially African American smokers (Doucet, Velicer, & Laforge, 2007).

The purpose of the present study was to fill a gap in the literature by exploring African American adult smoker perspectives on menthol smoking and reactions to local menthol policy restrictions. Findings have the potential to inform messaging and community education campaigns on the harms of menthol tobacco products and inform efforts to address menthol use in the African American community.

3.2 Methods

Semi-structured interviews (n=28) were conducted with adult smokers who self-identified as African American, Black, or African immigrant. Additional inclusion criteria included age (25 years and older) and being an established smoker, which was defined as daily cigarette use for five years or more. The age range was selected to account for later age of initiation among black smokers (National Cancer Institute, 2017). The focus on established smokers reflects the aims of the parent study, which sought to identify barriers to cessation. Because this study was focused on gaining an in-depth understanding of individual smokers' reactions, interviews were selected over focus groups to avoid influence of others' responses to policy change. Interviews were conducted by Rainbow Research. The PI provided input on

all key phases of the research including study conceptualization, sample recruitment, and the development of the interview guide.

A convenience sample was recruited in community locations in selected geographic neighborhoods in the Minneapolis-St. Paul metro area from June – September 2017. Recruitment focused on historically black neighborhoods and areas of concentrated poverty, defined as areas where 50% or more of residents are people of color and 40% or more of the residents have family incomes that are less than 185% of the federal poverty level (Metropolitan Council, 2014).

Participants completed a phone screening to establish eligibility and responded to demographic questions (age, gender, sexual orientation, race/ethnicity, and highest level of education completed) and tobacco use characteristics (types of tobacco products used, menthol smoking status, cigarette brand preference, and number of cigarettes per day). During the in-person interview, participants were asked about the relative harm of menthol compared to non-menthol cigarettes, whether they viewed menthol as a problem in their community, and their awareness of and reactions to potential menthol restriction policies. Specifically, participants were asked what would happen if they were unable to purchase menthol cigarettes at their usual location, and how this restriction would influence their smoking and purchasing habits. A copy of the interview protocol is available in Appendix B. Interviews lasted an average of 60 minutes and participants received $40 cash incentive for participation.

Interviews were conducted by Rainbow Research and were audio recorded and transcribed. The PI analyzed the interview transcripts using established

guidelines for the framework method (Ritchie & Lewis, 2003), which emphasizes both a priori issues and emergent data-driven analysis. Transcripts were first thoroughly reviewed to develop familiarity with the text. Next, emerging themes and sub-themes were identified from the data, developed both deductively based on research questions identified a priori and inductively from emerging concepts within the data, and were compiled into a framework. Codes were then applied to all transcripts in NVivo 12 Pro (www.qsrinternational.com). A matrix, including direct participant quotes under each key theme, was then generated, and finally, findings were synthesized for reporting. The PI and a second trained researcher coded 20% of the interviews (Kappa > 0.73) (McHugh, 2012). Disagreements in coding were discussed until consensus was reached. IRB approval was obtained from the Minnesota Department of Health and the University of Maryland.

3.3 Results

3.3.1 Demographics and Smoking Characteristics

Table 3.1 depicts participant characteristics (n=28). Almost all participants (n=27; 96%) usually smoked menthol cigarettes with 93% (n=26) citing Newport as their preferred brand.

3.3.1.1 Brand Preference

Participants smoked Newport cigarettes because they not only enjoyed the taste and flavor of menthol but also found that it helped satisfy their cravings better

than other brands. Several participants also described Newports as being the "right blend" (i.e., the right amount of menthol and nicotine to give smokers the desired hit without being too harsh). Some compared Newports to Kools, which were deemed too strong and harsh. At the same time, regular Newports were perceived as stronger than other "light" or "smooth" varieties of Newport, which were described as "smoking air." Participants felt that the overall experience of smoking menthol was more pleasurable compared to smoking non-menthol cigarettes, which were associated with headaches, choking, burning in the throat, and other unpleasant sensory experiences. Some noted that non-menthol cigarettes, like Marlboro "Reds," did not give them the satisfaction or taste they were seeking.

> *I done smoked everything and Newport is the strongest one… Even if I got Newport smooths, it's not Newports. Even though I know it's better because it is smooth, I don't know, Newport is just something for me… it's just stronger than all the other ones. It makes you more calmer for some reason. I [smoked] other cigarettes and really didn't feel nothing. I would smoke other cigarettes and want one right after I smoked that one. (Female, 26)*

Participants also cited preferring menthol cigarettes because it was commonplace within their social network and prevalent in the African American community.

> *Black people smoke Newports. I see some white people smoke Newports, but majority of them smoke non-menthol. I don't know. It's segregated. (Male, 44)*

One participant noted that Newports were also associated with a certain image of being “hip” and that they would be embarrassed to be seen smoking other brands or generic cigarettes in their community.

Another reason why Newports were popular among participants is that they were easily accessible from peers and family members, who also smoked Newports. Several recalled initiating smoking by obtaining a Newport cigarette from a friend or sibling or secretively taking one from a parent’s pack of cigarettes. There was also mention of Newports as being the only brand sold as “loose squares,” slang for loose cigarettes (or loosies), which contributed to their easy access.

> *It's just what I prefer because that's what does it for me, I'm so used to Newport. That's what does for me like the flavor, the way when I inhale it, like I said, how it goes down, and stuff like that. It's just the right blend. I think a lot of people of color, I know for one, it's been generational, it's been handed down … like the parents smoked Newports. (Male, 26)*

3.3.1.2. History of Menthol Smoking

Most participants reported initiating with and continuing to smoke menthols for the duration of their smoking history. Once participants discovered liking the taste of Newports, they stuck with the brand.

It's what I've been smoking. Some people just stick to one particular cigarette and that's what I've done. That's what I smoke, Newport. (Male, 40)

I started out smoking Newport 100's, ended smoking Newport 100's. Well, not ended, still smoke. (Male, 37)

Some menthol smokers explained that they had tried switching to other menthol brands –including Marlboro, Kool, Camel and Maverick – but ended up returning to Newports because of its distinctive taste and ideal strength. Similarly, older participants reported initiating with Kools then switching to Newports.

Back in the old days, it was Kool and then everybody transferred to Newport where I come from. (Male, 56)

I used to smoke Kools but they don't make them like they used to. Newport [is] milder to me. (Female, 61)

3.3.2 Perspectives on Menthol Cigarettes

3.3.2.1 Harm Perceptions

Participants were asked to consider the relative harm of menthol compared to non-menthol cigarettes and other tobacco products. For many participants, perceptions of

harm were tied to perceptions of strength: Newports were considered stronger and therefore perceived as more harmful.

> *I think menthols are more stronger, and I think it's worse for you, I really do. Like I say, I don't know too much about cigarettes, but I know menthol is the strongest cigarette out there. I feel like if that's the strongest cigarette out there, I think menthol is bad for you, [worse] than the other brands like the light cigarettes. I'm going to just say it like that. (Female, 52)*

Participants also felt that menthol cigarettes contained extra chemicals and additives, including the menthol itself, which some attributed to increased harm. Some attributed increased harm perceptions to a belief that the menthol, particularly in Kool cigarettes, caused crystalized lungs.

> *...it's because the menthol's are more stronger than the non-menthol. They got more stuff in them. I don't know. Whatever they put in the nicotine to get it going. (Female, 28)*

> *...the menthol isn't good for your lungs. I hear it crystallizes your lungs. It started from Kool cigarettes. [They] say that Kool cigarettes crystallize your lungs. (Male, 51)*

Along the same lines, a few participants noted that non-menthol cigarettes were less harmful because of the lack of menthol as an additive, which made the product less carcinogenic.

> *Menthol gives you cancer. Non-menthol doesn't give you cancer. I really don't know if it's true or not, but that's the thing that I'm always hearing all the time. Like, people talking. They got this thing on TV, they'll advertise it like, "Non-menthol," in other words like sugar-free. (Male, 32)*

Others were less certain about the relative harm of menthol compared to non-menthol cigarettes.

> *Yeah, somehow I heard on TV they said that a lot of people who are now starting to smoke and now they're getting on menthol and for some reason they've put an emphasis on the menthol and they were insinuating that menthol were worse than just any kind of cigarette. Is there some data to prove that? That menthol is worse? (Male, 56)*

Participants also indicated perceptions of increased harm from menthol cigarettes because they were primarily smoked by low-income individuals or African Americans (vs. white smokers). Some attributed these increased harm perceptions to the additives in menthol cigarettes that were intended to cause more harm to African American smokers.

I think the brands that black people smoke are way more harmful. I think all of them are harmful, but typically Newports. The reason I say that, because they're definitely stronger, so stronger when it come to drugs or alcohol or cigarettes always mean worse to me. It [goes] hand in hand. (Male, 32)

Because most menthols are middle-class or low-class people that smoke. And they keep putting more chemical into this stuff so we could die more… (Female, 29)

I think on a scale of one to ten, I think they're a ten. I think they're the most, they're more harmful. I think it's the reason why most Blacks smoke menthol, most whites smoke non-menthol. I think everybody knows something that we don't know. (Male, 37)

While many commented that menthols were more risky compared to non-menthol cigarettes, the majority of participants felt that all cigarettes were the same and ultimately harmful to health. This sentiment extended to other tobacco products as well.

I think all nicotine, tobacco products is bad. Menthol, non-menthol it's still all the same. (Female, 43)

I think they all the same. I think it's equal. It's like I say, you know? It's still a tobacco product, period. You know what I'm saying? I think it's equal. That's how I feel. (Female, 37)

When participants were asked to consider which particular tobacco products may be less harmful, a few compared Newports to Newport "lights" but did not see light or low tar cigarettes as different in harm to "regular" strength cigarettes.

You have lights that are supposed to be less this, less that. I believe it all is going …if you keep doing it... it's going to kill you eventually. I don't care if it's a light, a menthol, a non-menthol. I don't think one is better than the other, no. (Male, 40)

They say that the light cigarettes are better for you, but I think all of it's bad. All of it got the tobacco, all of it got whatever's in the tobacco that makes you want it, that makes you addicted to it, so I think all of it's bad. (Female, 52)

Several participants did note that other tobacco products, in particular roll-your-own cigarettes and Black and Mild cigars, were more harmful than cigarettes. These harm perceptions were attributed to the lack of a filter, a harsher taste, and other adverse reactions such as coughing or choking when using these products. The idea that smoking one Black and Mild was the equivalent of smoking in the range of 10-20 cigarettes was also common. One participant noted that chewing smokeless tobacco

was more harmful than cigarettes because it was certain to cause mouth cancer. Another noted that “liquid cigarettes” or e-cigarettes seemed harmful because they were unregulated and did not include a listing of ingredients.

3.3.3 Perspectives of Menthol in the Community

When asked to consider whether menthol was a problem in their community, participants had mixed reactions. Some participants did not feel that menthol was a problem because they felt that the decision to smoke menthols was a matter of personal choice. Others stated that it was not the menthol in particular that was the issue, but rather that all cigarettes were harmful to health regardless of the type.

> *Everybody got their own preference. You want a menthol, you want a menthol. You don't, you don't. I don't know, I don't see a problem personally. (Female, 37)*

> *No, I see cigarettes as a problem, period. Not just because it's menthol. All cigarettes, whether it's menthol, light, tobacco, the leaf. All of it's dangerous for your health. All of it. It's not just the menthol that makes it more dangerous. A cigarette. Period. Tobacco. (Male, 48)*

On the other hand, participants who perceived menthol as more harmful acknowledged menthol as problematic in the community. Reasons cited included the addictive nature of menthol and the additives in the product.

I don't know how big of a problem it might be, but I could tell you one thing; in the African American community, that's all they smoke is menthols. I could see where it could be a problem, because that's all they smoke... Menthol is a problem with the Black community, it really is, because only thing it's doing is killing them slowly. (Female, 52)

Yep. Because there's just something about that menthol. Something in that menthol. We crave it. We like it. It's something that [it] does to our body chemically. (Female, 52)

Several participants poignantly pointed out the role of the tobacco industry in promoting menthol cigarettes to the Black community. Participants specifically noted the predominance of Newport cigarette use in African American communities as a result of targeted marketing. Indeed, it was apparent that for most study participants, smoking was synonymous with smoking Newports. Often, participants did not identify them as a menthol (vs. non-menthol) cigarette; it was just the cigarette that everyone around them smokes. Some provided vivid descriptions of Newport advertising in particular.

I've seen ... posters or pictures and there'll be [a] black male, black woman, and they're all in this cool scene and there's Newport ... I forget what the slogan was, but it was something about smooth and ... It's keywords they use. Or you'll go into the store, the corner store, they're advertising, they have the

posters up. The posters look good, the colors, the color scheme that they're using, the green … that symbolizes of money. (Male, 26)

Participants described several elements of marketing that contributed to this perception including the pervasiveness of Newport advertising in convenience stores with ads featuring black models and geographically focused in black communities and the "inner city" compared to the suburbs and areas where white smokers reside.

There's a big push somewhere in our community with these Newports. More so than any other community that I've noticed. (Male, 50)

I think they target African American smokers… look you don't see an African American with a Marlboro, it's a white cowboy. Though a Kool or a Newport - you see an African American, and so I think they are targeting African American smokers. Why, I don't I know. (Male, 57)

Menthol, Kools, Salems, Newports. They target African-Americans. Any convenience store or store, they have them big ol' Newport signs plastered up there. (Female, 43)

Some participants also recalled Newports handing out samples in the 1980s and the advertising on billboards, magazines, and television. Others noted currently receiving promotional coupons via direct mail or from industry representatives at retail stores or other venues such as bars or clubs.

Whose agenda is it, like I said, why are they back in my mailbox? Why are they back in my magazines? In the neighborhoods, yes... Menthol cigarettes are really being pushed. (Male, 50)

In addition to targeting of the African American community, participants also expressed disdain for advertising to young people. The targeted marketing was seen as a way to attract and addict a new generation of smokers. There was an overwhelming concern for young people and their future.

It's taken over the generation. The corner store is right next to the high school. These kids, that's what they see – cigarettes and tobacco everywhere, and that's what they gonna wanna do, "When I grow up I'm gonna go get me my own cigarettes one day." That's not a [expletive] hope. (Female, 29)

It's advertising for the kids. Not just for kids, adults too, but it draws more kids than it does adults 'cause we're already smoking. They gotta get the ones that isn't. (Female, 43)

Some participants who expressed strong feelings toward menthol being a problem in the community shared their perspectives that the issue could be addressed by doing away with menthol while others felt that the issue was irreparable.

> *I see menthol as a problem in any community. But like I said, and I'll say it again, if you don't put it out there, you don't have to worry about it. But you can't put something out there and leave it out there for years and then now you want to rectify the situation. It's too late. Everybody is already addicted and all that other stuff. What are you gonna do? What are you gonna do? (Female, 45)*

Even so, many shared the perspective that in order to address smoking in the community, the focus should be on discouraging young people from initiating smoking and educating youth on the harms of smoking.

3.3.4 Policy Awareness and Reactions

3.3.4.1. Awareness of Discussions surrounding Local Menthol Sales Restrictions

When asked if they had heard of any recent policy discussions or changes in laws, in particular related to menthol, the majority of participants responded that they were unaware of the proposed restrictions on menthol cigarettes. At the time of the interviews, the cities of Minneapolis and Saint Paul were considering policies to reduce access to menthol tobacco. The Minneapolis policy was passed on August 4,

2017 (during data collection) and the Saint Paul policy was passed on November 1, 2017 (following the completion of data collection). Both policies restrict the sale of menthol tobacco products to adult-only tobacco shops and liquor stores and were implemented one year later.

A few participants familiar with the upcoming changes were unsure of policy details or were misinformed about the extent of the restrictions. Although policy discussions were focused on local sales restrictions on menthol, some had heard that the policy would apply to all tobacco products or the entire state of Minnesota. Others were concerned that the legislation was intended to penalize menthol smokers.

> *They planning to cut all cigarettes out of the state of Minnesota. Yeah. And if you get caught you get in a lot of trouble… I know they'll come down on the people that are selling them. Yeah, we probably gonna pay the price too. Probably you get caught outside smoking, probably gonna have to pay a $100 fine or something. (Female, 61)*

Often, participants cited retail store clerks as the source of their information on the proposed legislation. Clerks were encouraging smokers to call their legislators to oppose the proposed policies. One participant also cited hearing about the policy via a direct mail flyer, which portrayed the legislation as intending to take away her right to smoke.

Oh, when I went to the liquor store they had a piece of paper that's giving out cards, telling us we need to go to St. Paul to get our rights synced because they trying to stop menthol smoking.... The mailman even put some stuff in our mailbox advertising, telling us about they trying to stop us from smoking period. (Female, 51)

3.3.4.2. Reactions to Local Menthol Restrictions

After participants were asked about their awareness of menthol restrictions, a brief summary of the policy approach was presented. Participants were then asked to indicate their support or opposition for the policy idea and to what extent it would influence their purchasing and smoking behaviors.

Reactions to the proposed menthol policy restriction were mixed. Initially, many smokers reacted negatively because they were frustrated with the inconvenience of having to travel to find their menthol cigarettes. There was also concern that their cigarettes would cost more at the tobacco shops.

They're already a dollar and something higher than what it is at the [convenience] stores. So it's like they're trying to take advantage and I don't like being taken advantage of. (Female, 43)

In addition to increased cost, there was also anger that the policy would lead to reduced access to menthol cigarettes because there are fewer tobacco shops

compared to corner or convenience stores, and because tobacco shops tend not to be open as late as convenience stores.

> *...so no I'm not down with that one because I'm not trying to go to a tobacco store and do that. No and them things close at what seven, eight? (Female, 49)*

Some felt they were being unfairly treated and did not understand why the restrictions singled out menthol and did not apply to non-menthol products.

> *Not just ... but I'm like, if you take the menthol but you leave the regular that's just stupid. It's only ... and I ain't gonna lie, it gave me an attitude. How are you gonna take the menthol but you gonna leave everybody else a cigarette? It just don't make no sense. (Female, 45)*

On the other hand, some viewed the attention on menthol cigarettes as an indication that menthol cigarettes were more harmful than non-menthol cigarettes. After hearing the description of the proposed menthol restriction, a participant noted:

> *If they're saying a thing like that means menthol's are worser than ... If there are more questions ... (Male, 27)*

However, one participant was unconvinced:

Yeah, somehow I heard on TV they said that a lot of people who are now starting to smoke and now they're getting on menthol and for some reason they've put an emphasis on the menthol and they were insinuating that menthol were worse than just any kind of cigarette. Is there some data to prove that? That menthol is worse? (Male, 56)

Despite noting the hassle of commuting, in some cases to the other side of town, participants who opposed the policy noted that it would not deter them from finding their preferred cigarettes wherever they were available. In particular, participants who lived near a tobacco shop indicated that the policy would not have an effect on their purchasing or smoking habits.

Some participants declared that policy would not have an effect on their smoking behavior because they would find a way to access their preferred brand - including asking a friend to purchase cigarettes for them wherever they were available. Others mentioned that they might stock up on cigarettes to avoid a daily commute, might travel to neighboring cities that do not have menthol sales restrictions, or may seek out "bootleg" sources, such as homes, where menthol cigarettes could be sold during after-hours.

[The policy is] not going to stop anything. People will get on the bus to go to the other side of town and get their cigarettes…. They'll be sending somebody

out, "Bring me a couple of packs back." I'm going to Bloomington to get Newports. It's like going to Wisconsin to buy fireworks. (Male, 44)

While a few indicated that they might try non-menthol cigarettes, most participants indicated that they would not substitute non-menthol for menthol cigarettes. When asked whether they would consider switching to non-menthol, participants responded that switching was unlikely given the strong taste preference for menthol and aversion to non-menthol cigarettes.

No, it wouldn't change mine. Because I would just find where it is. If a person smokes a specific brand that's not something they are going to switch up quickly they are going to find where it is and go get it. Just because they don't sell it at the gas stations I'm not going to switch to Marlboro or anything. (Male, 57)

No, I can't, actually, because I don't like non-menthol cigarettes. Like I said, I will smoke them if I don't have any, because see when I do I got to pull the filter out, and then smoke it. Because if I put the filter in there, like I say, I don't get no satisfaction. No, I would never buy a pack of non-menthols with my money. (Female, 37)

Some participants who initially expressed their dislike for the policy idea, eventually saw merit in a menthol restriction. As smokers contemplated how the policy would

impact their daily purchasing behaviors, they acknowledged that menthol restrictions might impact smoking behavior in the long run.

> *Yes, I think that some of them may still smoke. They may go to non-menthol; however, I think that would curve a lot of people's want or at least open up their mind to quitting. If they can't get menthol, then hey, what's the use? (Male, 38)*

> *You know what? I'd probably get on a bus and go. But eventually I'd get tired of doing that. Your money is not always long enough to get a carton of cigarettes…and I'm thinking about the Winter time. I mean who wants to get on a bus to go get a cigarette? To go get packs of cigarettes. I think I probably will stop. (Female, 43)*

For several participants, reducing access to the product by taking it out of convenience stores was seen as a positive outcome, especially for those individuals who were already contemplating quitting smoking. These smokers viewed the policy as helping nudge them towards quitting.

> *I'd feel like my chances of quitting would be a lot better, most definitely. Because it gives me a way out, an easier way out. I'm not going to drive*

around looking for no tobacco store. Especially when I don't ... when I'm trying to quit myself right now. (Male, 27)

I probably would have to quit. Because if there's not a tobacco store too close to me, so… I'm quitting. Yes. I would have to quit. There's nothing in a regular cigarette. There's nothing in the ... No taste. Yeah, I'd quit. (Female, 49)

Because participants would no longer have unfettered access to their preferred brand and their unwillingness to switch to another brand, some noted that the policy would lead to reductions in the number of cigarettes consumed.

I might slow down, because it probably wouldn't be around the corner no more, but it wouldn't stop me from smoking. Yeah. To make them last longer… because I know I would have to go to the tobacco shop. Because, like I said, it might not be around the corner no more. It depends on where it's at. (Female, 28)

Those who intended to cut down on smoking viewed the policy as having a potentially positive impact on their health and their wallet.

Yeah, it would affect me, because I [have] to walk a distance to get my pack of cigarette. If the tobacco store is far away, how do I smoke? It reduces... the cost, I'll say reduces. (Male, 35)

Well, it's gonna be far for me to go get it. I'm gonna be hesitant to go get it every day, and that probably leaves me with what, two, three cigarettes a day, instead of 10 cigarettes? So health-wise [it] is good. (Female, 29)

Beyond distance, participants factored the cost of transportation into the overall cost of cigarettes. For example, one participant noted that their cigarettes cost around $9 at their corner store. Adding in the cost of a $2 bus ticket as well as anticipating the higher cost likely at a tobacco shop, would put them well over $10. Many participants noted that the $10 cost for a pack was a "tipping point," and once the cost exceeded $10, it would prompt them to quit.

As far as getting on the bus to go to the tobacco shop that's gonna charge me two dollars more, it might. No, it might just make me quit because they're already a dollar and something higher than what it is at the stores. (Female, 43)

Yeah, I'd probably consider quitting all together, because it's already somewhat of a hassle for how much they cost. Then to add on expenses, to

having to travel to other places further than the convenience of your convenient store would probably be the tipping point for me. (Female, 38)

Other participants who expressed support stated that although taking menthol cigarettes out of convenience stores were a good first step, the regulations should go even further. Some suggested that all tobacco products (including non-menthol) be sold out of tobacco shops and others suggested that all cigarettes should be banned.

You shouldn't be selling cigarettes in the convenience store. Why are you making it convenient to kill yourself? …Take them out of the tobacco shops, too….Eliminate cigarettes, period. (Male, 26)

3.4 Discussion

To our knowledge, this is the first study to explore African American smokers' perspectives on local menthol policy restrictions. Our results indicate limited awareness and uneven support for policies designed to restrict access to menthol tobacco products. While many participants were receptive to policy change, there was an overall lack of understanding about intended policy consequences and misperceptions regarding the parameters of a local policy restriction. These findings suggest the need for public education efforts to reach those most likely to be impacted by the policy. In particular, the perspectives of African American smokers are critical for advocates and public health officials to consider, especially noting the prospect of

growing national momentum to pursue menthol restrictions at the local level (Glantz & Gardiner, 2018).

While there was no consensus among participants that menthol sales restrictions would lead to immediate smoking cessation, some indicated that traveling further to access menthol cigarettes would eventually become burdensome and costly, and may lead to future quit attempts. Conversely, several smokers in our study who were already contemplating quitting noted that a menthol restriction was encouragement to decrease consumption and prompt a quit attempt, indicating an important opportunity for intervention by promoting and facilitating access to evidence-based smoking cessation treatment. Previous research has found that quitlines can be an effective tool in helping menthol smokers quit (D'Silva, Boyle, Lien, Rode, & Okuyemi, 2012) but few menthol smokers report using cessation aids in prior quit attempts (D'Silva et al., 2015). Further, few interventions have been specifically designed for this population (Richards et al., 2015). Findings suggest a need to complement advocacy efforts with increased outreach and tailored cessation support to capitalize on smokers' intentions to quit following a menthol policy restriction.

It is interesting to note that the menthol restriction was viewed not just as an inconvenience, but was perceived as a measure that would likely lead to an increase in the cost of a pack of cigarettes after factoring in travel costs and higher prices at tobacco shops. Accordingly, menthol restriction policies may indirectly be a strategy that increases the cost of tobacco to consumers thereby contributing to decreased consumption, similar to the relationship observed between taxation that increases

cigarette prices and decreases smoking consumption (Chaloupka, Yurekli, & Fong, 2012; Choi & Boyle, 2018). On the other hand, some participants noted that an underground market for menthol cigarettes may emerge, noting a potential unintended consequence of the policy. However, a recent study from Nova Scotia found no increase in illicit menthol cigarettes following a 2015 ban on menthol cigarette sales (Stoklosa, 2018). Future research is needed to understand how smokers access menthol cigarettes after a menthol restriction is implemented.

Reported intentions to quit in the event of a local menthol restriction were supported with the finding that most participants did not intend to switch to non-menthol cigarettes. This finding is consistent with prior research that found low rates of switching among menthol smokers (Rath et al., 2015) and low intentions to switch to non-menthol cigarettes in the event of a federal menthol ban (Wackowski et al., 2014). Minnesota African American menthol smokers were two times more likely to report quitting intention compared to white menthol smokers (D'Silva et al., 2015). Further, no participants referenced intentions to switch to other menthol tobacco products, including e-cigarettes, which corresponds to the low uptake of e-cigarettes among black smokers (Harlow, Stokes, & Brooks, 2018). Together, these results highlight the potential for menthol policies to significantly impact tobacco use among African Americans. Future research that examines the impact of menthol policies on smoking cessation outcomes is warranted.

Alongside policy efforts and cessation programs, more public education is needed to expose the industry's predatory marketing practices and the unique role of menthol in contributing to increased tobacco disparities among African Americans.

This information may help increase support for menthol policies as pro-equity and help combat opposition messages that seek to distort the issue as unfairly targeting African American smokers and taking away smokers' rights. Prior work has suggested that exposing community members to tobacco industry documents that provide evidence of the tobacco industry's insidious targeting strategies can activate community mobilization (Yerger, Daniel, & Malone, 2005).

In contrast to earlier community-based research that found the inverse relationship (Richter et al., 2008; Unger et al., 2010), a majority of smokers in our study perceived menthol as more harmful than non-menthol cigarettes. These findings, however, are consistent with more recent survey studies (Cohn et al., 2017; Wackowski, Delnevo, & Lewis, 2010). As such, the effect of earlier menthol marketing messages that portrayed menthol as safer may have become diluted over time (Lee & Glantz, 2011) and perceptions may be realigned in part due to efforts of local and national public health education directed at exposing the harms of smoking. Even so, smokers were unclear about menthol's specific mechanisms of harm, and myths regarding menthol cigarettes "crystallizing lungs" continue to perpetuate (Richter et al., 2008). Several participants attributed the harm of menthol to the additives in and strength of the product, which relates to their sensory experiences of smoking, versus their consideration of the long-term health impacts of menthol smoking. These findings may, in part, help explain why increased harm perceptions among menthol smokers do not necessarily translate to increased quitting (Cohn et al., 2017). Messages that reinforce the disproportionate burden of tobacco-related

disease, including increased risk for lung cancer, should be tailored to reach African American smokers.

Results from this study may be limited by its focus on established older smokers because it excludes the perspectives of younger adult smokers who may have different perceptions of menthol (Cohn et al., 2017). There was no biochemical verification of smoking status and menthol smoking was self-reported. Participants were limited to the Minneapolis-St. Paul metro area and participant responses may have been influenced by dialogues regarding menthol restrictions that were underway; however, our findings indicated low overall awareness of menthol policy discussions. Future studies in other geographic settings and in different policy contexts are needed to confirm these findings. Moreover, smokers' perceptions of menthol cigarettes and attitudes toward menthol policy may be influenced as momentum around menthol policies expands across the US. Despite these limitations, this study is an important first step in understanding African American smoker perspectives of menthol sales restrictions at a local level.

Study findings suggest many opportunities for public education to increase support for menthol policies and tailored messaging to reach and help African American smokers quit. Additional education is needed on the unique health harms of menthol smoking in African American communities. Advocacy efforts should also focus on engagement of community members to increase support for menthol sales restrictions and increase community-driven action.

Table 3.1 African American Adult Interview Participant Demographics and Smoking Characteristics

DEMOGRAPHICS	Total (n=28)
Gender	
Female	46.4%
Male	53.6%
Sexual Orientation	
LGBT	17.9%
Heterosexual/straight	82.1%
Education level	
Less than high school	14.8%
GED/High school diploma	51.9%
Some college or technical school	25.9%
College degree or more	7.1%
Mean age (years; range)	40.9 (25-61)
SMOKING CHARACTERISTICS	
Mean age at smoking initiation (years; range)	17.3 (12-23)
Mean cigarettes per day	
<10	57.1%
10-20	28.6%
>20	14.3%
Time to first cigarette	
Within 5 minutes	50.0%
6-30 minutes	28.6%
31 minutes or more	21.4%
Usual menthol brand	
Newport	92.9%
Marlboro	3.6%
Non-menthol smoker	3.6%

Chapter 4: Case Study - Lessons Learned from the Passage of the Minneapolis Menthol Tobacco Sales Restriction (Study 2 Brief Report)

4.1 Introduction

Restricting the sale of menthol tobacco products is one local policy-level approach that has the potential to have a positive impact on reducing the burden of smoking among African Americans. In 2017, the Minneapolis city council amended Title 13 Tobacco, Chapter 281 of the Minneapolis Code of Ordinances relating to Licenses and Business Regulations: Tobacco Dealers to restrict the sale of menthol, mint, and wintergreen flavored tobacco products to adult-only tobacco shops and liquor stores. This policy was a result of a robust community engagement process and educational campaign, which included youth advocates and active leadership from members of communities most affected by menthol tobacco-related disparities. The Minneapolis policy was among the first in the country to enact a comprehensive restriction on menthol tobacco sales, including e-cigarettes. Lessons learned from the policy passage process can help inform other jurisdictions around the country that may be interested in pursuing menthol sales restrictions.

According to the WHO (2005), there are five key phases in health policy-making as follows: 1) problem identification; 2) policy formulation; 3) policy adoption; 4) policy implementation; and 5) policy evaluation. The purpose of this case study is to describe phases one through three as they relate to the 2018 Minneapolis menthol tobacco sales restriction as well as to identify key factors that

led to successful policy passage and lessons learned to inform other communities considering similar policy efforts.

4.2 Methods

Key stakeholders (n=12) in the policy process, including elected officials (n=2), city staff (n=1), lead advocates (n=3), community advocates (n=5), and funding agency staff (n=1) were interviewed in person. The PI provided input on all key aspects of the research including the conceptualization of the study, recruitment strategy, and development of the interview guide.

Purposive sampling was employed to ensure that a variety of perspectives on the policy change process were included. Participants were selected in concert with local advocates and stakeholders who were instrumental in the efforts that lead up to the Minneapolis menthol policy. Participants received a $25 Target gift card for participation. To protect the confidentiality of participants, direct quotations in this text are unidentified.

Questions focused on the preparation, strategies, and key elements that led to the passage of the menthol policy. Participants were asked about the key factors involved in driving the work, the opposition response, and lessons learned from the policy process during the hour-long interview. A copy of the interview protocol is available in Appendix C.

Interviews were conducted by Bosma Consulting, LLC and were audio recorded and transcribed. The PI uploaded the transcripts into NVivo to facilitate analysis using the framework method. Interview responses were coded and categorized under the key phases of policy-making. Responses were also synthesized

across stakeholders to extract key lessons learned from the policy process. IRB approval was obtained from the Minnesota Department of Health and the University of Maryland.

4.3 Key Elements of the Policy-Making Process

4.3.1 Phase 1: Problem Identification

Restricting flavored tobacco: Discussions regarding the Minneapolis effort to restrict flavored tobacco products began in 2014 among funders, key advocates, and community leaders. A decision was made to first pursue the restriction of flavored tobacco products and exclude menthol because community leaders and advocates believed that additional time was needed for community mobilization. Moreover, there was uncertainty about political feasibility of passing a flavored tobacco restriction that included menthol. At the time of initial discussions, the Tobacco Control Act had exempted menthol from its ban on other flavored cigarettes. Furthermore, Chicago was the only major city to restrict menthol and that move was still under litigation whereas others (NYC and Providence, Rhode Island) had passed flavored restrictions with menthol exemptions and successfully defended them in court. The Minneapolis flavor restriction ordinance, which restricted the sales of flavored tobacco products exempting menthol, to adult-only tobacco shops passed in 2015. The overall strategy in Minneapolis was a to use the first win on flavors as a stepping stone towards restricting menthol.

It was always our intent to do this in a two-step process. As things moved forward, it became clear to us that as a strategy, it was a good thing, because it already set a legal precedent.

Coalition building: To increase readiness to take action on menthol, a dedicated menthol coalition was formed co-led by the Americans for Nonsmokers Rights-Minnesota (ANSR) and NorthPoint Health and Wellness. NorthPoint is a non-profit community services organization that serves low-income families, adults, and youth primarily residing in North Minneapolis and is viewed as a trusted leader in the Minneapolis black community. The menthol coalition included an expansive base of support including youth-serving agencies, community-based organizations, faith-based groups, physicians' associations, and public health advocacy groups. By the time of policy passage, over 50 organizations were included in the coalition.

And I think it's very important in any community that you involve the diversity that's in your community. Not just the African American organizations but all the other organizations that came on board to let the powers [that] be know that we're not out in isolation. There is a coalition, as it says, of individuals that are working together for the same cause.

Education: A series of educational initiatives were launched to raise awareness and increase community engagement around the need to address menthol in January 2015. Menthol experts from the African American Tobacco Control Leadership and National African American Prevention Network were invited to educate and foster support for menthol polices. They met with advocates, coalition partners, clergy leaders, city public health staff, elected officials, and funding organizations to elevate the social justice issue surrounding menthol. A second round of educational sessions was held in June 2015 for the larger community. Meetings were intentionally held in community spaces, such as libraries and other community centers, to foster broader community engagement. These efforts addressed the use of menthol among African Americans and other priority populations, the long history of tobacco industry targeting of marginalized communities, and the missed opportunity at the federal level to take action on menthol.

The "Beautiful Lie, Ugly Truth" campaign was developed with materials that were tailored to the community regarding the harms of menthol. The goal of the campaign was to "increase awareness that menthol tobacco is a problem in our communities and motivate leaders to recognize the health impact of menthol tobacco use" (The Association for Nonsmokers-Minnesota, n.d.). Advocates commented on the extensive process of vetting campaign materials with community members. Campaign messaging include images of actual community members (vs. stock photos or models), which made the campaign much more authentic and resonate within the community. One facet of the campaign was a video titled "Beautiful Lie Ugly Truth about Menthol Tobacco" featuring a poem by Joe Davis, a spoken word artist

(available at http://beautifullieuglytruth.org/resources/). The video, produced by ANSR and Breathe Free North, included community members and youth speaking their native language, reciting words from the poem:

We see the ugly truth behind the smoke screen

The beautiful lies that we won't believe

Stop selling us these beautiful lies and ugly truths

Because we ain't buying 'em…

Laying the groundwork: Once the issue of menthol was elevated and a base of support was mobilized, a Minnesota State Senator led a legislative effort at the state level that resulted in the funding of a community-based project, the "Menthol Cigarette Intervention Grant," from the Minnesota Department of Health (Minnesota Department of Health, 2015). This grant resulted in an intervention study that employed change agents from within the community to educate and raise awareness on the harms of menthol tobacco use within the African American community. Findings from the baseline survey reinforced the high rates of menthol smoking among African Americans in the Twin Cities and supported the need for ongoing educational and policy efforts to counter tobacco industry targeting (African American Leadership Forum, 2017; Minnesota Department of Health, 2015). Despite the strong evidence base and national data on the impact of menthol, it was powerful to have local-level data to support the policy effort. The faith-based community was also engaged around "No Menthol Sunday," a national effort sponsored by the

African American Tobacco Prevention Network to enlist clergy in spreading information on the harms of menthol to their congregations. Together, these efforts further generated grassroots support and created synergy from multiple partners.

Framing the issue: The menthol issue was framed primarily around two key themes - youth and social justice. Reducing youth exposure and access to menthol tobacco products were key elements of the coalition's messaging. The underlying message of these efforts centered around preventing addiction among the next generation of young people. Further, these messages were even more powerful since youth were active participants in the advocacy process and spoke of the impact of tobacco use on their peers.

[The youth] came and reported [on] … the work that they've been doing, and they essentially asked [the council] to help do something to help them keep their friends from getting hooked on tobacco by helping restrict their access to flavored tobacco.

Highlighting the tobacco industry's long history of predatory marketing to African American communities was also important. It was essential to highlight the disproportionate toll of menthol smoking not only among African Americans but also other racial/ethnic subgroups and the LGBTQ groups to demonstrate its far-reaching community impact.

While the issue of social justice was paramount in these policy efforts, advocates acknowledged that messaging did not always resonate with policy-makers.

The targeting was important, but you had ... from the communities of color … you had to measure how you led with that. You had to be strategic about that.

The political climate: The Minneapolis City Council had recently dealt with other policy issues that affected small businesses. These included a $15 minimum wage, sick leave, and a plastic bag ban, so there was concern about the timing of working on the menthol issue around the same time. Furthermore, 2017 was an election year for the City Council. Thus, the coalition decided to move forward with the ordinance introduction in summer 2017 prior to election season ramping up.

4.3.2 Phase 2: Policy formulation

Type of menthol restriction: There was consensus that the menthol policy should follow the same parameters as the precedent set with the flavored tobacco policy i.e. restriction of sales to adult-only tobacco shops. Other types of policies, such as the Chicago buffer zone approach, were not viable in Minneapolis and a complete ban on menthol (without exemptions) was not considered. The exemption of adult-only tobacco shops helped make the case that the policy was intended to restrict youth access and was not targeting adults. A one-year implementation delay to

August 1, 2018, was built-in to give tobacco retailers sufficient lead time to make the transition within their businesses.

Liquor store compromise: Minneapolis is divided into 13 wards, each with approximately 30,000 residents. During the policy-making process, it was noted that one of the wards in the Northside of Minneapolis did not contain a tobacco shop, which would inconvenience adult smokers. After much negotiation, a compromise was made to include liquor stores in the exemption in order to gain votes on the council. The rationale to include liquor stores followed the premise that young people were already prohibited from entering the store without an adult guardian, so these retail stores should be excluded from the ordinance.

Opposition: Those against the ordinance included tobacco retailers, retailers' associations, and the tobacco industry. The opposition launched a campaign "Enough is Enough Minneapolis," which was opposed to further government intervention on businesses, citing the other discussions surrounding the minimum wage and plastic bag ban. Local retailers stated that the menthol policy would hurt their businesses, lead to a loss of jobs, and push customers to take their business to surrounding cities where menthol tobacco would still be available. They also highlighted the argument that this policy went against adults' freedom of choice to smoke and would lead to an illicit market for menthol cigarettes.

In January 2017, Reynolds American, Inc., maker of Newport cigarettes, sponsored prominent civil rights activist the Reverend Al Sharpton, founder and

President of the National Action Network, to hold a meeting at a black church in Minneapolis on "Decriminalizing the Black Community: Banning of Menthol Cigarettes." Panelists included former FL congressman Kendrick Meek and former VA police chief John Dixon, past president of the National Organization of Black Law Enforcement Executives. Discussions centered around how the menthol policy would lead to increased interactions with law enforcement and the criminalization of black men, a topic at the forefront of public consciousness.

... And the tobacco industry really fueled those racism arguments. They sent in Al Sharpton to try to kind of have misdirection. Well, this is targeting black people and they were trying to claim that this would result in more jailing of black men. So there was definitely a lot of fear around this issue, I would say.

The opposition also spread misinformation that this policy was a full prohibition on menthol tobacco and in some cases, a ban on all tobacco products. Finally, the opposition argued that enacting Tobacco 21, which would increase the legal sales age from 18 to 21, would be more effective in curbing the impact of menthol than a menthol sales restriction and urged the City Council to consider Tobacco 21 as a policy alternative.

Countering opposition: Advocates countered these opposition and scare tactics in various ways. They countered information on economic impact by

highlighting the distinction between sales and profits, which demonstrated that the retailers' claims of lost profit were overstated.

At the meeting with Sharpton, coalition leaders countered the misdirection around the criminalization argument by educating that the policy would result in retail stores' being subject to fines; menthol smokers would not be penalized. Advocates emphasized that the retailers, not the consumers, are responsible parties in policy implementation.

> *…the Minneapolis ordinance [was about] licensing restrictions, having nothing to do with purchase, use, or possession. It was strictly who's selling the product. Their arguments were untrue, and because we'd already met with people, they knew them to be untrue. Our partners played an essential role, not a peripheral role at all in the meetings that had taken place with law enforcement …*

An interesting juxtaposition appeared: While advocates viewed leaving menthol on the market as discriminatory when other flavored products had already been restricted, opponents saw restricting menthol as unfairly targeted towards black smokers. The racial arguments also led to some pushback from white City Council members who did not want to appear paternalistic to the black community or to be targeting black smokers. These concerns were contradicted by prominent black community members and leaders by reaffirming that the tobacco industry had been discriminatory in their targeting of black communities with menthol products in the

first place. In these discussions, community leaders also expressed criticism of the federal policy, which did not address menthol cigarettes, leaving black youth unprotected while other flavors were taken off the market.

4.3.3 Phase 3: Policy adoption

The first step in the legislative process was for the sponsors, Council members Gordon and Bender, to submit a proposal providing notice of intent. Following this step, Ordinance 2017-038 was introduced and the first reading took place on June 16, 2017. It was then referred to the Health, Environment & Community Engagement (Health) Committee for Committee Action. At its meeting on July 24, 2017, the Health Committee heard an introductory presentation by the Minneapolis Health Department. Health Department staff set the stage by stating that over 6000 Minnesotans die every year from smoking and explaining that smoking is related to disparities among African Americans, American Indians, and individuals with low income and less educational attainment. Following the Health Department's presentation, Dr. Phil Gardiner, a prominent African American menthol researcher and advocate, provided additional compelling information about the impact of menthol on the African American community and other priority populations.

These comments were followed by a public hearing period where over 70 individuals signed up to testify. Each individual was limited to two minutes, with alternating speakers in support of and in opposition to the policy. Those who testified in support of the policy were organized by lead advocates who selected credible messengers to present sound data on the impact of menthol alongside powerful

personal stories. Those in opposition testified primarily about lost sales and the potential impact on businesses. Due to the lengthy period of public testimony, the Committee lost quorum before a vote could be taken.

Rather than delay the issue and wait for the next regularly scheduled meeting, a special meeting of the Health Committee was convened on August 2, 2017. At this meeting, the Health Committee passed the ordinance and moved it to the full Council. The Committee of the Whole met two days later on August 4, 2017, and voted 10 to 2 to pass the policy (with one City Council member not present for the vote). The Mayor approved the measure.

The menthol restriction took effect on August 1, 2018. The goal was to substantially reduce the availability of menthol tobacco from 318 tobacco retail stores to 23 tobacco shops and 24 liquor stores. The policy stipulates enforcement of the legislation as follows. Compliance with the policy coincides with annual license inspections. The city also responds to complaints of violations on a rolling basis. Those in violation of the ordinance receive a $200 citation for the first offense; this fine doubles at every subsequent offense. There is also a possibility of misdemeanor criminal prosecution and potential tobacco license suspension, revocation or non-renewal if there are repeat offenses.

4.4 Lessons Learned

Align key players prior to beginning the legislative process: Before the ordinance could be introduced, the "go ahead" was needed from the African American community and leaders, lead advocates, the city health department, and

Council Member champions. Once these groups were aligned, the legislative process could proceed. The timing of the policy was also affected by the surrounding political context; other policy discussions were impacting the same group of businesses and City Council members were up for re-election later that year in Fall 2017. Furthermore, Minneapolis was the first community in the state to address menthol so it took over two years bring the issue of menthol to the forefront, increase awareness, and build buy-in and community support.

Champions are critical to drive the issue forward: the importance of strong champions at every step of the way and from multiple sectors was key to policy success. This issue was supported at every level of government, including the city, county, and state. The policy would not have passed without the courageous leadership of lead advocates and a strong coalition. Along with leadership of the City Council sponsors, their aides played an instrumental role in keeping the advocates informed about the status of the policy. The city public health department also was invaluable in keeping the dots connected between the City Council, advocates, and community members. The city Mayor was also supportive.

Community as the face of advocacy: The inclusion of community leaders, in particular black leadership, as leaders of the advocacy effort helped bring credibility and buy-in to the issue. The mobilization of coalition members and broader community was invaluable in meeting with City Council members, writing letters to the editor, sending postcards and letters of support, participating in radio interviews,

conducting press conferences and other media, and packing the room every time the City Council met on the issue with their green *Beautiful Lie Ugly Truth* t-shirts. Community engagement was especially critical when faced with opposition claims of discriminatory policy-making to persuade City Council members to remain supportive of this community-driven advocacy effort.

Authentic youth engagement: The active engagement and cultivation of youth throughout the process and the framing of the policy in terms of youth prevention were critical pieces to policy success. The youth voice on this issue was compelling, prominently heard by City Council members, and a cited as a primary reason for taking up the menthol issue. There was also a sense of pride and hopefulness, particularly that engagement in this work may serve as a catalyst for the youth's engagement in future public policy efforts.

4.5 Conclusion

This case study highlighted the key factors that led to successful passage of the Minneapolis menthol restriction. The policy was intended to change the retail landscape by reducing youth access to menthol tobacco in order to prevent youth initiation and decrease smoking rates and related health impacts, especially among African Americans. The menthol coalition was effective in harnessing community support and mobilizing leadership from the communities most adversely impacted by menthol towards successful policy passage. At the time of passage, the Minneapolis policy was ground-breaking and paved the way for other jurisdictions to take action

on menthol. As of this writing, five other cities within Minnesota have restricted sales of menthol tobacco, including Saint Paul, Duluth, Falcon Heights, Lauderdale, and Mendota Heights. Future directions for research include examining the impact of menthol tobacco availability in exempted liquor stores. Enforcement of the policy and long-term surveillance will help determine whether the policy has the intended impact on alleviating health disparities among African American and other impacted communities.

This study is limited in its focus on key stakeholders who were supportive of the menthol policy; no constituents from the opposition were interviewed. Further, as this was a retrospective study, recall bias may have also impacted study findings. Despite these limitations, this study offers important insights to advocates in anticipating and crafting counter-arguments to tobacco industry and opposition efforts to influence political decision-making. The successes and challenges encountered during the policy change process can inform other policy efforts to address the harm of menthol tobacco.

Chapter 5: Evaluating the Impact of the 2018 Minneapolis Menthol Policy on the Retail Environment (Study 3 Manuscript)

5.1 Introduction

Menthol cigarettes, which account for 36% of the retail cigarette market in the U.S. (Federal Trade Commission, 2018), have been linked to increased initiation among youth, higher levels of addiction and decreased quitting among adults (Tobacco Products Scientific Advisory Committee, 2011; U.S. Food and Drug Administration, 2013). Since 2000, the U.S. market share of menthol cigarettes has increased by over 25% while sales of non-menthol cigarettes have decreased (Federal Trade Commission, 2018). The tobacco industry has disproportionately targeted menthol cigarettes to racial/ethnic minorities, particularly African Americans, and low-income communities and youth (Anderson, 2011; Cruz et al., 2010; Gardiner, 2004). Menthol cigarettes remain on the market and are widely available (Lee et al., 2015) despite overwhelming evidence that supports their removal from the marketplace (Tobacco Products Scientific Advisory Committee, 2011; U.S. Food and Drug Administration, 2013; Villanti, Collins, et al., 2017). In November 2018, the FDA announced its intention to move towards a ban on menthol cigarettes and cigars (Center for Tobacco Products, 2018), yet a timeline for action was not specified. Further, menthol e-cigarettes and other tobacco products, such as smokeless tobacco, were left unaddressed by this announcement.

In the absence of a federal ban on menthol cigarettes and continued availability of other menthol tobacco products, localities are exercising their authority to enact sales restrictions on these products. These policies range from partial restrictions, which apply to stores within a radius of schools such as the 2014 policy enacted in Chicago, to complete city-wide bans such as the 2018 San Francisco policy (Public Health Law Center, 2018). In 2017, the city of Minneapolis was the second city in the U.S. to pass an ordinance restricting the sale of menthol, mint, and wintergreen tobacco products to adult-only tobacco shops or liquor stores. The Minneapolis ordinance passed on August 4, 2017, and implemented a year later on August 1, 2018, comprehensively covers all menthol tobacco products including cigarettes, cigars, and e-cigarettes.

According to the city of Minneapolis, the policy was intended to reduce the availability from 318 licensed tobacco retail stores to 23 tobacco shops and 24 liquor stores (City of Minneapolis, 2017), an 85% reduction in the number of outlets. The ordinance defined a tobacco shop as a "retail establishment with an entrance door opening directly to the outside that derives at least 90% of its gross revenue from the sale of tobacco products" and does not permit individuals under the age of 18. The liquor store exemption applies to those liquor stores that do not permit entrance to individuals under the age of 21 unless accompanied by a parent or guardian. According to the Minneapolis Health Department, the purpose of the policy was to "prevent youth tobacco use, lifelong addiction to nicotine, the negative health effects of tobacco use and the tobacco-related health disparities between white populations and people of color" (Minneapolis Health Department, 2017).

Evaluations of non-menthol flavored tobacco sales restrictions have found that these types of policies can be effective in reducing sales of flavored tobacco and youth smoking prevalence (Farley & Johns, 2017; Rogers et al., 2017; Welsh, Guardino, Abdullahi, Larson, & Pearlman, 2017). However, because menthol has often been excluded from sales restrictions, there is a paucity of published literature about the potential impact of menthol tobacco sales restrictions. We are only aware of one published study to date that examines the impact of a menthol restriction. Czaplicki et al. (2018) conducted retail store assessments one year following the implementation of the Chicago buffer zone menthol policy, where menthol tobacco cannot be sold within 500 feet of high schools. The study found that over 40% of tobacco retail stores were non-compliant, continuing to sell Newport cigarettes, the primary outcome measure (Czaplicki et al., 2018). Moreover, the study found a significant positive association between non-compliance and the presence of menthol cigarette advertising. Therefore, further research is needed to evaluate whether sales restrictions also impact advertising, even though no language on advertising restrictions is included in the legislation.

Recent studies have also demonstrated that the tobacco industry has attempted to undermine intended flavored tobacco policy effects by introducing products with ambiguous names or concept flavors (such as Show “TaTa” cigarillos and Rock ‘n’ Roll “Blue” cigars) in NYC (Farley & Johns, 2017) and replacing products previously labeled as menthol with the word “green” in Ontario, Canada (Brown et al., 2017). These studies suggest it is important not only to assess compliance with menthol

restrictions but to monitor unintended consequences and potential tactics to circumvent restrictions following policy-implementation.

The present study builds on the previous literature by examining changes in the availability and marketing of menthol tobacco using a quasi-experimental design. Specifically, this study builds on the Czaplicki et al. (2018) study in two important ways. First, this study assesses compliance with the policy as it applies to all menthol tobacco products (not just menthol cigarettes). Second, it utilizes a quasi-experimental design that includes baseline data pre-policy as well as observations from a comparison city to assess changes in menthol tobacco availability and marketing. The primary research questions for the study included:

1. What was the overall rate of compliance for Minneapolis intervention stores?
2. How did menthol tobacco availability and marketing change following policy implementation?

We hypothesized that intervention stores in Minneapolis have a significant decline in the availability of menthol tobacco products post-policy implementation compared to Brooklyn Park and compared to exempt stores in Minneapolis. We further hypothesized that intervention stores in Minneapolis have a significant decline in menthol tobacco marketing following policy implementation. Findings can inform other jurisdictions and federal regulatory action on menthol to reduce the burden of tobacco use.

5.2 Methods

This observational study used a quasi-experimental, pre/post design with Minneapolis, MN as the intervention city and Brooklyn Park, MN as the comparison city. Tobacco retail store assessments were conducted two months prior to (June 2018) and two months following (October 2018) policy implementation. Brooklyn Park was selected for comparison because it is located in the Twin Cities metro area and is similar in demographic characteristics (median income, percent of the population with a high school education, age distribution, and racial/ethnic make-up) to Minneapolis (U.S. Census Bureau, 2018). Further, to our knowledge, Brooklyn Park does not have any restrictions on the sale of menthol or other flavored tobacco products nor did it have any resolutions or advocacy efforts focused on this topic underway at the time this study was designed.

The PI provided input on all key aspects of the research including study conceptualization, sampling strategy, and the development of the instrument. A stratified random sample of 48 intervention tobacco retail stores as well as 12 stores exempted from the policy (6 tobacco shops and 6 liquor stores) in Minneapolis and 18 tobacco retail stores (16 convenience/grocery/mass merchandiser stores and 2 tobacco shops) in the comparison city were selected from the cities' tobacco licensing lists. These lists were obtained from the Minnesota Department of Revenue in May 2018. The sample size was selected to detect a 50% difference in the proportion of convenience stores that were selling menthol tobacco (primary outcome) and a 30% difference in secondary outcomes (marketing), accounting for 20% attrition (G*Power 3.1.9.2). The final sample included 59 pairs of stores in Minneapolis (45

intervention; 6 liquor; and 8 tobacco shops) as well as 18 pairs of stores in Brooklyn Park. In one Minneapolis intervention store, the data collector was asked to leave. Two convenience stores in Minneapolis stores split their stores and added tobacco shops; these are coded as tobacco shops in the final sample.

Pairs of trained data collectors independently conducted discrete (unannounced) observational assessments of the retail environment using the Streetwyze platform (Streetwyze.com). Prior to conducting assessments, data collectors completed training on assessing the retail environment on each of the measures below and recording them on Streetwyze via mobile phone as well as field practice on stores not included in the study. Percent agreement across coders ranged from 62.5% - 100.0%. The University of Maryland Institutional Review Board reviewed this study and determined it was exempt from human subjects review.

5.2.1 Measures

The assessment tool was based on the Standardized Tobacco Assessment for Retail Settings (STARS) (Henriksen et al., 2016). The STARS tool was developed as a retail marketing monitoring and policy advocacy tool; measures for this study were adapted for policy evaluation purposes. The majority of STARS measures were found to have moderate or high reliability (Henriksen et al., 2016).

Menthol tobacco availability: The presence of menthol tobacco products including cigarettes, little cigars/cigarillos, e-cigarettes, smokeless, shisha/hookah, and blunt wraps. A composite based on the availability of any of the aforementioned products was created as a binary variable: menthol tobacco products available

(yes/no). Additionally, the availability (yes/no) of Newport menthol cigarettes, Marlboro menthol cigarettes, JUUL menthol e-cigarette pods, and Grizzly wintergreen smokeless tobacco was assessed. These tobacco products were selected based on their market share in the cigarette, e-cigarette, and smokeless tobacco categories for the Minneapolis market area from the Nielsen Company.

Menthol tobacco marketing: The number of ads for menthol and non-menthol tobacco products were counted for the exterior of the store. The number of ads and promotions (combined) for menthol and non-menthol tobacco products were also assessed for the interior of the store. These items were recoded as a binary variable: the presence of menthol tobacco marketing (yes/no).

Store type: Stores were categorized as convenience/grocery store, pharmacy, tobacco shop, and liquor store. Dollar and discount stores were categorized as "mass merchandisers" (Mills et al., 2018). Intervention stores included convenience/grocery stores, pharmacies, and mass merchandisers. We also assessed whether stores sold gas (yes/no).

Neighborhood-level information: Neighborhood-level Census tract data for the percent of minority (non-white) residents as well as residents living under the poverty line were obtained from Census 2010 and linked to store addresses (U.S. Census Bureau, 2018). Previous research has indicated that menthol advertising is prevalent in neighborhoods with a higher proportion of minority residents (Mills et al., 2018).

5.2.2 Analyses

The PI retrieved data from the Streetwyze platform and uploaded it into IBM SPSS Statistics 23 for analysis. Summary statistics were calculated for each measure. Differences in baseline characteristics (store type, neighborhood-level percent minority residents and percent of residents living under the poverty line) of tobacco retail stores in Minneapolis and Brooklyn Park were assessed.

A two-sample Z-test was used to compare the proportion of stores selling menthol tobacco in Minneapolis post-policy implementation vs. Brooklyn Park. McNemar's test was used to compare menthol tobacco availability in Minneapolis pre- vs. post-policy implementation. Two-sample t-tests were used to compare the interior and exterior number of menthol tobacco ads in Minneapolis vs. Brooklyn Park. Paired t-tests were used to compare the interior and exterior number of menthol tobacco ads in Minneapolis pre- vs. post-policy implementation. Fisher's Exact Test was used to calculate the association between noncompliance and the presence of menthol marketing. Test statistics were considered significant at a p-value of <0.05.

5.3 Results

The baseline characteristics of stores that comprised the final study sample are detailed in Table 5.1.

5.3.1 Menthol tobacco availability

The majority (88.9%) of Minneapolis intervention stores were compliant with the menthol restrictions two months following policy implementation. The availability of menthol tobacco in Minneapolis intervention stores decreased significantly from 100.0% pre-policy to 11.1% post-policy ($p<.001$) (Figure 5.1). Minneapolis intervention stores also had significantly less availability of menthol tobacco products post-policy implementation compared to Brooklyn Park (11.1% vs. 100.0%, respectively, $p<.001$).

Among non-compliant Minneapolis intervention stores (n=5), menthol cigarettes were the most prevalent menthol tobacco product available (80.7%), followed by roll your own (40.0%), little cigars or cigarillos (20.0%), and e-cigarettes (20.0%).

We also examined the availability of specific brands including Newport menthol cigarettes, Marlboro menthol cigarettes, JUUL menthol e-cigarette pods, and Grizzly Wintergreen smokeless tobacco (Figure 5.2). Newport was the most widely available menthol tobacco product, with all stores selling the product in Minneapolis and Brooklyn Park pre-policy implementation. Following policy implementation, the prevalence of Newport menthol cigarettes decreased to 2.2% in Minneapolis.

Menthol tobacco products continued to be available in all (100.0%) exempted Minneapolis tobacco-shops and liquor stores following policy implementation. Additionally, two convenience stores in Minneapolis underwent transitions between data collection rounds and added interior tobacco shops, increasing the number of

tobacco shops in our sample from 6 to 8. No products with ambiguous names, or replacement menthol products, were observed in the overall sample.

5.3.2 Menthol tobacco marketing

Pre-policy, 87.23% of all Minneapolis intervention stores displayed interior marketing and 23.4% had exterior ads for menthol tobacco products. Following policy implementation, 24.44% and 17.78% of intervention stores displayed interior and exterior ads, respectively. The presence of menthol tobacco marketing in the exterior or interior of the store was not associated with compliance in Minneapolis intervention stores ($p=.645$ and $p=.375$, respectively). However, some compliant Minneapolis intervention stores ($n=40$) continued to display ads for menthol tobacco products; 20.0% displayed exterior menthol ads and a quarter (25.0%) had interior ads and promotions.

There was no significant difference in the mean number of outdoor ads for menthol products (including cigarettes, little cigars/cigarillos, e-cigarettes, and smokeless tobacco) in Minneapolis intervention stores from pre- to post-policy (0.44 vs. 0.32, $p=.455$). However, there was a significant decrease in the mean number of indoor ads and promotions for menthol products (including cigarettes, little cigars/cigarillos, e-cigarettes, and smokeless tobacco) in Minneapolis intervention stores from 5.23 ads pre-policy to 0.37 ads post-policy ($p<.001$).

5.4 Discussion

To our knowledge, this study is among the first to examine the impact of menthol sales restrictions on the retail environment using a quasi-experimental design. Our results indicate a high rate of compliance, indicating that menthol sales restrictions can significantly reduce the availability of menthol tobacco products in tobacco retail stores. Study findings also suggest that policies designed to restrict the sale of menthol tobacco products can significantly reduce menthol tobacco marketing at the point-of-sale, potentially contributing to creating a health-promoting built environment. Longitudinal studies are needed to assess how menthol availability and exposure to menthol marketing, impact initiation, progression to regular use and cessation, especially for African Americans who are disproportionately impacted by menthol smoking (Alexander et al., 2016)

Compared with the Chicago buffer zone menthol policy evaluation (57% compliance) (Czaplicki et al., 2018), we found a higher rate of compliance with the Minneapolis menthol restriction (89% compliance). Prior work examining the impact of the 2015 Minneapolis flavored restriction found a 61% compliance rate five months following policy implementation (Brock et al., 2019). This rate increased to 85% nine months later, similar to the compliance rate found in this study. It is plausible that educational and enforcement activities by advocates and city officials associated with the 2015 flavored restriction, and ahead of the menthol restriction implementation date, prepared retailers to adhere to the menthol restriction and resulted in relatively high rates of compliance.

Similar to the Czaplicki et al. (2018) study, we did not find any products with ambiguous names or products designed to replace menthol, such as was observed in Alberta, Canada (Brown et al., 2017). However, some challenges to policy adherence remain. For example, data collectors noted that two convenience stores had erected walls and created "separate" tobacco shops within the interior of the convenience store (it is unclear at the time of this writing how these cases will be handled by compliance officers). The emergence of these type of establishments underscores the challenges to a partial menthol restriction. Unlike a complete ban on menthol tobacco city-wide, exemptions offer opportunities for tobacco retail stores to take action to circumvent the intended impact of the policy. Therefore, it is important not only to monitor compliance with the menthol restriction but with the ordinance's tobacco shop language, which mandates an entrance door opening to the outside and deriving 90% of its sales from tobacco. Moreover, menthol tobacco and marketing continued to be available in exempted tobacco shops and liquor stores, as well as in the comparison city, highlighting opportunities for policy-makers to expand regulations both within Minneapolis and across the state to continue to curtail menthol tobacco availability.

It is notable that the menthol sales restriction led to decreases in menthol marketing especially given that restrictions on advertising could be subject to legal challenges due to First Amendment protections (Public Health Law Center, 2018). However, the Tobacco Control Act gave localities the regulatory authority to enact restrictions on the time, place, and manner, of advertising and promotions. Because tobacco marketing is associated with youth smoking initiation and progression (U.S.

Department of Health and Human Services, 2012), strategies to reduce youth exposure to advertising and promotions at the point of sale are imperative. In 2016, the tobacco industry spent $9.5 billion in marketing expenses nationwide; in Minnesota, the tobacco industry spent over $117 million (Campaign for Tobacco Free Kids, 2017), with the majority spent at the point of sale. While there was no decrease in the mean number of outdoor ads for menthol products, the mean number of ads was low overall (less than one, both pre- and post- policy). However, the significant decrease in the mean number of indoor ads and promotions for menthol products from 5.25 to 0.37 post-policy suggests that consumers may be less exposed to tobacco marketing at the point-of-sale.

This study has several limitations and strengths to note. First, our findings are limited to Minneapolis and may not be generalizable to other jurisdictions that have enacted menthol sales restrictions. Future studies are needed in other jurisdictions to confirm our findings. Second, we were unable to adjust to differences in neighborhood-level differences in residents living under the poverty line due to lack of variation in the outcome in the comparison city. Third, data collection occurred two months prior to and following policy implementation, which could have impacted study findings. Specifically, the policy was implemented one year following policy passage so it is plausible that tobacco retailers made changes to their stores prior to baseline data collection, which would have resulted in more conservative estimates. In regards to post-policy data collection, it is plausible that retailer education and news media surrounding policy passage could be contributing to high rates of compliance. Ongoing monitoring will be needed to assess whether high levels of

compliance are sustained over time. However, short-term data is valuable to identify implementation challenges early on as well as to inform compliance officers and city officials of resources needed for policy implementation. It may also be likely that more tobacco retailers may try to make adjustments to circumvent policy restrictions as they hear of similar changes enacted by their counterparts as further time passes. Future studies that employ a longer-term follow-up period are needed along with examination of sales data to validate the present study's findings.

Notwithstanding these limitations, our study is among the first to investigate the impact of a menthol sales restriction using a quasi-experimental design. The inclusion of the comparison city increases our confidence that the observed differences are due to the menthol policy vs. secular trends. These findings contribute to the literature on the positive impact of partial menthol sales restrictions, considering that menthol tobacco products were no longer available in a majority of tobacco retail stores and that the policy significantly reduced menthol tobacco marketing in the store interior.

Despite high levels of compliance in Minneapolis, menthol tobacco products continue to be available in some intervention stores as well as all exempted tobacco shops and liquor stores. These findings suggest that existing retailer exemptions provide opportunities for reducing menthol tobacco availability to be further addressed by policymakers. Ongoing monitoring of compliance is also warranted to ensure that retailer efforts to circumvent policies are minimized so policies are implemented as intended for maximum public health benefit.

Table 5.1 Characteristics of Stores in the Final Sample Minneapolis and Brooklyn Park, MN, 2018

Characteristic	**Minneapolis**		**Brooklyn Park**		**p-value**
	n	%	n	%	
Overall	59		18		
Store type					p=.168
Intervention stores	47	79.66	-		
Convenience store/grocery store (no gas)	22	37.29	4	22.22	
Convenience store/grocery store with gas	20	33.90	10	55.56	
Mass merchandiser	1	1.69	2	11.11	
Pharmacy	4	6.78	0	0.00	
Tobacco shop	6	10.17	2	11.11	
Liquor store	6	10.17	0	0.00	
Neighborhood-Level Variables	mean	SD	mean	SD	
Minority Residents (%)	45.39	24.21	43.75	14.42	p=.786
Residents Living under the Poverty Line (%)	21.69	14.57	7.03	5.36	p<.001

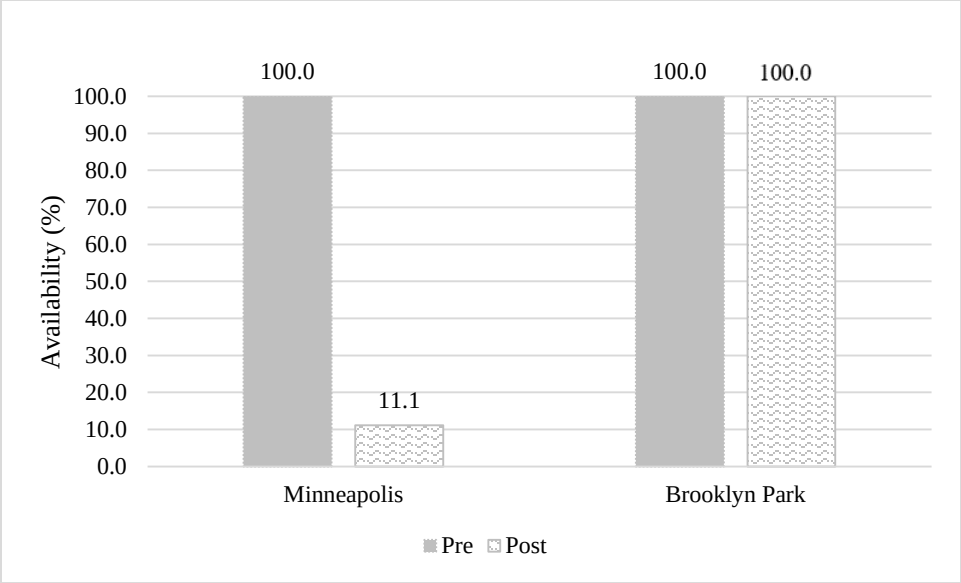

Figure 5.1 Availability of Menthol Tobacco Products in Minneapolis and Brooklyn Park Two Months Pre- and Post-Policy Implementation, 2018

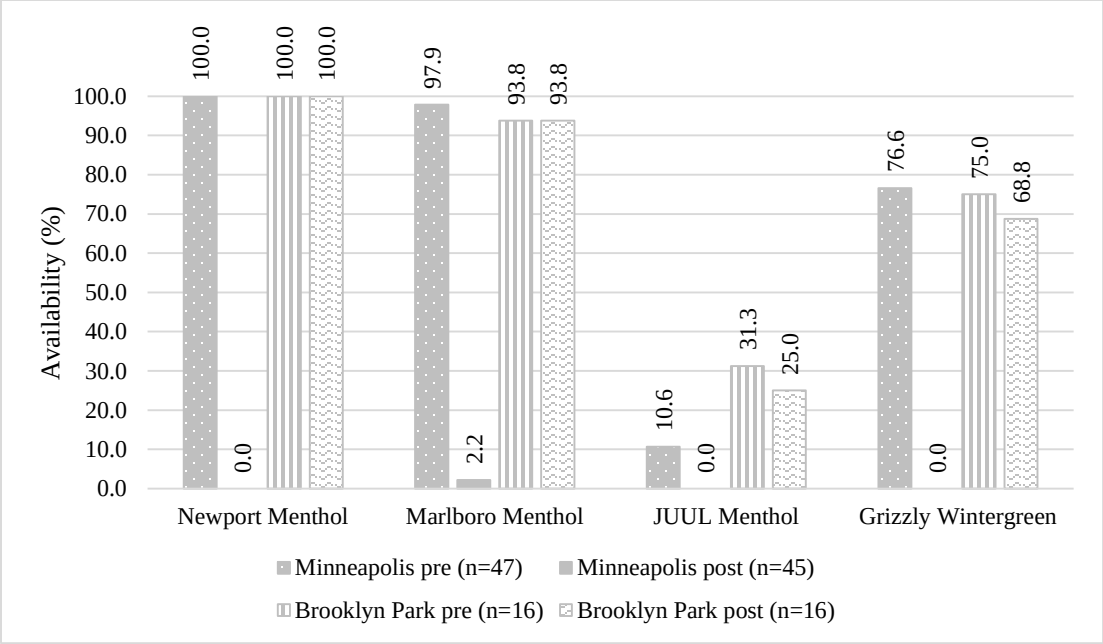

Figure 5.2 Availability of Selected Menthol Tobacco Brands in Minneapolis and Brooklyn Park, 2018

Chapter 6: Summary and Conclusion

6.1 Overview

The overarching purpose of this dissertation was to examine the experience and impact of the Minneapolis menthol policy. The overall public health objectives of restricting menthol tobacco sales are to reduce youth initiation and to encourage adult cessation, thereby alleviating tobacco-related health disparities. Grounded in the Social Ecological Model, the three studies examined various aspects of health policy-making: Problem Identification (Phase 1); Policy Formulation (Phase 2); Policy Adoption (Phase 3); and Policy Evaluation (Phase 5).

The aim of study 1 was to identify African American adult smoker perceptions of menthol cigarettes and reactions to menthol policy. Study 1 added to our understanding of intrapersonal- and community-level factors related to smokers' perceptions of menthol and local menthol tobacco sales restrictions. Many participants perceived menthol as more harmful relative to non-menthol cigarettes, due to additives and a stronger taste, but simultaneously expressed that all tobacco was harmful to health. However, smokers were misinformed about how menthol smoking contributes to adverse health outcomes, particularly for African American communities. Participants who highlighted menthol as problematic at the community level emphasized the role of tobacco industry targeting in historical and present-day efforts to target menthol cigarettes to African Americans and youth.

Study 1 participants also indicated limited awareness of ongoing menthol policy discussions occurring in the Twin Cities in early 2017. Participants indicated uneven support for policies designed to restrict access to menthol tobacco products to

tobacco shops. Lack of support was linked to misinformation about the intended policy impact and a perceived sense of unfairness that the policy was targeting black smokers. Those contemplating quitting tended to be in support of the policy and intended to take advantage of the opportunity towards quitting. Participants indicated that the sales restrictions would make menthol cigarettes less convenient to locate and more expensive after factoring in increased transportation costs.

The aim of Study 2 was to identify key factors that led to successful passage of the Minneapolis menthol policy. Through in-depth interviews with key stakeholders, we identified lessons learned from the policy-making process as well as highlighted elements of the community- and organizational-level influences in policy passage. As identified by key advocates, community members, and City Council members, the menthol policy was successful due to community-led advocacy, strategic framing of the menthol issue, and the active engagement of youth. Over two years a strong coalition was developed with broad representation from over 50 organizations. The coalition created community-tailored "Beautiful Lie Ugly Truth" campaign materials that resonated within the community. These efforts alongside a robust educational initiative resulted in a strong contingent of supporters who were able to withstand pushback from the tobacco retailers, retailer groups, and other tobacco industry-sponsored opponents.

The aim of study 3 was to evaluate the impact of the Minneapolis menthol policy on the retail environment. Study 3 focused on policy compliance and the resulting changes at the organizational level, specifically in tobacco retail stores. Results demonstrated that the menthol policy was effective in reducing menthol

tobacco availability two-months following policy implementation, with 89% compliance among Minneapolis intervention stores in our sample. Consistent with our hypotheses, we observed significant reductions in menthol tobacco availability (100% pre- vs. 11.1% post-policy, $p<.001$) and the mean number of ads and promotions (5.23 pre- vs. 0.37 post-policy, $p<.001$) in the stores' interior in intervention stores. However, no significant marketing reductions were observed in the stores' exterior. Furthermore, unintended consequences of the policy were identified i.e. the splitting of convenience stores (n=2) to create add-on tobacco shops, where menthol tobacco products continue to be sold. Menthol tobacco products continued to be available in all exempted liquor stores and tobacco shops in the sample as well as tobacco retail stores in the comparison city of Brooklyn Park.

Reflexivity statement: The qualitative inquiries in studies 1 and 2 should be considered with respect to the researcher's positionality, specifically, my role as a middle-class, Indian American immigrant, first-generation student, training as a behavioral scientist and researcher at a prominent tobacco control funding organization. My biases are shaped by my life experiences, including witnessing the loss of family members due to tobacco-related disease. This background alongside my cultural values and beliefs influenced every stage of this research from the selection of this dissertation topic through the interpretation of my findings, primarily through my social justice lens and personal objective of working towards advancing health equity for priority populations.

6.2 Strengths and Limitations

As menthol sales restrictions are relatively novel, the examination of the Minneapolis menthol restriction provides a unique and timely opportunity to build the evidence base for menthol policies. By taking advantage of a real-world opportunity, we documented the policy process and compliance with the ordinance using a quasi-experimental design. Other strengths of this dissertation include the use of multiple methods – qualitative and quantitative – to examine various phases of the policy process through the lens of various sectors that played a role in or are impacted by policy passage.

The qualitative inquiry in study 1 highlighted the voice of adult community members to help us gain a more in-depth understanding of their experiences with menthol smoking and is among the first to explore local policy reactions. It also provided an opportunity to explore the rationale behind these perceptions and reactions, which is more challenging to ascertain from survey research. Semi-structured interviews also provided a space for participants to share their perspectives beyond the specific interview questions to include examples that are a critical part of their lived experiences. For example, even though participants were not directly asked about the role of tobacco industry influence, targeted marketing by the industry organically arose in these conversations as participants noted how some brands were ubiquitous in their neighborhoods vs. others. These community insights emphasize how race and menthol are inextricably linked. Another important strength is the study's focus on African American smokers, who are most impacted by menthol tobacco-

related disparities yet were historically underrepresented in tobacco control efforts.

Through qualitative interviews, we generated unique insights from community members, advocates, and policy-makers in study 2, an often missing component in examining policies following adoption. These insights showcased how policy-making is an iterative process, and that the work does not always follow a linear pattern from policy formulation to adoption through evaluation. The idea of a menthol restriction was seeded during the adoption of the 2015 flavored tobacco restriction; policy formulation and reformulation are ongoing, dynamic processes influenced by a myriad of social, cultural, and political factors. This qualitative inquiry also underscored how community power could be harnessed towards achieving public health goals.

Study 3 included a robust sample of retail stores for the policy evaluation component and a comprehensive tool to assess both intended and unintended consequences of the policy on the retail environment. The inclusion of the comparison city of Brooklyn Park increases our confidence that the observed differences are due to the menthol policy vs. other environmental factors. Furthermore, the quasi-experimental design is the most practical for policy evaluation studies; it is not possible to experimentally test real-world policy impact due to inability to randomly assign policies to different locales.

Findings should be interpreted with consideration of the studies' limitations. Overall, this dissertation did not include study of the implementation phase (Phase 4 of policy-making); the extent to which policies are enforced and

implemented can impact policy outcomes. In addition, studies 1 – 3 may not have captured all possible factors that influence menthol tobacco use and its unique context. For example, study 1 did not focus on the influence of peers and other interpersonal-level factors that influence menthol perceptions.

Study 1 focused on established African American smokers, aged 25 and over; however, the perspectives of youth and young adult smokers (aged 18-24) who may have different perceptions of menthol were excluded (Cohn et al., 2017). Also, there was no biochemical verification of smoking status, and menthol smoking was self-reported.

Study 2 was limited by its focus on policy proponents. Tobacco retailers whose businesses were impacted by the policy and other opponents were excluded from the study. Findings may have been subject to recall bias as this was a retrospective study; key stakeholder interviews were conducted several months following policy passage.

Study 3 was focused on policy compliance in one Midwestern city and findings may not be generalizable to other communities. Future studies are needed in other jurisdictions to confirm our findings. Further, study 3 relied on observational retail assessments as sales data were unavailable. The short-term timing of data collection, two months prior to and following policy implementation, could have also impacted study findings. Specifically, the policy was implemented one year following policy passage so it is plausible that tobacco retailers made changes to their stores prior to baseline data collection, which would have resulted in more conservative estimates. However, results indicated a

high level of menthol tobacco availability two months prior to policy implementation. Further, study 3 relied on observational retail assessments because sales data were unavailable.

Threats to internal validity include instrumentation and measurement bias. Specifically, we were unable to assign the same data collectors to the pre- and post- rounds due to staff turnover and scheduling challenges. Reporting bias could have also occurred at follow-up because data collectors were aware that menthol policy had passed and may have reported data to demonstrate a positive impact of the policy on study outcomes.

6.3 Implications

Taken together, findings from these three studies highlight how changes at the policy level can impact changes at the intrapersonal, community, and organizational levels as well as demonstrate the complex interplay of various levels of influence on individual smoking behavior and subsequent health impacts. For example, tobacco industry targeting of African American communities and the promotions and discounting of menthol cigarettes influence community norms around menthol. These norms and the pervasiveness of Newport cigarettes in particular cited by study 1 participants allow for menthol cigarettes to be easily accessible in the community. The levels of influence presented in the Social Ecological Model (Figure 1.1) also provide a framework for reflecting on the implications of study findings for policy, prevention, and practice.

At the highest level of influence, policies, such as menthol restrictions, can foster health-promoting environments wherein "the healthy choice is the easy choice." Reduced availability of menthol tobacco and reduced marketing at the point-of-sale can help mitigate the social context and unhealthy environmental cues prevalent in African American communities that promote menthol smoking. However, as the Minneapolis policy is a partial restriction, menthol tobacco continues to be available in noncompliant stores, tobacco shops and liquor stores that were exempted from the policy, as well as establishments that split their stores and added tobacco shops to continue selling menthol tobacco.

In late 2018, the city of Minneapolis issued a one-year moratorium on "the creation of new tobacco products shops and the issuance of new tobacco licenses" (Cano, 2018)." According to the ordinance, the moratorium was issued in response to the increase in tobacco shop licenses following the menthol policy passage (Cano, 2018). The ordinance also directs the Minneapolis Department of Community Planning and Economic Development to conduct a study to determine how the city's regulations should be amended to avoid further proliferation of tobacco retail outlets, particularly in vulnerable communities. This policy development further emphasizes the iterative and ongoing nature of policy-making and demonstrates the need for sustained efforts to monitor policy impact and retailer response.

One viable policy strategy to address the unintended increase in tobacco shops is to pair partial menthol restrictions with retailer density requirements. These types of policies can cap the number of total licenses within a given jurisdiction or prohibit tobacco shops within a certain distance of other shops with tobacco licenses. The

latter approach could be effective in mitigating attempts to circumvent regulations in the case of split stores where two adjacent tobacco licenses to operate. Other strategies to address menthol tobacco availability include imposing restrictions without retailer exemptions on a city-wide or a state level to more comprehensively address issues of continued access in bordering communities.

In terms of prevention, restricting youth access to menthol tobacco and limiting exposure to menthol tobacco marketing is paramount while menthol continues to be available in the marketplace. In Minneapolis, youth access compliance checks conducted in 2017 found that 13% of stores visited sold tobacco to minors (City of Minneapolis, 2017). Several cities, including Minneapolis, and some states have enacted Tobacco 21 to help address youth access concerns; however, the equity impact of Tobacco 21 policies is unknown. It is also notable that during the menthol policy-making process in Minneapolis, the opposition presented Tobacco 21 as a substitution for the menthol sales restriction. While Tobacco 21, if fully implemented, may impact youth access, it does not address the pervasiveness of menthol marketing or encourage adult smoking cessation. These actions suggest that public health advocates and policy-makers should consider the equity impact of various tobacco control strategies in resource allocation and decision-making processes.

Additionally, potential policy strategies to address youth initiation include reducing marketing exposure by enacting restrictions on the place, time, and manner of advertising. However, restrictions on advertising are subject to First Amendment protections on commercial speech and possible pre-emption at the state and federal

levels (Lange, Hoefges, & Ribisl, 2015). Increasing the price of tobacco through taxation has been shown to deter young people from smoking; accordingly, taxation of menthol tobacco products at a higher rate than other tobacco products has been proposed as a viable policy option (Freiberg, 2015).

Other prevention strategies include mass media campaigns to increase awareness of the public health harms of menthol tobacco relative to non-menthol tobacco. Like the Minneapolis menthol policy campaign, messages should be culturally-tailored so that they resonate within the community and are specifically designed to reach those communities most adversely impacted by menthol. As menthol and race are inextricably linked, community mobilization is critical to address the impact of menthol among those most impacted by tobacco disparities. The tobacco industry has a long history of targeted marketing to African American communities and providing funding to community leaders to oppose public health advocacy efforts (Cheyne, Dorfman, Daynard, Mejia, & Gottlieb, 2014; Yerger & Malone, 2002; Yerger et al., 2007). Counter-marketing strategies are needed to address ongoing tobacco industry influence.

Practice implications include the need to identify menthol smokers by assessing menthol smoking status, helping smokers quit with evidence-based treatment, and implementing strategies to prevent relapse. Menthol restrictions can be an opportune moment to encourage smokers to make a quit attempt. Study 1 participants who initially expressed lack of enthusiasm for the policy idea, noted that the restrictions could prompt a quit attempt. These findings suggest the need for promotion of smoking cessation services alongside efforts to raise awareness and

support for the policy. Trusted community-based organizations can be engaged to link menthol smokers to existing tobacco addiction treatment programs (Specktor & Keller, 2019).

6.4 Future Research Directions

Study findings suggest future directions for research to continue to build the evidence base for menthol policies. In particular, future research should examine how reducing menthol tobacco availability and tobacco marketing at the point-of-sale impacts youth initiation and adult cessation. The need for studies examining health outcomes is critical, particularly among African Americans, to demonstrate how policies are impacting lung cancer and other tobacco-related diseases. These questions should be examined both quantitatively using oversampling in existing surveillance systems as well as via qualitative research to gain an in-depth understanding of both youth and adults' attitudes, intentions and behavior change following policy implementation.

As a follow-up to study 1, a cohort of African American menthol smokers could be followed over time to examine the extent to which intentions to quit prior to policy passage translates to smoking cessation. Further information is also needed about the avenues by which youth and adults continue to access menthol cigarettes following policy implementation. In addition, it will be crucial to examine how policy support or opposition by smokers and non-smokers changes after policy implementation.

While there is a growing evidence base of the positive impact of menthol policy at the provincial and national level in Canada (Chaiton, Schwartz, Cohen, Soule, & Eissenberg, 2018; Soule et al., 2019), the context of menthol use in Canada differs significantly than that of the U.S. Menthol smoking prevalence in Canada is significantly lower than the U.S. (approximately 5% vs. 30%) (Glantz & Gardiner, 2018) and there is no evidence of the decades-long history of industry targeted marketing to priority populations. However, findings from these studies and in other global contexts (e.g. the European Union menthol ban scheduled to be implemented in 2020) can not only help advocates make a case for the positive impact of a menthol ban in the interest of public health but can help complement the limited resources currently being devoted to menthol policy evaluation.

As more localities in the U.S. take action on menthol, research is needed to examine how various types of policies (i.e., partial restrictions to citywide bans) impact tobacco use outcomes and the potential synergistic impact of other policies currently gaining momentum nationally (e.g., Tobacco 21, minimum pack restrictions, limits on price discounting and coupons). Future studies could also examine the trajectory of menthol policy efforts nationally and the diffusion and uptake of such work.

Another important area of study is Phase 4 of policy-making – the policy implementation process. It is essential to sustain compliance monitoring and to document enforcement in order to understand potential differential impacts of the policy. For example, if tobacco shops proliferate in lower-income or minority

neighborhoods, residents may not fully benefit from intended public health impacts of menthol policies.

The two months pre-/post-policy design for study 3 was implemented taking into consideration the focus of this study on short-term outcomes, available resources, and feasibility of data collection. A future study with a longer follow-up period (e.g. one year following implementation) is needed to continue to monitor changes in the retail environment. Future studies should consider the inclusion of border cities to examine how menthol marketing may change in neighboring communities.

Finally, future economic impact studies are needed to counter retailer claims of lost income. Future research is also needed to help address opposition statements that menthol restrictions will lead to the emergence of an illicit market with repercussions (Stoklosa, 2018). Given that these types of opposition claims have been unfounded in previous tobacco control policy efforts, irrefutable evidence to counter these tobacco industry tactics is urgently needed. Study of enforcement agency actions can provide invaluable information towards discrediting industry arguments against policy action (Stoklosa, 2018).

6.5 Conclusion

Partial local menthol sales restrictions laid an important foundation for more comprehensive action towards limiting the availability of menthol tobacco. Nonetheless, banning menthol at the federal level has the ultimate potential to level the playing field and save hundreds of thousands of lives. Indeed, the federal

regulatory framework put in place by the 2009 Tobacco Control Act provides a tremendous opportunity to enact pro-equity policies, including a menthol ban, to alleviate tobacco-related disparities. As urged by community members, advocates, public health agencies for over a decade, the "prompt elimination of menthol should not be delayed" (World Health Organization, 2016).

Appendices

Appendix A: Methods

The purpose of this dissertation was to gain an in-depth understanding of community perceptions, identify lessons learned from the policy process, and evaluate the impact of the menthol policy on the retail environment. Each of three studies outlined below provided critical insights from several phases of the policy process: problem identification (study 1), policy formation and adoption (study 2), and policy evaluation (study 3).

A.1 Study 1: African American Community Perceptions of Menthol Cigarettes and Reactions to Menthol Policy

The aim of study 1 was to identify African American adult smoker perceptions of menthol cigarettes and potential menthol policy options. This study involved qualitative analysis of interviews conducted prior to policy adoption in early summer 2017.

A.1.1 Study Sample

Participants for study 1 included adult smokers (n=28) who resided in the Twin Cities metro area including Minneapolis. Additional eligibility criteria included: self-identification as African American; Black; or African immigrant; adults 25 years and older; and established smoker, which was defined as daily cigarette use for five years or more. The age range was selected to account for later age of initiation among black smokers (National Cancer Institute, 2017). Established smokers were selected because one of the aims of the parent study was to identify barriers to cessation.

A.1.2 Sampling Procedure

A convenience sample was recruited in community locations, including churches, clinics, as well as through word of mouth. Flyers and business cards with study information were also distributed at tobacco retail outlets as well as bus stops in selected geographic neighborhoods. These included historically black neighborhoods and areas of concentrated poverty, defined as areas where 50% or more of residents are people of color and 40% or more of the residents have family incomes that were less than 185% of the federal poverty line (Metropolitan Council, 2014).

Participants completed a phone screener to establish eligibility, which included demographics (age, gender, sexual orientation, race/ethnicity, and highest level of education completed) and tobacco use characteristics (types of products used, menthol smoking status, cigarette brand preference, and number of cigarettes per day). Once eligibility was determined, an interview location was selected. Participants received $40 cash incentive for participation. The incentive amount was chosen in consultation with a Community Advisory Group, who also provided input on the interview questions and recruitment methods.

A.1.3 Interview Questions

This study focused on a subset of questions where participants were asked about the relative harm of menthol compared to regular cigarettes, whether they viewed menthol as a problem in their community, and their awareness of and reactions to potential menthol policies (see Appendix B for interview protocol). Specifically, participants were asked what would happen if they were unable to

purchase menthol cigarettes at their usual location, and how that would influence their smoking and purchasing habits. Interviews were audio recorded and transcribed.

A.1.4 Data Analysis

Interview transcripts were uploaded into NVivo 12 software. The PI and a second trained researcher maintained a research diary with reflexive notes and impressions of the data throughout the analysis process. Data were analyzed using the framework method, which was well suited to applied policy research with a priori issues identified (Srivastava & Thomson, 2009). Following established guidelines for the framework method (Ritchie & Lewis, 2003), the transcripts were first reviewed to develop familiarity with the text. Next, emerging themes from the data, developed both deductively and inductively, were compiled into a thematic framework. The third step involved coding, where sections of the transcript data that corresponded to particular themes were coded. In the fourth step, a chart that detailed each theme and the corresponding transcript text were created. Finally, the mapping and interpretation stage involved synthesis of the key findings. Disagreements in coding were discussed until consensus was reached. Cohen's kappa was calculated to test interrater reliability between codes for a sub-sample of interviews (McHugh, 2012).

A.2 Study 2: Lessons Learned from the Passage of the Minneapolis Menthol Policy

The aim of Study 2 was to identify key factors that led to successful policy passage. This study involved qualitative analysis of key stakeholder semi-structured interviews conducted following policy passage in December 2017 – April 2018.

A.2.1 Study Sample

Participants for study 2 included key stakeholders (n=15) involved in the policy process, including elected officials, city staff, advocates, and community members.

A.2.2 Sampling Procedure

Purposive sampling was employed to ensure that a variety of perspectives on the policy change process were included. Participants were identified in concert with local advocates and stakeholders who were instrumental in the efforts leading up to the Minneapolis menthol policy. Participants received a $25 Target gift card for participation.

A.2.2 Interview Questions

Questions focused on the preparation, strategies and key elements that led to the passage of the menthol policy. Participants were asked about the key individuals and organizations who were involved in driving the work, the opposition response, and lessons learned from policy adoption (see Appendix C for interview protocol). Interviews were audio recorded and transcribed.

A.2.2 Data Analysis

Study 2 analyses were conducted following similar established qualitative analysis procedures as study 1. Data were analyzed and synthesized across key stakeholders to extract lessons learned from the policy-making process.

A.3 Study 3: Menthol Policy Evaluation at the Retail Level

The aim of Study 3 was to evaluate the impact of the menthol policy on the retail environment. Observational assessments were conducted two months pre-policy (June 2018) and two months post-policy (October 2018) implementation.

A.3.1 Study Design

Evaluation of the menthol policy at the retail level was conducted using a quasi-experimental, pre-post design, with Brooklyn Park as the comparison city (Figure A.1).

Intervention: Minneapolis	O_1	X	O_2
Comparison: Brooklyn Park	O_1		O_2
	2 months pre (June 2018)	(August 2018)	2 months post (October 2018)

Figure A.1 Evaluation Design for Study 3

Brooklyn Park was selected for comparison because it was similar in demographic characteristics (median income, percent of the population with a high school education, age distribution, and racial/ethnic make-up) to Minneapolis (U.S. Census Bureau, 2018). To our knowledge, Brooklyn Park did not have any restrictions on the sale of menthol or other flavored tobacco products nor did it have any resolutions or advocacy efforts focused on this topic that could have affected this study.

A.3.2 Study Sample

When the ordinance was passed, it was intended to reduce the availability of menthol from 318 tobacco retail stores to 23 tobacco shops and 24 liquor stores with

tobacco licenses. Table A.1 presents sample size calculations for a range of effect sizes.

Table A.1 Sample Size Calculations for Study 3

Effect size	Group 1	20% attrition	Intervention sample	Group 2	20% attrition	Comparison sample
0.5	21	26.25	27	7	8.75	9
0.4	29	36.25	37	10	12.5	13
0.3	40	50	50	13	16.25	16
0.2	61	76.25	77	20	25	25
0.1	135	168.75	169	45	56.25	56

To address the primary aim of this study, a stratified random sample of 50 convenience stores, 5 tobacco shops, and 5 alcohol outlets in Minneapolis and 16 retail stores in the comparison city were selected from the cities' tobacco licensing lists (highlighted in Table A.1). Sample size calculations accounted for a potential 20% attrition rate (due to potential business turnover) and ensured at least 80% power and an error rate α of .05. This sample size was sufficient to detect a 50% difference in the proportion of convenience stores that were selling menthol tobacco (primary outcome) and a 30% difference in secondary outcomes (G*Power 3.1.9.2). Estimates were based on similar studies that evaluated the impact of flavored tobacco restrictions (excluding menthol) and found large intervention effects on product availability (Farley & Johns, 2017; Rogers et al., 2017).

A.3.3 Observational Assessments

Table A.2 outlines the measures included in the observational instrument. The instrument was based on the Standardized Tobacco Assessment for Retail Settings (STARS) (Henriksen et al., 2016). The STARS tool was developed as a retail marketing monitoring and policy advocacy tool; measures for this study were adapted for menthol policy evaluation purposes. The majority of STARS measures were found to have moderate or high reliability (Henriksen et al., 2016). A pair of trained data collectors conducted observational assessments of the retail environment using a mobile app, which allowed for customization of measures. Percent agreement was used to assess reliability across a sub-sample (20%) of assessments.

Table A.2 Operationalization of Measures for Study 3

Measure		Variable Type	Data Collection		Operationalization
			2 mo-pre	2 mo-post	
Product Availbility	Availability of menthol cigarettes	Outcome	x	x	Dichotomous (Yes/No)
	Availability of menthol cigarillos or little cigars	Outcome	x	x	Dichotomous (Yes/No)
	Availability of menthol e-cigarettes	Outcome	x	x	Dichotomous (Yes/No)
	Availability of wintergreen smokeless	Outcome	x	x	Dichotomous (Yes/No)
	Availability of menthol hookah	Outcome	x	x	Dichotomous (Yes/No)
	Availbility of menthol blunt wraps	Outcome	x	x	Dichotomous (Yes/No)
	Availability of menthol tobacco	Outcome	x	x	Composite; Dichotomous (Yes/No)
Marketing	Number of menthol tobacco ads (interior)	Outcome	x	x	Continuous
	Number of menthol tobacco ads (exterior)	Outcome	x	x	Continuous
Brands	Availability of Newport menthol cigarette	Outcome	x	x	Dichotomous (Yes/No)
	Availability of Marlboro menthol cigarette	Outcome	x	x	Dichotomous (Yes/No)
	Availability of JUUL menthol pods	Outcome	x	x	Dichotomous (Yes/No)
	Availability of Grizzly wintergreen	Outcome	x	x	Dichotomous (Yes/No)
Presence of menthol policy		Independent	-	-	Minneapolis/Brooklyn Park
Store type		Potential co-variate	x	-	Categorical (Convenience/grocery store, pharmacy, mass merchandiser tobacco shop, liquor store, other)
Neighborhood-level minority residents (%)		Potential co-variate	x	-	Continuous
Neighborhood-level residents living under the poverty line (%)		Potential co-variate	x	-	Continuous

A.3.4 Data Analysis

Data retrieved from the app was downloaded into excel and then uploaded into SPSS Statistics 23. Descriptive analyses included examination of the distributions and frequencies of all variables.

Hypothesis 3A: Convenience stores in Minneapolis showed a significant decline in the *availability* of menthol tobacco products post-policy implementation compared to Brooklyn Park, the comparison city.

Analysis for Hypothesis 3A: A two-sample z-test was used to compare the proportion of convenience stores selling menthol tobacco in Minneapolis vs. Brooklyn Park. Differences in baseline characteristics of retail stores in Minneapolis and Brooklyn Park was also assessed.

Hypothesis 3B: Convenience stores in Minneapolis showed a significant decline in the *marketing* of menthol tobacco products post-policy implementation compared to Brooklyn Park, the comparison city.

Analysis for Hypothesis 3B: A two-sample t-test was used to compare the number of menthol tobacco ads in Minneapolis vs. Brooklyn Park.

Hypothesis 3C: Convenience stores in Minneapolis showed a significant decline in the *availability* of menthol tobacco products post-policy implementation compared to tobacco shops and liquor stores, who were exempt from this policy restriction.

Analysis for Hypothesis 3C: A two-sample z-test was used to compare the proportion of convenience stores vs. tobacco shops and liquor stores selling menthol tobacco in Minneapolis.

A.4 Data Use Agreement

Access to the data for studies 1 – 3 have been secured through a data use agreement and memorandum of understanding with the PI's employer, ClearWay Minnesota (Appendix D).

Appendix B: Study 1 Interview Protocol

ClearWay Minnesota Smoker Interview Study

Note: Highlighted areas denote the focus of this study.

Introduction

- Thank you for taking time to talk with us. Introduce ourselves & Rainbow Research.
- The purpose of this study is to better understand smoking habits as well as gain feedback and reactions to potential policy actions in the priority populations of LGBTQ individuals and African Americans. ClearWay is funding this project and they will be using the information to guide future programming.
- I want to assure you that this conversation is confidential—that means that we will not share who said what. The only people who will see your direct responses are Rainbow Research staff.
- We will summarize themes across all interviews and share these findings, again without names or identifying information, to help Clear Way and other community organizations understand smoking habits and cessation support needs. Just so you know, there are no right or wrong answers. We want to hear your opinions and ideas. It's your experience so all answers are right.
- Review consent forms, respond to questions
- We really value what you have to say, and to that end, we'd like your permission to record our conversation so that we make sure we get everything right. Are you okay with us recording this session?

As we mentioned, in this project we are talking with individuals who identify as African American and/or LGBTQ.

1. How do you define your race/ethnicity?
2. How do you define your sexual orientation?

Smoking Habits and Preferences:

1. How would you describe your **smoking habits** on the average day?
- Are there particular times or locations where you smoke? Certain activities or situations where you tend to smoke? Do you smoke with certain people?
- Are there particular reasons why you prefer to smoke at those times/ locations/ situations?

2. What is your **preferred brand or type of cigarette**? Have you always smoked [brand]?
- What is it about your brand that you like? What does that brand/type mean to you?

- What are some of the reasons why you smoke [brand]?
- What do you like about smoking?
- What do you not like about smoking?
- How does smoking make you feel?

3. Tell me a little about your **history of smoking**. Looking back, can you tell me about the first time you smoked a cigarette?
- **How old where you?** Who were you with? What made you want to have that first cigarette? How did you feel about smoking at the time?

4. Have any of your smoking related behaviors [brand, purchasing, where you smoke, amount/frequency of smoking, etc.] **changed over time**?
- How have they changed? Why have they changed?
- Have you changed any of your smoking habits because they seem more healthy or less harmful?

5. Do certain types of tobacco products seem less harmful to you?

a. Are there brands that seem less harmful?
b. What is it about [rolling your own/natural/organic etc.] that seems less harmful or safer?
c. Do you ever smoke menthol? How risky do you think menthol cigarettes are compared to other cigarettes?

What keeps people smoking?

The next few questions are about experiences with quitting smoking. [emphasis on what keeps you smoking]

6. Do you think you'll always be a smoker?

a. Do you believe you can quit smoking?

7. If yes, what are some of the factors that make you believe you can quit? [Think of you family, neighborhood, community, social services, institutions…]
8. If no, why not? What are some of the factors that make you NOT believe you can quit? [Think of you family, neighborhood, community, social services, institutions…]

9. Have you tried to **quit smoking** at any point, or considered quitting? What happened?
10. *[If yes]* What motivated you to try quitting? How did your longest quit attempt go? What supports did you have? What were the triggers that pulled you back into regular smoking?

11. *[For those who have attempted to quit and those who haven't]* What has been your **experience (if any) interacting with quit smoking supports systems or the experience of those in your community**? What barriers

or challenges did you encounter? Any particular barriers to those supports due to race/ethnicity or sexual orientation?

12. People's triggers, the unconscious situations that make them want to smoke, are really varied. They often include stress from family, work, or other life pressures like challenges with finding employment or housing instability. For other's, smoking triggers might include who they spend time with, daily habits or their social circles**. What do you find makes you want to smoke? What would make it possible for you to quit or would need to be in place for you to quit?**

Thinking particularly about supporting quit attempts for AA/LGBTQ individuals, where do you see change or emphasis needed? Could include programmatic **assistance or supports** or more **community or system** changes like job and housing support, etc…

Reactions to Policy

We have a few other ideas we'd like to get your feedback on related to rules and laws about where and when you can smoke or purchase cigarettes.

13. Have you heard of any recent changes in smoking laws? If so, what? **[Awareness/Perceptions of current smoking changes & legislation]**

For example, Edina recently increased the legal age to purchase tobacco to age 21. It's expected that other areas will follow. What do you think of that change?

14. Some people are considering putting **limits or restrictions on coupons for cigarettes**, for example where coupons can be distributed or restricting coupons entirely as a way to discourage smoking. What are your reactions to that idea?
15. Have you used promotional discounts [such as BOGO, coupons or aps] to buy cigarettes? What do you use most regularly? [Are the discounts/promotions app-based, available where you buy the cigarettes, or those that you receive in the mail?]

16. Another big topic of discussion currently has to do with **menthol cigarettes**. What have you heard about menthol?

[If No, I haven't heard anything:] In the Twin Cities, a conversation is happening about limiting where menthol is sold. The restrictions would focus on limiting convenience stores ability to sell menthol.

17. Do you see menthol as a problem in your community [African American and/or LGBTQ community]? Why or why not?

18. One idea is a **restriction on menthol cigarettes**. In fact, some cities may restrict where menthol cigarettes can be sold, such as removing them from convenience stores. If your brand was only sold in tobacco shops, what would you do? [Leave open for options of menthol or other flavors, natural/organic]
19. If you were not able to purchase menthol cigarettes at your usual location, would you purchase a different brand, go somewhere else that does sell it, or consider quitting altogether?

20. There is discussion on **reducing the nicotine content in cigarettes sold**. Would you support this?

Conclusion:

21. Do you have **other concerns** about smoking in your community or **recommendations** about what actions can be taken to support people in quitting or discourage people from starting to smoke?
22. Is there anything else on this topic you'd like to share?

Thank you so much for sharing your time and experience!

Appendix C: Study 2 Interview Protocol

Case Study of Stakeholders Engaged in Passage of Menthol Policy

Semi-structured interview conducted with people who have been involved in effort to pass a policy to restrict menthol tobacco in Minnesota cities.

Introduction

Thank you for taking time to meet with me today to discuss the passage of the menthol policy in <city/cities>. As I mentioned when we scheduled our interview, you were invited to be interviewed because you were someone who was involved in efforts leading up to restriction of menthol tobacco products. Our conversation will require up to 1 hour.

I'd like to record our interview, to facilitate my note taking and help me transcribe our discussion accurately later. The recording will not be shared with anyone other than me, so that I can transcribe it. Your name will not be associated with any of the comments you make in any written text or reports. Is it ok if I record our conversation today?

OK to tape? YES NO

Do you have any questions before we begin?

1. **Duration of engagement and motivation**
    a. When did you become engaged in the efforts in <your city> to restrict sales of tobacco products that contain menthol?
    b. Tell me a bit about how you became interested in (or aware of) the proposal to restrict sales of tobacco products that contain menthol?
        i. (If needed, probe) Had you been involved in tobacco control efforts previously?
        ii. (If needed, probe) Was there a key person or aspect of the issue that motivated you to become involved?
    c. In your own words, tell me briefly how the policy process happened in <your city>. If needed, probe as to how long the process took.

2. **Role/activities undertaken**
    a. Tell me about how you participated in this effort? (Probe if needed to learn how interview respondent participated, what types of activities they undertook.)
        i. Probes only if needed: Did you do any of the following?:

1. Write drafts/review drafts of policy
2. Meet with elected officials to educate
3. Meet with community members to educate and raise awareness of the issue
4. Present to school leaders, church groups, other community and advocacy organizations
5. Write letters to the editor, speak at events, post to social media
6. Particpate in radio and TV interviews
7. Attend public hearings
8. Testify at public hearings
9. Make calls to elected officials/decision-makers
10. Email or write letters to elected officials
11. Part of a committee or task force that worked on the policy?
    a. If yes to the committee/task force, ask: Describe the group and your role in this group.

3. **Support and Opposition to the Policy: Now I'd like to learn more about who, or what organizations were in support of or opposed to a policy, and their reasons.**
    a. Who (or what organizations) were most supportive of a policy to restrict menthol?
        i. If needed, probe: What were the reasons they were supportive?
    b. Who (or what organizations) were most opposed to a policy to restrict menthol?
        i. If needed, probe: What were the reasons they were opposed?
    c. What was the response of retailers—business people—who sell tobacco products?
        i. If needed, probe: How did they show their opinion—what did they do?
        ii. How influential were they?
        iii. Did you (or your organization) meet with retailers?
        iv. How were their concerns addressed?
    d. Was the Tobacco Industry engaged in trying to influence the policy? (If needed, clarify that this question refers to the producers and manufacturers of tobacco, not local retailers.)
        i. If needed, probe: What did they do to try to influence the policy?
    e. How did you address (or counter) their efforts?

f. Was the alcohol industry or alcohol retailers engaged to influence the policy? (If needed, clarify that this question refers to the MN License and Beverage Association, not local retailers.)
    i. If needed, probe: What did they do to try to influence the policy?

4. **Background of the issue: Now I'd like to ask you about how menthol became an issue, and how that was important to the campaign.**
    a. How did menthol become an issue as a policy effort?
    b. How important was education on target marketing by the Tobacco Industry to the campaign's messaging?

5. **Champions/leaders key to successful passage: Now I want to ask a few questions about people who were important to the policy passage effort, who played key leadership roles.**
    a. Who was/were the champions of the policy effort? In other words, who—it can be individuals or organizations—took on key leadership or important roles to get the policy passed?
    b. If needed, probe: How were these people/organizations key to passage? Tell me more about what they did and why it was important.
    c. Was there someone who was a major barrier to passage—a person or organization(s) that made passage difficult?
        i. If yes, ask how they made passage difficult.

6. **City Council response: Now I'd like to learn about how the City Council responded, and who on the Council was supportive or not supportive, and roles they played.**
    a. How supportive was the City Council when the effort began?
    b. Did you have a sponsor on the City Council who led efforts?
        i. If answer to b is yes, ask: How did that City Council Member(s) work to get the restriction passed?
    c. Were there City Council Member(s) who were opposed?
        i. If answer to c is yes, ask: How did those Members who opposed it work against passage?
    d. How were you able to influence the City Council?
    e. What was important in working with the City Council?
    f. How supportive was the Mayor in this effort?

7. **City Staff engagement: Now I'd like to know more about the role of City Staff, and if they were involved.**
    a. Were there City Staff involved (such as from the Public Health Department, or Council Member staff, or Planning or Licensing)? (If respondent says no, skip the rest of this section.)
        i. If yes, ask the following: What role did they play?
        ii. How important were these staff people to passage?
        iii. What was important to working with Staff people?

8. **Organizations Involved/Roles: Often there are organizations that help promote passage of a policy. I'm going to ask about organizations now.**
    a. What role did organizations play—(refer to each of the organizations identified earlier. If no organizations were identified earlier, inquire again to see if there were organizations involved; if respondent says no, continue to section 9)?
    b. How did they move the policy forward?
    c. What was important to working with these organizations?
    d. Did the organizations ever disagree on strategy or priorities? If yes, how did they resolve these issues and decide how to proceed?
    e. What was important about the contribution/effort of each of these organizations?

9. **The policy process at the City Council**
    a. Tell me how the policy process evolved with the City Council. For example, how did it get introduced, hearings, amendments, voted—tell me what you know about how it progressed over time.
    b. Were there times you needed to pull back and regroup, and if so how?
    c. Were there opportunities, things that happened that created a more receptive environment to passage of the policy? (If yes, ask them to describe)
    d. What were the challenges and obstacles?
    e. Were there times you thought it might not pass? Tell me about that.

10. **The final policy as passed**
    a. Was the policy passed as you originally hoped it would be?
        i. If no to a, continue to section 11; If yes to a, ask: What was different, or had to change?
        ii. Did that feel like a compromise?

iii. Was it necessary—do you think the policy would have passed without these changes?
iv. Do you have concerns about this (the change the respondent identified in previous questions)?

11. Future steps

a. How successful do you think the policy will be?

12. Personal reactions: Now I'd like you to think a bit about this process on a more personal level.

a. What did it mean to you personally to be involved in this process?
b. Was this experience new for you? Had you worked on policy before? (Specifically, had you worked on tobacco policy before?)
c. What did you learn from participating in this process?
d. Do you think it will impact you in the future—will you undertake policy work in the future, or work on tobacco control issues in the future?

13. Conclusion

a. That is everything I have for structured questions today. Is there anything I did not ask about that you would like to add, or something else you think it is important for me to know?

Thank you again for talking with me today!
Close and end interview.

Appendix D: ClearWay Minnesota Data Use Agreement & Memorandum of Understanding

Data Use Agreement

This data use agreement ("Agreement") is effective upon execution, and is entered into by and between Joanne D'Silva, 6244 Light Point Place Columbia, MD ("Recipient") and ClearWay Minnesota, 8011 34th Ave S. Suite 400, Minneapolis, MN 55425 ("Data Provider").

1. **Smoker Interview Study & Menthol Policy Evaluation Data.** Upon Recipient's execution of this Agreement and completion of data collection, Data Provider will provide Recipient data collected as part of the smoker interview study and menthol policy evaluation.

2. **Recipient's Permitted Uses and Disclosures.** Recipient is permitted to use and disclose the data in order to conduct analyses. The information will be used in a dissertation and any resultant presentations and publications. The purpose of the analysis is to examine smoker perceptions, menthol policy passage and implementation.

3. **Prohibition on Unauthorized Use or Disclosure.** Recipient will neither use nor disclose the dataset for any purpose other than as permitted in Section 2 of this Agreement.

4. **Information Safeguards.** Recipient will adopt and use appropriate administrative, physical, and technical safeguards to preserve the integrity and confidentiality of the data and to prevent its use or disclosure other than as permitted by Section 2 of this Agreement.

5. **Subcontractors and Agents.** Recipient will seek written approval from the Data Provider's authorized representative, Dr. Barbara Schillo, before disclosing any data to any agent or subcontractor. In the event Dr. Schillo is unavailable, David Willoughby will act as the authorized representative. Recipient will require any agent or subcontractor to agree by written contract to comply with the same restrictions and conditions that apply to Recipient's use and disclosure of the data pursuant to this Agreement.

6. **Breach of Privacy Obligation.**

    a. Reporting. Recipient will report to Data Provider any use or disclosure of the data not permitted by this Agreement or in writing by Data Provider. Recipient will make the report to Data Provider within 5 business days after Recipient learns of such non-permitted use or disclosure. Recipient's report will at least:

        i) Identify the nature of the non-permitted use or disclosure;

        ii) Identify the content used or disclosed;

        iii) Identify who made the non-permitted use or disclosure and who received the non-permitted disclosure;

        iv) Identify what corrective action Recipient took or will take to prevent further non-permitted disclosures;

        v) Identify what Recipient did or will do to mitigate any deleterious effect of the non-permitted uses or disclosures; and

        vi) Provide such other information, including a written report, as Data Provider may reasonably request.

    b. Termination for Breach. Data Provider may terminate this Agreement, if it determines, in its sole discretion, that the Recipient has breached any provisions of this Agreement Data Provider may exercise this right to terminate this agreement by providing Recipient

written notice of termination that states the breach of this Agreement that provides the basis for the termination. Any such termination will be effective immediately or at such other date specified in Data Provider's notice of termination. The provisions of Sections 3 and 9 of this Agreement will survive termination of this Agreement.

7. **Expiration.** This Agreement will expire upon four years after the execution of the agreement. The provisions of Sections 3 and 9 of this Agreement will survive expiration of this Agreement.

8. **Data Management.** Upon termination or expiration of this Agreement, Recipient will, destroy the Recipient's copy of the data, including all copies of the data set and any derivative work from the data set that may allow identification of any individual whose information is contained in the data set, in whatever form or medium (including in any electronic medium under Recipient's custody or control) in which Recipient has retained it. Recipient will complete such return or destruction as promptly as possible, but not later than 45 days after the effective date of the termination or expiration of this Agreement, and will within such 45 days certify in writing to Data Provider that such return or destruction has been completed. If return or destruction is not feasible, Recipient will provide Data Provider with a written explanation why return or destruction is nor feasible, and will certify in writing to Data Provider that Recipient will neither use nor disclose the Ordinance Impact Study Employee Hours for any purpose other than the purposes that make return or destruction of the data set infeasible.

9. **Indemnity.** Recipient will indemnify and hold harmless Data Provider and any affiliate, officer, director, employee or agent of data Provider from and against any claim, cause of action, liability, damage, cost or expense, including attorneys' fees and court or proceeding costs, arising out of or in connection with any non-permitted use or disclosure of the Ordinance Impact Study Employee Hours or other breach of this Agreement by Recipient or any agent, subcontractor, person or entity under Recipient's control.

IN WITNESS WHEREFORE, Data Provider and Recipient execute this Agreement in multiple originals to be effective on the last date written below.

ClearWay Minnesota

David Willoughby, MA
CEO

DATE: 11/8/2018

Joanne D'Silva, MPH

Joanne D'Silva, MPH

DATE: 11/8/18

Memorandum of Understanding

November 8, 2018

To: David J. Willoughby, Chief Executive Officer
Fr: Joanne D'Silva, Associate Director of Health Equity Research
CC: Barbara Schillo, Vice President
Re: Dissertation Research Data Use Agreement Addendum

This Memorandum of Understanding supports the Data Use Agreement (DUA) between Joanne D'Silva and ClearWay Minnesota pertaining to data from the smoker interview study and menthol policy evaluation. In my current role as Senior Research Program Manager, I serve as the organization's lead for the menthol policy evaluation and am directly involved in designing and implementing evaluation efforts. In this capacity, I have access to all data concerning the smoker interview study and menthol policy evaluation. This MOU was updated to reflect the inclusion of smoker interview data as part of study 1 for the dissertation. Vice President Barbara Schillo have agreed to support my use of these data for the purposes of dissertation research. In my role as a doctoral student at the University of Maryland School of Public Health, I am proposing to utilize smoker interview study and menthol policy evaluation data for my dissertation project. The terms of the use of data for this academic pursuit are outlined in the attached DUA. Further, the terms of the DUA will be upheld regardless of the status of my employment at ClearWay Minnesota.

Appendix E: UMD IRB Application Materials

University of Maryland College Park
Institutional Review Board
IRB Initial Application - Part 1

Last edited by: Joanne D'Silva
Last edited on: April 6, 2018
[click for checklist]

☐ **Full**
☐ **Expedited**
☑ **Exempt**

[1210341-1] Menthol Cigarette Restrictions at the Local Level: Community Perceptions, Lessons Learned, and Policy Evaluation

Answer all questions on this form completely, include attachments and obtain signatures of Co-Investigators and your department IRB Liaison prior to final submission on IRBNet.

I. Principal Investigator

Name:	Joanne D'Silva, MPH	**Status:**	Graduate Student
Department:	SPHL- Public Health		
Phone:	516-639-9343	**Email:**	jdsilva@umd.edu
Address:	6244 Light Point Place; Columbia, MD 21045		

II. Faculty Advisor N/A ☐

Note: A faculty advisor is required if the PI is a student resident or fellow and the Faculty Advisor MUST sign this package through IRBNet.

Name:	Craig Fryer		
Department:	SPHL- Public Health		
Phone:	(301) 405-0818	**Email:**	csfryer@umd.edu
Address:	UMD | Building: 4200 Valley Drive, SPH | Room: 1234X		

III. Co-Investigators N/A ☑

Note: All co-investigators MUST sign this package through IRBNet.

Name:			
Department:			
Phone:		**Email:**	
Address:			

IV. Funding Information N/A ☑

Note: A copy of the awarded grant application (minus budgetary information) must be provided.

Status	Funding Type	Sponsor Name	ORAA #	COI

Funding Title:

V. Project Information

Lay Summary:

Menthol tobacco products are a significant public health concern and are linked with increased tobacco initiation and decreased tobacco cessation. In 2017, the city of Minneapolis, MN enacted restrictions to limit the sale of menthol tobacco products. The overarching purpose of this study is to gain an in-depth understanding of community perceptions, identify lessons learned from the policy process, and evaluate the impact of the menthol policy.

Requested Review Path:

- ☐ Full
- ☐ Expedited
- ☑ Exempt

Projected Completion Date: 05/31/2019

Research Category:

- ☐ Faculty or Staff Research
- ☑ Graduate Student Research
- ☐ Student/Faculty Collaboration
- ☐ Undergraduate Student Research
- ☐ Other:

Academic Committee Review:

- ☐ Yes - Masters committee
- ☑ Yes - Dissertation committee
- ☐ No additional academic review required

Participant Incentives:

- ☐ Cash
- ☐ Check
- ☐ Raffle/ Lottery:
- ☐ Extra Credit/ Course Credit:
- ☐ Gift:

☐ Food:

☐ Other:

☑ Not Applicable

VI. Performance Sites

Performance Sites Engaged in Human Subject Research:
(where the research will be conducted)

☑ UMCP - Campus:
☐ University of Maryland - Extension:
☐ Campus Health Center
☐ Universities at Shady Grove:
☐ Schools:
☐ Prison/Jail:
☐ Other:

Is this an international study?

☐ Yes *[complete Section 10 of Initial Application Part 2]*
☑ No

If yes: **International Sites:**

VII. Subject Information

Targeted Populations:

☑ Normal adult/healthy persons
☐ Cognitively impaired persons
☐ Economically disadvantaged persons
☐ Educationally disadvantaged persons
☐ Elderly/aged persons
☐ Hospital patients or outpatients
☐ Illiterate persons
☐ Individuals with physical disabilities
☑ Minority group(s)
☐ Minors/children
[inclusion of anyone under 18 requires a Parental Consent Form]
☐ Non-English speakers
☐ Pregnant women

- ☐ Prisoners
- ☐ Students (non-minors)
- ☐ UMCP employees
- ☐ Other special characteristics and special populations:

Informed Consent Process:

- ☐ Informed consent will be obtained from subjects and documented with a signed, written consent form
- ☐ Informed consent will be obtained from subjects, but no signed consent form will be used. This includes oral consent and implied consent (e.g., completing a survey).
  [please see the Requesting a Waiver of Informed Consent Guidance]
- ☑ Fully informed consent will not be obtained from all subjects. This includes deception, withholding information, etc.
  [please see the Requesting a Waiver of Informed Consent Guidance]

Will health information be collected?
(See the HIPAA section of the IRB website for more information and additional resources.)

- ☑ No
- ☐ Yes, data are de-identified or constitute a limited data set.
- ☐ Yes, subject's authorization will be obtained or a waiver or alteration of authorization will be requested.
  [complete IRB Form HIPAA]

VIII. Research Procedures

Research Procedures:

- ☑ Records review - retrospective
- ☐ Records review - prospective
- ☐ Education research
- ☐ Behavioral experiments
- ☐ Behavioral observation
- ☐ Questionnaires/surveys
- ☐ Interviews
- ☐ Audiotaping/videotaping
- ☐ The Internet
- ☐ Deception
  [describe debriefing process in Section 7 of Initial Application Part 2]
- ☐ Cancer Interventions (health promotion, implementation, etc.)
- ☐ None of the above

Biomedical Procedures:

- ☐ Tissue banking
- ☐ Biopsy

- ☐ Blood draw:
- ☐ Use of pre-existing tissues
- ☐ Clinical tests
- ☐ Radiology
- ☐ Radiation/X-ray/DEXA
- ☐ fMRI
  [use IRB fMRI templates]
- ☐ Pregnancy screening
- ☐ EKG
- ☐ EEG
- ☐ Genetic analysis
- ☑ None of the above

IX. Assurances and Signatures

Assurances
This research, once approved, is subject to continuing review and approval by the IRB. The principal investigator will maintain records of this research according to IRB guidelines. If these conditions are not met, approval of this research could be suspended or terminated.

Electronic signatures certify that:

- The signatory agrees that he or she is aware of the policies on research involving participants of the University of Maryland College Park and will safeguard the rights, dignity, and privacy of all participants.
- The information provided in this application form is correct.
- The principal investigator will seek and obtain prior written approval from the IRB for any substantive modification in the proposal, including but not limited to changes in cooperating investigators/ agencies as well as changes in procedures.
- Unexpected or otherwise significant adverse events in the course of this study which may affect the risks and benefits to participation will be reported to the IRB.
- The research will not be initiated and subjects cannot be recruited until final written approval is granted.

The following signatures are required for new project submissions:

- Principal Investigator
- Research Advisor(s)
- IRB Liaison (click here for list)

INSTRUCTIONS TO RESEARCHERS

[top]

Now that you have completed this document, check your work, attach all appropriate documents, electronically sign and submit your work. Based on your responses, the following additional

documentation must be included with this package before submission. Upload additional documentation in the Designer.

Documents available in the IRBNet Forms and Templates Library:
No additional documents from the Library are required for this project.

Additional required documentation:

- Request for Consent Waiver

If you have any questions, please refer to the guidelines in the IRBNet Forms and Templates Library or contact irb@umd.edu.

INITIAL APPLICATION PART 2

1. Abstract:

Menthol cigarettes are a significant public health concern. While sales of regular cigarettes have declined in recent years, menthol cigarette sales are increasing. In 2017, Minneapolis, Minnesota was among the first cities to regulate menthol by restricting sales to exclusive tobacco shops and liquor stores. The overarching purpose of this dissertation is to gain an in-depth understanding of community perceptions, identify lessons learned from the policy process, and evaluate the impact of the menthol policy.

Study 1 focuses on identifying African American adult smoker perceptions of menthol cigarettes and policy options. This study involves secondary analysis of in-depth interviews conducted prior to policy adoption.

Study 2 focuses on identifying key factors that led to successful policy passage. This study involves secondary analysis of key stakeholder interviews including elected officials, city staff, advocates, and community members.

Study 3 is an evaluation of the impact of the policy on the retail environment. Observational assessments of a random sample of tobacco retail stores will be conducted two months pre- and post-policy implementation in August 2018.

Findings can inform other jurisdictions around the country interested in pursuing menthol sales restrictions to reduce the burden of tobacco use.

2. Subject Selection:

a. Recruitment:

Study 1: This study involves secondary analysis of in-depth interviews conducted with smokers prior to adoption of the menthol policy. A convenience sample was recruited in community locations, including churches, clinics, as well as through word of mouth. Flyers and business cards with information about the study were also distributed at tobacco retail stores and bus stops in historically black neighborhoods.

Study 2: This study involves secondary analysis of in-depth interviews conducted with key stakeholders involved in the policy process. Purposive sampling was employed to ensure that a variety of perspectives (city council members, advocates, community members) on the policy change process were included.

Study 3: This study involves primary data collection from tobacco retail stores (businesses that have a license to sell tobacco) two months pre-policy (June 2018) and two months post-policy (October 2018). No human subjects are involved.

b. Eligibility Criteria:

Study 1: Participants included adult smokers who reside in Minneapolis metro area. Additional eligibility criteria included: self-identification as African American; Black; or African immigrant; adults 25 years and older; and established smoker, which was defined as daily cigarette use for five years or more.

Study 2: Participants included elected officials, city staff, advocates, and community members who were involved in passing the policy. All participants were 18 years of age or older. No other inclusion criteria were established.

Study 3: Tobacco retail stores will be selected from tobacco licensing lists maintained by city government officials in Minneapolis and Brooklyn Park, Minnesota.

c. Rationale:

Study 1: The tobacco industry has a long history of predatory marketing to African Americans, who are four times more likely to smoke menthol cigarettes, have lower quit rates, and experience higher tobacco-related mortality than white smokers. The age range was selected to account for later age of initiation among African American smokers. Established smokers were selected because one of the aims of the parent study was to identify barriers to cessation.

Study 2: Participants were selected for their contributions to the policy process. Advocates and community members were involved in lobbying efforts to garner support for the policy. City staff conducted education with city council members. Elected officials passed the policy.

Study 3: The aim of Study 3 is to evaluate the impact of the menthol policy on the retail environment. The change in availability of menthol tobacco and marketing in Minneapolis retail stores will be assessed and compared to a sample of retail stores in Brooklyn Park, Minnesota, which will serve as the comparison city.

d. Enrollment Numbers:

Study 1: 28 participants were enrolled.

Study 2: 15 participants were enrolled.

Study 3: The sample will include 27 convenience stores, 3 exclusive tobacco shops, and 3 liquor stores in Minneapolis and 9 retail stores in the comparison city.

e. Rationale for Enrollment Numbers:

Study 1 & Study 2: Enrollment was completed when saturation occurred, i.e. the point at

which no additional perspectives or themes emerged.

Study 3: Sample size calculations account for a potential 20% attrition rate (to account for potential business turnover) and ensures at least 80% power (α=.05) to detect a 50% difference in the proportion of stores that are selling menthol tobacco.

3. **Procedures:**

Data for all three studies are made available to the PI via a Memorandum of Understanding (MOU) with ClearWay Minnesota, the PI's employer.

Study 1: This dataset is comprised of de-identified transcripts. Participant interviews were transcribed and will be uploaded in NVivo qualitative analysis software. Data elements to be extracted include responses to questions regarding the relative harm of menthol compared to regular cigarettes, whether they viewed menthol as a problem in their community, and their reactions to potential menthol policies.

Study 2: This dataset is comprised of de-identified transcripts. Participant interviews were transcribed and will be uploaded in NVivo qualitative analysis software. Data elements to be extracted include responses to questions regarding key individuals and organizations who were involved in driving the policy change, the opposition response, and lessons learned from the policy adoption process.

Study 3: This dataset will include information on the availability of menthol tobacco products, the presence of menthol advertising on the exterior and in the interior of the store, the number of cigarette promotions available, and the price of Newport menthol cigarettes.

4. **Risks:**

There are no known risks to participants because of the use of de-identified data in studies 1 and 2 and no human subjects in study 3.

5. **Benefits:**

There are no direct benefits to participants. We hope to use the information from this study to better understand community perceptions, identify lessons learned from the policy process and the impact of the menthol policy on the retail environment.

6. **Confidentiality:**

The PI and a trained researcher (second coder for qualitative data) will have access to the data. Any potential loss of confidentiality will be minimized by storing electronic data on a password-protected secured server at ClearWay Minnesota. No physical data will be maintained. All electronic data will be backed up periodically to avoid potential data loss. Interview transcripts and retail store assessment data will be kept on a secure server. All data will be destroyed seven years after the completion of the study.

7. **Consent Process:**

   Not Applicable – Study 1 and 2 utilizes a de-identified existing dataset. Study 3 does not involve human subjects.

8. **Conflict of Interest:**

   No Conflicts of Interest

9. **HIPAA Compliance:**

   Not Applicable

10. **Research Outside of the United States:**

    Not Applicable

11. **Research Involving Prisoners:**

    Not Applicable

12. **SUPPORTING DOCUMENTS**

    Your Initial Application must include a **completed Initial Application Part 1 (On-Line Document)**, the information required in items 1-11 above, and all relevant supporting documents including: consent forms, letters sent to recruit participants, questionnaires completed by participants, and any other material that will be presented, viewed or read to human subject participants.

The consent forms in your approved IRBNet PACKAGE must be used. When creating or editing your consent form, please provide the most recent IRBNet package number at the bottom, right corner of the consent form. This ensures you are using the most "up-to-date" version of the form.

To find your IRBNet package number, go to the MY PROJECTS tab and click on the title of your project. In the PROJECT OVERVIEW page, your IRBNet package number will be listed at the top, next to your project title.

Appendix F: UMD IRB Determination of Exempt Status

UNIVERSITY OF MARYLAND
INSTITUTIONAL REVIEW BOARD

1204 Marie Mount Hall
College Park, MD 20742-5125
TEL 301.405.4212
FAX 301.314.1475
irb@umd.edu
www.umresearch.umd.edu/IRB

DATE:	April 30, 2018
TO:	Joanne D'Silva, MPH
FROM:	University of Maryland College Park (UMCP) IRB
PROJECT TITLE:	[1210341-1] Menthol Cigarette Restrictions at the Local Level: Community Perceptions, Lessons Learned, and Policy Evaluation
REFERENCE #:	
SUBMISSION TYPE:	New Project
ACTION:	DETERMINATION OF EXEMPT STATUS
DECISION DATE:	April 30, 2018
REVIEW CATEGORY:	Exemption category # *2*

Thank you for your submission of New Project materials for this project. The University of Maryland College Park (UMCP) IRB has determined this project is EXEMPT FROM IRB REVIEW according to federal regulations.

We will retain a copy of this correspondence within our records.

If you have any questions, please contact the IRB Office at 301-405-4212 or irb@umd.edu. Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within University of Maryland College Park (UMCP) IRB's records.

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