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Objective 2: Advocating for FDA Ban on Menthol Cigarettes

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2. Brief Report

Brief Description of the project context (political, social norms, etc.)

"In a historic victory for America's children and health, President Obama on June 23 2009, signed into law legislation giving the U.S Food and Drug Administration authority to regulate the manufacturing, marketing and sale of tobacco products. Because of this new law, the Family Smoking Prevention and Tobacco Act, the most deadly product sold in America is finally being regulated to protect public health."[1] This legislation gave the FDA unprecedented authority to:

- Create a tobacco control center within the FDA and gives the FDA authority to regulate the content, marketing and sale of tobacco products.
- Require tobacco companies and importers to reveal all product ingredients and seek FDA approval for any new tobacco products.
- Allow the FDA to change tobacco product content. (The current ban on flavoring applies to any product meeting the definition of a "cigarette." This includes any tobacco that comes rolled, such as cigarettes and cigars, and added to this definition in the Family Smoking Prevention and Tobacco Control Act is any tobacco with the purpose of being rolled such as rolling tobacco.)
- Call for new rules to prevent sales except through direct, face-to-face exchanges between a retailer and a consumer.
- Limit advertising that could attract young smokers.
- Require cigarette warning labels to cover 50 percent of the front and rear of each pack, with the word WARNING in capital letters.
- Ban the use of expressions such as "light," "mild," or "low" that give the impression that a particular tobacco product poses less of a health risk.

Congress banned candy and spice flavorings such as chocolate and clove, saying cigarette makers used those products to hook youngsters into a lifetime of addiction. But it exempted menthol from the ban, saying it wanted to FDA to study the issue and report by 2012 whether restrictions on it would serve the public health.

"It is shameful for our government to ban all cigarette flavorings except the one that is deadliest for communities of color and teens"

Dr. Phil Gardner
African American Tobacco Control Leadership Council

The job of the FDA Tobacco Products Scientific Advisory Committee (TPSAC) is to advise the commissioner or designee in discharging responsibilities as they relate to the regulation of tobacco products. TPSAC reviews and evaluates safety, dependence, and health issues relating to tobacco products and provides appropriate, advised information and recommendations to the Commissioner of Food and Drugs. One of the first charges of TPSAC was to study and collect information on the impact of the use of menthol in cigarettes on the public health, including such use among children, African Americans, Hispanics and other rural and ethnic minorities and to issue a recommendation of whether or not the flavoring menthol should be banned in

[1] Campaign for Tobacco Free Kids "FDA Authority Over Tobacco, 2009

cigarettes. Though all other flavors were banned through the Family Smoking and Prevention Act, the flavor menthol was excluded. After a summer of protest from the public health community, an eleventh hour amendment was added directing the FDA to study and issue a recommendation on what should be done about menthol.

Congress took an important step to prevent youth smoking when they banned flavored cigarettes as part of the Family Smoking Prevention and Tobacco Control act of 2009. However despite menthol's appeal to youth, as well as its popularity among adult smokers, including a large proportion of minority populations, menthol was exempted from the Act's flavor prohibition. To ensure the FDA was advised about menthol and other issues, the Tobacco Products Scientific Advisory Committee and Menthol Regulation was created to advise and inform the FDA as it moves forward in implementing the Family Smoking and Prevention Action of 2009.

> *"Menthol is a minty flavor that makes cigarettes attractive to many consumers. The flavor itself is popular with many smokers, and it also produces a cooling sensation that many smokers enjoy, particularly those new to smoking. Tobacco industry marketing of menthol cigarettes has particularly been aimed at African Americans. Menthol cigarettes constitute about one third of the American cigarette market... Menthol makes it easier to start smoking and harder to quit, especially children and Africans."*
>
> *Tobacco Control*

San Francisco's Tobacco Free Coalition has successfully advocated for a number of tobacco ordinances and resolutions in San Francisco over the last two decades including the banning of vending machines, tobacco and alcohol advertising on city property, smoke free work sites and restaurants, the prohibition of tobacco self-service merchandising displays, tobacco retailer permit ordinance and more recently landlord disclosure of smoking and non-smoking multi-unit housing, and smoke free outdoor events. The SF Tobacco Free Project (TFP) has also provided funding, training and technical assistance to help the communities most negatively impacted by tobacco to fight back and protect the public health. Specifically, TFP has developed a Community Action Model (CAM) Curriculum in English, Spanish and Chinese to train coalition and community members to advocate for healthier communities and to address social disparities faced by their communities. TFP TA and trainings also cover the content areas of second hand smoke and tobacco availability and countering pro-tobacco influences. TFP staff also act as staff to the well respected and community-driven coalition Tobacco Free Coalition.

Statement of objective and indicator/asset

By June 20, 2013, San Francisco City and County will adopt a resolution in support of an FDA ban of menthol and/or the use of an artificial or natural flavor, herb, spice or other flavoring additive in other tobacco products (e.g. smokeless, little cigars, hookah tobacco and dissolvable tobacco products) including but not limited to strawberry, grape, orange, clove cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry or coffee flavorings) in tobacco products.

Brief description of the rationale for choosing the objective

While there is no research/survey data in the Communities of Excellence (CX)/Partners database indicating public awareness about the menthol issue, there is anecdotal evidence that sectors of the community (particularly those experiencing social disparities that negatively impact their health) such as the African American and LGBT communities are unaware of the FDA carve out of menthol cigarettes. It seems that very few people outside of the tobacco control arena are aware of the issues with menthol. There was no media attention in 2007, and while there were 5 issue-related stories in 2008, around the time of the FDA regulation of menthol discussion, public education by the Congressional Black Congress, Tobacco Free Kids, American Lung Association, American Heart Association, and other policymakers, was concentrated mainly around the summer of 2008, and it is **difficult to judge how much of this coverage trickled down to general public. Tobacco control professionals are still being educated about some of the** intricacies of the menthol issue

As mentioned earlier, the Family Smoking Prevention and Tobacco Control Act requires the FDA Tobacco Products Scientific Advisory Committee (TPSAC) to submit a report and recommendation to the Secretary of the U.S. Department of Health and Human Services (HHS) on the impact of the use of menthol in cigarettes on the public health – including use among children, African Americans, Hispanics, and other racial/ethnic minorities.

At its meeting in March 2011, the advisory panel released a statement that "removal of menthol cigarettes from the marketplace would benefit the public health" but **stopped short of recommending a ban** on menthol cigarettes (which make up about 30% of the $80 billion dollar market).[2] TPSAC deliberated on the issue for over a year before releasing their draft findings and recommendations.

In June 2011, FDA updated the public on the agency's review of the available science. FDA announced that experts within the FDA Center for Tobacco Products (CTP) were conducting an independent review of the available science related to the impact of menthol in cigarettes on public health, including peer-reviewed literature, secondary data analyses, and independent CTP analyses of relevant large data sets. CTP's extensive analysis and evaluation of the available science relating to public health impact of the use of menthol in cigarettes included a thorough review of scientific literature and data in the areas of chemistry, toxicology, and physiology, patterns of menthol smoking, biomarkers of exposure to toxic constituents; and initiation of cigarette smoking, dependence and cessation.

FDA submitted its draft to an external peer review panel in July 2011. The FDA has been working on its final report to be released for public comment in the Federal Register since June 2011 but as of May 2013, no report has been forthcoming and the FDA has taken no action on menthol.

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2 Washington Post 2011

Members of the Tobacco Free Coalition, spearheaded by subcommittee of representatives from the LGBT and African American communities voted to advocate for the San Francisco Board of Supervisors and the San Francisco Health Commission to pass resolutions urging the FDA to ban menthol in cigarettes and to then submit the resolutions to the FDA during its "public comment" portion of their deliberations hopefully adding existing public pressure for the ban.

Overview of the intervention activities

The Tobacco Free Coalition, staffed by Tobacco Free Project staff, and comprised of representatives from community-based organizations and individuals representing those communities most negatively impacted by tobacco, voted to advocate for the FDA to ban on menthol in cigarettes. Spearheaded by members of the African American and LGBT communities, Coalition members received training to conduct a diagnosis or research the level of support for the FDA's regulation of menthol, and/or the use of artificial or natural flavor, herb, spice or other flavoring additives in other tobacco products (e.g. smokeless, little cigars, hookah tobacco, dissolvable tobacco products) including but not limited to strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry or coffee flavorings.

As mentioned earlier, the Coalition utilized the 5-step CAM to guide their advocacy efforts. Step 1 is conducting a "diagnosis" or research phase. During their this phase, in the latter half of 2010, advocates **gathered information** about FDA menthol issues by viewing websites of other projects working on FDA menthol regulation, such as statewide tobacco control projects, Tobacco Education Clearinghouse of California, Technical Assistance Legal Center, Competitive grantees, and the Tobacco-related Disease Research Program. Staff also participated in a meeting of Bay Area county project directors to discuss what each county was planning to do with respect to an FDA menthol resolution.

> *"As San Francisco moves forward with the resolution process it is recommended that they work closely with neighboring jurisdictions to educate the public and build support for the FDA's much debated ban on menthol. Local jurisdictions need to be empowered to understand that they can impact the final FDA decision. The egregious menthol targeting of African Americans as evidenced by the December 2010 Boston ruling against Lorillard in the Marie Evans estate lawsuit is a topical current event that can be used to garner support for a*

One 30 minute coalition training session was held on April 7 2011 and second 1.5 hour training held on May 9 to inform coalition members about the menthol issue. The training covered health issues related to menthol cigarettes, history of marketing and promotion of menthol cigarettes to the general public and to the African American community specifically, and health disparities experienced by the general public with specific focus on the African American community due to their high use mentholated cigarettes. At the May training five coalition members volunteered to participate on an **FDA subcommittee** to educate members of the Board of Supervisors regarding FDA regulations including issues with menthol and other flavorings and the benefits of a resolution.

Utilizing the 5-step Community Action Model, coalition members and TFP project staff completed a **community diagnosis** in which they further researched the health issues related to menthol cigarettes. **A report describing** all of the research undertaken was compiled into a report which was submitted to the Tobacco Control Section in December of 2010 along with a draft model resolution.[3]

Education Material Development: Tobacco Free Project staff and FDA subcommittee members also developed educational packets for use during upcoming educational visits to stakeholder groups and policymakers. A presentation was made during the April 7th Tobacco Free Coalition meeting. Another presentation was made at the July 7, 2011 Tobacco Free Coalition meeting. Coalition members were asked to obtain endorsements from their own organizations and ally organizations to endorse the Tobacco Free Coalition's FDA resolution. .

The **Midwest Academy Strategy** Chart was completed in July 2011. The Midwest Academy Strategy chart was utilized for developing a campaign strategy, including an analysis of potential barriers, allies and targeted policy makers for the proposed resolution. Given that no opposition was identified to the BOS or the Health Commission supporting a non-binding resolution regarding the menthol ban, the chart was relatively easy to complete. However it was during completion of the chart that advocates realized that since things appeared for a time to be moving slowly as far as obtaining a Board of Supervisor sponsor for their resolution that it might also be useful also to seek a similar recommendation from the San Francisco Health Commission, which was later accomplished.

During the Fall of 2011, eight stakeholder groups were contacted by Coalition FDA subcommittee members and **all eight groups agreed to endorse the Coalition's resolution calling on the FDA to ban menthol and other flavorings.**

Presentations to Policy Makers. Three Menthol Subcommittee members **presented at the Community and Public Health Committee of the San Francisco Health Commission** hearing on November 15, 2012 regarding the need for a resolution urging the FDA to ban menthol. In preparation of the meeting, rather than a formal training, the subcommittee members held more of a strategy planning meeting, developed a power point presentation for use in their upcoming meetings with policymakers, and then allocated key messages and speaking points amongst the three of them. As all three presenters were very knowledgeable about the menthol issue a formal training session was unnecessary. Following their presentation to the Health Commission the **resolution was passed unanimously by the full Health Commission on December 6, 2011.**

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[3] San Francisco FDA Menthol Report, 2010

Three educational visits were made by Coalition subcommittee members to three members of the **San Francisco Board of Supervisors.** The first two visits in June 2011 were made to request sponsorship by the Board of a resolution calling on the FDA to ban menthol. One of those visits was partially successful and **Supervisor Cohen agreed to sponsor her own resolution calling for an FDA ban, which was adopted by the full Board on July 26, 2011**.[4] The last visit was made to a member of the BOS to ask him to individually endorse the Coalition's own resolution to call on the FDA to ban menthol. Multiple attempts to meet with two other members of the BOS were unsuccessful as the November elections were close and supervisors were busy with election-related activities.

Soon after Brazil decided to ban menthol, **an article, rather than a press release** was sent on May 9, 2012 to increase the awareness that the FDA had still not taken any action to regulate menthol following the Tobacco Product Scientific Advisory Committee's declaration that "removing menthol largely because of its role in youth smoking initiation the US is still weighing the scientific evidence and deciding what to do." The article also discussed the tobacco industry's delaying strategies. The recent decision of Brazil to ban menthol was used as the "media hook" for the article as there had not been any other recent developments around FDA menthol regulation to draw media attention.

Brief description of the evaluation design

The evaluation design selected was "Policy Adoption" and evaluators tracked a series of process measures to assess the extent to which the Tobacco Free Coalition was successful in its effort to get the City and County of San Francisco to adopt a resolution in support of FDA regulation of the use of menthol in cigarettes and/or the use of an artificial or natural flavor, herb, spice or other flavoring additives in other tobacco products (e.g. smokeless, little cigars, hookah tobacco, dissolvable tobacco products) including but not limited to strawberry, grape, orange, clove cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry or coffee flavorings.

Data collection methods revolved around four major activities including: development of a Media and Policy Records, participant observation, surveys and key informant interviews. A description of the process measures used by the evaluator is described below:

- **Participant observation**. The evaluator participated in coalition meetings, subcommittee phone calls and observed Board of Supervisors and Health Commission meetings during which the resolutions were presented.

- **FDA Menthol Subcommittee Evaluation Training Survey**. Following a total of two hours of training coalition members including the Subcommittee, members were

[4] Supervisor Cohen agreed to sponsor a resolution but basically elected to do it on her own without additional input or support from the Coalition (although her resolution mirrored the one provided to her by the Coalition.)

given a **retrospective pre-test** to try to judge the impact of the FDA Menthol training. The training covered health issues related to menthol cigarettes, history of marketing and promotion of menthol cigarettes to the general public and to the African American community specifically, health disparities experienced by the general public with specific focus on the African American community due to their high use mentholated cigarettes.

- **Subcommittee Member Educational Visit Survey.** Following the visits to policymakers, subcommittee members were given a survey in which they were asked to reflect on their comfort level in participating in educational visits to members of the Board of Supervisors, how prepared they felt when conducting the visits, the adequacy of educational materials they were given to use in the visits to educate policymakers, and if they could name three key points they were able to make during their visit with Board members.

  Key Informant Interviews: A total of 4 telephone interviews were conducted by the evaluator with Tobacco Free Coalition FDA Subcommittee members in 2012. The interview protocol was developed by the evaluator and consisted of seven open-ended questions trying to tease out why members of the Coalition elected to get involved in the FDA issue, benefits of the proposed resolution, the strategy used to influence key decisions makers, how the FDA subcommittee handled any opposition to the resolution and the results of the resolution. Telephone interviews were conducted shortly after the educational visits were made and were "retrospective" in that coalition members were asked to reflect back on their experiences after conducting the visits.

- **Media Activity Record**: The Media Record tracked coverage generated about the proposed resolution.

- **Policy Record**: The policy record tracked all key dates, and documented any changes that occurred. It also documented when the resolution was introduced, by whom, and recorded the final Board of Supervisor's vote on the resolution.

Synopsis of main evaluation findings

Highlights from the retrospective FDA Menthol Subcommittee Evaluation Training survey reflected increased levels of knowledge about the menthol issue among participants, and that the Subcommittee demonstrated strong leadership in addressing the menthol issue within the Coalition. Participants also reported an increased likelihood to meet with elected officials about the menthol issue following the training.

- Before the training only 20% of participants considered themselves to be "very well informed" that African Americans are over-represented among menthol smokers, and that menthol use among all smokers in growing, compared to 80% following the training.

- **Before** the training 40% of participants said it was "not at all likely" they would meet with an elected official to get them to support an FDA ban on menthol in cigarettes, compared to 80% that said they were either "very likely" (60%) or "somewhat likely" (20%) **after** the training..

- 60% of participants reported the Subcommittee's leadership as "strong."

Using a 5 point scale with 1 being "not at all prepared" and 5 being "extremely prepared," participants rated themselves 4.75 overall. Those members who felt the most prepared (75%) also reported the highest level of comfort with conducting the visits.

The completed Midwest Academy Strategy Chart shows coalition members that:

- There was virtually no local opposition to the non-binding resolutions within the board or the community. The resolution urging the FDA to ban menthol and other flavorings in cigarettes was passed unanimously by the Health Commission and the Board of Supervisors.

Educational Visit Surveys completed by 4 Subcommittee members revealed that:

- Not surprisingly, the more prepared members felt, the higher their comfort level with conducting the visits to policymakers.

Key informant interviews were also conducted with Subcommittee members and other key stakeholders. Highlights from the surveys included:

- All of the advocates had some prior advocacy experience and three had a great deal of experience.
- The fact that the tobacco industry targets both the LGBTQ and African American communities was the compelling reason the majority of advocates got involved in the issue.
- Resolutions are not binding and usually passed for symbolic reasons by the Board of Supervisors to take a stance on a certain issue.

"They (resolutions) are usually generated from constituents or a base of people and groups that a Supervisor may regularly work with. Sometimes resolutions are not taken on if there are higher priority legislative things that need to happen."

Board of Supervisor's Aide

Data from the Policy Record below reveals the dates the proposed resolutions were passed by the Health Commission and the San Francisco Board of Supervisors.

Menthol Ban Policy Record	
Menthol Subcommittee formed at Coalition meeting	4/7/11
Subcommittee's first meeting	5/9/11
Supervisor Cohen approved by Coalition to introduce resolution re: ban on menthol	5/20/11
Supervisor Avalos approached because Coalition never heard from Supervisor Cohen. Avalos said he would do	6/14/11

it if Malia was not going to, but that Supervisor Cohen would be best person because of her District	
Supervisor Cohen's office finally responds; says it wants to go ahead but may want to do something more global. She wants to proceed without help from Coalition	6/27/11
Midwest Academy Chart completed and strategy devised	5/15/11
Meeting with Supervisor Cohen	5/11
Resolution introduced by Cohen (Supervisors Mar and Avalos asked to be added as co-sponsors). Resolution passed unanimously	7/11/
Coalition collected endorsements of ban to be submitted when public comment is opened on FDA ban. Collected total of 8 endorsements of Coalition's resolution calling on FDA to ban menthol.	7/19/11
Resolution passed by the full Board of Supervisors	7/26/11
Two Coalition members and one TFP staff presented at the Community and Public Health Committee of the San Francisco Health Commission. Committee members unanimously voted to approve the Health Commission's own similar resolution and put it before the entire Board.	11/15/11
Resolution passed by full Health Commission	11/11/11
Tobacco Control Legal Consortium files Citizens Brief to force the FDA to rule on the menthol ban.	4/13/13

Print and broadcast media were used to raise the community's awareness that passage of the Family Smoking Prevention and Tobacco Act called for the FDA to regulate the manufacturing, marketing and sale of tobacco products and banned flavorings such as chocolate and strawberry in marketing cigarettes; however Congress exempted menthol from the ban.

The Media Record highlights media and online coverage of the resolutions and the slow movement of the FDA to rule on the menthol ban.

Media Record	
San Francisco Menthol Report	2010
FDA ban taking flavored cigarettes off the market	Examiner, Sept. 2009
FDA pondering the ban of menthol cigarettes	Examiner, January 2011
Menthol cigarettes may soon join	Examiner, March 2,1 2011

the flavored cigarette ban	
ABC's of the FDA and the Black Community	Webinar, African American Tobacco Control Leadership Council, May 26 2011
Slow Burn, The U.S. Menthol debate Screeches to a Simmer	May 2011 (online)
Bay Area elected officials urge FDA to ban menthol in cigarettes	Fighting for Air, American Lung Association Newsletter, September 18, 2011
African Americanization of Menthol	No date
FDA Citizens Brief	Public health Newsletter, April 12, 2013
Potential Ban on Menthol gets big tobacco's attention	Huffington Post, May 27, 2013

Conclusions and recommendations

The FDA submitted its draft to an external peer review panel in July 2011. The FDA has been working on its final report to be released for public comment in the Federal Register since June 2011 but as of May 2013, no report has been forthcoming and the FDA has taken no action on menthol. As a result, the Tobacco Free Project has been waiting to submit the resolutions passed by the San Francisco Board of Supervisors and the San Francisco Health Commission.

Once again, it appears that lobbying by the tobacco industry has contributed to the federal government's unwillingness to act to protect the public health in a timely fashion. In response to the long delay, on April 11, 2013, the Tobacco Control Legal Consortium, (on behalf of a host of national public health advocates) delivered a Citizens Brief to the FDA urging it to prohibit menthol as a characterizing flavoring in cigarettes. Filing of the brief now **requires the FDA to begin a formal consideration process** that could include the gathering of public testimony and **will result in a formal FDA ruling on the matter.**