TALKING POINTS: THE FDA'S PRODUCT STANDARD PROHIBITING MENTHOL AS A CHARACTERIZING FLAVOR IN CIGARETTES

On April 28, 2022, the U.S. Food and Drug Administration proposed an historic rule to prohibit menthol as a characterizing flavor in cigarettes. The agency will accept comments for only sixty days, unless the comment period is extended. It is critical that the public health community engage with the FDA by submitting comments during this period. State and local perspectives must inform and improve the final rule. Submitting comments to the FDA is an easy process. As you draft your comments to the FDA, please consider the issues below and be sure to attach copies of any material that you reference. Anything submitted to the FDA is part of the official record and the agency is required to read and consider it all.

- In proposing a product standard like this one, the FDA must examine a rule's potential effects on commercial tobacco initiation, cessation, and the impacts on users and non-users of tobacco products. If you are aware of any published or unpublished information about menthol that is relevant to those areas, consider referencing and including it in your comment.

- It is vital that the FDA use its power to advance health equity. While the FDA's proposed rule includes much analysis of health equity and social justice issues, comments to the FDA should highlight the importance of centering tobacco regulation in health equity.

- If you are part of a state, local, or Tribal government that has implemented a ban on menthol cigarettes, any information about what you learned about the process will be useful.

- The FDA has proposed to prohibit menthol as a "characterizing flavors" in cigarettes, a term that has not been given a legal definition. The agency has provided some factors that it believes will clarify how the prohibition will be implemented on a case-by-case basis. The FDA has requested comments on alternative approaches such as banning all flavor additives. Suggestions for alternative approaches should provide supporting data and research.

- The FDA has proposed that this rule would take effect one year after the final rule is issued. The agency has the authority to shorten this period of time if it is necessary to protect public health. Given the number of lives that the rule would save, the FDA should be strongly urged to act quickly.

- There is no requirement that the FDA issue a final rule by a particular date once a rule is proposed, nor is there a requirement that a final rule be issued at all. Again, it is important to push the FDA to finalize this rule as soon as it can.

- While the FDA has not proposed this, it has indicated that it may be open to exempting heated cigarette products like iQOS or so-called Very Low Nicotine (VLN) cigarettes from this rule. Given the potential harm of these products, it is critical that they not be exempted from the proposed standard.

- The FDA has indicated that it would consider establishing a process by which a manufacturer could request an exemption from the standard for a particular product on a case-by-case basis. Given the FDA's poor track record with case-by-case review involving premarket authorizations, it is hard to imagine that such a process would have any public health benefits at all.