

tiation. Menthol, however, is a major contributor to smoking initiation and continued addiction, and for this reason, it will continue to enjoy the protection of a federal government that seems afraid to alienate any corporation, whether it's part of Big Pharma, Big Insurance, or Big Tobacco.

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The Threat of Menthol Cigarettes to U.S. Public Health

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The 2009 Family Smoking Prevention and Tobacco Control Act gave the Food and Drug Administration (FDA) authority to regulate certain tobacco products with the goal of protecting public health.¹ The law provides the FDA with regulatory tools for reducing harm to health from products that cause nicotine addiction and disease. It specifically banned flavored cigarettes, except those containing menthol, which account for about 30% of the current U.S. cigarette market. It also created the Tobacco Products Scientific Advisory Committee (TPSAC), consisting of nine voting members and three nonvoting members representing the tobacco industry, and charged it with preparing a report on “the impact of use of menthol cigarettes on the public health including such use among children, African Americans, Hispanics, and other racial and ethnic minorities.”

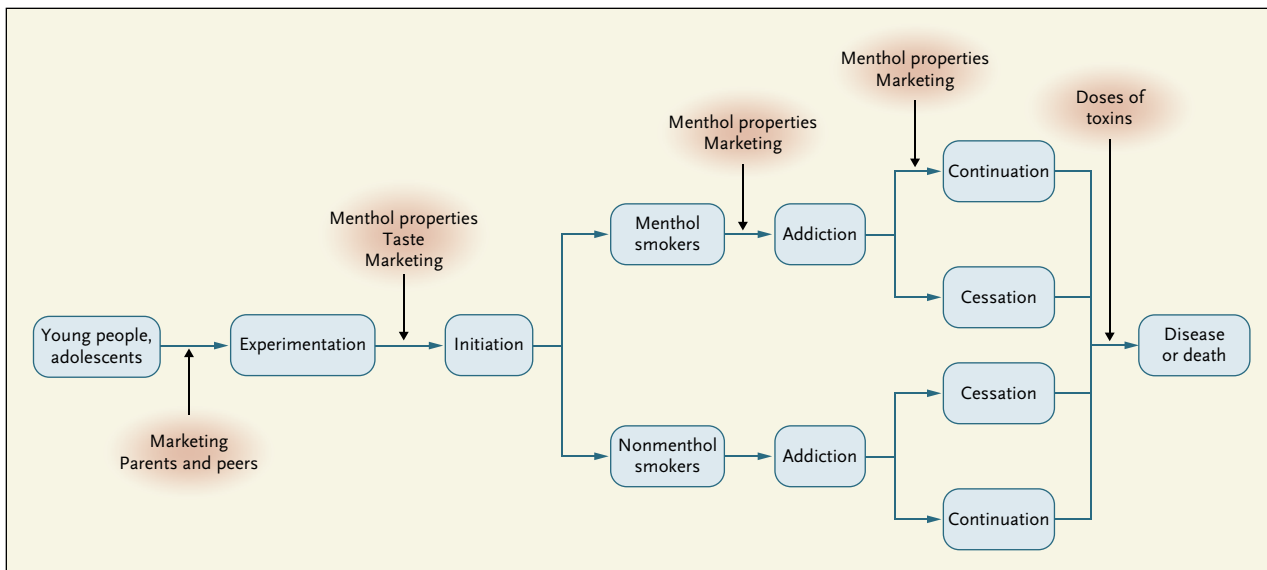
Menthol, a naturally occurring monocyclic terpene alcohol, has long been used in consumer and medicinal products because of its minty taste and aroma and its cooling and analgesic properties. It acts primarily on transient receptor

potential channels that contribute to the detection of physical stimuli, including temperature and chemical irritation. Mentholation of cigarettes resulted from a chance discovery made in the 1920s by Lloyd “Spud” Hughes, an Ohio man who smoked cigarettes that had been stored in a tin containing menthol crystals. Hughes accidentally identified an additive whose pharmacologic actions reduce the irritating properties of smoke generally and nicotine specifically. Menthol contributes to perceptions of cigarettes’ strength, harshness or mildness, smoothness, coolness, taste, and aftertaste. Research also shows that menthol has druglike characteristics that interact at the receptor level with the actions of nicotine.

The TPSAC, on which we serve, submitted its menthol report to the FDA on March 23, 2011, with a conclusion that menthol cigarettes damage public health and a general recommendation that “removal of menthol cigarettes would benefit public health in the United States.”² The report has generated controversy that reflects misunderstanding of the roles of the TPSAC and the FDA.

For its report, the TPSAC drew on sources including the peer-reviewed literature, presentations and submissions from the tobacco industry and its consultants, internal industry documents, and analyses of relevant data and modeling. Industry members of the committee provided their perspectives throughout the review process and submitted their own report. The TPSAC review was directed at answering key questions related to both individual smokers and impact on the population; we used a conceptual framework defining points in the processes of smoking initiation, continuation, addiction, and attempted cessation at which menthol cigarettes’ availability could theoretically harm health (see flow chart). The committee classified the relevant evidence in terms of its strength with regard to equipoise, assessing its sufficiency to determine whether a relationship between menthol cigarettes and a specific effect was at least as likely as not.

In assessing menthol cigarettes’ effect on public health, the TPSAC considered whether their



Model of Effects of the Availability of Menthol Cigarettes on Smoking, from Experimentation to Disease and Death.

Adapted from the TPSAC report.²

availability increased the number of smokers or the risk of cigarette-caused diseases as compared with a counterfactual scenario in which such cigarettes had never existed. The committee found that the evidence from toxicologic research, studies of biomarkers in humans, and epidemiologic studies did not support a conclusion that smokers of menthol cigarettes have greater disease risk than smokers of nonmenthol cigarettes.

However, we found convincing evidence that menthol cigarettes' availability increases the number of smokers by increasing the rate of smoking initiation and reducing the rate of cessation, particularly among black Americans. In concluding that menthol cigarettes increase initiation rates, the TPSAC noted that the proportion of adolescent smokers who smoke menthol cigarettes is higher than the proportion of adult smokers who do so, that more younger adolescent smokers than older adolescent smokers use menthol cigarettes, and that people who have smoked for less than a year are more likely than established smok-

ers to prefer menthol cigarettes. A key cohort study showed that initiating smoking with menthol cigarettes is more likely to lead to established smoking than is initiating with nonmenthol cigarettes. Such a relationship is biologically plausible because of menthol's cooling and anesthetic properties, which can reduce the harshness of cigarette smoke for new smokers. The TPSAC further concluded that menthol cigarettes increase the likelihood of addiction and the degree of addiction in new smokers. Together, increased initiation rates and a greater risk of addiction among menthol-cigarette smokers increase the total number of smokers.

Moreover, the availability of menthol cigarettes could further harm public health by reducing the rate of successful quitting. The committee concluded that it's more likely than not that the availability of menthol cigarettes reduces the rate of successful smoking cessation among blacks and that such a relationship is as likely as not to pertain to other racial or ethnic minority groups. According

to several national surveys, quitting rates are lower among menthol-cigarette smokers than among nonmenthol-cigarette smokers, particularly among blacks. Studies in animals show that once drug self-administration is experimentally established, taste and other sensory stimuli substantially enhance the extent and persistence of self-administration. Furthermore, empirical and qualitative research, including industry-sponsored studies, show that some consumers, particularly blacks, hold beliefs about implicit health benefits of menthol cigarettes that may interfere with their quitting.

The TPSAC reviewed the marketing of menthol cigarettes, combing through industry documents and the peer-reviewed literature. Our report documents how marketing messages for menthol cigarettes differ from those for nonmenthol cigarettes, linking menthol to images of "freshness" and reduced risk and successfully targeting certain population groups, particularly blacks. We found it as likely as not that such marketing has resulted in

higher smoking prevalence than that which would otherwise be anticipated among blacks and Hispanics.

At the population level, the TPSAC found that the availability of menthol cigarettes probably increases the likelihood of experimentation and regular smoking in the general population and particularly among blacks. By increasing the number of smokers, menthol cigarettes' availability increases the public health impact of smoking, even though the risk associated with smoking for an individual smoker does not appear to be increased by smoking menthol cigarettes.

In answer to the Tobacco Act's overall charge, the committee concluded that menthol cigarettes adversely affect U.S. public health and that there are no public health benefits to menthol cigarettes as compared with nonmenthol cigarettes. Using our model comparing a scenario reflecting the current pattern of smoking of menthol and nonmenthol cigarettes with one that assumed the nonavailability of menthol cigarettes, we estimated that by 2020 about 17,000 more premature deaths will have occurred and 2.3 million more

people will have started smoking than would have been the case if menthol cigarettes were not available.

The TPSAC's overall recommendation that "removal of menthol cigarettes from the marketplace would benefit public health in the United States" parallels the conclusion of the 1964 Surgeon General's report on smoking and health: "Cigarette smoking is a health hazard of sufficient importance in the United States to warrant appropriate remedial action."³ The committee has been criticized for not directly recommending banning menthol as an additive or providing specific recommendations on implementing such a ban. The TPSAC report answered the committee's charge of assessing the public health impact of menthol cigarettes and offers a foundation for future action by the FDA, which holds regulatory authority. The TPSAC, a scientific advisory committee, was not charged with addressing regulatory options and did not have the time or expertise to analyze regulatory scenarios, including any involving inadvertently opening a door for the introduction of contraband menthol ciga-

rettes into the U.S. market. The committee issued a clear message that menthol in cigarettes poses a significant public health risk. Now, the TPSAC stands prepared to respond to FDA questions on additional scientific issues that may arise as the agency does its regulatory job.

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Going Horizontal — Shifts in Funding of Global Health Interventions

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Health systems researchers have long debated whether health care is better organized separately for one or a few specific diseases (vertically) or jointly for many diseases through general health care systems (horizontally). Examples of vertical interventions in global health have included programs to fight

smallpox and polio; horizontal approaches have included comprehensive primary care to improve population health (advocated by the World Health Organization's 1978 Alma Ata Declaration) and sectorwide approaches to promoting health care reform (supported by the World Bank).

The U.S. President's Emergency

Plan for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, Tuberculosis, and Malaria are recent examples of disease-specific funding initiatives for global health. The Global Alliance for Vaccines and Immunisation (GAVI) is also vertically structured, targeting vaccine-preventable diseases. The funding these