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. 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.” 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

Please note: This article (10.1056/NEJMp1103403) was published on May 4, 2011, at NEJM.org.

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 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
Till Bärnighausen, M.D., Sc.D., David E. Bloom, Ph.D., and Salal Humair, Ph.D.

Interventions

Going Horizontal — Shifts in Funding of Global Health Interventions

Till Bärnighausen, M.D., Sc.D., David E. Bloom, Ph.D., and Salal Humair, Ph.D.

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