FDA Tobacco Products Scientific Advisory Shadow Panel

Monitoring the FDA's Regulation of Tobacco to Make Sure the Public's Health is Being Best Served

Recommendations

March 2011

Shadow Panel Statement on TPSAC Menthol Report

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Of Mice and Menthol

A Strong Report, but a Weak-Willed Committee

On June 22, 2009 President Obama signed into law the Family Smoking Prevention and Tobacco Control Act charging the Food and Drug Administration (FDA) with regulation of tobacco products. The Tobacco Control Act provided for creation of a Tobacco Products Scientific Advisory Committee (TPSAC) to advise the FDA. One of the express charges for the TPSAC was to create a "report and recommendation" on "the issue of the impact of the use of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities."

On June 8, 2010 a panel of experts shadowing the TPSAC (the FDA Tobacco Products Scientific Advisory Shadow Panel) issued a press release calling for "the elimination of the use of menthol in cigarettes." The Shadow Panel's recommendation was based on strong evidence that menthol acts as an anesthetic agent that makes cigarette smoking more appealing by masking the harshness of burning tobacco. Further, that menthol deceives smokers into thinking that cigarettes are less harsh and therefore safer, and that menthol brands are disproportionately targeted at African-Americans.

On March 18, 2011 the TPSAC issued a report entitled, "Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations." What follows is the Shadow Panel's review and assessment of the TPSAC report:

For a 231-page report that at first reads more like a legal document than a scientific one, clearly careful to keep every word within its "conceptual framework for cigarette smoking" authorized by Congress, the understated prose packs a wallop. There is surprisingly little arcane methodology or jargon. The notable exception is an appendix consisting of a

lengthy series of unexplained complex equations entitled, "Results from a Population Dynamics Model of the Consequences of Menthol Cigarettes for Smoking Prevalence and Disease Risks," apparently calculated to the year 2050).

The report painstakingly defines the parameters of the public health impact of menthol cigarettes its authors sought to ascertain. The committee sought to apply an innovative "systems science" approach, which it describes as consisting of "the factors that drive the tobacco epidemic and resultant disease burden" as well as an assessment of "the potential consequences of tobacco control measures." The result is that no stone has been left unturned, and it is doubtful that a single relevant study on the subject of menthol cigarettes was overlooked.

Any attempt by the tobacco industry or pro-tobacco financial analysts to find fault either with the scientific analysis or the strength of the conclusions will be futile. If anything, the report bends over backwards to acknowledge the input of the tobacco industry and the "non-voting members of the committee," i.e., the representatives from the industry. The report even includes a quotation (page 70) from a submission by Newport maker Lorillard that the company's marketing expenditures have not been disproportionately weighted toward African-American smokers or any other ethnic group or gender. An etymologist might point out that this is technically true only by virtue of the fact that African-Americans are still a minority population. In other words, while the greater part of the advertising budget might not be specifically targeted at African-Americans, the company's spending on Newport is indeed proportionate to the high market share that brand has among African-Americans.

The summary of the evidence for a causal relationship between advertising and promotion of cigarettes and an increase in tobacco use is meticulously presented. The report importantly notes the dramatic increase in retail marketing since the end of billboard and most print advertising under the Master Settlement Agreement, but it fails to put into perspective the relative impact of such point-of-sale expenditures compared to the past century's far more ubiquitous advertising.

The report cites the 1964 Surgeon General's Report on Smoking and Health as the landmark scientific publication in the field of tobacco control. That achievement is all the more remarkable when one considers that the authors of the 1964 report completed the work of reviewing the 11,000 studies to that time on smoking and disease in less than one year, the same length of time it took to write the present report on this single aspect of smoking.

But the present report suggests we have come a long way from the 1964 report (and many subsequent ones by the

Surgeon General) that did not even mention cigarette brand names. The strongest and lengthiest part of the report, Chapter 5 on Marketing and Consumer Perception, covers the gamut of product and package design, as well as marketing tactics. A fascinating section on the role of branding and labeling in consumers' taste perception and sensory evaluation cites manufacturers' various uses of the color green and includes this sentence: "Menthol packaging reflects the tobacco industry's knowledge about how color, labeling and other elements of branding will improve the consumer experience of the product's characterizing flavor."

Ultimately, the report's findings are a split decision. On the one hand, the committee did not find that menthol cigarettes increase the risk of disease. But on the other hand, it found that the availability of menthol cigarettes "has led to an increase in the number of smokers and that this increase does have adverse public health impact in the United States." The finding that menthol is associated with lower levels of cessation among African-Americans is compelling, as is the finding of a higher prevalence of menthol cigarette use by the youngest adolescents.

Despite the strength of its conclusion that menthol cigarettes substantially harm the public's health, the committee fails to recommend a ban on menthol cigarettes. The committee's "recommendation" is printed in boldface on page 208: "Removal of menthol cigarettes from the marketplace would benefit public health in the United States." This, unfortunately, is a conclusion, not a recommendation.

The big mystery and disappointment is why the committee did not recommend the removal of menthol cigarettes from the marketplace. One answer lies in the concerns about a black market for menthol cigarettes and "after market mentholation" (i.e., do-it-yourself menthol kits with roll-your-own cigarettes) acknowledged in the final section of the report. But this is reasoning that puts the cart before the horse. In the end, the committee proved weak-willed.

The devastating impact menthol cigarettes have had on the African-American community should necessitate a greater degree of input of that community in the ultimate decision by the FDA. Upon reading this report, African-American and all anti-tobacco organizations should demand nothing less than the addition of menthol to the list of far less common but already banned candy flavorings.

The action of the TPSAC on menthol was also the first test of how effective the new FDA law will be. The Committee's failure to recommend a ban on menthol cigarettes calls into question the effectiveness of the new law and regulatory process. Not recommending the banning of menthol cigarettes means the current market of mentholated cigarettes continues unchecked. This stark reality stands in contrast to promises that FDA regulation of tobacco would be

a panacea for the tobacco pandemic. Clearly, the first important test of this claim has been a failure. Congress and the FDA should revisit the viability of this law, including and up to consideration of repealing the law.

March 2010

FDA Shadow Panel Statement on Menthol

The FDA Tobacco Products Scientific Advisory **Shadow** Panel supports the elimination of the use of menthol in cigarettes. There is strong evidence that menthol acts as an anesthetic agent that makes cigarette smoking more appealing by masking the harshness of burning tobacco. The addition of menthol deceives consumers into thinking that cigarettes are less harsh and therefore safer. Furthermore, for more than half a century, menthol cigarette brands have been disproportionately targeted to African Americans.

The FDA **Shadow** Panel wishes to emphasize two additional points. First, we believe that the FDA is digging a hole for itself by trying to provide a scientific argument for increased addiction, morbidity, or mortality attributable to menthol cigarettes. The central question is not a scientific one, but a marketing matter.

Second, there is no evidence that any safer cigarette exists. Congress chose to ban flavored cigarettes not because they are more harmful or addictive, but because it believed that candy and fruit flavors were a significant factor in the marketing of cigarettes. The FDA Tobacco Products Scientific Advisory Committee has no choice but to use the same criteria to evaluate menthol. The central question is whether menthol plays a role in marketing cigarettes to consumers. The FDA **Shadow** Panel believes it is undeniable that menthol is used to increase the appeal of cigarettes.

February 2010

FDA Shadow Panel Statement of Priorities for the FDA

There is a difference in opinion among members of the FDA Shadow Panel on what should be the FDA's priority in implementing its authority to regulate tobacco products. Below, each of the panelists presents his or her own recommendations for the Agency. The disparity in

ideas about the FDA's priority reflects one of the major problems with the legislation: there was never any clear idea of what the FDA would specifically do to make cigarettes safer or reduce tobacco use. The fact that 10 leading experts in tobacco control have 10 different opinions about how the FDA should implement its regulatory authority demonstrates the lack of a clear connection between FDA authority over tobacco products and the protection of the public's health.

Michael Siegel: I believe that it makes no sense whatsoever to ask the FDA to approve tobacco products - which kill hundreds of thousands of Americans each year - for sale in the United States. It is equally absurd to think that by regulating specific ingredients in cigarettes, the FDA will be able to produce a safer cigarette. Instead, the fraud committed by tobacco companies through their "safer cigarette" myths will now be transferred over to the federal government. Regulating the product is not an evidence-based approach to the control of tobacco-related disease. In contrast, increasing cigarette prices and allocating the resources to aggressive, anti-smoking media campaigns are a scientifically proven way of reducing tobacco use. My recommendation, therefore, is for the FDA to devote all of the resources of its Center for Tobacco Products to an aggressive, hard-hitting, anti-smoking campaign directed at preventing youth smoking and encouraging adult smoking cessation. In addition, the FDA should levy fees on tobacco companies, in proportion to the number of youths smoking each company's cigarette brands, to be used to fund anti-smoking media campaigns in all 50 states. I have detailed my proposal for what a true, evidence-based national tobacco control strategy would look like on my blog.

Alan Blum: I would like to see the FDA issue and publicize a major statement informing the public that filtered cigarettes---now consumed by more than 95% of all smokers in the false belief that they are safe---do not confer any reduction of health risk whatsoever and represent consumer fraud. Nothing would debunk the lies of the tobacco industry better than that. I would also like to see the FDA ban tobacco products in drugstores, a trend that has dramatically worsened in the past 20 years with the wiping out of the independent local pharmacies by CVS, Rite-Aid, Walgreens, and other large retain chains. The chain drugstores continue to derive substantial profit from cigarette sales and undermine the image of pharmacies as a place for healthful products. I would also like the FDA to bar tobacco companies from funding university-based research and claiming to be

part of the solution and not the source of the problem. The commingling of money from the tobacco industry with taxpayer-supported funding from the National institutes of Health is obscene and needs to be stopped once and for all. It is particiularly odious when the tobacco industry continues to recruit students on college campuses to become cigarette sales managers and continues to deny in court that its products cause lung cancer, emphysema, and heart disease.

Heinz Ginzel: Any regulatory actions concerning tobacco taken under the auspices of the FDA are jeopardizing, contaminating, degrading and corrupting the declared original mission of the FDA. However you turn or bend it, tobacco, as much as any other potentially lethal self-exposure (including involuntary exposure to second-hand smoke), simply does not fit under the regulatory scheme of the FDA. Therefore, a new agency should be created, such as the FTA - the "Federal Tobacco Administration" - to address the health risks of all types of tobacco use (as well as nicotine itself), be it smoking, the most toxic form, or smokeless by whatever route of application.

John Polito: In my view the most critical FDA action under the new Family Smoking Prevention Act would be to insulate youth, as much as possible, from more than $15 billion in annual store tobacco marketing by issuing regulations requiring: (1) that tobacco products may only be "sold" indoors; (2) that all doors be marked with standardized tobacco sales location stickers; and (3) that underage youth be prohibited from entering tobacco sales locations. Section 906(d)(1) of the Act states that "The Secretary may by regulation require restrictions on the sale and distribution of a tobacco product, including restrictions on the access to and the advertising and promotion of, the tobacco product, if the Secretary determines that such regulation would be appropriate for the protection of the public health." While advertising restrictions imposed under the Act will likely face insurmountable first amendment commercial speech Constitutional challenges, regulations focused on preventing youth access to tobacco
will likely pass Constitutional muster.

Edward Anselm: Comprehensive assessment of all ingredients in cigarettes and their combustion products. Priority one: menthol. Congress has given the FDA authority to regulate nicotine and nicotine containing products. Although cigarettes have been established as a major cause of disease and death, and have been extensively studied from the epidemiological perspective, the actual ingredient content is a closely held business secret. It is not possible to regulate the nicotine without a complete understanding of all of the components of cigarettes and the processes involved in their manufacture. These ingredients interact when burned to create combustion products that affect not only the

pathophysiology of tobacco-related disease, but the behavior of smoking as well. The highest priority must go to those agents known to be present but not well understood. Among these, menthol is a high priority as it was specifically excluded from discussion in order to allow passage of the legislation.

Martin Pion: With the increasing promotion of electronic cigarettes it is important to determine objectively if they are safer than regular cigarettes, and then require appropriate labeling. Even if the evidence concludes that they pose no health risk to exposed non-smokers, they should still not be allowed wherever smoking conventional cigarettes is prohibited. To do otherwise would create serious smoke-free air enforcement problems.

Michael Givel: Before the U.S. Food and Drug Administration (FDA) implements any regulations or actions approving any new tobacco products or modified products as "safer" the FDA must conduct a full scale, open, and comprehensive peer reviewed short and long-term scientific study to assess the feasibility of making tobacco products safer by reducing individual ingredients or through general approaches. The test for safety should assume a precautionary mode in that no significant health harm will come to humans directly or through secondhand smoke or vapors as a result of smoking, using smokeless tobacco products, or smoking E-cigarettes. At the same time, the FDA should also publicly acknowledge and recommend for immediate federal, state, and local policy adoption current scientifically verified approaches to reduce tobacco consumption. These should include but are not limited to: tobacco tax measures to reduce demand, wide restrictions on public exposure to secondhand tobacco smoke, maximum size graphic warning labels on cigarette and smokeless tobacco packages on the direct dangers of tobacco use, aggressive anti-smoking media campaigns, similar to the Florida "Truth" campaign, regulation of tobacco product disclosures and promotions to ensure truth-in-advertising, widespread adoption of demand reduction tobacco cessation programs, and viable restrictions on sales to minors. If after careful scientific study, it is found that no approach to significantly eliminate tobacco use harm is feasible, the FDA should widely report these scientific findings to Congress, the media, and the public. The FDA should then recommend and reiterate as an alternative and primary federal programmatic and policy strategy and approach the use of current scientifically verified approaches to reduce tobacco consumption.