

To: Docket FDA-2013-N-0521

From: Lauren Berkowitz, Office of Regulations

Date: January 31, 2014

Subject: Summary of Write-in Campaigns to docket FDA-2013-N-0521

The United States Food and Drug Administration (FDA) is aware of the large difference that exists between the number of comments publicly posted on www.regulations.gov and the total number of comments received in response to the menthol advance notice of proposed rulemaking (ANPRM) docket (Docket FDA-2013-N-0521).

The bulk of the comments received for this docket were submitted as part of write-in campaigns, which we are defining in this memo as a group of submissions that are comprised of form letters (submissions that are identical or share identical text) that were submitted either electronically or by paper. Where there are form letters submitted to the docket by paper, FDA's general practice, for all of its dockets, is to post only sample letters for each such write-in campaign. If these sample letters contain individual identifying information, they are redacted before they are posted to www.regulations.gov. In the summary section of this docket on www.regulations.gov, it identifies the total number of comments received and the total number of paper (but not electronic) write-in campaigns.

In addition, docket FDA-2013-N-0521 has received many thousands of comments from individuals the vast majority of which were submitted as part of the write-in campaigns described above (both those received by paper and electronically). As a matter of Agency practice, FDA generally does not publicly post comments submitted by individuals in their individual capacity on www.regulations.gov due to concerns raised by some individuals that personal information not be disclosed in the docket. The practice applies to all FDA dockets, not just docket FDA-2013-N-0521.

All comments submitted to the docket are considered by FDA, regardless of whether they are publicly posted on www.regulations.gov. Furthermore, the public may view all comments that are not confidential by going to the FDA Docket's Management Reading room located at Room 1061, 5630 Fishers Lane, Rockville Maryland, 20852.

Because not all write-in campaigns are identified as such on www.regulations.gov and given the high volume of comments received and the number of write-in campaigns in this docket, below we give a general description of all the write-in campaigns (submitted either by paper or electronically) that we have identified. Please note that while the summary section of this docket on www.regulations.gov states that there are six paper write-in campaigns, this memo describes 18 write-in campaigns because it includes those submitted either by paper or electronically.

Write-in campaigns are presented in order of most to least comments received to the docket.¹ We also have attached a representative example of a comment submission for each of the campaigns.

Write-In campaign 1: In a write-in campaign with approximately 67,862 comments, individuals express their opposition to FDA's regulation of tobacco products. They say that a ban on menthol cigarettes would "not just constitute a vast invasion on American purchasing freedoms – it would also expand the illicit contraband market, increase crime, increase enforcement costs and further stake the fire of cynicism against a government that is out of control with burdensome laws and regulations."

Write-In campaign 2: This write-in campaign has approximately 60,909 comments written on behalf of retailers and their employees. The form letter states that a ban on menthol would expand the underground market. Further, the form letter states that retailers are responsible and better at checking age and ID to prevent underage use than would be the case on the illegal market. Further, the form letter notes that these retailers depend on the sales of menthol cigarettes for revenue. The form letter argues that a ban on these products could hurt their bottom line, cause a reduction in their sales force, and reduce Federal taxes received from cigarettes as sales go underground.

Write-in Campaign 3: This write-in campaign has approximately 36,116 comments. In this write-in campaign letter, individuals express their solidarity with The Black Police Association in opposing a menthol ban and assert that a ban on menthol cigarettes will cause additional profiling, arrests, and problems within the African-American community.

Write-In campaign 4: This write-in campaign has approximately 838 comments and requests that FDA immediately act to remove menthol cigarettes from the market. "There is compelling scientific evidence that menthol flavoring leads more young people to take up smoking, increases nicotine addiction and makes it more difficult for smokers to quit." This campaign asks FDA to remove menthol from the market and notes the impact of cigarette smoking on preventable death, heart disease, and stroke.

Write-in campaign 5: This write-in campaign has approximately 71 comments written on behalf of individuals and their company. The comments contend that FDA regulation of menthol up to and including a ban would have unintended consequences. The comments state that FDA regulation would lead to the black market for cigarettes, which would become uncontrollable. The comments also state that FDA regulation would lead to additional unhealthy options on the black market as products could become illicitly mentholated. Furthermore, the comments state that wholesalers comply with laws, and FDA action on menthol would result in more underground activity. Lastly, the comments argue that FDA regulation in this area will also negatively affect jobs.

¹ Please note that the numerical identifiers assigned to each write-in campaign in this memorandum do not match the numerical write-in campaign identifiers used on www.regulations.gov. The reason for this is that this memorandum includes both electronic write-in campaigns and paper write-in campaigns, and www.regulations.gov includes only paper write-in campaigns.

Write-in campaign 6: This write-in campaign has approximately 39 comments from employees of two companies. The comments state that “severe regulations or a complete ban of menthol cigarettes . . . will result in substantial job loss for companies like [theirs].” Furthermore, the comments also state that “if the government simply bans menthol cigarettes, you will do little to reduce smoking, but make a significant step towards increasing unemployment, increasing risks to public health from unregulated cigarettes, increase youth access through the black market and put companies like mine out of business.”

Write-in campaign 7: This write-in campaign has approximately 21 comments that support FDA’s regulation of tobacco and support a ban on menthol cigarettes. The comments note that limiting or banning menthol cigarettes would encourage people to quit, and would not expand the illicit market, increase crime, increase enforcement costs or “undermine other tobacco control efforts.”

Write-in Campaign 8: This write-in campaign has 15 comments which are from various trade associations, wholesalers, and a local government entity. Their comments describe the unintended consequences of strict regulation or a ban on menthol, and that such an action will drive sales underground. Furthermore, the comments argue that criminal activity would increase, including by organized crime and terrorist groups, and that current legitimate sellers of menthol cigarettes will lose revenues, tax revenues would decrease, and people will lose jobs.

Write-in campaign 9: This write-in campaign has approximately 14 comments. The comments state that a ban will hurt federal, state, and local governments, and that retailers and manufacturers are the best to educate on menthol. The comments also state that a ban on menthol would drive black market sales, and that banning menthol cigarettes is the wrong way to reduce teen smoking.

Write-in campaign 10: This write-in campaign has approximately 13 comments and says “Do not ban menthol cigarettes please.” or “Do not ban menthol cigarettes.”

Write in campaign 11: This write-in campaign has approximately 12 comments written by individuals stating that menthol should not be banned because it will hurt jobs. The comments argue that FDA should look at this issue from a purely economic mindset and that regulation will hurt state tax revenues. The comments also argue that FDA should not regulate 30% of the tobacco market out of existence and that banning menthol will be a huge expense to law enforcement as a result of illegal sales of the product.

Write-in campaign 12: This write-in campaign has approximately 10 comments. Individuals write to express that menthol cigarettes should be treated no differently than regular cigarettes. The comments state “restrictions on menthol cigarettes **WILL** affect more jobs and have a negative impact on the Convenience Retail community, warehousing and distribution channels that sell tobacco . . . **A LEGAL PRODUCT!**”

Write-in campaign 13: This write-in campaign has approximately 10 comments. These individuals support the FDA and tell us to, “Keep up the good work!”

Write-in campaign 14: This write-in campaign has approximately 10 comments submitted by individual union members. The comments say that a ban on menthol will cause them to lose their jobs. They state that underage smoking will increase because a menthol ban would remove the legitimate channel for cigarette sales, and that retailers are the best deterrent against underage smoking since they monitor underage sales. The comments state that a ban on menthol cigarettes would put 1/3 of the cigarette industry out of business.

Write-in campaign 15: This write-in campaign has approximately 9 comments, and is written by individuals who request that FDA not ban menthol because of the toll that it will have on jobs, including those in sales, retail, distribution and manufacturing. This campaign also notes that they are aware of studies that show menthol cigarettes are no more harmful to smoke than non-menthol cigarettes.

Write-in campaign 16: This write-in campaign has approximately 8 comments written by individuals who request that menthol not be banned. The comments state that menthol cigarettes make up approximately 1 in 3 taxed cigarettes and it would hurt, state, local, and federal governments not to receive this money. The comments argue that FDA should focus on existing regulations and on contraband to reduce teen smoking. Furthermore, the comments also state that manufacturers and retailers are the ones who currently help to reduce underage smoking.

Write-in campaign 17: This write-in campaign has approximately 8 comments. The comments request that menthol not be banned, and note that states and localities compete for jobs, and if menthol makes up 1/3 of a market, FDA regulation would take away jobs. The comments also note that banning menthol will put sales of menthol products underground.

Write-in campaign 18: This write-in campaign has approximately five (5) comments and is written on behalf of tobacco wholesalers and their employees. The wholesalers say that, “The contraband market would thrive under unreasonable regulation of menthol cigarettes and would increase criminal activity, including activities by organized crime and terrorist groups.” Additionally, “restrictive regulation” could have “adverse effects” on jobs in their industry.