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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD, 20852

The U.S. Food & Drug Administration's Advanced Notice of Proposed Rulemaking Tobacco Product Standard for Nicotine Level of Combusted Cigarettes

Dear Commissioner Gottlieb:

Reason Foundation is grateful for the opportunity to submit this comment regarding the Food and Drug Administration's (FDA) "Advance Notice of Proposed Rulemaking, Tobacco Product Standard for Nicotine Level of Combusted Cigarettes."

Reason Foundation's nonpartisan public policy research promotes choice, competition and a dynamic market economy as the foundation for human dignity and progress.

Introduction

Suggestions to reduce nicotine in cigarettes to minimally addictive or non-addictive levels have been around for decades but have never been implemented anywhere in the world. The justification for a tobacco product standard setting a maximum nicotine level in cigarettes is twofold; first, to preclude a pathway from youth smoking experimentation to cigarette addiction; second, to degrade the appeal of the product to such a level that current adult smokers will either quit or switch to safer nicotine alternatives.

If adopted, a maximum nicotine standard would represent the biggest regulatory intervention ever undertaken by FDA in the cigarette market, affecting 34 million adult smokers and a product category worth $94 billion.[1]

Under the Food, Drugs & Cosmetics Act the Secretary of Health and Human Services must consider scientific evidence concerning: (1) The risks and benefits of the proposed standard to the population as a whole, including users and nonusers of tobacco products; (2) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (3) the increased or decreased likelihood that those who do not use tobacco products will start using such products (section 907(a)(3)(B)(i) of the FD&C Act).

[1] Euromonitor International, Cigarettes in the US, July 2017. http://www.euromonitor.com/cigarettes-in-the-us/report

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As it stands, the scientific evidence surrounding the possible impact of a maximum nicotine standard is inadequate to sufficiently satisfy the criteria set out in the FD&C Act. In order to answer FDA's questions regarding the possible introduction of such a standard, this comment will focus on questions of scope, smoking initiation and cessation, countervailing effects, consumer surplus, ethics, political accountability, and FDA's analysis of the possible public health benefits that could be derived from such a standard published in the New England Journal of Medicine.

Scope

Given the purported public health benefits of a maximum nicotine standard for combustible cigarettes, FDA requested comments on whether such a standard should also apply to any or all of the following products: cigarette tobacco, roll-your-own (RYO) tobacco, little cigars, premium cigars, pipe tobacco, and waterpipe tobacco. Any tobacco product standard must be based on sound scientific evidence and careful consideration of both efficacy and countervailing effects.

The only body of scientific literature that currently exists examining the effects of reducing nicotine in combusted tobacco products is for Very Low Nicotine Cigarettes (VLNCs). This literature itself is subject to severe limitations and there is almost no evidence examining what effect such a standard would have on illicit markets, consumer surplus or the wider economy. Without any data on the technical feasibility, impacts on cessation, initiation, appeal, addictiveness, withdrawal symptoms, or user experience there exists no evidence base on which FDA can draw to justify an extension of a maximum nicotine standard to include other combusted tobacco products.

If the FDA did introduce a maximum nicotine standard for cigarettes there is a possibility of some substitution to other combusted products, particularly RYO and little cigars. But the more likely scenario is that smokers will continue to use combustible cigarettes that do not comply with the new standard, obtaining these cigarettes from the illicit market or altering VLNCs to increase nicotine levels.

In terms of other product categories such as premium cigars, pipe tobacco, and waterpipe tobacco there is no justification for including these products in a maximum nicotine standard under any circumstances. Premium cigars and pipe tobacco present lower risks to users than combustible cigarettes. Exclusive cigar and pipe tobacco smokers do have an elevated risk of death compared to nonsmokers, but it is five to ten times lower than it is for exclusive cigarette

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smokers.[2] The primary reason for these differences is not the toxicity of the tobacco smoke but the patterns of use. Pipe tobacco and cigars tend toward mouth-puffing rather than inhalation.

In 2015, a systematic review of the risks of cigar smoking led by FDA showed a modest increase in risks for all-cause mortality from cigar smoking.[3] However, mortality risks from cigar smoking varied by level exposure as measured by cigars smoked per day and levels of inhalation. Research conducted by FDA's Center for Tobacco Products shows primary cigar smokers use one and a half cigars per day when they smoke.[4] According to the studies in the 2015 analysis, reported relative risks for smoking one to two cigars per day are elevated but none are statistically significant.[5]

Premium cigars are a popular adult product whose risks are well-known, with use generally being moderate to occasional. They represent a high barrier to entry for young people both because of price and user experience. It is unclear whether a maximum nicotine standard for premium cigars is technically feasible without fundamentally altering the product and destroying the adult user experience. The possibility of youth or adult smokers migrating from cigarettes to premium cigars to satisfy their nicotine addiction is extremely low especially if safer nicotine alternatives such as Electronic Nicotine Delivery Systems (ENDS) are available.

In the case of waterpipe tobacco, the toxicity and patterns of use differ from combustible cigarettes. Waterpipe tobacco operates on the principle of heat-not-burn. Because the tobacco is heated rather burnt, the smoke created by a waterpipe presents a substantial but different risk to the user due to the pyrolysis of tobacco caused by the partial combustion of charcoal. The temperature inside the bowl of a waterpipe typically reaches around 300 degrees centigrade compared with the end of a lit cigarette which can exceed 700 degrees centigrade.[6]

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[2] Christensen, Carol H. et al. "Association of Cigarette, Cigar, and Pipe Use with Mortality Risk in the US Population," JAMA Internal Medicine. 2018;178(4):469–476.
https://www.ncbi.nlm.nih.gov/pubmed/29459935

[3] Chang, Cindy M et al. "Systematic review of cigar smoking and all cause and smoking related mortality," BMC Public Health. 24 April, 2015.
https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-015-1617-5

[4] Chen J et al. "Biomarkers of exposure among U.S. cigar smokers: an analysis of 1999-2012 National Health and Nutrition Examination Survey (NHANES) data," Cancer Epidemiology, Biomarkers & Prevention. December, 2014.
https://www.ncbi.nlm.nih.gov/pubmed/25380733

[5] Rodu, Brad. "FDA Study: Cancer risks nearly nil for 1-2 cigars per day," R Street Institute. August 24, 2016.
https://www.rstreet.org/2016/08/24/fda-study-cancer-risks-nearly-nil-for-1-2-cigars-per-day/

[6] University of Cincinnati. "Smoking hot: Study finds heat of hookah pipe the biggest health culprit for smokers." ScienceDaily.com. April 03, 2017
https://www.sciencedaily.com/releases/2017/04/170403193049.htm

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Research from the Royal University of Saudi Arabia shows waterpipe smoke is 30 times less concentrated in chemicals than cigarette smoke.[7] Chemists and pharmacologists also from Saudi Arabia found 142 chemicals in waterpipe smoke compared to 7,000 in cigarette smoke. Waterpipe users often experience the same high levels of carbon monoxide exposure as cigarette and cigar smokers, however, their exposure is seldom chronic. Regular cigarette smokers are typically daily smokers whereas waterpipe smokers are more often than not occasional users. A study of students who used waterpipes found only six percent reported smoking daily or mostly daily, with daily cigarette smokers being at higher odds of using a waterpipe at all and at a higher frequency than non-smokers.[8]

To apply a maximum nicotine standard to these products without accounting for differential risk, use patterns, technical feasibility, economic impacts or consumer surplus would be highly irresponsible. The latest figures from the Centers for Disease Control and Prevention show the prevalence of these products among youth is already low, occasional and declining.[9]

Traditional public health policies would be more conducive to remedying any problems of youth use among these product categories or potential substitution. Furthermore, if satisfying alternatives such as ENDS, other heat-not-burn tobacco products, and smokeless tobacco are allowed to enter and remain on the market this would likely mitigate substitution to these products. In all cases, however, many current adult smokers will continue to smoke full nicotine cigarettes from the illicit market rather than migrate to other combustible products.

Maximum nicotine levels and effects on smoking cessation

As part of its consideration of a maximum nicotine standard, FDA reviewed the existing peer-reviewed literature regarding VLNCs and the likely effects of reducing nicotine in combustible cigarettes. Specifically, FDA requested comment regarding the conclusions of a 2013 survey paper by Benowitz et al.[10] The paper argues a maximum nicotine standard of 0.5 mg per rod would minimize the addictiveness of cigarettes and is both feasible and necessary to "prevent children from becoming addicted smokers and to give adults greater freedom to stop smoking when they so decide to quit by reducing the addictiveness of cigarettes."

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[7] Qureshi, Huma. "Smoking shisha: how bad is it for you?." The Guardian. August 22, 2011. https://www.theguardian.com/society/2011/aug/22/shisha-smoking-how-bad-is-it

[8] M. Rifat Haider et al. "Factors Associated with Smoking Frequency among Current Waterpipe Smokers in the United States: Findings from the National College Health Assessment II," Drug and Alcohol Dependence. May 21, 2015. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4821569/

[9] Wang, Teresa W. et al. "Tobacco Product Use Among Middle and High School Students — United States, 2011–2017." Centers for Disease Control and Prevention. June 8, 2018 / 67(22);629–633. https://www.cdc.gov/mmwr/volumes/67/wr/mm6722a3.htm

[10] Benowitz et al. "Reducing the nicotine content to make cigarettes less addictive," Tobacco Control. April 15, 2013. https://tobaccocontrol.bmj.com/content/22/suppl_1/i14#ref-19

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Preventing children from becoming addicted smokers is and should remain a top FDA priority. But the latest data shows just how successful FDA has already been in achieving this goal, with 7.6 percent of high school students and 2.1 percent of middle school students reporting cigarette use in the past month,[11] compared with 15.8 percent and 4.3 percent, respectively, in 2011. Existing tobacco control policies are preventing youth from both initiating and continuing to smoke. The need for a maximum nicotine standard to prevent youth experimentation and addiction is therefore unclear, especially as addiction and experimentation are not synonyms in the case of smoking.

While it is possible a maximum nicotine standard may preclude a pathway from youth experimentation to youth addiction in the legal market, this is a hypothesis, not an empirical statement. A maximum nicotine standard would not prevent youth experimentation in the illicit cigarette market, which would continue to provide full nicotine strength, as acknowledged by supporters of VLNCs. Such markets will require no age verification and illicit cigarettes may be priced lower than legal VLNCs or ENDS products.

There is very little research on how teen smokers or teens susceptible to smoking will react to VLNCs. One study conducted by Hatsukami et al examines acute effects on withdrawal symptoms and subjective evaluations of VLNC among adolescent smokers.[12] The study's findings mirror many adult studies of VLNCs. Young smokers found VLNCs less satisfying while withdrawal symptoms and craving were reduced.

The study, however, suffers severe limitations so as to make it of extremely limited value when trying to examine the effects of a real-world maximum nicotine standard. The study only compares effects within the laboratory and not under realistic market conditions, with participants presented with each cigarette once, and under abstinence conditions. The researchers relied on "subjective measures as an index of abuse liability, rather than using a behavioral choice procedure," while participants also received cash incentives.

Significantly more research is needed to examine the possible impact of VLNCs on youth to confirm the hypothesis that a maximum nicotine standard will prevent youth smoking initiation and subsequent addiction. While the hypothesis may appear persuasive, there is no evidence as of yet to support it.

The Benowitz paper claims a maximum nicotine standard is needed: "so that the smoker can be truly free to consider the benefits versus risks of smoking or not smoking and to then act on their

[11] ibid
[12] Hatsukami, Dorothy et al. "Adolescent smokers' response to reducing the nicotine content of cigarettes: Acute effects on withdrawal symptoms and subjective evaluations," Drug and Alcohol Dependence. July 1, 2018. https://www.ncbi.nlm.nih.gov/pubmed/29775959

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decision to quit if that is their choice." The assumption that smokers are not currently free to weigh the benefits versus risks of smoking is highly contentious. It is plausible to argue a smoker's free will is undermined by their nicotine addiction which may, in turn, change the costs and benefits of smoking but it does not render a cost-benefit analysis from the smoker's point of view worthless.

According to the rational addiction model, smokers become addicted when the benefits of smoking outweigh the costs. As Nobel-Prize winning economist, Gary Becker observed, people stop smoking when they "find a way to raise long-term benefits sufficiently above the short-term costs of adjustment."[13] Cigarette addiction itself may make smokers unhappy but as Becker points out "people often become addicted because they are unhappy" and "would be even more unhappy if they were prevented from consuming the addictive goods." According to this model, smokers are not inherently irrational or unfree even when addicted to nicotine.

Many smokers say they want to quit but stated preferences are often unreliable particularly when strong social pressure is involved. It is hard to disentangle whether these stated preferences are actually second-order preferences. Most smokers who try to quit struggle and many are unsuccessful but this does not mean more weight should be given to their stated preferences than to their revealed preferences when considering a policy which removes choice entirely. Addiction may limit freedom of choice to an extent, but the total removal of the option to smoke cigarettes with nicotine levels above a proposed standard is a denial of choice and a reduction in freedom.

Smokers are currently free to decide to quit nicotine entirely or switch to safer alternative sources of nicotine such as Nicotine Replacement Therapies (NRT) or ENDS. There are far more ex-smokers in the U.S. than there are current smokers.[14] Despite the difficulties, it is clear smokers are able to quit. If smokers were totally beholden to their addiction, tobacco taxation would not be an especially effective tool in reducing smoking rates. A maximum nicotine standard fundamentally differs from traditional tobacco control policies. While taxation acts as a disincentive to smoke, a maximum nicotine standard is a prohibition via the degradation of the product and a denial of choice.

In terms of the effect a maximum nicotine standard would have on smoking cessation in the adult market, the evidence base as it stands is weak. As FDA has acknowledged, some studies show smokers who switched to VLNCs reduced the number of cigarettes smoked and reduced nicotine dependence but others show the reported use of VLNCs did not change the number of cigarettes smoked.

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[13] Becker, Gary S. "A Theory of Rational Addiction," Journal of Political Economy. August, 1988. https://www.journals.uchicago.edu/doi/10.1086/261558

[14] Manning, Kay. "Ex-smokers now outnumber smokers, but cessation efforts still face uphill battle." Chicago Tribune. July 11, 2017. http://www.chicagotribune.com/lifestyles/health/sc-hlth-smoking-cessation-0719-story.html

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Even in studies showing a reduction in the number of cigarettes smoked, the reduction was small.[15] While nicotine is the key ingredient that addicts smokers, smokers are also accustomed to the cigarettes themselves, particularly their preferred brand.[16] Adult smokers have typically smoked for many years are remarkably loyal to their brand and their behavior is not so easily changed. This behavior shows not just a consistent demand for nicotine but a consistent demand for nicotine delivered via the combustible cigarette of the consumer's preference.

Most studies show VLNCs reduce the reinforcing power of cigarettes but it is not reduced to zero. Furthermore, in clinical trials where participants are asked to smoke only the VLNC cigarettes provided to them for free, most participants continue to smoke their preferred cigarettes. The fact that so many participants continue to smoke albeit at somewhat lower volumes shows a strong preference for smoking continuation.

According to a 2018 evidence review of nicotine reduction in cigarettes, "these data suggest that if a nicotine reduction policy were implemented, many would likely find VLNC cigarettes to be unsatisfying and may seek out alternative sources of nicotine."[17]

The attrition rate is also higher in clinical trials where smokers switch directly from their regular brand to VLNCs rather than stepping down their nicotine content over time before switching to VLNCs. This suggests smokers find VLNCs extremely unattractive when compared with their usual brand.[18]

Not only does the research base for VLNCs show limited promise in terms of efficacy, the research itself is fundamentally unreliable and is therefore likely to be overly optimistic in terms of what VLNCs can achieve in terms of smoking cessation. The vast majority of studies on VLNCs use volunteers who are given financial incentives and free VLNCs. These circumstances necessarily mean they do not reflect any real-world scenarios of what would happen if a maximum nicotine standard were to be introduced.

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[15] Donny et al. "Randomized Trial of Reduced-Nicotine Standards for Cigarettes," New England Journal of Medicine. October 1, 2015.
https://www.nejm.org/doi/full/10.1056/NEJMsa1502403

[16] Fagerström, Karl, Eissenberg, Thomas."Dependence on Tobacco and Nicotine Products: A Case for Product-Specific Assessment," Nicotine & Tobacco Research. March 29, 2012.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3611984/

[17] Benowitz et al. "Whether to push or pull? Nicotine reduction and non-combusted alternatives - Two strategies for reducing smoking and improving health," Preventative Medicine. 29 March, 2018.
https://www.ncbi.nlm.nih.gov/pubmed/29604326

[18] Mercincavage, Melissa et al. "Attrition during a randomized controlled trial of reduced nicotine content cigarettes as a proxy for understanding acceptability of nicotine product standards," Addiction. January 20, 2017.
https://onlinelibrary.wiley.com/doi/abs/10.1111/add.13766

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As has already been discussed, rates of non-compliance in these studies are high,[19] as are dropout rates. Although compensatory smoking is not observed to a significant degree in most of the recent literature, some studies suggest signs of compensatory smoking in more dependent users.[20] Taken together this suggests there will be significant behavior change among consumers, most of which will not tend towards harm reduction.

FDA has asked how youth and adult risk perceptions of VLNCs might impact initiation, use, and cessation habits of combusted tobacco products. FDA mentions that one potential risk of a maximum nicotine standard is that adults and young people may perceive VLNCs as safer than regular combustible cigarettes.

Due to widespread misperceptions about the dangers of nicotine, there is a possibility some consumers could confuse VLNCs as presenting less risk than regular combustible cigarettes. A 2016 study found 73 percent of respondents incorrectly believed nicotine is the principal substance in cigarettes that cause cancer. More than a quarter believed low nicotine cigarettes were less harmful than traditional cigarettes. Those who were white and more educated were less likely to believe VLNCs were safer than traditional cigarettes.[21]

Over time, It is unlikely VLNCs will be perceived to be significantly less harmful than regular combustible cigarettes. Any misperception can be corrected by FDA through public health information campaigns. In order to maximize the impact of these campaigns, FDA should highlight the relative risk of safer nicotine alternatives such as ENDS and snus as well as accurately communicating the risk of VLNCs. These campaigns would also help correct the public's broader misunderstanding of the risks of nicotine.

If FDA were to adopt a maximum nicotine standard, the resulting rates of smoking cessation due to the standard would be low. Under a highly optimistic scenario there would likely be increased quit attempts but even in the best case scenario public health gains would likely be extremely modest. In a realistic scenario, the public health gains would be minimal and would be significantly outweighed by other factors.

There already exists a substantial market for safer nicotine alternatives and while there has been much success in switching smokers to these products, there remains a significant demand for combustible cigarettes. Even if public misperceptions around the relative risks of nicotine

[19] Bandiera FC et al. “Nicotine Dependence, Nicotine Metabolism, and the Extent of Compensation in Response to Reduced Nicotine Content Cigarettes,” Nicotine & Tobacco Research. Oxford University Press; 2015 Sep;17(9):1167–72.
[20] Nardone N et al. “Estimations and predictors of noncompliance in switchers to reduced nicotine content cigarettes.” Addiction. 2016 December;111(12):2208–16.
[21] Nguyen, Anh B et al. “U.S. adults' addiction and harm beliefs about nicotine and low nicotine cigarettes,” Preventative Medicine. December 27, 2017. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5328980/

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were reduced and a regulatory environment created where safer alternatives can thrive there would still be a demand for combustible cigarettes with satisfying nicotine content.

Countervailing effects

FDA discusses a number of countervailing effects which could undermine the alleged public health benefits of a maximum nicotine standard. There is little research on which to draw any firm conclusions about what countervailing problems will emerge or their extent. FDA has, however, provided a draft concept paper examining possible countervailing effects.[22] FDA should be applauded for undertaking this initial research and should continue to do build on its initial paper.

The paper discusses at length the problems that will be posed to suppliers of illicit cigarettes due to the difficulty of manufacturing products of comparative quality currently available in the legal market. Both consumers and suppliers could produce tobacco products that exceed the maximum nicotine standard but for reasons highlighted in the FDA's paper, this production will likely be minimal.

FDA rightly recognizes the possibility that other products such as concentrated e-liquids could be added to VLNCs to raise nicotine levels, which could ameliorate the degraded user experience of VLNCs. While it is unknown to what extent consumers may engage in such product alteration, there is little the FDA could do to prevent such actions without hampering the second part of its plan to reduce smoking through encouraging the innovation and availability of reduced risk products like ENDS.

It is, however, highly likely consumers would use the internet to purchase illicit cigarettes. While the Prevent All Cigarette Trafficking Act makes such purchases illegal, consumers already engage in such behavior to evade tobacco taxes.[23] Contraband is easily smuggled into the U.S., as seen with products such as fentanyl, heroin, marijuana, and other illegal drugs as well as alcohol during prohibition.

[22] "Illicit Trade in Tobacco Products after Implementation of an FDA Product Standard." Food and Drug Administration. March 15, 2018. https://www.fda.gov/downloads/tobaccoproducts/newsevents/ucm601047.pdf

[23] Gregorian, Dareh. "FedEx hit with $235m lawsuit from Attorney General Eric Schneiderman for shipping untaxed cigarettes." New York Daily News. March 30, 2014. http://www.nydailynews.com/new-york/fedex-hit-235m-lawsuit-shipping-untaxed-cigarettes-article-1.1739975

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The illegality of purchasing illicit cigarettes is unlikely to weigh heavily with consumers. FDA cites data from the U.K. showing just one percent of current U.K. smokers who were offered illicit tobacco considered illegality as part of their purchasing decision.[24]

FDA hypothesizes that illicit cigarettes may be priced higher than VLNCs due to the costs of manufacturing and supplying the illegal market. This is extremely unlikely. Illicit suppliers will likely trade in products manufactured in countries not affected by a maximum nicotine standard. Illicit suppliers will have strong incentives to price their goods lower than those in the legal market, and will bear little to no production costs while avoiding U.S. taxation entirely. The price of VLNCs will also likely reflect the already high prices of combustible cigarettes and will rise over time as states and localities increase tobacco taxes.

While FDA believes some smokers will be satisfied with VLNCs there's no reason to believe this will be the case. As previously discussed, smokers in VLNC studies show high rates of noncompliance and attrition even under highly unrealistic conditions involving financial incentives and free VLNCs. All commercial ventures in VLNCs have proved failures when competing with standard combustible cigarettes.[25]

FDA also claims that limited evidence suggests the demand for regular combustible cigarettes would be "modest" citing the "Understanding the U.S. Illicit Tobacco Market report," from the National Research Council and Institute of Medicine.[26] But the report itself provides no evidence limited or otherwise to support this claim. The report cites the need for illicit suppliers to have established distribution networks, new sources of product and profit potential given the availability of legal products that are close substitutes for cigarettes. There is no empirical data to lend credence to FDA's assumption of a modest demand for illicit combustibles.

Established distribution networks for these products already exist in the form of grey market suppliers trafficking cigarettes from low tax states to high tax states. The portion of the U.S. tobacco market represented by illicit sales was between 8.5 percent and 21 percent as of 2015. This share nearly tripled over the past two decades, according to the report. With legal cigarette

[24] NEMS Market Research (2013). North East Illicit Tobacco Survey 2013, Executive Summary. Billingham, United Kingdom. http://www.illicit-tobacco.co.uk//wp-content/uploads/2014/03/NE_Illicit_Tobacco_Report_key_findings.pdf
[25] Bates, Clive, Wade, Carrie. "Reducing Nicotine in Cigarettes: Challenges and opportunities," R Street Institute. October, 2017. https://www.rstreet.org/wp-content/uploads/2017/10/115.pdf
[26] Reuter, Peter, Majmundar, Malay. "Understanding the U.S. Illicit Tobacco Market characteristics, Policy Context, and Lessons from International Experiences." National Research Council and Institute of Medicine. https://www.nap.edu/catalog/19016/understanding-the-us-illicit-tobacco-market-characteristics-policy-context-and

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prices as high as they are, illicit suppliers could bear significant distribution costs and sell for significantly less than the current legal product and still make substantial profits.[27]

Organized crime networks trafficking in illicit drugs also have highly developed distribution networks and may be incentivized to enter or expand the cigarette trade as profits from marijuana continue to fall amid domestic legalization.

The report concedes there is "insufficient evidence to draw strong conclusions about how the illicit tobacco market would adapt in response to permanent modifications to tobacco products as the result of any new regulations." Substantial additional research is needed across a range of areas to assess the possible effect on the illicit market. These areas of research will need to include individual and criminal networks that traffick in illicit tobacco, how smokers will respond to the loss of the product, how and in what proportion consumers may switch to reduced risk nicotine products.

A market of 34 million adults and potentially children would not be off limits to organized crime and presents a huge profit opportunity. If consumers continue to demand full nicotine cigarettes and they can be supplied at a reasonable price, the market will continue to exist. In terms of possible effects on the illicit drug market, a maximum nicotine standard could enlarge the drug market by providing larger profit centers for organized crime.

By encouraging an expansion of the illicit tobacco market, the imposition of a maximum nicotine standard could lead consumers seeking to obtain illicit cigarettes to come into contact with individuals or organizations selling illicit drugs. This would remove a barrier to access to those drugs potentially increasing drug consumption.[28]

To ameliorate countervailing effects which would negate the alleged public health benefits of a maximum nicotine standard, FDA would need to accurately communicate the relative risks of reduced risk products such as ENDS and snus while making clear that nicotine is not the principle cancer-causing agent in cigarettes. FDA should actively encourage smokers who are considering switching to reduced risk products to do so.

FDA would need to significantly reform the Premarket Tobacco Application process to ensure a wide range of reduced risk products can enter and remain on the market. The PMTA process presents an enormous regulatory barrier to reduced risk products. Only the largest companies, mostly existing tobacco manufacturers, can comply with the current regulatory regime. To ensure maximum success of switching smokers to safer nicotine alternatives, consumers need

[27] Phillips, Carl V. "FDA Doesn't Understand Black Markets." Daily Vaper. http://dailyvaper.com/2018/06/18/fda-doesnt-understand-black-markets/
[28] Morris, Julian. "The Gateway Effect of Marijuana." Reason Foundation. May 2018. https://reason.org/wp-content/uploads/2018/05/gateway-effect-of-marijuana.pdf

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access to a wide-range of reduced risk products as well as traditional NRT and counseling services.

FDA would also need to reform the Modified Risk Tobacco Application process so that manufacturers of reduced risk products can accurately communicate the relative risks of their products to consumers. FDA has yet to grant a single MRTP. This is especially worrying in the case of Swedish Match's application for its snus products. There are decades worth of epidemiological evidence showing beyond any doubt the harm reduction effects of switching from smoking to snus.[29] ENDS have also been shown to assist with quit rates and are unlikely to exceed five percent of the risks of smoking.[3031]

But even if these measures were taken there is a strong likelihood there would still be a large and profitable illicit market for organized crime to exploit, which would degrade the welfare of smokers for little or no public health benefit.

Consumer surplus

FDA rightly recognizes that consumer surplus and utility loss must be considered when examining the costs and benefits of a maximum nicotine standard.

There's certainly precedent for such analysis. In August 2011, FDA issued analysis measuring lost consumer surplus associated with graphic health warnings on cigarette packages. FDA concluded that lost consumer surplus offset 76-93 percent of the predicted health benefits.[32]

FDA has also estimated the impact of mandatory calorie counts, finding they would cost between $2.2 billion and $5.27 billion over 20 years in lost consumer surplus due to foregone

[29] Ramstrom, Lars, Borland, Ron, Wikmans, Tom. "Patterns of Smoking and Snus Use in Sweden: Implications for Public Health," International Journal of Environmental Research and Public Health. November, 2016.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5129320/
[30] Shu-Hong Zhu, et al. "E-Cigarette Use and Associated Changes in Population Smoking Cessation: Evidence from US Current Population Surveys," British Medical Journal 2017; 358: j3262.
[31] "Nicotine without the Smoke." Royal College of Physicians. April 28, 2016.
https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0
[32] Norton, Edward, Smith, Jeffrey A., Levy, Helen. "Improving Cost-Benefit Analysis of Tobacco Regulation," August 2011.
https://www.psc.isr.umich.edu/research/project-detail/35956

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consumption of energy-dense food.[33] FDA has rolled back its approach to such analysis there is little reason to do so.[34]

Critics of measuring consumer surplus in the realm of tobacco regulation often advance two objections. The first is that such analysis is a misapplication of rational choice theory that doesn't account for cognitive biases and any analysis of tobacco regulation should begin by quantifying health benefits and ignore any utility smokers derive from cigarettes.[3536] The second objection is that measuring lost utility "makes it a lot harder to justify regulations on cost-benefit grounds."[37]

The second objection is simply a desire for policymakers to discard cost-benefit analysis all-together and only value public health outcomes when it comes to tobacco regulation. There is no justification for ignoring a particular form of analysis that is well-understood and valued in welfare economics (and has formed a part of regulatory decision-making in the U.S. for over 30 years) simply because it makes life more difficult for proponents of a particular tobacco regulation.

In terms of the first objection, a standard model does account for gains in health from any particular policy. As Levy et al explain: "calculating health gains is redundant, because consumer surplus already reflects the consumer's valuation of any health gains resulting from the change in demand...there is no good reason why the welfare analysis of regulations that reduce smoking should begin by calculating health benefits. [38]

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[33] "Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments Final Regulatory Impact Analysis," Office of Regulations, Policy, and Social Sciences Center for Food Safety and Applied Nutrition. November, 2014. https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/LabelingNutrition/UCM423985.pdf

[34] Begley, Sharon, Clarke, Toni. "Exclusive: U.S. to roll back 'lost pleasure' approach on health rules." Reuters. March 18, 2015. https://www.reuters.com/article/us-usa-health-lostpleasure/exclusive-u-s-to-roll-back-lost-pleasure-approach-on-health-rules-idUSKBN0ME0DD20150318

[35] Glantz, SA, Brown, P, Song, AV. "When health policy and empirical evidence collide: the case of cigarette package warning labels and economic consumer surplus," American Journal of Public Health. February, 2014. https://www.ncbi.nlm.nih.gov/pubmed/24328661

[36] Chaloupka et al. "An evaluation of the FDA's analysis of the costs and benefits of the graphic warning label regulation," Tobacco Control. December 30, 2014. https://tobaccocontrol.bmj.com/content/early/2014/12/30/tobaccocontrol-2014-052022

[37] Begley, Sharon. "FDA calculates costs of lost enjoyment if e-cigarette rules prevent smoking." Reuters. June 2 , 2014. https://www.reuters.com/article/us-fda-tobacco-insight/fda-calculates-costs-of-lost-enjoyment-if-e-cigarette-rules-prevent-smoking-idUSKBN0ED0A620140602

[38] Levy, Helen G., Norton, Edward C., Smith, Jeffrey A. "Tobacco Regulation and Cost-Benefit Analysis: How Should We Value Foregone Consumer Surplus?," American Journal of Health Economics. January 23, 2018. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5796550/

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Furthermore, models can be adjusted to take account of cognitive biases such as hyperbolic discounting. Excluding consumer surplus from cost-benefit analysis entirely negates the results of such an analysis from the outset. This is especially important in the realm of a maximum nicotine standard whose entire purpose is degradation of the product to reduce consumer surplus.

If VLNCs fail in forcing a smoker to quit or switch to a safer product the smoker will receive no health benefits but will suffer a welfare loss. This would represent a net cost to the individual and such deadweight losses would likely be large under a maximum nicotine standard.

Despite the availability of ENDS and NRT, there is still a large demand for combustible cigarettes. Even if FDA were willing to accommodate a diverse and liberal market for ENDS there would likely still be a strong demand among a number of adult smokers for full nicotine cigarettes due to the utility they derive from smoking.[39] Discounting the idea that smokers derive pleasure from cigarettes is to ignore the views of smokers themselves. According to a survey of U.K. smokers, 95 percent cited enjoyment as their reason for smoking with 35 percent indicating that in their view smoking was part of their identity.[40]

Consider how consumers of caffeinated beverages, legal cannabis or alcohol would respond to a policy that reduced levels of caffeine, alcohol, or tetrahydrocannabinol (THC) to minimal or non-psycho-active levels. The effect would be a prohibition of the product from which consumers derived utility.

Ethical considerations

Even supporters of a maximum nicotine standard concede it is “undeniably a more invasive tobacco control policy, and thus it is important to justify its necessity.” The questionable evidence of public health benefits does not in isolation justify its implementation.

Prohibiting a product used by 34 million adults, despite its well-known health consequences, as well as record low levels of youth smoking, requires a high degree of ethical justification. Questions of whether the policy works in terms of public health outcomes must be paired with the question of whether it is ethically justifiable. If health is the only consideration, a maximum nicotine standard could theoretically be justified if it extended a single life on net. But no

[39] Benowitz NL. “Nicotine Addiction,” The New England Journal of Medicine. 17 June, 2010. https://www.nejm.org/doi/pdf/10.1056/NEJMra0809890

[40] McKeganey et al. “The Pleasure of Smoking The Views of Confirmed Smokers,” Centre for Substance Use Research. December 2016. http://static1.1.sqspcdn.com/static/f/782462/27390673/1482788582747/CSUR_Pleasure_of_Smoking.pdf

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reasonable person would conclude that a prohibition on this scale could be justified in such terms. As Phillips notes, this does not fit with any recognized framework of welfare economics and is more akin to a pseudo-ethic:

"It is not welfarist, because the measure is not welfare, but merely one arbitrarily-chosen component of welfare, reduction of disease. No one tries to defend this goal by claiming that if it were adopted as an ethic it would make the world a better place. It clearly would not do so. It certainly does not reflect the empirical reality of how anyone chooses to live their life"[41]

In an article advocating cigarette prohibition, Grill and Voight argue "more life is better" and "more freedom is not always better."[42] This raises the question, according to who? These statements are fundamentally subjective. Policies that act against people's revealed preferences raise costs and reduce benefits to consumers and are certain to result in a welfare loss. Policies that interfere with consumer freedom to advance one component of welfare cannot be justified on either liberal grounds or utilitarian grounds. Public health policies can, however, be justified on the grounds of negative externalities and correcting market failures.

A maximum nicotine standard does not meet either of these criteria. Rather, It is a form of ends paternalism in which health and longevity are the overriding goals with other considerations ignored. The claim that a maximum nicotine standard helps people pursue their true preferences as stated by themselves is highly contentious. John Stuart Mill makes the point that a person's "voluntary choice is evidence that what he chooses is desirable."

Revealed preferences must be given more weight than stated preferences. When there are a plethora of options open to FDA to help those smokers who wish to quit or switch to a safer alternative do so, there is no ethical justification for a maximum nicotine standard that respects both consumer autonomy or societal welfare. If FDA is to introduce a maximum nicotine standard, it must provide a compelling ethical as well as a technocratic argument that takes into account consumer welfare and autonomy.

Political accountability

While FDA is authorized to reduce nicotine levels in combustible cigarettes under the 2009 Tobacco Control Act, it is not authorized to prohibit cigarettes outright or reduce nicotine content to zero. The decision to pursue either of these policies is reserved to Congress. It is unclear whether the kinds of nicotine standards being considered by FDA would be covered by the TCA. Since the effect of a maximum nicotine standard of 0.5mg per rod or lower would be the same

[41] Phillips, Carl V. "Understanding the Basic Economics of Tobacco Harm Reduction," Institute of Economic Affairs. August, 2016. https://iea.org.uk/wp-content/uploads/2016/08/Economics-of-tobacco-PDF.pdf

[42] Grill, Kalle, Voigt, Kristin. "The case for banning cigarettes," Journal of Medical Ethics. November 17, 2015. https://jme.bmj.com/content/early/2015/11/15/medethics-2015-102682.short

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as prohibiting the original product there's little doubt the policy would be challenged in the courts.

Such a far-reaching policy would have widespread economic impacts some of which would be extremely disproportionate, such as Native American tobacco producers who are a significant source of revenue for the Native American community. A maximum nicotine standard would place a greater burden of law enforcement across the country and has the potential to create a whole new class of scofflaws. A maximum nicotine standard represents a major intrusion into the consumer decisions of 34 million Americans via a government agency instead of a democratically elected chamber.

It is inconceivable that such a standard would not raise significant questions in Congress over whether FDA is overreaching and implementing a policy that should be decided by the people's elected representatives.

NEJM analysis

FDA's analysis of the potential public health impact of a maximum nicotine standard, published in the New England Journal of Medicine, makes extremely optimistic assumptions about reduced rates of initiation, switching, and smoking cessation.[43] For its analysis, FDA used a process of formal expert elicitation to estimate the likely behavioral responses to such a maximum nicotine standard.

Since such a policy has never been adopted anywhere else in the world and the existing evidence from both clinical and randomized controlled trials are subject to severe limitations, using expert elicitation to assess the impact of such a policy is highly questionable. While all the experts who participated are no doubt credible in the field of Tobacco Control, the question must be asked: what is the relevant expertise when examining a maximum nicotine standard and does such expertise for the purpose of such analysis even exist?

Examining the countervailing effects which might diminish the benefits of a maximum nicotine standard, the NEJM paper cites the National Research Council and Institute of Medicine study of the illicit market, arguing a maximum nicotine standard is unlikely to produce substantial demand for illicit cigarettes. As has already been discussed, there is no empirical evidence to support this claim. There is no substantial body of research which considers how consumers and illicit suppliers of cigarettes will react to this policy. Until such an evidence base emerges this assertion should be discounted.

[43] Apelberg et al. "Potential Public Health Effects of Reducing Nicotine Levels in Cigarettes in the United States," New England Journal of Medicine. May 3, 2018. https://www.nejm.org/doi/full/10.1056/NEJMsr1714617

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The analysis also assumes the widespread availability of satisfying, safer nicotine alternatives. But under current FDA rules, this remains far from certain. Without experts from the fields of law and economics, this analysis is of extremely limited value.

Expert elicitation can be a valuable addition to other forms of evidence in support of public policy decision making. But is this an area in which there are experts who have knowledge that provides a basis for making informed predictive judgments? Expert elicitation should only be undertaken when there are a sufficient evidence base and expertise in all areas of the policy. The NEJM analysis is, therefore, a misuse of expert elicitation.

Conclusion

A maximum nicotine standard will take years to implement and will undoubtedly face significant legal challenges from the tobacco industry. As of yet, the evidence is unsatisfactory to support the implementation of a maximum nicotine standard. Both youth and adult smoking rates are in steady decline and are responding to both traditional public health policies and innovation in the nicotine market such as ENDS. Instead of pursuing a maximum nicotine standard, FDA should pursue a policy of tobacco harm reduction by encouraging innovative and safer alternatives to smoking.[44] These strategies have proven successful in Sweden and are proving successful in the United Kingdom. Prohibiting a tobacco product whose dangers are well-known but is still used by 34 million adults is not justifiable in a free society which values individual autonomy. If the cigarettes of today are to be prohibited, it should be done through the democratic process and with the consent of the people's representatives, not through the will of a lone federal agency.

Sincerely,

Guy Bentley, Research Associate

[44] Kozlowski LT. “Prospects for a nicotine-reduction strategy in the cigarette endgame: Alternative tobacco harm reduction scenarios.” International Journal of Drug Policy. June 26, 2015. https://www.ncbi.nlm.nih.gov/pubmed/25795345