Before the

Food and Drug Administration

Silver Spring, MD 20993

July 10, 2017

In the Matter of	)	
	)	
Tobacco Product Standard for	)	
N-Nitrosonornicotine Level in Finished	)	
Smokeless Tobacco Products	)	Docket ID No. FDA-2016-N-2527-0286
	)	
	)	

Comments of FreedomWorks Foundation

FreedomWorks Foundation is a 501(c)(3) nonprofit and educational foundation dedicated to building, educating, and mobilizing the largest network of activists advocating the principles of smaller government, lower taxes, free markets, personal liberty, and rule of law. In doing so, FreedomWorks Foundation acts as a "service center" for the millions of citizen-leaders who make a difference in the fight for lower taxes, less government, and more freedom.

FreedomWorks Foundation appreciates the opportunity to provide comments to the Food and Drug Administration (FDA) in response to the proposed Tobacco Product Standard for N-Nitrosonornicotine (NNN) Level in Finished Smokeless Tobacco Products.

One of the core projects of FreedomWorks Foundation is the Regulatory Action Center. The Regulatory Action Center is dedicated to educating Americans about the impact of government regulation on economic prosperity and individual liberty. FreedomWorks Foundation is committed to lowering the barrier between millions of FreedomWorks citizen

activists and the rule-making process of government bureaus to which they are entitled to contribute.

In line with this core project, FreedomWorks Foundation is concerned that the manner in which this rule was proposed violates the intent of Congress regarding public participation in the rulemaking process—subsequently casting substantial doubt on the arguments put forward by FDA and others in support of this rule while lending significant credence to arguments in opposition. Further, FDA's promulgation process of this rule exposes the administration to a compelling legal challenge. Finally, this rule is a textbook example of "midnight" regulation, a phenomenon of clear concern to Congress and something FreedomWorks Foundation has previously encouraged the Trump administration to curb as part of its ongoing effort to reform the Executive Branch. For these reasons, it is the position of FreedomWorks Foundation that FDA should withdraw this proposed rule.

Background

FreedomWorks Foundation's objection to the proposed NNN standards stems from a fact pattern suggesting FDA, under the previous administration, sought to limit as much public knowledge and participation on this rulemaking as possible while remaining within the legal bounds of the Administrative Procedures Act (APA). Reiterating a point raised by the Reason Foundation in its comments on this rulemaking, this proposed rule did not follow the Advanced Notice of Proposed Rule Making (ANPRM) process. While ANPRMs are not broadly required under the APA, the Reason Foundation notes that in each instance FDA has proposed rules under

the same legal authority as the proposed NNN standard it has followed the ANPRM process.[1] An ANPRM would have allowed for increased public input and knowledge in regards to this rulemaking, particularly from stakeholders in the regulated industry.

Again, however, public input to this rulemaking appears to be something the previous administration's FDA sought to avoid, additionally evidenced by the fact that this regulation was announced on Thursday, January 19th of this year.[2] This was the day before the inauguration of President Trump and a long weekend for many in the Washington, D.C. area due to inaugural festivities. In short, this rule was announced at a time when very few would be paying attention to the Federal Register.

The lack of an ANPRM and highly-questionable timing of the announcement call into question FDA's adherence to Congressionally-imposed rulemaking standards and thus the legality and efficacy of the rule itself.

Congressional Intent, Agency Transparency, and Legal Vulnerability

Ultimately, all regulations are an extension of Congress's legislative power and thus the intent of Congress via laws governing regulation should weigh heavily on the decisions of regulatory agencies. There is a plethora of evidence to suggest that by announcing this rule under the cover of the inaugural weekend and without an ANPRM, FDA's proposed NNN standard violates the checks imposed by Congress, and the courts, on Executive Branch rulemaking. This

[1] Fojtik, Brian, "The Proposed Tobacco Product Standard for NNN Level in Smokeless Tobacco Should be Withdrawn," March 9, 2017, http://reason.org/news/show/proposed-tobacco-product-standard

[2] DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration 21 CFR Part 1132 [Docket No. FDA-2016-N-2527] Tobacco Product Standard for N-nitrosonornicotine Level in Finished Smokeless Tobacco. FR Doc. 2017-01030 **Filed: 1/19/2017 8:45 am**; Publication Date: 1/23/2017. https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-01030.pdf

severely undermines not only the legitimacy of the proposed NNN standard, but also erodes invaluable public trust of FDA.

Congress has repeatedly stressed the importance of *meaningful* public participation in the rulemaking process, not simply technical compliance with the APA. According to a Congressional Research Service summary of Section 553 rulemaking under the APA, applicable to the FDA's proposed NNN standard, "agencies are required to provide the public with adequate notice of a proposed rule" and further, "the legislative history of the APA suggests that '[matters] of great importance, or those where the public submission of facts will be either useful to the agency or a protection to the public, should naturally be accorded more elaborate public procedures.'"[3]

Public participation has also been extensively emphasized by the Administrative Conference of the United States (ACUS), an independent regulatory agency created by Congress through the Administrative Conference Act. ACUS's recommendation on *Public Participation in Administrative Hearings* states the following regarding informal rulemaking, such as FDA's proposed NNN standard:

> "*Notice-and-comment rulemaking proceedings.* Agencies engaging in notice-and-comment rulemaking should, to the extent feasible; (a) make available documents, materials and public submissions upon which the proposed rule is based; (b) invite the presentation of all views so that agency may be apprised of any relevant consideration before formulating policy; (c) develop

[3] Garvey, Todd, "A Brief Overview of Rulemaking and Judicial Review," Congressional Research Service, March 27. 2017. https://fas.org/sgp/crs/misc/R41546.pdf

> effective means of providing notice to the affected public and to groups likely to possess useful information…"[4]

ACUS has since reaffirmed this feasibility principle. In *Guidelines for Choosing the Appropriate Level of Agency Policy Articulation*, ACUS states, "The Administrative Conference continues to support the general principle, stated in Recommendation 71-3, that 'agency policies which affect the public should be articulated and made known to the public to the greatest extent feasible.'"[5]

If regulatory matters of "great importance" should "be accorded more elaborate public procedures," such as an ANPRM, and agencies should inform the public to "the greatest extent feasible," then FDA should carefully consider what kind of message is sent via this particular rulemaking process. In each instance of regulation under the legal authority at issue here, FDA has been able to provide an ANPRM. Thus, it was clearly *feasible* for FDA to provide an ANPRM as part of the proposed NNN standard.

Further evidence of the feasibility of an ANPRM for this rulemaking is the fact that the very first comment submitted to the public docket, submitted on the same day the docket was opened, was a formal comment cosigned by several leading anti-tobacco groups.[6] The first comment not in support of the rulemaking, and also the first comment from a tobacco industry stakeholder, was submitted over a week later and primarily asked FDA for more time to review

[4] Recommendation 71-6 of the Administrative Conference of the United States—Public Participation in Administrative Hearings, Adopted Dec. 7,1971. https://www.acus.gov/recommendation/public-participation-administrative-hearings

[5] Administrative Conference of the United States—Guidelines for Choosing the Appropriate Level of Agency Policy Articulation, Adopted June 10, 1983. https://www.acus.gov/recommendation/statement-9-guidelines-choosing-appropriate-level-agency-policy-articulation

[6] Comments submitted by the American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Lung Association, Campaign for Tobacco-Free Kids and Truth Initiative, FDA-2016-N-2527-0002. https://www.regulations.gov/document?D=FDA-2016-N-2527-0002

the rule.[7] This seems to suggest that some members of the public did in fact receive advanced notice, while others did not.

While FDA may have met all technical requirements of the APA, this does not necessarily protect this rule from being vacated and remanded back to FDA by the courts in the future. It is true that Supreme Court precedent, established by the *Vermont Yankee Power Corporation v. Natural Resources Defense Council, Inc.,* substantially limits the courts' ability to impose rulemaking standards not explicitly outlined in the APA. However, as noted in a review of the decision published in the DePaul Law Review, the *Vermont Yankee* precedent is subject to certain exclusions:

> "Practitioners may be able to argue that *Vermont Yankee* is inapplicable in certain instances if, for example, an agency tradition of hybrid procedures exists. A second argument for hybrid procedures, again in accordance with *Vermont Yankee,* is dependent upon an analysis of the number of parties and interests involved in the administrative proceeding. The argument could be made that even *Vermont Yankee* holds that due process may require hybrid procedures when the number of parties is small and their interests are exceptionally affected."[8]

[7] Comment from RAI Services Company, FDA-2016-N-2527-0221 https://www.regulations.gov/document?D=FDA-2016-N-2527-0221

[8] Notaro, Karen Anne, "Judicial Imposition of Rulemaking Procedures on Administrative Agencies: The Impact of Vermont Yankee Nuclear Power Corporation v. Natural Resources Defense Council, Inc." *DePaul Law Review*, Volume 28, Issue 1, Fall 1978. http://via.library.depaul.edu/cgi/viewcontent.cgi?article=2454&context=law-review

While "hybrid procedures" generally refers to a combination of both formal and informal rulemaking procedures, under the Magnuson-Moss Warranty Federal Trade Commission Improvement Act, Congress established that ANPRMs are a recognized form of hybrid rulemaking.[9] Thus, FDA clearly demonstrated a tradition of hybrid procedures while exercising the legal authority used to propose this NNN standard, yet did not in this instance. Should the agency not withdraw the proposed NNN standard, FDA will expose itself to a compelling legal challenge to vacate these rules as a violation of the APA without protection from *Vermont Yankee.*

As noted, *Vermont Yankee* may also lack applicability in cases where the regulation "exceptionally" affects a concentrated group. The proposed NNN standard is a textbook example of such a regulation.

As previously stated, the manner in which FDA promulgated this rule naturally lends significant deference to the opposing arguments made by industry stakeholders. The key argument germane to this rulemaking's exceptional impact is that the proposed standard is not technically achievable. Industry stakeholders have repeatedly asserted that the proposed NNN level is impossible to achieve due to the fact that NNN levels are largely independent of controllable factors in the growing and product manufacturing process—chief among these factors being weather variations. Six farmers growing tobacco used in the production of smokeless products regulated under this proposed rule explained in a recent editorial:

> "[NNN] levels in smokeless tobacco have a lot to do with weather conditions – especially temperature and humidity – which change

[9] Garvey

every day. If it were possible to reduce NNN levels as low as specified by the proposed rule, we would already be doing it.

One thing we know for certain is that we are unable to control the weather. It seems as though the FDA should know this. It would have been helpful to talk to growers and industry experts about the feasibility of this rule before making a proposal like this. Now, all that we are able to do is submit statements to the FDA and hope that someone in authority has enough common sense to revoke this proposed rule. Short of revocation, additional time is needed to hear from growers and other stakeholders whose livelihoods stand to be wiped out."[10]

The industry asserts the proposed rule amounts to a *de-facto* ban on these products. This is certainly an exceptional impact. To further meet the standard of an exception to *Vermont Yankee,* the impact must also be concentrated. Per the Kentucky Farm Bureau Federation, "virtually all" of the American-grown tobacco used in the products regulated under the proposed NNN standard is grown in just 23 counties in Kentucky and Tennessee.[11] Therefore, this proposed rule unequivocally imposes an exceptional impact on a small party of stakeholders and thus exposes FDA to a process-based lawsuit without *Vermont Yankee* protection on yet a second front.

[10] Head, Jay, Alfred Slate, Dale Palmore, Elvis Bellar, Sammy Bryant, and Bobby Clay Riley, "New FDA rule impossible for tobacco farmers," The Leaf-Chronicle, March 24, 2017. http://www.theleafchronicle.com/story/opinion/readers/2017/03/24/commentary-new-fda-rule-impossible-tobacco-farmers/99586556/

[11] Haney, Mark, Comments of the Kentucky Farm Bureau Federation, April 10, 2017. https://cdn.kyfb.com/KYFB/assets/File/Federation/Legislative%20Affairs/Action%20Alerts/KFB%20Comments%20on%20FDA%20NNN%20Proposed%20Standard.pdf

By choosing to limit public participation through a publication camouflaged by the inauguration of President Trump and selective advanced notice, FDA appears to have deliberately cut corners in the rulemaking process. Doing the bare minimum is hardly enough when it comes to gaining public trust and legitimacy for the arguments in support of a new regulation. It is certainly not enough when the regulating agency breaks its own precedent of increased transparency and backpedals to the minimum standard. These concerns are not merely pragmatic. FDA established a precedent of issuing ANPRMs for rules proposed under the same legal authority and had the ability to give advanced notice of this rule—demonstrated by the fact leading anti-tobacco advocacy groups were able to mutually agree to a common position of support and submit a cosigned comment the day the docket opened and a week before any opposing stakeholders offered input. This exposes FDA to a significant legal challenge based solely on process should it not withdraw this proposed rule, with the agency committing taxpayer resources to litigating a defense of a process that implicitly violates the intent of Congress, if not explicitly.

Midnight Regulation

FreedomWorks Foundation also objects to this rule because it is an egregious example of "midnight" rulemaking—announced literally hours before the inauguration of the Trump administration. Midnight rulemaking is a phenomenon that results in generally poor public policy. Congress is actively working to curb this issue and FreedomWorks Foundation believes it is something the Trump administration should address broadly in its efforts to institute government-wide reforms and conduct a reorganization of the Executive Branch.

The incentives and evidence suggest midnight rules result in sub-optimal public policy outcomes. Midnight rules are generally defined as those with rulemakings initiated between the

election and inauguration of a new president by an outgoing administration. This problem is naturally exacerbated if the new administration is of the opposite political party. The proposed NNN standard obviously meets this definition.

The incentives facing administrators proposing midnight rules raise obvious concerns about any rule proposed under qualifying circumstances. First, midnight rules are those that likely conflict with public opinion. This is because the outgoing administration isn't very concerned about votes, if it all, and will likely try to get policies across the finish line that enjoy limited support and are in conflict with the agenda just voted-in by the American people. This creates the second concern, which is that such rules are rushed and thus poorly vetted. Finally, the incentives suggest that outgoing administrations will work to increase the volume of rules proposed, thus further hampering proper formulation and evaluation.

The Mercatus Center at George Mason University has studied midnight rules and determined that these natural incentives do indeed impact rulemaking. Per a 2012 study:

> "New research suggests that midnight regulations proposed during the second half of a presidential election year are more likely to have lower-quality regulatory analysis and less likely to use the results of analysis to inform decisions. Thus, these regulations may be particularly costly or ineffective."[12]

This phenomenon clearly occurred again before the transition to the Trump administration. The Federal Register, the best measure of annual regulatory activity, jumped by

[12] Ellig, Jerry, "Midnight Regulation: Decisions in the Dark?" Mercatus Center, August 28, 2012. https://www.mercatus.org/publication/midnight-regulation-decisions-dark

over 15,000 pages, to a total of nearly 96,000, from 2015 to 2016.[13] As scholars at the Regulatory Studies Center at George Washington University explain:

> "President Obama left office with a bang, issuing 41 economically significant rules between November 1, 2016 and January 19, 2017… models indicated that during last three months of President Obama's time in office, his Administration issued an average of 13.6 rules per month, showing that President Obama was an even more active midnight regulator than his predecessors."[14]

Congress has signaled that midnight rulemaking, like this NNN standard, is an abuse of the power it has delegated to the Executive Branch. Just this year, The House of Representatives passed the Midnight Rules Relief Act.[15] Again, all rulemaking power is an extension of legislative authority to the Executive Branch. Rulemaking agencies, including the FDA, should be conscious of this, not exploit processes loopholes and ambiguities for certain agendas.

It is for these reasons that FreedomWorks Foundation's comments in response to the Office of Management and Budget's Government-Wide Reform agenda included recommendations aimed at curbing midnight rulemaking.[16] It is also for these reasons that the

[13] Crews, Clyde Wayne, "Ten Thousand Commandments 2017," Competitive Enterprise Institute May 31, 2017. https://cei.org/10KC/Chapter-2

[14] Miller, Sofie E. and Daniel R. Pérez, "Measuring the Obama Administration's Historic Midnight Surge," *The Regulatory Review*, February 6, 2017. https://www.theregreview.org/2017/02/06/miller-perez-measuring-obama-administration-historic-midnight-surge/

[15] 115th Congress, H.R. 21- Midnight Rules Relief Act of 2017, accessed at https://www.congress.gov/bill/115th-congress/house-bill/21

[16] Brandon, Adam, Ken Cuccinelli II, and Patrick Hedger, Comments of FreedomWorks Foundation, Docket ID No. OMB_FRDOC_001-0201, June 12, 2017. http://d7.freedomworks.org.s3.amazonaws.com/Comments%20of%20FreedomWorks%20Foundation%20Government-Wide%20Reform%20OMB_FRDOC_0001-0201_0.pdf

FreedomWorks Foundation opposes the FDA's proposed NNN standard, as it is a particularly illustrative example of midnight rulemaking.

Conclusion

FreedomWorks Foundation appreciates the opportunity to provide comments on the FDA's proposed NNN standard. However, considering the glaring problems with the promulgation process outlined above, FreedomWorks Foundation is compelled to recommend, on behalf of our millions of activists across the country, that FDA withdraw this proposed rule at this time.

Respectfully submitted,

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&

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