

United States Senate

WASHINGTON, DC 20510

August 6, 2021

The Honorable Louis DeJoy
United States Postmaster General
1050 Connecticut Avenue NW
Washington, D.C. 20036-5303

Dear Mr. DeJoy:

I write to forward the attached letter from a coalition of stakeholders that has raised concerns to me about United States Postal Service Proposed Rule on the Treatment of E-Cigarettes in the Mail, 39 C.F.R. Part 113, 86 Fed. Reg. 10218-20, Doc. No. 2021-03393 (Feb. 19, 2021).

As Ranking Member of the United States Senate Committee on Small Business and Entrepreneurship, I have deep concerns about the potential scope of this proposed rule and the impact it may have both on small businesses and on the customers they serve. In this case, I am especially troubled by the concern raised by the coalition that no economic impact analysis has been conducted pursuant to the Regulatory Flexibility Act of 1980 (P.L. 96-354). The lack of such an economic impact analysis means that the implementation of this rule may have unforeseen and unintended economic consequences.

In crafting the final rule, I urge you to take into account the interests of Americans in rural areas who want to access vapor products. The U.S. Food and Drug Administration has acknowledged that electronic nicotine delivery systems “can reduce the use of combustible cigarettes and may be less harmful than traditional cigarettes”.¹ For rural Americans residing far from brick-and-mortar stores that sell vapor products, the United States Postal Service is their most reliable means of accessing these harm-reduction products. The science of addiction medicine suggests that if these Americans lose access to less harmful alternatives, they are likely to relapse, thereby increasing their risk of developing serious illness.

Thank you in advance for your full and fair consideration of this matter.

Sincerely,



Rand Paul, M.D.
United States Senator

Attachment

¹ Ned Sharpless, M.D., Acting Commissioner, U.S. Food and Drug Admin., *How FDA is Regulating E-Cigarettes*, FDA VOICES (last updated Sept. 10, 2019), <https://www.fda.gov/news-events/fda-voices/how-fda-regulating-e-cigarettes>.

Dr. Rand Paul
United States Senate
Ranking Member of the U.S. Senate Committee on Small Business and Entrepreneurship
Washington, D.C. 20510-6350

July 16, 2021

Re: United States Postal Service Proposed Rule on the Treatment of E-Cigarettes in the Mail, 39 C.F.R. Part 113, 86 Fed. Reg. 10218-20, Doc. No. 2021-03393 (Feb. 19, 2021)

Dear Dr. Paul:

We, the below signed stakeholders, have serious concerns with the United States Postal Service (USPS) *Proposed Rule on the Treatment of E-Cigarettes* (86 FR 10218) (Proposed Rule). Our concern is twofold. The Proposed Rule is counter to the principles of the Regulatory Flexibility Act (RFA)¹ and will have a devastating impact on small businesses. The Proposed Rule also exceeds its statutory authority by capturing products beyond the express legislative text and clear legislative intent. At a minimum, an economic impact analysis is warranted to better understand the implications of the Proposed Rule on the multiple industries that are affected.

In your role as the Ranking Member of the Senate Small Business Committee, we bring these concerns to your attention and are hopeful a course of action can be charted to promptly resolve our concerns.

1. Who We Are²

The signatories to this letter are collectively parties that are advocates or work in, service, advocate on behalf of or have clients in industries that will be impacted by the Proposed Rule, to include the e-cigarette, tobacco, smoking cessation, cannabis, and hemp industries. Because we are stakeholders and/or work closely with stakeholders that operate in the implicated industries - intrastate, nationwide and across the globe - we are uniquely situated to provide insight into the application of rules and regulations on our respective industries.

¹ The Regulatory Flexibility Act of 1980 (P.L. 96-354), (5 U.S.C. §§601–612) (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (P.L. 104-121), the Dodd-Frank Wall Street Reform and Consumer Protection Act (P.L. 111-203), and the Small Business Jobs Act of 2010 (P.L. 111-240).

² For the signatories of this letter that are employed by or members of various companies, non-profits, trade associations and bar associations, unless the signatory is of any such specific association, this letter does not represent an official policy position of any particular company, non-profit, or association, and instead solely represents the view of the individual signatories to this letter.

The signatories' primary concern is that the Proposed Rule was not subject to an economic impact analysis under the RFA. Had this analysis been conducted, the below outlined considerations would have been revealed, and the Proposed Rule could have been written taking into account the findings to minimize the significant economic impact on small entities. Because measures under the RFA were not taken, this group provides the following insights and recommendations.

2. Background

On December 21, 2020, Congress passed a coronavirus relief package as part of an omnibus bill known as the Consolidated Appropriations Act, 2021 (the "Omnibus Bill").³ The Omnibus Bill – over 5,500 pages in length – contained provisions that addressed a range of issues not related to coronavirus economic relief, including legislation known as the Preventing Online Sales of E-Cigarettes to Children Act (the "Act").⁴

The Act, effective March 27, 2021, amends other tobacco laws, specifically, the Jenkins Act ("Jenkins"),⁵ and Jenkins' 2010 amendments known as the Prevent All Cigarette Trafficking Act of 2009 ("PACT").⁶ As amended by PACT, Jenkins generally prohibits the mailing of cigarettes to consumers through the USPS, and, through PACT, requires common carriers to register with the Attorney General and state tobacco tax administrators as well as meet certain shipping and reporting requirements.

The objective of the Act was to include electronic nicotine delivery systems ("ENDS"), which are modern delivery devices for nicotine and nicotine-related flavoring substitutes, in the definition of "cigarette," as defined in Jenkins.⁷ The Act then subjects ENDS to the terms of Jenkins, as amended, to include the "prohibition on mailing of cigarettes." This was a measure designed to ensure children would not have access to nicotine-containing products or delivery devices. Congress tasked USPS with promulgating rules to clarify the applicability of the "prohibition on mailing of cigarettes" to ENDS devices, and the Proposed Rule is what the USPS promulgated in response to the Congressional instruction.

3. The RFA and the Proposed Rule's Impact on Small Businesses

The signatories' overarching concern with the Proposed Rule is the indisputable effect it would have on small businesses. The Proposed Rule does not contain an RFA analysis, which is

³ *Consolidated Appropriations Act, 2021*.

⁴ *Preventing Online Sales of E-Cigarettes to Children Act*, 116th Cong., S.1253, H.R.3942.

⁵ *Jenkins Act*, 15 U.S.C. § 375 et seq.

⁶ *Prevent All Cigarette Trafficking Act of 2009*, Pub. L. 111-154; 18 U.S.C. §1716E.

⁷ 15 U.S.C. § 375 (2)(A).

the best means available to identify if a proposed rule would have a significant economic impact on a substantial number of small entities.

Although the USPS holds the position that they do not need to comply with the RFA, the USPS mailability rules are subject to Chapter 5 of the Administrative Procedure Act (APA), and all agency rules subject to Chapter 5 of the APA are subject to Chapter 6 of the APA.⁸ Under RFA § 603(b), an initial regulatory flexibility analysis (IRFA) must describe the impact of the proposed rule on small entities and contain the following information:

- (1) a description of the reasons why the agency action is being considered;
- (2) a succinct statement of the objectives of, and legal basis for, the proposed rule;
- (3) a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- (4) a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;
- (5) an identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap, or conflict with the proposed rule.

An IRFA would have been highly informative in this rulemaking process. An IRFA would have revealed the role of ENDS in the process of smoking cessation. This consideration is critical as the goal of the underlying bill was to stop the sale of ENDS to children; hence, the Proposed Rule should be drafted in a manner to achieve the goal without compromising the availability of ENDS to individuals that use an ENDS product as a harm reduction measure.

An IRFA would also have exposed the cost to comply with the Proposed Rule – to include finding alternative methods to ship their products, and completing multiple registrations, extensive disclosures of customer identities and locations, and additional tax schemes. These costs could put most, if not all, of the small businesses the Proposed Rule impacts out of business. Furthermore, an IRFA would expose the duplicative, overlapping, and conflicting nature of the Proposed Rule with other federal rules.⁹ This type of finding would ultimately draw into question whether the goal of the underlying bill will even be achieved. With a proper IRFA as the RFA requires, the Proposed Rule's disastrous effects on small businesses would have been fully and appropriately analyzed.

⁸ There are exceptions to the RFA; however, the applicability of any of the exceptions to this matter remains outstanding.

⁹ Please see section 4 (III) of this letter for further explanation.

4. The Proposed Rule Exceeds the Scope of the Underlying Bill

In addition to the significant impact that the Proposed Rule would have on small businesses, the following considerations highlight the flaw in the Proposed Rule's sweep of non-tobacco-related devices and products.

I. The Proposed Rule is a power grab that captures products outside Congress' intent.

The entire premise of the underlying bill is in relation to tobacco and nicotine, including the definition of ENDS.

Yet, as currently written, the Proposed Rule expands the definition of ENDS beyond tobacco and nicotine-containing devices:

Despite the name, an item can qualify as an ENDS without regard to whether it contains or is intended to be used to deliver nicotine; liquids that do not actually contain nicotine can still qualify as ENDS, as can devices, parts, components, and accessories capable of or intended for use with non-nicotine-containing liquids.

If the USPS sweeps in cannabis and hemp-related products and devices into the definition of ENDS, this capture of non-tobacco or nicotine products is without a legislative mandate and would subject products and devices that are already regulated and taxed under other statutory schemes to *another* suite of crippling regulations, unnecessarily.

II. Repeated use of "nicotine" and "tobacco" throughout Jenkins, PACT, and the Act.

The Act's repeated references to nicotine, cigarettes, and tobacco reflect Congress's unmistakable intent to limit the Act's sweep:

- a) The term 'Electronic Nicotine Delivery System' is self-defining and limiting.
- b) Jenkins:¹⁰ a law passed in 1949 designed to assist states in collecting sales and use tax on cigarettes.

(2) Cigarette

(A) In general

The term "cigarette" -

(i) has the meaning given that term in section 2341 of title 18; and

(ii) includes roll-your-own tobacco (as defined in section 5702 of title 26).

¹⁰ *Id.*

- c) The name of the chapter of 18 U.S.C. § 2341, referenced in Jenkins, is 'Trafficking in Contraband Cigarettes and Smokeless Tobacco.'
- d) PACT: a law enacted in 2009 to address the sale of "illegal cigarettes and smokeless tobacco" products. Specifically, "[t]o prevent tobacco smuggling, to ensure the collection of all tobacco taxes, and for other purposes."¹¹
- e) The Act: includes a shipping and packaging requirement to include "nicotine" on the bill of lading and on the outside of the package to read,

CIGARETTES/NICOTINE/SMOKELESS TOBACCO: FEDERAL LAW REQUIRES
THE PAYMENT OF ALL APPLICABLE EXCISE TAXES, AND COMPLIANCE WITH
APPLICABLE LICENSING AND TAX-STAMPING OBLIGATIONS.

In light of this plain statutory text that repeatedly and consistently references tobacco and nicotine, the Proposed Rule's treatment of *non-tobacco* and *non-nicotine*-related products and devices as ENDS contravenes canons of statutory construction and the manifest will of Congress.

While the Act does not establish its own findings and purpose, it amends Jenkins and subjects ENDS to PACT, which are laws Congress expressly limited to tobacco and nicotine products. In passing PACT, Congress made various findings, among them that mail order of cigarettes made it easier for children to obtain tobacco products.¹² Neither PACT's findings nor its purpose even hints that Congress intended PACT to apply to anything other than tobacco and nicotine-related products.

III. Historic use of the term "ENDS" is in relation to tobacco.

Even though ENDS are a relatively new nicotine delivery device, the devices have been subject to regulation by the U.S. Food and Drug Administration ("FDA") under FDA's authority to regulate tobacco products. FDA's use of the term "ENDS" has been strictly in relation to tobacco products or as a substance to be used with a tobacco product. As noted in April 2020 FDA guidance on ENDS,¹³ FDA has defined ENDS as follows:

Electronic nicotine delivery systems (or ENDS) include devices, components, and/or parts that deliver aerosolized e-liquid when inhaled. For example, FDA considers vapes or vape pens, personal vaporizers, e-cigarettes, cigalikes, e-pens, e-hookahs, e-cigars, and e-pipes to be ENDS

¹¹ PACT, Public Law 111-154.

¹² *Jenkins*, 15 U.S.C. § 375, Findings And Purpose (b)(4), (5).

¹³ FDA Guidance for Industry, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)*, April 2020.

E-liquids are a type of ENDS product and generally refer to liquid nicotine and nicotine-containing e-liquids (i.e., liquid nicotine combined with colorings, flavorings, and/or other ingredients). Liquids that do not contain nicotine or other material made or derived from tobacco, but that are intended or reasonably expected to be used with or for the human consumption of a tobacco product, may be components or parts and, therefore, subject to FDA's tobacco control authorities.

...

Tobacco product means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term "tobacco product" does not mean an article that under the FD&C Act is a drug (section 201(g)(1) (21 U.S.C 321(g)(1))), a device (section 201(h)), or a combination product (section 503(g) (21 U.S.C 353(g))). Section 201(rr) of the FD&C Act.

Furthermore, state regulatory agencies use of the term "ENDS," as defined in their ensuing regulations, is again in relation to tobacco. Please see California Department of Tax and Fee Administration, Tax Guide for Cigarettes and Tobacco Products, [Cigarette and Tobacco Products Taxes](#).

'... the definition of "tobacco products" was amended to include:

- Any product containing, made of, or derived from any amount of nicotine that is intended for human consumption and sold with or without a delivery device or system, and
- Electronic cigarettes or any device or delivery system sold in combination with nicotine, and
- Any component, part, or accessory of an electronic cigarette that is used during the operation of the device when sold in combination with nicotine (for example, a battery used in the operation of the device sold with nicotine for a single price).

Tobacco products do not include delivery devices sold without liquid or substance containing nicotine.'

ENDS may be relatively a new term; however, there is an historic use pattern and established precedence among federal and state regulatory bodies to support that ENDS are limited to tobacco and nicotine products.

5. Conclusion

The Proposed Rule is rife with challenges and for the above cited reasons, we welcome your support to ensure that small businesses are not unnecessarily impacted, especially if the underlying goal will not even be achieved. We specifically request that the Proposed Rule in its current iteration be either withdrawn so that an IRFA can be published for public notice and comment, or that the USPS publish a supplemental IRFA for public notice and comment before a final rule is published in the Federal Register.

Thank you for the consideration.

If you are interested in discussing this matter or connecting with any of the below signatories, as identified on the following pages, please ring Tami Wahl, 202.975.9221.

American E-Liquid Manufacturing
Standards Association (AEMSA)
Scott Eley, President

The New York Cannabis Growers &
Processors Association
Allan Gandelman, President

American Vaping Association (AVA)
Greg Conley, President

Minnesota Cannabis Association
Parker Smith, President

Smoke-Free Alternatives Trade
Association (SFATA)
April Meyers, President

South Carolina Vapor Association
(SCVA)
Allison Boughner, President

Tennessee Smoke-Free Association
Dimitris Agrafiotis, Executive Director

U.S. Vaping Association
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Consumer Advocates for Smoke-free
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Planet of the Vapes
Patrick Bissen, CEO
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The Magic Mist
Amit Aggarwal, CEO
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Vape Element, LLC dba BLVK
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Nicholas Denuccio, Co-Founder
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Crown Distributing, LLC
Mansoor Alibhai
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America Juice Co, LLC
Zain Meghani
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Alleviate Labs LLC
Josh Horwitz

Red Star Vapor LLC
James Willett, Operations Manager
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Mighty Vapors
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Kai's Virgin Vapor
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Black Note Inc.
Moe Hamade, Owner & CEO
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Canna Brand Solutions LLC
Daniel F. Allen, CEO
Everett, WA

Howard Enterprises, Inc. dba
Netvapes
Jeremy Howard, President
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Artisan Vapor Franchise LLC
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Apollo Future Technology Inc.
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Big D Vapor, LLC
Adam Winfrey, President
Carrollton, TX

Innevape, LLC
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DFW Vapor Inc.
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