No. 20-850

In the Supreme Court of the United States

BIG TIME VAPES, INCORPORATED, *et al.*

Petitioners,

v.

FOOD & DRUG ADMINISTRATION, *et al.*

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

MOTION FOR LEAVE TO FILE AND BRIEF OF 19 NATIONAL AND STATE ELECTRONIC NICOTINE DELIVERY SYSTEM PRODUCT ADVOCACY ASSOCIATIONS AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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MOTION FOR LEAVE TO FILE[1]

Amici respectfully move for leave to file a brief as *amici curiae* in support of Petitioners' Petition for Certiorari. *Amici* respectfully request that the Court consider the arguments herein and in the enclosed *amici* brief. There are myriad reasons to grant certiorari. This *amici* brief seeks to inform the Court about the facets of the specific industry, Electronic Nicotine Delivery System (ENDS) products, which is the subject of the challenged governmental action addressed in the Petition.

The *amici* further seek to address the underlying merits of the Petitioners' arguments from the perspective of a broad spectrum of interests. *Amici* members are positioned at the manufacturer, distributor and retailer rungs of the ENDS product industry. The *amici* thus offer the Court a view of the ENDS product industry through a different prism than the Petitioners.

I. STATEMENT OF MOVANTS' INTEREST.

The *amici* are 19 non-profit federal or state ENDS product advocacy associations. These associations represent a panoply of interests which touch all facets of the ENDS product industry. The *amici* seek to advance arguments in support of the Petitioners from the perspective of these industry stakeholders.

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[1] Pursuant to Supreme Court Rule 37.6, counsel for *amici curiae* states that no counsel for a party authored this brief in whole or in part or made a monetary contribution toward its preparation.

The *amici* associations share a core common mission: advocating for a reasonably regulated marketplace; providing smoke-free alternative products to adult smokers; promoting a positive image for such products; and educating elected officials, policymakers and the public. This case concerns the manner in which Congress has chosen to regulate ENDS products. The constitutionality of such regulations cuts to the heart of the core mission of the *amici* and their members. It is vital to the core mission of the *amici* that Congress has acted in a constitutional manner when crafting the regulatory regime to which they are subjected.

Amici respectfully request that the Court consider the arguments herein and in the enclosed *amici* brief. There are myriad reasons to grant certiorari in this case. The *amici* focus their arguments on advising the Court of the history of ENDS products. *Amici* then attempt to demonstrate the reasons why the congressional here at issue is inconsistent with the Framers' concept of constitutional equilibrium.

II. STATEMENT REGARDING COMPLIANCE WITH RULE 37.2.

In accordance with SUPREME COURT RULE 37.2, the *amici* advise the Court that they communicated with petitioners' and respondent's counsel on January 4, 2021, more than ten days prior to its due date, to request permission to file their *amici* brief. The petitioners granted such permission with no response received from the respondents. The *amici* further sought permission

from the respondents on January 10, 2021 and January 11, 2021 and the respondents have not responded to such request.

CONCLUSION

The Court should grant *amici curiae* leave to file the enclosed brief in support of Petitioners.

Respectfully submitted,

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

CONSTITUTION AND STATUTES

REGULATIONS

OTHER AUTHORITIES

GLOSSARY

CTP	Center for Tobacco Products
ENDS	Electronic Nicotine Delivery System
FDA	Food and Drug Administration
FDCA	Food, Drug and Cosmetic Act
SORNA	Sexual Offender Registry and Notification Act.
TCA	Family Smoking Prevention and Tobacco Control Act

INTEREST OF THE *AMICI CURIAE*[1]

The *Amici Curiae* are 19 non-profit federal or state Electronic Nicotine Delivery System (ENDS) product advocacy associations.[2] They have a common mission: advocating for a reasonably regulated marketplace; providing smoke-free alternative products to adult smokers; promoting a positive image for such products; and educating elected officials, policymakers and the public.

The constitutionality of Congress delegating authority to an executive agency to deem ENDS products as being subject to an existing statutory rubric is of critical importance to the *Amici* and their members, as the ramifications thereof affect their businesses and advocacy efforts.

SUMMARY OF THE ARGUMENT

Congress enacted the Family Smoking Protection and Tobacco Control Act (TCA), Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified as 21 U.S.C. §§ 387, *et seq*.), to grant the Secretary of the Department of Health and Human Services (Secretary) the authority to regulate "tobacco products." Congress defined such term in TCA § 101(a), 123 Stat at 1783 (codified as 21 U.S.C. § 321(rr)(1). It narrowly applied such term in Section 901(b) to subject only a limited subset of products to immediate regulation, exclusive of

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[1] Pursuant to Supreme Court Rule 37.6, counsel for *amici curiae* states that no counsel for a party authored this brief in whole or in part or made a monetary contribution toward its preparation.

[2] The names of all *Amici* are listed in the Appendix.

ENDS products. Congress granted the Secretary authority in Section 901(b) to "deem" by regulation all other tobacco products as subject to the TCA's requirements. In May 2016, the Food & Drug Administration (FDA), as the Secretary's delegee,[3] invoked this authority with respect to all tobacco products not otherwise itemized in TCA § 901(b), including ENDS products.

First, the *Amici* herein recite the history of the regulation of tobacco products, the brief history of ENDS products, and the federal regulatory efforts. This history frames the context of the issues before the Court.

Second, the *Amici* assert that Congress impermissibly abdicated its legislative authority in violation of Article I, § 1 of the United States Constitution in granting the Secretary deeming authority. The deeming provision in TCA § 901(b) is unconstitutional because Congress did not provide the Secretary sufficient guidance to govern the exercise of the delegated authority. Instead, Congress granted the Secretary complete and unfettered discretion to determine if, when, and to

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[3] The Secretary delegated the TCA's deeming authority to the FDA Commissioner. See FDA Staff Manual Guide 1410.10 (November 17, 2015). The FDA Commissioner then sub-delegated such deeming authority to the agency's Associate Commissioner for Policy. See FDA Staff Manual Guide 1410.21 (July 5, 2012).

Although not at issue in this case, *Amici* ponder whether the Secretary's sub-delegation of deeming authority to the FDA Commissioner, and the Commissioner's sub-delegation of that authority to a non-appointment level civil servant, violates the Constitution's Appointments Clause, U.S. Const, art. II, § 2, cl. 2.

what extent it exercised such delegated deeming authority.

Third, the *Amici* assert the importance of protecting the Framers' vision of constitutional equilibrium between Congress and the executive agencies. Delegations of legislative power to agencies allow Members of Congress to upset this equilibrium while also escaping the political consequences of their actions. The delegation of legislative power evidenced by TCA § 901(b) is contrary to the Framers' vision of a balanced constitutional system.

Finally, the *Amici* assert that congressional delegations of legislative authority improperly inject unelected and unaccountable agency bureaucrats into the political process. *Amici* demonstrate herein the manner in which unelected and unaccountable bureaucrats create broad-reaching policies which affect millions of citizens.

ARGUMENT

I. Background history of tobacco regulation and ENDS products.

Understanding the history of the federal regulation of tobacco products and both the nascent history of ENDS products and the federal attempts to regulate them is necessary to contextualize the unconstitutionality of Congress abdicating its legislative powers to the Secretary.

A. Regulation of tobacco products.

Until the early years of this century, a "tobacco product" was something you either ignited and

inhaled, chewed, or placed between the cheek and gum. For a myriad of reasons, federal regulatory efforts repeatedly failed although the dangers of the products were unquestioned.

The FDA got tired of waiting and issued a regulation in August 1996 which asserted authority over tobacco products. It classified nicotine as a "drug" under the Food, Drug, and Cosmetic Act (FDCA), 52 Stat. 1040, as amended, 21 U.S.C. § 301 *et seq*., and classified cigarettes and smokeless tobacco as "combination products" that deliver nicotine to the body. 61 Fed. Reg. 44,619 – 45,318 (1996).

Several tobacco companies challenged the FDA's regulation. In March 2000, this Court affirmed the lower court's striking down of the regulation in *FDA v. Brown & Williamson Tobacco Corp.,* 529 U.S. 120 (2000). Specifically, this Court held that Congress had not granted the FDA authority either to classify tobacco products as a drug or to independently regulate them. 529 U.S. at 142.

B. History of ENDS products.

In 2003, a Chinese pharmacist, Mr. Hon Lik, developed the first marketable ENDS product using a piezoelectric element to vaporize a liquid nicotine and propylene glycol solution.[4] Mr. Hon sought a safer way to inhale nicotine as a tobacco

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[4] Nguyen, *et al.*, Electronic Cigarettes the Past, Present and Future (The History of E-cigarettes). Available at https://www.dentalcare.com/en-us/profesional-education/ce-courses/ce451/the-history-of-e-cigarettes. (Accessed January 25, 2021).

cessation alternative in response to his father dying from lung cancer.[5]

ENDS products do not contain any part of a tobacco leaf or stalk, and their use does not involve either combustion or the emission of the many toxic substances associated with smoking. ENDS products instead use a liquid solution of propylene glycol, vegetable glycerin, food-grade flavorings, and in some cases, nicotine of varying concentrations. Such nicotine may be derived from tobacco plants, another plant (like tomatoes, potatoes, celery, cauliflower, peppers or eggplant), or made synthetically.

In 2004, Mr. Hon introduced his ENDS product to the Chinese market and its success soon resulted in worldwide marketing and sales.[6] ENDS products first came to the United States in 2007. The initial market participants were non-tobacco companies which solely manufactured and sold ENDS products.[7] Traditional tobacco companies did not enter the market until approximately 2012 after ENDS products had gained a significant amount of market traction.

American entrepreneurialism soon resulted in the establishment of thousands of small domestic manufacturers, distributors and retailers. Many of these entrepreneurs were first-time business owners who drove significant market innovations

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[5] Nguyen, *supra*.

[6] *Id.*

[7] *Id.*

by improving product quality and consistency.[8] By 2018, the United States market had grown to $4.2 billion dollars and is expected to have a compound annual growth rate of 24.1% from 2019 to 2025.[9] This increased use of ENDS products among adult smokers correlates with a statistically significant decrease in the smoking rate.[10]

C. Initial regulation of ENDS products.

In early 2009, the FDA added several ENDS products to Import Alert 66-41 and directed U.S. Customs and Border Protection to reject their entry as unapproved drug delivery devices.[11] These Chinese-manufactured ENDS hardware devices were imported for sale in the United States by domestic distributors and retailers.

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[8] A Billion Lives (Attention Era Media 2016) at 30:13 to 37:20. https://tubitv.com/movies/499729/a-billion-lives.

[9] https://www.grandviewresearch.com/industry-analysis/us-e-cigarette-vapemarket#:~:text=The%20U.S.%20e%2Dcigarette%20and,24.1%25%20from%202019%20to%202025.&text=As%20a%20result%2C%20e%2Dcigarette,alternatives%20to%20conventional%20tobacco%20cigarettes./ (Accessed January 25, 2021).

[10] Shu-Hong Zhu, *et al.*, E-cigarette use and associated changes in population smoking cessation: evidence from US current population surveys. BMJ, 2017; j3262 DOI: 10.1136/bmj.j3262.

[11] Import Alert 66-41, *Detention Without Physical Examination of Unapproved New Drugs Promoted in the U.S.*, March 30, 2009 (Shenzen Kanger Technology Co.) and April 6, 2009 (Desonic Industrial and Loongtotem Science and Technology Co.). Available at https://www.accessdata.fda.gov/cms_ia/importalert_190.html. (Accessed January 25, 2021).

In April 2009, one of those distributors sued to enjoin the FDA, arguing the subject products were "tobacco products" over which the FDA lacked regulatory authority. In December 2010, the D.C. Circuit Court of Appeals affirmed the district court's injunction and upheld its holding that the FDA lacked authority to independently classify ENDS products as a drug or drug/device combination. See *Sottera, Inc. v. FDA*, 627 F.3d 891 (D.C. Cir. 2010).

D. The Tobacco Control Act.

Congress enacted the TCA in June 2009. It added a new Chapter IX to the FDCA and granted the Secretary the authority to regulate "tobacco products". Therein, Congress defined such term in relevant part as being:

> "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory...."

TCA § 101. Congress, however, did subject all tobacco products to the immediate reach of the TCA's various requirements. Instead, it subjected only a limited subset of products (*i.e.* cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco) to the TCA. TCA § 901(b), 123 Stat. at 1781 (codified as 21 U.S.C. § 387a(b)).

Congress specifically left all other tobacco products which satisfied the TCA § 101 definition, including cigars, pipe tobacco, hookah and ENDS products, outside the TCA's immediate scope. Congress was aware ENDS products were on the

market[12] yet chose not to immediately subject them to the TCA's requirements. This was no accident as Congress' forty-nine findings evidence the primary goal of addressing the harms caused by traditional tobacco products and the prior bad conduct of their manufacturers. TCA § 2, 123 Stat. at 1776 – 81 (codified at 21 U.S.C. § 387 note).

Congress, instead, granted the Secretary the plenary authority to subject all other tobacco products to the TCA's requirements through a regulatory deeming. TCA § 901(b). However, Congress did not mandate that the Secretary ever exercise such authority; place a timetable upon any such exercise; or mandate that the Secretary deem all additional tobacco products, any particular class of tobacco products, or even all products within a particular class. Finally, Congress did not mandate that the Secretary make any particular predicate findings when exercising deeming authority.

Congress also retroactively applied the TCA's requirements to both the products itemized in TCA § 901(b) and any deemed tobacco products which were not on the market as of February 15, 2007, a date more than two years prior to the law's enactment. See TCA § 910(a).

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[12] 155 Cong. Rec. No. 50 at H3802 - H3805 (daily ed. March 24, 2009) (statement by Rep. Buyer); 155 Cong. Rec. No. 55 at H4366 - H4367 (daily ed. April 1, 2009) (statement by Rep. Buyer); 155 Cong. Rec. No. 82 at S6009 - S6012 (daily ed. June 3, 2009) (statement by Sen. Burr); 155 Cong. Rec. No. 83 at S6161 - S6164 (daily ed. June 4, 2009) (statement by Sen. Burr); 155 Cong. Rec. No. 85 at S6335 - S6340 (daily ed. June 9, 2009) (statement by Sen Burr).

E. The FDA Deeming Rule.

On May 10, 2016, the FDA published what is colloquially known as its "Deeming Rule".[13] This Rule applied the TCA's requirements to all other tobacco products (including ENDS products) containing, or intended to be used with, nicotine derived from tobacco. 81 Fed. Reg. 28,974 – 29,106. The Deeming Rule took effect on August 8, 2016. *Id*., at 28,974.

The question presented here is whether Congress violated Article I, § 1 of the United States Constitution in delegating the authority to deem additional tobacco products as subject to the TCA, or whether it had to modify TCA § 901(b) to provide for such regulation.

II. TCA Section 901(b) represents an unconstitutional delegation of legislative authority.

The *Amici* do not ask the Court to opine whether ENDS products are good, effective, or safe. Instead, they urge the Court to grant certiorari in this case to opine whether the congressional delegation of legislative authority set forth in TCA § 901(b) violates Article I, Section 1 of the United States Constitution.

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[13] U.S. Food & Drug Admin., *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, 81 Fed. Reg. 28,973 (May 10, 2016) (codified at 21 C.F.R. § 1143.1).

This case requires the Court to tread into the delicate balance of constitutional physics: the friction combating faction which underlies the Constitution's Separation of Powers doctrine.[14] This separation counter-intuitively results in an equilibrium borne of conflict. *Collins v. Mnuchin*, 938 F.3d 553, 562 (5th Cir. 2019). Its perpetuation presumes the three separate branches will constantly remain locked in synchronous orbit by competing interests such that they behave not as willing partners but as wary rivals. *Collins*, at 562.

The Framers presumed the three branches would behave neither centripetally (seizing other branches' powers) nor centrifugally (ceding their own powers). *Collins*, *supra.* at 562. Instead, they Framers presumed the three branches would each jealously defend their assigned powers against encroachment. *Id.* This equilibrium, however, can only be maintained if each branch aggressively and consistently follows such course. Regrettably, an aggressive and consistent adherence to this course has not occurred for most of the past century and the result endangers the integrity of our Republic.

The Framers understood their concept of constitutional equilibrium would be unsustainable over time if Congress could:

> "merely announce vague aspirations and then assign to others the responsibility of adopting legislation to realize its goals."

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[14] THE FEDERALIST NO. 51, p. 319 (C. Rossiter ed. 1961) (Madison).

Gundy v. U.S., 588 U.S. ___, 139 S.Ct. 2116, 2133 (2019) (Gorsuch, J., dissenting). Why? Well, the Framers recognized the government's most dangerous power was the power to enact laws which restrict the people's liberty.[15] They also recognized that allowing Congress to defer its legislative function to another branch through broad delegations would render meaningless the entire concept of constitutional equilibrium.[16]

That recognition brings us to why this case has constitutional significance. This case is about much more than merely analyzing the scope of a statute. The importance lies in the fact that Congress and the judiciary have either forgotten or ignored the Framers' wise lessons by abdicating their respective roles in defending constitutional equilibrium. They have done so by allowing an expansion of executive authority well beyond the Framers' vision. Instead of defending their respective positions with the ferocity and tenacity of Dennis Rodman seeking a rebound, both Congress and the judiciary have played with the timidity of a 98-pound weakling. This case presents an opportunity to re-establish the Framers' vision of constitutional equilibrium which has been missing for nearly a century.

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[15] THE FEDERALIST NO. 48, pp. 306-308 (C. Rossiter ed. 1961) (J. Madison).

[16] Lawson, Delegation and Original Meaning, 88 Va. L.Rev. 327, 340 (2002).

A. The TCA's delegation of deeming authority is inconsistent with Article I, § 1 of the Constitution.

Congress premised the TCA upon the foundational statutory definition in TCA § 101 of the term "tobacco product". It, however, subjected only a limited universe of such products to regulation in TCA § 901(b) and therein delegated authority to the Secretary to expand the scope of such universe. Congress thus declined to legislate in favor of allowing executive legislation.

Article I, § 1 of the United States Constitution vests all legislative powers in Congress. U.S. Const., art., I, § 8, para. 18, in turn, empowers Congress "[t]o make all Laws which shall be necessary and proper for carrying into Execution" its general powers. The constitutional questions presented here are the extent to which Congress can slough off its legislative authority to the executive agencies, and whether Congress' delegation of deeming authority in TCA § 901(b) is consistent with Article I, § 1

This Court held in *Panama Refining Co. v. Ryan*, 293 U.S. 388, 430 (1935) that a congressional delegation is unconstitutional if it declares no policy or standard and articulates no requirement, definition of circumstances and conditions guiding the executive agency. Stated more succinctly, Congress must set out an "intelligible principle" to guide the delegee's exercise of authority. *J.W. Hampton, Jr. & Co. v. U.S.*, 276 U.S. 394, 409 (1928). The TCA § 901(b) delegation, by any metric, fails both standards.

Ryan involved a congressional delegation which authorized the President to prohibit the interstate or foreign transportation of certain petroleum products. This Court held those powers were legislative. 293 U.S. at 415. Reminiscent of the delegation here, the delegation in *Ryan* neither required any predicate executive findings nor placed any meaningful parameters upon its exercise. Instead, Congress gave the President:

> "an unlimited authority to determine the policy and to lay down the prohibition, or not to lay it down, as he may see fit."

293 U.S. at 415. Further, Congress "establishe[d] no criteria to govern the President's course." *Id.* When viewed in juxtaposition, the delegation challenged here is not meaningfully different and is cut from the same cloth as *Ryan*.

Although, this Court has not upheld a non-delegation challenge in the 85 years since *Ryan*, it came excruciatingly close in *Gundy, supra*. At issue therein was the constitutionality of Congress delegating authority to the Attorney General to determine the registration requirements of pre-Act offenders under the Sexual Offender Registration and Notification Act (SORNA), Pub. L. 109-248, 120 Stat. 591 (2006) (codified as 34 U.S.C. § 20911, *et. seq*.). This case is significantly distinguishable from *Gundy*.

A plurality of this Court held the delegation in *Gundy* was constitutional because Congress sufficiently articulated an intention through

SORNA's text to require registration of pre-Act offenders. 139 S.Ct. at 2124. The plurality also found that Congress gave the Attorney General sufficient guidance by requiring him to act "as soon as feasible" in effectuating such registration. *Id*., at 2123, citing *Reynolds v. United States,* 565 U.S. 432, 442-43 (2012). Congress articulated the underlying policy requirements regarding pre-Act offenders and simply delegated the development of the regulatory parameters for registration. The master dictated the policy and left the servant to determine how to implement that policy.

This case differs significantly from *Gundy* because TCA § 901(b) does not evidence a congressional delegation of either: (1) a legislative policy which authorizes the agency to "fill in the details;" (2) the application of a statutory rule based upon executive fact finding; or (3) a non-legislative responsibility. Instead, this case involves the master (Congress) empowering the servant (Secretary) to both make the substance of the policy by determining the products which will be under its regulatory control and then decide how to implement such control.

In this instance, Congress did not give the Secretary any guidance regarding the exercise of the delegated authority save that any deemed products had to be a "tobacco product". The Fifth Circuit felt this was sufficient guidance. It, however, ignored two key points: (1) the FDA's own admitted absence of guidance and another

court's agreement[17] and (2) the TCA's plain text demonstrates that Congress entirely left the timing of any exercise solely to executive fiat without the benefit of guidance. This absence of guidance means the Secretary could have exercised the deeming authority immediately after the TCA became law, at some indeterminate future time, or even never.[18]

Further, the Fifth Circuit ignored the fact that the TCA's language does not articulate any substantive guidance as to which tobacco products the Secretary should deem subject to its regulatory rubric. The plain text of TCA § 901(b) leaves the Secretary free to either decline to deem any new tobacco products, deem all remaining tobacco products, deem only a certain class of tobacco products, or even deem specific product subsets. Thus, the Secretary could have deemed ENDS products but wholly ignored cigars, or could have deemed only those cigars having a suggested retail price less than an arbitrarily fixed dollar amount. Yet, the TCA's text is bereft of any Congressional guidance which governed any of these issues.

The determination of which tobacco products should be subject to the TCA's various regulatory requirements is a quintessential example of a legislative decision. Subjecting ENDS products to

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[17] *Nicopure Labs, LLC v. Food and Drug Admin.*, 266 F. Supp. 3d 360, 393 (D.D.C. 2017), *aff'd*, 944 F.3d 267 (D.C. Cir. 2019).

[18] The FDA did not publish the notice of its proposed exercise of deeming authority for five years after the TCA's enactment and did not publish its final rule for another two years.

the TCA should have occurred through Congress specifically itemizing them in Section 901(b) or through a subsequent amendment to Section 901(b). *Amici* thus ponder whether Congress' delegation of unbridled authority to the Secretary violates the letter and spirit of *Brown & Williamson*, *supra*.

B. Delegations of legislative authority lead to the potential for regulatory mischief.

Finally, the District of Columbia Circuit's recent opinion in *Cigar Assoc. of America v. FDA*, 964 F.3d 56 (D.C. Cir. 2020) highlights the foundational problem resulting from the subject delegation found in TCA § 901(b). Therein, the court found the FDA violated Section 553 of the Administrative Procedures Act[19] when crafting the Deeming Rule's warning label requirements mandated by the TCA for deemed cigars and pipe tobacco.

Congress predicated the triggering of the requirements for these product warning labels upon the FDA making a predicate finding that such warnings "would be appropriate for the protection of the public health." TCA § 906(d)(1), 123 Stat at 1796 (codified as 21 U.S.C. § 387f(d)(1)). In making this finding, Congress required the FDA to consider several key benchmarks, including "the risks and benefits to the population as a whole" and both "the increased or decreased likelihood that existing users of tobacco products will stop using such products"

[19] Pub. L. 89–554, 80 Stat. 383 (codified as 5 U.S.C. § 553).

and "the increased or decreased likelihood that those who do not use tobacco products will start using such products." *Id*. Notwithstanding the improper manner in which the FDA invoked its authority in rolling out the warning label requirements, TCA § 906(d) is a perfect example of what congressional guidance should look like when making a delegation.

Cigar Assoc. evidences that Congress gave the FDA far more guidance in the TCA regarding how to regulate various aspects of deemed tobacco products than it did with respect to the FDA exercising the threshold deeming decision in TCA § 901(b). *Cigar Assoc.* also crystalizes the dangers of legislative delegations to executive agencies: a delegation which is unconstitutional at the outset begets more mischief during the course of regulating.

The circumstances of this case lead *Amici* to subscribe to Justice Alito's sentiment in his concurring opinion in *Gundy* that the time may be at hand to re-examine the jurisprudence which has allowed "agencies to adopt important rules pursuant to extraordinary capricious standards". *Gundy*, *supra*., at 2130 - 31 (Alito, J., concurring). This is the perfect case in which to re-examine such jurisprudence. It is time for the Court to re-establish the Framers' vision of constitutional equilibrium. After all, "if a single executive branch official can write laws restricting the liberty of [one] group of persons, what does that mean for the next?" 139 S.Ct. at. 2131 (Gorsuch, J., dissenting). It is almost as if such statement was written with this case in mind.

It is the people who vested Congress with its legislative power. Thus, the power to delegate such power does not belong to Congress but instead to the people. Congress has regrettably forgotten this fact, and the federal judiciary has largely turned a blind eye to it in the years since *Ryan*.

III. Maintaining a strong separation of powers is integral to preserving the democratic process.

It is an immutable truth that Members of Congress are elected by, and accountable to, the voters. It is also an immutable truth that executive bureaucrats are neither elected by, nor accountable to, those who they regulate. The Framers recognized this fact and sought to avoid an "excess of lawmaking"[20] because enacting laws forces legislators to bear the ultimate political accountability to their constituents and that delegations of legislative authority allow them to avoid these political consequences.

Delegations like that at issue here allow Members of Congress to essentially be chameleons by feigning support for a particular executive action to one group of constituents while feigning opposition to another. Legislators can point to a faceless bureaucracy, shrug their shoulders, and have plausible deniability for the consequences of the executive actions resulting from their abdication of authority.

The Framers foresaw this problem and responded by crafting a system which made it

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[20] THE FEDERALIST NO. 62, p. 378 (C. Rossiter ed. 1961) (J. Madison); THE FEDERALIST NO. 73, pp. 441-42 (C. Rossiter ed. 1961) (Hamilton).

difficult to exercise legislative power. The Framers designed this process so that only those with ultimate political accountability could make legislative policy decisions after engaging in sober deliberations. Their process may seem inefficient at times, and even give the appearance of fostering complete gridlock. Yet, the Framers calculated this process would promote vigorous debate, and ultimately result in compromise. This is the reason why legislators introduce many bills each year but only a select few of those bills are ever enacted. Those enacted bills are often radically different than originally proposed.

Members of Congress making delegations of legislative authority to executive bureaucrats allow them to side-step the Framers' safeguards because exercises of such authority occur outside the crucible of the political process of congressional lawmaking. The Framers did not intend for faceless agency bureaucrats to make important legislative policy decisions. This is so because unaccountable executive agency policymakers are outside the democratic process but face the political pressures of those who do. Honoring the Framers' intention is vitally important to maintain the integrity of their constitutional vision. This vision stands in stark contrast to the realities of the modern administrative state.

The Separation of Powers is supposed to operate by the analogy that Congress builds a skeleton in passing legislation which contains policy mandates and then delegates to the agencies the responsibility to nourish the body by interpreting and enforcing such mandates. Since

Ryan, Congress has increasingly made use of delegations of its legislative authority which have allowed the body to become morbidly obese due to agencies adding an abundant measure of fat. This occurred because Congress has increasingly deferred to executive agencies the task of setting the menu. The TCA is a prime example.

IV. Delegations of legislative authority allow unaccountable bureaucrats to make decisions which the Framers intended to be achieved through the political process.

Congress' willingness to delegate legislative authority is rooted in two realities: our world is more complicated than at the time of *Ryan,* and the process of legislating and regulating has correspondingly become more specialized and complex. This Court acknowledged in *Mistretta v. U.S.*, 488 U.S. 361, 377 (1989) that Congress defers legislative decisions to administrative agencies because its Members, as generalists, lack specific competence on the unlimited array of subjects which come before them.

It has thus become the norm that Congress defers legislative policymaking to agency bureaucrats. Congress countenances this norm because the agency bureaucrats are often armed with more technical expertise necessary to provide the specific subject matter competence not possessed by its Members and their staffs. However, Congress' desire to achieve technical competence does not outweigh the importance and necessity of maintaining the Framers' overarching concept of constitutional equilibrium.

Further, it is not possible to insulate the unelected and unaccountable agency bureaucrats from the factional and political influences which have little to do with their technical expertise.[21] Since significant federal policymaking now occurs in the executive agencies, the K Street lobbyists must seek influence over both the broad congressional legislative process and the granular agency regulatory process.[22] This means that unelected and unaccountable agency bureaucrats are thus thrust into an ever increasingly political vortex. The result has been a complete politicization of the administrative policymaking process.

This politicization comes as no surprise to the *Amici*. They have experienced it first-hand on many occasions. Such politicization is evidenced by the fact the interests involved in crafting federal tobacco regulatory policies have been universally aligned with those groups who stand opposed to ENDS products.

For instance, Mitch Zeller, the Director of the FDA's Center for Tobacco Products (CTP), is a former pharmaceutical industry lobbyist for

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[21] Epstein, Why the Modern Administrative State is Inconsistent with the Rule of Law, 3 N.Y.U. J. of Law & Liberty 491, 492 (2008).

[22] For example, the American Cancer Society spent $4,450,000 in 2019 lobbying expenditures with respect to the FDA. See https://www.opensecrets.org/federal-lobbying/clients/summary?cycle=2019&id=D000031468. (Accessed January 25, 2021).

tobacco-reduction products;[23] was instrumental in crafting the FDA 1996 regulations[24] struck down in *Brown & Williamson*; helped found the anti-tobacco organization now known as the *Truth Initiative*;[25] and became the CTP's Director after the TCA's passage.[26] In this capacity, Mr. Zeller was instrumental in both crafting the Deeming Rule and developing the agency's tobacco product regulatory policies arising under the TCA.[27]

Similarly, Matthew Myers, the President of the anti-tobacco organization known as the Campaign for Tobacco Free Kids (CFTFK) participated in drafting the TCA;[28] has universally pressed the opposition to ENDS products from their inception;[29] and has often walked arm-in-

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[23] A Billion Lives, *supra*., at 1:07:47 to 1:08:05.

[24] https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/mitch-zeller. (Accessed January 25, 2021).

[25] https://www.cspdailynews.com/csp-magazine/zellers-balancing-act. (Accessed January 25, 2021).

[26] https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/mitch-zeller. (Accessed January 25, 2021).

[27] https://www.cspdailynews.com/tobacco-regulation-report-2018/mitch-zeller-regulatory-achievements. (Accessed January 25, 2021).

[28] https://www.tobaccofreekids.org/about/our-team/matt-myers. (Accessed January 25, 2021).

[29] See *e.g.* https://docs.house.gov/meetings/GO/GO05/20190725/109846/HHRG-116-GO05-Wstate MyersM20190725.pdf. *See also* https://docs.house.gov/meetings/IF/

arm with FDA policymakers even though ENDS products have shown great potential to reduce smoking.

The World Health Organization has estimated that at least a billion people will die worldwide this century from smoking-related illnesses.[30] The Court may thus ponder why any organization committed to promoting a reduction of smoking would oppose products which help achieve such result. The reason for the opposition in this instance has little to do with the safety or efficacy of ENDS products, but instead because of their substantial potential to compromise important financial positions.

The FDA faces a compromised financial position because of ENDS product success. The FDA derives approximately forty-five percent of its annual budget from industry user fees.[31] Tobacco companies paid user fees totaling $667,000,000 in 2019.[32] User fees are based upon federal excise taxes paid by tobacco companies[33] which are tied to the total volume of product sales and facility

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IF14/20191016/110091/HHRG-116-IF14-Wstate-MyersM-20191016.pdf. (Accessed January 25, 2021).

[30] https://www.reuters.com/article/us-smoking-idUSBKK25206020070702. (Accessed January 25, 2021).

[31] https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance. (Accessed January 25, 2021).

[32] *Id*.

[33] TCA § 919(b), 123 Stat. at 1826 (codified as 21 U.S.C. § 387s).

fees.[34] ENDS product industry stakeholders, however, are not required to pay these FDA user fees. Thus, a decline in the sale of traditional tobacco products caused by an increased use of ENDS products correspondingly reduces the amount of revenues coming into the FDA's coffers.

Anti-tobacco organizations like CFTFK, American Cancer Society, American Lung Association and American Heart Association also face a similar compromise of financial interests. These organizations have long trumpeted the importance of reducing smoking.[35] Statistics show these organizations have gotten their wish as both adult and teen smoking rates presently stand at all-time lows[36] and these rates have declined precipitously since 2005 (from 20.9% to 13.7%) after many years of stagnation.[37]

These organizations should be ecstatic with these results, right? Well, not when one considers that these organizations essentially lose by winning because they draw a substantial measure of funding from grants and contributions. Thus, they have a significant financial stake in ensuring

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[34] See 26 U.S.C. §§ 5701, 5731.

[35] See *e.g.* https://www.cancer.org/healthy/stay-away-from-tobacco/e-cigarette-position-statement.html.(Accessed January 25, 2021).

[36] https://www.cdc.gov/media/releases/2019/p1114-smoking-low.html. (Accessed January 25, 2021).

[37] https://www.cdc.gov/tobacco/data_statistics/fact-sheets/adult_data/cig_smoking/index.htm. (Accessed January 25, 2021).

that combustible tobacco use falls to a level which shows progress to the public and its patrons but not below a level which ultimately nears the completion of their mission.[38]

It just so happens that the decline in the adult use of combustible tobacco over the past decade has largely coincided with an almost inverse increase in adult use of ENDS products. *Amici* hypothesize that a reduction in the adult smoking rate in the United States below the ten percent threshold will concomitantly comprise the grant and fundraising revenues of the anti-tobacco organizations. The proven success of ENDS products as a smoking-cessation tool in the adult population has thus resulted in a rapidly approaching tipping point which terrifies these anti-tobacco organizations.

The approach of this tipping point has led to a unique alliance between policymakers, tobacco companies, pharmaceutical companies and anti-tobacco advocates. This alliance is akin to the Prohibition-era alliance between the Baptists and the Bootleggers.[39] The result: federal executive agencies engaging in dubious funding of anti-tobacco organization lobbying efforts to ban ENDS products at the federal, state and local levels.[40]

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[38] A Billion Lives, *supra*., at 1:03:15 to 1:03:57.

[39] Alder, *et al.*, Baptists, Bootleggers & Electronic Cigarettes, 33 Yale J. on Regulation 313 (2016). *See also* A Billion Lives, *supra*., at 46:16 to 1:07:02.

[40] A Billion Lives, *supra*., at 1:17:43 to 1:19:25

It has also led to anti-tobacco advocates teaming with organizations like Bloomberg Philanthropies to fund anti-ENDS product lobbying efforts before federal agencies and state and local health boards.[41] Such organization laid out $160 million dollars in late 2019 to promote a broad national anti-ENDS product initiative.[42] Such initiative sought to ban the sale of flavored ENDS products under the guise of protecting children.[43] It was, however, little more than a smoke screen to protect the investment of Michael Bloomberg in Hava Health which manufactures a competing flavored ENDS product called *Hale*.[44]

The agency policymakers in this instance lack political accountability to those affected by their policies. The union of policymakers, anti-tobacco organizations and industry competitors to collectively place a thumb on the regulatory scale is, and should be, concerning.

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[41] You Don't Know Nicotine (Third Line Films 2020) at 1:13:52.

[42] https://www.bloomberg.org/press/releases/bloomberg-philanthropies-launches-new-160-million-program-end-youth-e-cigarette-epidemic/ (Accessed January 25, 2021).

[43] The *Amici* in no way discount the seriousness of youth access to, and use of, ENDS products. *Amici* and their members strongly oppose such youth access and use. It is something which the *Amici* and their members have aggressively fought to stem in their business and advocacy efforts. To this end, *Amici* and their members have focused efforts to guide policymakers in combatting youth access and use.

[44] https://www.ecigclick.co.uk/bloomberg-flavour-ban-plan-a-conflict-of-interest/ (Accessed January 25, 2021).

This lack of accountability has definite Main Street consequences. The decisions of bureaucrats resulting from legislative delegations allow them to pick market winners and losers. These choices ultimately affect the lives of millions of Americans. The concept of the federal government picking winners and losers is nothing new. Such choices, however, should only be made by those elected Members of Congress who ultimately bear political accountability to the losers.

The Deeming Rule is illustrative of this point. The FDA's Regulatory Impact Analysis promulgated with the Deeming Rule estimated that the Rule would cause 54% of ENDS delivery system hardware products to exit the market and 50% to 87.5% of e-liquid products to exit the market.[45] These losing stakeholders have a right to know that those policymakers who made the ultimate decision to cast them as losers bear political accountability to them. Article I, § I of the Constitution commands no less.

The delegation evidenced by the deeming provision of TCA § 901(b) is just a microcosm of a larger problem emanating from congressional delegations of authority. The Court could substitute any industry or product in place of ENDS products and any other federal agency in place of the FDA and it would encounter the same problem. The impact of an ultimate ruling by this Court will conceivably touch every delegation of

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[45] FDA Deeming Rule, Final Regulatory Impact Analysis Final Regulatory Flexibility Analysis Unfunded Mandates Reform Act Analysis, AR 23,912, 23,990 (May 10, 2016).

legislative power by Congress to every executive agency.

The combination of the politicization of policy making within the FDA and the lack of political accountability as evidenced by the Deeming Rule, upsets the Framers' creation of a foundational constitutional equilibrium between the three branches of federal government. This case presents a prime opportunity for the Court to return some measure of the Framers' vision of such equilibrium.

CONCLUSION

For the above reasons, the *Amici* respectfully ask this Court to grant certiorari to the U.S. Court of Appeals for the Fifth Circuit in order to determine whether TCA § 901(b) violates Article I, § 1 of the United States Constitution.

Respectfully submitted,

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APPENDIX

National ENDS Advocacy Organization

United Vapers Alliance

Regional and State ENDS Advocacy Organizations

Arizona Smoke Free Business Alliance
Florida Smoke Free Association, Inc.
Georgia Smoke Free Association, Inc.
Kansas Smoke Free Association
Kentucky Vaping Retailers Association, Inc., d/b/a Kentucky Smoke Free Association
Indiana Smoke Free Association, Inc.
Iowa Vape Association, Inc.
Michigan Vape Shop Owners, Inc.
Minnesota Smoke Free Alliance
Missouri Smoke Free, Inc.
Montana Smoke Free Association, Inc.
New York State Vapor Association, Inc.
North Carolina Vaping Council, Inc.
Ohio Vapor Trade Association, Inc.
Rocky Mountain Smoke Free Association, Inc.
Rhode Island Chapter of Smoke Free Alternatives Trade Association
South Carolina Vapor Association
Vapor Retailers and Manufacturers of Delaware