IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CIGAR ASSOCIATION OF AMERICA, *et al.*, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	Civil Action No. 16-1460 (APM)

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Pursuant to Federal Rule of Civil Procedure 56 and Local Rule 7(h), plaintiffs Cigar Association of America (CAA), Cigar Rights of America (CRA), and International Premium Cigar and Pipe Retailers Association (IPCPR) (collectively, "Plaintiffs") move for summary judgment against defendants United States Food and Drug Administration, United States Department of Health and Human Services, Thomas E. Price, MD, and Stephen Ostroff, MD (collectively, "FDA") on all of their claims.[1]

On May 10, 2016, the FDA promulgated a rule "deeming" all cigars and pipe tobacco subject to the Family Smoking Prevention and Tobacco Control Act ("TCA"), and imposed an onerous regulatory scheme on these newly deemed products. *See* Final Rule Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28,974 (the "Deeming Rule"). It promulgated a separate rule that same day that imposed user fees on some,

[1] Drs. Price and Ostroff are the current Secretary of Health and Human Services and Acting Commissioner of the United States Food and Drug Administration, respectively. In that the former Secretary and Commissioner were sued in their official capacities, the successor of each is automatically substituted into complaints in which each is a defendant. *See* Fed. R. Civ. P. 25(d).

but not all, newly deemed products. *See* Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Cigars and Pipe Tobacco, 81 Fed. Reg. 28,707 (the "User Fee Rule").

The Deeming Rule and User Fee Rule must be set aside. For the reasons stated below and further addressed in the accompanying Memorandum of Law, these rules are arbitrary, capricious, an abuse of discretion, and not in accordance with law; are contrary to constitutional right, power, privilege, or immunity; and exceed statutory jurisdiction, authority, or limitations, or are short of statutory right. 5 U.S.C. § 706(2)(A)-(C). In support of this argument, Plaintiffs state:

1. In the Deeming Rule, the FDA incorrectly concluded that it had no choice but to impose all aspects of the FDA's premarket review and testing scheme on cigars and pipe tobacco. The most prominent example of the agency's error was to apply a 2007 predicate date to exempt or adjust the process for products to go through premarket review for cigars and pipe tobacco first regulated in 2016. The result is a premarket review process that is far more burdensome for cigars and pipe tobacco than for cigarettes and smokeless tobacco—the products of most immediate concern to Congress. The agency's action is arbitrary, capricious, an abuse of discretion, and not in accordance with law; and in excess of statutory jurisdiction, authority, or limitations or short of statutory right. The Deeming Rule must be vacated to allow the FDA to exercise its full statutory discretion and consider whether and how to efficiently and appropriately regulate cigars and pipe tobacco.

2. The FDA also imposed the Deeming Rule on cigars and pipe tobacco without clarifying the premarket substantial equivalence pathway available to cigars and pipe tobacco. The FDA had statutory authority to do so, and appropriate guidance could have ameliorated

some of the burden of the premarket review scheme. The agency's action is arbitrary, capricious, an abuse of discretion, and not in accordance with law; and in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.

3. Cigarettes and smokeless tobacco products were permitted to remain on the market while product applications were pending with the FDA. The FDA initially considered, but ultimately rejected, a similar enforcement forbearance policy for cigar and pipe tobacco products. The agency's discriminatory treatment of cigars and pipe tobacco is arbitrary, capricious, an abuse of discretion, and not in accordance with law; and in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.

4. The FDA itself proposed a reasonable alternative to regulation of the entire cigar industry. The agency's so-called "Option 2" would have exempted premium cigars, which are expensive and minors almost never use, and the product variation of which results from factors such as weather and location, from the burdensome and unjustified requirements of premarket testing and review. The agency, however, failed to adequately consider this reasonable alternative. This was arbitrary, capricious, an abuse of discretion, and not in accordance with law; and in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.

5. The FDA had the authority to require "user fees" from all newly deemed products. It eschewed this authority, however, and refused to impose user fees on e-cigarettes in the User Fee Rule. Its selective imposition of user fees is arbitrary, capricious, an abuse of discretion, and not in accordance with law; contrary to constitutional right, power, privilege or immunity; and in excess of statutory jurisdiction, authority, or limitations, or short of statutory right. The User Fee Rule violates the Equal Protection component of the Fifth Amendment's Due Process Clause.

6. The FDA's cost-benefit analysis underlying the Deeming Rule was based on speculative benefits that the agency made no effort to quantify or justify through imposition of the premarket review regime. It relied on inaccurate data, improperly assumed that costs and benefits could be based on the agency's experience regulating other tobacco products, and failed to give due regard to the distinctly harsh impact of the regulation on the premium cigar and pipe tobacco markets. As a result, the Deeming Rule is arbitrary, capricious, an abuse of discretion, and not in accordance with law; in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; and violates the Regulatory Flexibility Act.

7. The FDA's warning label requirements, which mandate labels covering 30% of each of the two principal panels of cigar and pipe tobacco products, violate the First Amendment. They crowd out manufacturers' own trade dress and communications with customers, and are an unconstitutional restriction on this commercial speech. They also fail review as compelled speech. The warning label requirements further violate the Act and the APA, obviating the need to reach the First Amendment issues. The agency failed to make the findings required by the TCA to justify imposition of the warning labels, and imposed the new warning label requirements without accounting for the efficacy of existing warning label regimes. The warning label requirements are arbitrary, capricious, an abuse of discretion, and not in accordance with law; contrary to constitutional right, power, privilege, or immunity; and in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.

8. The FDA incorrectly interprets the TCA to treat retailers who blend pipe tobacco as "tobacco product manufacturers" subject to the full scope of regulatory burdens under the Rule. The agency's application of "manufacturer" obligations on small business retailers who are performing an act on finished (and fully regulated) tobacco products that consumers could do

on their own is arbitrary, capricious, and not in accordance with law; and in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.

9. The FDA also improperly treats pipes as "components" of a tobacco product and therefore subject to regulation. Its interpretation runs contrary to the statute and imposes wholly unreasonable obligations on pipe manufacturers, including many individual and small business artisans. The agency's imposition of regulatory authority over pipes is arbitrary, capricious, and not in accordance with law; and in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.

For these reasons and those set out in the accompanying Memorandum of Law, Plaintiffs request that the Court grant their motion for summary judgment on all claims and: (1) vacate and set aside the Deeming Rule; (2) vacate and set aside the User Fee Rule; (3) declare that the User Fee Rule violates the Fifth Amendment; (4) declare that the Deeming Rule warning label requirements violate the First Amendment; (5) enter a permanent injunction restraining the FDA from implementing or enforcing the Deeming Rule or User Fee Rule; (6) award Plaintiffs their litigation costs and attorneys' fees; and (7) order such other and further relief as the Court deems just and proper.

For the foregoing reasons and those stated in the accompanying Memorandum of Law, Plaintiffs' motion for summary judgment should be granted.

A proposed order is filed herewith. Pursuant to Local Rule 7(f), Plaintiffs respectfully request oral argument on this motion.

Dated: February 13, 2017

Respectfully submitted,

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MEMORANDUM IN SUPPORT OF
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Dated: February 13, 2017

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INTRODUCTION

In its Final Rule, the FDA "deems" cigars and pipe tobacco subject to a costly regulatory scheme that Congress immediately applied to cigarettes and smokeless tobacco in 2009. *See generally* Final Rule Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28,974 (May 10, 2016) ("Deeming Rule"). The Deeming Rule threatens to destroy cigar and pipe tobacco industries, including manufacturers and retailers, shuttering family-owned small businesses across the Nation. To bring about this result, the FDA relied on a 77-page statute—the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111–31, 123 Stat. 1776 (2009) (hereinafter the "TCA" or the "Act")—that mentions cigars and pipe tobacco only *twice*. The agency's rule misinterprets the Act, disregards comments demonstrating impending agency error, rolls over contrary evidence in the record, casts aside less costly alternatives advancing the public health, and tramples on manufacturers' First Amendment rights. It is a case study in arbitrary and capricious rulemaking.

First, the Deeming Rule mechanically imposes the entire weight of the FDA's premarket review and testing scheme on cigars and pipe tobacco without making any modifications for either the passage of time or the unique characteristics of these products. Because Congress believed that cigarettes and smokeless tobacco presented the most immediate public health concerns, it mandated immediate regulation of them to root out—product-by-product—allegations that cigarette companies had manipulated nicotine and other ingredients to make cigarettes more addictive or attractive to youth. By contrast, Congress took no view on whether or how cigars and pipe tobacco—products with a different history and presenting different public health issues—should be regulated.

The Deeming Rule results in cigars and pipe tobacco being regulated more harshly than cigarettes, a paradox that a Congress agnostic about any regulation of cigars and pipe tobacco

never intended. This is, in part, due to the passage of time. Congress exempted cigarettes and smokeless tobacco products that were on the marketplace as of February 15, 2007—and their "substantial equivalents"—from the arduous premarket review process. That meant only those cigarette products created within the two years before the Act had to navigate premarket review, and even those new products could use a less burdensome path if "substantially equivalent" to a pre-2007 product. The FDA, however, refused to update the 2007 predicate date for its 2016 regulation of cigars and pipe tobacco. If the Rule were to stand, cigars and pipe tobacco products created within the *last decade* would have to run the gauntlet of premarket review. And the less burdensome substantial equivalence pathway that was available to cigarettes and smokeless tobacco would be effectively denied to cigar and pipe tobacco manufacturers who would have the nearly impossible task of comparing current products with those marketed a decade ago.

Compounding this crushing burden on cigars and pipe tobacco is their vast variety: Each cigar manufacturer has many times more unique products than cigarette companies. While the FDA's hunt—product-by-product—for ingredient manipulation might have been justified given the allegations in the cigarette industry, there is no comparable history with cigars and pipe tobacco. Cigar and pipe tobacco businesses will close under the weight of regulation, wholly inconsistent with Congress's expressed intent to not ban segments of the tobacco industry and drive companies out of business.

The FDA said its hands were tied by the statute: It could not adjust the predicate date or anything else for the timing of its regulation or the different industries being regulated. The FDA got the scope of its statutory discretion wrong, and the remedy is to vacate the Rule for the agency to exercise its correctly defined authority. The Act plainly leaves *whether and how* to

regulate cigars and pipe tobacco to the FDA. The FDA was supposed to reach tobacco products other than cigarettes and smokeless tobacco "by regulation" and use its "flexible" authority to craft a scheme for products Congress was not sure should be regulated at all. *See* 21 U.S.C. §§ 387 note (Purpose), 387a(b) (2012). Congress did not set a regulatory cliff, where the agency's only option was to throw cigars and pipe tobacco over the edge or not.

Second, the FDA compounded its legal error by declining to exercise the authority it knew it had: The Final Rule could have, for example, allowed cigars and pipe tobacco to go through the substantial equivalence process in broad groups, greatly easing the burden of comparing them to a 2007 product. The agency arbitrarily rejected an alternative that would have saved the industry hundreds of millions of dollars, while still protecting the public health.

Third, the FDA denied cigars and pipe tobacco the stay of enforcement provided to cigarettes and smokeless tobacco while substantial equivalence applications were pending. For cigar and pipe tobacco products, if the FDA has not completed its review and declared them substantially equivalent to a 2007 product within at most 30 months after the effective date of the Deeming Rule, they must be pulled from the market. The FDA will never meet this deadline; similar cigarette applications have been pending for more than a half-decade. This is yet another example of the agency treating cigars and pipe tobacco more harshly than the cigarettes and smokeless tobacco for which Congress demanded immediate regulation.

Fourth, the agency rejected a less burdensome regulatory option it proposed in the first instance, exempting "premium cigars" from the Rule. Premium cigars are expensive and unused by minors. A recent FDA-funded study found *no* statistically significant youth use of premium cigars on any frequent basis. Tragically, the massive costs of the Rule on premium cigar manufacturers are inversely proportional to underaged premium cigar use: Premium cigars have

vast variety, turning on location, weather, and other factors. They are specialty products, hand-crafted by family-owned businesses through centuries-old artisan practices. There is no evidence in the record—none—that variations in premium cigars present any public health threat. The massive cost of running each premium cigar product through premarket review, without even identifying what the agency expects to detect, is the height of arbitrary and capricious rulemaking.

Fifth, the FDA simultaneously published a rule establishing "user fees" meant to fund the regulation of the cigars, pipe tobacco, and e-cigarettes the Deeming Rule reaches. *See generally* Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Cigars and Pipe Tobacco, 81 Fed. Reg. 28,707 (May 10, 2016) ("User Fee Rule"). But the FDA imposed no fees on e-cigarettes, leaving other tobacco product manufacturers to pay for the massive task of e-cigarette regulation. This is not a "user fee" at all, but a tax meant to fund the regulation of industries. The User Fee Rule violates the Act and any conception of fairness.

Sixth, the FDA cavalierly fumbled its cost–benefit analysis of the Deeming Rule. The FDA's error was hardly for lack of warning: The D.C. Circuit has invalidated rule after rule for guesswork in evaluating costs and benefits and declining to compile available data. *See, e.g.*, *Bus. Roundtable v. SEC*, 647 F.3d 1144, 1148–49 (D.C. Cir. 2011). Here, the FDA conceded that its Rule would shutter hundreds of small businesses in the cigar and pipe tobacco industries unable to absorb the costs of compliance, but claimed offsetting but unquantifiable public health benefits. On numerous occasions, the agency acknowledged it had not done necessary research to show health benefits but promised to do so in the future after the industry had borne all of the costs. Its analysis was arbitrary and capricious.

Seventh, the FDA imposed a new health warning scheme on cigars and pipe tobacco in violation of the First Amendment, the Act, and the Administrative Procedure Act (the "APA"). Most of the cigar industry currently puts health warnings on their packages and in advertising, pursuant to a Federal Trade Commission consent decree. The FDA did not materially change the content of the warnings, but it made them dramatically larger, to cover 30% of two panels of a cigar box and 20% of any advertisement, thereby crowding out and restricting manufacturers' ability to communicate with consumers. The agency never explained why the FTC warnings were inadequate and never claimed the larger warnings would reduce cigar use. But that is precisely the type of finding the Constitution requires—specifically, that a restriction of speech or a compelled disclosure *would* decrease *underaged* tobacco use. Congress knew this and responsibly demanded these types of agency findings before requiring new health warnings. *See* FD&C Act § 906(d)(1)-(2), 21 U.S.C. § 387f(d)(1)-(2).

Eighth, the agency required local pipe tobacco retailers, who blend FDA-approved finished pipe tobacco products at the request of their customers, to register with the FDA as "manufacturers." The FDA did so as an afterthought to regulating retailers who mix e-cigarette liquids, which of course might create some dangerous chemical reaction. Pipe tobacco has been blended by retailers for centuries, and there is no evidence in the record that two pipe tobacco products together are any more concerning than each apart. The FDA manipulates the Act's text to achieve this result, and the APA does not permit lumping these two different industries together, without explanation.

Ninth, the FDA threw a grandfather's traditional wooden pipe into the premarket review scheme, by concluding that "pipes" are "components" of a tobacco product. But the term "components" clearly refers to ingredients of and additives to tobacco products, not reusable

vessels (made without any tobacco constituents) for holding tobacco while it is being smoked. The small businesses manufacturing pipes today will never be able to shoulder the expense of FDA regulation, including premarket review. Here, the agency is destroying an entire industry, without ever bothering to identify how pipe variations are affecting the public health. Neither the Act nor the APA permits the agency's casual approach.

The Deeming Rule and User Fee Rule are invalid and must be vacated as arbitrary, capricious, and contrary to the Act and the Constitution.

BACKGROUND

I. PLAINTIFF ORGANIZATIONS

Plaintiff Cigar Association of America, Inc. ("CAA") is a non-profit trade association representing cigar manufacturers, importers, distributors, and major suppliers to the industry. CAA has members from all sectors of the industry, including manufacturers of handmade premium cigars and producers of machine-made small cigars.

Plaintiff International Premium Cigar and Pipe Retailers Association ("IPCPR") is a non-profit trade association representing premium cigar and tobacco retail shops, including many family-owned and operated small businesses, located throughout the United States and abroad. IPCPR is a "small organization" within the meaning of the Regulatory Flexibility Act ("RFA"), and IPCPR's members are "small businesses" for purposes of the RFA. 5 U.S.C. § 601(3), (4).

Plaintiff Cigar Rights of America ("CRA") is a non-profit association representing premium cigar manufacturers and consumers in the United States. CRA members include diverse artisan producers of handmade premium cigars and other members from across the supply chain—distributors, growers, mail-order houses, and logistics and associated supporting enterprises, among others—as well as consumers of premium cigars.

Plaintiffs CAA, IPCPR, and CRA have a vital interest in ensuring that any regulation of cigars, pipes, and pipe tobacco is consistent with statutory and constitutional requirements. Plaintiffs have standing to bring this suit because (a) their members would otherwise have standing to sue in their own right; (b) the interests they seek to protect are germane to the organizations' purposes; and (c) neither the claims asserted nor the relief requested requires the participation of individual members in the lawsuit. *See, e.g.*, *United Food & Commercial Workers Union Local 751 v. Brown Grp., Inc.*, 517 U.S. 544, 552–53 (1996).

II. CONGRESS ENACTS THE TOBACCO CONTROL ACT TO COMBAT PRODUCT MANIPULATION AND MARKETING TO YOUTH

In 1996, the FDA promulgated a regulation seeking to reduce or eliminate addiction to cigarettes and smokeless tobacco by "preventing children and adolescents from starting to use tobacco." Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,398 (Aug. 28, 1996); *see also FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125 (2000). A group of tobacco manufacturers, retailers, and advertisers filed suit challenging the FDA's jurisdiction, and the Supreme Court held that the FDA lacked authority to regulate these products under the Food, Drug, and Cosmetic Act ("FD&C Act"). *Brown & Williamson*, 529 U.S. at 161.

Thereafter, Congress passed the Family Smoking Prevention and Tobacco Control Act, which amended the FD&C Act to impose restrictions on cigarettes, smokeless tobacco, and "roll-your-own" tobacco. The Act also authorized the FDA to regulate other tobacco products by promulgating a regulation to "deem" such products subject to the requirements of the TCA. *See generally* Pub. L. No. 111–31, 123 Stat. 1776, 1776–1852 (2009) (codified at 21 U.S.C. §§ 387–387u). The TCA's explicit purposes were, among other things:

> (2) to ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco; [and] . . .
>
> (7) to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers[.]

TCA § 3, 123 Stat. at 1781–82.[1]

These statements of purpose followed a lengthy recitation of legislative findings accompanying the statute primarily focused on cigarettes and underage tobacco use. *See id.* § 2, 123 Stat. at 1776–81.[2] The findings never mention cigars or pipe tobacco. In the Act, Congress incorporated the substance of the 1996 FDA regulations that were at issue in *Brown & Williamson*, stating they "will directly and materially advance the Federal Government's substantial interest in reducing the number of children and adolescents who use cigarettes and smokeless tobacco and in preventing the life-threatening health consequences associated with tobacco use." *See id.* § 2(31), 123 Stat. at 1779. The Act also highlighted judicial findings regarding alleged abuses by the cigarette industry, including that: "the major United States cigarette companies continue to target and market to youth"; "the major United States cigarette companies dramatically increased their advertising and promotional spending in ways that encourage youth to start smoking subsequent to the signing of the Master Settlement Agreement in 1998"; and "the major United States cigarette companies have designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain

[1] Citations to the TCA herein are limited to sections 1–6 of the Act (TCA §§ 1–6), which were not codified in the United States Code but can be found in the Statutes at Large (123 Stat. at 1776–83). Other citations are to the applicable sections of the FD&C Act (FD&C Act §§ 901–920) and to the sections of the United States Code where those provisions are codified (21 U.S.C. §§ 387–387u).

[2] Nearly half of the legislative findings (21 out of 49) address youth and adolescents, in terms of either use or marketing of tobacco. *See* TCA § 2, 123 Stat. at 1776–81. Many others (e.g., findings 16, 38, 39, and 49) are directed specifically to the cigarette industry. *See id.*, 123 Stat. at 1778, 1780, 1781.

addiction while also concealing much of their nicotine-related research." *See id.* § 2(47)–(49), 123 Stat. at 1781.

Enactment of the Act was grounded in significant concerns regarding the cigarette industry's history of product manipulation and youth marketing schemes and other closely related tobacco products. Accordingly, the *only* products that Congress mandated for immediate regulation under the Act were cigarettes, roll-your-own tobacco, and smokeless tobacco (the "Originally Regulated Products"). *See* FD&C Act § 901(b), 21 U.S.C. § 387a(b). Regulation of other tobacco products was left to the FDA, subject to the APA. *See id.*

III. THE STATUTORY PREMARKET REVIEW SCHEME

The Act established a detailed premarket review scheme for cigarettes, smokeless tobacco, and roll-your-own tobacco. With certain exceptions, such products that were not on the market as of February 15, 2007 (the "predicate date") cannot be marketed until a premarket application is submitted to, and a marketing authorization order is received from, the FDA. *See id.* § 910(a), 21 U.S.C. § 387j(a). A marketing authorization order is not required if: (a) a manufacturer submits a substantial equivalence report to the FDA under section 905(j) of the FD&C Act and obtains an order under section 910(a)(2) finding that the new tobacco product is "substantially equivalent" to a tobacco product commercially marketed in the United States as of February 15, 2007, or to a tobacco product that the FDA determined was substantially equivalent to a tobacco product commercially marketed as of February 15, 2007 and in compliance with the requirements of the FD&C Act (such products are commonly referred to as the "predicate product"); or (b) a tobacco product is exempt from the substantial equivalence process because it makes only an immaterial modification to an already approved product. *Id.* §§ 905(j), 910(a)(2)(A), 21 U.S.C. §§ 387e(j), 387j(a)(2)(A).

A "substantially equivalent" tobacco product is a product that (i) "has the same characteristics as the predicate tobacco product"; or (ii) "has different characteristics," but the information and/or data submitted to the FDA "demonstrates that it is not appropriate to regulate the product [through the premarket review process] because the product does not raise different questions of public health." *Id.* § 910(a)(3)(A), 21 U.S.C. § 387j(a)(3)(A).[3] The substantial equivalence process itself requires extensive and expensive testing and submissions, and the availability of predicate products is central to the substantial equivalence showing. Congress understood the process would take time, so it permitted cigarettes and smokeless tobacco that were introduced in the 21 months after the Act's enactment to continue to be sold until the FDA completed its review of the substantial equivalence applications submitted for them. *Id.* § 910(a)(2)(B), 21 U.S.C. § 387j(a)(2)(B).

The Act's ongoing substantial equivalence process from the inception of the Act was intended to update predicate tobacco products and is critical to the continued function of the Act's substantial equivalence provisions. That is because, with an ongoing process, a manufacturer could compare a new product to an earlier substantially equivalent version that is reasonably proximate in time to the proposed marketing date for the new tobacco product. This mechanism becomes practically unavailable when regulation of a product class does not begin until ten years after the predicate date.[4]

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[3] The term "characteristics" means "the materials, ingredients, design, composition, heating source, or other features of a tobacco product." FD&C Act § 910(a)(3)(B), 21 U.S.C. § 387j(a)(3)(B).

[4] The TCA's substantial equivalence process, including its specification of predicate products, was derived from the FD&C Act's device provisions. Those provisions were updated in the Safe Medical Devices Act of 1990 and reflected fourteen years of agency practice that included the ability to update predicates with devices found to be substantially equivalent. *See* H.R. Rep. No. 101-808, at 25 (1990) (permitting predicates to be updated will cause "the standard for safety and effectiveness in a determination of substantial equivalence [to] evolve slowly as the prevailing

It is difficult, if not impossible, to show that a new product is substantially equivalent to a predicate product if the predicate product is so remote from the present that the company cannot gather the data required by the FDA, through testing or otherwise. For cigarettes and smokeless tobacco, FDA requires that substantial equivalence reports include, among other things, "a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product" and "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product." *Id.* § 910(b)(1), 21 U.S.C. § 387j(b)(1).

In addition to the premarket review process, the FD&C Act imposes other regulatory burdens on manufacturers and retailers of cigarettes, smokeless tobacco, and roll-your-own tobacco products. Among other things, the statute: (a) requires manufacturers to submit detailed health information on each tobacco product (including lists of ingredients and harmful or potentially harmful constituents ("HPHCs"), descriptions of the form and delivery of nicotine, and documents relating to the health and toxicological effects of products, ingredients, and additives) to the FDA; (b) mandates registration and biannual inspection of manufacturing facilities; and (c) directs manufacturers to maintain extensive records and reports. *Id.* §§ 904(a), 905(b)–(d), (g), 909(a), 21 U.S.C. §§ 387d(a), 387e(b)–(d), (g), 387i(a). The Act also authorizes the FDA to require warning labels on tobacco products, to impose restrictions on the sale and distribution of tobacco products, to regulate manufacturing methods, to prescribe wide-ranging tobacco product standards, and to issue record-keeping regulations directed at manufacturers,

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level on the market changes"); *see also* U.S. Food & Drug Admin., *Guidance on the CDRH Premarket Notification Review Program, 510(k) Memorandum K86-3* at 2 (June 30, 1986) ("[T]he Center requires submitters to provide information that compares the new device to a marketed device of a similar type, regardless of whether this marketed device was marketed before or after enactment of the Amendments . . . .").

importers, and retailers of tobacco products. *Id.* §§ 903(a)–(b), 906(d)–(e), 907(a)(3)–(4), 920(b), 21 U.S.C. §§ 387c(a)–(b), 387f(d)–(e), 387g(a)(3)–(4), 387t(b).

IV. THE FDA "DEEMS" ALL CIGARS AND PIPE TOBACCO SUBJECT TO THE REGULATORY SCHEME CONGRESS CREATED FOR IMMEDIATE APPLICATION TO CIGARETTES AND SMOKELESS TOBACCO

On April 25, 2014, the FDA issued a proposed rule deeming cigars, pipe tobacco, and e-cigarettes subject to the TCA. *See generally* Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, 79 Fed. Reg. 23,142 (Apr. 25, 2014). From the beginning, the FDA acknowledged that cigars and pipe tobacco were an awkward fit with Congress's scheme for regulating cigarettes and smokeless tobacco. Specifically, the FDA admitted doubt that cigar and pipe tobacco "manufacturers would in fact be able to use the SE [substantial equivalence] pathway for many proposed deemed tobacco products because they may not be able to identify a viable predicate." *Id.* at 23,176. The FDA sought comments on whether, among other things: (1) it should "consider a different compliance policy for proposed deemed tobacco products that cannot, as a practical matter, use the SE pathway"; (2) if it did "establish a compliance policy or an expedited review process, . . . the policy or expedited process [should] apply to all proposed deemed products or only to certain categories of products, such as based on their relative impact on public health"; and (3) there are "unique challenges faced by small manufacturers of proposed deemed tobacco products" and how they should be addressed. *Id.*

The FDA simultaneously issued a Preliminary Regulatory Impact Analysis ("PRIA"), in which it announced that it would not carry out a meaningful cost–benefit analysis any time before the rule went final. Instead, the agency said it would worry about that later. It suggested it would conduct a so-called "retrospective review" after implementing the final rule, a concept

nowhere contemplated in Executive Order 12,866. *See* AR010643; *see also* Exec. Order No. 12,866 § 1(b)(6), 58 Fed. Reg. 51,735 (Sept. 30, 1993).

The FDA sought comments on two "options" for what tobacco products it would now regulate. "Option 1" would "deem" all cigars subject to the Act. "Option 2" would exempt "premium cigars" from any regulation. 79 Fed. Reg. at 23,150. The proposed rule defined "premium cigars" by distinguishing "covered" and "non-covered" cigars. A "non-covered" cigar was a cigar that:

> (1) Is wrapped in whole tobacco leaf; (2) contains a 100 percent leaf tobacco binder; (3) contains primarily long filler tobacco; (4) is made by combining manually the wrapper, filler, and binder; (5) has no filter, tip, or non-tobacco mouthpiece and is capped by hand; (6) has a retail price (after any discounts or coupons) of no less than $10 per cigar (adjusted, as necessary, every 2 years, effective July 1st, to account for any increases in the price of tobacco products since the last price adjustment); (7) does not have a characterizing flavor other than tobacco; and (8) weighs more than 6 pounds per 1000 units.

Id.

Plaintiffs and numerous other parties submitted detailed comments on the proposed rule. They explained the significant burdens that would be imposed on their businesses if the TCA were applied to their products and the obvious inequities and impossibilities presented by the proposed February 15, 2007 predicate date for grandfathering and substantial equivalence given the seven years that had passed since enactment of the TCA.[5] Plaintiffs also urged the agency to adopt "Option 2," but with certain modifications to the definition of premium cigar.[6]

The FDA largely rejected the comments received and finalized a rule almost identical to the one it had proposed. On May 10, 2016, the agency promulgated a Final Rule imposing the entire weight of the Act's regulatory scheme on all cigars, pipe tobacco, and e-cigarettes (the

[5] *See, e.g.*, AR129900–09; AR130348–50, AR130354–56; AR159757–64.

[6] *See* AR129915–24; AR130345–48; AR134763–67.

"Newly Deemed Products"). No exemption was made for premium cigar manufacturers. *See generally* 81 Fed. Reg. at 28,974–29,106.[7] The FDA concluded that it lacked authority to make changes to much of the regulatory scheme Congress crafted for cigarette and smokeless tobacco, applying it to cigars and pipe tobacco in rote fashion. That included disclaiming discretion to modify the predicate date, requiring showings of substantial equivalence between Newly Deemed Products and products on the market as of February 15, 2007. Cigar and pipe tobacco manufacturers now have to look back more than *nine years*, nearly four times longer than the two-and-a-half years cigarettes and smokeless tobacco had to cover. *Id.* at 28,993. This requirement not only makes it extraordinarily difficult to find predicates for cigars and pipe tobacco due to the changing characteristics of products made from agricultural components, but also effectively eliminates the prospect of relying on more current substantially equivalent cigars and pipe tobacco as predicates.

The Rule created other arbitrary inequities between the cigarettes and smokeless tobacco products for which Congress directed immediate regulation and the cigars and pipe tobacco the regulation of which Congress left to the FDA's discretion. Foremost was the forbearance of enforcement during the pendency of FDA applications. Cigarettes and smokeless tobacco for which a substantial equivalence report was filed by March 22, 2011, were allowed to remain on the market unless and until the FDA rejected the product's application. FD&C Act § 910(a)(2)(B), 21 U.S.C. § 387j(a)(2)(B). Cigar and pipe tobacco manufacturers, in contrast, were provided set forbearance periods—24 months for substantial equivalence exemption requests, 30 months for substantial equivalence reports, and 36 months for premarket applications. 81 Fed. Reg. at 29,011. After these periods expire—even if the FDA has taken no

[7] Tobacco pipes were also subject to regulation as "components" of pipe tobacco. *See* 81 Fed. Reg. at 29,042.

action—manufacturers will have to pull these products from the market. *See id.* ("Once the continued compliance period ends, new tobacco products on the market without authorization will be subject to enforcement."). The rule leaves cigar and pipe tobacco manufacturers at the mercy of the FDA's speed in performing its review of their products. The FDA's history with cigarettes and smokeless tobacco applications leaves little hope that the FDA will complete review within these time limits.[8]

The FDA simultaneously promulgated a separate rule that imposed user fees on some, but not all, newly deemed products. *See generally* 81 Fed. Reg. at 28,707–16. To fund regulation under the TCA, Congress authorized the FDA to prescribe "user fees" to be paid by regulated entities. FD&C Act § 919, 21 U.S.C. § 387s. Congress provided an initial assessment formula that included those tobacco products that existed on the market at the time of the statute's enactment. *See id.* § 919(b)(2)(B)(i), 21 U.S.C. § 387s(b)(2)(B)(i). The FDA declined to impose user fees on newly deemed products that were not specifically identified in Congress's initial allocation formula. Although the FDA acknowledged that this selective imposition of user fees would result in "free riders," the agency stated that it lacked authority under the TCA to impose user fees on newly regulated tobacco products not identified in Congress's initial formula. 81 Fed. Reg. at 28,709–12.

[8] The FDA has received a total of 6,589 Product Applications—premarket applications, regular and provisional substantial equivalence reports, exemptions, and modified risk submissions—since program inception, and only 2,819 have received Final Actions, representing a 42.8% completion rate. *Cumulative Number of Product Applications Received Since Program Inception*, U.S. Food & Drug Admin., http://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=ctp&status=public&id=CTP-OS-total-product-submissions-since-Program-Inception (last updated Sept. 30, 2016). The FDA's statement that it *may*, on a case-by-case basis, extend the forbearance periods therefore provides little comfort to manufacturers. 81 Fed. Reg. at 29,012.

V. THE RULE THREATENS TO RUIN THE CIGAR AND PIPE TOBACCO INDUSTRIES

The Deeming Rule imposes extraordinary and disproportionate burdens on the cigar and pipe tobacco industries. This crushing regulatory scheme is all but certain to compel many manufacturers and retailers to close their doors or radically change the way they do business. What the regulation ignored is the vast diversity of products in the cigar and pipe tobacco industries, with differences of taste and aesthetics that do not, in and of themselves, affect the health risks of such products.[9] By the FDA's own estimates, the number of unique cigar and pipe tobacco products dwarfs the varieties of cigarettes.[10] This is so even though the cigar industry is roughly eight percent the size of the cigarette industry, and the premium cigar industry represent less than 0.1 percent of the U.S. tobacco market. AR129899; AR130336; *see also* AR129595. The premium cigar industry, for instance, manufactures significant numbers of limited run products, based on the quality and characteristics of tobacco leaf harvested, varying further based on season, location, and weather. Given the nearly ten years that have passed since the predicate date, it will be nearly impossible to find predicate products for today's cigar products to support a substantial equivalence report. Manufacturers therefore face a Hobson's choice of either preparing expensive premarket applications for each of their numerous and diverse products, or ceasing to offer many of their products altogether.[11] Even with substantial equivalence availability, each product will be subject to laborious paperwork and testing. The result will be dramatically narrowed product offerings.

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[9] *See, e.g.*, AR129897, AR129899–900; AR130337, AR130349–50; AR130239; AR081246–47; *see also* 81 Fed. Reg. at 29,079 (discussing premium cigars).

[10] AR023989 (estimating 7,500 cigar UPCs, 1,100 pipe tobacco UPCs, and 4,610 pipe UPCs). These numbers are likely *understated* for cigars, which industry estimates place no lower than 8,000 or 10,000, and potentially as high as 20,000. *See* AR129900; AR130349; AR159690.

[11] *See, e.g.*, AR129901, AR129920; AR129613–14.

The crushing effect of the rule will be felt by the cigar industry generally, and particularly in the premium cigar and pipe tobacco industries, where product variation reigns supreme.[12] These same features of the cigar and pipe tobacco markets will render the ingredient-listing and HPHC-testing mandates exorbitantly costly for industry participants, in part because each such manufacturer must test a vastly greater number of products at significantly lower gross revenues per product than the Originally Regulated Products.[13] The agency's required warning labels also place a disproportionate burden on cigar and pipe tobacco manufacturers, who must prepare and place (at significant expense) a large and obtrusive warning label on each unique product, regardless of the distinctive packaging to which both consumers and sellers assign value.[14] These costs lack any meaningful parallel in the market for cigarettes, which are homogenized and mass-produced, capable of testing under existing procedures, and packaged uniformly and in bulk.[15] Small manufacturers, including premium cigar manufacturers, are unlikely to survive the rule. The cigar industry will consolidate, leaving behind only those large corporate entities who can absorb the costs of compliance.

ARGUMENT

I. STANDARD OF REVIEW

Summary judgment under the APA "serves as the mechanism for deciding, as a matter of law, whether [an] agency action is supported by the administrative record and otherwise

[12] In the premium cigar market, consumers expect a constant stream of new and innovative products. *See* AR129897; AR130337, AR130349; AR129596; AR159690. Pipes are characterized by vast diversity as well. *See, e.g.*, AR150694 (noting that "[t]here are innumerable variations of pipes"); AR161116 (citing "hundreds of styles" of pipes). In the pipe tobacco market, consumers desire consistency in taste, which requires the use of different blends, casings, and flavorings. AR130239.

[13] *See, e.g.*, AR130352; AR129614–15; AR159714–17; AR130245.

[14] *See, e.g.*, AR129929–30; AR130350–52; AR134770; AR129615–16.

[15] *See* AR129896, AR129899; AR130337; AR129614–15; AR159689, AR159716.

consistent with the APA standard of review." *All. for Nat. Health U.S. v. Sebelius*, 775 F. Supp. 2d 114, 118 (D.D.C. 2011). The APA demands that a court "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). In assessing agency action under the APA, "the Court must engage in a 'thorough, probing, in-depth review'" to determine "whether the agenc[y] ha[s] 'examine[d] the relevant data and articulate[d] a satisfactory explanation for its action.'" *Individual Reference Servs. Grp., Inc. v. FTC*, 145 F. Supp. 2d 6, 25 (D.D.C. 2001). The court "considers whether the agency acted within the scope of its legal authority, whether the agency has explained its decision, whether the facts on which the agency purports to have relied have some basis in the record, and whether the agency considered the relevant factors." *Id.* Counsel's "*post hoc* rationalizations" will not do; "an agency's action must be upheld, if at all, on the basis articulated by the agency itself." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983).

When the constitutionality of an agency's action is challenged, the court "must (like any appellate tribunal) determine for itself whether the agency based its decision on the appropriate constitutional standard." *United Space All., LLC v. Solis*, 824 F. Supp. 2d 68, 78 (D.D.C. 2011). The court's role is the same whether the suit proceeds under the APA or directly under the Constitution. *All. for Nat. Health U.S. v. Sebelius*, 786 F. Supp. 2d 1, 12 n.10 (D.D.C. 2011). "'[A] reviewing court owes no deference to the agency's pronouncement on a constitutional question,' and must instead make 'an independent assessment of a citizen's claim of constitutional right when reviewing agency decision-making.'" *Poett v. United States*, 657 F. Supp. 2d 230, 241 (D.D.C. 2009). This sort of searching "'[i]ndependent judicial judgment is especially appropriate in the First Amendment area.'" *Id.*

II. THE FDA'S REGULATION SUBJECTING CIGARS AND PIPE TOBACCO TO ALL ASPECTS OF THE PREMARKET REVIEW SCHEME CONGRESS APPLIED TO CIGARETTES AND SMOKELESS TOBACCO, WHILE DENYING THEM ACCESS TO SUBSTANTIAL EQUIVALENCE, IS ARBITRARY, CAPRICIOUS, AND CONTRARY TO LAW

The FDA imposed a premarket review scheme Congress intended for immediate regulation of cigarette and smokeless tobacco on all cigars and pipe tobacco, and it did so in a way that regulated cigars and pipe tobacco *more harshly* than cigarettes and smokeless tobacco.[16] The agency concluded that this result was *statutorily required* once it "deemed" cigars and pipe tobacco subject to the Act, yet supplied no explanation for why such regulation is justified for cigars and pipe tobacco, through scientific evidence or otherwise. As a result of the agency's mistaken interpretation of the statute, cigar and pipe tobacco manufacturers are subjected to a premarket review process more burdensome than the cigarettes and smokeless tobacco products Congress believed required immediate regulation to protect public health. The agency's regulatory approach is arbitrary, capricious, and contrary to law. Its rule cannot stand.

The FDA concluded that all cigars and pipe tobacco should be regulated and that it had only one choice to do so: Using its Section 901 authority to "deem" those products subject to the Act. *See* FD&C Act § 901(b), 21 U.S.C. § 387a(b). According to the agency, "deeming" a tobacco product "automatically" subjects that product to "all statutory provisions that apply to all tobacco products" covered by the Act. 81 Fed. Reg. at 29,000; *see also, e.g.*, *id.* at 29,034. The FDA then distinguished the Act's "automatic provisions" from what it calls "additional provisions" of the Act that the FDA could apply to cigars and pipe tobacco as it wishes. *Id.* at 28,976, 28,980. According to the FDA, once it deems a tobacco product subject to the TCA, it must apply the "automatic" provisions without regard for whether doing so would lead to results

[16] Because of its erroneous inclusion of tobacco pipes as "components," tobacco pipes also are subject to this process. *See infra* Section XI.

that Congress could not possibly have intended, such as the destruction of large segments of the market for the products newly subject to regulation. *Id.* at 29,000.

This agency interpretation leads to absurd results, the greatest of which is the FDA's retention of the February 15, 2007 predicate date. The predicate date is at the heart of the premarket review process and is determinative of the regulatory pathway for non-exempt tobacco products. That date was designed for the cigarette and smokeless tobacco products Congress regulated in 2009, but makes no sense for the cigars and pipe tobacco products first regulated in 2016. The date Congress chose for cigarettes and smokeless tobacco reflects *proximity* to the initiation of regulation, and would facilitate substantial equivalence comparisons between tobacco products marketed by and after that date. Substantially equivalent "new" products could be marketed without the premarket review that Congress envisioned would enable the FDA "to obtain needed data on the risks of *novel* tobacco products, and to assure that such products do not introduce more risks than *conventional* tobacco products." S. Rep. No. 105-180, at 23 (1998) (emphases added). These "new" substantially equivalent products could serve as predicates for still further product development through the substantial equivalence process.

But for cigars and pipe tobacco, if the FDA's rule were allowed to stand, a predicate date from nearly a decade ago would result in undermining the ability to differentiate "novel" products from "conventional" products and effectively preclude cigar and pipe tobacco manufacturers from marketing products created after 2007. Under the Rule, cigar and pipe tobacco manufacturers must compare today's products to, and amass extensive data about, those marketed in 2007 to have any hope of establishing substantial equivalence and avoiding a separate premarket tobacco product application. *See* FD&C Act §§ 905(j), 910(a)(3)–(4), 21 U.S.C. §§ 387e(j), 387j(a)(3)–(4).

That is practically an insurmountable burden, as data and samples for products in the marketplace nearly a decade ago have long since disappeared. The result of the FDA's wooden predicate date is that virtually *every* cigar and pipe tobacco product will have to go through the full premarket review process, a crushing expense Congress largely spared the cigarette industry by choosing a predicate date for cigarettes just two years before the initiation of regulation. *See, e.g.*, AR129901 (the 2007 predicate date "would result in a paucity of predicates available for comparisons, . . . creating a situation in which substantial equivalence showings would be enormously difficult, if not impossible"); AR023949 ("premarket tobacco applications are more expensive, on average, than substantial equivalence or SE exemptions").

This unnecessary and unjustified burden is exacerbated by the substantially greater number of cigar and pipe tobacco products compared to the cigarette and smokeless tobacco industries. Although some cigars and pipe tobacco are mass-produced, premium cigars, by the FDA's own definition, are never mass produced. *See* 79 Fed. Reg. at 23,150 (defining premium cigars to be "made by combining manually the wrapper, filler, and binder"). They differ according to the tastes of the master blender and the conditions of the component crops. Special edition and seasonal blends comprise a substantial portion of the market and account for a considerable share of the average tobacconist's sales.[17] Pipe tobacco manufacturers and retailers also often make blending changes to provide variety or to preserve the pipe tobacco's character.[18]

In addition, weather and local growing conditions have a much greater impact on cigar manufacturing than cigarette manufacturing, which drive manufacturers to blend tobaccos to

[17] AR129896, AR129899–900, AR129915; AR130337, AR130349, AR130352; AR129614; AR130239; AR081246.

[18] AR130239, AR130244; AR081246–47.

maintain a cigar's identity and taste from year to year.[19] The artisanal process of manufacturing a premium cigar takes three to five years from the time the tobacco seed is planted.[20] Whereas four manufacturers control more than 90% of the cigarette market, there are hundreds of cigar manufacturers, many of whom may have 50 to 100 stock-keeping units ("SKUs").[21] Just looking at premium cigars, there are between 10,000 and 20,000 unique SKUs in the United States,[22] and that number is a fraction of the total number of cigar SKUs available in this country. By contrast, cigarettes are mass-produced by machines capable of generating millions of identical products per hour, and the FDA has estimated that there are approximately 5,300 active UPCs for cigarettes, smokeless tobacco, cigarette or smoking tobacco, and cigarette paper *together*.[23]

Importantly, variations in cigar and pipe tobacco products are directed at flavor, taste, or aesthetics, rather than aimed at altering the health risks of such products.[24] Unlike cigarettes, there has been no claim that the cigar or pipe tobacco industries have manipulated ingredients and components to affect nicotine or tar levels. *Compare* TCA § 2(47)–(49), 123 Stat. at 1781. Nor is there any systematic history of introducing new cigar or pipe tobacco products with any alleged suggestion that they are healthier than others. The defining features of cigars and pipe tobacco—vast product diversity and comparatively slow and small-scale manufacturing—will make the premarket tobacco product application and review process prohibitively expensive.

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[19] AR129899; AR159688–89; AR157821 .

[20] AR129899; AR130377; *see also* AR129613 (describing the unique manufacturing process of premium cigars); AR159688–89 (same); AR159757–58 (same).

[21] AR130336–37.

[22] *See* AR130349; AR159690.

[23] *See* AR159689; AR010618–19.

[24] *See* AR129899, AR129905–06; AR130349; AR159759; AR159689; AR130239; AR081246–47.

For this reason, the availability of the substantial equivalence process is of vital importance to the industry. Yet the FDA's insistence on the February 15, 2007 predicate date ignores the logic and purpose behind the Act, including that Act's prohibition on banning segments of the tobacco industry, and largely forecloses relief for cigars and pipe tobacco from the TCA's prohibitively expensive premarket review provisions. *See* FD&C Act § 907(d)(3), 21 U.S.C. § 387g(d)(3) (regulation banning all cigars and pipe tobacco is "prohibited"). Indeed, the FDA's imposition of the 2007 predicate date effectively deprives cigar and pipe tobacco manufacturers of the ability to update their predicate products in the way that cigarettes and smokeless tobacco have been able to do as their products have evolved over time.

This interpretation of the Act as requiring it to regulate cigars and pipe tobacco more harshly than Originally Regulated Products stands the statutory structure on its head. Congress intended that the substantial equivalence pathway would be available to "all tobacco products," not just cigarettes, smokeless tobacco, and roll-your-own tobacco. 81 Fed. Reg. at 28,993. Denying cigars and pipe tobacco the same access to this pathway as that enjoyed by the Originally Regulated Products is contrary to the Act's structure and represents a textbook case of arbitrary and capricious treatment. *See Burlington N. & S.F. Ry. Co. v. Surface Transp. Bd.*, 403 F.3d 771, 777 (D.C. Cir. 2005) ("Where an agency applies different standards to similarly situated entities and fails to support this disparate treatment with a reasoned explanation and substantial evidence in the record, its action is arbitrary and capricious and cannot be upheld.").

This outcome—a premarket review process more burdensome than the one for cigarettes and smokeless tobacco, weighed down by a predicate date ten years old—was far from necessary or required by statute. Nothing in the Act, textual or otherwise, indicates that Congress intended to impose a more burdensome regulatory structure on newly deemed products. Rather, Congress

gave the agency the discretionary authority to determine through the rulemaking process *whether* and *how* to regulate cigars and pipe tobacco in Section 901: "This chapter shall apply to . . . any other tobacco products that the Secretary *by regulation* deems to be subject to this chapter." FD&C Act § 901(b), 21 U.S.C. § 387a(b) (emphasis added). Congress's reference to the agency acting "by regulation" clearly connotes the discretion to calibrate a regulatory scheme for the tobacco products the agency later chooses to regulate. *See Ethicon, Inc. v. FDA*, 762 F. Supp. 382, 386 (D.D.C. 1991) (statute mandating that the effectiveness of a device be determined "in accordance with regulations promulgated by the Secretary" conferred "sweeping discretion" on the agency).

Other provisions reinforce the FDA's discretion to make changes to the regulatory scheme Congress designed for immediate application to cigarette and smokeless tobacco when regulating other products. The Secretary's primary authority in promulgating regulations under the FD&C Act is rooted in Section 701 of the statute, which vests the Secretary with "authority to promulgate regulations for the *efficient* enforcement" of the Act. FD&C Act § 701(a), 21 U.S.C. § 371(a) (emphasis added). Likewise, Congress granted the FDA "*flexible* enforcement authority" and directed the agency to "impose *appropriate* regulatory controls on the tobacco industry." TCA § 3(4), (8), 123 Stat. at 1782 (emphases added). At a minimum, these provisions make clear that rote application of the February 2007 predicate date in a way that disfavors cigars or pipe tobacco is in no manner "compelled" by the TCA itself.

Importantly, Congress chose not to regulate cigars and pipe tobacco in the first instance. That is because Congress was focused on cigarettes and smokeless tobacco, and did not mandate whether or how cigars and pipe tobacco should be regulated. *See* FD&C Act § 901(b), 21 U.S.C. § 387a(b). Neither cigars nor pipe tobacco are mentioned in the committee reports on the Act.

See H.R. Rep. No. 111-145 (2009); H.R. Rep. No. 111-72 (2009); H.R. Rep. No. 111-58, pts. 1–2 (2009); H.R. Rep. No. 110-762 (2008). Similarly, hearings on the Act contain no discussion of the proper level of regulation for cigars and pipe tobacco. Nor do they reference these products as problems for youth initiation or access, deceptive marketing as healthier alternatives, or the manipulation of nicotine or other constituents, in the course of their long appraisal of cigarette public health problems.[25] And the only references to cigars or pipe tobacco in the Congressional Record appear in the floor remarks of a single Representative who observed, on three occasions, that cigars and pipe tobacco are beyond the scope of the legislation. 155 Cong. Rec. H6626, H6654 (daily ed. June 12, 2009) (remarks of Rep. Steve Buyer); 155 Cong. Rec. H3802 (daily ed. Mar. 24, 2009) (remarks of Rep. Steve Buyer).

The structure of the Act, and the FDA's effort to classify some of its provisions as "automatic" and some as "additional" or "discretionary," also demonstrate that the FDA retained the discretion to calibrate aspects of the cigarette and smokeless tobacco regulatory scheme when extending it to cigars and pipe tobacco. Take, for example, the agency's treatment of Section 904, which requires tobacco product manufacturers to submit lists of ingredients and constituents to the FDA by certain deadlines. FD&C Act § 904(a)(1)–(4), 21 U.S.C. § 387d(a)(1)–(4). The agency labels Section 904 as "automatic," but goes on to revise statutory dates therein, which had already passed, as applied to cigars and pipe tobacco. 81 Fed. Reg. at 28,976, 29,006. The FDA has offered no explanation for why it may adjust an "automatic" statutory provision like Section 904 because of the passage of time, but is forbidden to modify the 2007 predicate date

[25] *See* The Family Smoking Prevention and Tobacco Control Act: Hearing Before the Subcomm. on Health of the Comm. on Energy & Commerce on H.R. 1108, 110th Cong. (2007); The Need for FDA Regulation of Tobacco: Hearing of the Comm. on Health, Educ., Labor, & Pensions on Examining S. 625, to Protect the Public Health by Providing the Food and Drug Administration with Certain Authority to Regulate Tobacco Products, 110th Cong. (2007).

that is equally absurd when applied to cigars and pipe tobacco. Indeed, the impossibility of applying all statutory provisions to products first regulated years in the future shows that Congress expected the agency to tailor the predicate date, as well as aspects of the regulatory scheme, to the circumstances of the newly regulated industry and the timing of the regulation.

Importantly, the FDA is not entitled to any deference in its incorrect interpretation of the Act as depriving it of discretion. The law of this circuit is settled that "deference to an agency's interpretation of a statute is not appropriate when the agency wrongly believes that interpretation is compelled by Congress." *Peter Pan Bus Lines, Inc. v. FMCSA*, 471 F.3d 1350, 1354 (D.C. Cir. 2006). Indeed, when an agency incorrectly concludes that a statute unambiguously compels a particular regulatory outcome, its action cannot stand—regardless of whether it could have achieved the same end through proper regulation. *See Arizona v. Thompson*, 281 F.3d 248, 259 (D.C. Cir. 2002). Because of its erroneous interpretation of the statute, the agency passed by multiple options for tailoring the regulatory scheme for cigars and pipe tobacco.

The proper remedy is to vacate the Deeming Rule for the agency to exercise its full statutory discretion and, in doing so to ensure that cigars and pipe tobacco at least are regulated no more harshly than the Originally Regulated Products. *See Int'l Swaps & Derivatives Ass'n v. CFTC*, 887 F. Supp. 2d 259, 283–84 (D.D.C. 2012) (vacating final rule where agency erroneously deemed statute unambiguous and therefore "failed to bring its expertise and experience to bear when interpreting the statute and offered no explanation for how its interpretation comported with the policy objectives of the Act"); *Humane Soc'y of U.S. v. Kempthorne*, 579 F. Supp. 2d 7, 20–21 (D.D.C. 2008) (vacating final rule and instructing agency on remand to, "[a]t a minimum, . . . explain how its interpretation of the statute conforms to the text, structure and legislative history of the [act]; how its interpretation is consistent with judicial

interpretations of the [act] (if there are any on point); and how its interpretation serves the [act's] myriad policy objectives").

III. THE RULE'S IMPOSITION OF PREMARKET REVIEW WITHOUT CLARIFYING THE SUBSTANTIAL EQUIVALENCE PATHWAY FOR CIGARS AND PIPE TOBACCO IS ARBITRARY, CAPRICIOUS, AND AN ABUSE OF DISCRETION

Even if the FDA were somehow required to implement all aspects of the premarket review scheme Congress applied to cigarettes and smokeless tobacco—including a nearly decade-old predicate date—the FDA has other authorities to tailor the scheme to the unique aspects of cigars and pipe tobacco. Foremost among them is the FDA's authority to provide rules governing its substantial equivalence determinations. *See* FD&C Act § 905(j)(1), 21 U.S.C. § 387e(j)(1).

For those products the FDA sought to deem, the FDA sought comments on whether and how it should clarify the application of substantial equivalence to those products in the Final Rule. Commenters answered and requested that the FDA couple any deeming rule with regulations facilitating substantial equivalence for cigars and pipe tobacco.[26] Rules governing the substantial equivalence process could have treated cigars in the same product family (those with the same type of tobacco blend, filler, and wrapper, but in different shapes and sizes) as substantially equivalent and limited premarket review to new product families, or could have adopted an alternative system for premium cigars where the manufacturer provides notice of a new product and asserts its substantial equivalence subject to an agency call for further information.[27]

[26] *See, e.g.*, AR161086, AR161090.

[27] *See* AR130345; AR157840 .

Any of these alternatives would have tempered, but not eliminated, the extraordinary burdens of pre-market review on a cigar and pipe tobacco industry with tens of thousands of products, varied in ways having nothing to do with public health. But the agency declined to clarify or modify the substantial equivalence procedure for cigars and pipe tobacco when it issued its Final Rule, saying only that it *might* later issue rules specific to cigars and pipe tobacco. 81 Fed. Reg. at 29,011–12. Recognizing that such rules were necessary, the agency has drafted a rule but not publicly released it. *See* Regulatory Agenda, 81 Fed. Reg. 94,742, 94,742, 94,745 (Dec. 23, 2016).[28] Cigars and pipe tobacco were even less fortunate than electronic cigarettes, for which the agency issued industry-specific guidance simultaneously with the Final Rule. 81 Fed. Reg. at 29,012; *see also* Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems, 81 Fed. Reg. 28,781 (May 10, 2016).

Substantial equivalence applications are due on February 8, 2018. The industry is incurring the costs of preparing for that process—individual product by product—now. The FDA created a premarket review scheme—focused on comparing today's products to those on the market ten years ago—with burdens unrelated to advancing public health. If commenters propose a less burdensome scheme, equally effective at achieving the agency's goals, the agency must explain why it declines that option. *Del. Dep't of Nat'l Res. & Envtl. Control v. EPA*, 785 F.3d 1, 18 (D.C. Cir. 2015) ("Because EPA too cavalierly sidestepped its responsibility to address reasonable alternatives, its action was not rational and must, therefore, be set aside.");

[28] In 2011, the agency published answers to "frequently asked questions" regarding the substantial equivalence process and has revised it several times since. *See* Ctr. for Tobacco Prods., U.S. Food & Drug Admin., *Draft Guidance for Industry and FDA Staff – Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions* (Sept. 2011); *see also* Ctr. for Tobacco Prods., U.S. Food & Drug Admin., *Guidance for Industry – Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 3)* at 20 (Dec. 2016). But that guidance makes no specific reference to cigars or pipe tobacco.

State Farm, 463 U.S. at 48 (agency arbitrarily failed to address alternative way of achieving statutory purpose). A promise of future rules, which now almost certainly will occur after the industry incurs all the costs of compliance with the Rule, does no good. Creating a regulatory mess—and promising a solution later, after the industry bears all of the costs—is the definition of capricious.

IV. THE FDA ARBITRARILY DENIED CIGARS AND PIPE TOBACCO THE SAME STAY OF ENFORCEMENT PENDING APPROVAL OF THEIR SUBSTANTIAL EQUIVALENCE APPLICATIONS PROVIDED TO CIGARETTES

The FDA permitted cigarettes and smokeless tobacco products to remain on the market until the FDA completed review of their substantial equivalence applications. *See* FD&C Act § 910(a)(2)(B), 21 U.S.C. § 387j(a)(2)(b). The FDA originally proposed a similar approach for cigars and pipe tobacco. *See* 79 Fed. Reg. at 23,175. Recognizing that it was "not certain that manufacturers would in fact be able to use the SE pathway for many proposed deemed tobacco products because they may not be able to identify a viable predicate," the agency even proposed expanding the cigarette stay of enforcement to the pendency of premarket approval applications. *Id.* at 23,176.

The Final Rule, however, radically changes course and declines to permit products to remain on the market while the FDA considers applications of any kind. Instead, cigar and pipe tobacco products may remain on the market only during the 18-month period between the effective date of the rule and the deadline for making substantial equivalence applications and then only for another 12 months while their applications are pending. Thereafter the products must be pulled from the market, even if the FDA has not made up its mind. 81 Fed. Reg. at 28,978, 29,010–11.

The agency provided no meaningful justification for this difference in treatment, much less the "reasoned analysis" courts require for changing a longstanding regulatory policy. *State*

Farm, 463 U.S. at 56–57; *see also Lilliputian Sys., Inc. v. Pipeline & Hazardous Materials Safety Admin.*, 741 F.3d 1309, 1313 (D.C. Cir. 2014). The FDA says it is concerned about unreviewed cigars and pipe tobacco remaining on the market, with potential exposure to minors, while the FDA's decisionmaking process continues to grind. 81 Fed. Reg. at 29,014. But that is no distinction from cigarettes, many of which for years have remained on the market pending review and to which the underaged seek access in dramatically higher numbers. *See* Declaration of Cecil Reynolds ("Reynolds Decl.") ¶¶ 25, 30. To put it sharply, nothing in the Rule explains why cigars and pipe tobacco should be treated more harshly than cigarettes.

If anything, the facts over the last eight years have shifted more strongly in favor of forbearance throughout the pendency of cigar and pipe tobacco applications, because of the agency's now demonstrated inability to process those applications in any timely fashion. The agency still has not processed cigarette substantial equivalence applications filed six years ago; twelve months after application submission will not be nearly enough time for the agency to act. Of 6,589 product applications, only 2,819 have received final action.[29] This backlog will only get worse, given that the cigar and pipe tobacco products have much higher numbers of SKUs than cigarettes and smokeless tobacco. The absence of forbearance is flatly contrary to one of the primary purposes of the TCA: "[T]o continue to permit the sale of tobacco products to adults[.]" TCA § 3(7), 123 Stat. at 1782. And, as above, it results in the imposition of a harsher regulatory scheme on Newly Deemed Products than on the Originally Regulated Products.

[29] *Cumulative Number of Product Applications Received Since Program Inception*, U.S. Food & Drug Admin., http://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=ctp&status=public&id=CTP-OS-total-product-submissions-since-Program-Inception (last updated Sept. 30, 2016).

V. THE FDA'S REJECTION OF "OPTION 2" EXEMPTING PREMIUM CIGARS IS ARBITRARY, CAPRICIOUS, AND CONTRARY TO LAW

At most, the FDA attempted to justify a painstaking product-by-product premarket review and testing process through anecdote. *See, e.g.*, 79 Fed. Reg. at 23,146–47. None of the agency's stories, however, ever implicated the *premium* cigar industry. Premium cigars are expensive (and thus practically inaccessible to minors) and are used by adults with far less frequency than other tobacco products.[30] They represent less than 0.1 percent of the U.S. tobacco market.[31] More importantly for purposes of the Final Rule, differentiation among premium cigars falls along lines having nothing to do with public health. There is no history in the premium cigar industry of manipulating nicotine levels or of additives making the products more attractive to minors. Rather, premium cigar varieties arise from aesthetic and taste preferences and natural agricultural variations that do not merit the arduous testing and crushing paperwork required for the agency to approve each separate product.

Agencies attacking a perceived regulatory problem are obligated to draw lines rationally. *See Bus. Roundtable*, 647 F.3d at 1154. The FDA knew this, so it proposed a regulation that would have more appropriately and effectively regulated the cigar industry by exempting premium cigars. *See* 79 Fed. Reg. at 23,151–52. The FDA proposed two options: "Option 1," which would subject all cigars to FDA regulation, and "Option 2," which would exempt premium cigars from the Rule. *Id.* The premium cigars exempted would be comprised solely of

[30] *See, e.g.*, AR130340–41; AR134768.

[31] AR130336; *see also* AR129595.

tobacco, would be made largely by hand, would lack characterizing flavors, and would be priced over a certain threshold, among other qualifications. *Id.* at 23,150.[32]

As a facially reasonable alternative, the FDA "had an obligation to consider" Option 2, a duty that entailed "respond[ing] to serious objections" and "adequate[ly]" explaining its decision. *Del. Dep't of Natural Res.*, 785 F.3d at 16–18; *see Chamber of Commerce v. SEC*, 412 F.3d 133, 145 (D.C. Cir. 2005). But the agency made no such effort to deal with the evidence in the record regarding its own proposal.

Instead, the FDA waved its hands at generalized public health concerns, claiming premium cigars were also unhealthy. *See* 81 Fed. Reg. at 29,020. It never once explained how running all types of premium cigars through the premarket review process, however, would advance the public health. Foremost in the agency's explanation should have been what the agency expected to find through premarket review of premium cigars, with some evidence that the anticipated conditions currently exist. The agency says nothing on the subject. *See id.* at 29,020–27.

The agency, in fact, seems to acknowledge that applying its full force to premium cigars is unnecessary. The FDA found that subjecting premium cigars to some, but not all, of the FDA's regulatory authority both would advance the public health and would dramatically reduce costs on small businesses. AR010647–48. In the Final Rule, however, the agency never runs to ground this alternative of its own creation.

Moreover, the agency seems to concede that it must make some finding that minors use premium cigars to include them in the Deeming Rule. *See* 81 Fed. Reg. at 29,020 (as basis for rejecting Option 2, "FDA has concluded that . . . premium cigars are used by youth and young

[32] The FDA's definition of "premium cigars" itself has problems but would have been a substantial improvement over the blanket rule issued by the agency. On remand, the agency would be required to reasonably address the nuances of its definition.

adults."). But the FDA's conclusion is not based on "substantial evidence." *See R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1219 (D.C. Cir. 2012), *overruled on other grounds by Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18 (D.C. Cir. 2014) (en banc). The FDA prominently announced that 3.8% of persons aged 12 to 17 who are "past 30 day cigar smokers" reported using an amorphously defined "premium" brand. *Id.* at 29,023 (citing AR020897-902 (Ref. 59)). What the agency leaves out is that 30-day cigar smokers are only approximately 3.3 percent of this age group, meaning that the agency was only referring to 0.001% of persons aged 12-17. *See* AR020898. Indeed, a recent FDA-funded study found that the frequent use of "traditional cigars," which would include premium cigars, by minors was so small that it could not be reliably measured. *See* Reynolds Decl. ¶ 26. In short, the agency risked the continued existence of a whole industry to benefit a statistically insignificant percentage of minors, without even explaining how the regulation will help reduce underaged use. In these circumstances, the D.C. Circuit has invalidated regulations under the APA. *See R.J. Reynolds.*, 696 F.3d at 1220 (a 0.088% projected reduction in cigarette use not "substantial evidence" supporting warning requirement).

Further, the FDA impermissibly failed to respond to important points and meaningful objections voiced in public comments. The FDA's responses to comments on Option 2 followed a common pattern: Commenters raised specific objections to Option 1's coverage of premium cigars, and the FDA responded in conclusory fashion that all cigar use causes health risks, thereby justifying the full panoply of TCA regulations. *See* 81 Fed. Reg. at 29,025–27. But that response omitted the entire consideration of the distinctly higher costs to premium cigar manufacturers resulting from imposing those regulations. In doing so, the FDA "entirely failed to consider an important aspect of the problem," namely the immense financial burdens of

regulation, the prospect of shuttering hundreds of small businesses, and the possibility of achieving the agency's public health goals through a less onerous alternative. *State Farm*, 463 U.S. at 43. This industry destruction is hardly justified when the agency cannot explain what it will detect in premarket review of premium cigars and how the regulation will address health risks.

If the agency still thought regulation of premium cigars were needed, it could have relied on Section 907 of the Act to devise appropriate tobacco product standards for premium cigars, without subjecting them to the full statutory premarket and testing scheme. *See* FD&C Act § 907(a)(3)(A), 21 U.S.C. § 387g(a)(3)(A) ("The Secretary may adopt tobacco product standards . . . if the Secretary finds that a tobacco product standard is appropriate for the protection of the public health."). The FDA disclaimed this approach, asserting that Section 907's authority to create a tobacco product standard is unavailable unless the FDA first "deems" a product subject to the TCA. *See* 81 Fed. Reg. at 29,055. But Section 907 simply refers to "*tobacco product* standards," and does not reference the FDA's "deeming" authority. There is no reason why Section 907 does not draw from the general definition of "tobacco product" in the Act, which includes cigars. *See* FD&C Act § 201(rr)(1), 21 U.S.C. § 321(rr)(1).

The agency repeats the same mistake over and over again: It is all of the Act or none of the Act for premium cigars. That legal conclusion has no grounding in the Act, and is arbitrary and capricious. The proper remedy for the agency's failure adequately to consider alternatives for regulating premium cigars is remand to the agency to consider the full scope of its legal authority and adequately deal with the evidence and comments in the record. *See supra* at Section II.

VI. THE FDA'S DECISION TO IMPOSE USER FEES ON SOME BUT NOT ALL NEWLY DEEMED PRODUCTS IS CONTRARY TO LAW AND IN EXCESS OF STATUTORY AUTHORITY

To pay for the TCA's regulatory scheme, Congress imposed "user fees" on the "manufacturer[s] and importer[s] of tobacco products subject to" the TCA. FD&C Act § 919(a), 21 U.S.C. § 387s(a). Congress established an allocation formula that would assign user fees based on the classes of tobacco products in existence at the time of the TCA. *Id.* § 919(b)(2)(B)(i)–(ii), 21 U.S.C. § 387s(b)(2)(B)(i)–(ii). Nonetheless, Congress made clear that user fees *may* be imposed on tobacco products if they were either originally regulated by Congress or later deemed subject to the Act by the FDA. *Id.* § 919(b)(2)(B)(iii), 21 U.S.C. § 387s(b)(2)(B)(iii) ("[N]o user fees shall be assessed on a class of tobacco products unless such class of tobacco products is listed in section 901(b) [originally regulated] or is deemed by the Secretary in a regulation under section 901(b) to be subject to this chapter [newly deemed]."). All newly deemed products, including e-cigarettes, meet that simple standard.

The FDA, however, imposed user fees on all regulated tobacco products, except e-cigarettes. *See* 81 Fed. Reg. at 28,712. The FDA acknowledged that its decision created a "free rider" problem: Manufacturers and importers of e-cigarettes would not pay for their regulation; instead it would be charged to all other tobacco products, including cigars and pipe tobacco. *Id.* The FDA's only rejoinder is that it somehow lacked statutory discretion to impose user fees on e-cigarettes because they were not listed in Congress's initial allocation formula. *Id.* ("[T]he requirements of section 919 of the FD&C Act . . . prevent FDA from assessing user fees for deemed products other than cigars and pipe tobacco."). Even if it *could* create a new fee regime, the FDA said it would decline to do so because substantial work would be involved. *Id.* ("FDA would need to demarcate a new set of tobacco product classes among newly deemed tobacco products, and fashion an entirely novel framework for determining class percentage allocations

and allocations within each class of tobacco product."). In reaching the conclusion that it was all too hard, the FDA passed by common metrics that would subject new tobacco products to Congress's allocation formula (e.g., "20 cigarettes = 1 e-cigarette cartridge = 1 standard container of moist snuff = 4 large cigars"). *Id.*

The FDA's selective implementation of a user fee is contrary to law for three reasons. First, by levying assessments against cigar and pipe tobacco, but not e-cigarette, manufacturers, the FDA turned what Congress designated as a "user fee" into a tax. Second, contrary to the FDA's claim, the Act explicitly grants authority to charge user fees for all products, including e-cigarettes. Finally, the FDA's User Fee Rule is bald economic favoritism raising constitutional problems under the equal protection component of the Fifth Amendment's Due Process Clause, which the Court should construe the statute to avoid.

A. Congress Deliberately Imposed a "User Fee," Not a Tax

Congress imposed "user fees," a phrase with a particular definition that is commonly understood. "User fees" are: (1) predicated on a voluntary act by a payer; (2) paid for a specific service or benefit, including the "benefit" of regulation; and (3) not meant for the benefit of others. *Nat'l Cable Television Ass'n v. United States*, 415 U.S. 336, 340–41 (1974); *see also* U.S. Gov't Accountability Office, GAO-08-386SP, *Federal User Fees: A Design Guide* 4–5 (2008). When a person or an entity is obligated to provide funds for government regulation of someone else, the payment is no longer a user fee but a tax. *See United States v. La Franca*, 282 U.S. 568, 572 (1931) (discussing difference between "tax" and "penalty"). With the TCA, the "bargain" of the user fee is straightforward: In exchange for the "benefit" of FDA regulation, manufacturers of tobacco products pay a user fee for the tobacco products they produce that funds the regulatory scheme. FD&C Act § 919(c)(2)(B)(i), 21 U.S.C. § 387s(c)(2)(B)(i) (user fees "are the only funds authorized" for agency's tobacco regulation activities).

The User Fee Rule, however, calls for *some* manufacturers of tobacco products to pay for the system as a whole, while others "free ride" by obtaining the "benefits" of regulation without any of the costs. Manufacturers that are required to pay user fees effectively subsidize the entry of "free riders" into the tobacco market. Because cigar, pipe tobacco, cigarette, and other manufacturers provide a benefit for "other members of society," e-cigarette manufacturers, the FDA's rule transforms Congress's user fee into a tax. *See Nat'l Cable Television Ass'n*, 415 U.S. at 341 (distinction between "fee" and "tax" depends on whether payer receives "benefit not shared by other members of society").

B. Congress Did Not Limit User Fees to the Tobacco Products Listed in its Allocation

Contrary to the agency's halfhearted suggestion, the text of the Act plainly does not restrict user fees to those tobacco products listed in the statutory allocation formula. The statute says that "the Secretary shall in accordance with this section assess user fees on, and collect such fees from, each manufacturer and importer of *tobacco products subject to this chapter*." FD&C Act § 919(a), 21 U.S.C. 387s(a) (emphasis added). It then sets out yearly total assessments, followed by allocations by product class, drawn from another statute. *Id.* § 919(b)(1)–(2), 21 U.S.C. § 387s(b)(1)–(2). That statute, the American Jobs Creation Act of 2004, lists product class allocations for fiscal years 2005 through 2014. 7 U.S.C. § 518d(b)–(c). Neither statute says that user fees shall be imposed *only* on those tobacco products identified in the allocation provisions. Yet "Congress generally knows how to use the word 'only' when drafting laws." *Adirondack Med. Ctr. v. Sebelius*, 740 F.3d at 692, 697 (D.C. Cir. 2014).

Moreover, Section 919(b)(2)(B)(iii) states that user fees may be assessed so long as a tobacco product is "listed in section 901(b)" (*i.e.*, a product is originally regulated) or is "deemed by the Secretary in a regulation under section 901(b)" (*i.e.*, a product is newly deemed). FD&C

Act § 919(b)(2)(B)(iii), 21 U.S.C. § 387s(b)(2)(B)(iii). In other words, *all* deemed products, regardless of whether they are listed in Section 919(b)(2)(B)(i), are subject to user fees. Section 919(b)(2)(B)(iv) similarly shows Congress's intent that manufacturers and importers of regulated tobacco products pay their own way: If a product is not "deemed" but "otherwise would be assessed" user fees, the "amount of user fees . . . shall be reallocated to the classes of tobacco products [that are deemed and subject to user fees] . . . based on the same relative percentages otherwise determined under clause (ii)." *Id.* § 919(b)(2)(B)(iv), 21 U.S.C. § 387s(b)(2)(B)(iv). What the statute does *not* provide for is a shifting of user fees from deemed products not identified in the TCA to other tobacco products that happened to exist at the time of the TCA's enactment. The FDA's contrary interpretation flies in the face of these provisions.

The structure of the Act reinforces that user fees must be collected for all regulated entities. *Cty. of L.A. v. Shalala*, 192 F.3d 1005, 1014 (D.C. Cir. 1999) (courts consider "the structure and context of the statutory scheme"). Taken to its logical end, FDA's interpretation of the user fee statute would yield absurd results that defy Congressional intent. *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1069 (D.C. Cir. 1998) (absurd results from an agency interpretation that are "gravely inconsistent with the text and structure of the statute" invalidate a rule). Congress intended for the TCA to be self-sustaining, and to pay for regulation using "fees assessed on manufacturers and importers of *tobacco products*," not just the manufacturers of cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco. H.R. Rep. No. 111-58, pt. 1, at 21 (2009) (emphasis added). If e-cigarettes were not "tobacco products" as defined in the Act, the FDA would not have any authority to deem e-cigarettes subject to the Act. *See Sottera, Inc. v. FDA*, 627 F.3d 891, 897 (D.C. Cir. 2010) (the TCA "broadly defines tobacco products as extending to '*any* product made *or derived from tobacco*,'" including e-cigarettes).

Should e-cigarettes overtake large segments of the marketplace for tobacco products (a trend consistent with the current data), the FDA either would lack sufficient funding for its regulatory activities or saddle other tobacco products with the crushing expense of regulating e-cigarettes. Not only does the FDA's interpretation give rise to absurd results, but those results are "plainly at variance with the policy of the legislation as a whole"—for the TCA to be a self-sustaining regime. *See Nat'l Treas. Emps. Union v. Devine*, 733 F.2d 114, 120 (D.C. Cir. 1984) ("court[s] must look beyond the words to purpose of statute where its literal terms would lead to absurd results").

Should the Act be ambiguous, the agency's interpretation is plainly unreasonable. The FDA offered no reason why alternative methods of calculating user fees were too difficult to implement. *See* 81 Fed. Reg. at 28,712. While administrative convenience could potentially justify the reasonableness of FDA's construction of the user fee provisions, that rationale must be "reasonably explained." *Emily's List v. FEC*, 581 F.3d 1, 22 n.20 (D.C. Cir. 2009).

C. The User Fee Rule, As Impermissible Economic Favoritism, Raises Serious Constitutional Questions Under the Fifth Amendment

The FDA, without providing any meaningful reason, preferentially treats e-cigarettes by mandating that all other tobacco products fund their regulation. This is naked economic favoritism. While economic discrimination does not call for the most exacting form of judicial scrutiny, such discrimination still requires a rational basis under the Fifth Amendment's Due Process Clause. *St. Joseph Abbey v. Castille*, 712 F.3d 215, 223 (5th Cir. 2013) ("naked economic preferences," standing alone, are not a sufficient rational basis for economic discrimination). Administrative convenience—avoiding a few more paragraphs in the final rule—is hardly a rational basis. Although such a rationale could potentially satisfy rational basis review, it is contingent upon a showing that equal treatment would give rise to an administrative

inconvenience that would obviate whatever benefits that such treatment would yield. *See, e.g.*, *Armour v. City of Indianapolis*, 132 S. Ct. 2073, 2081 (2012) (holding that there was a sufficient rational basis because equal treatment would have yielded benefits "too small to justify the administrative expense"). The FDA made no attempt to clear that low bar, relying only on an incorrect understanding of the authorizing user fee statute.

To the extent there is any doubt about the Act's proper interpretation, the Court should resolve that doubt to require user fees to be distributed among all regulated tobacco products and to avoid an otherwise serious constitutional problem. *Nat'l Mining Ass'n v. Kempthorne*, 512 F.3d 702, 711 (D.C. Cir. 2008) ("[C]ourts make every effort to construe statutes so as to find their constitutional foundations and thus avoid needless constitutional confrontations.").

VII. THE FINAL RULE WAS BASED ON A FLAWED COST–BENEFIT ANALYSIS AND IMPOSES AN UNREASONABLE BURDEN ON SMALL BUSINESSES WITHOUT ADEQUATE EXPLANATION

A. The FDA's Cost–Benefit Analysis Was Fundamentally Flawed, Rendering its Rule Arbitrary and Capricious

The FDA found that the benefits of the deeming rule justified its staggering costs. 81 Fed. Reg. at 28,981. The agency was required to undertake a thorough cost–benefit analysis, but both its process and its conclusion were arbitrary and capricious.[33]

[33] Section 3(8) of the TCA declares that one of the purposes of the Act is "to impose *appropriate* regulatory controls on the tobacco industry." TCA § 3(8), 123 Stat. at 1782 (emphasis added). The Supreme Court has made clear that this sort of value-laden language mandates consideration of all relevant factors, including the rule's costs and benefits. *See Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015) (a statutory directive to find regulations "appropriate and necessary" entails a cost–benefit analysis). Moreover, by endeavoring to perform a cost–benefit analysis, the FDA assumed the obligation to ensure that its calculations were accurate. *See Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1039–40 (D.C. Cir. 2012) ("[W]hen an agency decides to rely on a cost–benefit analysis as part of its rulemaking, a serious flaw undermining that analysis can render the rule unreasonable."); *see also, e.g.*, 81 Fed. Reg. at 28,980–81 (describing the costs and benefits of the rule); *id.* at 29,074–76 (summarizing the FDA's analysis of impacts under Executive Order 12,866 and the Regulatory Flexibility Act, among other authorities); *id.* at

First, the FDA's analysis was premised on unquantifiable and speculative benefits. The agency admitted that it was unable to predict the rule's benefits: "The direct benefits of making each of the newly deemed tobacco products subject to the requirements of chapter IX of the FD&C Act are difficult to quantify, and we cannot predict the size of these benefits at this time." 81 Fed. Reg. at 29,075. The Small Business Administration criticized this approach from the beginning, but the agency did nothing to marshal any additional data in the two years between its Preliminary Regulatory Impact Analysis and the Final Rule.[34] The agency's only effort was to lean on data regarding the benefits of regulating cigarettes and smokeless tobacco, notwithstanding their different user cohort and patterns, an exercise fraught with error as explained below.[35]

At the bottom of the FDA's reliance on unquantifiable benefits is its inability to show that and how the Rule will *cause* benefits to public health. There is a difference between an agency identifying a public health problem and showing it has a regulatory solution. It is little surprise, for example, that the agency could not demonstrate how much premarket review of

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29,075 ("For the reasons provided elsewhere in this preamble and in the analysis of impacts, FDA has concluded that the benefits of the final rule justify the costs.")

[34] *See* AR082216–18; *see also* AR129925–26; AR130357–58; AR129611–12; AR159724. *Compare* AR010643 ("The lack of direct evidence and uncertainty associated with the indirect evidence prevented quantification of the benefits and some part of the costs of the proposed rule."), *with* AR023932 ("We note that we have not quantified the benefits of the proposed or final rule, and we are unable to quantify any possible unintended offsetting effects."), *and* AR023978 ("[W]e cannot quantify the benefits of the final rule due to lack of information and substantial uncertainties associated with estimating its effects.").

[35] *See* AR023974–75 (predicting "[i]mproved effectiveness of sales restrictions" and "curb[ed] sales to youth," without considering the differing sales avenues for various tobacco products); AR023976 (predicting "fewer harmful or addictive products reaching the market" and "increase[d] product consistency" from premarket review, without distinguishing among tobacco products); AR023976 (predicting "reductions in use, switching to less risky products, and compensating health behaviors" from all combusted tobacco products, without differentiation).

cigars will benefit the public health, given the absence of evidence that variations in cigars and pipe tobacco, in and of themselves, are threatening the public health.

All the agency could do is point to the future. It says the deeming rule is different: It is an "enabling regulation" that will allow the "FDA to issue further regulations" that "will have their own costs and benefits." 81 Fed. Reg. 29,075. But the costs of the Rule are real and immediate, not contingent on future agency action. The FDA was fully capable of coupling the deeming rule with other attempted regulations of cigars and pipe tobacco, as the warning provisions of the rule so demonstrate. The agency cannot justify the costs of this Rule by what it *might* do through future rules. The result is nothing but hope and assertions of health benefits to offset the demonstrably devastating costs of the Rule on small businesses in the cigar and pipe tobacco industries.

These failings render the FDA's rulemaking arbitrary and capricious. An agency "may not shirk a statutory responsibility simply because it may be difficult." *NetCoalition v. SEC*, 615 F.3d 525, 539 (D.C. Cir. 2010). Regulatory bodies "by nature work under conditions of serious uncertainty, and regulation would be at an end if uncertainty alone were an excuse to ignore a congressional command." *Pub. Citizen v. FMCSA*, 374 F.3d 1209, 1221 (D.C. Cir. 2004). Consistent with these principles, courts have not hesitated to hold rules arbitrary and capricious where the issuing agency has failed to quantify important costs and/or benefits. *See Bus. Roundtable*, 647 F.3d at 1150–51 (agency "did nothing to estimate and quantify the costs it expected companies to incur" from its proxy-access rule, despite the "read[y] availabil[ity]" of empirical evidence on the subject, and "relied upon insufficient empirical data," which were "admittedly (and at best) 'mixed'"); *Chamber of Commerce*, 412 F.3d at 143–44 (agency arbitrarily declined to estimate costs of corporate-governance rule).

The FDA tried to distract from the absence of quantifiable benefits through the "breakeven" method. *See* 81 Fed. Reg. at 29,075. The "breakeven" method takes the *quantified* costs of a rule, and asks how much in otherwise *unquantified* benefits the rule would need to yield to "break even." AR023922. One problem with this analysis is that it compares apples to oranges, contrasting the costs the agency can prove, which are far smaller than the actual costs of the regulation, with the broader and amorphous benefits it cannot. *Id.* It then takes those quantified costs and divides them by the total number of users, to derive what each person would have to pay for the regulatory benefits. AR024026–27. Here, the agency conveniently concluded that its regulation costs only $2 a user and it must be worth at least that much. AR024027. The agency's conclusion is nothing more than assertion, and hardly a relevant one, but even its work along the way was arbitrary.

The FDA assumed that *all roughly 35 million current users of all newly deemed tobacco products*, adults and youth alike, would benefit *equally* from *all provisions* of the deeming rule; the agency conflated all users, regardless of patterns of usage, and all newly deemed tobacco products, with no regard for their vast diversity. A smaller denominator, or even the obvious recognition that all users of cigars, pipe tobacco, and e-cigarettes might not derive the same benefits from the rule, would dramatically change the calculation. Scholars have broadly criticized "breakeven analysis," and the FDA's version is a case in point.[36]

[36] *See, e.g.*, Daniel A. Farber, *Breaking Bad? The Uneasy Case for Regulatory Breakeven Analysis*, 102 Calif. L. Rev. 1469, 1479 (2011) ("although breakeven analysis may sometimes be a useful gauge, it also poses some significant risks," including the risk that "we will make off-the-cuff comparisons that seem intuitively appealing but that actually have no logical basis because they compare magnitudes along entirely different dimensions"); Richard L. Revesz, *Quantifying Regulatory Benefits*, 102 Calif. L. Rev. 1423, 1427 (2014) (breakeven analysis is "only a second-best alternative to the actual valuation of [a] nonquantifiable benefit").

Second, the FDA's analysis explicitly rested on incomplete and inaccurate data. Among the data the FDA said was missing: Data on "usage patterns and health risks for deemed products," AR023927; data on the number of retailers who blend pipe tobacco or the number of hand rollers of premium cigars who sell directly to retailers or consumers, AR023938; data on the number of cigar products in the market, AR023939, AR023984–86; data on the costs of HPHC testing, AR023945; data on cigar samples and associated costs and benefits, AR023953; data on "the impacts of warning labels, premarket review, and marketing restrictions" on cigars and pipe tobacco, AR023973; and data on the cost of premarket applications, AR023996, and substantial equivalence reports, AR024003–04. And this list is hardly exhaustive.[37]

The FDA attempted to fill the glaring gaps in its data through estimates and extrapolations from the agency's experience regulating cigarettes. *See* AR023934 (costs), AR023973 (benefits). However, the agency failed to account for the many material differences in products, user bases,

[37] *See, e.g.*, AR023929 (explaining that the "literature concerning the extent to which individuals are exposed to second-hand cigar and pipe tobacco smoke is limited"); *id.* ("We do not predict the effects of this rule on price, partly because estimating the price increase of newly deemed products due to product consolidation or exit is not straightforward."); *id.* (noting that "the substitutions that occur when many tobacco products' prices rise would be highly uncertain, with the public-health implications impossible to predict"); AR023932 ("Potential substitution towards black market or do-it-yourself products could affect the public health benefits of this final rule. We are unable to predict the likelihood or size of this effect."); AR023933 (discussing the "uncertainty about the effects of premarket authorization requirements on the magnitude of exit across market segments" and the agency's resulting difficulty "quantify[ing] with confidence the number of products that would be taken off the market"); AR023938 ("Without knowing baseline numbers of such entities, it is not possible to estimate exit or compliance costs associated with the rule's expectations for manufacturing activities."); AR023957 ("[W]hile we think the price increase will likely be small for traditional tobacco products, we are unable to estimate the effect of this regulation on prices."); AR023958 ("While we acknowledge that there likely will be product exit and a reduction in variety, we are unable to estimate the value of this loss in consumer choice."); *id.* ("We are unable to estimate the reduction in revenues that would be associated with a possible reduction in consumption."); AR023996 (remarking that PMTAs "may or may not require significant outlays on original research and testing, depending on the extent to which firms can compile the expected elements of the PMTA from existing information").

and usage patterns between cigars and cigarettes.[38] This reasoning lays bare the dearth of analysis behind the premarket review scheme, as cigars and pipe tobacco lack the history of product manipulation allegations in the cigarette industry. Casually hopping from industry to industry, the FDA relied on speculation, arbitrarily rejected contrary evidence, and failed to account for material differences among regulated entities. *See Bus. Roundtable*, 647 F.3d at 1150–51, 1154–56 (agency rested on "mere speculation" regarding director behavior, and failed to consider the distinctive features of investment companies, in projecting the costs and benefits of the proxy-access rule).

Third, many of the FDA's estimates were based on assumptions contradicting the evidence in the administrative record. For instance, the FDA predicted "relatively low" rates of market exit for cigars, pipes, and pipe tobacco "because many products will be grandfathered and most new products will be able to use generally lower-cost pathways to marketing authorization." AR023989; *see also* AR023994–95 (estimating a 60% grandfather rate for cigars, a 90% grandfather rate for pipes, and a 50% grandfather rate for pipe tobacco). Yet the overwhelming evidence confronting the agency suggested that the immense product variety, coupled with the 2007 predicate date, would close the grandfathering and substantial equivalence pathways for swaths of cigars and pipe tobacco.[39] Stunningly, the FDA *did not even estimate* the costs of premarket applications for cigars and pipe tobacco; it simply assumed that *not a single one of these products* would require such an application. AR024006–07; *see* AR023996–4003 (estimated premarket application costs for e-liquids and electronic nicotine delivery systems).

These empirical shortcomings further doom the rule. "[A]gencies do *not* have free rein to use inaccurate data." *Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 56 (D.C. Cir. 2015). "If an agency fails to examine the relevant data—which examination could reveal, *inter alia,* that the

[38] *See supra* Section II.

[39] *See supra* Section II.

figures being used are erroneous—it has failed to comply with the APA." *Id.* at 57. Equally, an agency may not "duck serious evaluation" of potential costs identified in public comments. *Bus. Roundtable*, 647 F.3d at 1152.

B. The FDA's Rule Places an Unreasonable Burden on Small Businesses, Contrary to the APA and the Regulatory Flexibility Act

The FDA's final rule imposes staggering costs on small businesses without adequate justification by the agency. As the Regulatory Flexibility Act ("RFA") makes the interests of small businesses a "relevant factor" for qualifying rules, 5 U.S.C. §§ 603–604, "the APA together with the Regulatory Flexibility Act require that a rule's impact on small businesses be reasonable and reasonably explained," *Nat'l Tel. Coop. Ass'n v. FCC*, 563 F.3d 536, 540 (D.C. Cir. 2009).

The record is replete with evidence demonstrating that the costs of the rule fall disproportionately on small businesses. The agency acknowledged that 90 percent of the entities affected by the final rule were small businesses, AR024044; up to half of the handmade cigars currently available would cease to be marketed in the United States, AR023933; and the estimated costs to small cigar manufacturers or importers would be between $277,750 and $397,350 upfront and no less than $235,060 annually thereafter, AR024043. In a moment of remarkable candor, the FDA conceded that "the traditional segment of the cigar market . . . may be more affected to the extent that it is characterized by a large number of low volume products," that it was "unable to rule out the potential for [the smallest establishments] to be significantly affected by this rule," and that "some firms may exit the market." AR024042–43.

The FDA refused to give due consideration to regulatory alternatives projected to afford meaningful relief to small businesses. The FDA recognized that it could achieve its stated public health goals by subjecting premium cigars to only some of the regulatory regime, and that this

option would considerably reduce the burden on small businesses, but it rejected the option without any serious quantitative analysis. AR023968, AR024045.[40] An office within the Small Business Administration ridiculed the agency's treatment of less destructive alternatives.[41] Likewise, the FDA unreasonably declined to even consider changing the 2007 predicate date as a regulatory alternative, despite evidence that this approach would significantly alleviate the burden on small businesses.[42] And it only compounded this error by assuming, contrary to all available evidence, that 60% of cigars, 90% of pipes, and 50% of pipe tobacco products would be grandfathered using the 2007 predicate date, artificially reducing the incidence of the 220-hour outlays it estimated for *each* full substantial equivalence application. AR023947, AR023995, AR024003.

In short, the FDA failed to engage in the requisite "reasonable, good faith effort to canvass major options and weigh their probable effects." *Nat'l Ass'n of Psychiatric Health Sys. v. Shalala*, 120 F. Supp. 2d 33, 43 (D.D.C. 2000). As "[t]here is no discussion of what, if any, steps the agency took to minimize the significant economic impact on small business," or of "why those alternatives were rejected," the rule violates the APA and must be vacated. *Id.* at 44.

[40] In its general assessment of alternatives, the agency had projected cost savings of between $15.2 million and $42.6 million from Option 2. AR024033. The agency's only explanation for its decision not to perform a like quantitative analysis in its RFA assessment was that it "d[id] not know the number of manufacturers and importers of premium and non-premium cigars." AR024045.

[41] AR082217–18.

[42] *See, e.g.*, AR129901–04; AR159712.

VIII. THE FINAL RULE'S WARNING LABEL REQUIREMENTS VIOLATE THE FIRST AMENDMENT

For sixteen years, the majority of the cigar market has been required to display health warnings mandated by a settlement with the FTC. *See* 79 Fed. Reg. at 23,163.[43] Those not covered by the FTC consent decree post warnings required by the State of California on all of their U.S. packaging. AR021315. The FDA, without studying the efficacy of the existing warnings, made them bigger, expanded them to cover two principal product panels, and confiscated a *dramatically* larger amount of cigar packaging, crowding out manufacturers' ability to speak to their consumers. *See* Declaration of Rocky Patel ("Patel Decl.") ¶¶ 7, 9-11 & Exs. A and B; Declaration of Janelle Rosenfeld ("Rosenfeld Decl.") ¶¶ 3-5 & Ex. A.

Under the FDA's new rule, packages and advertisements for cigars must display one of six warnings randomly over a 12-month period in accordance with a "warning plan" submitted to and approved by the FDA. 81 Fed. Reg. 29,061. As to content, the FDA rule adds one statement to the FTC consent decree rotation. *Id.* at 28,979. The big differences are in size and placement. On labels and packages, the warnings must occupy *30 percent* of the *two* principal display panels and must be in at least 12-point font. *Id.* at 29,061. The "principal display panels" are those "most likely to be displayed, presented, shown, or examined by the consumer." *Id.* at 29,104. For advertisements, the required warning statements must be rotated quarterly, in alternating sequence, and must cover at least 20 percent of print advertisements and other advertisements

[43] On June 26, 2000, seven leading cigar firms, comprised of about 95% of the U.S. cigar market, agreed to display a series of five warning statements "clearly and conspicuously" on their advertising and packaging in settlement agreements with the FTC. *See* Press Release, Fed. Trade Comm'n, FTC Announces Settlements Requiring Disclosure of Cigar Health Risks (June 26, 2000), *available at* https://www.ftc.gov/news-events/press-releases/2000/06/ftc-announces-settlements-requiring-disclosure-cigar-health-risks (hereinafter "FTC consent decree"). The FTC consent decree set out specific requirements for the location and size of the warnings depending on the size and shape of the package. *See* FTC Decision and Order, *In the Matter of Consolidated Cigar Corporation*, Docket No. C-3966 (Aug. 18, 2000).

with a visual component. *Id.* at 29,061. For cigars sold individually and not in product packages, retailers are required to post signs within three inches of the point-of-sale register listing the six warnings on a sign no smaller than 8.5" x 11". *Id.* These new warnings for packages and advertisements are 300-400% larger than those required by the FTC consent decree, and cover two display panels, rather than one. *See* Patel Decl. ¶¶ 6-7 & Exs. A and B; Rosenfeld Decl. ¶¶ 3-5 & Ex. A. Compared to the California labels, the FDA's labels are approximately ten times larger. *Id.* ¶ 5.

The FDA also imposed new warning label requirements on pipe tobacco. 81 Fed. Reg. at 29,060. Under the labeling rule, all pipe tobacco packages must bear the following warning statement on the package label: "WARNING: This product contains nicotine. Nicotine is an addictive chemical." *Id.* at 29,104. The warning must occupy at least 30 percent of the two principal display panels and must be printed in at least 12-point font. *Id.* For print advertisements and other advertisements with a visual component (e.g., signs, shelf-talkers, websites, and e-mails), the warning must occupy at least 20 percent of the area of the advertisement and must be printed in at least 12-point font. *Id.* at 29,104–05.

These new warning label requirements violate the First Amendment. A hallmark of cigar and pipe tobacco marketing, particularly in the premium cigar industry, is aesthetically pleasing packaging connoting luxury and distinctiveness.[44] They also communicate information about the products, such as country of origin, seed varietal, and the process of manufacture. The symbols, trademarks, and trade dress of the package send a message to consumers about the qualities of

[44] *See* AR130350 ("Premium cigars routinely come packaged in ornate boxes, which are part and parcel of the consumer buying experience, and an integral part of cigar manufacturers' marketing."); AR134770 ("Premium cigars are usually packed in decorative boxes, which our customers have come to appreciate as part of the buying experience. As retailers, our humidors are filled with those ornate boxes."); Declaration of John Anderson ("Anderson Decl.") ¶ 9.

the product and the craftsmanship with which it was assembled. *See generally Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 647 (1985) ("The use of illustrations or pictures in advertisements serves important communicative functions: [I]t attracts the attention of the audience to the advertiser's message, and it may also serve to impart information directly."). Commercial packaging is a medium of commercial speech and is entitled to First Amendment protection. *See Rubin v. Coors Brewing Co.*, 514 U.S. 476, 480-83 (1995) (First Amendment applies to information conveyed on beer labels); *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 567 (1980) ("[T]he suppression of advertising reduces the information available for consumer decisions and thereby defeats the purpose of the First Amendment."); *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 762, 765 (1976) (speech "which does 'no more than propose a commercial transaction'" is protected by the First Amendment); *Bad Frog Brewery, Inc. v. N.Y. State Liquor Auth.*, 134 F.3d 87, 96–97 (2d Cir. 1998) (beer label that "communicates no information beyond the source of the product" is entitled to protection as commercial speech).

The FDA's required warning labels will commandeer a significant amount of space on cigar and pipe tobacco packaging and advertisements and effectively crowd out manufacturers' own communication with consumers. As such, the Rule must pass the standard for commercial speech restrictions under *Central Hudson* and the standard for compelled commercial warnings under *Zauderer*.[45] The warning label regulation fails both tests.

[45] The D.C. Circuit has cautioned that compelled disclosure may violate the First Amendment as a prohibition on speech but has declined precisely to specify "when the compulsion to speak becomes more like a speech restriction than a disclosure." *Pursuing Am.'s Greatness v. FEC*, 831 F.3d 500, 507 & n.3 (D.C. Cir. 2016).

A. The FDA Has Failed to Justify its Restriction of Cigar and Pipe Tobacco Manufacturers' Commercial Speech

The FDA has the burden of justifying a regulation restricting the space and prominence of a company's communication with consumers. *See Edenfield v. Fane*, 507 U.S. 761, 770 (1993). The FDA must prove that: (1) the asserted governmental interest is substantial; (2) the regulation directly advances the governmental interest asserted; and (3) the regulation is not more extensive than is necessary to serve that interest. *Cent. Hudson*, 447 U.S. at 566. It cannot do so.

1. The FDA's cigar and pipe tobacco warning label requirements do not serve a substantial government interest

The FDA's stated interest in the new warning label requirements is "to help current and potential tobacco users understand and appreciate the serious adverse health consequences associated with tobacco use and the addictive nature of tobacco products." 79 Fed. Reg. 23,163; *see also id.* at 23,165, 23,166; 81 Fed. Reg. at 28,981; AR023975. Standing alone, this is not a substantial interest under *Central Hudson*.

In *R.J. Reynolds Tobacco Co. v. FDA*, the FDA attempted to justify a cigarette warning label because it was "'effectively communicating health information' regarding the negative effects of cigarettes." 696 F.3d at 1221.[46] The D.C. Circuit found that an interest in "'effective' communication is too vague to stand on its own," as it is "merely a description of the means by which it plans to accomplish its goal of reducing smoking rates, and not an independent interest capable of sustaining the Rule." *Id.* Likewise, efforts to reduce *adult* use of a legal product, such as cigarettes or cigars, cannot justify restrictions of speech:

[46] *American Meat Institute* overruled *R.J. Reynolds*, a compelled speech case, to the extent that it "may be read as . . . limiting *Zauderer* to cases in which the government points to an interest in correcting deception." *Am. Meat Inst.*, 760 F.3d at 22–23. But *R.J. Reynolds*' analysis of *Central Hudson* still stands.

> The State's interest in preventing underage tobacco use is substantial, and even compelling, but it is no less true that the sale and use of tobacco products by adults is a legal activity. We must consider that tobacco retailers and manufacturers have an interest in conveying truthful information about their products to adults, and adults have a corresponding interest in receiving truthful information about tobacco products. . . . As the State protects children from tobacco advertisements, tobacco manufacturers and retailers and their adult consumers still have a protected interest in communication.

Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 564 (2001) (citations omitted). The Supreme Court has recognized only one legitimate interest justifying restrictions of commercial speech regarding tobacco products: Reducing underaged initiation and use. *Id.* at 555.

Underaged use, however, simply is not the same issue for cigars, particularly premium cigars, as it is for cigarettes. *See* Reynolds Decl. ¶¶ 25-48. Only a small percentage (2.5%) of the underaged reported using cigar products, and dramatically fewer for premium cigars, and the number of the underaged using cigars and pipe tobacco has decreased over time. *Id.* ¶¶ 25-27, 29, 39, 44-46. Indeed, a recent FDA-funded study reported *no statistically significant use* of premium cigars by the underaged. *Id.* ¶¶ 25-26. The agency made *no* specific findings regarding underaged pipe tobacco use in the Final Rule and ignored a study reporting youth usage rates of 0.2% for pipe tobacco. 81 Fed. Reg. at 29,048–49. Nor have there been congressional findings that cigar or pipe tobacco manufacturers are targeting their marketing or advertising at the underaged or manipulating their products to appeal to the underaged. *Compare* TCA § 2(47)–(49), 123 Stat. at 1781 (findings regarding marketing and product manipulation in *cigarette* industry). The evidence in the record simply does not indicate a regulatory problem with respect to underaged use of cigars or pipe tobacco, much less one that the warning labels would begin to solve.

2. The warning labels do not directly or materially advance the reduction of underaged cigar and pipe tobacco initiation and use

The FDA also has failed to show that the new warning labels will actually reduce underaged cigar and pipe tobacco initiation and use. The FDA's burden "'is not satisfied by mere speculation or conjecture; rather, a government body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.'" *Rubin*, 514 U.S. at 487 (quoting *Edenfield*, 507 U.S. at 770–71). The agency has conceded, however, that "[r]eliable evidence on the impacts of warning labels . . . on users of cigars [and] pipe tobacco . . . does not, to [the agency's] knowledge, exist," AR023973, and claims it needs to study the issue, *see, e.g.*, 81 Fed. Reg. at 29,065. This is a problem: "*Central Hudson* requires FDA to find and present data supporting its claims *prior to* imposing a burden on commercial speech." *R.J. Reynolds*, 696 F.3d at 1221.

Evidence regarding the efficacy of larger warning labels in reducing *cigarette* use is not enough to justify the agency's broad speech restrictions on cigars and pipe tobacco, which have dramatically different usage patterns, especially among the underaged. Even if such evidence were relevant, it shows that warning labels do not materially affect the causes of underaged smoking. *See* Reynolds Decl. ¶¶ 71-80. The causes of underaged smoking concern peer pressure, modeling, and underaged access and availability. *See id.* ¶¶ 54-70. The record does not include, and Plaintiffs' expert has not found, evidence that underawareness of the health risks of smoking is a cause for underaged use. The agency—just like in *R.J. Reynolds*—did not present data showing that better communication of health risks will reduce smoking among the underaged, a population that regrettably feels invincible no matter what they are told. *See id.* ¶ 59.

3. The warning label requirements are not narrowly tailored

The FDA fails both aspects of the "narrowly-tailored" requirement. First, narrow tailoring "requires a reasonable fit between the means and ends of the regulatory scheme." *Lorillard Tobacco*, 533 U.S. at 561 (discussing *Cent. Hudson*, 447 U.S. at 569). Second, the FDA must show that there are no other options available that "could advance [its] asserted interest in a manner less intrusive to [Plaintiffs'] First Amendment rights." *Rubin*, 514 U.S. at 491.

The FDA hardly has shown a "reasonable fit" between its required warning labels and its stated goals. The warnings commandeer a significant portion of a product's packaging and advertising, occupying 30% of the product's two principal displays and 20% of any advertising. *See Entm't Software Ass'n v. Blagojevich*, 469 F.3d 641, 652 (7th Cir. 2006) (finding that a four-square-inch warning label required to be placed on a 7.5 by 5.5 inch DVD box "*literally* fails to be narrowly tailored—the sticker covers a substantial portion of the box"). The agency has failed to demonstrate why the FTC consent decree or California label requirements for cigars are not adequate or, most importantly, why larger warnings would be more effective. *See* 81 Fed. Reg. at 29,066.[47]

And, of course, the FTC consent decree and California labels on cigars are alternatives less restrictive of speech than the FDA's larger warnings. But the FDA marshalled no data

[47] The FDA may argue, as it did in its Final Rule, that the decision in *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509 (6th Cir. 2012), supports the size of the warning labels. *See* 81 Fed. Reg. at 28,988. In *Discount Tobacco*, however, the court addressed only the standard for compelled commercial disclosures under *Zauderer*. *See* 674 F.3d at 558. Intermediate scrutiny under *Central Hudson* is required here, given the restrictive impact of the warning labels on cigar packaging. *See supra* at Section VIII(A)(1). The *Discount Tobacco* court also reviewed the warning label requirements in that case in the context of decades of alleged conspiracy by certain cigarette companies to deceive the public about the risks and addictiveness of cigarette smoking and their own product manipulation. *See* 674 F.3d at 562–63. There have been no similar findings in the case of cigar manufacturers.

demonstrating the FTC warnings were failing to inform consumers about the health risks of smoking, despite having *sixteen years* to study their effect. The FTC warnings are only one of many alternatives less restrictive of speech that the agency failed to analyze. The government "could disseminate its anti-smoking message itself" through government advertising and public information campaigns. *R.J. Reynolds Tobacco Co. v. FDA*, 845 F. Supp. 2d 266, 276 (D.D.C. 2012), *aff'd on other grounds*, 696 F.3d 1205 (D.C. Cir. 2012), *overruled on other grounds by Am. Meat Inst.*, 760 F.3d 18. There are numerous other established methods that are more likely than larger health warnings to reduce underage tobacco use, including: Raising the minimum legal age to purchase tobacco products; increasing penalties and enforcement measures relating to selling, possessing, or using tobacco products by the underaged; increasing support for programs aimed at the social factors underlying tobacco use by the underaged; and raising the prices of tobacco products. *See* Reynolds Decl. ¶¶ 81-83. All of these measures are directed at the root causes of underaged tobacco use, and involve no restrictions of speech. After all, "regulating speech must be a last—not first—resort." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 373 (2002).

Nor has the FDA shown that it "'carefully calculated' the costs and benefits associated with the burden on speech imposed by its prohibition." *Greater New Orleans Broad. Ass'n, Inc. v. United States*, 527 U.S. 173, 188 (1999); *see also Lorillard*, 533 U.S. at 564–65. Many manufacturers rely on their ornate packaging as a significant way to differentiate their products at the point-of-sale. *See* Patel Decl. ¶ 4; Anderson Decl. ¶ 9. This is particularly important in the premium cigar industry, where customers are often not brand-loyal and regularly look for new products, such that packaging is a means of brand competition.[48] The warnings nearly destroy

[48] *See* AR129897.

this medium, *see* Patel Decl. ¶ 11, but to no end as the agency admits there is no reliable evidence on the impact of warning labels on users of cigars or pipe tobacco, AR023973. The FDA failed to consider the differences from cigarettes in its regulatory scheme. *See Lorillard*, 533 U.S. at 565 ("[T]o the extent that cigar products and cigar advertising differ from that of other tobacco products, that difference should inform the inquiry into what speech restrictions are necessary.").

B. The FDA's Warning Label Requirements Also Fail the Standard for Compelled Commercial Warnings

The Rule also fails the First Amendment standards for compelled commercial disclosures set forth by the Supreme Court in *Zauderer*.

First, there has been no charge of consumer "deception" by cigar or pipe tobacco manufacturers, which is the historical foundation for *Zauderer*'s relaxed scrutiny. *See* 471 U.S. at 651.

Second, the new and unduly burdensome warning labels are "unjustified." In *American Meat Institute*, the D.C. Circuit questioned, but did not resolve, "whether *Zauderer* would permit government reliance on interests that do not qualify as substantial under *Central Hudson*'s standard, a standard that itself seems elusive." 760 F.3d at 23. As discussed above, the agency's stated interest in increasing understanding of the health risks of cigar and pipe tobacco products is not itself an independent value, and the agency has shown no data demonstrating that large (or larger) labels will reduce the incidence of smoking. *See supra* at pp. 51-55.

Third, in the absence of demonstration of need, the size of FDA's warning labels is "unduly burdensome." *See Am. Meat Inst.*, 760 F.3d at 26 (citing *Zauderer*, 471 U.S. at 651). The warning labels confiscate a significant amount of space on cigar and pipe tobacco manufacturers' product packages, where manufacturers would otherwise communicate the

qualities of their products through distinctive trade dress. This is quintessential undue burden. *See, e.g.*, *Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation, Bd. of Accountancy*, 512 U.S. 136, 146 (1994) (disclosure requirement which effectively prevented certain advertisements was unduly burdensome); *Dwyer v. Cappell*, 762 F.3d 275, 284 (3d Cir. 2014) (attorney advertisement rule requiring publication of complete court opinions rather than excerpts commenting on attorney's abilities "is so cumbersome that it effectively nullifies the advertisement"). The warning label requirements therefore fail to satisfy First Amendment scrutiny under either a *Zauderer* or *Central Hudson* analysis.

IX. THE AGENCY UNREASONABLY IMPOSED NEW WARNING LABEL REQUIREMENTS WITHOUT MAKING THE STATUTORILY-MANDATED FINDINGS

The Court, however, need not reach the constitutional question. That is because the FDA's warning label mandate also violates the Act.

The FDA has imposed the new warning labels requirements without even attempting to make the findings Congress required before mandating warning labels. Section 906(d) of the Act authorizes the FDA to require health warnings, "if the Secretary determines that such regulation would be appropriate for the protection of the public health." FD&C Act § 906(d)(1)–(2), 21 U.S.C. § 387f(d)(1)–(2). The Secretary is required to make specific findings in this regard:

> The finding as to whether such regulation would be appropriate for the protection of the public health shall be determined with respect to the risks and benefits of the population as a whole, including users and nonusers of the tobacco product, and taking into account—
>
> > (A) *the increased or decreased likelihood that existing users of tobacco products will stop using such products*; *and*
> >
> > (B) *the increased or decreased likelihood that those who do not use tobacco products will start using such products.*

Id. § 906(d)(1), 21 U.S.C. § 387f(d)(1) (emphases added).

The agency, however, made no determination about the warnings' effect on decreasing cigar or pipe tobacco use or increasing cessation of such use. Instead, the agency simply asserted that the warning labels would help consumers "appreciate the risks" of cigars and pipe tobacco. *E.g.*, 81 Fed. Reg. at 29,064, 29,065, 29,070, 29,075. But that is not the inquiry Congress required. It required a finding that warnings would actually reduce cigar and pipe tobacco use. Stunningly, the FDA admitted it could not make the statutorily mandated finding: "***Reliable evidence on the impacts of warning labels . . . on users of cigars . . . [and] pipe tobacco . . . does not, to our knowledge, exist***." AR023973 (emphasis added). It said it would have to study the issue in the future. *See* 81 Fed. Reg. at 29,065 (the agency intends to "conduct research and keep abreast of scientific developments regarding the efficacy of the health warnings in the final rule and the ways in which their efficacy could be improved"). The statute requires findings on the "increased or decreased likelihood" of smoking initiation or cessation before warnings are imposed, not after. FD&C Act § 906(d)(1), 21 U.S.C. § 387f(d)(1).

Congress was wise to require explicit agency findings that a warning requirement would reduce tobacco use. That is because the *Constitution* requires the same evidence before the government restricts speech. *See supra* at pp. 52-53. If there were any ambiguity about the statutorily required findings before imposing a warning mandate, the Court should demand that the agency find specifically and with evidence that the warnings would reduce tobacco use to avoid the serious constitutional problems that would otherwise result.[49] *See Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988).

[49] This would not solve the constitutional problem altogether, given that reducing tobacco use *by adults* is not a substantial government interest, but it would certainly narrow the scope of the agency's constitutional error. *See supra* at pp. 51-52.

In any event, the statutory mandate to specifically reach whether and how the warnings mandate would reduce tobacco use demonstrates that the Rule is arbitrary and capricious in violation of the APA. "When Congress says a factor is mandatory, that expresses its judgment that such a factor is important. In accordance with this principle, we have held that 'the complete absen[c]e of any discussion' of a statutorily mandated factor 'leaves us with no alternative but to conclude that [the agency] failed to take account of this statutory limit on [its] authority,' making the agency's reasoning arbitrary and capricious." *Pub. Citizen*, 374 F.3d at 1216; *see State Farm*, 463 U.S. at 42–43. The agency conceded that it did not and could not reach an issue Congress made important. The rule is by definition arbitrary and capricious.

Further, the agency did not attempt to show why a change from the FTC consent decree or California schemes was needed for cigars, much less so much to justify the massive costs of the change. Each product will undergo a "major" labeling change, the labeling requirements are "a large contributor to the costs of this rule," and the costs are astronomical. AR023952, AR024017, AR024019. For example, one premium cigar manufacturer has 1,670 unique products.[50] Under the FDA's calculation of the cost for a warning change per product, this manufacturer will need to spend between $2,571,800 and $27,820,530. *See* AR024019.

In the face of these costs, the FDA summarily stated that it "has concluded that the formatting requirements for the health warnings, which are similar to the requirements for smokeless products and similar to those suggested by [WHO Framework Convention on Tobacco Control], are appropriate for the protection of the public health." 81 Fed. Reg. at 29,066. This does not explain why the existing requirements of the FTC consent decree are not also "appropriate for the protection of public health" or what the new warnings add that justifies

[50] AR130285–86 ; AR130361.

their massive costs. There is no question that making the FTC warnings mandatory for that segment of the market not covered by the consent decree would have been dramatically less costly.[51] It was arbitrary and capricious for the agency to upset the status quo without articulating a satisfactory explanation for its decision or considering reasonable alternatives. *See State Farm*, 463 U.S. at 43; *Del. Dep't of Natural Res.*, 785 F.3d at 16–18.

X. THE FDA ERRONEOUSLY INTERPRETED THE TCA TO TREAT RETAILERS WHO BLEND FINISHED PIPE TOBACCO AS TOBACCO PRODUCT MANUFACTURERS

The agency also erred in rewriting the statute to treat small-business pipe tobacco retailers as manufacturers when they blend two finished pipe tobacco products for their customers. In the preamble to the Final Rule, the FDA provided:

> All entities that meet the definition of "tobacco product manufacturer" in section 900(20) of the FD&C Act, ***including retail establishments that blend pipe tobacco***, are subject to and must comply with all applicable statutory and regulatory requirements for tobacco product manufacturers.

81 Fed. Reg. at 29,049 (emphasis added).[52] The agency's interpretation has consequences rippling throughout the Final Rule, including by potentially roping retailers who blend pipe tobacco into its reference to "domestic tobacco manufacturing establishments" and the burdensome requirements of Section 905 of the Act to register with the agency, among many

[51] The agency's failure to seriously analyze the efficacy of larger warnings dovetails with the agency's disregard for the study and research Congress required from the Tobacco Products Scientific Advisory Committee (the "TPSAC" or the "Committee"). FD&C Act § 917(c), 21 U.S.C. § 387q(c). Citing First Amendment concerns, at least one commenter suggested that the FDA defer imposing the warning label requirements on Newly Deemed Products until the FDA or the TPSAC could complete scientific research on dependence issues, taking into account the distinctive usage patterns among different tobacco products. AR160638–39. The FDA declined and made no effort to avail itself of the TPSAC's institutional resources and expertise before subjecting cigars and pipe tobacco to an onerous new labeling regime.

[52] "Tobacco product manufacturer" is defined under the statute as "any person, including any repacker or relabeler, who—(A) manufacturers, fabricates, assembles, processes, or labels a tobacco product; or (B) imports a finished tobacco product for sale or distribution in the United States." FD&C Act § 900(20), 21 U.S.C. § 387(20).

other things. *See* 81 Fed. Reg. at 29,004, 29,049. The consequences of being classified as a tobacco product manufacturer are dramatic: Such retailers will be dragged through the extraordinarily expensive premarket review, product testing, ingredient listing, annual registration, and recordkeeping requirements described above. *See* FD&C Act §§ 904, 905, 909, 910, 21 U.S.C. §§387d, 387e, 387i, 387j. The result will be that retailers cease all blending of pipe tobacco, despite their customers' requests for it.

The agency's interpretation is wrong. Retailers blending finished pipe tobacco are not "manufacturers." They are simply taking two end-use, FDA-approved products and performing a service that consumers themselves could do on their own.[53] Congress understood this. When it referred to "manufacture" of tobacco products in Section 905 of the FD&C Act, it expressly distinguished retailers: "The term 'manufacture, preparation, compounding, or processing' shall include repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package in furtherance of the distribution of the tobacco product from the original place of manufacture to *the person who makes final delivery or sale to the ultimate consumer or user*." *Id.* § 905(a)(1), 21 U.S.C. § 387e(a)(1) (emphasis added). Thus, a retailer—"the person who makes final delivery or sale to the ultimate consumer or user"—cannot be the same as a manufacturer under the Act.

Even if the statute were ambiguous on this point, the agency's interpretation is not reasonable. Instead, the FDA's position threatens to eliminate long-standing and well-known aspects of the industry without any clear statement of justification. Bulk tobacco that is "blended" is itself a finished tobacco product produced by a regulated tobacco product

[53] *See* AR130239–40 ("As a practical matter, FDA should not want to regulate mixing of blends by retailers because retailers receive products that were manufactured by persons subject to FDA's laws and regulations, and blend already mixed and/or processed products on a relatively small scale in a somewhat imprecise way."); AR081246–47 (same); Anderson Decl. ¶¶ 6-7.

manufacturer who will be subject to premarket review. The FDA has not suggested (nor could it) that blending of finished pipe tobacco chemically or physically alters the tobacco in any way, may cause a dangerous chemical reaction in combination, or presents any public health risk distinct from the end consumer products already approved by the FDA.[54] Presumably, the hundreds of years' experience in blending pipe tobacco would have alerted someone to an acute health risk by this point. In marked contrast, the agency specifically explained that the manifold chemicals in cutting-edge e-cigarette liquids could react in ways unforeseen by anyone other than experts. *See* 81 Fed. Reg. at 29,044–46.

The absence of any similar explanation for pipe tobacco is a hallmark of arbitrary and capricious overregulation. The APA expects and demands that agencies distinguish between industries: If there is evidence of public health problems for blended vaping, but not for pipe tobacco, the agency must treat those industries differently. *See Nat'l Wildlife Fed'n v. Hodel*, 839 F.2d 694, 722-23 (D.C. Cir. 1988) (affirming remand of rule where secretary "too swiftly equated surface mining with underground mining for the purpose at hand," despite "'basic differences' between the two operations").

The FDA's interpretation also is unreasonable because it imposes a significant burden and expense on numerous small businesses around the country.[55] The agency admitted that it was "unable to estimate the number of retailers who blend pipe tobacco" and that, "[w]ithout

[54] *See* AR130204 ("To require both the manufacturer and a tobacco retailer to register, list pipe tobaccos and file product ingredient lists would be redundant, especially because pipe tobaccos that are blended together retain their characteristics after the blending, except a new overall flavor is created through the blend.").

[55] *See* AR130240–41 (requesting that FDA include fiscal impact of rule that would regulate retailers who blend tobacco and "include the impact on small, often family-owned, retail stores that blend pipe tobacco"); AR081247 (requirements are "burdensome for a small business owner and superfluous given that the products blended at my shop will have already been approved by the FDA").

knowing baseline numbers of such entities, it is not possible to estimate exit or compliance costs associated with the rule's expectations for manufacturing activities." AR023938; *see also* AR023917. The agency unreasonably punted on this issue. *See Bus. Roundtable*, 647 F.3d at 1148-49; *Chamber of Commerce*, 412 F.3d at 144 ("[U]ncertainty may limit what the Commission can do, but it does not excuse the Commission from its statutory obligation to do what it can to apprise itself—and hence the public and Congress—of the economic consequences of a proposed regulation before it decides whether to adopt the measure."); *supra* at Section VII(B).

XI. THERE IS NO BASIS IN THE STATUTE OR ADMINISTRATIVE RECORD TO TREAT PIPES AS "COMPONENTS" OF A TOBACCO PRODUCT

The FDA concluded that pipes are "components" of a tobacco product and therefore subject to the TCA. *See* 81 Fed. Reg. at 29,042. Its interpretation of the statute would require every pipe manufacturer, from one-man shops in the garage to large corporations, to undergo the crushingly expensive registration and premarket review process. The agency's contention is without merit.

The term "component" in the definition of "tobacco product" in § 201(rr) of the FD&C Act does not include pipes. "Tobacco product" is defined as "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)." FD&C Act § 201(rr)(1), 21 U.S.C. § 321(rr)(1). A "component" is a "*constituent part*" or an "*ingredient*." *See Component*, Merriam-Webster, http://www.merriam-webster.com/dictionary/component; New Webster's Comprehensive Dictionary of the English Language 207 (1985 ed.) ("component" means

"constituent").[56] A pipe is not a *constituent part* or *ingredient* of a product *made or derived from tobacco*, and therefore is not subject to regulation as a tobacco product under the Act.

This is borne out by the use of the term "component" in other parts of the statute. Elsewhere in the statute, the term "component" is used as a concept similar to terms such as "additive," "ingredient," and "constituent." *See, e.g.*, FD&C Act §§ 907(a)(3)(B)(ii) (discussing "an additive, constituent (including a smoke constituent) or other component of a tobacco product"), 907(a)(4)(B)(i) (discussing "provisions respecting the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the tobacco product"), 910(b)(1)(B) (requiring "a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product"), 21 U.S.C. §§ 387g(a)(3)(B)(ii), 387g(a)(4)(B)(i), 387j(b)(1)(B); *see also* TCA § 3(5), 123 Stat. at 1782 (designating as one purpose of the Act "to vest the Food and Drug Administration with the authority to regulate the levels of tar, nicotine, *and other harmful components of tobacco products*" (emphasis added)). A statutory term is known by the traits of its companions, including other terms in a series. *See Gustafson v. Alloyd Co., Inc.*, 513 U.S. 561, 575 (1995) (applying canon of *noscitur a sociis*). All of these terms denote a material that is integrated with a product made of tobacco. A pipe carries tobacco, it is not a part of it, and thus is not a "component" of a tobacco product.

Even if the term "component" were ambiguous, the agency's interpretation is not reasonable, particularly as applied to pipes. The FDA defined "component or part" to mean:

> any software or assembly of materials intended or reasonably expected: (1) [t]o alter or affect the tobacco product's performance, composition, constituents or characteristics; or (2) [t]o be used with or for the human consumption of a tobacco

[56] "In interpreting statutory texts courts use the ordinary meaning of terms unless context requires a different result." *Gonzales v. Carhart*, 550 U.S. 124, 152 (2007).

> product. Component or part excludes anything that is an accessory of a tobacco product.

81 Fed. Reg. at 29,102. The agency separately defined "accessories" because "accessories, unlike components or parts, are expected to have little direct impact on the public health." *Id.* at 28,975. There is nothing in the record to suggest that pipe architecture is being manipulated to make tobacco more addictive or dangerous and have any other direct effect on public health. *See id.* at 29,042.[57] Instead, differentiation among pipes is almost all for aesthetic reasons. *See* Anderson Decl. ¶¶10-11. Pipes are better classified as "accessories."

The FDA's interpretation will lead to regulatory burdens that pose an existential threat to the small craftsmen carving premium pipes. The FDA has not adequately considered the effect of this regulatory action on these particular small businesses. *See, e.g.*, AR023986 (estimating there are at least 4,610 different types of pipes, excluding hand-crafted pipes); AR023989 ("assum[ing]" that 5 percent of baseline newly deemed products, including pipes, will exit the market rather than submit a marketing application); AR024042–44 (failing to specifically address premium pipe craftsman in analysis of economic effect of rule on small entities); *see also supra* at Section VII(B). Thus, once again, the agency acted arbitrarily and capriciously in its failure to adequately assess the economic effects of its rule. *See Bus. Roundtable*, 647 F.3d at 1148–49.

CONCLUSION

Plaintiffs' motion for summary judgment should be granted.

[57] *See also, e.g.*, AR130248 ("PTC believes that there is no public health basis for regulating smoking pipes because pipes have no more of an impact on the public health than humidors or lighters that are exempt from regulation. Subjecting pipes to regulation would overwhelmingly increase the burden on FDA and on pipe manufacturers with no concomitant benefit to the public health.").

Dated: February 13, 2017

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CIGAR ASSOCIATION OF AMERICA, *et al.*,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants.

Civil Action No. 16-1460 (APM)

[PROPOSED] ORDER

This matter is before the Court on the motion of plaintiffs Cigar Association of America (CAA), Cigar Rights of America (CRA), and International Premium Cigar and Pipe Retailers Association (IPCPR) (collectively, "Plaintiffs") for summary judgment against defendants United States Food and Drug Administration, United States Department of Health and Human Services, Thomas E. Price, MD, and Stephen Ostroff, MS (collectively, "FDA") on all of their claims.

Having considered Plaintiffs' motion and supporting papers, the FDA's opposition thereto, the administrative record in this matter, and the argument of counsel, the Court is of the opinion that Plaintiffs are entitled to judgment as a matter of law on their claims.

It is hereby **ORDERED** that:

1. Plaintiffs' motion for summary judgment is **GRANTED**.

2. The Deeming Rule (81 Fed. Reg. 28,974 (May 10, 2016)) is vacated and set aside.

3. The User Fee Rule (81 Fed. Reg. 28,707 (May 10, 2016)) is vacated and set aside.

4. The Court declares that the User Fee Rule violates the Fifth Amendment.

5. The Court declares that the Deeming Rule violates the First Amendment.

6. The FDA is permanently enjoined from implementing or enforcing the Deeming Rule.

7. The FDA is permanently enjoined from implementing or enforcing the User Fee Rule.

8. Plaintiffs shall be awarded reasonable costs and attorneys' fees.

It is **SO ORDERED**.

Dated: _____

AMIT P. MEHTA
United States District Judge

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CIGAR ASSOCIATION OF AMERICA et al.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 16-1460 (APM)
UNITED STATES FOOD AND DRUG ADMINISTRATION et al.,	)	
Defendants.	)	

DECLARATION OF CECIL R. REYNOLDS, PH.D.

I, Cecil R. Reynolds, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

I. Introduction and Issues to be Addressed

1. I am a Professor Emeritus at Texas A&M University, specializing in Educational Psychology and Neuroscience. I taught and conducted research at Texas A&M University from 1981-2007, when I retired, and was subsequently granted Emeritus status by the University Board of Regents. I received my B.A. in Psychology from the University of North Carolina at Wilmington in 1975; an M.Ed. in Psychometrics in 1976 from the University of Georgia; an Ed.S. in School Psychology in 1977, also from the University of Georgia; and a Ph.D. in Educational Psychology in 1978 from the University of Georgia. A true and correct copy of my curriculum vitae is attached as Exhibit 1.

2. I am Board Certified in Clinical Neuropsychology, School Psychology (retired), and Forensic Examination (retired). For approximately 25 years, I maintained a clinical practice as a licensed psychologist, primarily involving the treatment of children and adolescents with a

host of psychological problems, and during that time also served as Chief of Psychology and Director of Neuropsychology at a private psychiatric hospital which had both adolescent and adult addiction units. My clinical experience deals mostly with issues related to child and adolescent development, with an emphasis on evaluation, diagnosis, and treatment of disorders in children and adolescents, including behavioral development. I have served as an editor of various scholarly journals for the last 23 years, having served as editor-in-chief of *Archives of Clinical Neuropsychology* (official journal of the National Academy of Neuropsychology), *Applied Neuropsychology* (official journal of the American Academy of Professional Neuropsychology), and *Psychological Assessment*, an official journal of the American Psychological Association and tEhe leading journal in its field), and currently serve as Editor-in-Chief of the American Psychological Association's open access and data-sharing journal *Archives of Scientific Psychology*. I have served as an Associate editor of many scholarly journals as well and currently serve as an Associate editor of the *Journal of Pediatric Neuropsychology* (official journal of the American Academy of Pediatric Neuropsychology, of which I am also immediate Past-President).

3. I have been asked to address three subjects: (i) the scientific literature and data regarding underage cigar use and the reasons why some underage youth use tobacco; (ii) whether the warnings that are part of the FDA's new deeming rule involving cigars[1] will be more effective in reducing underage cigar use than the warnings currently existing in the marketplace; and (iii) whether there exist alternative programs and activities that could be employed to reduce underage cigar use, and if so, their characteristics.

[1] Final Rule Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28,974 – 29,106 (May 10, 2016) (the "Final Rule").

4. I reviewed scientific literature and leading data sources regarding underage tobacco use for the purposes of my opinions. The data sources that I have reviewed include the U.S. Centers for Disease Control and Prevention Youth Risk Behavior Surveillance System; the National Survey on Drug Use and Health; the National Institute of Child Health and Human Development's National Longitudinal Study of Adolescent to Adult Health; and the University of Michigan's national annual survey of 8th, 10th, and 12th grade students, commonly referred to as the Monitoring the Future survey, which is sponsored by the National Institute on Drug Abuse.

5. In addition, I have relied upon my general knowledge, training, and experience both in teaching about the nature of child and adolescent development and decision-making, as well as my clinical experience in the evaluation, diagnosis, and treatment of children and adolescents developed over my 38 years of clinical experience.

6. I also have reviewed the complete text of both the proposed rule and final rule for deeming additional products subject to the Family Smoking Prevention and Tobacco Control Act (the "Act").[2] The proposed rule was published on April 25, 2014, and the Final Rule was promulgated by the FDA on May 10, 2016. The Final Rule deems all cigars and pipe tobacco subject to the Act. I also have reviewed the Complaint in *Cigar Association of America, et al. v. United States Food and Drug Administration, et al.*, No. 1:16-cv-01460-APM (D.D.C.).

7. The Final Rule includes comprehensive warning label requirements for newly deemed products. Specifically, packages and advertisements for cigars must display one of six warnings randomly over a 12-month period in accordance with a "warning plan" submitted to and approved by the FDA. On labels and packages, the warnings must occupy 30 percent of the two principal display panels and must be at least 12-point font. For advertisements, the required

[2] 79 Fed. Reg. at 23,142-23,207 (the "Proposed Rule"); 81 Fed. Reg. 28,974-29,106 (the "Final Rule").

warning statements must be rotated quarterly, in alternating sequence, and must cover at least 20 percent of print advertisements and other advertisements with a visual component. For cigars sold individually and not in product packages, instead of being required to place warnings directly on the product, retailers are required to post signs at the point of sale listing the six warnings on a 8.5 x 11 inch sign. *See* 81 Fed. Reg. 29,061.

8. A primary purpose of the cigar warning label requirements is educating youth about the effects of cigar smoking and preventing youths from initiating use. 79 Fed. Reg. 23,167; *see also* 79 Fed. Reg. 23,163. The Proposed Rule expresses particular concern for cigarillos and small cigars. *See, e.g.*, 79 Fed. Reg. 23,167 ("Young adults appear to be particularly interested in cigarillos, as opposed to large cigars. . . . Young consumers appear to view little cigars and cigarillos as being less expensive and more convenient than large and premium cigars, contributing to their popularity.").

9. I understand that, in 2000, approximately 95% of the U.S. cigar market reached settlements with the FTC whereby they were required to display conspicuous health warnings on cigar packaging and advertising, the content of which is substantially similar to that outlined in the Final Rule. These warnings were implemented in 2001. I also understand that cigar manufacturers who are not covered by the FTC consent decree often post warnings required by the State of California on all of their U.S. packaging.

II. Summary of Conclusions

10. Underaged tobacco use rates are at historic lows in this country today. Most underaged persons do not smoke cigars and certainly do not smoke them on a regular basis. Surveys show that many more underaged persons have used an illicit drug (a drug banned for persons of any age) in the month before the data collections referred to herein than have smoked a cigar. Some underaged persons engage in a variety of risk behaviors, and those who engage in

risk behaviors are likely to engage in multiple risk behaviors. Underaged risk behavior is typically a result of personal social environment (family and friends) and personality factors (sensation seeking and risk taking preferences), some of which may have biological underpinnings.

11. There are numerous risk factors for underaged tobacco use. The primary factors are peer influence, familial smoking (including particularly smoking by older siblings and parental attitudes about tobacco use), access to tobacco products (especially via parents, older siblings, and older peers), personality factors (sensation seeking and risk taking preferences), and overestimation of prevalence of tobacco use through actual exposure to disproportionate numbers of smokers. The Final Rule's proposed health warnings do nothing to target these primary risk factors.

12. In promulgating the Final Rule, the FDA fails to consider properly that prominent health warnings have been in place on most cigar packaging and advertisements for more than a decade now and fails to establish that the new mandated warnings will have any added impact in terms of preventing underaged youth from smoking cigars, especially as measured against what the data show are the primary risk factors associated with underaged tobacco use. The FDA's rule keeps the content of the marketplace's existing warning scheme largely in place but increases their size, thereby reducing the space on packages, advertisements, and products on which manufacturers may place content of their choosing. I have not been able to locate any reliable or valid scientific evidence demonstrating the changes to the warnings mandated by the Final Rule, at the margins, will be more effective in stopping underaged smoking initiation via cigar use or will contribute to cessation efforts by underaged youth who already use cigars, as compared to warnings already prevalent in the marketplace. From my vantage point as a

behavioral scientist, I do not see the new warning requirements as being incrementally effective interventions.

13. Moreover, the FDA does not introduce data showing the warnings to be incrementally effective interventions with regard to reducing underage *cigar* use. Rather, the FDA relies on findings from cigarette research and attempts to generalize their application to the use of cigars. However, there is no reliable data in the Final Rule or that I have been able otherwise to locate demonstrating the generalizability of warnings-related research on cigarette use to cigar use, especially as it may apply to underage cigar use. In its discussion, the FDA itself recognizes this defect, noting that "reliable evidence on the impact of warning labels . . . on users of cigars . . . does not, to our knowledge, exist."" FDA Final Regulatory Impact Analysis, at 62 (May 2016). The FDA acknowledges the need for such research wherein it indicates in the Final Rule that it intends to conduct research regarding the efficacy of the new warning scheme and further notes that it is acting, at this time, on belief. 79 Fed. Reg. 23,165; 81 Fed. Reg. 29,065.

14. To the extent that it may be appropriate to use data regarding cigarette use, which I do not concede, to predict the effects of anti-smoking or smoking cessation interventions on cigar use, (notwithstanding the lack of reliable evidence supporting such a generalization), those data show there are a number of alternatives to the new warning scheme that could be implemented to reduce underaged tobacco use, including raising the minimum age for the sale, possession, and consumption of tobacco products to 19 years; increasing penalties for underage tobacco use (including penalties with enhanced salience for the underage user (*e.g.*, loss of driver's license)); encouraging parents who may use cigars to restrict access to their tobacco in the home; and increasing the price of the few cigars that are priced at levels accessible to the

underaged. These are simple, straightforward, effective and well-recognized interventions to reduce underaged tobacco use. The Final Rule ignores the numerous alternative programs that the Centers for Disease Control and Prevention ("CDC"), the Substance Abuse and Mental Health Services Administration ("SAMHSA"), and others have identified as being effective (on the basis of empirical research) in reducing tobacco use. These efforts to reduce smoking prevalence—which do not involve the warning changes contemplated by the Final Rule—work.

III. Education, Training, and Experience

15. As noted above, I am a Professor Emeritus at Texas A&M University. I have held the positions of: Distinguished Research Scholar, beginning in 1995; Professor of Neuroscience, beginning in 1993; and Professor of Educational Psychology, beginning in 1984 when I earned tenure. I taught courses primarily in the areas of psychological testing and diagnosis, and neuropsychology. I also supervised clinical practice in testing and assessment. In addition to that work, from 1982 to 1987, I was the Director of the Texas A&M Doctoral School Psychology Training Program.

16. Prior to joining Texas A&M University, I was an Assistant Professor at the University of Nebraska-Lincoln from 1979 to 1981, and I earned tenure there. During the same time, I was Acting Director, then Associate Director, of the Buros Institute of Mental Measurements. The Buros Institute reviews newly published and newly revised psychological testing instruments to determine their appropriateness as compared to standards established in the field.

17. Among my publications are more than forty books that I have authored, coauthored, or edited, including:

- D'Amato, R., Fletcher-Janzen, E., Reynolds, C.R., eds. *The Handbook of School Neuropsychology* (John Wiley & Sons 2005);

- Reynolds, C.R., Kamphaus, R.W., eds. The Handbook of Psychological and Educational Assessment of Children: Vol. 1, Intelligence and Achievement and Vol. 2, Personality, Behavior, and Context (The Guilford Press 2003);

- Reynolds, C.R., Kamphaus, R.W. The Clinician's Guide to the Behavioral Assessment System for Children: BASC (The Guilford Press 2002);

- Ramsay, M., Reynolds, C.R., Kamphaus, R.W. *Essentials of Behavioral Assessment* (John Wiley & Sons 2002);

- Reynolds, C.R., Fletcher-Janzen, E., eds. *Handbook of Clinical Child Neuropsychology* (Plenum 1997); and

- Reynolds, C.R., Gutkin, T.B., eds. *The Handbook of School Psychology*, (John Wiley & Sons 3d ed. 1999).

18. I have authored or co-authored more than three hundred scholarly publications, including refereed journal articles, books, and chapters in edited books. They include the following:

- Bush, S.S., Ruff, R., Troster, A., Barth, J., Koffler, S., Pliskin, N., Reynolds, C.R., Silver, C., *Symptom Validity Assessment: Practice Issues and Medical Necessity*, 20 Archives of Clinical Neuropsychology 419 (2005);

- Reynolds, C.R., Hays, J.R., Ryan-Arredondo, K., When Judges, Laws, Ethics, and Rules of Practice Collide: A Case Study of Assent and Disclosure in Assessment of a Minor, 2 Journal of Forensic Neuropsychology 41 (2001);

- Reynolds, C.R., Inferring Causality From Relational Data and Designs: Historical and Contemporary Lessons for Research and Clinical Practice, 13 The Clinical Neuropsychologist 386 (1999);

- Reynolds, C.R., Richmond, B.O., *What I Think and Feel: A Revised Measure of Children's Manifest Anxiety*, 25 Journal of Abnormal Child Psychology, 15-20 (1997);[3] and

- Ajchenbaum, M., Reynolds, C.R., *A Brief Case Study Using Behavioral Consultation for Behavior Reduction*, 10 School Psychology Review 407 (1981).

[3] This article was reprinted as the most-cited article in the twenty-five year history of the Journal of Abnormal Child Psychology.

19. In addition to writing and editing my own works, I am, and have been, a member of a number of editorial boards for scholarly and scientific journals. Some of the positions that I hold and have held are:

- Editor-in-chief, *Archives of Scientific Psychology* (2014-current);
- Editor-in-Chief, *Psychological Assessment* (2009 to 2014);
- Editor-in Chief, *Applied Neuropsychology* (2004 to 2008);
- Editor-in-Chief, *Archives of Clinical Neuropsychology*, the official scholarly journal of the National Academy of Neuropsychology (1991 to 2002);
- Editorial Advisor, *Child Assessment News* (1992 to 2001);
- Associate Editor, *School Psychology Quarterly* (2002 to 2006 and 1995 to 1997);
- Associate Editor, *Journal of Pediatric Neuropsychology* (2014-indefinite);
- Editorial Board Member, *Psychological Assessment* (2002 to 2008 and 1997 to 1999);
- Editorial Board Member, *Journal of Clinical Child Psychology* (1994 to 1997);
- Editorial Board Member, *Research in the Schools* (1993 to present);
- Editorial Board Member, *Canadian Journal of School Psychology* (1992 to present);
- Editorial Board Member, *Educational and Psychological Measurement* (1980 to present); and
- Editorial Board Member, *Journal of School Psychology* (1980 to 2005).

20. I created several widely used tests of personality and behavior, including the Behavior Assessment System for Children and the Revised Children's Manifest Anxiety Scale.

21. I am a member of, and have held leadership positions in, professional organizations for psychologists and neuropsychologists. Among them are:

- the American Psychological Association, for which I have served as President of the Divisions of School Psychology (2004 and 2005), Clinical Neuropsychology (1999 to 2000), and Evaluation, Measurement, & Statistics (1997 to 1998); have

chaired or served on national task forces for; and have served on association and division committees;

- the American Academy of Pediatric Neuropsychology, for which I served as President from 2014-2016, and currently serve as Past-President;
- the American Board of Professional Neuropsychology, for which I served as President (1996 to 1998) and Executive Committee Member (1993 to 1995);
- the National Academy of Neuropsychology, for which I served as an Executive Board Member-at-large (1999 to 2005) and as President (1986 to 1988); and
- the Coalition of Clinical Practitioners in Neuropsychology, for which I served as an Executive Board Member (2000 to 2002).

22. I have received a number of awards for my work in psychology and neuropsychology, including:

- the Lifetime Achievement Award for Distinguished Contributions from the American Board of School Neuropsychology (2007);
- the Lifetime Achievement Award in Neuropsychology from the National Association of School Psychologists, Neuropsychology Interest Group (2003); and
- the Distinguished Clinical Neuropsychologist Award from the National Academy of Neuropsychology (2000).

23. Since 1983, I have been a Fellow of the American Psychological Association and the National Academy of Neuropsychology.

24. In addition to my academic work, I had an active clinical practice from 1978 to 2003—diagnosing and treating patients, including children and adolescents. Many of the young people who I treated had substance abuse problems. Similarly, I served as Director of Psychology for Sandstone Psychiatric Hospital, in College Station, Texas, from 1990 to 1992. From 1987 to 1989, I was Neuropsychology Director for Sandstone Systems, Inc., and Sandstone Psychiatric Hospital. One of my duties for the Sandstone entities was to conduct psychological assessments of adolescents with substance abuse problems as well as supervise other allied

health professionals conducting such evaluations in the hospital, where I was also charged with quality assurance reviews of all psychological service providers.

IV. Demographics and Trends of Underage Cigar Use

25. Before addressing the risk factors and methods for preventing underage tobacco use in this country, it will be useful to provide some data to illustrate the prevalence of this behavior. A very recent publication I have seen on this issue analyzes data from the FDA Center for Tobacco Products' Population Assessment of Tobacco and Health (PATH) Study, a "nationally representative, longitudinal study of tobacco use and health in the United States." K.A. Kasza, *et al*., *Tobacco-Product Use by Adults and Youths in the United States in 2013 and 2014*, 376 N. Engl. J. Med. 342, 343, 350 (2017) ("Kasza"). Regarding youth (ages 12-17 years of age), the study demonstrated that, as of the data collection period (September 2013 to December 2014):

> Overall, 21.8% of youths had ever used tobacco, 13.4% had ever used cigarettes, 10.7% had ever used e-cigarettes, 7.5% had ever used cigars (with use of cigarillos being most prevalent at 6.5%), 7.5% had ever used hookah, and 4.8% had ever used smokeless tobacco including snus pouches . . . . The overall prevalence of tobacco use in the previous 30 days among youths was 8.9%, with prevalences of 4.6% for cigarette use, 3.1% for e-cigarette use, ***2.5% for cigar use (with cigarillo use being most prevalent at 2.2%)***, 1.7% for hookah use, and 1.6% for use of smokeless tobacco including snus pouches.

Id. at 347 (emphasis added).

26. The Supplementary Appendix to the study reflects more detailed data. Among other things, it shows the use of "traditional cigars"[4] by underaged persons on a "daily" or "frequent" basis is so small or infrequent that it cannot be reliably measured. It is my

[4] "Traditional cigars" were described in the PATH study as follows: "Traditional cigars contain tightly rolled tobacco that is wrapped in a tobacco leaf. Some common brands of cigars include Macanudo, Romeo y Julieta, and Arturo Fuente, but there are many others."

understanding that "traditional cigars" includes premium cigars. (Table S4, at p. 14). It also shows only 2.3% of youths had ever used a traditional cigar. (Table S3, at p. 11).

27. It is clear, then, that the numbers for youth cigar use are quite low and are much lower than the numbers for youth cigarette use. And the very small portion of youths who do use cigars do so on an infrequent basis.

28. I also note that studies the FDA cites (e.g., Final Rule, Ref. 97, 98, 99, 100; Proposed Rule, Ref. 65, 66, 161, 162), do not seem to indicate confusion or under-reporting of *premium* cigar usage by youth. Indeed, a report cited by the FDA shows that, when youth ages 12 to 17 were asked their preferred cigar brand, almost 97 percent of respondents identified non-premium brands as their "preferred" brand (Ref. 59 at FDA 020900). The eight "premium" brands identified in the survey were the "preferred" brand of only 3.8% of the youth survey respondents. (*Id.*) Given these findings, I do not see support for the presumption of Soldz et al. (Ref. 102) that students who did not list certain specified cigar brands "may" prefer premium cigars. I also note that the FDA relies on reports of premium cigar use by "young adults," 81 Fed. Reg. 29,023, but these individuals (ages 18 to 25) are lawful cigar smokers. It also relies on reports of cigar use by adults (Ref. 90, discussed at 81 Fed. Reg. 29,023), which is not directly relevant to youth initiation issues.

29. In September 2016, SAMHSA released similar data reflecting that just 2.1 percent of adolescents aged 12 to 17 were current cigar smokers in 2015. Center for Behavioral Health Statistics and Quality, *Key substance use and mental health indicators in the United States: Results from the 2015 National Survey on Drug Use and Health*, at 16 (2016) ("2016 SAMHSA Report"), *available at* https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR1-2015/NSDUH-FFR1-2015/NSDUH-FFR1-2015.pdf. The report also notes: "A lower percentage of

adolescents in 2015 were current cigar smokers than in 2002 to 2012, although the 2015 estimate was similar to the estimates in 2013 and 2014." *Id*. at 16-17. SAMHSA's data indicate that, as with youth cigarette smoking,[5] there is a downward trend in youth cigar smoking over the past decade and a half. Importantly, there is no reliable scientific evidence demonstrating that current interventions regarding tobacco use have reached a saturation point. Indeed, as discussed further below, many of the known effective interventions are not widely applied.

30. Similar to the PATH study, the SAMHSA report explains that "[t]he majority of current (i.e., past month) tobacco users in 2015 were current cigarette smokers (Figure 13), as has been the case historically. . . . Th[e] same pattern was observed across the three age groups in 2015 (adolescents aged 12 to 17, young adults aged 18 to 25, and adults aged 26 or older), with most current tobacco use consisting only of cigarette smoking[.]" 2016 SAMHSA Report at 13.

31. The University of Michigan has been monitoring the national prevalence of tobacco use (and prevalence of certain other risk behaviors) for high school seniors since 1975, and for 8th and 10th grade students since 1991. The Monitoring the Future ("MTF") survey is large (in 2016, the MTF survey encompassed over 45,000 8th-, 10th-, and 12th-grade students in almost 400 secondary schools nationwide). Because the study includes 12th graders, it reaches a significant number of legal-aged smokers. The MTF survey is considered to produce reliable data regarding tobacco use among these populations.

[5] *See* Kann, L., et al., *Youth Risk Behavior Surveillance — United States, 2015*, MMWR, Vol. 65, at 47 (June 10, 2016) ("MMWR"), *available at* https://www.cdc.gov/healthyyouth/data/yrbs/pdf/2015/ss6506_updated.pdf ("Long-term linear decreases occurred overall in the prevalence of nine of the 10 tobacco use-related risk behaviors (for which long-term trend data were available) (ever trying cigarette smoking; smoking a whole cigarette before age 13 years; current cigarette use; current frequent cigarette use; smoking more than 10 cigarettes per day; currently smoking cigarettes daily; current cigar use; current cigarette or cigar use; and current cigarette, cigar, or smokeless tobacco use. The prevalence of current smokeless tobacco use was the only tobacco-use related risk behavior for which a long-term linear decrease was not identified.").

32. Unfortunately, MTF data regarding cigars only reaches back to 2010 for small cigars and 2014 for cigarillos and large cigars, meaning the data do not outline a broad trend. The data do show, however, significant declines in cigarette and alcohol use.[6]

33. As indicated above, the researchers only introduced questions about cigarillos[7] and large cigars in 2014. They asked about use of these products in the prior 30 days and also asked about flavored versus unflavored little cigars/cigarillos. The report states that there was "no significant change between 2014 and 2015 in the 30-day prevalence of either type, but in 2016, there were declines in all 3 grades, significant in 8th and 12th". *Id*. at 45. "Thirty day prevalence in 2016 was 2.8%, 4.9%, and 9.5% for flavored and 1.9%, 3.0%, and 6.1% for regular small cigars or cigarillos in grades 8, 10, and 12, respectively." *Id*. Regarding large cigars, the rates "were 1.5%, 2.3%, and 6.5% in 2016—with all three grades showing declines in 2016 (significant in 8th and 10th grades)." *Id*.

34. Thus, reliable data clearly illustrate that most students are not smoking any type of cigar; that those who do smoke cigars are not smoking on a regular basis; and that most of those who do smoke cigars are not smoking large or premium cigars. As previously noted, this study includes students in grade 12, many of whom are legal-age smokers.

35. By contrast, underage alcohol use is much more common than cigar smoking among the 8th, 10th, and 12th grade respondents in the University of Michigan's annual survey. This is particularly striking because many high school seniors are of legal smoking age, while almost none are of legal age to possess or consume alcohol.

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[6] *See* Johnston, L.D., *et al*., *Monitoring the Future: National Survey Results on Drug Use: 2016 Overview, Key Findings on Adolescent Drug Use*, at 5 (2017) ("MTF 2016 Key Findings"), *available at* http://www.monitoringthefuture.org/pubs/monographs/mtf-overview2016.pdf ("[C]igarettes and alcohol continued to show significant declines, reaching their lowest levels in the history of the study.").

[7] The report described cigarillos as follows: "Cigarillos lie between little cigars and large cigars in size—length and thickness—and are wrapped in tobacco leaf like large cigars."

> ***Alcohol*** remains the substance most widely used by today's teenagers. Despite recent declines, six out of every ten students (61%) have consumed alcohol (more than just a few sips) by the end of high school, and about a quarter (23%) have done so by 8th grade. In fact, nearly half (46%) of 12th graders and one in eleven (9%) 8th graders in 2016 reported having been drunk at least once in their life.
>
> . . .
>
> In 2016 the proportions of 8th, 10th, and 12th graders who reported drinking an alcoholic beverage in the 30-day period prior to the survey were 7%, 20%, and 33%, respectively.

MTF 2016 Key Findings at 7, 37. The 30-day prevalence alcohol rates are roughly *four to eight times* the large cigar rates for the same period.

36. In fact, according to the MTF data, as reflected in the table attached as Exhibit 2, more than four times as many students in the 8th, 10th, and 12th grades reported using any illicit drug in the past 30 days than reported smoking a large cigar or regular little cigar. And almost three times as many students reported using any illicit drug than reported using a flavored little cigar.

37. I have analyzed data from the National Longitudinal Study of Adolescent to Adult Health (Add Health). This survey is the largest effort by the federal government to collect data concerning risk behaviors among youth and adolescents in the United States, and it was mandated by Congress to collect data for the purpose of measuring the impact of social environment on adolescent health. The survey focuses on factors that promote health and that are detrimental to health. It also seeks to provide insight into factors particular to communities in which adolescents reside. I have presented on the results of that research at a conference held by the National Institute of Child Health and Human Development. These data show that young people and adolescents engage in a variety of risk behaviors. The Add Health data also demonstrate that multiple risk behaviors tend to cluster in those young people who engage in risk behavior. This conclusion has been discussed widely in the scientific literature.

38. The prevalence of various risk taking behaviors is tracked by the CDC as part of its Youth Risk Behavior Surveillance System ("YRBS"). These data are collected from all public and private schools with students in at least one of grades 9-12 in the 50 states and in the District of Columbia. Employing a three-stage cluster sample design, the researchers produced a nationally representative sample of students in grades 9-12 who attended public and private schools. MMWR at 2. This survey seeks to monitor: behaviors that contribute to unintentional and intentional injuries, tobacco use, alcohol and other drug use, sexual behaviors that result in HIV infection or other sexually-transmitted diseases, unintended pregnancies, unhealthy dietary behaviors, and physical inactivity. *Id*. The results of this YRBS survey are published by the CDC and are considered to be reliable and valid. The YRBS data demonstrate that young people in high school engage in a wide variety of risk behaviors. For example, the report notes that:

- During the 30 days before the survey, 32.8% of high school students nationwide had consumed alcohol, and 21.7% had used marijuana. *Id*. at 1.
- Nationwide, 11.5% of students had had sexual intercourse with four or more persons during their life. And among currently sexually active students, only 56.9% had used a condom during their last sexual intercourse. *Id*.

39. The CDC report states that "[n]ationwide, 10.3% of students had smoked cigars, cigarillos, or little cigars on at least 1 day during the 30 days before the survey (i.e., current cigar use)". MMWR at 16. This number is similar to those in the MRF survey but higher than the PATH and SAMHSA numbers, undoubtedly because the CDC and MRF surveys include 18-year olds while the other reports did not. The CDC report also notes: "During 1997–2015, a significant linear decrease occurred overall in the prevalence of current cigar use (22.0%–10.3%). . . . The prevalence of current cigar use decreased significantly from 2013 (12.6%) to 2015 (10.3%)." *Id*. at 17.

40. Notably, the FDA does not rely on the most recent data. The cigar usage numbers cited in the 2015 CDC report are even lower than the numbers in the 2009 CDC report, on which the FDA relies. *See* 79 Fed. Reg. 23,159; *see also* 79 Fed. Reg. 23,160 (citing Ref. 117; data cited were from 2004); 79 Fed. Reg. 23,167 (citing Ref. 35, a 1999 report on youth use of cigars); *id*. (citing Ref. 166, a 2001 report).

41. Similarly, the FDA relies on old data (or data related to cigarettes) to conclude that youth misperceive cigars as being less harmful than cigarettes and underestimate the risks of smoking cigars.[8] *See, e.g*., 79 Fed. Reg. 23,158 (citing, in addition to Ref. 35 (the 1999 report), Ref. 116, a 2001 report discussing cigar risk perceptions in focus groups of urban African American youth, to claim that certain youth "had received very little cigar-specific health education, ***reinforcing the importance of alerting consumers about the dangers of smoking cigars***") (emphasis added); 79 Fed. Reg. 23,159 (citing Ref. 123, a 2000 study regarding adolescent smokers' perception of health risks from *cigarettes*); 79 Fed. Reg. 23,168 (citing Ref. 28, a 1998 report, for the proposition that "FDA believes that a warning regarding . . . . potential health consequences is necessary because of consumers' widely held, but erroneous, belief that cigars are safe products if users do not inhale the smoke"); *id*. (citing Ref. 30, a 2000 report identifying cigar smokers' "optimistic bias" in estimates of their risk of developing cancer, in support of a claimed need for warnings to help smokers "better understand and internalize" potential and critical health consequences).

42. These older studies on which the FDA relies may not reflect current levels of awareness or the impact of national, state, and local education campaigns and other measures that have taken place over more recent years. Critically, these studies cited by the FDA also

[8] Some of the sources the FDA cites for this proposition do not support it. *See, e.g*., 79 Fed. Reg. 23,158 (citing Ref. 117).

predate the 2001 implementation of the FTC's 2000 settlement with the seven largest U.S. cigar companies, which, as I understand it, required that almost every cigar package and advertisement prominently display an approved warning about cigar smoking. One of the approved warnings is: "SURGEON GENERAL WARNING: Cigars Are Not A Safe Alternative To Cigarettes."

43. When the FDA does cite some newer data, it often relates solely to cigarettes. For example, the FDA points to the 2010 MTF report to claim that the proportions of students seeing a great risk associated with being a smoker and disapproving of smoking or attaching negative connotations to it have leveled off. 79 Fed. Reg. 23,159 (citing Ref. 83). However, this discussion in the report is only referring to cigarettes. *See also, e.g.*, 79 Fed. Reg. 23,1598 (citing Ref. 120 and 121, which do not concern cigars, regarding mistaken beliefs about product risks).

44. The FDA relies on a June 2014 Morbidity and Mortality Weekly Report discussing results of the Youth Risk Behavior Surveillance – United States, 2013. 81 Fed. Reg. 29,023 (discussing Ref. 96). It picks two pieces of data that appear to show that cigar use is as prevalent as cigarette use. Instead, when total numbers are reviewed, it shows that cigar use is less prevalent (12.6 percent – Table 39) than cigarette use (15.7 percent – Table 31). The report also notes a "significant linear decrease occurred overall in the prevalence of current cigar use" between 1997 and 2013. FDA 018195.

45. The FDA also discusses that, in 2014, the 2011–2014 National Youth Tobacco Surveys reported that among high school Non-Hispanic black students, 8.8 percent reported smoking cigars in the past 30 days, whereas 4.5 percent reported smoking cigarettes in the past 30 days. 81 Fed. Reg. 29,023 (discussing Ref. 22). Once again, the agency seems to pick out isolated pieces of data that are most favorable to its position. When total use is measured, cigar use is less than cigarette use at both middle school and high school levels. FDA 015634.

E-cigarettes were the most commonly used tobacco products at the high school level. The report also notes statistically significant nonlinear decreases for current cigar use for middle and high school students. FDA 015635-36.

46. The FDA suggests there is a lack of decline in cigar smoking (81 Fed. Reg. 29,023), but the research report it cites (Ref. 101) focuses primarily on concurrent use of multiple products. The data in this report also only extend to 2011. Other data cited by the FDA itself in fact show a decrease in cigar use in more recent time (Ref. 22 at FDA 015635).

47. The FDA also expresses concern that non-cigarette tobacco products may be a gateway to cigarette addiction. 79 Fed. Reg. 23,159. However, after citing studies that do not appear to involve cigars (bur rather concern smokeless tobacco, e-cigarettes, and waterpipes), the FDA admitted that "[i]t is not yet clear whether users of the proposed deemed products go on to become addicted to cigarettes."[9] *Id*.

48. In sum, very few youth are currently using cigar products, and the rate of usage is decreasing over time—without the FDA's newly required changes to the warning label scheme.

V. The New York City Tobacco Control Program and New York Smoking Rates

49. To the extent that it may be appropriate to use data regarding cigarette use to predict the effects of anti-smoking or smoking cessation interventions on cigar use, the New York City Tobacco Control Program's effect on New York City (hereinafter the "City") smoking rates is instructive. The City implemented a comprehensive tobacco control program in 2002. *See* T. Frieden, *et al., Adult Tobacco Use Levels After Intensive Tobacco Control Measures: New York City, 2002-2003*, 95 Am. J. Pub. Health 1016 (2005) ("Frieden"). This program was based on a five factored approach. *First*, the City increased cigarette taxes; *second*, the City passed the

[9] The FDA also cites a 1999 report (Ref. 35) for the proposition that "young people who start as cigar-only users are more susceptible to becoming future cigarette users than other youth" (79 Fed. Reg. 23,167); but the report does not appear to discuss this issue.

Smoke Free Air Act ("SFAA"), which banned virtually all smoking in bars; *third*, the City sent nicotine treatment guidelines to all physicians within the City and began giving away nicotine patches; *fourth*, the City increased its public communication efforts regarding smoking and health; and *fifth*, the City began a process of systematically evaluating smoking-related health data. *Id*. at 1016; *see also* New York City Global Partners, *Best Practice: Tobacco Control Program*, at 1-2 (Feb. 3, 2014) ("Global Partners"), *available at* http://www.nyc.gov/html/ia/gprb/downloads/pdf/NYC_Health_TobaccoControl.pdf.

50. The City Department of Health conducted multiple surveys a year after these measures were implemented and concluded that the measures were having a significant impact on smoking rates in New York City across the board. In particular, the City concluded that increased taxation of cigarettes, which otherwise would have a lower and more accessible unit cost, was the "primary reason" for the decline. Frieden at 1020-21.

51. After 2002, the City continued to pursue its five-pronged tobacco control program, and smoking rates continued to decline. For example, the City put in place a dedicated smoking cessation hotline and combined it with media campaigns aimed at reducing smoking in the City. *New York City Department of Health and Mental Hygiene: Triennial Report* 15 (2006). Similarly, the City increased its cessation programs by providing the public with large numbers of free nicotine replacement therapy treatments. *Id*. at 16. The City also enacted additional legislation to limit smoking. In 2009, the City amended the SFAA to prohibit smoking on hospital grounds and within 15 feet of any hospital entrance or exit. Global Partners at 1. It also restricted the sale of flavored non-cigarette tobacco products in 2009. *Id*.

52. Between 2001 and 2011, there was a 52% decline in smoking among New York City public high school students. And between 2002 and 2012, there was an almost 30% decline in smoking prevalence among New York City adults. *Id*. at 4-5.

53. Thus, the use and implementation of similar programs is a clearly available option, with data to support effectiveness in reducing tobacco use, including among underage users.

VI. Risk Factors for Underage Tobacco Use

54. To the extent that it may be appropriate to use data regarding cigarette use to predict the effects of anti-smoking or smoking cessation interventions on cigar use, social science researchers have, for decades, studied the factors that appear to be associated with underage tobacco use. Because most tobacco use by the underaged is of cigarettes, much of the data concern cigarettes, although some do reach other tobacco products. Risk factors for tobacco and alcohol use in adolescents may number near 100 (for example, see variables noted in Stephenson, *et al*., *Brief measures of sensation seeking for screening and large-scale surveys*, 72 Drug & Alcohol Dependence 279 (2003); Oscar G. Bukstein, *Disruptive Behavior Disorders & Substance Use Disorders in Adolescents*, 32 J. Psychoactive Drugs 67 (2000); A. Johnson & John P. Hoffman, *Adolescent Cigarette Smoking in the U.S. Racial/Ethnic Subgroups: Findings from the National Education Longitudinal Study*, 41 J. Health & Social Behavior 392 (2000)). This literature has reported that smoking by peers, other family members (particularly older siblings and/or the mother), girlfriends/boyfriends, and personality factors (e.g., propensity for engaging in risk taking behavior) are consistently and highly correlated with underage tobacco use. This conclusion is consistent with the importance of interpersonal influence on social lifestyle behaviors, such as tobacco use or alcohol use.

55. More particularly, in my research, I have identified a number of factors that predict underage tobacco use, including:

(a) Parental influence—The adolescent's interactions with and observations of his parents or primary caretakers concerning tobacco use can be influential. If one or both parents smoke, an adolescent is at higher risk for smoking, especially if tobacco products are easily available to him in the home. When an adolescent lives in a home with one parent, or none, or if his daily life otherwise contains a large amount of unsupervised time, risk of tobacco use also increases. But if the adolescent perceives that one or both parents disapprove of smoking, even if they are smokers, risk of smoking initiation is reduced. In addition, an adolescent is protected from initiating smoking behavior if he feels emotionally connected to one or both parents, he spends time with his parents, and his parents have high expectations for his educational success.

(b) Peer influence—The data show the perceived attitudes of an adolescent's friends about smoking and smoking behavior are highly correlated to smoking initiation and prevalence. In seeking independence, a child begins to value peer approval and acceptance over parental approval and acceptance. Therefore, if an adolescent's friends approve of smoking, the subject adolescent is more likely to start smoking himself. If the friends do not approve of smoking, the risk of initiation is lessened. Similarly, as the number of an adolescent's smoking friends increases, so does the risk that the adolescent will begin smoking. In addition, girlfriends and boyfriends can exert influence regarding tobacco use. Adolescents also may identify with other attributes of adolescents who smoke and initiate smoking in order to be like them or to become a part of their peer group. Adolescent girls who date older males who smoke (and who

may or may not be legal age smokers) are more likely to initiate smoking in association with such dating patterns.

(c) Sibling influence—Sibling influence is similar to parental influence in that the presence of older siblings who smoke is a risk factor for younger adolescents. Adolescents may be influenced to try smoking because an older sibling is doing it. Siblings also are a source for tobacco products for younger adolescents.

(d) School environment—Several aspects of the school environment can be relevant to the likelihood of tobacco use, including lack of enforcement of underage nonsmoking or other tobacco use policies, as well as use of tobacco products by students, teachers, and other school personnel. Tobacco use at school may be influential for a number of reasons, including peer exposure and use, and the modeling of tobacco use by adults (and/or the extent of disapproval of such use). High schools with higher rates of senior class smokers (the majority of whom are projected to be legal age smokers) have higher rates of underage/underclass smoking initiation. School factors such as those described above may also result in a young person's overestimation of the prevalence of tobacco use.

(e) The nature of adolescence—During adolescence, youth seek independence from their parents and families. They seek new sensations. They experiment. They take risks to push the boundaries from protected childhood. This is, of course, true not only for tobacco products, but for a range of other risk behaviors, such as reflected in the data discussed above from the MTF and YRBS surveys.

56. The 1994 Surgeon General's report entitled Preventing Tobacco Use Among Young People: A Report of the Surgeon General collected and summarized approximately 160 studies on the subject of the psychosocial risk factors associated with underage tobacco use. *Id*.

at 149-156 (chapter references). Chapter 4 discusses numerous risk factors for underage tobacco use, including:

- *Socio-economic status* (*id*. at 93 ("Low socioeconomic status (SES) has been shown to predict smoking initiation in multiple longitudinal studies.));
- *Parental education level* (*id*. ("The level of parental education has been shown to have a significant impact on adolescent smoking behavior in some studies.));
- *Poor academic achievement* (*id*. at 99 ("The onset of smoking has been shown repeatedly to be related to poor academic achievement.));
- *Single-parent household* (*id*. at 93 ("Several studies document an association between beginning to smoke during childhood or adolescence and living in a single parent home.));
- *Ethnic background* (*id*. at 94 ("Research also indicates that the rate of smoking initiation varies among ethnic groups.")), for example, African American minors are much less likely to smoke than their Caucasian peers;
- *Access to tobacco products* (*id*. at 95 ("Several studies have found that the general availability of cigarettes predicts the onset of smoking.));
- *Over-estimating the prevalence of smoking* (*id*. at 98 ("adolescents who made relatively high estimates of regular smoking prevalence were more likely to try smoking, to become smokers, or to increase the amount they smoked" and observing that overestimation of the prevalence of smoking "may be a function of these beginning smokers' actual exposure to a disproportionate number of smokers, including adults and peers"));
- *Social support for smoking* (*id*. ("Social support includes perceived approval or disapproval of adolescent cigarette smoking by parents, siblings, peers, and important others, such as teachers or employers. One way that social support is manifested is through peer-group pressure, either through support or discouragement of smoking.));
- *Parental smoking* (*id*. at 95-96 (reporting this to be an influential factor in some research, while also suggesting that results have been mixed));
- *Parental attitudes towards smoking* (*id*. at 98 ("Parental reaction to use and perceived parental strictness have also been associated with onset.));
- *Sibling smoking* (*id*. at 96 ("Over the past two decades, extensive research on the influence of sibling smoking indicates a primarily positive relationship between an older sibling's smoking and a younger (adolescent) sibling's beginning to smoke.));

- *Peer/friend smoking* (*id*. at 97 ("Multiple cross-sectional and longitudinal studies worldwide substantiate the relationship between smoking onset and peers' (or friends') smoking."; "One of the areas of widest investigation in the antecedents of cigarette smoking concerns peer smoking and related peer behaviors. . . . The influence of peers has been posited as the single most important factor in determining when and how cigarettes are first tried.")));

- *Personality factors* (*id*. at 99-100 ("A risk-taking orientation (that is, an inclination toward excitement and chance taking) was similarly associated with trying a cigarette for the first or second time (Leventhal, Fleming, Glynn 1988). Risk taking also was a significant predictor of smoking initiation in the Collins et al. (1987) study of 11- and 12-year-olds in Los Angeles." "Some adolescents see problem behaviors as a way to achieve—and signal to others—the precocious transition to independence and autonomy.")).

57. Of the 23 psychosocial risk factors discussed in detail by the Surgeon General, tobacco advertising is designated a distal or indirect risk factor (as opposed to a proximal or direct risk factor). In a tabled summary (p. 96) of research on predictors of smoking onset, 17 predictors were noted, 15 of which were seen to have support in a majority of the research studies of these predictors or risk factors; yet advertising did not appear in these predictors.

58. In 2012, the Surgeon General updated this report. *See* Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General, 2012 ("2012 Surgeon General Report"), *available at* https://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/prevent_youth_by_section.html. While the 2012 report is largely consistent with the 1994 report, it highlights new areas of research related to the causes of youth smoking gleaned since publication of the 1994 report. The 2012 report organizes risk factors for smoking initiation into four conceptual groupings to promote a better understanding of these influences and how they might act:

- *Large Social and Physical Environments* that may promote the use of tobacco.

    - "The large social environment defines the norms within a society about whether, when and for whom smoking is acceptable." *Id*. at 431. Large social environments include religious doctrines, race, gender,

socioeconomic status, educational and academic achievement, schools, and extracurricular activities. *Id*. at 431-37.

- Large physical environments are "public and private spaces that may make tobacco use more . . . tolerated or enjoyable. Features of the environment that promote smoking include the tolerance of this activity in public spaces; proximity to entertainment, recreation, and social interaction; and locations that are relatively unlikely to be monitored by adults." *Id*. at 437.

- *Small Social Groups*, such as family and friends who smoke and social approval of smoking. *Id*. at 439-40. "***Peer influences seem to be especially salient***, perhaps because adolescence is a time during which school and peer group affiliations take on particular importance." *Id*. at 458 (emphasis added).

- *Cognitive and affective processes* play an important role in adolescent smoking. *Id*. at 445.

  - Adolescents who "demonstrate higher levels of negative affect . . . are likely related to smoking initiation." *Id*. "A robust association between youth smoking and negative affect has been demonstrated in the literature." *Id*. at 450.

  - Both automatic and controlled cognitive processes influence behavior and youth initiation to tobacco use. "Implicit associations, or more spontaneously activated cognitions, may help to explain why some people engage in apparently irrational behaviors, such as smoking, while clearly knowing that the behavior can have negative consequences." *Id*. at 450.

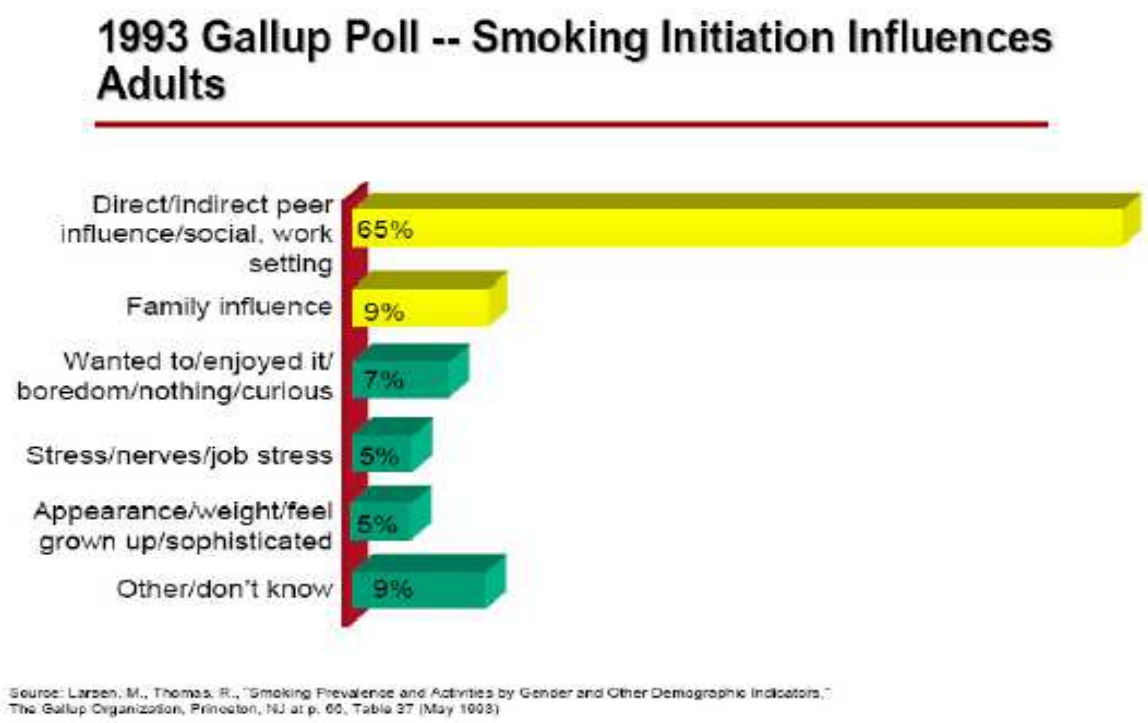
- *Genetic factors and neurobiological and neurodevelopmental processes*, including addiction to nicotine may predispose a person to seek out the use of tobacco. *Id*. at 451. The evidence in the 2012 report suggests that smoking behavior may be heritable. *Id*.

59. The research does not support the conclusion that awareness (or perhaps lack of awareness) of the long-term health effects of smoking is predictive in distinguishing between underage persons who smoke and those who do not. And as the Surgeon General notes, people engage in smoking while clearly knowing that it can have negative health consequences. For adolescents who initiate smoking while underaged, this may be due to their tendency to believe these negative consequences, as well as the negative consequences of most all other risky behaviors, will only manifest in others and not themselves as individuals.

60. Hudmon, *et al*., *Psychometric Properties of the Decisional Balance Scale and the Temptations to Try Smoking Inventory in Adolescents*, 6 J. Child & Adolescent Substance Abuse 1 (1997) developed a decisional scale that may shed light on factors relating to underage tobacco use. They determined that four summary factors appear related to when and perhaps why (causal determinations being extremely difficult with relational data) young people decide to smoke: social interactions, emotional modulation, peer pressure, and simple curiosity. These researchers subsequently were able to differentiate smokers and nonsmokers quite well. They also asked direct questions about the decision to smoke.

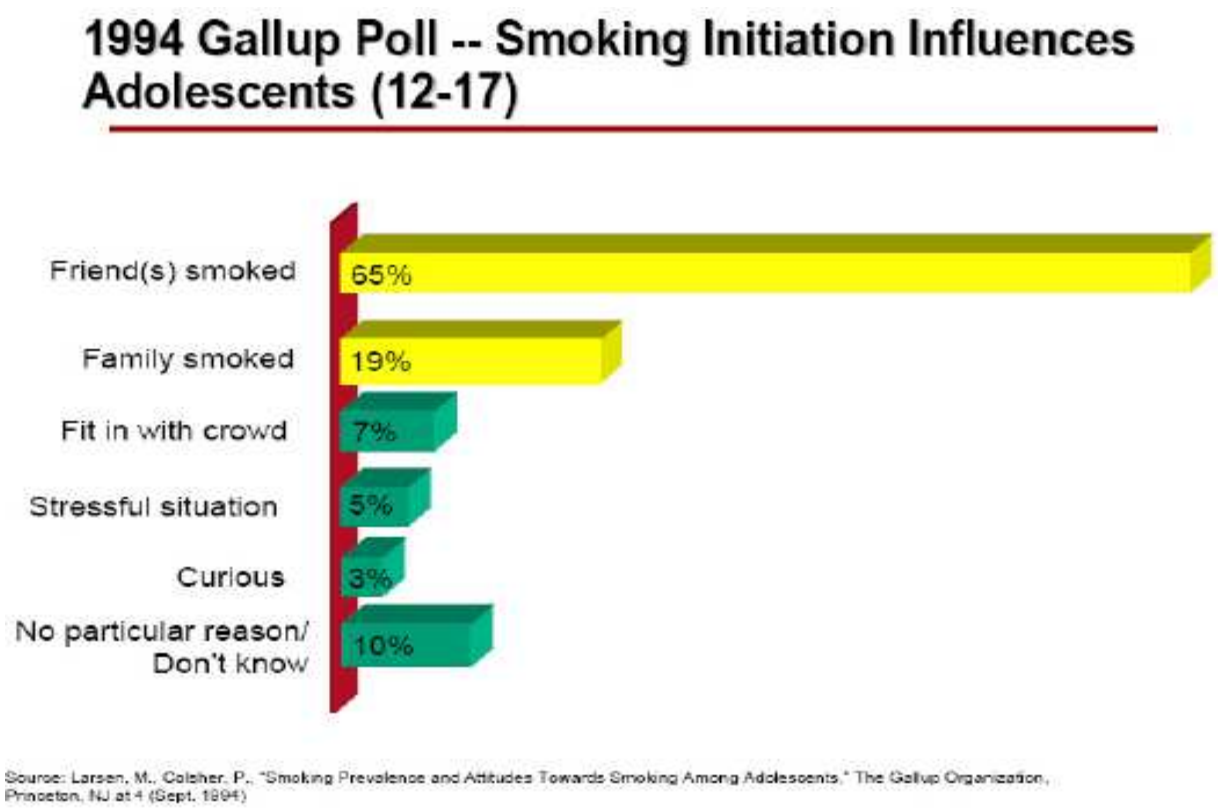
61. In my clinical practice, I routinely asked my underage patients who used tobacco (and other substances such as alcohol and illicit drugs) about their experience and reasons for initiation, and these patients consistently tied their tobacco use to the important interpersonal relationships in their lives. I never had a patient mention advertising or a lack of knowledge about the health effects of smoking as a component of their decision.

62. There is limited polling data including questions that have asked both adults and youth why they smoke. The Gallup polling organization asked adults in 1993: "We are interested in knowing, as best you can recall, what influenced you to start smoking. Please think back to when you first started smoking. What person or event caused you to start smoking?" The Gallup Org., *Smoking Prevalence, Beliefs and Activities, by Gender and Other Demographic Indicators* at 66, Table 37 (May 1993). The results are reflected in the chart below:



63. The question was open-ended and the responses were recorded and reflected the powerful role of peer and familial influence from the perspective of the adults who reported they smoked.

64. A similar national poll was conducted by Gallup the following year involving persons age 12-17. The Gallup Org., *Smoking Prevalence and Attitudes Towards Smoking Among Adolescents* (Sept. 1994). The results are reflected in the chart below:



Source: Larsen, M., Colsher, P., "Smoking Prevalence and Attitudes Towards Smoking Among Adolescents," The Gallup Organization, Princeton, NJ at 4 (Sept. 1994)

65. As these data similarly reflect, if you ask young people to describe why they smoke, they almost always attribute that decision to the influences of friends or family members' smoking. I understand this question has not been asked again by the Gallup Organization to adults or minors.

66. The FDA conducted focus groups with underage persons in the mid-1990s in connection with its proposed regulations of cigarettes and smokeless tobacco. *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents: Findings of the Focus Group Testing of Brief Statements for Cigarette Advertisements*, 60 Fed. Reg. 61,670 (Dec. 1, 1995). According to the FDA's summary of these focus groups of 12-17 year-olds, "[t]he major reasons given for why teens try smoking included: peer pressure; doing something that adults would not approve of; the perception of smoking as a 'cool' activity; curiosity; and being around parents, other family members and

friends who smoke." *Id*. at 61,673. The FDA apparently specifically prompted the participants about the role of cigarette marketing and reported: "Most of the participants indicated that they did not believe that they were influenced by cigarette advertisements." *Id*. at 61,674.

67. The results obtained by the Gallup Organization and the FDA are consistent with my own clinical experience interacting with young people who indicated they used tobacco.

68. My research and experience indicate that most youth who smoke have a friend and/or family member that smokes and usually started smoking with their peers. For example, the Surgeon General observed in her 1994 report: "Adolescents usually try their first cigarettes with their peers; peer groups may subsequently provide expectations, reinforcement, and opportunities for continuation." 1994 Surgeon General Report at 105. The 2012 follow-up to this report concluded that "[t]he evidence is sufficient to conclude that there is a causal relationship between peer group social influences and the initiation and maintenance of smoking behaviors during adolescence." 2012 Surgeon General Report at 460; *see also* Miech, R.A., *et al*., *Monitoring the Future: National Survey Results on Drug Use: 2015 Volume 1, Secondary School Students*, at 442 (2016), *available at* http://www.monitoringthefuture.org/pubs/monographs/mtf-vol1_2015.pdf ("It is generally acknowledged that peer influences are among the most powerful mechanisms of substance use initiation during adolescence. Much youthful drug use is initiated through a peer social-learning process, and research, including our own, has shown a high correlation between an individual's illicit drug use and that of his or her friends.").

69. My analyses of the Add Health data are consistent with the previous literature regarding the risk factors associated with underage tobacco use. These data establish that smoking by parents, siblings, and friends are the major factors predicting smoking of respondents in the survey data, regardless of the amount smoked by the respondent. The Add

Health data also establish that personality factors are associated with underage risk behavior, including smoking.

70. The Add Health data also reflect that access to tobacco products is an important risk factor for initiation. One report on these data notes: "Not only is parent behavior important in shaping health outcomes, so, too, is the home environment. If adolescents have easy access to cigarettes, alcohol, and marijuana at home, they are more likely to use these substances." Blum, *et al*., *Reducing the Risk, Connections That Make a Difference in the Lives of Youth*, 31 (1997).

VII. There Is No Reliable Evidence Demonstrating The Final Rule's Changes to the Cigar Warning Scheme Will Have an Incremental Effect on Underaged Cigar Use

71. I have reviewed the warning requirements of the Final Rule. I have seen no reliable or valid scientific evidence demonstrating the changes to the warnings mandated by the Final Rule, at the margins, will stop first-time underaged cigar use or will contribute to cessation efforts by those few underaged persons who already smoke cigars.

72. In discussing the "Effectiveness of Warnings" in the Proposed Rule (and the "appropriateness" of the warnings in the Final Rule), the FDA relies on reports and studies that are principally works related to cigarette usage as opposed to cigars and that:

- concern warnings that differ from those at issue in the Proposed Rule (for example, graphic warnings)[10];
- look at warnings through surveys conducted well over a decade ago, when there was less awareness of the harms of smoking; and/or
- examine warnings instituted in other countries, with different cultures, levels of education, and legal restrictions on tobacco.[11]

[10] *See, e.g*., 79 Fed. Reg. 23,164 (citing Ref. 150, Elliott & Shanahan Research, "Literature Review: Evaluation of the Effectiveness of the Graphic Health Warnings on Tobacco Product Packaging 2008," prepared for Department of Health and Ageing, Commonwealth of Australia, 2009).

See 79 Fed. Reg. 23,164 – 23,165; 81 Fed. Reg. 29,064. The FDA's sources tend to discuss specifically cigarettes or smokeless tobacco—or at least are not specific to cigars—as well as adult smokers. I find it puzzling that some of the references cited by the FDA in this section do not even concern warnings and therefore cannot be read to support its conclusions about the effectiveness of warnings concerning cigarette usage, much less cigars.[12]

73. It is my understanding that, since 2001, companies representing approximately 95% of the U.S. cigar market at that time have been required to display warning statements about "significant adverse health risks of cigar use"—the content of which is substantially similar to those outlined in the Final Rule—"clearly and conspicuously" on their advertising and packaging.[13] The consent orders require that the cigar warnings be rotated, and they set out detailed format requirements "designed to ensure that the warnings are visible and readable." FTC Announcement. The only significant change made by the Final Rule was to increase the size of the warning statement. As far as I can tell, the FDA has not directly addressed whether the warnings for cigars already required by the FTC consent decree are failing to achieve their purpose, or provided reliable evidence showing that increasing the size of the warnings as proposed would have an incremental effect on the incidence of smoking initiation via cigars by

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[11] *See, e.g.*, 79 Fed. Reg. 23,164 (citing Ref. 153, which states, at page iii20: "At present [2005], cigarette packages in virtually every country carry warning labels, yet the size, number, and the way the health information is presented differs notably between countries. Labelling policies range from vague statements of risk (for example, 'Smoking can be harmful to your health'), to graphic pictorial depictions of disease.").

[12] *See, e.g.*, 79 Fed. Reg. 23,164 (citing Ref. 56, an article entitled "Adolescent vs. adult-onset nicotine self-administration in male rats: Duration of effect and differential nicotinic receptor correlates," for the proposition that "[t]he messages on packages also help the public at large, including potential tobacco users, better understand and appreciate the health and addictiveness risks of using the products.").

[13] *See* FTC Announces Settlements Requiring Disclosure of Cigar Health Risks: Landmark Agreements Require Strong Warnings on Both Packaging and Advertisements, Federal Trade Commission (June 26, 2000), *available at* https://www.ftc.gov/news-events/press-releases/2000/06/ftc-announces-settlements-requiring-disclosure-cigar-health-risks ("FTC Announcement"); *see also* Federal Trade Commission, Nationwide Labeling Rules for Cigar Packaging and Ads Take Effect Today. Federal Trade Commission (Feb. 13, 2001), *available at* https://www.ftc.gov/news-events/press-releases/2001/02/nationwide-labeling-rules-cigar-packaging-and-ads-take-effect.

underaged persons. This is surprising, given that the rate of cigar usage by youth has decreased since the 2001 warnings were put in place.

74. It is also my understanding that cigar manufacturers who are not covered by the FTC consent decree often post warnings required by the State of California on all of their U.S. packaging.[14] But the FDA also has not addressed the efficacy of these warning statements in its Final Rule.

75. The FDA's discussion of health warnings in the Proposed Rule also points to what the FDA characterizes as the "small warnings labels" that have existed for cigarettes and smokeless tobacco products for decades in support of a claimed need for bigger health warnings that admittedly "adopt[ ] the existing FTC warning language." 79 Fed. Reg. 23,165. But even if the FDA correctly concluded that the size of the cigarette warnings is insufficient to convey the health risks of smoking to consumers in a manner that would affect the incidence of smoking initiation by the underaged, the FDA provides no reliable evidence demonstrating that data regarding the cigarette marketplace (or regarding smokeless tobacco) are generalizable to cigars, which have markedly different usage patterns. Instead, the FDA simply asserts its belief: "FDA *believes* that the fundamental similarities between cigarettes and smokeless tobacco and other tobacco products allow for the application of data regarding the effectiveness of cigarette and smokeless tobacco warnings to warnings for other tobacco products." 79 Fed. Reg. 23,165 (emphasis added).

76. The federal government agency charged with reviewing and approving tobacco prevention interventions, SAMHSA, employs an "evidence-based" approach to evaluating

[14] *See* "Proposition 65 in Plain Language," *available at* http://oehha.ca.gov/proposition-65/general-info/proposition-65-plain-language; "Clear and Reasonable Warnings," *available at* http://oehha.ca.gov/media/downloads/proposition-65/general-info/regsart6.pdf.

smoking interventions.[15] The agency defines an "evidence-based practice" as "[a] practice that is based on rigorous research that has demonstrated effectiveness in achieving the outcomes that it is designed to achieve." (SAMHSA website, http://nrepp.samhsa.gov/05f_glossary.aspx#E (last visited Jan. 22, 2017)). SAMHSA's *minimum* requirements to be eligible for review for potential inclusion in the NREPP include the following:

> 1. Research or evaluation of the intervention has assessed mental health or substance use outcomes among individuals, communities, or populations OR other behavioral health-related outcomes on individuals, communities, or populations with or at risk of mental health issues or substance use problems.
>
> 2. Evidence of these outcomes has been demonstrated in at least one study using an experimental or quasi-experimental design. Experimental designs require random assignment, a control or comparison group, and pre- and post-intervention outcome assessments. Quasi-experimental designs do not require random assignment, but do require a comparison or control group and pre- and post-intervention outcome assessments. Comparison/ control groups must be a no-treatment control group, a wait-list control group, a treatment-as-usual comparison group, or an intervention that is presumed to be ineffective or substantially less effective than the intervention (e.g., a "placebo" control or, in cases in which providing no treatment might be considered unethical, less effective treatments, even if not treatment-as-usual, such as "supportive therapy"). Studies with single-group, pretest-posttest designs or single-group, longitudinal/multiple time series do not meet this requirement, but will be considered to identify emerging programs and practices for consideration in the Learning Center.
>
> Comparative effectiveness trials, in which two interventions, both presumed to be equally effective, are compared, and studies in which the effects of the same intervention on various subpopulations are compared or in which various doses or components of the same intervention are compared will not be reviewed, but may be submitted as supporting documentation

[15] Part of SAMHSA's mission is to reduce or eliminate substance abuse problems among youth. One of the programs in furtherance of this mission is the National Registry of Evidence-based Programs and Practices ("NREPP") which collects evidence-based, scientifically proven, and reliable curricula for drug and alcohol youth interventions, including tobacco use. *Substance Abuse and Mental Health Services Administration (SAMHSA)*, 70 Fed. Reg. at 50,381-83 (Aug. 26, 2005). As discussed in this section, evidence-based smoking interventions seeking a place on the NREPP must undergo a rigorous scientific and academic review, which includes an examination of a variety of the intervention's characteristics including reliability, validity, and utility. *Id*. at 50,384-87. Evidence-based interventions that meet the demands of the evaluators are deemed ready for dissemination and posted on the NREPP website for the public to access.

> 3. The results of these studies have been published in a peer-reviewed journal or other professional publication, or documented in a comprehensive evaluation report, published within the previous 25 years. Comprehensive evaluation reports must include a review of the literature, theoretical framework, purpose, methodology, findings/results with statistical analysis and p values for significant outcomes, discussion, and conclusions.
>
> (SAMHSA website, http://nrepp.samhsa.gov/04f_reviews_submission.aspx (last visited Jan. 22, 2017)).

77. Currently, SAMHSA's website identifies at least seven smoking prevention programs and one smoking cessation program for adolescents and/or children that have satisfied SAMHSA's most recent updated and more rigorous requirements for inclusion in the NREPP.[16] There are many more such programs listed on SAMHSA's website that were reviewed under NREPP review criteria in effect from 2008 through September 2015 ("Legacy Programs").

78. The warning requirements of the Final Rule have not been proven to be an effective intervention for underaged cigar initiation and/or use in the United States by evidence-based, scientific evaluations that would meet the minimum requirements of SAMHSA.

79. I also have been informed that, in the Final Regulatory Impact Analysis accompanying the Final Rule ("FRIA"), the FDA stated that it is unaware of any "reliable evidence" on the impact of warning labels on users of cigars or pipe tobacco. In the FDA's own words, "[r]eliable evidence on the impacts of warnings labels, premarket review, and marketing restrictions on users of cigars, pipe tobacco, waterpipe tobacco, and ENDS does not, to our knowledge, exist." FRIA at 62 (*available at* http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM500254.pdf). And as the FDA states clearly, it is "unable to estimate the extent to which this final rule would lead to a reduction in the use of tobacco products." *Id*. at 49. The FDA recognizes these are significant shortcomings

[16] Here, I am only referring to programs that were reviewed under the new NREPP review criteria that took effect after September 2015.

and has indicated it intends to rectify them in the future by conducting its own research to attempt to fill in these significant omissions in the data. 81 Fed. Reg. 29,065 ("FDA intends to conduct research and keep abreast of scientific developments regarding the efficacy of the health warnings in the final rule and the ways in which their efficacy could be improved."); *see also* 79 Fed. Reg. 23,165.

80. I agree with the FDA here. Based on my knowledge of the scientific literature, there is no reliable scientific evidence demonstrating that the FDA's new required warning labels will reduce smoking initiation via cigars among underaged persons. As discussed above, and as required by a sister agency of HHS (SAMHSA), experimental data are required to demonstrate the efficacy of an intervention, and no such data have been offered by the FDA. The warnings fail to address the most important risk factors for underaged initiation of smoking: personal social environment (family and friends) and personality factors (sensation seeking and risk taking preferences).

VIII. There Are Established Methods That Are More Likely To Reduce Underage Tobacco Use Further

81. There are numerous alternatives to the Final Rule's warning requirement that, unlike the Final Rule, are directed at affecting the repeatedly empirically demonstrated risk factors for the incidence of underaged smoking. There is empirical support for the methods listed below in reducing underaged tobacco use. Many of these methods are especially likely to be successful because they correctly focus on the interpersonal factors that are strongly associated with, and that distinguish between, underaged persons who use tobacco and those who do not:

(a) Raise the legal age to purchase, possess, or consume tobacco products to 19 years. This would (1) remove the majority of legal age smokers from the secondary public and private school environments; (2) reduce modeling of smoking behavior; (3) reduce the

number of legal age smoking peers at all high schools; (4) reduce estimates of smoking prevalence by underage individuals; (5) reduce the impact of the dating-smoking link noted previously, and (6) lead to a decrease in underage smoking initiation in the current 14-17 year old population, and most likely in the 18 year old population as well. Indeed, the Department of Health and Human Services developed a model statute to prevent the sale of tobacco products to minors that recommended raising the legal age for the purchase of tobacco products to 19. *See* Institute of Medicine, *Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths* (Barbara S. Lynch and Richard J. Bonnie, eds., 1994).

(b) Increase support for interventions that address the personal social factors that influence risk behaviors, including tobacco use (e.g., programs training young people on recognizing and avoiding peer influence, including developing refusal skills);

(c) Enhance the penalties for underaged tobacco use and identify penalties that will be motivational and meaningful to the adolescents involved (e.g., loss of driver's license);

(d) Enforce laws to constrict unregulated, unlicensed sales of tobacco products;

(e) Enforce strict, prohibitive, policies regarding tobacco possession or use by anyone (students, faculty, or staff) at schools, including at all school-sponsored events, whether on school grounds or not (*see* The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General, at 793, 795 (2014) ("2014 Surgeon General Report"), *available at* https://www.surgeongeneral.gov/library/reports/50-years-of-progress/index.html);

(f) Increase penalties for adults who unlawfully provide tobacco products to minors (*see id*. at 796);

(g) Increase support for programs that emphasize negative personal social consequences of tobacco use (e.g., socially ostracizing, peer disapproval);

(h) Increase support for programs that encourage all parents actively to express disapproval of underage tobacco use to their children;

(i) Increase support for programs that encourage parents who use tobacco products to avoid using those products around their children and prevent access to those products in the home;

(j) Increase support for programs to encourage siblings to neither encourage nor facilitate tobacco use and to explain the important role that siblings may have on one another;

(k) Increase support for programs that further reduce underage access to tobacco at retail by educating clerks and store personnel about the importance of vigorous enforcement of underage-sales laws (*see id*. at 796);

(l) Increase support for employers to offer smoking cessation programs through the workplace;

(m) Increase financial and logistical support for implementation of programs appropriately identified as evidence-based tobacco use prevention interventions by SAMHSA;

(n) Increase the effective price of those tobacco products that are currently priced at levels that make them readily accessible to underaged purchasers by increasing taxes on such products. New York City believes that raising the price of cigarettes, which would otherwise have a low unit cost, has proven an effective way to discourage youth smoking. *See* Frieden at 1016 ("Increased taxation appeared to account for the largest proportion of the decrease [in smoking prevalence between 2002 and 2003 in New York City]."). The Surgeon

General similarly noted in 2012 that "[t]here is compelling evidence from CDC, as well as the reviewed research, that increasing tobacco prices is effective at lowering both smoking prevalence and consumption levels of tobacco products, especially by youth and young adults and other price-sensitive populations." 2012 Surgeon General Report at 809; *see also* 2014 Surgeon General Report at 788 ("Previous Surgeon General's reports (USDHHS 2000, 2012) have concluded that increases in cigarette prices, including those that result from increases in excise taxes, reduce the initiation, prevalence, and intensity of smoking among youth and adults.").

82. The CDC believes that tobacco control programs using a mix of these interventions can reduce underaged tobacco initiation and use:

> Investing in comprehensive tobacco control programs and implementing evidence-based interventions have been shown to reduce youth initiation, tobacco-related disease and death, and tobacco-related health care costs and lost productivity. These interventions include:
>
> - Increasing the price of tobacco products
> - Enacting comprehensive smokefree policies
> - Funding hardhitting mass-media campaigns
> - Making cessation services fully accessible to tobacco users

CDC, *Best Practices for Comprehensive Tobacco Control Programs*—2014, at 12 (*available at* https://www.cdc.gov/tobacco/stateandcommunity/best_practices/pdfs/2014/comprehensive.pdf); *see also id*. at 19 (listing the following recommendations for preventing tobacco use among youth: increasing the unit price of tobacco products; conducting mass-media education campaigns in combination with other community interventions and mobilizing the community to restrict minors' access to tobacco products in combination with additional interventions (stronger local laws directed at retailers, active enforcement of retailer sales laws, and retailer education

with reinforcement)); CDC, *New Study Shows Tobacco Control Programs Cut Adult Smoking Rates* (Jan. 30, 2008), *available at* http://www.cdc.gov/media/pressrel/2008/r080130.htm ("'These results show that if states consistently fund programs at recommended levels—outlined in *Best Practices for Comprehensive Tobacco Control Programs*—they could substantially reduce adult smoking prevalence, and thus reduce smoking-related morbidity, mortality, and economic costs,' said Terry Pechacek, Ph.D., associate director for science, Office on Smoking and Health, CDC, and one of the authors of the study.").

83. In its Youth and Tobacco Use Fact Sheet on its website, the CDC has listed national, state, and local program activities that "have been shown to reduce and prevent youth tobacco use when implemented together." CDC Fact Sheet, Youth and Tobacco Use, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/index.htm (last visited Feb. 1, 2017). While many of the items I have listed above appear on the CDC's list; increasing the size or changing the content of warning labels do not.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 13th day of February, 2017 at Austin, Texas.

Dr. Cecil R. Reynolds

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CIGAR ASSOCIATION OF AMERICA et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION et al., Defendants.	)	Civil Action No. 16-1460 (APM)

DECLARATION OF CECIL R. REYNOLDS, PHD
EXHIBIT 1

VITA

NAME: Cecil R. Reynolds, PhD
Emeritus
Professor of Educational Psychology
Professor of Neuroscience
Distinguished Research Scholar
Texas A&M University

ADDRESS: 40 N Interstate 35 Apt 12B1
Austin, TX 78701-4332
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EDUCATION: BA, Psychology, 1975 University of North Carolina at Wilmington
M Ed, Psychometrics, 1976 University of Georgia
EdS, School Psychology, 1977 University of Georgia
PhD, Educational Psychology, 1978 University of Georgia
Major: School Psychology Minors: Statistics and Clinical Neuropsychology

DISSERTATION: Differential Validity of Several Preschool Assessment Instruments for Blacks, Whites, Males, and Females

Major Professor: Alan S. Kaufman, PhD
Chair, Reading Committee: E. Paul Torrance, PhD

LICENSURE AND CERTIFICATION

Licensed Psychologist, Texas State Board of Examiners of Psychologists (1982-2004, Retired in good standing, February 29, 2004).
Certified Health Service Provider, Texas State Board of Examiners of Psychologists (1983-2004).
Diplomate, Clinical Neuropsychology, American Board of Professional Neuropsychology (ABPN), 1983, with special qualifications in Forensics, Developmental Disabilities, and in Pediatrics.
Diplomate, Pediatric Neuropsychology, American Board of Pediatric Neuropsychology, 2011.

Listed, National Register of Health Service Providers in Psychology (1985-2003).
Licensed Psychologist, Nebraska State Board of Examiners of Psychologists (1978-1994).
Diplomate, School Psychology, American Board of Professional Psychology (ABPP), (1998, retired February 29, 2004).
Diplomate, Forensic Examination, American Board of Forensic Examiners (ABFE), (1995- retired 2003).
Certified Clinical Psychologist, Nebraska Department of Health (1981-1994).
Professional School Psychologist, Texas Education Agency (1982).
Professional School Psychologist 7, Nebraska Department of Education (1978).
School Psychologist, Georgia Department of Education (1976).
Certified Special Education Servicing Agency, State of Nebraska, Department of Special Education (1978-81).
Frequent qualification as expert witness in clinical neuropsychology, psychology, education, tests and measurement, and child mental health in local, state, and federal district courts.
Oral Examiner, Texas State Board of Examiners of Psychologists, 1987 (first year of oral exams in Texas)-2003.
Oral Examiner, American Board of Professional Neuropsychology (1995-).
Oral Examiner, American Board of Professional Psychology (2002-2003).

EXPERIENCE

Cecil R. Reynolds, Forensic Neuroscience	2008-	Private forensic consulting practice
Emeritus Professor	2008-	Texas A&M University, College Station, TX
Distinguished Research Scholar	1995-2008	Texas A&M University, College Station, TX
Professor of Neuroscience	1993-2008	Texas A&M University; College Station, TX (Charter member, Faculty of Neuroscience)
Professor of Educational Psychology	1985-2008	Texas A&M University; College Station, TX (tenured, 1984)
Director, Doctoral School Psychology Training Program (APA Accredited)	1982-1987	Texas A&M University; College Station, TX
Associate Professor	1981-1985	Texas A&M University; College Station, TX

Associate Director	1980-1981	Buros Institute of Mental Measurements
Acting Director	1979-1980	Buros Institute of Mental Measurements
Assistant Professor	1978-1981	University of Nebraska; Lincoln Nebraska (tenured, 1981)
Psychologist 1/2 time	1976-1978	Rutland Center; Athens, Georgia
Player	1969-1974	N.Y. Metropolitan Baseball Club; New York, NY

INTERNSHIP

One year of internship divided between the following two agencies: Clarke County Public Schools (Division of Exceptional Children, Rutland Center for Severely Emotionally Disturbed Children); and Medical College of Georgia, Pediatric and Adult Neuropsychology.
Postdoctoral supervision in the Educational Psychology Clinic at the University of Nebraska-Lincoln.

PRIMARY CONSULTANTSHIPS

1996 - 2008	Neuropsychology and Education and Training Consultant to Medical Horizons Unlimited, San Antonio, TX.
1994 - 2004	Neuropsychology consultant to PBS, project to revise "The Brain."
1993 -	Reviewer, Grants and contracts, National Institute of Drug Abuse (NIDA).
1990 - 1992	Director of Psychology, Sandstone Hospital.
1987 - 1989	Sandstone Systems, Inc. and Sandstone Psychiatric Hospital, Neuropsychology Director.
1985 -	The Psychological Corporation, WPPSI Revision, WISC-III, Differential Ability Scales, and related projects.

1987 - 1991	Consultant to Texas Education Agency/Texas Department of Mental Health and Mental Retardation Task Force on Emotional Disturbance, a legislatively mandated task force.
1985 - 1987	Riverside Publishing Co., Training Consultant (Stanford-Binet Fourth Ed.)
1985 - 1993	Greenleaf Psychiatric Hospital, Bryan, TX, Psychological Consultant.
1984 - 1986	Brenham State School, Psychological Consultant.
1983 - 1985	Training Consultant, American Guidance Services.
1983 -	Field Reader, United Stated Office of Education.
1981 - 1995	Consultant on psychology and education, Christian Law Association.
1978 - 1985	Research Consultant, American Guidance Services, Kaufman Assessment Battery for Children Project, Kaufman Adolescent and Adult Intelligence Test for Adolescents and Adults Project, Kaufman Assessment Battery for Children-Spanish Edition.
1980 - 1981	Psychometric Consultant, Project for the revision of Detroit Tests of Learning Aptitude, Bobbs-Merrill Pub. Co.
1978 - 1980	Psychological Consultant, Beatrice State Developmental Center; Beatrice, Nebraska.
1978	Research Consultant, N.E. Georgia Area Agency on Aging; Athens, Georgia.
1977 - 1978	Staff Development Consultant, N.E. Georgia Cooperative Educational Service Agency; Athens, Georgia.
1976 - 1978	Psychological Consultant, Department of Education, State of Georgia, Atlanta, Georgia.

CURRENT SPECIAL INTERESTS

Major Areas:	Individual Assessment and Diagnosis Cultural Bias in Testing

Childhood Emotional Disturbance
Neuropsychology
Behavioral Assessment and Actuarial Classification

Minor Areas: Learning Disorders
Personality Measurement
Creativity

TEACHING

Graduate Courses Taught: Assessment of the Emotionally Disturbed
Clinical Neuropsychology
Field Practicum in Applied Research
Foundations of Research
Individual Assessment
Individual Preschool Assessment
Internship in School Psychology
Neurodevelopmental and Genetic Disorders in Children
Neuropsychological Assessment
Neuropsychology of Low Incidence Handicaps
Nonbiased Assessment of Special Populations
Practicum in Assessment
Practicum in School Psychology
Psychopathology of Childhood and Adolescence
Seminar in Neuropsychology
Special Topics in Forensic Psychology

Undergraduate Courses Taught: None

UNIVERSITY AND PROFESSIONAL ORGANIZATIONS, HONORS

Professional Organizations (past and current)

American Association for the Advancement of Science
American Creativity Association (Charter Member)
American Educational Research Association
American Psychological Association (Fellow of Divs. 1, 5, 15, 16, 40, 53)
American Psychological Society (Fellow)
Coalition of Clinical Practitioners in Neuropsychology
Council of Directors of School Psychology Programs (1982-1987)
International Neuropsychological Society
National Academies of Practice (Distinguished Fellow)
National Academy of Neuropsychology (Fellow)
National Association of School Psychologists

National Council on Measurement in Education
Reitan Society (Charter Member)
Society for the Scientific Study of School Psychology (Charter member)
Trainers of School Psychologists

Honor Societies	Honorary Listings
Phi Delta Kappa	Men of Achievement
Phi Kappa Phi	Personalities of the West and Midwest
Kappa Delta Pi	Outstanding Young Men of America (1980)
	Marquis' Who's Who in the Midwest
	Dictionary of International Biography
	Marquis' Who's Who in the South and
Social Fraternity	Southwest
	Marquis' Who's Who in the Frontiers of
Tau Kappa Epsilon	Science
	Others

HONORS, AWARDS, AND DISTINCTIONS

2014 Samuel J. Messick Distinguished Scientific Contributions to Measurement Award, APA Division 5 (Evaluation, Measurement, and Statistics)

2014 Lifetime Award for as Distinguished Assessment Psychologist, APA Division 12 (Clinical Psychology) Section on Clinical Assessment

2011 Elected Distinguished Fellow of the National Academies of Practice.

2010 Jack Bardon Distinguished Service Award , Division of School Psychology of the American Psychological Association.

2009 Published interview as a "Legend in the Field," The International Journal of Creativity and Problem Solving, *19*(1), 123-139.

2007 Distinguished Achievement Award for Research, TAMU Former Students Association. (University wide award). First two-time College of Education faculty member to receive this award in the history of TAMU.

2007 Lifetime Achievement Award for Distinguished Contributions, American Board of School Neuropsychology.

2006 Distinguished Reviewer of 2006, Buros Institute of Mental Measurements.

2005 University of Georgia, Distinguished Alumnus Award for Lifetime Achievement. Also inducted into the College of Education "Hall of Fame."

2003 National Association of School Psychologists, Neuropsychology Interest Group, Lifetime Achievement Award in Neuropsychology.

2002 Distinguished Visiting Professor, Wilford Hall, USAF showcase hospital and training facility, Lackland AF Base, San Antonio, TX.

2001 National Academy of Neuropsychology, Distinguished Service Award.

2000 National Academy of Neuropsychology, Distinguished Clinical Neuropsychologist Award

1999 American Psychological Association, Division 16, Senior Scientist Award

1998 Razor Walker Award for service to the youth of America, The University of North Carolina at Wilmington and CAPE. (50th Anniversary Award).

1997 President's Gold Medal for service to the National Academy of Neuropsychology.

1995 Distinguished Research Scholar Award, Texas A&M University, COE.

1995 Faculty co-author of National Academy of Neuropsychology, Student Research Award, winning paper, 1995 NAN Annual Convention.

1994 Society for the Psychological Study of Social Issues (APA Division 9), Robert Chin Award for Distinguished Contributions (co-recipient).

1994 Faculty co-author of National Academy of Neuropsychology, Student Research Award, winning paper, 1994 NAN Annual Convention.

1988 Paper of the Year, Mid-South Educational Research Association, with A. Kaufman and J. McLean.

1987 Interviewed as an "Eminent School Psychologist" in the Communique', Official Newsletter of the 30,000 member National Association of School Psychologists.

1987 Encyclopedia of Special Education named by American Library Association as one of the Top 25 Reference Works in All Fields (Dr. Reynolds is senior editor of this work).

1986 Distinguished Achievement in Research, award from the Texas A&M University Former Students Association (University wide award). First College of Education faculty member to receive this award in the history of TAMU.

1984 Outstanding Alumnus of the Year, University of North Carolina at Wilmington (one chosen each year).

1984 Outstanding New Faculty Award, College of Education Development Council, Texas A&M University.

1983 American Psychological Association, Division of Educational Psychology (15), Early Career Award, with accompanying invited address to the annual meeting of the APA.

1983 Awarded Fellow status, American Psychological Association (first year of eligibility).

1983 Awarded Fellow status, National Academy of Neuropsychology (first year of eligibility).

1983 Earned Diplomate status, clinical neuropsychology, American Board of Professional Neuropsychology, by assembled examination process, and voluntarily re-examined through new written and oral examination process, 1993.

1983 Certificate of Research Achievement, Instructional Research Laboratory, College of Education, Texas A&M University.

1981 Invited by the Division of Evaluation and Measurement (5) of the American Psychological Association to deliver a special invited address as an Outstanding Contributor in First Ten Postdoctoral Years to the annual meeting of the APA.

1981 Appointed to the Graduate Faculty of Texas A&M University.

1980 American Psychological Association, Division of School Psychology (16) Lightner Witmer Award (awarded annually to the outstanding young school psychologist in the Association).

1979 Awarded Fellow status on the Graduate Faculty of the University of Nebraska.

1978 Kappa Delta Pi Award of Excellence for Outstanding Contributions to Education (awarded annually to the individual judged the most outstanding graduate student in a school of education in the state of Georgia).

1978 Paper of the Year, Gifted Child Quarterly (awarded annually by the National Association for Gifted Children, the professional sponsoring agent of Gifted Child Quarterly) with E. P. Torrance.

1977, 1978 Certificate of Recognition, National Association of School
1979, 1980 Psychologists.

OFFICES AND COMMITTEES

2015-2016 President, American Academy of Pediatric Neuropsychology.

2014 President-elect, American Academy of Pediatric Neuropsychology.

2015- Member, APA Task Force on Previously Published Material

2009- Member, APA Task Force on Violence Against Teachers.

2006- Member (SSSP Representative) of the School Psychology Specialty Council.

2005-2006 Chair, American Psychological Association Task Force on Zero Tolerance Policies in the Schools (final report published in American Psychologist).

2004 and 2005 President, American Psychological Association, Division of School Psychology.

2000-2002 Member-at-large, Executive Board of the Coalition of Clinical Practitioners in Neuropsychology.

1999-2005 Member-at-large, Executive Board of the National Academy of Neuropsychology.

2002-2003 Chair, National Academy of Neuropsychology, Long Term and Strategic Planning Task Force.

1999-2000 Immediate Past-President, APA Division 40 (Clinical Neuropsychology).

1998-1999 President, APA Division 40 (Clinical Neuropsychology).

1998-1999 Immediate Past President, APA Division 5 (Evaluation, Measurement,

& Statistics.

2000-2008 Member-at-large, Executive Committee of the American Board of Professional Neuropsychology.

1998-2000 Immediate Past President, American Board of Professional Neuropsychology (ABN).

1999- Member, APA Division 40 Committee on Empirically Supported Practice.

1998-1999 Immediate Past-President, APA Division 5.

1997-1998 President, APA Division 5 (Evaluation, Measurement, & Statistics).

1997-1998 President-Elect, APA Division 40 (Clinical Neuropsychology)

1996-1997 President-Elect, APA Division 5 (Evaluation, Measurement, & Statistics)

1997- Member, Research Grants Committee, National Academy of Neuropsychology

1996-1998 President, American Board of Professional Neuropsychology (ABN)

1995-1996 President-Elect, American Board of Professional Neuropsychology (ABN)

1993-1995 Member-at-large, Executive Committee, American Board of Professional Neuropsychology.

1994-1995 Chair, Awards Committee, American Board of Professional Neuropsychology.

1994- Oral Examiner and Work Sample Reviewer, American Board of Professional Neuropsychology

1991-1992 Member, American Psychological Association, Board for the Advancement of Psychology in the Public Interest Working Group on the Use of Anatomically Detailed Dolls.

1991-1997 Member, Medical Advisory Council, JMA Head Injury Foundation, Inc., Washington, D.C.

1990- Member, Content Area Consultant Bank, National Research Center on the Gifted and Talented, a USOE Funded OERI Project.

1990 Chair, NAN Nominations Committee

1989	Chair, NAN Fellows Committee
1983-2000	Member, NAN Program Committee
1983-1999	Chair, NAN Site Selection Committee
1988-1991	Past-President, National Academy of Neuropsychology
1986-1988	President, National Academy of Neuropsychology, 2 year term (NAN)
1986-1988	Executive Board, Federation of Cognitive, Behavioral, and Social Sciences.
1986-1990	Member (BPA), Committee on Psychological Testing and Assessment, American Psychological Association.
1988	Chair, APA, Division 5 Program Committee
1986-1988	Member, American Psychological Association Task Force on Psychology in the Schools.
1987	Member, APA Div. of Evaluation and Measurement (Div. 5), Program Committee.
1985-1987	Member-at-large, Executive Board, Division of Clinical Neuropsychology (40) of the APA
1985	Chair, APA Division 16, Lightner Witmer Award Committee
1985	Member, United States Department of Education Special Education Programs, Task Force on Eligibility for Learning Disabilities
1984-1985	Member, Oral Examination Task Force, Texas State Board of Examiners of Psychologists
1984-1986	Member-at-large, Executive Board of the National Academy of Neuropsychology
1982-1988	Chair, APA Division 16 Committee on Testing Issues
1983-1984	Chair, United States Department of Education, Special Education Programs, Work Group on Measurement Issues in the Identification of Specific Learning Disabilities
1983-1986	APA, Division 16, Monitor for Scholarly Knowledge (1983-1984), Vice

President for Education, Training, and Scientific Affairs (1985-1986)

1983-1985 NASP, West Central Regional Director

1983 Co-chair, APA Division 16 SIG - Preschool Children

1981-1984 Advisor to the APA, AERA, NCME Joint Committee to Revise the Standards for Educational and Psychological Tests

1981 Member, APA, BSERP Task Force to Prioritize APA's Response to the Needs of Children, Youth, and Families.

1980-1981 Chair, APA Division 16 Convention Program Committee.

1979-1980 Co-Chair, APA Division 16 Convention Program Committee.

1979-1981 Chair, Ethics Committee, Nebraska School Psychologists Association.

1978-1981 National Liaison and Executive Committee, National Future Problem Solving Program.

1978-1982 Member, APA, Division 16 Publications Committee.

1978-1979 Chair, Reference Committee, Nebraska School Psychologists Association.

1977-1978 Vice President, University of Georgia Phi Delta Kappa Chapter.

1977-1978 President, Graduate Student Organization.

1977-1978 Student Representative, Departmental Coordinating Committee.

1976-1978 Student Member, APA, Division 16 Committee on Learning Disabilities.

1975 President, SSH Jaycee Chapter

SCHOLARLY REVIEWING AND EDITING ACTIVITIES

2015-2021 Editor-in-Chief, Archives of Scientific Psychology, a journal of the American Psychological Association.

2009-2015 Editor-in-Chief, Psychological Assessment, a journal of the American Psychological Association ("incoming editor" calendar year 2009).

2015- Associate Editor, Journal of Pediatric Neuropsychology

2012-2015 Associate Editor for measurement and assessment, Archives of Scientific Psychology, an APA open access psychology journal.

2011-2014 Senior Scientist and Editorial Consultant, Journal of School Psychology.

2004-2008 Editor-in Chief, Applied Neuropsychology (A Lawrence Erlbaum Associates journal).

1991-2002 Editor-in-Chief, Archives of Clinical Neuropsychology (Official journal of the National Academy of Neuropsychology).

2008 Guest editor, Journal of Attention Disorders.

1990 Editor-Elect, Archives of Clinical Neuropsychology

1984-2004 Series Editor, Critical Issues in Neuropsychology, Plenum Pub. Co.

1981-2004 Series Editor, Perspectives on Individual Differences, Plenum Pub. Co.

1992-2001 Editorial Advisor, Child Assessment News

1995-1997 Associate Editor, School Psychology Quarterly
2002- 2007

1985-1992 Associate Editor, Journal of School Psychology

1985-1987 Associate Editor, Journal of Special Education

1986-1990 Associate Editor, Archives of Clinical Neuropsychology

1984-1986 Editor, K-ABC Information Edge (quarterly)

2014- Editorial Board, Child Development

2002-2003 Editorial Board, Applied Neuropsychology

1997-1999 Editorial Board, Psychological Assessment
2002-2008

1996-2005 Editorial Board, Journal of Forensic Neuropsychology

1996- Editorial Board, Learning Disability Quarterly

1996- Editorial Board, Neuropsychology Review

1994-1997 Editorial Board, Journal of Clinical Child Psychology

1993-1997 Editorial Board, Neuropsychology

1993- Editorial Board, Research in the Schools

1992 - Editorial Board, Canadian Journal of School Psychology

1988-1997 Editorial Board, Journal of Experimental Education

1986-1991 Editorial Board, Archives of Clinical Neuropsychology

1984-1989 Editorial Board, Professional School Psychology

1984- Editorial Board, Journal of Learning Disabilities

1984- Editorial Board, Computers in Human Behavior

1982-2001 Editorial Board, Journal of Psychoeducational Assessment

1982-1985 Editorial Board, Journal of Special Education

1980- Editorial Board, Educational and Psychological Measurement

1980-2008 Editorial Board, Journal of School Psychology

1980-1988 Editorial Board, Psychology in the Schools

1980- Editorial Board, Special Education Assessment Matrix

1979-1989 Editorial Board, School Psychology Review

2002 Guest Action Editor, American Psychologist

1983 Guest Editor, Special issue of Journal of Special Education on the K-ABC. (Fall, 1984 issue).

1980- Corresponding Commentator and Associate, Behavioral and Brain Sciences

1980-1984 Test Review Editor and Editorial Board, International Journal of Clinical Neuropsychology

2010- Ad Hoc Reviewer, Alberta Journal of Educational Research

2002- Ad Hoc Reviewer, Journal of Attention Disorders

2002- Ad Hoc Reviewer, British Journal of Developmental Psychology

1995- Ad Hoc Reviewer, Journal of Abnormal Child Psychology

1995- Ad Hoc Reviewer, Developmental Psychology

1993- Ad Hoc Reviewer, Assessment

1990- Ad Hoc Reviewer, Child Development

1990- Ad Hoc Reviewer, American Psychologist

1990 - Ad Hoc Reviewer, Journal of the American Association on Mental Retardation.

1987-1994 Ad Hoc Reviewer, Journal of Clinical Child Psychology
1998-

1987- Ad Hoc Reviewer, Educational Psychologist

1986- Ad Hoc Reviewer, Journal of Educational Measurement

1986- Ad Hoc Reviewer, Journal of Educational Statistics

1999- Ad Hoc Reviewer, Journal of the International Neuropsychological Society

1985- Ad Hoc Reviewer, Journal of Personality Assessment

1984- Ad Hoc Reviewer, Journal of Pediatric Psychology

1984- Ad Hoc Reviewer, American Educational Research Journal

1984- Ad Hoc Reviewer, Review of Educational Research

1982- Ad Hoc Reviewer, Personality and Individual Differences

1982- Ad Hoc Reviewer, The Southern Psychologist

1981- Ad Hoc Reviewer, Journal of Consulting and Clinical Psychology

1979- Ad Hoc Reviewer, Journal of Educational Psychology

1979- Ad Hoc Reviewer, Perceptual and Motor Skills

1979- Ad Hoc Reviewer, Psychological Reports

1980-1981 Ad Hoc Reviewer, School Psychology Monograph

Convention Paper Reviewing:

AERA, 1979, 1980, 1981, 1982, 1984, 1988, 1990, 1993,1995-2001
APA, 1980, 1981, 1982, 1983, 1984, 1986, 1987, 1996-2002.
NAN, 1982, 1983, 1984, 1985.
NCME, 1984, 1995-2005.

Other Reviewing

Publisher's reviewer for the 2nd edition of Assessment of Children's Intelligence by Jerry Sattler, 4th edition of Cronbach's Essentials of Psychological Testing, 3rd edition of Kerlinger's Foundations of Behavioral Research, and other major texts in the field.

Grant and contract review panels for National Institute on Drug Abuse, National Institutes of Mental Health, U.S. Department of Education, March of Dimes, and others.

Miscellaneous reviews of books and book proposals for academic publishing houses and university presses including Johns Hopkins University Press, Syracuse University Press, University of Texas Press, The University of Nebraska Press, Oxford University Press, and Cambridge University Press.

External reader of dissertations and theses for universities in India, Israel, Nigeria, and Malaysia.

External reviewer for promotion and tenure of faculty at more than 40 universities in the USA, Canada, Europe, and the Far East.

RESEARCH AND DEVELOPMENT FUNDING

Since 1978, funding for various research and development projects in excess of 5 million dollars from various agencies including the U.S. Department of Education (OSER), National Science Foundation, Texas Education Agency, Nebraska Development Foundation, American Guidance Service, The Psychological

Corporation, PRO-ED, Western Psychological Services, Nevada Department of Education, International Lead-Zinc Research Organization, Medical Horizons Unlimited, and John Wiley & Sons.

BOOKS

Vannest, K.
Reynolds, C. R.
Kamphaus, R. W.
(2015). Behavior intervention guide. Bloomington, MN: Pearson Clinical Assessment.

Vannest, K.
Reynolds, C. R.
Kamphaus, R. W.
(2015). Behavioral and emotional skill building guide. Bloomington, MN: Pearson Clinical Assessment.

Saklosfke, D.
Reynolds, C. R.
Schwean, V.
(Eds.)
(2013). The Oxford Handbook of Psychological Assessment of Children and Adolescents. NY: Oxford University Press.

Reynolds, C. R.
Vannest, K.
Fletcher-Janzen, E.
(Eds.)
(2013). Encyclopedia of special education, 4th Ed. (4 vols), NY: Wiley-Interscience.

Reynolds, C. R.
Livingston, R. B.
(2012). Mastering modern psychological testing: Theory and methods. Boston: Pearson Higher Education.

Reynolds, C. R.
Vannest, K.
Harrison, J.
(2012). The Energetic Brain: Understanding and Managing ADHD. San Francisco: Jossey-Bass.

Reynolds, C.R.
Horton, A.
(Eds.)
(2012). Detection of Malingering During Head Injury Litigation. 2nd edition. NY: Springer.

Vannest, K.
Stroud, K.
Reynolds, C. R.
(2011). Strategies for academic success: An instructional handbook for teaching K-12 students how to study, learn, and take tests. Los Angeles: Western Psychological Services.

Goldstein, S.
Reynolds, C. R.
(Eds.)
(2010). Handbook of neurodevelopmental and genetic disorders in children. 2nd Edition. NY: Guilford Publications.

Vannest, K. J. Reynolds, C. R. Kamphaus, R. W. (2009). Classroom guide to interventions for behavioral and emotional issues. Vols. 1 and 2. Bloomington, MN: Pearson Assessments.

Reynolds, C.R. Fletcher-Janzen, E. (Eds.) (2009). Handbook of Clinical Child Neuropsychology, 3rd Edition. NY: Plenum.

Adams, W. Reynolds, C. R. (2009). Essentials of WRAML2 and TOMAL-2 assessment. NY: Wiley.

Reynolds, C.R Livingston, R. L Willson, V.L. (2009). Applications of measurement and assessment in the classroom. Second edition. Boston: Pearson Education.

Gutkin, T. B. Reynolds, C. R. (Eds.) (2009). The Handbook of School Psychology, 4th Edition. NY: John Wiley & Sons.

Vannest, K. J. Reynolds, C. R. Kamphaus, R. W. (2008). Intervention guide for behavioral and emotional issues. Bloomington, MN: Pearson Assessments.

Fletcher-Janzen, E. Reynolds, C. R. (Eds.) (2008). Neuropsychological perspectives on learning disabilities in the era of RTI: Recommendations for diagnosis and intervention. NY: Wiley.

Reynolds, C. R. Fletcher-Janzen, E. (Eds.) (2007). Encyclopedia of special education, 3rd Ed. (3 vols), NY: Wiley-Interscience.

Homack, S. Reynolds, C. R. (2007). Essentials of assessment with brief intelligence tests. NY: Wiley.

Reynolds, C.R Livingston, R. L Willson, V.L. (2006). Applications of measurement and assessment in the classroom. Boston: Pearson Education.

Reynolds, C. R. Fletcher-Janzen, E. (Eds.) (2006). Special education almanac. NY: Wiley..

Frisby, C. Reynolds, C. R. (2005). Comprehensive handbook of multicultural school psychology. NY: John Wiley & Sons.

Goldstein, S. Reynolds, C. R. (Eds.) (2005). Handbook of neurodevelopmental and genetic disorders in adults. NY: Guilford Publications.

D'Amato, R. Fletcher-Janzen, E. Reynolds, C. R. (Eds.) (2005). Handbook of school neuropsychology. NY: John Wiley & Sons.

Reynolds, C.R. Kamphaus, R.W. (Eds.) (2003). Handbook of psychological and educational assessment of children: Vol. 1, Intelligence and achievement. 2nd ed. New York: The Guilford Press.

Reynolds, C.R. Kamphaus, R.W. (Eds.) (2003). Handbook of psychological and educational assessment of children: Vol. 2, Personality, behavior, and context. 2nd ed. New York: The Guilford Press.

Fletcher-Janzen, E. Reynolds, C. R. (Eds.) (2003). Diagnostic reference manual of childhood disorders. New York: John Wiley & Sons.

Reynolds, C. R. Kamphaus, R. W. (2002). The clinician's guide to the Behavioral Assessment System for Children: BASC. NY: Guilford Publications.

Ramsay, M Reynolds, C. R. Kamphaus, R. W. (2002). Essentials of behavioral assessment. NY: John Wiley and Sons.

Reynolds, C. R. Fletcher-Janzen, E. (Eds.) (2002). Concise encyclopedia of special education, 2ndEd. NY: Wiley-Interscience.

Riccio, C. A. Reynolds, C. R. Lowe, P. A. (2001). Clinical applications of continuous performance tests: Measuring attention and impulsive responding in children and adults. NY: John Wiley and Sons.

Reynolds, C. R. Fletcher-Janzen, E. (Eds.) (2000). Encyclopedia of special education, 2ndEd. (3 vols), NY: Wiley-Interscience.

Fletcher-Janzen, E. Strickland, T. Reynolds, C. R. (Eds.) (2000). Handbook of cross-cultural neuropsychology. NY: Plenum.

Goldstein, S.
Reynolds, C.R.
(Eds.)
(1999). Handbook of Neurodevelopmental and Genetic Disorders in Children. NY: Guilford Publications.

Reynolds, C.R.
(Ed.)
(1999). Assessment. Volume 4 of M. Hersen & A. Bellack (Eds.), Comprehensive Clinical Psychology. Oxford: Elsevier Science.

Reynolds, C.R.
Gutkin, T.B.
(Eds.)
(1999). The Handbook of School Psychology, 3rd Edition. NY: John Wiley & Sons.

Reynolds, C.R.
(Ed.)
(1998). Detection of Malingering During Head Injury Litigation. NY: Plenum.

Reynolds, C.R.
Fletcher-Janzen, E.
(Eds.)
(1997). Handbook of Clinical Child Neuropsychology, 2nd Edition. NY: Plenum.

Reynolds, C.R.
(Ed.)
(1994). Cognitive assessment: An interdisciplinary perspective. New York: Plenum Publishing Company.

Reynolds, C.R.
Kamphaus, R.W.
(Eds.)
(1990). Handbook of psychological and educational assessment of children: Vol. 1, Intelligence and achievement. New York: The Guilford Press.

Reynolds, C.R.
Kamphaus, R.W.
(Eds.)
(1990). Handbook of psychological and educational assessment of children: Vol. 2, Personality, behavior, and context. New York: The Guilford Press.

Gutkin, T.B.
Reynolds, C.R.
(1990). The handbook of school psychology. 2nd edition. New York: John Wiley & Sons.

Reynolds, C.R.
Fletcher-Janzen, E.
(1990). Concise encyclopedia of special education. New York: Wiley-Interscience.

Reynolds, C.R.
Fletcher-Janzen,
E. (Eds.)
(1989). Handbook of clinical child neuropsychology. New York: Plenum Publishing Co.

Glover, J.A.
Ronning, R.R.
Reynolds, C.R.
(Eds.)
(1989). Handbook of creativity. New York: Plenum Publishing Co.

Kamphaus, R.W.
Reynolds, C.R.
(1987). Clinical and research applications of the K-ABC. Circle Pines, MN: American Guidance Service.

Reynolds, C.R.
Mann, L.
(Eds.)
(1987). Encyclopedia of special education, 3 vols. New York: John Wiley & Sons.

Reynolds, C.R.
Willson, V.L.
(Eds.)
(1986). Methodological and statistical advances in the study of individual differences. New York: Plenum Publishing Co.

Brown, R.T.
Reynolds, C.R.
(Eds.)
(1986). Psychological perspectives on childhood exceptionality: A Handbook. New York: Wiley-Interscience.

Reynolds, C.R.
Gutkin, T.B.
Elliott, S.N.
Witt, J.C.
(1986). School Psychology: Essentials of Theory and Practice. New York: John Wiley & Sons.

Reynolds, C.R.
Brown, R.T.
(Eds.)
(1984). Perspectives on bias in mental testing. New York: Plenum Publishing Co.

Reynolds, C.R.
Gutkin, T.B.
(Eds.)
(1982). The handbook of school psychology. New York: John Wiley & Sons.

TESTS & TEST MANUALS

Reynolds, C. R.
Kamphaus, R. W.
(2016). *Reynolds interference test*. Lutz, FL: Psychological Assessment Resources

Reynolds, C. R.
(2016). *Reynolds adaptable intelligence test-nonvberbal.* Lutz, FL: Psychological Assessment Resources

Reynolds, C. R. Kamphaus, R. W. (2016). *The Flex Monitor*. Bloomington, MN: Pearson Clinical Assessment.

Reynolds, C. R. Kamphaus, R. W. (2015). *Behavior assessment system for children, third edition*. Bloomington, MN: Pearson Clinical Assessment.

Kamphaus, R. W. Reynolds, C. R. (2015). Parenting relationship questionnaire, second edition. Bloomington, MN: Pearson Clinical Assessment.

Kamphaus, R. W. Reynolds, C. R. (2015). Behavioral and emotional screening system, second edition. Bloomington, MN: Pearson Clinical Assessment.

Reynolds, C. R. (2014). *Test of general reasoning ability (TOGRA).* Lutz, FL: Psychological Assessment Resources.

Reynolds, C. R. (2014). *Reynolds adaptable intelligence test (RAIT).* Lutz, FL: Psychological Assessment Resources

Reynolds, C. R. Voress, J. Kamphaus, R. W. (2014). *Mathematics fluency and calculation tests, elementary and secondary editions*. Austin, TX: Pro-Ed.

Stroud, K. C. Reynolds, C. R. (2013). *School motivation and learning Strategies inventory--College Form (SMALSI-CF).* Los Angeles: Western Psychological Services.

Reynolds, C. R. Voress, J. A (2012). *Test of memory and learning-senior edition.* Austin, TX: Pro-Ed.

Reynolds, C. R. Livingston, R. (2010). *Children's measure of obsessive-compulsive symptoms.* Los Angeles: Western Psychological Services.

Reynolds, C.R. Richmond, B.O. (2008). *The Revised Children's Manifest Anxiety Scale (RCMAS-2)*. 2nd Ed. Los Angeles: Western Psychological Services.

Reynolds, C. R. Voress, J. A. Pierson, N. (2008). *Developmental test of auditory perception.* Austin, TX: Pro-Ed.

Reynolds, C. R. Kamphaus, R. W. (2007). *Test of irregular word reading efficiency (TIWRE).* Lutz, FL: Psychological Assessment Resources

Reynolds, C. R. (2007). *Koppitz-2: The Koppitz Developmental scoring system for the Bender-gestalt test, second edition*. Austin, TX: Pro-Ed.

Kamphaus, R. W. Reynolds, C. R (2007). *BASC-2 Progress Monitor for ADHD*. Minneapolis, MN. Pearson Assessment.

Kamphaus, R. W. Reynolds, C. R (2007). *BASC-2 Progress Monitor for Internalizing problems.* Minneapolis, MN. Pearson Assessment.

Kamphaus, R. W. Reynolds, C. R (2007). *BASC-2 Progress Monitor for Social Withdrawal problems.* Minneapolis, MN. Pearson Assessment.

Kamphaus, R. W. Reynolds, C. R (2007). *BASC-2 Progress Monitor for Adaptability problems.* Minneapolis, MN. Pearson Assessment.

Kamphaus, R. W. Reynolds, C. R (2007). *Behavioral and emotional screening system*. Minneapolis, MN. Pearson Assessment.

Reynolds, C. R. Voress, J. A (2007). *Test of memory and learning, second edition.* Austin, TX: Pro-Ed.

Kamphaus, R. W. Reynolds, C. R. (2006). *Parenting relationship questionnaire.* Bloomington, MN: Pearson Assessments.

Stroud, K. C. Reynolds, C. R. (2006). *School motivation and learning Strategies inventory*. Los Angeles: Western Psychological Services.

Reynolds, C.R. Horton, A. M. (2006). *Test of verbal conceptualization and fluency*. Austin, TX: PRO-ED.

Reynolds, C.R. Kamphaus, R.W. (2004). *Behavior assessment system for children-2 (BASC-2*). Circle Pines, MN: American Guidance Service.

Hammill, D. A. Pierson. N. Voress, J. Reynolds, C. R. (2004). *Full range test of visual motor integration.* Austin: PRO-ED.

Reynolds, C. R. Hickman, J. A. (2003). *The DAP: IQ, The Draw-a-Person Intelligence Test for Children, Adolescents, and Adults.* Austin, TX: PRO-ED.

Reynolds, C.R. Kamphaus, R.W. (2003). *Reynolds intellectual assessment scales: RIAS* Odessa, FL: Psychological Assessment Resources.

Kamphaus, R. W. (2003). *Reynolds Intellectual Screening Test: RIST.*
Reynolds, C. R.

Reynolds, C.R. (2003). *Adult manifest anxiety scale.* Los Angeles: Western
Richmond, B. Psychological Services.
Lowe, P.

Reynolds, C. R. (2003). *Adult manifest anxiety scale: College Student Edition.*
Richmond, B. Los Angeles: Western Psychological Services.
Lowe, P.

Reynolds, C. R. (2003). *Adult manifest anxiety scale: Elderly Edition.* Los Angeles:
Richmond, B. Western Psychological Services.
Lowe, P.

Reynolds, C. R. (2002). *Comprehensive trail-making test.* Austin: PRO-ED.

Reynolds, C. R. (2002). *Developmental test of visual perception: Adolescent*
Pierson. N. *and adult (DTVP-A).* Austin: PRO-ED.
Voress, J.

Reynolds, C.R. (2001). *Clinical assessment scales for the elderly.*
Bigler, E.D. Odessa, FL: Psychological Assessment Resources.

Kamphaus, R.W. (1998). *BASC Monitor for ADHD*. Circle Pines, MN: American
Reynolds, C.R. Guidance Service.

Reynolds, C.R. (1994). *Test of memory and learning*. Austin: PRO-ED
Bigler, E.D. Publishing.

Reynolds, C.R. (1992). *Behavior assessment system for children*. Circle
Kamphaus, R.W. Pines, MN: American Guidance Service.

Reynolds, C.R. (1985). *The Revised Children's Manifest Anxiety Scale*.
Richmond, B.O. Los Angeles: Western Psychological Services.

Torrance, E.P. (1980). *Norms-technical manual for "Your style of learning*
Reynolds, C.R. *and thinking:" Form C*. Athens, GA: Georgia Studies of Creative
Behavior.

Torrance, E.P.
Reynolds, C.R.
Riegel, T.R.
(1978). *Revised Manual for your style of learning and thinking.* Athens, GA: Georgia Studies of Creative Behavior.

PAPERS

Refereed journal publications

Reynolds, C. R. (in press). Contextualized evidence and empirically-based testing and assessment. Clinical Psychology: Science and Practice.

Horton, A. M. Jr
Reynolds, C. R
(2015) *Ralph M. Reitan: Evidenced Based Before Evidence Based Was Cool.* Archives of Clinical Neuropsychology 2015 30 (8): 740-747. doi: 10.1093/arclin/acv070

Horton, A.M. Jr.
Soper, H. V.
Reynolds, C. R.
(in press). Assessment and treatment of impaired executive functions in children with traumatic brain injury. Journal of Head Injury.

Thaler, N. S.
Goldstein, G.
Pettegrew, J. W.
Luther, J.
Reynolds, C. R.
Allen, D.
(in press). Developmental aspects of working and associative memory. Archives of Clinical Neuropsychology.

Brooks, B.
Iverson, G.
Koushik, N.
Mazur-Mosiewicz, A.
Horton, A.
Reynolds, C. R.
(in press). Prevalence of low scores in children and adolescents on the Test of Verbal Conceptualization and Fluency (TVCF). Applied Neuropsychology-Child.

Riccio, C. A.
Blakely, A.
Yoon, M.
Reynolds, C. R.
(2013). Two-factor structure of the Comprehensive Trail-making test in adults. Applied Neuropsychology: Adult. 20, 1-4.

Harrison, J.
Vannest, K.
Davis, J.
Reynolds, C. R.
(2012). Common problem behaviors of children and adolescents in general education classrooms in the United States. Journal of Emotional and Behavioral Disorders, 20(1), 55-64.

Kahn, D.
Riccio, C.
Reynolds, C. R.
(2012). Comprehensive Trail-Making Test: Gender and ethnic differences for ages 8 to 18 years old. Applied Neuropsychology: Child, 1(1), 53-56.

Thaler, N.
Mayfield, J.
Reynolds, C. R.
Hadland, C.
Allen, D.
(2012). Teacher-reported behavioral disturbances in children with traumatic brain injury: An examination of the BASC-2. Applied Neuropsychology: Child, 1(1), pp.30-37

Brooks, B.
Iverson, G.
Lanting, S.
Horton, A.
Reynolds, C. R.
(2012). Improving test interpretation for detecting executive dysfunction in adults and older adults: Prevalence of low scores on the Test of Verbal Conceptualization and Fluency. Applied Neuropsychology, 19(1), 61-70.

Reynolds , C. R.
(2011). Perspectives on specialization in school psychology training and practice. Psychology in the Schools, 48(9), 922-930.

Harrison, J
Vannest, K.
Reynolds, C. R.
(2011). Behaviors that discriminate ADHD in children and adolescents: Primary symptoms, symptoms of comorbid conditions, or indicators of functional impairment? Journal of Attention Disorders, 15(2), p.147-160

Thaler, N.
Barney, S.
Reynolds, C. R.
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Reynolds, C.R.
Bigler, E.D. — Factor Structure, Factor Indexes, and Other Useful Statistics for Interpretation of the Test of Memory and Learning (TOMAL). Paper presented at the annual meeting of the National Academy of Neuropsychology, November 1994, Orlando.

James, E.M.
Henington, C.
Reynolds, C.R. — Juvenile Parkinson's Disease: Symptoms, Etiologies, and Treatments. Paper presented at the annual meeting of the National Association of School Psychologists, March 1994, Seattle.

James, E.M.
Reynolds, C.R. — Serving Children with Brain Injury in the Public Schools. Paper presented at the annual meeting of the National Association of School Psychologists, March 1994, Seattle.

Palomares, R.S.
Reynolds, C.R. — Comparison of Factor Invariance Methods: Pearson Correlation, Coefficient of Congruence, and Salient Variable Similarity Index. Paper presented at the annual meeting of the Southwest Educational Research Association, January 1994, San Antonio.

Farrell, D.
Robinson, C.
Orozco, S.
Reynolds, C.R. — Neuropsychological Status of Extremely Low Birth weight Infants at Early School Ages. Paper presented at the annual meeting of the American Psychological Association, August 1992, Washington, D.C.

Kamphaus, R.W.
Smith, K.H.
Reynolds, C.R.
Matazow, G.S. — Exploratory Factor Analysis of the Parent and Teacher Rating Scales of the BASC. Paper presented at National Association of School Psychologists, March 1991, Dallas.

Reynolds, C.R. — Technical characteristics of the Texas Features of Emotional Disturbance. Paper presented at National Association of School Psychologists, March 1991, Dallas.

Palomares, R.S.
Thompson, B.
Reynolds, C.R. — Characteristics of normal, LD, ED, and ADHD/ADD children: A behavioral assessment. Paper presented at National Association of School Psychologists, March 1991, Dallas.

Reynolds, C.R. — Myths and meaning in the measurement of intelligence. All day invited training session at annual meeting of National Association of School Psychologists, April 1990, San Francisco.

McLean, J.E.
Kaufman, A.S.
Reynolds, C.R. (1988). What role does formal education play in the IQ-age relationship across the adult life span. Paper presented at the meeting of the Mid-South Educational Research Association, Louisville, KY. Mid-South Educational Researcher, 17(1), 6-8, 13-18.

Reynolds, C.R. The Golden Rule decision: CPTA takes a position. Paper presented to the annual meeting of the American Psychological Association, New York, August, 1987.

Reynolds, C.R. Invited discussant. Symposium on marketing school psychological services at the annual meeting of the American Psychological Association, New York, August, 1987.

Hickman, J.A.
Reynolds, C.R. Barriers to school consultation in head injury cases. Paper presented to the American Psychological Association, New York, August, 1987.

Reynolds, C.R.
Kamphaus, R.W. Factor structure of the Stanford-Binet Fourth Edition at 18 age levels. Paper presented to the annual meeting of the American Psychological Association, New York, August, 1987.

Reynolds, C.R. Diagnosing learning disabilities. Invited presentation to the annual meeting of the National Academy of Neuropsychologists, Las Vegas, October, 1986.

Reynolds, C.R. Invited discussant. Symposium on the development of a system on test user qualifications at the annual meeting of the American Educational Research Association, Washington, D.C., April, 1986.

Clark, J.H.
Reynolds, C.R. An experimental test of Harrington's hypothesis of race differences. Paper presented to the annual meeting of the American Psychological Association, Los Angeles, August, 1985.

Scholwinski, E.
Reynolds, C.R. Race differences in patterns of adult intellectual ability independent of "g." Paper presented to the annual meeting of the American Psychological Association, Los Angeles, August, 1985.

Chastain, R.
Reynolds, C.R. Test scatter on the WAIS-R. Paper presented to the annual meeting of the American Psychological Association, Los Angeles, August, 1985.

Reynolds, C.R. Assessment research: The state of the art. Invited address to the annual meeting of the American Psychological Association, Los Angeles, August, 1985.

Reynolds, C.R. Perspectives on the National Academy of Science report on testing in special education. Invited address to the annual meeting of the American Psychological Association, Los Angeles, August, 1985.

Reynolds, C.R. K-ABC and controversy. Invited discussant at the annual meeting of the American Psychological Association, Los Angeles, August, 1985.

Reynolds, C.R. Sex differences on the WISC-R. Paper presented to the annual meeting of the National Association of School Psychologists, Las Vegas, April, 1985.

Kaiser, S.A.
Reynolds, C.R. Sex differences on the WPPSI. Paper presented to the annual meeting of the National Association of School Psychologists, Las Vegas, April, 1985.

Reynolds, C.R. Practical applications of neuropsychology in a school setting. A case study. Paper presented to the annual meeting of the National Association of School Psychologists, Las Vegas, April, 1985.

Reynolds, C.R. Standard practice of today, malpractice of tomorrow. Keynote address to the annual spring conference of the Georgia Association of School Psychologists, Jekyll Island, April, 1985.

Reynolds, C.R. Fundamentals of intelligent testing with the Kaufman Assessment Battery for Children. Invited address to the annual meeting of the Association for Children and Adults with Learning Disabilities, San Francisco, February, 1985.

Reynolds, C.R. Diagnostic and remedial implications of the Kaufman Assessment Battery for Children. Paper presented to the annual meeting of the Association for Children and Adults with Learning Disabilities, San Francisco, February, 1985.

Reynolds, C.R. New conceptions of intelligence measurement. Invited address to the annual meeting of the National Association for Gifted Children, St. Louis, November, 1984.

Reynolds, C.R.
Clark, J.H. Profile analysis of intelligence test performance of very high IQ children. Paper presented to the annual meeting of the National Association for Gifted Children, St. Louis, November, 1984.

Reynolds, C.R. — Evaluating subscale performance on the Adaptive Behavior Inventory for Children. Presented at the annual meeting of the American Psychological Association, Toronto, August, 1984.

Reynolds, C.R. — Invited participant in the annual Great Debate series. Annual meeting of the National Association for Gifted Children, St. Louis, November, 1984.

Reynolds, C.R. — Introduction to neuropsychological applications of the Kaufman Assessment Battery for Children. Invited presentation to the annual meeting of the National Academy of Neuropsychologists, San Diego, October, 1984.

Reynolds, C.R.
Clark, J.H. — Profile analysis of standardized test performance of low functioning individuals. Presented at the annual meeting of the American Psychological Association, Toronto, August, 1984.

Chastain, R.
Reynolds, C.R. — Analyzing WAIS-R performance by sample stratification variables used during standardization. Presented at the annual meeting of the American Psychological Association, Toronto, August, 1984.

Reynolds, C.R. — Chair, Symposium on measurement issues in learning disabilities diagnosis. Presented at the annual meeting of the American Psychological Association, Toronto, August, 1984.

Reynolds, C.R. — Problems in neuropsychological assessment of educational disorders. Paper presented to the annual meeting of the National Association of School Psychologists, Philadelphia, April, 1984.

Reynolds, C.R. — Evaluating aptitude achievement discrepancies in LD diagnosis. Paper presented to the annual meeting of the National Association of School Psychologists, Philadelphia, April, 1984.

Ash, M.J.
Reynolds, C.R. — A shoplifting diversion program for adolescents. Paper presented to the annual meeting of the American Educational Research Association, New Orleans, April, 1984.

Reynolds, C.R.
Willson, V.L. — Consistency of sequential and simultaneous processing for Blacks and Whites. Paper presented to the annual meeting of the American Educational Research Association, New Orleans, April, 1984.

Reynolds, C.R.
Willson, V.L.
Black-White differences in sequential and simultaneous processing independent of "g." Paper presented to the annual meeting of the American Educational Research Association, New Orleans, April, 1984.

Willson, V.L.
Reynolds, C.R.
Another look at evaluating aptitude-achievement discrepancies in diagnosis of learning disabilities. National Council on Measurement in Education, New Orleans, April, 1984.

Reynolds, C.R.
Willson, V.L.
Selz and Reitan Scatter on the WAIS-R: National Normative Data. Paper presented to the annual meeting of the National Academy of Neuropsychologists, Houston, October, 1983.

Reynolds, C.R.
Barona, A.
Predicting premorbid intelligence on the WAIS-R: National Normative Data. Paper presented to the annual meeting of the National Academy of Neuropsychologists, Houston, October, 1983.

Reynolds, C.R.
Clinical acumen, psychometric naiveté, and traditional psychometric concepts in neuropsychological assessment. Invited address to the annual meeting of the National Academy of Neuropsychologists, Houston, October, 1983.

Reynolds, C.R.
Changing conceptualizations of race differences in intelligence. Invited address to the annual meeting of the American Psychological Association, Anaheim, August, 1983.

Reynolds, C.R.
Clinical acumen but psychometric naiveté in neuropsychological research and practice. Paper presented to the annual meeting of the American Psychological Association, Anaheim, August, 1983.

Reynolds, C.R.
Milam, D.A.
Measurement concept complexity in educational psychology versus other disciplines. Paper presented to the annual meeting of the American Psychological Association, Anaheim, August, 1983.

Brown, R.T.
Reynolds, C.R.
Experimentum crucis in psychology. Paper presented to the annual meeting of the American Psychological Association, Anaheim, August, 1983.

Willson, V.L.
Reynolds, C.R.
Chatman, S.P.
Regression analyses of bias on the Kaufman Assessment Battery for Children. Paper presented to the annual meeting of the American Psychological Association, Anaheim, August, 1983.

Chatman, S.P.
Reynolds, C.R.
Willson, V.L.
Test scatter on the K-ABC. Paper presented to the annual meeting of the American Psychological Association, Anaheim, August, 1983.

Reynolds, C.R.
Willson, V.L.
Chatman, S.P.
Age and raw score increases on the K-ABC. Paper presented to the annual meeting of the National Association of School Psychologists, Detroit, April, 1983.

Willson, V.L.
Reynolds, C.R.
Chatman, S.P.
Kaufman, A.S.
Confirmatory analysis of simultaneous and sequential factors on the K-ABC. Paper presented to the annual meeting of the National Association of School Psychologists, Detroit, April, 1983.

Reynolds, C.R.
Invited discussant to the symposium "Development of a new apperception test for children." Paper presented to the annual meeting of the National Association of School Psychologists, Detroit, April, 1983.

Reynolds, C.R.
Willson, V.L.
Item bias on the 1981 revision of the PPVT using a new method of detecting bias. Paper presented to the annual meeting of the American Educational Research Association, Detroit, April, 1983.

Reynolds, C.R.
Willson, V.L.
Standardized grade equivalents. Really! no, well, sort of, but they lead to the valley of the shadow of misinterpretation and confusion. Paper presented to the annual meeting of the Southwestern Educational Research Association, New Orleans, February, 1983.

Reynolds, C.R.
Willson, V.L.
Clark, P.L.
A four-test short form of the WAIS-R for clinical screening. Paper presented to the annual meeting of the National Academy of Neuropsychologists, Atlanta, October, 1982.

Willson, V.L.
Reynolds, C.R.
Methodological and statistical problems in determining membership in clinical populations. Paper presented to the annual meeting of the National Academy of Neuropsychologists, Atlanta, October, 1982.

Reynolds, C.R.
Scholwinski, E.
Dimensions of anxiety among high IQ children. Paper presented to the annual meeting of the National Association for Gifted Children, New Orleans, October, 1982.

Reynolds, C.R.
Convergent and divergent validity of the Revised Children's Manifest Anxiety Scale. Paper presented to the annual meeting of

the American Psychological Association, Washington, August, 1982.

Reynolds, C.R. Regression analyses of race and sex bias in seven preschool tests. Paper presented to the annual meeting of the American Psychological Association, Washington, August, 1982.

Reynolds, C.R. Strength models of remediation in behavioral neuropsychology. Paper presented to the annual meeting of the American Psychological Association, Washington, August, 1982.

Reynolds, C.R.
Harding, R.E. Outcome in studies of factorial similarity under six methods of comparison. Paper presented to the annual meeting of the American Psychological Association, Washington, August, 1982.

Reynolds, C.R.
Willson, V.L. Intellectual differences among Mexican-Americans, Papagos, and Whites independent of "g." Paper presented to the annual meeting of the American Psychological Association, Washington, August, 1982.

Paget, K.D.
Reynolds, C.R. Dimensions and level of anxiety among learning disabled children. Paper presented to the annual meeting of the American Psychological Association, Washington, August, 1982.

Reynolds, C.R. Issues of cultural bias in the assessment of minority handicapped children. Paper presented to the Nebraska National Conference on Assessment and Programming for Children with Low Incidence Handicaps, Lincoln, June, 1982.

Jean, P.J.
Reynolds, C.R. Sex and attitude distortion: The faking of liberal and traditional attitudes about changing sex roles. Paper presented to the annual meeting of the American Educational Research Association, New York, March, 1982.

Reynolds, C.R.
Plake, B.S.
Harding, R.E. Group by item interaction in the assessment of children's anxiety levels: Effects of race and sex on item responses. Paper presented to the annual meeting of the American Educational Research Association, New York, March, 1982.

Reynolds, C.R.
Elliott, S.N. Trends in test development and test publishing. Paper presented to the annual meeting of the National Council on Measurement in Education, New York, March, 1982.

Plake, B.S. The influence of ethnic group membership on the measurement

Piersel, W.C.
Harding, R.E.
Reynolds, C.R.
and meaning of attitudes towards reading. Paper presented to the annual meeting of the National Council on Measurement in Education, New York, March, 1982.

Reynolds, C.R.
Revised Children's Manifest Anxiety Scale - Its clinical use and interpretation. Invited discussant, annual meeting of the National Association of School Psychologists, Toronto, March, 1982.

Gutkin, T.B.
Galvin, G.A.
Reynolds, C.R.
Factor analysis of the WAIS-R standardization sample. Paper presented to the annual meeting of the National Association of School Psychologists, Toronto, March, 1982.

Reynolds, C.R.
Paget, K.D.
National normative data for the Revised Children's Manifest Anxiety Scale. Paper presented to the annual meeting of the National Association of School Psychologists, Toronto, March, 1982.

Reynolds, C.R.
Bradley, M.
Emotional stability of gifted children as estimated by chronic anxiety levels. Paper presented to the annual meeting of the Southwestern Educational Research Association, Austin, February, 1982.

Reynolds, C.R.
Struer, J.A.
Use of the WAIS-R with emotionally disturbed children. Paper presented to the annual Midwestern Conference on Psychology in the Schools, Omaha, October, 1981.

Reynolds, C.R.
Test bias: In God we trust, all others must have data. Invited address to Division 5 at the annual meeting of the American Psychological Association, Los Angeles, August, 1981.

Reynolds, C.R.
Gutkin, T.B.
Patterns of WPPSI scatter: Normative analyses of the standardization sample. Paper presented to the annual meeting of the American Psychological Association, Los Angeles, August, 1981.

Leigh, C.J.
Reynolds, C.R.
Morning versus afternoon administration and children's intelligence test performance. Paper presented to the annual meeting of the American Psychological Association, Los Angeles, August, 1981.

Clark, J.H.
Reynolds, C.R.
Trends in school psychology research: 1974-1980. Paper presented to the annual meeting of the American Psychological Association, Los Angeles, August, 1981.

Reynolds, C.R.
Human mental abilities: A health psychology perspective. Paper presented to the annual meeting of the American Psychological Association, Los Angeles, August, 1981.

Reynolds, C.R.
Struer, J.
Factor structure of the WISC-R for emotionally disturbed children. Paper presented to the annual meeting of the National Association of School Psychologists, Houston, April, 1981.

Carlson, L.C.
Reynolds, C.R.
Gutkin, T.B.
Comparative WISC-R factor analysis for upper and lower SES groups. Paper presented to the annual meeting of the National Association of School Psychologists, Houston, April, 1981.

Reynolds, C.R.
Piersel, W.C.
A regression analysis of bias in the predictive validity of the Boehm Test of Basic Concepts (Forms A & B) for White and Mexican-American children. Paper presented to the annual meeting of the American Educational Research Association, Los Angeles, April, 1981.

Reynolds, C.R.
Internal validity of the WISC-R as a measure of intelligence for Blacks, Whites, Males, and Females. Paper presented to the annual meeting of the National Council on Measurement in Education, Los Angeles, April, 1981.

Reynolds, C.R.
The McCarthy Screening Test: Is it valid? Invited discussant, annual meeting of the National Council on Measurement in Education, Los Angeles, April, 1981.

Hynd, G.W.
Reynolds, C.R.
Neuropsychological assessment of the school-aged child. Paper presented to the annual meeting of the Southwestern Psychological Association, Houston, April, 1981.

Piersel, W.C.
Plake, B.S.
Reynolds, C.R.
Harding, R.D.
Conceptual development and ethnic group membership: Item bias on the Boehm Test of Basic Concepts. Paper presented to the annual meeting of the Iowa Educational Research Association, Iowa City, December, 1980.

Reynolds, C.R.
The fallacy of grade equivalents and an alternative statistical approach to diagnosing specific learning disabilities. Paper

presented at the Annual Midwestern Conference on Psychology in the Schools, Omaha, October, 1980.

Reynolds, C.R. — The importance of norms and other psychometric concepts to assessment in clinical neuropsychology. Invited address to NATO/ASI International Conference on Neuropsychology and Cognition, Augusta, GA, September, 1980.

Reynolds, C.R.
Jensen, A.R. — Patterns of intellectual ability between Blacks and Whites matched on "g." Paper presented at the annual meeting of the American Psychological Association, Montreal, September, 1980.

Reynolds, C.R.
Wright, D.
Wilkinson, W.A. — Incremental validity of two common preschool screening measures. Paper presented at the annual meeting of the American Psychological Association, Montreal, September, 1980.

Gutkin, T.B.
Reynolds, C.R. — WISC-R factor equivalence across race: Examining the standardization sample. Paper presented at the annual meeting of the American Psychological Association, Montreal, September, 1980.

Piersel, W.C.
Reynolds, C.R. — Factorial validity of the Boehm Test of Basic Concepts. Paper presented at the annual meeting of the American Psychological Association, Montreal, September, 1980.

Reynolds, C.R.
Gutkin, T.B. — WISC-R performance of blacks and whites matched on four demographic variables. Paper presented at the annual meeting of the American Psychological Association, Montreal, September, 1980.

Carlson, L.C.
Reynolds, C.R. — Specific variance of the WPPSI subtests at six age levels. Paper presented at the annual meeting of the American Psychological Association, Montreal, September, 1980.

Plake, B.S.
Reynolds, C.R.
Gutkin, T.B. — Comparing profile variance across independent groups. Paper presented at the annual meeting of the American Psychological Association, Montreal, September, 1980.

Reynolds, C.R.
Gutkin, T.B. — Normative data for interpreting Reitan's index of Wechsler subtest scatter. Paper presented at the annual meeting of the American Psychological Association, Montreal, September, 1980.

Reynolds, C.R.
Hartlage, L.C.
Haak, R.A.
Lateral preference as determined by neuropsychological performance and aptitude/achievement discrepancies. Paper presented at the annual meeting of the American Psychological Association, Montreal, September, 1980.

Reynolds, C.R.
Bradley, M.
Steele, C.
The objective measurement of anxiety with kindergarten children. Paper presented to the annual meeting of the National Association of School Psychologists, Washington, April, 1980.

Reynolds, C.R.
Differential predictive validity of a preschool battery across race and sex. Paper presented to the annual meeting of the American Educational Research Association, Boston, April, 1980.

Reynolds, C.R.
Predictive validity of the WISC-R for White and Mexican-American children. Paper presented to the annual meeting of the American Educational Research Association, Boston, April, 1980.

Reynolds, C.R.
Bossard, M.D.
Gutkin, T.B.
A regression analysis of test bias on the Stanford-Binet Intelligence Scale. Paper presented to the annual meeting of the American Educational Research Association, Boston, April, 1980.

Reynolds, C.R.
Development of a measurement consultation service through the Buros Institute of Mental Measurements. Paper presented to the Annual Midwestern Conference on Psychology in the Schools, Boys Town Center for the Study of Youth Development, October, 1979.

Reynolds, C.R.
Critical issues in the identification of gifted children. Paper presented to the annual meeting of the Nebraska Council for Exceptional Children, Lincoln, October, 1979.

Reynolds, C.R.
Factor stability of the MRT across race and sex. Paper presented to the annual meeting of the American Psychological Association, New York, September, 1979.

Reynolds, C.R.
Gutkin, T.B.
Statistical aids to interpreting the Peabody Individual Achievement Test. Paper presented to the annual meeting of the American Psychological Association, New York, September, 1979.

Gutkin, T.B.
WISC-R factor structures for Whites and Chicanos referred

Reynolds, C.R. to psychological services. Paper presented to the annual meeting of the American Psychological Association, New York, September, 1979.

Jean, P.J.
Reynolds, C.R. The Bias in Attitudes Survey. A female/male role questionnaire. Paper presented to the annual meeting of the Nebraska Academy of Sciences, Lincoln, April, 1979.

Reynolds, C.R. Referral and consultation with the pediatric neurologist. Paper presented to the annual meeting of the National Association of School Psychologists, San Diego, March, 1979.

Reynolds, C.R.
McBride, R.D.
Gibson, L.J. Black-White IQ discrepancies may be related to differences in hemisphericity. Paper presented to the annual meeting of the National Association of School Psychologists, San Diego, March, 1979.

Reynolds, C.R. Understanding your style of learning and thinking. Paper presented to the 25th Jubilee Annual Creative Problem Solving Institute, Buffalo, June, 1979.

Reynolds, C.R. A children's form of "Your Style of Learning and Thinking:" Preliminary data. Paper presented to the 25th Jubilee Annual Creative Problem Solving Institute, Buffalo, June, 1979.

Reynolds, C.R. Modifying styles of learning and thinking (hemisphericity). Paper presented to the 25th Jubilee Annual Creative Problem Solving Institute, Buffalo, June, 1979.

Reynolds, C.R. Your style of learning and other R/L matters. Invited prize paper address to the annual meeting of the National Association for Gifted Children, Houston, November 1978.

Reynolds, C.R. Styles of learning and thinking. Invited discussant to the annual meeting of the National Association for Gifted Children, Houston, November, 1978.

Reynolds, C.R. Problems in preschool assessment. Invited address to the fall meeting of the Nebraska Association of School Psychologists, Lincoln, September, 1978.

Reynolds, C.R.
Richmond, B.O. Factor structure and construct validity of the Revised Children's Manifest Anxiety Scale. Presented to annual meeting of the American Psychological Association, Toronto, August, 1978.

Reynolds, C.R.	Factor structure of the Peabody Individual Achievement Test. Presented to annual meeting of the National Association of School Psychologists, New York, March, 1978.
Reynolds, C.R. Kaufman, A.S.	Conjugate lateral eye movements in preschool and primary grade children. Presented to annual meeting of the Southeastern Psychological Association, Atlanta, March, 1978.
Reynolds, C.R. Hartlage, L.C.	Comparison of WISC and WISC-R racial regression lines for academic prediction. Presented to annual meeting of the Southeastern Psychological Association, Atlanta, March, 1978.
Reynolds, C.R.	Educating the split-brain: A review of research on hemispheric specialization and its implications for special education. Presented to first joint meeting of the Georgia Association of School Psychologists and Georgia Council for Exceptional Children, Atlanta, October, 1977.
Reynolds, C.R.	The normative approach to interpreting test scatter: The WISC-R example. Presented to annual meeting of the Georgia Association of School Psychologists, Atlanta, May, 1977.
Reynolds, C.R. Richmond, B.O.	The Revised Children's Manifest Anxiety Scale: A potential screening and clinical tool for the school psychologist. Presented to annual meeting of the National Association of School Psychologists, Cincinnati, March, 1977.
Reynolds, C.R. McBride, R.D.	Effective psychological communication within a school setting with a note on writing recommendations. Presented to annual meeting of the National Association of School Psychologists, Cincinnati, March, 1977.
Reynolds, C.R.	Use of the McCarthy drawing tests as a group screening instrument. Presented to annual meeting of the National Association of School Psychologists, Cincinnati, March, 1977.
Reynolds, C.R.	The role of the school psychologist and its relation to pediatric neurology. Invited address to Medical College of Georgia Conference on Pediatric Neurology, Augusta, GA, June, 1977.

INVITED PRESENTATIONS TO STATE AND REGIONAL ASSOCIATIONS (and related organizations)

Annual Midwestern Conference on Psychology in the Schools
APA, Division of School Psychology (Preconvention Institute)
Arizona Association of School Psychologists
Arkansas Department of Education
Arkansas Counselors Association
California Association of School Psychologists
Children's National Mental Health Conference (First Annual, Seattle)
Cleveland Area Association of School Psychologists
Colorado Association of School Psychologists
Creative Problem Solving Institute (CPSI, Buffalo, NY)
Dallas-Ft. Worth Regional Association of School Psychologists
Developmental Therapy Institute
Florida Association of School Psychologists
Georgia Association of School Psychologists
Georgia Council for Exceptional Children
Illinois Psychological Association
Illinois School Psychologists Association
Idaho Psychological Association
Indiana Association of School Psychologists
Kansas School Psychologists Association
Louisiana School Psychologists Association
Louisiana Educational Diagnosticians Association
Maryland Association of School Psychologists
The Mayo Clinic (Grand Rounds, Rochester)
Montana Association of School Psychologists
NATO/ASI International Conference on Neuropsychology and Cognition
National Conference on Assessment and Programming for Children with Low Incidence Handicaps
Nebraska Association of School Psychologists
Nevada Alliance on Special Education
Nevada Association of School Psychologists
Nevada Personnel and Guidance Association
New Hampshire Association of School Psychologists
New Jersey Association of School Psychologists
New Jersey Neuropsychological Association
New Mexico Association of School Psychologists
New York Association of School Psychologists
North Carolina Association of School Psychologists
Penn State University School Psychology Conference
Oklahoma School Psychologists Association
Ontario Psychological Association
Psi Chi (University of North Carolina at Wilmington Chapter)
Rocky Mountain Educational Research Association
Saskatchewan Educational Psychologists Association
Tennessee Psychological Association

Texas Association of School Psychologists
Texas Bar Association Capital Defense Project Conference
Texas Criminal District Attorneys Association
Texas Educational Diagnosticians Association (Hou-Met Chapter)
Texas Educational Diagnosticians Association (State)
Wisconsin Conference on Assessment and Programming for Exceptional Students
Wyoming Association of School Psychologists

WORKSHOPS AND COLLOQUIA: MORE THAN 700 SINCE AUGUST 1982.

Reynolds, C.R.	Design and follow through in the assessment process. Invited workshop for Educational Service Center #6, Huntsville, TX: August, 1982.
Reynolds, C.R.	Conference coordinator. Nebraska Conference on Assessment and Programming for Children with Low Incidence Handicaps, Lincoln, NE: June, 1982.
Reynolds, C.R. Hartlage, L.C.	Neuropsychological appraisal of the young handicapped child. Invited workshop for Nebraska Diagnostic Resource Center, Cozad, NE: March, 1982.
Reynolds, C.R.	Objective evaluation of emotional disorder of children. Invited workshop for Nebraska Diagnostic Resource Center, Cozad, NE: April, 1982.
Reynolds, C.R.	Individual assessment of preschool handicapped children. Invited workshop for Nebraska Department of Education, Lincoln, NE: June, 1981 (repeated 7/81, 10/81 and 7/82).
Reynolds, C.R.	Preschool assessment with the McCarthy Scales. Invited workshop for Texas Association of Educational Diagnosticians, Hou-Met, Houston, TX: October, 1981.
Reynolds, C.R.	Design of a nonbiased assessment process. Invited address to the Sixth Annual Conference on Personality Assessment for the School Age Child, Glassboro, NJ: May, 1981.
Reynolds, C.R.	Neuropsychological assessment of school-aged children. Invited full day workshops for the Florida Association of School Psychologists, Tallahassee, Tampa, and Ft. Lauderdale, FL: May, 1981.

Reynolds, C.R. Effects of test bias on minority groups. Invited colloquium for Dean's Inquiry Session at Texas A&M University, College Station, TX: April, 1981.

Reynolds, C.R. Empirical assessment of bias in mental tests. Invited colloquium presented to the Ontario Institute for Studies in Education, Toronto, Canada: April, 1981.

Reynolds, C.R. Assessment of the preschool child. Invited workshop for the Nebraska Diagnostic Resource Center, Cozad, NE: April, 1981.

Reynolds, C.R. The problem of bias in psychological and educational tests. Invited address to the Cleveland Area Association of School Psychologists, Cleveland, OH: January, 1981.

Reynolds, C.R. Applying brain-behavior research to teaching and learning in the classroom. Invited conference leader to Utah State University, Logan, UT: July, 1980.

Reynolds, C.R. Empirical evaluation of the cultural test bias hypothesis. Invited colloquium presented to the Department of Psychology, North Carolina State University, Raleigh, NC: February, 1980.

Reynolds, C.R. Accurate identification of preschool handicapped children. Invited presentation to Lincoln Public Schools, Psychological Services Division, Lincoln, NE: October, 1979.

Reynolds, C.R. Problems and practices in the early identification of gifted and creative children. Invited presentation to the Parent's Advisory Council on Gifted Programs, Lincoln Public School, Lincoln, NE: March, 1979.

Reynolds, C.R. Comprehensive evaluation of the preschool child. Invited workshop for Omaha Public Schools, Psychological Services Division, Omaha, NE: February, 1979.

Reynolds, C.R. Early evaluation of the severely mentally impaired. Invited workshop for Beatrice State Developmental Center, Psychology Division, Beatrice, NE: March, 1979.

Reynolds, C.R. Application of the McCarthy Scales with the severely and profoundly retarded. Invited workshop for Beatrice State Developmental Center, Psychology Division, Beatrice, NE: April, 1979.

Reynolds, C.R. Psychological aspects of epilepsy and other common neurological problems of childhood. Invited workshop for Beatrice State Developmental Center, Psychology Division, Beatrice, NE: May, 1979.

Reynolds, C.R. Presentation of psychological data in the schools. Invited workshop for Lincoln Public Schools, Lincoln, NE: November, 1978.

Reynolds, C.R. Current conceptualizations of hemisphericity. Invited colloquium, University of Texas-Austin, Austin, TX: April, 1978.

Reynolds, C.R. Lateral dominance, cerebral specialization, and interhemispheric integration for information processing. Invited colloquium, University of Nebraska-Lincoln, Lincoln, NE: April, 1978.

Reynolds, C.R. Preschool assessment with the McCarthy Scales. Workshop presented at the Developmental Therapy Institute Training Seminar, Wilmington, NC: January, 1978.

Reynolds, C.R.
Spivack, G.S. Developing self-concept and self-awareness in the elementary school child. Invited workshop for Statham Schools, Statham, GA: October, 1977.

Reynolds, C.R. Relating test interpretation to educational programming. Invited workshop for Griffin Cooperative Educational Service Agency, Griffin, GA: September, 1977.

Reynolds, C.R.
Spivack, G.S. Self-concept in elementary school children. Workshop presented to Barrow County School District, Winder, GA: July, 1977.

Reynolds, C.R. Administration and scoring of the AAMD Adaptive Behavior Scale. Workshop presented to Clarke County Schools, Division of Exceptional Children, Athens, GA: November, 1976.

Technical Reports, Limited Distribution Papers, and Non-Refereed Publications:

Koocher, G.P.
Goodman, G.S.
White, S.
Freidrich, W.N.
Sivan, A.B. (1994). Psychological science and the use of anatomically detailed dolls in sexual abuse assessments. Report of the Anatomical Doll Task Force to American Psychological Association Council of Representatives, February.

Reynolds, C.R.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CIGAR ASSOCIATION OF AMERICA et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION et al., Defendants.	)	Civil Action No. 16-1460 (APM)

DECLARATION OF CECIL R. REYNOLDS, PHD
EXHIBIT 2

TABLE 3

Trends in 30-Day Prevalence of Use of Various Drugs for Grades 8, 10, and 12 Combined

(Entries are percentages.)

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
Any Illicit Drug[b]	10.9	10.5	13.3	16.8	18.6	20.6	20.5	19.5	19.5	19.2	19.4	18.2	17.3	16.2	15.6
Any Illicit Drug other than Marijuana[b]	5.4	5.5	6.5	7.1	8.4	8.4	8.4	8.2	7.9	8.0‡	8.2	7.7	7.1	7.0	6.7
Any Illicit Drug including Inhalants[b]	13.0	12.5	15.4	18.9	20.7	22.4	22.2	21.1	21.1	21.0	20.8	19.5	18.6	17.5	17.5
Marijuana/Hashish	8.3	7.7	10.2	13.9	15.6	17.7	17.9	16.9	16.9	16.3	16.6	15.3	14.8	13.6	13.4
Inhalants	3.2	3.3	3.8	4.0	4.3	3.9	3.7	3.4	3.3	3.2	2.8	2.7	2.7	2.9	2.9
Hallucinogens	1.5	1.6	1.9	2.2	3.1	2.7	3.0	2.8	2.5	2.0‡	2.3	1.7	1.5	1.5	1.5
LSD	1.3	1.5	1.6	1.9	2.8	2.1	2.4	2.3	2.0	1.4	1.5	0.7	0.6	0.6	0.6
Hallucinogens other than LSD	0.5	0.5	0.7	1.0	1.0	1.2	1.2	1.2	1.1	1.1‡	1.4	1.4	1.2	1.3	1.2
Ecstasy (MDMA)[c], original	–	–	–	–	–	1.5	1.3	1.2	1.6	2.4	2.4	1.8	1.0	0.9	0.9
Revised	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Cocaine	0.8	0.9	0.9	1.2	1.5	1.7	1.8	1.9	1.9	1.7	1.5	1.6	1.4	1.6	1.6
Crack	0.4	0.5	0.5	0.7	0.8	0.9	0.8	1.0	0.9	0.9	0.9	1.0	0.8	0.8	0.8
Other cocaine	0.7	0.7	0.8	1.1	1.2	1.3	1.5	1.6	1.7	1.4	1.3	1.3	1.2	1.4	1.3
Heroin	0.2	0.3	0.3	0.4	0.6	0.6	0.6	0.6	0.6	0.6	0.4	0.5	0.4	0.5	0.5
With a needle	–	–	–	–	0.3	0.4	0.3	0.4	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Without a needle	–	–	–	–	0.4	0.4	0.5	0.4	0.4	0.4	0.3	0.4	0.3	0.3	0.3
Amphetamines[b]	3.0	3.3	3.9	4.0	4.5	4.8	4.5	4.3	4.2	4.5	4.7	4.4	3.9	3.6	3.3
Methamphetamine	–	–	–	–	–	–	–	–	1.5	1.5	1.4	1.5	1.4	1.1	0.9
Tranquilizers	1.1	1.1	1.1	1.3	1.6	1.7	1.7	1.9	1.9	2.1‡	2.3	2.4	2.2	2.1	2.1
Alcohol	39.8	38.4‡	36.3	37.6	37.8	38.8	38.6	37.4	37.2	36.6	35.5	33.3	33.2	32.9	31.4
Been drunk	19.2	17.8	18.2	19.3	20.3	20.4	21.2	20.4	20.6	20.3	19.7	17.4	17.7	18.1	17.0
Flavored alcoholic beverages	–	–	–	–	–	–	–	–	–	–	–	–	–	23.0	21.6
Cigarettes	20.7	21.2	23.4	24.7	26.6	28.3	28.3	27.0	25.2	22.6	20.2	17.7	16.6	16.1	15.3
Smokeless Tobacco	–	9.2	9.1	9.7	9.6	8.5	8.0	7.0	6.3	5.8	6.1	5.2	5.3	5.1	5.3
E-cigarettes	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Large Cigars	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Flavored Little Cigars	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Regular Little Cigars	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Steroids	0.6	0.6	0.6	0.7	0.6	0.5	0.7	0.7	0.9	0.9	0.9	1.0	0.9	0.9	0.7

Table continued on next page.

TABLE 3 (continued)
Trends in 30-Day Prevalence of Use of Various Drugs for Grades 8, 10, and 12 Combined

(Entries are percentages.)

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2015–2016 change	Peak year–2016 change: Absolute change	Peak year–2016 change: Proportional change (%)*	Low year–2016 change: Absolute change	Low year–2016 change: Proportional change
Any Illicit Drug[a]	14.9	14.8	14.6	15.8	16.7	17.0	16.8	17.3‡	**16.5**	15.9	15.5	-0.4	-1.0	-6.0	—	—
Any Illicit Drug other than Marijuana[a]	6.4	6.4	5.9	5.7	5.7	5.7	5.2	5.4‡	**5.4**	5.1	4.6	-0.5 s	-0.9 ss	-15.7	—	—
Any Illicit Drug including Inhalants[a]	16.5	16.5	16.1	17.3	18.0	18.3	17.6	18.4‡	**17.3**	16.8	16.0	-0.7	-1.3 s	-7.4	—	—
Marijuana/Hashish	12.5	12.4	12.5	13.8	14.8	15.2	15.1	15.6	14.4	14.0	13.7	-0.3	-4.2 sss	-23.4	+1.4 ss	+10.9
Inhalants	2.7	2.6	2.6	2.5	2.4	2.1	1.7	1.5	1.4	1.3	1.2	-0.1	-3.1 sss	-72.8	—	—
Hallucinogens	1.3	1.4	1.4	1.3	1.4	1.3	1.1	1.1	1.0	1.0	1.0	0.0	-1.3 sss	-57.3	—	—
LSD	0.6	0.6	0.7	0.5	0.7	0.7	0.5	0.6	0.6	0.7	0.7	0.0	-2.1 sss	-74.9	+0.1	+26.7
Hallucinogens other than LSD	1.1	1.1	1.1	1.0	1.2	1.0	0.9	0.8	0.7	0.6	0.5	-0.1	-0.9 sss	-62.9	—	—
Ecstasy (MDMA)[b], original	1.0	1.1	1.2	1.2	1.5	1.4	0.8	1.0	0.8	—	—	—	—	—	—	—
Revised	—	—	—	—	—	—	—	—	**1.1**	0.8	0.6	-0.3 ss	-0.5 s	-49.1	—	—
Cocaine	1.6	1.4	1.3	1.0	0.9	0.8	0.8	0.8	0.7	0.8	0.5	-0.3 ss	-1.3 sss	-71.8	—	—
Crack	0.7	0.7	0.6	0.5	0.5	0.5	0.4	0.4	0.4	0.4	0.3	-0.1	-0.7 sss	-73.9	—	—
Other cocaine	1.4	1.1	1.1	0.8	0.8	0.7	0.7	0.6	0.6	0.7	0.4	-0.3 sss	-1.3 sss	-75.9	—	—
Heroin	0.4	0.4	0.4	0.4	0.4	0.4	0.3	0.3	0.3	0.2	0.2	0.0	-0.4 sss	-64.4	—	—
With a needle	0.3	0.3	0.3	0.2	0.3	0.3	0.2	0.2	0.3	0.1	0.2	0.0	-0.2 sss	-57.6	0.0	+15.6
Without a needle	0.3	0.3	0.2	0.2	0.3	0.3	0.2	0.2	0.2	0.2	0.1	-0.1	-0.4 sss	-74.8	—	—
Amphetamines[b]	3.0	3.2	2.6	2.7	2.7	2.8	2.5	3.2‡	**3.2**	2.7	2.5	-0.3	-0.7 sss	-22.3	—	—
Methamphetamine	0.7	0.5	0.7	0.5	0.6	0.5	0.5	0.4	0.3	0.3	0.3	-0.1	-1.3 sss	-63.1	—	—
Tranquilizers	2.1	2.0	1.9	1.9	1.9	1.7	1.5	1.5	1.5	1.5	1.4	-0.1	-1.0 sss	-43.0	—	—
Alcohol	31.0	30.1	28.1	28.4	26.8	25.5	25.9	24.3	22.6	21.8	19.8	-2.0 sss	-19.0 sss	-49.0	—	—
Been drunk	17.4	16.5	14.9	15.2	14.6	13.5	14.7	13.5	11.9	11.0	10.1	-0.9 s	-11.1 sss	-52.4	—	—
Flavored alcoholic beverages	21.7	20.4	18.6	17.9	17.0	15.2	14.9	14.0	12.9	12.8	10.9	-1.9 sss	-12.2 sss	-52.7	—	—
Cigarettes	14.4	13.6	12.6	12.7	12.8	11.7	10.6	9.6	8.0	7.0	5.9	-1.1 sss	-22.4 sss	-79.3	—	—
Smokeless Tobacco	5.1	5.2	4.9	6.0	6.5	5.9	5.6	5.7	5.4	4.7	4.1	-0.5	-5.5 sss	-57.3	—	—
E-Vaporizers	—	—	—	—	—	—	—	—	—	**12.8**	9.9	-2.9 sss	-2.9 sss	-22.8	—	—
Large Cigars	—	—	—	—	—	—	—	—	3.9	**4.2**	3.3	-0.9 sss	-0.9 sss	-20.9	—	—
Flavored Little Cigars	—	—	—	—	—	—	—	—	**7.4**	7.1	5.6	-1.5 sss	-1.8 sss	-24.4	—	—
Regular Little Cigars	—	—	—	—	—	—	—	—	4.5	**4.9**	3.6	-1.3 sss	-1.3 sss	-26.9	—	—
Steroids	0.7	0.6	0.6	0.6	0.6	0.5	0.5	0.6	0.5	0.5	0.4	-0.1	-0.6 sss	-57.6	—	—

Source. The Monitoring the Future study, the University of Michigan.

Notes. '–' indicates data not available. '‡' indicates a change in the question text. When a question change occurs, peak levels after that change are used to calculate the peak year to current year difference.
Values in bold equal peak levels since 1991. Values in italics equal peak level before wording change. Underlined values equal lowest level since recent peak level.
Level of significance of difference between classes: s = .05, ss = .01, sss = .001.
Any apparent inconsistency between the change estimate and the prevalence estimates for the two most recent years is due to rounding.

[*] The proportional change is the percent by which the most recent year deviates from the peak year [or the low year] for the drug in question. So, if a drug was at 20% prevalence in the peak year and declined to 10% prevalence in the most recent year, that would reflect a proportional decline of 50%.

[a] In 2013, for the questions on the use of amphetamines, the text was changed on two of the questionnaire forms for 8th and 10th graders and four of the questionnaire forms for 12th graders. This change also impacted the any illicit drug indices. Data presented here include only the changed forms beginning in 2013.

[b] In 2014, the text was changed on one of the questionnaire forms for 8th, 10th, and 12th graders to include "molly" in the description. The remaining forms were changed in 2015. Data for both versions of the question are presented here.

MTF 2016 Key Findings at 58-59.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CIGAR ASSOCIATION OF AMERICA et al.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 16-1460 (APM)
UNITED STATES FOOD AND DRUG ADMINISTRATION et al.,	)	
Defendants.	)	

DECLARATION OF ROCKY PATEL

I, Rocky Patel, declare as follows:

1. I am the President and CEO of Rocky Patel Premium Cigars. I have personal knowledge of the following facts.

2. Rocky Patel Premium Cigars is a market-leading manufacturer and retailer of premium cigars and cigar accessories. We are a family company based in Bonita Springs, Florida, with production facilities in Nicaragua and Honduras.

3. A new FDA rule requires that we place very large warning labels on our premium cigar products that would cover 30% of each of the two principal display panels of a cigar box.

4. Our cigar packaging is very special and unique. We create beautiful cigar boxes to reflect and communicate the care and craftsmanship that went into the production of our cigars. We want consumers to feel that they are purchasing a luxury item when they buy a box of our premium cigars, and we use our distinctive and trademarked logos and product designs to market and differentiate our products. We also use the packaging to communicate information about the cigars contained therein that are of interest to consumers, including the country of

origin, seed varietal of the tobacco leaf, and amount of time the product has been aged, among many other things. Customers often retain our decorative boxes to use for other purposes after they have finished enjoying the cigars themselves, and the boxes remind the consumer of the distinctiveness of the Rocky Patel brand versus others.

5. We currently apply labels warning consumers of the health risks of cigar smoking, in part to comply with California law. The warning labels required under the FDA's new rule are significantly larger (approximately 10 times or more on a typical-sized cigar box) than the labels required by California law and restrict our ability to communicate the qualities of our product and process to consumers.

6. The FDA warning labels must occupy **30 percent** of the **two principal** display panels of a cigar box. I understand that the top of a cigar box would be one principal display panel. It is not yet clear whether the FDA would consider the front of the box or the inside cover of the box as the second principal display panel.

7. I am aware that other cigar companies are subject to a consent decree with the Federal Trade Commission (FTC) that requires them to carry certain warning labels on their cigar packages. My company is not a party to a consent decree with the FTC, but I know that the FTC warning label requirements are substantially smaller than the warning labels required by the new FDA rule and only have to appear on one display panel. On a typical cigar box, the FDA's new warning labels will be approximately 300 to 400% percent larger than warning labels required under the FTC consent decree.

8. My company has prepared graphics showing how the warning labels required by the new FDA rule would affect the packaging of two of our existing premium cigar products:

Rocky Patel Fifty-Five Handmade Premium Cigars ("Fifty-Five Cigars") and Rocky Patel Special Edition handmade premium cigars ("Special Edition Cigars").

9. Exhibit A to this declaration relates to our Fifty-Five Cigars. Page A-1 shows our current product packaging for Fifty-Five Cigars. Page A-2 shows the California warning label as it appears on our Fifty-Five Cigars package. Page A-3 shows a projection by our company's graphics department of how the FTC warning label would fit on our current product packaging for Fifty-Five Cigars. Page A-4 shows a projection by our company's graphics department of how the FDA's new warning labels would apply to our current product packaging for Fifty-Five Cigars.

10. Exhibit B to this declaration relate to our Special Edition Cigars. Page B-1 shows our current product packaging for Special Edition Cigars. Page B-2 shows the California warning label as it appears on our Special Edition Cigars package. Page B-3 shows a projection by our company's graphics department of how the FTC warning label would fit on our current product packaging for Special Edition Cigars. Page B-4 shows a projection by our company's graphics department of how the FDA's new warning labels would apply to our current product packaging for Special Edition Cigars.

11. As these exhibits demonstrate, the sheer size of the FDA-mandated warnings overtake our ornate packaging symbols and trade-dress, by which we communicate the luxury and hand-made distinctiveness of our products. By taking fully a third of the most prominent panels on the package, our story of distinctiveness and hand-crafted care is dramatically reduced in prominence. Instead of rich colors and premium wooden components, consumers will see a sea of white plastic space with the government's message. The warnings will transform the way we communicate with our consumers. With its glaring white background—compared with our

subtle raised text—the government message will dominate our effort to communicate with consumers. I expect the need to change our trade dress to make it more prominent by comparison, and I do not know whether that will work or whether we will lose customers who no longer recognize our products.

12. The new FDA rule subjecting premium cigars to regulation also will have dramatic effects on my business. Premium cigars generally only improve with age, so premium cigar companies maintain significant inventories of products. The Rule provides compliance periods of two to three years for both premarket and substantial equivalence approvals and the warning labels. We could almost never liquidate our inventories during the Rule's compliance periods, leaving us with the distinct risk of being left with significant amounts of product that cannot be sold and in which we have invested great sums.

I declare under penalty of perjury that the foregoing is true and correct. Executed on February 13, 2017.

Rocky Patel

Rocky Patel

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CIGAR ASSOCIATION OF AMERICA et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION et al., Defendants.	)	Civil Action No. 16-1460 (APM)

DECLARATION OF ROCKY PATEL
EXHIBIT A

Current Product Packaging

Current warning label

Projected FTC warning label

Projected FDA warning labels

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CIGAR ASSOCIATION OF AMERICA et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION et al., Defendants.	)	Civil Action No. 16-1460 (APM)

DECLARATION OF ROCKY PATEL
EXHIBIT B

Current Product Packaging

Current warning label

Projected FTC warning label

B-3

Projected FDA warning labels

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CIGAR ASSOCIATION OF AMERICA et al.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 16-1460 (APM)
UNITED STATES FOOD AND DRUG ADMINISTRATION et al.,	)	
Defendants.	)	

DECLARATION OF JANELLE ROSENFELD

I, Janelle Rosenfeld, declare as follows:

1. I am Vice President - Marketing of Altadis U.S.A. Inc. ("Altadis"). I have personal knowledge of the following facts.

2. Altadis is one of the largest cigar manufacturers in the world, and has been crafting cigars since 1918.

3. In 2000, Altadis (formerly known as Consolidated Cigar Corporation) entered into a consent decree with the United States Federal Trade Commission (the "Consent Decree") that requires and continues to require Altadis to display "clear and conspicuously" warning statements on all of its cigar labels. The size of the warning label depends on the size of the package, and is set out by the terms of the Consent Decree. The FTC warnings are required to be set out on **one** principal panel of the product.

4. A new FDA rule requires new warning labels. The FDA warning labels must occupy **30 percent** of the **two principal** display panels.

5. Exhibit A to this declaration shows the FTC Consent Decree warnings and Altadis's projection of the warnings required by the FDA's rule on two Altadis products. The products on the left show the FTC Consent Decree required warnings and the products on the right the projection of the warnings required by the FDA rule. The FDA rule warnings are considerably larger and take space that Altadis uses to communicate the identity and qualities of its products with consumers.

I declare under penalty of perjury that the foregoing is true and correct. Executed on February 13, 2017.

Janelle Rosenfeld

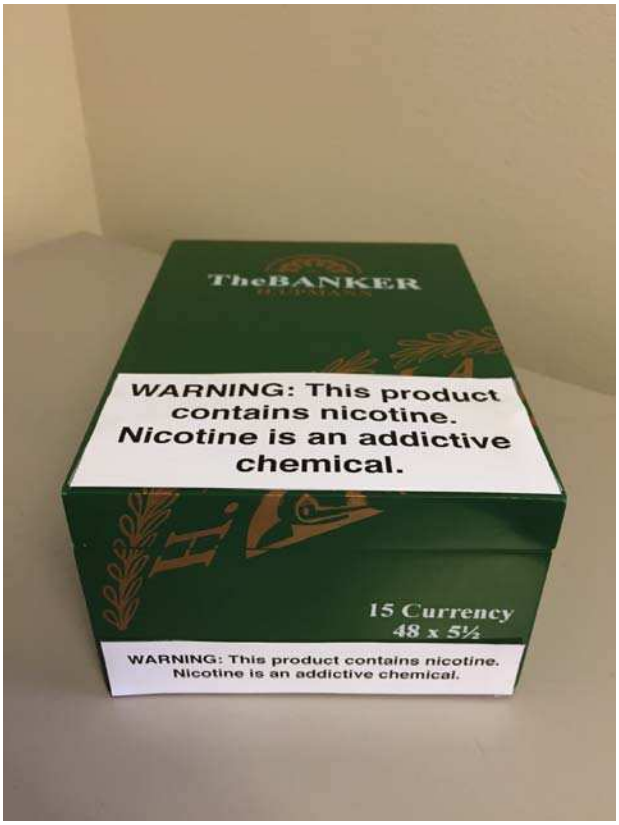
IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CIGAR ASSOCIATION OF AMERICA et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION et al., Defendants.	)	Civil Action No. 16-1460 (APM)

DECLARATION OF JANELLE ROSENFELD
EXHIBIT 1

Current FTC Warning

New FDA Warning



Current FTC Warning

New FDA Warning

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CIGAR ASSOCIATION OF AMERICA, *et al.*,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants.

Civil Action No. 16-1460 (APM)

DECLARATION OF JOHN ANDERSON

I, John Anderson, declare as follows:

1. I am the owner of W. Curtis Draper Fine Tobacconists in Washington, D.C. and Bethesda, Maryland. I am over eighteen (18) years of age and, unless otherwise indicated, have personal knowledge of the facts discussed below.

2. I am a retail tobacconist who sells high quality tobacco products, including premium cigars, pipes, and pipe tobacco. I am a small business owner who strives to provide the utmost in quality products and service for my customers.

3. I am concerned about the effect on my business of the FDA's new "deeming" rule (81 Fed. Reg. 28,974 (May 10, 2016)), which subjects premium cigars, pipes, and pipe tobacco to numerous regulatory burdens.

4. For example, I sell pipe tobacco in my store. Customers who smoke pipes frequently look for new and special blends to try. I am constantly working to introduce new pipe tobacco products in my store to increase consumer interest and sales.

5. Under the new FDA rule, however, I understand that pipe tobacco manufacturers are now subject to a pre-market review process. The new pre-market review process will be cost-prohibitive for many of these manufacturers, who are themselves small businesses, effectively eliminating their ability to release special editions and seasonal blends. These products, however, have been a unique part of my product offerings, and represent a large volume of my sales.

6. I also make my own custom pipe tobacco blends in my store. I receive pipe tobacco in bulk. I will then blend different types of tobacco to suit my customers' tastes. This is a specialty service that I offer, and it helps distinguish my store from less sophisticated retail establishments.

7. Under the FDA's new rule, however, I can no longer blend tobacco products for my customers unless I first register as a manufacturer and comply with all of the requirements applicable to tobacco product manufacturers. In effect, I would have to receive premarket clearance from the FDA for any possible blend of tobacco I could offer to my customers. This does not make any sense to me, because the pipe tobacco manufacturer will have already received approval from the FDA to market this product. Nothing in the "blending" process itself changes the tobacco; blending simply achieves different tastes and aromas.

8. In addition to being unnecessary, this process is completely impractical and certainly cost-prohibitive. Instead, I will have to cease blending tobacco in my store altogether.

9. Pipe tobacco is commonly sold in decorative tins and similar packaging. Pipe tobacco packaging commonly reflects distinctive designs and logos. Customers are frequently attracted to pipe tobacco products because of the interesting product designs, and may try new products based on an eye-catching package. At the same time, other customers are very brand loyal and seek out their favorite pipe tobacco products by their distinctive packaging.

10. The FDA is also now regulating tobacco pipes. Of course, pipes themselves are not made of tobacco. They may be made from briar wood, meerschaum (made from a calcium-based mineral called sepiolite), clay, corncobs, porcelain, olive wood, cherry wood, and maple. Pipes come in a variety of shapes and finishes, and are typically made of three components: a bowl, a shank, and a mouthpiece. Many also have different ornaments, such as bands or rings.

11. Many pipes, including most of the specialty pipes I offer in my store, are made by hand, often by artisans who themselves are small businesses. Each pipe is unique, but the differences are purely a matter of aesthetics. Many of these artisanal manufacturers will not be able to incur the expense or burden of the FDA's "pre-market" requirements, and may have to cease their handcrafted pipe business. If that is the case, I will again lose the ability to offer a specialty product to my customers.

12. The less specialty products I can offer, the less reason customers will have to come to my high-end retail store. I am deeply concerned that the FDA's new deeming rule could put me out of business.

I declare under penalty of perjury that the foregoing is true and correct. Executed on February 10, 2017.

John Anderson