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FDA-Required Tobacco Product Inserts & Onserts—and the First Amendment

ERIC N. LINDBLOM, MICAH L. BERMAN, AND JAMES F. THRASHER*

ABSTRACT

In 2012, a federal court of appeals struck down an FDA rule requiring graphic health warnings on cigarettes as violating First Amendment commercial speech protections. Tobacco product inserts and onserts can more readily avoid First Amendment constraints while delivering more extensive information to tobacco users, and can work effectively to support and encourage smoking cessation. This paper examines FDA’s authority to require effective inserts and onserts and shows how FDA could design and support them to avoid First Amendment problems. Through this process, the paper offers helpful insights regarding how key Tobacco Control Act provisions can and should be interpreted and applied to follow and promote the statute’s purposes and objectives. The paper’s rigorous analysis of existing First Amendment case law relating to compelled commercial speech also provides useful guidance for any government efforts either to compel product disclosures or to require government messaging in or on commercial products or their advertising, whether done for remedial, purely informational, or behavior modification purposes.

INTRODUCTION

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) became law, specifically directing the U.S. Food & Drug Administration (FDA) to issue regulations requiring graphic health warnings on all cigarette packs by June 22, 2011,¹ which FDA did on that same date.² Members of the tobacco industry challenged the new rule in court, and the D.C. Circuit Court of

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¹ Family Smoking Prevention and Tobacco Control Act, 15 U.S.C. § 1333(d) (2012); Pub. L. No. 111-31, § 201(a). Pursuant to an apparent typo in the Tobacco Control Act, there are now two subsection (d)’s in 15 U.S.C. § 1333. This reference refers to the first (d).

² Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628 (June 22, 2011) (to be codified at 21 C.F.R. pt. 1141).

Appeals struck down the rule as violating First Amendment protections for commercial speech.³ Since then, FDA has supported significant new research regarding graphic health warnings, but has not yet taken any other publicly visible action to develop or implement any new rule requiring warning labels for cigarettes or any other disclosure of information through cigarette packaging or labels. FDA's May 2016 final "deeming" rule requires only text-based warnings (no graphics) on the tobacco products it put under the agency's active tobacco control jurisdiction for the first time (e.g., e-cigarettes, cigars, hookah).⁴

At some point, FDA will likely issue a legally viable final rule that requires either graphic health warnings or new, stronger text-only warnings on all cigarette packs. However, the amount of information any new warnings could provide consumers would be quite limited because of the relatively small size of the packs—and similar limitations apply to warning labels on the packaging of most other tobacco products. To provide more extensive information directly to tobacco product users, governments could communicate through small printed leaflets either placed inside the product package (inserts) or temporarily attached to the outside of the product packaging (onserts). For example, inserts and onserts are used with prescription and over-the-counter drugs to provide health warnings, instructions for use, and other information directed at making sure consumers understand the related health risks and use the products as effectively, safely, and beneficially as possible. For quite different purposes, the tobacco companies have used inserts and onserts with their products in the form of coupons, collectable cards, and other promotional materials for over 100 years.⁵

To date, however, Canada is the only country or other major jurisdiction that has adopted an insert or onsert strategy as part of its tobacco control regulations, requiring cigarette pack inserts with cessation messaging since 2001. Studies of the Canadian inserts provide further evidence that inserts and onserts can work both independently or in conjunction with warnings on tobacco product labels to help consumers make more informed decisions about their tobacco product use or to promote other public health objectives.⁶ Indeed, inserts and onserts provide an effective way to reach users of different types of tobacco products with relevant information each time they first handle or open the package of each tobacco product they use. Although users might not read them every time, tobacco product inserts and onserts offer a regularly

³ *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1208 (D.C. Cir.), *aff'g* 845 F. Supp. 2d 266 (D.D.C. 2012). *But see* *American Meat Inst. v. USDA*, 760 F.3d 18, 22–23 (D.C. Cir. 2014) (overruling one of the core holdings in *Reynolds v. FDA*). These rulings are discussed more fully, below.

⁴ Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,974 (May 10, 2016) (to be codified at 21 C.F.R. pts. 1100, 1140, & 1143) at 1143.3.

⁵ *See, e.g.*, GERARD S. PETRONE, TOBACCO ADVERTISING: THE GREAT SEDUCTION 54–60, 147–48, 154–55 (1996); ARLENE B. HIRSCHFELDER, ENCYCLOPEDIA ON SMOKING AND TOBACCO 2–3 (1999); Joseph G. L. Lee et al., *Promotions on Newport and Marlboro Cigarette Packages: A National Study*, NICOTINE & TOBACCO RES. (Sept. 29, 2016), <http://0-ntr.oxfordjournals.org.gull.georgetown.edu/content/early/2016/09/29/ntr.ntw226.full>.

⁶ James F. Thrasher et al., *Cigarette Package Inserts Can Promote Efficacy Beliefs and Sustained Smoking Cessation Attempts: A Longitudinal Assessment of an Innovative Policy in Canada*, 88 PREVENTIVE MED. 59, 62–65 (2016); James F. Thrasher et al., *The Use of Cigarette Package Inserts to Supplement Pictorial Health Warnings: An Evaluation of the Canadian Policy*, 17 NICOTINE & TOBACCO RES. 870, 872–75 (2015).

available resource users can consult whenever motivated to do so, and each time an insert or onsert is seen, even if discarded unread, it provides a physical and visual reminder of its contents.⁷

FDA appears to have all the statutory authority it needs to establish effective inserts and onserts for different types of tobacco products. The Tobacco Control Act gives FDA extensive authority to regulate tobacco products, including their packaging and labeling, to protect the public health, and also provides FDA with separate, additional authority to regulate tobacco products to educate consumers about tobacco product harms and constituents (some of which specifically mention inserts). But it is not yet clear how FDA will interpret and apply its Tobacco Control Act authorities or the related specific provisions. Nor is it clear how the courts will interpret those provisions when FDA uses them to implement new regulations that will almost certainly face legal challenges from members of the tobacco industry.

Because product onserts can be removed from the outside of the package and inserts are not even seen by consumers until after purchase, they interfere with the communicative aspects of tobacco product packaging much less than warnings printed on the products' labels. These characteristics should make it much easier for FDA to design and require inserts and onserts that can survive the likely First Amendment attacks from the tobacco industry. But federal court case law continues to evolve relating to First Amendment protections of commercial speech, and considerable uncertainty exists as to how this evolving law might apply to new FDA efforts to require inserts or onserts.

Accordingly, this paper outlines the applicable statutory authorities and constraints relating to FDA requiring tobacco product inserts or onserts and suggests how they might be interpreted and applied most constructively by FDA and the courts. The paper then reviews applicable First Amendment law and carefully considers how the content and other characteristics of any required tobacco product inserts or onserts could be structured to minimize the risk of being blocked by First Amendment challenges. Although focusing on tobacco product inserts and onserts, this analysis also provides more generally applicable insights into how some key provisions of the Tobacco Control Act could be interpreted and applied to best promote the Act's purposes, and on how FDA and other government regulators in other contexts might use product disclosures or other packaging, labeling, or advertising requirements to educate consumers or protect the public health without encountering First Amendment constraints.

⁷ Research on the efficacy of product inserts and onserts in non-tobacco contexts is sparse. *See, e.g.*, D. Grober-Gratz et al., Der Einfluss des Beipackzettels auf die medikamentöse Adhärenz bei hausärztlichen Patienten: Influence of Package Inserts on Adherence to Medication in Primary Care Patients, 137 DEUTSCH MED WOCHENSCHR 1395, 1400 (2012); Rowa Al-Ramahi et al., *Attitudes of Consumers and Healthcare Professionals Towards the Patient Package Inserts – a Study in Palestine*, 10 PHARMACY PRACTICE 57 (2012). It is possible that government-required health-information-directed inserts and onserts for cigarettes and other tobacco products would be more frequently and carefully considered by consumers due to their novelty and the typical absence of any product information or directions from sources other than the manufacturers and because the vast majority of smokers have concerns about tobacco use and want to reduce related harms or quit. The effectiveness of tobacco product inserts or onserts could also be increased by ensuring they could be quickly and easily understood by those with lower literacy levels. *See, e.g.*, Stephanie M. Weiss & Stephanie Y. Smith-Simone, *Consumer and Health Literacy: The Need to Better Design Tobacco-Cessation Product Packaging, Labels, and Inserts*, 38 (3S) AM. J. PREVENTIVE MED. S403 (2010).

I. SPECIFIC FDA AUTHORITY TO REQUIRE INSERTS AND ONSETS TO DISCLOSE TOBACCO PRODUCT CONSTITUENTS AND PROVIDE OTHER INFORMATION TO CONSUMERS

In its amendments to the Federal Cigarette Labeling and Advertising Act (FCLAA), the Tobacco Control Act specifically mentions product inserts when it describes FDA's authority to disclose information to consumers about tobacco product and tobacco smoke constituents.⁸ That text gives FDA authority to "prescribe disclosure requirements regarding the level of any cigarette or other tobacco product constituent including any smoke constituent . . . if the Secretary determines that disclosure would be of benefit to the public health, or otherwise would increase consumer awareness of the health consequences of the use of tobacco products."⁹ It also states that, although such disclosures may not be required "on the face of any cigarette package or advertisement," they may be provided "through a cigarette or other tobacco product package or advertisement insert, or by any other means."¹⁰ And "by any other means" would presumably include onsets.¹¹

This language suggests that FDA could require inserts or onsets to disclose constituent levels (either generally or specifically) if it determined that doing so either "would be of benefit to the public health" or "would increase consumer awareness of the health consequences of the use of tobacco products," even if it was not clear that the inserts or onsets would produce any actual reductions in tobacco use or its harms.¹² Based on applicable evidentiary standards, however, FDA would at least need to make a reasonable determination, based on available evidence, that the disclosures of constituent levels in the inserts or onsets likely would produce either a specific public health benefit (without any offsetting public health harms) or an increase in some specific type of consumer awareness of tobacco product health consequences.¹³ [For a possible example of such an insert or onset, see Exhibit One.]

⁸ 15 U.S.C. § 1333(e)(3) (2012); Pub. L. No. 111-31, § 206 (amending Section 4 of the Federal Cigarette Labeling and Advertising Act). A tobacco product "constituent" includes tobacco product additives and ingredients, as well as any new substances created during the product's use (e.g., through the combustion of the original ingredients). That is expressly stated in Sec. 915(b)(1) and (2) [21 U.S.C. §§ 387o(b)(1), (2)] and clearly implied in the FCLAA provision, as amended by the TCA, which refers to "any cigarette or other tobacco product constituent, including any smoke constituent." 15 U.S.C. § 1333 (e)(3).

⁹ 15 U.S.C. § 1333(e)(3) (2012).

¹⁰ *Id.*

¹¹ It is possible that the 15 U.S.C. § 1333 (e)(3) ban on requiring constituent disclosures "on the face" of any cigarette packs might be interpreted to block FDA from using this section to require that an onset disclosing constituent levels be affixed to the face of a cigarette package, despite its being readily removable from the pack face by the consumer. But, even under such an interpretation, placing such an onset on the back or side of cigarette packs would still be permitted. In addition, this pack-face restriction does not, by its terms, apply at all to any tobacco products other than cigarettes or to any FDA onset requirements not based on this specific section of the Tobacco Control Act (although the tobacco companies would certainly argue that it should be interpreted to apply to any FDA onset requirement placed on any tobacco product).


¹² *Id.*

¹³ See *infra*, notes 16–19 and 27–28, and corresponding text.

Exhibit One

What's in this cigarette?

WARNING:
Inhaling tobacco smoke releases
benzopyrenes into your body.
Benzopyrenes damage how your
body protects itself from getting
cancer.



**Some chemicals in your cigarette
that cause serious diseases:**

Cancer

- 2-Aminonaphthalene
- 4-Aminobiphenyl
- Benzo[a]pyrene
- Catechol
- Crotonaldehyde
- NNK
- NNN

Cardiovascular Issues

- Acrolein
- Benzene

Addiction

- Nicotine

Respiratory Problems

- Acetaldehyde
- Acrylonitrile
- Formaldehyde
- Hydrogen Cyanide

Reproductive & Developmental Issues

- 1,3-Butadiene
- Carbon Monoxide

[The above is a speculative, fact-based mock-up provided solely for illustrative purposes. It is not an actual FDA document.]

A provision adjacent to the Tobacco Control Act's requirement that FDA "issue regulations that require color graphics depicting the negative health consequences of smoking" on cigarette packs provides FDA direct authority to adjust any cigarette warnings it establishes "or establish the format, type size, and text of any other disclosures required under the . . . Act" if FDA finds that doing so "would promote greater public understanding of the risks associated with the use of tobacco products."¹⁴ This text shows that the Act anticipated required disclosures other than those in the required warning labels, and further supports the legitimacy of disclosure requirements that promote greater public understanding of the risks associated with cigarette smoking, from other forms of tobacco use, or from tobacco use in general (even if it has not been determined that the disclosures will also reduce tobacco use or its harms).¹⁵

¹⁴ 15 U.S.C. § 1333(d) (2012); Pub. L. No. 111-31, § 202(b) (amending the Federal Cigarette Labeling and Advertising Act). Pursuant to the TCA amendments, there are two subsection (d)'s in 15 U.S.C. § 1333. This reference refers to the second (d). For parallel provisions relating to warning labels and disclosures on smokeless tobacco product labels, see Pub. L. No. 111-31, § 205(a) (amending the Comprehensive Smokeless Tobacco Health Education Act at 15 U.S.C. § 4402(d)).

¹⁵ Inserts or onserts could also be used pursuant to Pub. L. No. 111-31, § 915(b)(2), which states that FDA "may require that tobacco product manufacturers, packagers, or importers make disclosures relating to the results of the testing of tar and nicotine through labels or advertising or other appropriate means, and make disclosures regarding the results of the testing of other constituents, including smoke constituents, ingredients, or additives, that the Secretary determines should be disclosed to the public to protect the public health and will not mislead consumers about the risk of tobacco related disease." Pub. L. No. 111-31, § 915(b)(2); 21 U.S.C. § 387o(b)(2) (2012). They might also be used toward satisfying the requirement in Pub. L. No. 111-31, §§ 904(d)(1), (e) that FDA publish and periodically revise as appropriate "in a format that is understandable and not misleading to a lay person, and place on public

II. USING FDA'S GENERAL TOBACCO CONTROL AUTHORITIES TO REQUIRE INSERTS OR ONSETS TO PROVIDE INFORMATION TO CONSUMERS OR FOR OTHER PUBLIC HEALTH PURPOSES

FDA could also require inserts or onsets pursuant to the much broader and extensive authorities the Tobacco Control Act provides the agency to regulate the sale and promotion of cigarettes and other tobacco products¹⁶ or to establish tobacco product standards.¹⁷ To issue such regulations, FDA must determine that doing so would be “appropriate for the protection of the public health.”¹⁸ FDA must make that determination “with respect to the risks and benefits to 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.”¹⁹

The “appropriate for the public health” phrase and its statutory subparts have not been specifically interpreted by FDA or the courts. However, almost any possible reading or definition of the phrase suggests that it would be “appropriate for the protection of the public health” for FDA to require inserts or onsets to provide any accurate information relevant to the tobacco products and their use by consumers, so long as FDA reasonably determined, based on available research and other evidence, that doing so would likely produce a significant net benefit to the public health (with no risk of any unintended consequences that could completely offset those gains).²⁰

It is also possible that FDA could use this authority to require such inserts or onsets even if FDA were not able to determine whether they would likely produce a net decline in overall tobacco use harms but still reasonably found that the requirement

display (in a manner determined by [FDA]) . . . a list of harmful and potentially harmful constituents, including smoke constituents, to health in each tobacco product by brand and by quantity in each brand and subbrand.” Pub. L. No. 111-31, §§ 904(d)(1), (e); 21 U.S.C. §§ 387d(d)(1), (e).

¹⁶ Pub. L. No. 111-31, § 906(d)(1); 21 U.S.C. § 387f(d)(1).

¹⁷ Pub. L. No. 111-31, § 907(a)(3); 21 U.S.C. § 387g(a)(3).

¹⁸ FDA could also require inserts or onsets for specific tobacco products that must obtain a new product order to permit their legal sale in the United States if FDA determined that requiring the inserts or onsets as part of the orders were “appropriate for the protection of the public health” (or were necessary for the tobacco products to meet other requirements for qualifying for the orders). Pub. L. No. 111-31, § 910(c), (d); 21 U.S.C. §§ 387j(c), (d). Similarly, FDA could require inserts or onsets for specific tobacco products that must obtain a modified risk tobacco product (MRTP) order to permit their legal sale in the United States if FDA determined that requiring the inserts or onsets as part of the orders were necessary to ensure that allowing the product on the market would significantly reduce harm and the risk of tobacco-related disease to individual users and would “benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.” Pub. L. No. 111-31, § 911(g)(1), 21 U.S.C. § 387k(g)(1); *see also* Pub. L. No. 111-31, § 911(g)(2); 21 U.S.C. § 387k(g)(2)(A)(i).

¹⁹ Pub. L. No. 111-31, § 906(d)(1); 21 U.S.C. § 387f(d)(1).

²⁰ A plain reading of the terms also suggests that finding an insert or onset requirement to provide constituent information “appropriate for the protection of the public health” would be easier than finding that it would “be of benefit to the public health”—as in the FCLAA standard at 15 U.S.C. § 1333(e)(3)—or that its information “should be disclosed to the public to protect the public health”—as required in Pub. L. No. 111-31, § 915(b)(2). 21 U.S.C. § 387o(b)(2).

was “appropriate for the protection of the public health.” For example, it might be “appropriate for the protection of the public health” to require inserts or onserts to help prevent youth experimentation with or initiation into tobacco use. Or it might be enough to require inserts or onserts simply to provide consumers with information about the harmful and potentially harmful constituents in tobacco products or with other health-related information that would enable consumers of tobacco products to make more informed decisions about whether they consume the tobacco products or try to quit, how much they consume, or how they consume them—even if FDA could not determine whether doing that would also actually change consumer behavior or reduce overall tobacco use or tobacco use harms.²¹ [For a possible example, see Exhibit One, above.]

This same analysis applies to possible FDA tobacco product insert or onsert requirements for other purposes, beyond providing information about constituents, that would also be “appropriate for the protection of the public health.” For example, FDA might follow the example of its requirements for prescription and over-the-counter drugs and require tobacco product inserts and onserts to provide tobacco product consumers with “Instructions for Use” to inform them how to use the products to reduce risks and harms to the user and to others;²² or to provide information on such matters as dosage forms and strengths, contraindications, warnings and precautions, adverse reactions, drug interactions, use while pregnant, overdose, and dependence.²³ [For a possible example, see Exhibit Two overpage.]

²¹ Some might misconstrue the D.C. Circuit ruling in the *R.J. Reynolds Tobacco Co. v. FDA* graphic health warnings case as rejecting the idea that simply providing consumers with information could be “appropriate for the protection of the public health” because it struck down FDA’s health warning rule as not being likely to produce smoking reductions. 696 F.3d 1205 (D.C. Cir. 2012). In that case, however, the court stated that because “[t]he *only* explicitly asserted interest [by FDA] . . . is an interest in reducing smoking rates,” it would use only that interest in its First Amendment analysis (and not consider other possible government interests, such as informing consumers). *Id.* at 1218 (emphasis in original). Accordingly, the question of whether it would be “appropriate for the protection of the public health” solely to increase consumer knowledge about tobacco product harms or how to reduce them was not at issue and was not decided by the court. *Id.* at 1218–19.

²² See, e.g., *General Labeling Provisions: Drugs; Adequate Directions for Use*, 21 C.F.R. § 201.5 (2012).

²³ For examples of FDA-required labeling and inserts for prescription and over-the-counter drugs, see DRUGS@FDA, <https://www.accessdata.fda.gov/scripts/cder/drugsatfda> (last visited Aug. 12, 2016). See also Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 21 C.F.R. § 201.56 (2015); U.S. Dep’t of Health & Human Servs. et al., *Guidance for Industry: Labeling for Human Prescription Drug and Biological Products – Implementing the PLR Content and Format Requirements*, FDA (Feb. 2013), <http://www.fda.gov/downloads/drugs/guidancecompliance/regulatoryinformation/guidances/ucm075082.pdf>. Because of FDA’s much broader tobacco control authorities, the agency would have considerably more flexibility regarding what it might require in any tobacco product inserts or onserts than it does for drugs or other products it regulates.

Exhibit Two

Cigarette and Smoking Information from the U.S. Food & Drug Administration

Besides increasing each smoker's risk of lung cancer, other cancers, heart disease, and stroke, smoking cigarettes also increases the risk of many other health harms, such as diabetes, arthritis, periodontal disease, male erectile dysfunction, macular degeneration, blindness, premature aging of skin, and delayed or complicated recovery from injuries or surgery. Similarly, exposing people to cigarette smoke increases their risk of lung cancer, heart disease, stroke, and respiratory illness. Smoking or exposure to cigarette smoke among pregnant women can cause miscarriages and other pregnancy complications, low birth weight, still born births, and sudden infant death syndrome. Fires from cigarettes cause property loss, injury, and death. Eating cigarettes or cigarette butts can cause serious gastrointestinal distress, nausea, and vomiting, especially among young children and pets. Research indicates that exposure to residues from smoking on clothes, furniture, and other surfaces also causes some health harms and risks. [For more information, please go to www.cigarettefacts.gov.]

Directions for Use to Reduce Harms and Risks to Oneself and to Others: The only way to consume cigarettes without any significant harms or risks to oneself or others is to consume them without smoking or otherwise ingesting them, and to make sure that that no one else obtains the cigarettes who might smoke or eat them. While there is no way to smoke cigarettes without incurring significant harms and risks to oneself, consistently following the directions listed below can reduce (but not eliminate) the harms and risks smoking causes both to oneself and to others.

- **Smoke as few cigarettes as possible.**
- **Do not inhale. If you must inhale, do not inhale deeply.**
- **Do not smoke the entire cigarette but smoke only half the length or less.**
- **Do not smoke every day.**
- **As often as possible, take an extended break from smoking.**
- **Do not smoke when pregnant.**
- **Do not smoke in any enclosed space, such as a car.**
- **Do not smoke near any other people, pets, or animals.**
- **Do not smoke indoors or in any location where you or others spend a lot of time.**
- **Do not expose others to clothes, fabrics, or surfaces exposed to smoking.**
- **Do not smoke in bed or when tired and at risk of falling asleep.**
- **Do not leave cigarettes where others might find and smoke them.**
- **Do not leave cigarettes or cigarette butts where children, pets, or other animals might find and eat them.**
- **Make sure that each cigarette you finish smoking is thoroughly extinguished and discarded safely and securely.**

Warnings: Harms and risks from smoking and from exposure to smoking are highest among infants and young children and are higher than average among persons of any age with the following diseases or medical histories. For example, in extreme cases smoking or exposure to cigarette smoke could trigger a fatal heart attack among persons with heart disease. Smoking or cigarette smoke exposure among persons with these conditions can also interfere with treatment or recovery.

Asthma	Heart Disease	Stroke	Lung Cancer
Respiratory Illness	COPD	High Blood Pressure	Other Cancers
Peripheral Artery Disease	Macular Degeneration	Diabetes	Recovering from Surgery

[The above list is not comprehensive, for a complete list please go to www.cigarettefacts.gov.]

Warning for Women Who Are Pregnant or May Become Pregnant: Smoking or being exposed to secondhand smoke while pregnant can create pregnancy and birth difficulties, including miscarriages and stillborn births, and can cause health and developmental risks and harms for your child after birth, including sudden infant death syndrome (SIDS).

Warning for Parents and Caregivers: Exposing infants to cigarette smoke can cause sudden infant death syndrome (SIDS), and exposing any child to cigarette smoke can cause other health and developmental risks and harms.

Alternatives: Many people who smoke do so to obtain nicotine (e.g., to satisfy their nicotine addiction). Other available products can deliver nicotine to consumers with fewer harms and risks to oneself and others than smoking cigarettes, including nicotine replacement therapies, such as nicotine gum or patches (the least harmful and risky alternatives), e-cigarettes, and smokeless tobacco products. [For more information, please go to: www.cigarettefacts.gov.]

[The above is a speculative, fact-based mock-up provided solely for illustrative purposes. It is not an actual FDA document and www.cigarettefacts.gov is not, at this time, an actual government website.]

Similarly, FDA could use tobacco product inserts or onsets to notify consumers of the benefits from having regular medical tests to diagnose and treat tobacco-caused disease early; or to provide information regarding the health benefits from cessation or switching to less harmful types of tobacco/nicotine products. Or FDA could use inserts or onsets to address existing misleading aspects of cigarettes or other tobacco products and their packaging and labels through color coding, certain descriptors, and other characteristics that make consumers inaccurately believe that some brands or subbrands are less harmful than others.²⁴

Another possibility would be for FDA to require inserts or onsets specifically to provide consumers with information about how to quit using the tobacco product or where to get cessation assistance, or even to provide messaging to encourage quit attempts and overall cessation.²⁵ Recent studies from Canada, the only country that requires any cigarette inserts, suggest that they could be quite effective at increasing cessation. The Canadian inserts include eight rotating messages about the benefits of quitting and recommendations for increasing the likelihood of successfully quitting, which behavioral change theories stress as critical for promoting desired behaviors.²⁶ [For an example, see Exhibit Three.] Research on the impact of the inserts suggests that they promote downstream self-efficacy to quit, increased quit attempts, and sustained abstinence from cigarettes.²⁷

²⁴ See, e.g., Hua-Hin Yong, et al., *U.S. Smokers' Beliefs, Experiences and Perceptions of Different Cigarette Variants Before and After the FSPTCA Ban on Misleading Descriptors such as "Light", "Mild", or "Low,"* 18 NICOTINE & TOBACCO RES. 2115 (2016); Laura K. Lempert & Stanton A. Glantz, *Packaging Colour Research by Tobacco Companies: the Pack as Product Characteristic*, TOBACCO CONTROL (Jun. 2, 2016), <http://tobaccocontrol.bmj.com/content/early/2016/06/02/tobaccocontrol-2015-052656.full.pdf+html>; Ron Borland & Steven Savvas, *Effects of Stick Design Features on Perceptions of Characteristics of Cigarettes*, 22 TOBACCO CONTROL 331 (2013); Maansi Bansal-Travers, et al., *What do Cigarette Pack Colors Communicate to Smokers in the U.S.?*, 40 AM. J. PREVENTIVE MED. 683 (2011); Maansi Bansal-Travers, et al., *The impact of Cigarette Pack Design, Descriptors, and Warning Labels on Risk Perception in the U.S.*, 40 AM. J. PREVENTIVE MED. 674 (2011); David Hammond & Carla Parkinson, *The Impact of Cigarette Package Design on Perceptions of Risk*, 31 J. PUB. HEALTH 345 (2009); *United States v. Philip Morris USA*, 449 F. Supp. 2d 1, 430, 508, 515, 522, 526, 546–491, 609 (D. D. C. 2006) (Findings of Fact no. 2024, 2379, 2412–14, 2448–49, 2469, 2557–73); *aff'd in part, vacated in part*, 566 F.3d 1095, 1119–21 (D.C. Cir. 2009) (upholding findings of fact); Melanie Wakefield, et al., *The Cigarette Pack as Image: New Evidence from Tobacco Industry Documents*, 11 TOBACCO CONTROL (SUPPLEMENT 1) i73, i76–i77 (2002).

²⁵ As discussed below, any such inserts or onsets would also need to comply with First Amendment standards, which might be applied more strictly to compelled speech that discourages the legal use of the associated product.

²⁶ ALBERT BANDURA, SOCIAL LEARNING THEORY (1977); Albert Bandura, *Self-efficacy: Toward a Unifying Theory of Behavioral Change*, 84 PSYCHOL. REV. 191 (1977); James O. Prochaska & Carlo C. DiClemente, *Self Change Processes, Self-efficacy and Decisional Balance Across Five Stages of Smoking Cessation*, in ADVANCES IN CANCER CONTROL: EPIDEMIOLOGY & RESEARCH 131 (Alan R. Liss ed., 1984).

²⁷ James Thrasher, et al., *The Use of Cigarette Package inserts to Supplement Pictorial Health Warnings: An Evaluation of the Canadian Policy*, 17 NICOTINE & TOBACCO RES. 870, 872–73 (2015); James Thrasher, et al., *Cigarette package Inserts Can Promote Efficacy Beliefs and Sustained Smoking Cessation Attempts: A Longitudinal Assessment of an Innovative Policy in Canada*, 88 PREVENTIVE MED. 59, 61–62 (2016).

Exhibit Three

How can the quitline help me?

**WHEN YOU CALL THE TOLL-FREE QUITLINE
1-866-366-3667**

You'll speak one-on-one with a quit specialist who will help you:

- Create a quit plan that works for you.
- Access information and tools to become smoke-free.
- Cope with cravings and withdrawal symptoms.
- Find services and resources in your community.

**There are many reasons to quit.
What's yours?**



**Tobacco is the single most preventable cause of premature death and disease.
Health Canada**

For FDA to require inserts or onsets for any of these different purposes, the Tobacco Control Act requires only that FDA determine that such inserts or onsets would be “appropriate for the protection of the public health,” and that its determination not be “arbitrary or capricious.”²⁸ Related case law firmly establishes that nothing close to scientific certainty is required in agency determinations of this kind, and that the courts must give FDA’s determinations considerable deference, so long as the agency considers all relevant information, pro and con, and follows all the required procedures. For example, the U.S. Supreme Court has explained that all an agency must do to avoid being found “arbitrary and capricious” is “examine the relevant data and articulate a satisfactory explanation for its action” and, if that has been done, “a court is not to substitute its judgment for that of the agency.”²⁹

But even if FDA has clear authority to require such inserts or onsets as “appropriate for the protection of the public health” (or through any of its other authorities in the Tobacco Control Act), any such requirements must also fit within the constitutional constraints established by the First Amendment’s protections for “commercial speech.”

²⁸ TCA § 912(b); 21 U.S.C. § 387(b) (referencing the Administrative Procedures Act at 5 U.S.C. § 706).

²⁹ FCC v. Fox Television Stations, 129 S.Ct. 1800, 1810 (2009) (quoting Motor Vehicle Mfrs. Assn. of United States v. State Farm Mut. Auto. Ins., 463 U.S. 29, 43 (1983)); see Kroger Co. v. Reg’l Airport Auth., 286 F.3d 382, 389 (6th Cir. 2002) (“If there is any evidence to support the agency’s decision, the agency’s determination is not arbitrary or capricious.”).

III. FIRST AMENDMENT CONSTRAINTS ON GOVERNMENT-REQUIRED INSERTS OR ONSETS

Members of the tobacco industry would almost certainly file First Amendment challenges against any FDA or other government efforts to require tobacco product inserts or onsets, just as they did to strike down FDA's graphic health warning rule.³⁰ However, even if the existing court rulings on First Amendment protections for commercial speech are interpreted expansively, there appear to be ways to design government-required tobacco product inserts or onsets to survive any such constitutional attacks.

The courts typically review government measures that require product disclosures or warnings (whether through labeling or product inserts or onsets) as "compelled commercial speech," and apply much more permissive constitutional scrutiny than they do to government efforts to restrict what commercial entities may say on their own. As the U.S. Supreme Court has stated, "the First Amendment interests implicated by disclosure requirements are substantially weaker than those at stake when speech is actually suppressed."³¹ The standard First Amendment test for compelled commercial speech, initially established in the U.S. Supreme Court's *Zauderer* ruling, requires that the compelled speech (e.g., a warning label or disclosure requirement) be "factual and uncontroversial" and "reasonably related" to the government's interest (e.g., to prevent deception of consumers or reduce the possibility of consumer confusion), which includes not being so "unjustified or unduly burdensome" to "offend the First Amendment by chilling protected commercial speech."³²

In sharp contrast, government restrictions on what commercial entities themselves may say about their products and services must survive the more extensive 4-part First Amendment test first presented in the U.S. Supreme Court's *Central Hudson* case, which requires that:

1. To qualify for First Amendment protection, the commercial speech must relate to lawful activity and not be false or misleading.
2. The government's asserted interest in restricting the speech must be substantial.
3. The restriction must directly advance the government's asserted interest.
4. The restriction must not be more extensive than necessary to serve the asserted government interest.³³

In the appellate court case striking down FDA's graphic health warnings rule, the D.C. Circuit court panel of three judges ruled two to one that the less stringent *Zauderer* test for government compelled commercial speech applied only when the compelled speech was directed at "preventing deception to consumers"—and that any compelled commercial speech (such as required inserts or onsets) directed at other government purposes (e.g., disclosing health and safety risks) were subject to the more

³⁰ See, e.g., *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012).

³¹ *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, n.14 (1985).

³² *Id.* at 651; see *Milavetz, Gallop & Milavetz, P.A. v. U.S.*, 559 U.S. 229, 249–50 (2010); *Am. Meat Inst. v. USDA*, 760 F.3d 18, 21–22 (D.C. Cir. 2014) (en banc).

³³ *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980); see *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 527 (2001). *Lorillard Tobacco* is the most recent U.S. Supreme Court ruling on the constitutionality of government restrictions on tobacco product advertising.

restrictive *Central Hudson* test.³⁴ But the full D.C. Circuit (ruling en banc) directly reversed that ruling in the subsequent *American Meat Institute* case, finding that the less-stringent *Zauderer* test also applies to government compelled commercial speech directed at other legitimate government purposes.³⁵

Similarly, the Second Circuit has repeatedly found that the *Zauderer* test applies in compelled commercial disclosure cases, even when consumer deception is not at issue, and the *Central Hudson* test applies to statutes that restrict commercial speech.³⁶ Following that approach, it has upheld compelled commercial speech directed at purposes other than preventing consumer deception, including required disclosures directed at protecting the environment³⁷ and at combating obesity.³⁸

Although the U.S. Supreme Court has not directly considered the issue, the D.C. and Second Circuit rulings suggest that the less stringent *Zauderer* test should apply to all cases involving compelled commercial speech directed at legitimate government purposes, even when those purposes are not to prevent or reduce consumer deception or misunderstanding.³⁹ Moreover, the Supreme Court has stated that “the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides.”⁴⁰ That suggests that compelled commercial speech directed at providing consumers with any valuable information relating to the products at issue should qualify for the more lenient *Zauderer* test, whether it addresses consumer deception or misunderstandings or not.⁴¹

³⁴ *R.J. Reynolds Tobacco*, 696 F.3d at 1213, 1217.

³⁵ *Am. Meat Inst.*, 760 F.3d 18 at 21–22. The ruling upheld government requirements that certain meat products disclose their country of origin on their labels, referencing the long history of country-of-origin labeling directed at enabling consumers to choose American-made products, especially in regard to health concerns. *Id.* at 23–24. In an “en banc” session of a circuit court, the case is heard by all the judges of the circuit (typically on an appeal of a prior ruling by the typical three-judge circuit court panel), with all the judges in the circuit participating in the final ruling. *Am. Meat Inst.* was considered by eleven circuit court judges, with two judges dissenting from the final ruling.

³⁶ *Safelite Grp. v. Jepsen*, 764 F.3d 258, 262–63 (2d Cir. 2014).

³⁷ *Nat’l Elec. Mfrs Ass’n v. Sorrell*, 272 F.3d 104, 113–16 (2d Cir. 2001) (“To be sure, the compelled disclosure at issue here was not intended to prevent ‘consumer confusion or deception’ per se, but rather to better inform consumers about the products they purchase.”) (citation omitted).

³⁸ *N.Y. State Rest. Ass’n v. New York City Bd. of Health*, 556 F.3d 114, 120–21, 133 (2d Cir. 2009).

³⁹ In regard to a more expansive application of the *Zauderer* test, see *Int’l Dairy Foods Ass’n v. Boggs*, 622 F.3d 628, 641 (6th Cir. 2010) (*Zauderer* test applies to disclosures to address not only *inherently* misleading commercial speech but also *potentially* misleading commercial speech); *Pharm. Care Mgmt Ass’n v. Rowe*, 429 F.3d 294, n. 8 (1st Cir. 2005) (stating that a submitted brief offered no cases supporting its assertion that *Zauderer* is limited to potentially deceptive advertising directed at consumers and that “we have found no cases limiting *Zauderer* in such a way”). In regard to a more restrictive application of the *Zauderer* test, see *Borgner v. Brooks*, 284 F.3d 1204, 1210–13 (11th Cir. 2002) (applying *Central Hudson* test, instead of *Zauderer*, to required disclosures without explanation).

⁴⁰ *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985).

⁴¹ Coming at it the other way, the Second Circuit has stated that “consumer curiosity alone is not a strong enough state interest to sustain the compulsion of even an accurate factual statement.” *Int’l Dairy Foods Ass’n v. Amestov*, 92 F.3d 67, 74 (2d Cir. 1996) (quoted favorably by both a concurring opinion (Kavanaugh) and a dissent (Brown) in *Am. Meat Inst. v. USDA*, 760 F.3d 18, 32 (D.C. Cir. 2014). What might constitute “consumer curiosity, alone,” however, is quite controversial. See *Amestov*, 92 F.3d 73, 74 (holding a Vermont law requiring the disclosure of what milk products contained milk from cows treated with synthetic growth hormone was unconstitutional because it was compelled speech directed solely at addressing consumer curiosity; with that finding largely based on an FDA determination that the milk from such cows was no different from milk from non-treated cows and produced no related health harms

Even if *Zauderer* were interpreted narrowly to apply only to compelled commercial speech relating to consumer deception, inserts or onsets directed at providing consumers with accurate, not misleading information about tobacco product harms and risks would still be likely to qualify for and pass the *Zauderer* test. For example, the Sixth Circuit refused to apply strict scrutiny instead of the *Zauderer* test to the Tobacco Control Act's requirement that FDA issue a rule mandating graphic health warnings on all cigarette packs and ads, noting that disclosures of the serious risks that smoking involves were necessary "to avoid giving a false impression that smoking is innocuous" and to prevent advertising that "represents the alleged pleasures or satisfactions of cigarette smoking" from being deceptive.⁴² As detailed above, extensive research and court findings also firmly establish that certain ongoing characteristics of cigarettes and their packaging and labels continue to mislead smokers and others to believe, inaccurately, that some brands or sub-brands are less harmful than others.⁴³ Inserts and onsets to correct those misunderstandings would fit under even the most narrow views of what compelled speech falls under the more lenient *Zauderer* test. As the U.S. Supreme Court stated in the 2010 *Milavetz* case, all that the government must do to justify compelled speech directed at preventing consumers from being misled is show that likelihood of consumer deception (without the compelled speech) "is hardly a speculative one."⁴⁴

It is also possible that a narrow interpretation of *Zauderer*, permitting compelled speech only to address consumer deception, would not only allow compelled speech to stop the products and their packaging and labeling from deceiving and misleading consumers but would also allow remedial compelled speech directed at addressing the harms caused by such misleading product, packaging, and labeling characteristics.⁴⁵ Such permitted remedial compelled speech could, for example, include inserts or onsets designed to provide deceived and misled consumers with information about how to quit successfully (if they chose to try to do so once provided with correct and not misleading information).

On the other hand, it is possible that government-required tobacco product inserts and onsets might actually be subject to an even more lenient standard than the *Zauderer* test because they would not be seen by consumers prior to purchase and are

or risks to consumers). For a critique of the court's finding that consumer concerns about milk from cows treated with synthetic growth hormone amounts to only consumer curiosity and cannot justify the compelled speech at issue in the case, see, e.g., *Amestoy*, 92 F.3d at 74–81 (Leval, J., dissenting) and Sugarman, SD, *Should Food Businesses Be Able to Use the First Amendment to Resist Providing Consumers with Government-Mandated Public Health Messages*, 5 FDLI'S FOOD AND DRUG POLICY FORUM Apr. 29, 2015, at 4; see also *American Meat Inst.*, 760 F.3d at 23 (compelling product country-of-origin information includes health and safety interests and "has an historical pedigree that lifts it well above 'idle curiosity'").

⁴² *Discount Tobacco City & Lottery, Inc. v. U.S.*, 674 F.3d 509, 527 6th Cir. 2012) (quoting *Cipollone v. Liggett Group*, 505 U.S. 504, 527 (1992)).

⁴³ *Supra*, note 24; see *infra*, note 71.

⁴⁴ *Milavetz, Gallop & Milavetz, P.A. v. U.S.*, 559 U.S. 229, 251 (2010) (quoting *Zauderer*, 471 U.S. at 652).

⁴⁵ See, e.g., *Am. Meat Inst.*, 760 F.3d 18, note 3 (D.C. Cir. 2014) (en banc) (finding that compelled disclosures that provide purely factual and uncontroversial information "to correct deception" are subject to the basic *Zauderer* test and not subject to strict scrutiny); and *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1215–16 (D.C. Cir. 2012) (discussing remedial disclosures to dissipate the effects of past deceptive representations).

not displayed as part of the manufacturer's commercial speech.⁴⁶ This analysis applies most clearly to inserts because they are inside the tobacco product package, separate from the external package and its label, and completely invisible to consumers prior to purchase. But it could also apply to onserts that do not convey any messages to consumers until after they detach the onsert from the package and open it up. For example, in a different context the D.C. Circuit Court has ruled that onserts should not be considered to be statements on cigarette packaging because they are not a part of the packaging but only affixed to the packaging.⁴⁷ More generally, the existence of the different *Zauderer* and *Central Hudson* tests are based on the concept that less stringent First Amendment protections should apply to less burdensome requirements and restrictions relating to commercial speech, which indicates that the First Amendment scrutiny applied to product inserts should be less strict than for onserts, which should, in turn, be less strict than the First Amendment scrutiny applied to warnings required on external product labeling or in all product advertisements.

A less exacting constitutional standard than the *Zauderer* test might also apply if the required tobacco product inserts or onserts clearly identify the government as the entity making and delivering the information they contain (making it clear that the information is not coming from the product manufacturers).⁴⁸ In such a situation, “[w]here the law requires a commercial entity engaged in commercial speech merely to permit a disclosure by the *government*, rather than compelling speech out of the mouth of the *speaker*, the First Amendment interests are less obvious.”⁴⁹

Neither the U.S. Supreme Court nor any circuit court appears to have ruled on this exact issue. In *Johanns v. Livestock Marketing Ass’n*, however, the Supreme Court ruled that requiring manufacturers of a specific product to finance generic advertising

⁴⁶ See, e.g., *R.J. Reynolds Tobacco Co.*, 696 F.3d at 1236 (dissent) (suggesting that requiring cigarette package inserts is less burdensome, under First Amendment analysis, than requiring warning labels on the packs); *Nat’l Ass’n of Mfg. v. SEC.*, 800 F.3d 518, 522–24 (D.C. Cir. 2015) (finding that a government compelled speech requirement unconnected to voluntary advertising or to product labeling at the point of sale is not compelled commercial speech subject to the *Zauderer* test). Although the *Nat’l Ass’n of Mfg.* case applied the more stringent *Central Hudson* test to the compelled speech at issue, that was based on a finding that requiring certain public disclosures on company websites and in their regular reports to the SEC faced even stronger First Amendment constraints than requiring disclosures in product ads or labeling, and inserts or onserts are not as publicly visible or as directly and formally linked to the product’s manufacturer as disclosures on company’s own website or in its own SEC filings. See, also, the dissent in *Nat’l Ass’n of Mfg.*, noting the “strange” and “highly curious results” from providing stronger First Amendment protections for compelled statements on websites and SEC filings than for compelled statements on product labels or advertising, which “would impose a *more* searching First Amendment standard on a disclosure that imposes a *less* burdensome requirement on the speaker.” *Id.* at 535.

⁴⁷ *U.S. v. Philip Morris USA Inc.*, 566 F.3d 1095, 1140–42 (D.C. Cir. 2009) (noting that the tobacco companies consider onserts to be different from packaging or labeling on the packaging).

⁴⁸ See, e.g., *CTIA-The Wireless Ass’n v. City of Berkeley*, F. Supp. 3d (USDC, ND CA, 2015) (“There is a persuasive argument that, where, as here, the compelled disclosure is that of clearly identified *government* speech, and not that of the *private speaker*, a standard even less exacting than that established in *Zauderer* should apply.”).

⁴⁹ *Id.* In *Pacific Gas and Electric Co. v. Public Utilities Commission*, the U.S. Supreme Court struck down a law requiring a utility to include a third party’s newsletter, clearly identified as such, in the utility’s monthly billing statements to consumers. 475 U.S. 1 (1986). But the compelled speech in *Pacific Gas* was political not commercial speech, controversial opinion (including views hostile to or biased against the utility), neither factual nor noncontroversial information, and was from a third party not the government. Accordingly, it does not contradict the idea that compelled factual and noncontroversial commercial speech that would otherwise fit under the *Zauderer* test should be subject to an even less restrictive test if it is clearly identified as coming from the government and not the manufacturer.

by the government about the product does not raise any compelled speech or other First Amendment issues, even when the affected businesses objected to the government's message.⁵⁰ That ruling made a sharp distinction between compelling support for *government speech*, where the First Amendment does not apply, and either compelling individuals to personally express government messages as their own or compelling individuals or businesses to subsidize speech made by non-government third parties, where the First Amendment does apply.⁵¹ Following that same logic, a government-required insert or onset that, on its face, clearly presents only government speech, with no implied endorsement by the tobacco product manufacturer, would appear to raise no First Amendment issues, especially where the manufacturer's ability to deliver its own messages would not be restricted by the requirement.⁵²

⁵⁰ *Johanns v. Livestock Mktg. Ass'n*, 544 U.S. 550 (2005); see also *Walker v. Texas Div., Sons of Confederate Veterans, Inc.*, 135 S. Ct. 2239, 2245 (2015) ("When government speaks, it is not barred by the Free Speech Clause from determining the content of what it says. That freedom in part reflects the fact that it is the democratic electoral process that first and foremost provides a check on government speech." (internal citation omitted)). At the same time, the U.S. Supreme Court's ruling in *Wooley v. Maynard*—that the First Amendment prohibits state governments from requiring license plates with ideological government messages (New Hampshire's "Live Free or Die" motto)—remains good law. 430 U.S. 705 (1977), cited favorably in *Walker v. Texas Div., Sons of Confederate Veterans, Inc.*, 135 S. Ct. 2239, 2252 (2015). That ruling would not apply to insert or onset requirements that did not include any political or ideological messages. It also might not apply to required inserts or onsets with ideological messages because they, unlike license plates, are not "mobile billboards" required on a "virtual necessity for most Americans" that is inescapably visible to large numbers of the public. 430 U.S. at 1435. It also appears that the ideological government speech on license plates struck down in *Wooley v. Maynard* was not clearly labeled as coming only from the government.

⁵¹ *Johanns*, 544 U.S. at 557–59; see also *Walker v. Texas Div., Sons of Confederate Veterans, Inc.*, 135 S. Ct. 2239, 2245 (2015). The 5–4 ruling in *Walker v. Texas Div.* split sharply as to whether state-issued license plates were government speech if, besides certain non-ideological government messages, they displayed different government-approved messages that expressed individual vehicle owners' personal views that were not necessarily a government viewpoint (e.g., "Rather Be Golfing"). But government-required inserts or onsets would pass both the majority and the dissent opinions' tests for government speech. They pass the majority's test because: (a) product inserts and onsets have "long communicated messages from the government" (e.g., in prescription and over-the-counter drugs); (b) government-required inserts and onsets are "often closely identified in the public mind with the [government];" (c) the government "has sole control" over the content of the inserts or onsets; (d) inserts and onsets (or product packaging) are not "traditional public forums for private speech;" and (e) the inserts and onsets "are meant to convey and have the effect of conveying a government message" (e.g., would have indicia that their messages are owned and conveyed by the government). 135 S. Ct. at 2248–50, 2252. Similarly, they qualify as government speech under the dissent's test because: (a) governments have long used inserts and onsets "as a means of expressing a government message;" (b) there is no history of manufacturers allowing their products to be used as the site of inserts or onsets "that do not express messages that the [manufacturers] wish to convey;" (c) product packages can accommodate "only a limited number" of inserts or onsets; and (d) neither manufacturers nor consumers could pay to have certain messages included in the inserts or onsets. *Id.* at 2258–59.

⁵² See, e.g., Stephen D. Sugarman, *Compelling Product Sellers to Transmit Government Public Health Messages* 29 J.L. & POLITICS 557 (2014); Micah L. Berman, *Clarifying Standards for Compelled Commercial Speech*, 50 WASHINGTON UNIV. J.L. & POL'Y 53 (2016). An argument might be made that requiring government-message inserts or onsets would impede the manufacturers' ability to communicate to consumers through their own inserts or onsets. But manufacturers would not be prohibited from using their own inserts or onsets, and they could still use all other avenues of communication that are available to them to communicate with consumers. While having more than one insert or onset might reduce consumer attention to one or both, it might also increase consumer awareness because of the novelty. In any case, the insert-onset situation is quite different from required government warning labels on cigarette package that cover a large percentage of the display area, thereby preventing the manufacturer from using that are for its own messaging (although even there manufacturers could increase their display space by increasing the overall size of the package).

Even if the courts found that requiring a commercial product to deliver what was clearly the government's own speech still raised First Amendment issues, the U.S. Supreme Court's analysis in *Johanns* indicates that such compelled speech clearly identified as coming exclusively from the government should be subject to lesser First Amendment scrutiny compared to whatever the court might have applied if the speech were not identified as the government's own. In addition, any such First Amendment concerns should be much weaker regarding insert or onsert requirements as opposed to required warning labels on product packages or labels, where (unlike with inserts or onserts) the required speech is seen prior to purchase and takes up product packaging space that the manufacturer could otherwise use for its own speech.

Regardless of which First Amendment test or standard might be applied, they all require that the content of any government-compelled speech be accurate and not misleading to avoid being struck down. In addition, to satisfy the *Zauderer* test (however interpreted), the compelled speech must also be "purely factual and uncontroversial."⁵³ In a recent D.C. Circuit case, the court stated that "'uncontroversial, as a legal test, must mean something different than 'purely factual.'"⁵⁴ It found that the required speech at issue, although it could be seen as factual, failed the *Zauderer* test because it was ideological and metaphorical and suggested that the products were ethically tainted, which was a value judgment that could be contested.⁵⁵

In the D.C. Circuit's earlier *RJ Reynolds* case striking down FDA's final cigarette warning label rule, the court found that compelled speech cannot qualify as "purely factual and noncontroversial" if it includes graphic images that, while not "patently false" can be misunderstood; are "primarily intended to evoke an emotional response

⁵³ See, e.g., *Zauderer v. Office of Disciplinary Counsel*, 471 U.S.626, 651 (1985); see also *National Ass'n of Manufacturers v. SEC*, 800 F.3d 518, 527 (D.C. Cir. 2015) (finding that *Zauderer* "requires the disclosure to be of 'purely factual and uncontroversial information' about the good or service being offered") (quoting *Am. Meat Inst. v. USDA*, 760 F.3d 18, 27 (D.C. Cir. 2014) (emphasis added). That same opinion also discussed how opinions could be disguised as facts, and the difficulty in distinguishing between opinions and facts. *National Ass'n of Manufacturers*, 800 F.3d at 528.

⁵⁴ *National Ass'n of Manufacturers*, 800 F.3d at 528. But see *Disc. Tobacco City & Lottery Inc. v. U.S.*, 674 F.3d 509, n. 8 (6th Cir. 2012) (stating that to apply the *Zauderer* test the compelled speech need not be noncontroversial but only accurate and factual).

⁵⁵ *Id.* at 528–31. As the dissent noted, the compelled speech at issue ("not been found to be 'DRC conflict free'") communicated "truthful, factual information about a product to investors and consumers: it tells them that a product has not been found to be free of minerals originating in the DRC or adjoining countries that may finance armed groups." 800 F.3d at 532. For more in the dissent on the meaning of "noncontroversial," see 800 F.3d at 537–39; see also *Am. Meat Inst.*, 760 F.3d at 27 (finding compelled country-of-origin labeling factual and noncontroversial); *Evergreen Ass'n, Inc. v. N.Y.C.*, F.3d 233, note 6 (compelling pregnancy services centers to state the City's treatment preferences or to mention controversial pregnancy-related services which some centers oppose would be "controversial" if the *Zauderer* test applied); *CTIA-Wireless Ass'n v. City and Cnty of S.F.*, 494 F. App'x 752, 753–54 (9th Cir. 2012) (compelled commercial speech "controversial" because it included City's recommendations that could be interpreted as City's opinion that using cell phones is dangerous, which had not been established); *Video Software Dealers Ass'n v. Schwarzenegger*, 556 F.3d 950, 953, 966–67 (9th Cir. 2009) (compelled speech labeling a video game as violent fails *Zauderer* test because it is controversial opinion not purely factual information); *New York State Rest. Ass'n v. New York City Bd. of Health*, 556 F.3d 114, 118 (2d Cir. 2009) (compelled calorie counts in restaurant menus "factual and noncontroversial" despite objections that calorie amount disclosures should not be prioritized higher than other nutrient amounts); *Entm't Software Ass'n v. Blagojevich*, 469 F.3d 641, 652 (7th Cir. 2006) (compelled speech indicating that video game is "sexually explicit" not "factual or noncontroversial" because based on State's opinion-based definition).

or, at most, shock the viewer into retaining the information in the textual warning; are “not warnings but admonitions,” and are “unabashed attempts to . . . browbeat consumers into quitting.”⁵⁶ Similarly, both the majority opinion and the dissent found that including the phone number “1-800-QUIT-NOW” in the warning labels, as an exhortation to quit, was not “purely informational,” either.⁵⁷

Raising a possible additional constraint, a footnote in the majority opinion in *R.J. Reynolds* stated that: “Like the district court, we are skeptical that the government can assert a substantial interest in discouraging consumers from purchasing a lawful product, even one that has been conclusively linked to adverse health consequences.”⁵⁸ Although this statement is only dictum (not binding precedent), it raises the possibility that future court rulings might determine that—regardless of what First amendment test is applied and regardless of what substantial interest the government asserts—the government may not compel commercial speech by tobacco product manufacturers that includes any direct encouragement for adults not to purchase or use the manufacturers’ tobacco products so long as those tobacco products are lawful products. However, while the dissent in *R.J. Reynolds* noted that the “QUIT NOW” command in FDA-required cigarette warning labels “directly contradicts the tobacco companies’ desired message at the point of sale, thereby imposing a significant burden on their protected commercial speech,” it did not suggest that such compelled speech discouraging the use of the companies’ products was incompatible with the First Amendment. Instead, the dissent stated only that the “QUIT NOW” command could not be sustained under the *Central Hudson* test unless the government could explain why a less burdensome “alternative means of connecting smokers to cessation resources, such as a package insert,” would be inadequate.⁵⁹

The *R.J. Reynolds* ruling was not appealed to the U.S. Supreme Court, and it is not yet clear how the Supreme Court might handle a similar case. In the meantime, the Supreme Court’s rulings in the *Zauderer* case remain controlling law, clearly establishing that any government compelled commercial speech (including inserts or onsets) must not only present “purely factual and uncontroversial information” but must also be “reasonably related” to a substantial government interest.⁶⁰

⁵⁶ *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1216–17 (D.C. Cir. 2012). *But see Disc. Tobacco City & Lottery Inc.*, 674 F.3d at 526, 560–61 (finding that the Tobacco Control Act’s graphic health warnings requirement for cigarettes did not violate *Zauderer*, despite the fact that “there can be no doubt that the FDA’s choice of visual images is subjective, and that graphic, full-color images, because of the inherently persuasive character of the visual medium, cannot be presumed neutral.”).

⁵⁷ *R.J. Reynolds*, 696 F.3d at 1216–17 (“the provocatively named hotline cannot rationally be viewed as pure attempts to convey information to consumers” but is an “unabashed attempt[] to evoke emotion . . . and browbeat consumers into quitting.”). *Id.* at 1236 (“the number is prominently presented in imperative terms, directing consumers to ‘QUIT NOW.’ That command directly contradicts the companies’ desired message at the point of sale, thereby imposing a significant burden on their protected commercial speech.”). But the focus of these discussions on the 1-800-QUIT-NOW number, itself, indicates that providing a neutral phone number or website address that consumers could use to obtain information—with no exhortations to quit in the number, address, or the associated sources—would be purely informational.

⁵⁸ *Id.* at 1218 n. 13.

⁵⁹ *Id.* at 1236–37 (emphasis added).

⁶⁰ *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985); *see also* *Milavetz, Gallop & Milavetz, P.A. v. U.S.*, 559 U.S. 229, 250 (2010).

Zauderer notes that “unjustified or unduly burdensome [compelled speech] might offend the First Amendment by chilling protected commercial speech.”⁶¹ But *Zauderer* also states that such concerns do not apply “as long as [the compelled speech] requirements are reasonably related to the State’s interest in preventing deception of consumers;”⁶² and the U.S. Supreme Court followed that ruling in the *Milavetz* case, its most recent compelled speech case.⁶³

Moreover, the courts have not found warning labels that use large portions of the main display portions of product packaging to be overly burdensome;⁶⁴ and required inserts or onserts would be even less burdensome in that regard. It is possible, however, that a court might still find a government insert or onsert requirement overly burdensome if it were extremely costly for manufacturers to comply. But such cost concerns would not arise so long as the inserts or onserts did not require major changes to the packaging currently used for the tobacco products and roughly paralleled the insert and onsert requirements, and related costs, currently imposed on manufacturers in other areas, such as prescription and over-the-counter drugs. It would also be hard for the tobacco industry to argue that insert and onsert requirements are overly burdensome when they have been using both for their own purposes for decades.⁶⁵

IV. HOW MIGHT FDA DESIGN A NEW INSERT-ONSERT RULE TO COMPLY WITH EXISTING FIRST AMENDMENT CASE LAW

As discussed above, the existing case law suggests that a new FDA rule requiring tobacco product inserts or onserts would almost certainly avoid First Amendment constraints if the inserts or onserts:

- (a) Were purely factual, informative, and noncontroversial (which would also make them accurate and not misleading).⁶⁶
- (b) Provided consumers with valuable information about the tobacco products, such as information about the tobacco products’ harms and risks, how to use the products to minimize harms and risks, and how to dispose of the products safely.

⁶¹ *Zauderer*, 471 U.S. at 651.

⁶² *Id.*

⁶³ *Milavetz, Gallop & Milavetz, P.A.*, 559 U.S. at 250.

⁶⁴ In the *R.J. Reynolds* case, for example, the tobacco companies challenging the graphic health warnings did not dispute Congress’s authority to require health warnings on cigarette packs, did not challenge the substance of any of the health warning text in the graphic health warnings, and did not challenge the size or placement of the warning labels (e.g., top 50% of the front and back of the pack). *R.J. Reynolds*, 696 F.3d at 1211, 1215. In an earlier case, members of the tobacco industry did challenge the size and placement of the required cigarette warning labels and similar requirements for new non-graphic smokeless tobacco product warning labels (covering 30% of the front and back of the packaging), arguing that they were unduly burdensome because they would effectively overshadow and dominate their own commercial speech; but the 6th Circuit ruled against them. *Disc. Tobacco City & Lottery Inc. v. U.S.*, 674 F.3d 509, 530–31 (6th Cir. 2012).

⁶⁵ See, e.g., GERARD S. PETRONE, *TOBACCO ADVERTISING: THE GREAT SEDUCTION* 54–60, 147–48, 154–55 (1996); ARLENE B. HIRSCHFELDER, *ENCYCLOPEDIA ON SMOKING AND TOBACCO* 2–3 (1999).

⁶⁶ To be prudent, this standard should also be applied to the content of any website or other external sources that the insert or onsert referred to or incorporated (e.g., by providing a website address or phone number).

- (c) Were required in order to address consumer ignorance that could mislead consumers or otherwise prevent or reduce consumer deception or misunderstandings about the products and their use and related consequences.
- (d) Were unambiguously identified as coming from the government or some unit of the government (and not from the products' manufacturers).⁶⁷
- (e) Were not extremely costly or difficult for manufacturers to implement.

More rigorous First Amendment obstacles could arise, however, if the required inserts or onsets included text or graphic images that were subject to different interpretations or provoked emotional responses, or if they explicitly encouraged specific consumer behaviors contrary to the manufacturer's interests, such as not buying the product in the first place, quitting all future use, or switching to less harmful tobacco or nicotine products. To avoid this risk, such elements could simply be omitted.⁶⁸

At the same time, it should be perfectly acceptable under existing First Amendment law regarding compelled commercial speech if any FDA-required inserts or onsets provided consumers with *accurate, not misleading, factual information* about the health benefits from terminating or sharply reducing use of the subject tobacco product or from switching completely to using a less harmful tobacco or nicotine-delivery product—and perhaps even about how to quit successfully for those that choose on their own to do so—so long as there were no controversial or misleading graphic images, emotional appeals, or actual exhortations to quit or switch.

Although there are no court rulings directly on point, an FDA rule requiring such inserts or onsets should readily fall under the relaxed *Zauderer* test, even if *Zauderer* were held to apply only to compelled speech directed at reducing consumer deception and misunderstandings. As noted previously, courts have already found that informing consumers about tobacco use risks and harms qualifies as addressing consumer deception and related misleading commercial speech;⁶⁹ and also providing information on how to quit successfully would help to correct the harms caused by past deceptive or misleading speech that have misled consumers to start or not try to quit.⁷⁰ Moreover, it would not be difficult to show that providing the above-described information to consumers through inserts or onsets is “reasonably related” to the goal of reducing consumer misunderstandings and preventing consumer deception relating to such matters as the health benefits (or lack thereof) from: (a) switching between brands or sub-brands; (b) reducing one's consumption to different degrees; (c) switching completely to using a less-harmful product compared to engaging in dual use; or (d) quitting completely versus other harm reduction strategies.⁷¹

⁶⁷ Such clear attribution would ensure that consumers did not inaccurately think that the compelled speech messages were voluntarily coming from the manufacturer, thereby eliminating any risk of the government actually putting words into the manufacturers' mouths.

⁶⁸ For example, any use of the 1-800-QUIT-NOW phone number in the inserts or onsets could be switched to only listing the actual numbers in the phone number.

⁶⁹ See, e.g., *Disc. Tobacco City & Lottery Inc.*, 674 F.3d at 527 (quoting *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 527 (1992)).

⁷⁰ *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1215–16 (D.C. Cir. 2012).

⁷¹ On consumer ignorance or misunderstandings relating to tobacco products and their use, risks, and harms, and to how to reduce harms and risks. See, e.g., Olivia A Wackowski & Christine D. Delnevo, *Young Adults Risk Perceptions of Various Tobacco Products Relative to Cigarettes: Results from the National Young Adult Health Survey*, 43 HEALTH EDUC. & BEHAV. 328–36 (2015); Maria Roditis, et al., *Adolescent (Mis)perceptions about Nicotine Addiction: Results from a Mixed-methods Study*, 43 HEALTH EDUC. & BEHAV. 156–64 (Apr. 2015); Mark T. Kiviniemi & Lynn T. Kozlowski,

If the reviewing court found that *Zauderer* applied more broadly (beyond just preventing deception), it would be quite easy to establish that such purely informational disclosures or messages were also “reasonably related” to various alternative government interests, such as: (a) having adult consumers make more fully informed decisions about tobacco product use; (b) providing helpful information to the many smokers and other tobacco users who want to quit but have not been able to do so successfully because of their addiction; (c) preventing youth initiation and use; or even (d) reducing overall tobacco use and harms.

But if FDA wanted to require tobacco product inserts or onserts specifically to prevent and reduce youth tobacco use or to reduce overall tobacco use harms as effectively as possible, the agency would likely want to use such potentially helpful tools for breaking through the addictive power of cigarettes and other tobacco products as emotional appeals; not-purely-informational graphic images; or direct exhortations to quit, reduce use, or switch to less-harmful products. Including such elements in the inserts and onserts, however, could trigger the application of the more restrictive *Central Hudson* test. Accordingly, FDA would not want to include any of those elements unless it had formally determined that doing so would likely make the inserts or onserts significantly more effective at preventing youth use or reducing overall tobacco use harms—and based that determination on a careful consideration of the available relevant research and evidence, both pro and con.

In this regard, new research showing what specific elements or characteristics in tobacco product inserts or onserts would make them most effective at promoting different possible government goals would be especially helpful. In particular, research showing that including emotional appeals, different types of graphic images, and direct exhortations to quit, cut back, or switch in inserts or onserts would make them more effective at preventing youth initiation, promoting cessation, or otherwise reducing tobacco use harms would make it easier to pass the part of the *Central Hudson* test requiring a reasonable government determination that the inserts and onserts would directly promote the government’s substantial interests.⁷²

To satisfy the remainder of the *Central Hudson* test, FDA would also have to establish that there were no equally or more effective ways to promote the government interests that would interfere less with the manufacturer’s protected commercial

Deficiencies in Public Understanding about Tobacco Harm Reduction: Results from a United States National Survey, 12 HARM REDUCTION J. 21 (2015); Marianna Masiero, et al., *Personal Fable: Optimistic Bias in Cigarette Smokers*, INT. J. HIGH RISK BEHAVS. & ADDICTION (Mar. 4, 2015), [http://0-search.proquest.com.gull.georgetown.edu/docview/1800708645?pq-origsite=summon&accountid=36339](http://hf9an6bn9s.search.serialssolutions.com/?ctx_ver=Z39.88-2004&ctx_enc=info%3Aofi%2Fenc%3AUTF-8&rft_id=info%3Aasid%2Fsummon.serialssolutions.com&rft_val_fmt=info%3Aofi%2Ffmt%3Akev%3Amtx%3Ajournal&rft.genre=article&rft.atitle=Personal+Fable%3A+Optimistic+Bias+in+Cigarette+Smokers&rft.jtitle=International+Journal+of+High+Risk+Behaviors+and+Addiction&rft.au=Masiero%2C+Marianna&rft.a u=Lucchiari%2C+Claudio&rft.au=Pravettoni%2C+Gabiella&rft.date=2015-03-20&rft.issn=2251-8711&rft.eissn=2251-872X&rft.volume=4&rft.issue=1&rft_id=info:doi/10.5812%2Fijhrba.20939&rft.externalDBID=n%2Fa&rft.externalDocID=10_5812_ijhrba_20939¶mdict=en-US; Marcella H. Boynton, et al., <i>Understanding How Perceptions of Tobacco Constituents and FDA Relate to Effective and Credible Tobacco Risk Messaging: a National Phone Survey of U.S. Adults 2014-2015</i>, 16 BMC PUB. HEALTH 516 (June 23, 2016), <a href=); Christing D. Czoli, et al., *How Do Consumers Perceive Differences in Risk Across Nicotine Products? A Review of Relative Risk Perceptions Across Smokeless Tobacco, E-Cigarettes, Nicotine Replacement Therapy and Combustible Cigarettes*, TOBACCO CONTROL (Sept. 13, 2016), <http://tobaccocontrol.bmj.com/content/early/2016/09/13/tobaccocontrol-2016-053060>.

⁷² *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 554 (2001); *Central Hudson Gas & Electric Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 566 (1980).

speech.⁷³ That should not be too difficult because required inserts or onserts would burden manufacturers' commercial speech rights far less than advertising or labeling restrictions or compelled speech in product advertising or on product packaging or labels.⁷⁴ Most notably, consumers would not even see the inserts until after making a decision to purchase the product, the inserts would not obscure any manufacturer commercial speech made through externally visible packaging and labeling, and the inserts would not be visible to the general public. It is hard to imagine any other form of government-compelled speech to deliver information or other messages to product consumers that could possibly be less burdensome to the manufacturers' speech than product inserts.⁷⁵

Onserts that did not present any messages to consumers until detached from the package and opened would share these same less-burdensome characteristics with inserts, except for temporarily obscuring the part of the tobacco product package where the onsert was affixed (which could be its warning label). But an onsert could be harder to defend against First Amendment attacks if it were required to be affixed to the front of the tobacco product package, obscuring more of the manufacturer's commercial speech, or if it included text visible before purchase that directly contradicted the manufacturers' "Buy-Me" protected speech at point of sale (e.g., by the visible onsert stating "QUIT NOW"). Even then, however, research showing that such characteristics were necessary to make the onsert work more effectively to promote the government's substantial interests would make placing those burdens on the manufacturer's speech more constitutionally permissible.

⁷³ See *Sorrell v. IMS Health, Inc.*, 564 U.S. 552, 583 (2011) ("government laws and regulations may significantly restrict speech, as long as they also 'directly advance' a 'substantial' government interest that could not 'be served as well by a more limited restriction,'" quoting *Central Hudson*, 447 U.S. at 564 (emphasis added)); *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 371 (2002) ("if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so."); *Lorillard Tobacco Co.*, 533 U.S. at 554; *Central Hudson*, 447 U.S. at 566.

⁷⁴ See, e.g., *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1236 (D.C. Cir. 2012) (Rogers, J., dissenting) (suggesting that requiring cigarette package inserts is less burdensome, under First Amendment analysis, than requiring warning labels on the packs).

⁷⁵ There are, of course, other ways that the government could deliver information or other messages to tobacco product consumers, such as government consumer education campaigns, that would be less burdensome to the tobacco product manufacturers. Whether the courts might consider such non-compelled-speech alternatives if and when the fourth part of the *Central Hudson* test applies to an insert or onsert requirement is not clear. If they were considered, however, such government communications would not likely qualify as equally effective alternatives available to the government to promote the government's substantial interests because the alternatives would be much less successful at directly reaching all tobacco product consumers, compared to product inserts and onserts, and would not reach the consumers when they have the product in their hands and are likely to be most receptive to considering product-related information or messaging. Because they would be entirely separate from the tobacco products and their use, such government messaging would also be less effective than inserts or onserts at preventing those consumer misunderstandings caused by the product, itself, and by its packaging and labeling. In addition, if the government-required inserts or onserts were directed at minimizing youth initiation, maximizing cessation, or otherwise minimizing overall tobacco use or harms, it would be odd for a court to find that the government must not use certain effective tools at all because other effective tools are available when achieving the government's substantial interests would benefit from employing all available tools until the government's substantial interests were actually achieved. In other words, even if the government implemented a strong tobacco product consumer education campaign (or took other alternative action toward minimizing tobacco use and harms) that would not eliminate the need to require inserts or onserts, as well, in order to promote the government's substantial interests even more substantially and quickly.

Clearly, FDA has the statutory authority to require tobacco product inserts or onserts and could structure a new insert-onsert rule to fit within existing First Amendment constraints. Although currently available research and other evidence provides a sufficient basis for such FDA action, additional research would not only provide additional support but could also enable FDA to require inserts or onserts with additional specific characteristics and elements that would work even more directly and effectively to reduce tobacco use and its harms.

V. OTHER LEGAL ISSUES WITH INSERT OR ONSERT REQUIREMENTS AND HOW FDA COULD ADDRESS THEM

If FDA were to require inserts or onserts on cigarette packs or any other tobacco product packaging to provide consumers with information about product risks or harms or how to reduce them, tobacco product companies might argue (as they have in regard to government required warning labels) that complying with the insert-onsert requirement had reduced or eliminated any legal duty the tobacco companies otherwise had to warn or educate consumers, or even not to mislead consumers, through product packaging and labeling or other means.⁷⁶ This argument could be refuted, however, if the law authorizing or establishing an insert or onsert requirement explicitly stated that nothing in the insert or onsert requirement shall be construed to affect the legal duties of any tobacco product manufacturer, distributor, or seller, or any related legal actions. The Tobacco Control Act already has some provisions of this type built into it that cover subsequent FDA tobacco control rulemaking, but they could be fortified or supplemented.⁷⁷ In addition, FDA could explicitly state in any new insert-onsert rule that it did not intend the rule to provide any new legal protections for any tobacco industry members or to preempt any other laws establishing duties on tobacco product manufacturers to warn or inform consumers.

To provide additional protection against possible tobacco industry legal challenges, any new FDA insert-onsert rule could also provide a formal process that affected manufacturers could initiate to propose any changes to the required inserts or onserts necessary to make them more accurate, complete, and not misleading.⁷⁸ The Tobacco Control Act already provides for ways that interested parties can attempt to initiate FDA action relating to tobacco products, including amendments to FDA rules.⁷⁹ But the process proposed here would provide tobacco manufacturers and other interested

⁷⁶ See, e.g., *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 523–25 (1992). For an example of FDA-required labeling and inserts preempting a products liability claim outside of the tobacco context, see *Papike v. Tambrands Inc.*, 107 F.3d 737, 741 (9th Cir. 1997).

⁷⁷ See TCA §§ 4(a), 916(b) (21 U.S.C. § 387p(b)), 908(b) (21 U.S.C. § 387h(b)); see also Comprehensive Smokeless Tobacco Health Education Act (CSTHEA) at 15 U.S.C. § 4406(c).

⁷⁸ See, e.g., *Wyeth v. Levine*, 555 U.S. 555, 572–73 (2009) (stating that a failure-to-warn claim against drug manufacturer is not preempted where manufacturer did not seek to update FDA label after learning of safety risks); *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 800–01 (8th Cir. 2001) (Bye, J., dissenting) (stating no preemption of failure-to-warn claim against medical device manufacturer when FDA procedures enabled the medical device manufacturer to add new warnings of a newly-discovered risk to the FDA-approved medical device label and then initiate a process to get formal approval of the changes).

⁷⁹ See, e.g., TCA § 901(d) (21 U.S.C. § 387a(d)) and the related provisions of the Administrative Procedures Act; for FDA product standard amendments, see TCA § 907(c), (d)(4) (21 U.S.C. § 387g(c), (d)(4)).

parties a more direct and dispositive tool for seeking and securing timely corrections and improvements to the required inserts or onsets (e.g., by including related agency deadlines). To place more responsibility on the tobacco product manufacturers, the process could also require that they provide FDA with any relevant new research or other information relating to the accuracy, completeness, or effectiveness of the information provided in the inserts or onsets that the manufacturers develop or otherwise obtain that is not publicly available.

Establishing an administrative process that tobacco product manufacturers or others could use to correct or update any required inserts and onsets could also strengthen the insert-onset rule's defenses against First Amendment attacks. On the front end, the courts would likely look even more favorably on an industry-challenged insert-onset rule if it not only appeared to require inserts or onsets that, based on available research and other evidence, were wholly accurate, purely informational, and not misleading but also offered an explicit and effective process that manufacturers and others could initiate to revise the compelled speech if any new research or information appeared which established that the inserts or onsets were not accurate, purely informational, and not misleading.⁸⁰ On the back end, offering such a process would provide manufacturers a way to prompt FDA to fix the required inserts or onsets in a timely fashion whenever new evidence showed that doing so was necessary for constitutional compliance—instead of having to take the more extreme action of immediately bringing a new lawsuit to try to strike down the entire requirement.⁸¹

When used, this provided process would either produce a government agency determination, based on its expert review of the new research and evidence, that no First Amendment violations were occurring and no modifications to the required compelled speech were necessary, or prompt agency action to revise the compelled speech to eliminate any constitutional violations while still continuing to promote the government's related interests or purposes. Because these administrative outcomes would either resolve the issue completely (making any subsequent court review unnecessary) or provide a more complete evidentiary record and more refined controversy for any subsequent court review, the courts would likely require the tobacco companies to use this process to exhaust their administrative remedies before bringing any such constitutional challenges to the courts.⁸² To make such required

⁸⁰ The existing authorities and procedures for FDA to take action, unilaterally or in response to petitions from interested persons, to stop enforcing an implemented final rule or to amend it would likely be legally adequate, by themselves, to account for the possibility that future research or other information might show that the established rule is actually unconstitutional or otherwise flawed or inappropriate. *Id.* But the new administrative process suggested here would provide even stronger protections and procedures to account for that possibility.

⁸¹ When constitutional rights are at issue, such agency procedures need to provide for administrative relief, when deserved, "within a specified, reasonable time," or the manufacturer could be free to go straight to the courts for relief, instead. *See, e.g., Dream Palace v. County of Maricopa*, 384 F.3d 990, 1009 (9th Cir. 2003).

⁸² The Administrative Procedures Act (APA) explicitly provides that parties seeking judicial review under the APA (e.g., to seek relief for alleged agency APA violations during the rulemaking process) need not exhaust administrative remedies unless they are specifically required to do by an applicable statute or rule, and does not allow courts to require any such exhaustion beyond that required by statute or rule. 5 U.S.C. § 704 (2012); *see also Darby v. Cisneros*, 509 U.S. 137 (1993). Here, however, the complaining parties would not be claiming any violations of the APA during the rule's development and implementation. Instead, they would be challenging the constitutionality of an already established rule based on the subsequent appearance of new research or other new evidence, and there would be no new final agency action for the parties to challenge. Accordingly, the APA's provisions relating to exhaustion

prior exhaustion of administrative remedies even more certain, FDA's rule establishing this new process for prompting agency review and possible remedial action could directly require affected parties to use the process whenever they become aware of any new research or other evidence that they believe makes the required insert-omert text false or misleading or unconstitutional.

Existing provisions in the Tobacco Control Act already allow interested third parties to petition FDA to amend an established rule;⁸³ and the courts might consider them to be sufficiently explicit and dispositive to constitute available administrative remedies that manufacturers must exhaust before using new research or other new evidence to attack an already established insert or omert requirement in court.⁸⁴ But the more explicit and dispositive new procedures proposed here, with specific agency deadlines, would more easily and certainly qualify as a readily available administrative remedy that is neither "futile" nor "inadequate to prevent irreparable injury" which manufacturers must, consequently, exhaust before taking their related claims to court⁸⁵—especially if the final insert-omert rule also required manufacturers to submit any new research or other information they subsequently developed or obtained that indicated that the messaging in the required inserts or omerts was inaccurate, not purely informational, or misleading so that the agency could make any necessary changes to the messaging.⁸⁶

should not apply, and the courts should have discretion to require the parties to exhaust their administrative remedies before receiving judicial review. *See, e.g.,* *Darby*, 509 U.S. at 153–54 (stating that "the exhaustion doctrine continues to apply as a matter of judicial discretion in cases not governed by the APA"); *Gilmore v. Weatherford*, 694 F.3d 1160, 1167–70 (10th Cir. 2012); *Volvo GM Heavy Truck Corp. v. Dep't of Labor*, 118 F.3d 205, 210 (4th Cir. 1997) (stating that the "cause of action is based on an alleged constitutional violation, . . . and would not be subject to the APA's exhaustion requirement"); *see also* *Committee of Blind Vendors v. District of Columbia*, 28 F.3d 130, 134 (D.C. Cir. 1994) (finding that the "APA is inapplicable because no agency proceeding took place for the court to review"). In general, the fact that a plaintiff raises constitutional claims does not interfere with the operation of the exhaustion doctrine and can even make exhaustion of available administrative remedies more appropriate. *See, e.g.,* *Andrade v. Lauer*, 729 F.2d 1475, 1490 (D.C. Cir. 1984) (citing *Aircraft & Diesel Equipment Corp. v. Hirsch*, 331 U.S. 752, 771–72 (1947)); *see also* *Blackbear v. Norton*, 93 F. App'x. 192, 194 (10th Cir. 2004) ("[C]onstitutional claims against federal agencies can be heard in federal court prior to administrative exhaustion, only where those claims are 'collateral to the substantive issues of the administrative proceedings.' (internal citations omitted.) In this case, plaintiffs' constitutional claims appear to be central, not collateral, rendering this exception to exhaustion inapplicable."); *Nationsbank Corp. v. Herman*, 174 F.3d 424, 429 (4th Cir. 1999) (reviewing "unambiguous line of cases rejecting the contention that constitutional claims should be exempt from exhaustion requirements"). In addition, none of the major exceptions to the exhaustion requirement would apply in this situation. For example, there is no "clear and unambiguous violation of statutory or constitutional rights" and exhausting administrative remedies is neither futile nor "clearly and demonstrably inadequate to prevent irreparable injury." *Tutein v. Insite Towers, LLC*, 572 F. App'x. 107, 111 (3d Cir. 2014) (quoting *Lavellee Northside Civic Ass'n v. Virgin Islands Coastal Zone Mgmt. Comm'n*, 866 F.2d 616, 620 (3d Cir. 1989)); *see also* *Shearson v. Holder*, 725 F.3d 588, 594 (6th Cir. 2013); *U.S. ex rel. Saint Mohawk Tribe v. President R.C.*, 451 F.3d 44, 50 (2d Cir. 2006); *Eastern Bridge, LLC v. Chao*, 320 F.3d 84, 89, 91 (1st Cir. 2003).

⁸³ *See, e.g., supra* note 79..

⁸⁴ *See, e.g.,* *Ass'n of Am. Physicians v. FDA*, 358 F. App'x 179, 180–81 (D.C. Cir. 2009); *Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1377 (9th Cir. 1983).

⁸⁵ *Tutein*, 572 F. App'x. at 111 (quoting *Lavellee Northside Civic Ass'n v. Virgin Islands Coastal Zone Mgmt. Comm'n*, 866 F.2d 616, 620 (3d Cir. 1989)). *See also* *Shearson*, 725 F.3d at 594; *U.S. ex rel. Saint Mohawk Tribe*, 451 F.3d at 50; *Eastern Bridge, LLC*, 320 F.3d at 89.

⁸⁶ Because this proposed process relates to possible new legal challenges that arise *after* a final rule is implemented, based on the *subsequent* emergence of new research or other evidence, it is not invalidated or otherwise affected by the fact that the Tobacco Control Act provides for any legal

VI. CONCLUSION

Tobacco product inserts or onsets provide an effective way for governments to deliver constructive information and guidance to consumers and to promote related public health goals, yet they are rarely used or even considered. This paper has shown that FDA has clear statutory authority to implement tobacco product insert or onset requirements to educate and inform consumers about tobacco product use, harms and risks; to promote tobacco use cessation and prevent initiation and relapse; or to protect or promote the public health in other ways. In addition, any new FDA insert-onset rule would face more permissive First Amendment hurdles than those confronting rules requiring warning labels on tobacco product labels, packaging or ads. Indeed, FDA could readily design a new insert-onset rule to be entirely consistent with any First Amendment constraints on compelling or restricting the commercial speech of tobacco product manufacturers that the courts might reasonably apply.⁸⁷

Additional research regarding the effectiveness of different types of inserts or onsets to promote different possible government interests would provide increased insight into their value and effectiveness compared to other tobacco control options available to FDA and to other governments. Such new, additional research could also fortify the existing research and other evidence that would support any new insert-onset requirements against the First Amendment challenges and other legal attacks that members of the tobacco industry would likely bring to try to avoid or delay having to comply.

challenges to a new FDA final rule establishing or amending a product standard to be filed in court within 30 days after they are promulgated, with no prior exhaustion of possible administrative remedies. TCA § 912(a)(1)(A) (21 § U.S.C. 3871(a)(1)(A)).

⁸⁷ It is also possible that state, local, or Tribal governments could establish their own insert or onset requirements for tobacco products sold within their borders. But they would need to be carefully structured to avoid federal preemption, especially if FDA had already established a conflicting nationally required tobacco product insert or onset requirement. Eric N. Lindblom, et al., *The Legal Framework for Using Tobacco Product Inserts and Onsets to Help Consumers Make More Informed Choices and to Reduce Tobacco Use Harms*, O'NEILL INSTITUTE WORKING PAPER NO. 2, at 24–32, 40 (July 6, 2016), www.law.georgetown.edu/oneillinstitute/resources/documents/legalframeworkinsertsonsets.pdf.