

THE LEGAL FRAMEWORK FOR USING TOBACCO PRODUCT INSERTS AND ONserts TO HELP CONSUMERS MAKE MORE INFORMED CHOICES AND TO REDUCE TOBACCO USE HARMS

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ABSTRACT

This working paper describes the major legal authorities and legal constraints relevant to the possibility that the U.S. Food & Drug Administration or state or local governments might attempt to require tobacco product manufacturers to provide informative tobacco product inserts or onserts to provide consumers with useful information relevant to understanding or reducing the harms and risks caused from using those tobacco products. Given that any such insert or onsert requirements could be legally challenged by affected tobacco product manufacturers, this paper carefully considers how the courts might interpret and apply the relevant legal authorities and preemption provisions in the Federal Tobacco Control Act and other federal law and in light of the First Amendment's constraints on compelled commercial speech. Going further, the paper also provides guidance on how any government insert or onsert requirements could be structured to minimize the risk that any legal challenges would be successful, and on what related research could provide further support or guidance.

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INTRODUCTION

For decades, the vast majority of the world's countries have required warning labels on cigarettes and other tobacco products, typically printed on the exterior surfaces of their packaging, to provide health warnings to consumers or to directly discourage use. More recently, many countries have required larger warnings (e.g., covering 50% or more of the front and back of the packs) with graphic images,¹ which related research shows work even more effectively at preventing initiation and promoting cessation.² In the United States, however, the courts blocked a 2011 effort by the U.S. Food and Drug Administration (FDA) to require new graphic health warnings on all cigarette packs, concluding that they violated First Amendment protections for commercial speech.³ In addition, warning labels on tobacco packaging are limited in how much information they can provide by the relatively small sizes of cigarette packs and some other tobacco product packages. To provide more detailed information directly to tobacco product users, while avoiding many of the First Amendment concerns raised by warning labels, governments could communicate through small printed leaflets either placed inside the product package ("inserts") or attached to the outside of the product packaging ("onserts").

Because product onserts can be removed from the outside of the package and inserts are not seen by consumers until after purchase, they interfere less with the communicative aspects of the tobacco product packaging than warning labels, making it easier to design them to survive First Amendment scrutiny. At the same time, inserts and onserts provide an effective way to reach tobacco product users each time they first use or open the tobacco product packaging, producing both a physical and visual reminder of their contents. As studies of the Canadian inserts suggest, inserts and onserts could work independently to help consumers make more informed decisions about their tobacco product use or to promote other public health objectives or could be designed to complement any warnings required on the package labels.⁴

Although inserts and onserts are often used for other products, such as prescription and over-the-counter drugs, Canada – which has required cigarette inserts with cessation messaging since 2001 – is, so far, the only country or other major jurisdiction that has adopted an insert or onsert strategy as part of its tobacco control regulations. But tobacco companies have used

¹ See, e.g., Canadian Cancer Society, *Cigarette Package Health Warnings: International Status Report*, Fourth Edition (September 2014).

² See, e.g., Jung, M., "Implications of graphic cigarette warning labels on smoking behavior: an international perspective," *Journal of Cancer Prevention* 21(1):21-25 (March 2016).

³ *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012). But see *American Meat Inst. v. U.S. Dep't of Agriculture*, 760 F.3d 18 (D.C. Cir. 2014) [overruling one of the core holdings in *Reynolds v. FDA*]. These rulings are discussed more fully, below.

⁴ Thrasher JF, et al., "Cigarette package inserts can promote efficacy beliefs and sustained smoking cessation attempts: A longitudinal assessment of an innovative policy in Canada," *Preventive Medicine*, 88: 59-65 (2016); Thrasher JF, et al., "The use of cigarette package inserts to supplement pictorial health warnings: An evaluation of the Canadian policy," *Nicotine & Tobacco Research* 17(7): 870-875 (2015).

inserts and onserts in the form of coupons, collectable cards, and other promotional material as part of integrated marketing strategies for over 100 years.⁵

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act became law, giving FDA extensive authority to regulate cigarettes, cigarette tobacco, and smokeless tobacco products and their manufacture, packaging, distribution, marketing and sale to protect public health. That Tobacco Control Act also includes provisions that specifically mention product inserts and provide additional authorities for FDA to educate consumers about tobacco product harms and constituents. In these ways, the Act appears to give FDA clear authority to require either tobacco product inserts or onserts for various public health purposes. But it is not yet clear how the FDA will interpret and apply these provisions. Nor is it clear how the courts will interpret those provisions when FDA uses them to implement new regulations that will inevitably face legal challenges from members of the tobacco industry. Similarly, it is not yet clear how the preemption provisions in the Act and in other federal laws amended by the Act might apply to state and local efforts to require inserts or onserts.

At the same time, federal court case law continues to evolve relating to First Amendment protections of commercial speech – which the tobacco industry frequently relies on in its legal challenges -- and considerable uncertainty exists as to how it might apply to government efforts to require tobacco product inserts or onserts.

Accordingly, the following tries to provide a rough outline of the applicable legal authorities and constraints on requiring tobacco product inserts or onserts and how they might be interpreted and applied, with a special focus on how any such inserts or onserts could be structured and proposed to minimize the risk of being blocked by First Amendment challenges.

SPECIFIC FDA AUTHORITY TO REQUIRE INSERTS AND ONSERTS TO DISCLOSE TOBACCO PRODUCT CONSTITUENT AND OTHER INFORMATION

The following provisions of the Tobacco Control Act clearly anticipate possible FDA action to require tobacco companies to disclose tobacco product constituent information to consumers, and, along with other sections of the Act, clearly authorize FDA to do so through requiring inserts or onserts (as long as First Amendment constraints and various evidentiary and procedural requirements are also satisfied).

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.⁶ That text gives FDA authority to “prescribe disclosure requirements regarding the level of any cigarette

⁵ Brandt, Allan, *The Cigarette Century* (Basic Books, 2009).

⁶ Sec. 206, amending Section 4 of FCLAA, 15 USC 1333. 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 Section 915(b)(1) and (2) [21 USC 387o(b)(1) and (2)] and clearly implied in the FCLAA provision, as amended by the Tobacco Control Act, which refers to “any cigarette or other tobacco product constituent, including any smoke constituent.” 15 USC 1333(e)(3).

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.” It also states that, while 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.”⁷ And “by any other means” would presumably include onserts.⁸

This language suggests that FDA could require inserts or onserts 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 onserts would produce any actual reductions in tobacco use or its harms through related behavior changes. 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 onserts would be likely 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.⁹

While not specifically mentioning inserts, the Tobacco Control Act requires FDA to “issue regulations that require color graphics depicting the negative health consequences of smoking” on cigarette packs.¹⁰ While the Tobacco Control Act does not directly state the purpose of the required cigarette graphic health warnings, an adjacent provision in the Act 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 “would promote greater public understanding of the risks associated with the use of tobacco products.”¹¹ This text shows that the Act anticipated required disclosures other than those in the required

⁷ 15 U.S.C. 1333(e)(3).

⁸ 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 onsert 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 onsert 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 onsert 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 onsert requirement placed on any tobacco product).

⁹ See *supra*, notes 37 and 38, and corresponding text.

¹⁰ Sec. 201(a), amending FCLAA at 15 USC §1333(d). [Pursuant to the Tobacco Control Act amendments, there are two subsection (d)’s in 15 USC §1333. This reference refers to the first (d).]

¹¹ Sec. 202(b), amending FCLAA at 15 USC §1333(d). [Pursuant to the Tobacco Control Act amendments, there are two subsection (d)’s in 15 USC §1333. This reference refers to the second (d).] For parallel provisions relating to warning labels and disclosures on smokeless tobacco product labels, see Sec. 205(a), amending the Comprehensive Smokeless Tobacco Health Education Act at 15 USC §4402(d).

warning labels, and further supports the legitimacy of disclosure requirements that promote greater public understanding of the risks associated with the use of not just the subject cigarettes but tobacco products in general (even if it has not been determined that the disclosures will also reduce tobacco use or its harms).¹²

While also not specifically mentioning inserts, a different section of the Tobacco Control Act 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.”¹³ To use this section of the Act to support a new onsert or insert requirement, FDA would need to identify some public health benefit that the in onserts or inserts would be likely to produce by disclosing the required information from the constituent testing. But Sec. 915(b)(2) also requires FDA to determine that disclosing the information, as required, will not “mislead consumers about the risk of tobacco related disease.” While that phrase is not defined, either, the public health purpose of the Tobacco Control Act suggest that FDA must determine that the required disclosure of constituent levels will not only likely produce a public health benefit but also that it will not likely mislead any significant number of consumers into thinking that some tobacco products are less harmful or less addictive than others when that either is not true or has not been established one way or the other.¹⁴

¹² Since its final graphic health warning rule was struck down in 2012, FDA has supported significant new research into graphic health warnings, but has not yet taken any other publicly visible action to develop or implement any new warning label rule for cigarettes or to otherwise compel cigarette manufacturers to provide warnings or other information to consumers. But FDA’s new final “deeming” rule, asserting jurisdiction over all tobacco products not previously under the agency’s active tobacco control authorities, did require a new text-only nicotine and addiction warning on cigarette tobacco and roll-your-own tobacco. 21 CFR §1143.3

¹³ Sec. 915(b)(2); 21 USC §387o(b)(2).

¹⁴ In a separate section, the Tobacco Control Act directly requires FDA to publish and periodically revise as appropriate “in a format that is understandable and not misleading to a lay person, and place on public 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.” [Sec. 904(d)(1)&(e); 21 USC §387d(d)(1)&(e)] Although the Act does not specifically state the purpose of this required publicly displayed list, it appears directed at informing (without misleading) consumers about the harms and potential harms from using specific tobacco products, brands, and subbrands, and about the possible differences between the harms and potential harms from using different products, brands, and subbrands. While this section of the Act does not mention onserts or inserts – and the required list would not likely fit in a product onsert or insert – it provides useful insights, similar to those raised by Sec. 915(b)(2), regarding how any onserts or inserts used to provide any information about a tobacco product’s harmful or potentially harmful constituents, either alone or in comparison to any other tobacco products, needs to avoid misleading consumers about relative risk.

Both Sec. 915(b)(2) and the Tobacco Control Act's amendments to the Federal Cigarette Labeling and Advertising Act (FCLAA) specifically authorize FDA to disclose tobacco product constituent "levels." How "levels" is interpreted and applied will be important, because there is considerable evidence that providing information about differences in the numerical or quantitative levels of certain harmful or potentially harmful constituents in different brands or sub-brands of tobacco products can seriously mislead consumers about relative risks and harms.¹⁵

Since the health risks of smoking were first broadcast to the public in the 1950s, for example, tobacco manufacturers have communicated numeric levels of tar and nicotine directly to smokers through advertising and product packaging,¹⁶ prompting many smokers, including those from countries with high educational attainment, mistakenly to equate lower tar and nicotine levels with reduced exposure and health risk, even using these numbers when selecting their brand.¹⁷ Starting in 1955, the US Federal Trade Commission (FTC) began raising concerns, since fully confirmed, that industry communications around tar and nicotine levels were confusing and represented unsubstantiated and inaccurate health claims about the relative risks of different product varieties. The epidemiologic evidence is clear: "low-tar" cigarettes are at least as harmful as their higher tar counterparts.¹⁸ Indeed, the FTC has concluded that the levels of tar and nicotine as measured by current testing protocols "are

¹⁵ Hammond D, "Tobacco Packaging and Labeling Policies Under the U.S. Tobacco Control Act: Research Needs and Priorities," *Nicotine & Tobacco Research* 14(1): 62–74 (2012).

¹⁶ Pollay, R. W., & Dewhirst, T., "Marketing cigarettes with low machine measured yields," in *Smoking and Tobacco Control Monograph 13: Risks associated with smoking cigarettes with low machine-measured yields of tar and nicotine* (National Cancer Institute, 2001) at 199–233.

¹⁷ Bansal-Travers, et al, "The impact of cigarette pack design, descriptors, and warning labels on risk perception," *American Journal of Preventive Medicine* 40: 674–682 (2011). Hammond, D., & Parkinson, C., "The impact of cigarette package design on perceptions of risk," *Journal of Public Health* 31:345–353 (2009). "Tobacco: End of the tar derby," *Time*, 93 (1960), <http://www.time.com/time/magazine/article/0,9171,871506,00.html>. Chapman, S., Wilson, D., & Wakefield, M., "Smokers' understandings of cigarette yield labels," *Medical Journal of Australia*, 145: 376–379 (1986). Cohen, J. B., Report of the NCI Expert Committee, *Consumer/smoker perceptions of Federal Trade Commission tar ratings. The FTC cigarette test method for determining tar, nicotine, and carbon monoxide yields of U.S. cigarettes*, Smoking and Tobacco Control Monograph No. 7, National Institutes of Health, National Cancer Institute, NIH Publication No. 96–4028 (1996), http://cancercontrol.cancer.gov/tcrb/monographs/7/m7_complete.pdf. Devlin, E., Eadie, D., & Angus, K., "Low tar product category," Prepared for NHS Health Scotland. Glasgow, UK: Centre for Tobacco Control Research (2003), <http://www.tobaccopapers.com/casestudies/index.htm#lowtarproduct>. Gori, G. B., "Consumer perception of cigarette yields: Is the message relevant?," *Regulatory Toxicology and Pharmacology* 12: 64–68 (1990). O'Connor, R. J., et al., "Relationship between constituent labelling and reporting of tar yields among smokers in four countries," *Journal of Public Health* 28: 324–329 (2006).

¹⁸ U.S. Department of Health and Human Services. (2001). Risks associated with smoking cigarettes with low machine measured yields of tar and nicotine. Bethesda, MD: U.S. Department of Health and Human Services, Public Health Services, National Institutes of Health; National Cancer Institute.

confusing at best, and are likely to mislead consumers who believe they will get proportionately less tar and nicotine from lower-rated cigarettes than from higher-rated brands.”¹⁹

Evidence from other countries outside the US also indicates that quantitative information about constituent levels is confusing for consumers. After 2000, Canada required that emission levels for constituents besides tar and nicotine (e.g., formaldehyde, hydrogen cyanide, benzene) be printed on tobacco packaging. Although the vast majority of smokers reported that they did not understand this newly provided information, most said they would still use the reported emission levels to find what they perceived as less harmful cigarette brand varieties.²⁰ Similar results have been found in Australia.²¹ Consistent with this research, and because of related concerns about misleading consumers to believe inaccurately that some cigarette varieties are significantly less harmful than others, the World Health Organization’s Framework Convention on Tobacco Control recommends that specific emission levels for cigarettes not be shown.²²

In sharp contrast, providing consumers with only *qualitative*, rather than quantitative, descriptions of constituents in specific brands or subbrands of tobacco products and their impacts on health appears to be more informative and less likely to lead to misperceptions of relative risk, and smokers rate them as most effective.²³ Instead of providing quantitative information about constituent levels, for example, the FCTC’s implementation guidelines recommend that “relevant qualitative statements be displayed on each unit packet or package about the emissions of the tobacco product,” such as “Smoke from these cigarettes contains benzene, a known cancer-causing substance.”²⁴

¹⁹ Federal Trade Commission. (2008). Rescission of FTC guidance concerning the Cambridge filter method. (Vol. 73, No. 236), Federal Register. Retrieved from <http://www.ftc.gov/os/fedreg/2008/december/081208cambridgefiltermethod.pdf>.

²⁰ Environics Research Group. (2003b). Toxics information on cigarette packaging: Results of a survey of smokers. Prepared on behalf of Health Canada. Ottawa, Canada: Environics Research Group Limited. Retrieved from <http://www.tobaccolabels.ca/constitu/canada>.

²¹ Australia Department of Health and Ageing. (2009). Public health value of disclose cigarette ingredients and emissions data. Prepared by Ipsos-Eureka for the Department of Health and Ageing. Retrieved from <http://www.health.gov.au/internet/main/publishing.nsf/Content/phd-tobacco-phv-cig-ing-em-data>.

²² WHO Framework Convention on Tobacco Control. (2008). Elaboration of guidelines for implementation of Article 11 of the Convention. Retrieved from http://apps.who.int/gb/fctc/PDF/cop3/FCTC_COP3_7-en.pdf.

²³ Environics Research Group. (2003a). Summary report of Four Focus Groups in Toronto & Montreal on awareness and understanding on toxic emissions information on tobacco packaging. Prepared on behalf of Health Canada. Ottawa, Canada: Environics Research Group Limited. Phoenix Strategic Perspectives. (2007). *Qualitative testing of toxic emissions statements*. Prepared on behalf of Health Canada. Ottawa, Canada: Phoenix Strategic Perspectives. Retrieved from <http://www.tobaccolabels.ca/constitu/canada2007>.

²⁴ WHO Framework Convention on Tobacco Control. (2008). Elaboration of guidelines for implementation of Article 11 of the Convention. Retrieved from http://apps.who.int/gb/fctc/PDF/cop3/FCTC_COP3_7-en.pdf.

Fortunately, the authorities given to FDA by Sec. 915(b)(2) of the Tobacco Control Act and its separate amendments to FCLAA to disclose tobacco product constituent “levels,” could readily be interpreted to allow FDA to provide more general or qualitative information about constituent levels rather than only provide specific measured numbers of the levels of different constituents in each different tobacco product brand and subbrand, especially when providing additional numerical or comparative information regarding specific levels would only confuse or mislead consumers about relative risk. In fact, Sec. 915(b)(2) specifically prohibits FDA from providing constituent level information in any form that FDA determines would “mislead consumers about the risk of tobacco related disease.” A more restrictive interpretation, that FDA may only require the disclosure of specific, numerical constituent levels would directly contradict the purposes of Sec. 915(b)(2) and the FCLAA text (to provide relevant, not misleading information to consumers related to tobacco product harms and risks) as well as the overriding purpose of both the Tobacco Control Act and FCLAA (to reduce overall harms from tobacco use).

Even if Sec. 915(b)(2) and the amended FCLAA text were interpreted narrowly to authorize only the disclosure of specific, numerical constituent levels, FDA could still provide only qualitative information about constituents in tobacco products and specific brands or subbrands – through inserts, onserts, or other means – under its extensive, general Tobacco Control Act authorities to regulate tobacco products.²⁵

USING FDA’S GENERAL TOBACCO CONTROL AUTHORITIES TO REQUIRE INSERTS OR ONSERTS TO PROVIDE INFORMATION TO CONSUMERS OR FOR OTHER PUBLIC HEALTH PURPOSES

FDA could also require inserts or onserts 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 products²⁶ or to establish tobacco product standards²⁷ when FDA determines that doing so would be “appropriate for the protection of the public health.”²⁸ FDA

²⁵ It is possible that the courts might find that any new FDA requirement to disclose tobacco product constituent levels through inserts or onserts (or any other means) must be done consistently with Sec. 915(b)(2) and the FCLAA provision and cannot be done solely through FDA’s general authority under Sec. 907(3). But such an interpretation of the Act would ignore the fact that neither Sec. 915(b)(2) nor the FCLAA provisions says that the authority they grant is either exclusive or should be applied in tandem with the other provision, and if they stand separately and independently from each other they likely stand separately and independently from other grants of authority in the Act, as well.

²⁶ Sec. 906(d)(1); 21 USC §387f(d)(1).

²⁷ Sec. 907(a)(3); 21 USC §387g(a)(3).

²⁸ FDA could also require inserts or onserts 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 onserts as part of the orders was “appropriate for the protection of the public health” (or was necessary for the tobacco products to meet other requirements for qualifying for the orders). Sec. 910(c) and (d), 21 USC §387j(c) and (d). Similarly, FDA could require inserts or onserts for specific tobacco products that must obtain a modified risk tobacco product (MRTP) order to permit their legal sale in the United

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.”²⁹

While the “appropriate for the public health” phrase and its statutory subparts have not been specifically interpreted by FDA or the courts, 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 onserts for disclosing qualitative information about constituents in different types of tobacco products (or to provide any other information or messaging), 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).³⁰

It is also possible that FDA could use this authority to require such inserts or onserts even if FDA were not able to determine that they would likely produce a net decline in overall tobacco use harms but still reasonably found that the requirement 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.³¹

States if FDA determined that requiring the inserts or onserts as part of the orders was 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.” Sec. 911(g)(1), 21 USC §387k(g)(1). See, also, Sec. 911(g)(2), 21 USC §387k(g)(2), especially at (A)(i).

²⁹ Sec. 906(d)(1); 21 USC §387f(d)(1).

³⁰ A plain reading of the terms also suggests that finding an insert or onsert 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 §915(b)(2).

³¹ Some might misconstrue the DC 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 the 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

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,³² or also 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.³³ Similarly, FDA could use tobacco product inserts or onsert to notify consumers of the benefits from having regular medical tests to catch tobacco-caused disease early; 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 onserts 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.³⁴

consider other possible government interests, such as informing consumers). 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. *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d at 1218-19.

³² See e.g., 21 *Code of Federal Regulations* (CFR) 201.5, General Labeling Provisions: Drugs; adequate directions for use.

³³ For examples of FDA-required labeling and inserts for prescription and over-the-counter drugs, see the Drugs@FDA database at <https://www.accessdata.fda.gov/scripts/cder/drugsatfda>. See, also, e.g., 21 CFR 201.56, *Requirements on content and format of labeling for human prescription drug and biological products*; and Center for Drug Evaluation and Research, FDA, *Guidance for Industry: Labeling for Human Prescription Drug and Biological Products – Implementing the PLR Content and Format Requirements* (February 2013). 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.

³⁴ See, e.g., Yong, HH, 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,’” *Nicotine and Tobacco Research*, Epub April 15, 2016; Lempert L & Glantz S. “Packaging colour research by tobacco companies: the pack as product characteristic,” *Tobacco Control*, Epub June 2, 2016; Borland & Savvas, “Effects of stick design features on perceptions of characteristics of cigarettes,” *Tobacco Control* 22:331-37, 2013; Bansal-Travers, M., et al., “What do cigarette pack colors communicate to smokers in the U.S.?” *American Journal of Preventive Medicine*, 40, 683-689, 2011; Bansal-Travers, M., et al., The impact of cigarette pack design, descriptors, and warning labels on risk perception in the U.S., *American Journal of Preventive Medicine*, 40, 674–682, 2011; Hammond, D. & Parkinson, C., The impact of cigarette package design on perceptions of risk. *Journal of Public Health Advance Access* published July 27, 2009; *USA v. Philip Morris*, 449 F. Supp. 1, 1609 (DC Dist. Ct., August 17, 2006) and at findings of fact 2024, 2379. 2412-14, 2448-49, 2469, 262-28 [findings upheld in: *USA v. Philip Morris*, 566 F.3d 1095 (DC Cir. May 22, 2009)]; Wakefield, M., et al., “The cigarette pack as image: new evidence from tobacco industry documents,” *Tobacco Control* 11(Supp.1): i73-i80, 2002.

Another possibility would be for FDA to require inserts or onserts 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. Recent studies from Canada, the only country that requires any cigarette inserts, suggests 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.³⁵ Research on the impact of the inserts suggests that they promote downstream self-efficacy to quit, increased quit attempts, and sustained abstinence from cigarettes.³⁶

The Tobacco Control Act requires only that FDA's determination that it would be "appropriate for the protection of the public health" to require inserts or onserts for any of these different purposes not be "arbitrary or capricious."³⁷ 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.³⁸

But even if FDA has clear authority to require such inserts or onserts as "appropriate for the protection of the public health" (or through any of its other authorities in the Tobacco Control



³⁵ Bandura A: Social Learning Theory. New Jersey, Prentice Hall, 1977. Bandura A: Self-efficacy: Toward a unifying theory of behavioral change. *Psychol Rev* 84:191-215, 1977. Prochaska JO, DiClemente CC: Self change processes, self-efficacy and decisional balance across five stages of smoking cessation, in Liss AR (ed): *Advances in Cancer Control: Epidemiology and Research*. New York, Alan R. Liss, Inc., 1984.

³⁶ Thrasher J, Osman A, Abad-Vivero E, et al. The use of cigarette package inserts to supplement pictorial health warnings: An evaluation of the Canadian policy. *Nicotine & Tobacco Research* 2015;17(7):870-75. Thrasher J, Swayampakala K, Cummings KM, et al. Cigarette package inserts can promote efficacy beliefs and sustained smoking cessation attempts: A longitudinal assessment of an innovative policy in Canada. *Preventive Medicine* 2016;88:59-65.

³⁷ Sec. 912(b); 21 USC §387l(b) [referencing the Administrative Procedures Act at 5 USC §706].

³⁸ See, e.g., *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."). The 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." *FCC v. Fox Television Stations*, 129 S.Ct. 1800, 1810 (2009) (quoting *Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 43 (1983)). Once that has occurred, "a court is not to substitute its judgment for that of the agency." *Id.*

Act), any such requirements must also fit within the constitutional constraints established by the First Amendment's protections for "commercial speech."

1ST AMENDMENT CONSTRAINTS ON REQUIRING INSERTS OR ONSETS

The First Amendment has already been used to strike down an FDA rule to establish external graphic health warnings on all cigarettes³⁹ – and members of the tobacco industry would almost certainly make First Amendment arguments against any FDA or other government efforts to require tobacco product inserts or onsets, as well. Even if the existing court rulings on First Amendment protections for commercial speech are interpreted expansively, however, there appear to be ways to design any government-required tobacco product inserts or onsets to survive any such constitutional attacks.

FDA or other government efforts to require tobacco product inserts or onsets would be considered "compelled commercial speech," and would likely be subject to much more permissive constitutional scrutiny than government efforts to restrict what commercial entities may say on their own. As the Supreme Court has stated, "the First Amendment interests implicated by disclosure requirements are substantially weaker than those at stake when speech is actually suppressed."⁴⁰ 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."⁴¹

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.

³⁹ *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012). But see *American Meat Inst. v. U.S. Dep't of Agriculture*, 760 F.3d 18 (D.C. Cir. 2014)(en banc) [overruling one of the core holdings the *Reynolds v. FDA* ruling was based on]. These rulings are discussed more fully, below.

⁴⁰ *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985) at footnote 14.

⁴¹ *Zauderer*, 471 U.S. at 651. See, also, *Milavetz, Gallop & Milavetz, P.A. v. U.S.*, 559 U.S. 229 (2010); *Am. Meat Inst.* 760 F.3d 18, 21-22 (D.C. Cir., 2014) (en banc).

4. The restriction must not be more extensive than necessary to serve the asserted government interest.⁴²

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 onserts) directed at other government purposes (e.g., disclosing health and safety risks) were subject to the more restrictive *Central Hudson* test.⁴³ But the full DC Circuit (ruling en banc) directly reversed that ruling in the *American Meat Institute* case, finding that the less-stringent *Zauderer* test could apply to government compelled commercial speech directed at other legitimate government purposes.⁴⁴

In the *American Meat Institute* case, the D.C. Circuit 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.⁴⁵

Similarly, the Second Circuit has repeatedly found that *Zauderer* should apply in compelled commercial disclosure cases, even when consumer deception is not at issue, and the *Central Hudson* test should be applied to statutes that restrict commercial speech.⁴⁶ Following that approach, it has upheld compelled commercial speech directed at purposes other than preventing consumer deception, including required disclosures directed at protecting the environment⁴⁷ and at combating obesity.⁴⁸

The U.S. Supreme Court has not directly considered this question of whether the *Zauderer* test should apply to compelled commercial speech cases directed at purposes other than preventing

⁴² *Central Hudson Gas & Electric Corp. v. Pub. Serv. Commission of N.Y.*, 447 U.S. 557, 566 (1980). See, also *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001)[the most recent Supreme Court ruling on the constitutionality of government restrictions on tobacco product advertising].

⁴³ *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012).

⁴⁴ *Am. Meat Inst.*, 760 F.3d 18, 21-22 (D.C. Cir., 2014) (en banc). 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. The *American Meat Inst.* en banc case was considered by eleven circuit court judges, with two judges dissenting from the final ruling.

⁴⁵ *Am. Meat Inst.* 760 F.3d at 23-24.

⁴⁶ *Satelite Group, Inc. v. Jepsen*, 764 F.3d 258, 262-63.

⁴⁷ *National Electric Manufacturers Association v. Sorrell*, 272 F.3d 104, 115 (2d Cir.2001) [also noting that "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"].

⁴⁸ *New York State Restaurant Ass'n v. New York City Board of Health*, 556 F.3d 114, 118 (2d Cir.2009).

or reducing consumer deception or misunderstandings.⁴⁹ But the previously discussed D.C. and Second Circuit rulings suggest that other government purposes should qualify. 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.”⁵⁰ 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. But it appears that “consumer curiosity alone is not a strong enough state interest to sustain the compulsion of even an accurate factual statement.”⁵¹

Even if *Zauderer* were interpreted and applied narrowly to apply only to compelled commercial speech relating to consumer deception, inserts or onsert directed at providing consumers with information about tobacco product harms and risks would likely qualify. For example, the Sixth Circuit refused to apply strict scrutiny instead of the *Zauderer* test to federal 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

⁴⁹ But, in regard to a more expansive application of the *Zauderer* test, see *International 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]; and *Pharmaceutical Care Management Ass’n v. Rowe*, 429 F.3d 294, 310 at footnote 8 [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].

⁵⁰ *Zauderer* 471 U.S. at 651.

⁵¹ *International Dairy Foods Association v. Amestoy*, 92 F.3d 67, 74 (2nd Circuit 1996) [quoted favorably by both a concurring opinion (Kavanaugh) and a dissent (Brown) in *American Meat Institute v. U.S. Department of Agriculture*, 760 F.3d 18, 32 (DC Cir. 2014)]. What might constitute “consumer curiosity, alone,” however, is quite controversial. In *International Dairy Foods*, the court struck down a Vermont law requiring the disclosure of what milk products contained milk from cows treated with synthetic growth hormone 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 no related health harms or risks to consumers). 92 F.3d at 74, 73. 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., the dissent at 92 F. 3d at 74-81; and Sugarman, SD, “Should Food Businesses Be Able to Use the First Amendment to Resist Providing Consumers with Government-Mandated Public Health Messages,” *FDLI’s Food and Drug Policy Forum* 5(4) (April 29, 2015). See, also, *American Meat Institute v. U.S. Department of Agriculture* 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’”].

“represents the alleged pleasures or satisfactions of cigarette smoking” from being deceptive.⁵² As detailed above, there is also extensive research and court findings 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; and inserts and onserts to correct those misunderstandings would fit under even the most narrow views of what compelled speech falls under the more lenient *Zauderer* test.⁵³ As the 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.”⁵⁴

On the other hand, it is possible that government-required tobacco product inserts and onserts 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 not displayed as part of the manufacturer’s commercial speech.⁵⁵ While this analysis applies most clearly to inserts, which are inside the tobacco product package and completely invisible and separate from the external package and its label, 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.⁵⁶ 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

⁵² *Discount Tobacco City & Lottery Inc. v. U.S.*, 674 F.3d 509, 526 (6th Cir. 2012), quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 527 (1992).

⁵³ *Supra*, note 34.

⁵⁴ *Milavetz, Gallop & Milavetz, P.A. v. U.S.*, 559 U.S. 229, 251 (2010)[quoting *Zauderer*, 471 U.S. at 652].

⁵⁵ See, e.g., the dissent in *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1236 (D.C. Cir. 2012) [suggesting that requiring cigarette package inserts is less burdensome, under First Amendment analysis, than requiring warning labels on the packs]; and *National Association of Manufacturers v. S.E.C.*, 800 F.3d 518, 522-24 (DC 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 *National Association of Manufacturers* case then 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 1st 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 *National Association of Manufacturers*, 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.” 800 F.3d at 535.

⁵⁶ *U.S. v. Philip Morris USA Inc.*, 566 F.3d 1095, 1140-42 (DC Cir. 2009)[noting, also, that the tobacco companies consider onserts to be different from packaging or labeling on the packaging].

that the First Amendment scrutiny applied to product inserts should be less strict than for onserts, which should 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 (and make it clear that the information is not coming from the product manufacturers).⁵⁷ 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.”⁵⁸

Neither the Supreme Court nor any circuit court appears to have yet ruled on this exact issue. In *Johanns v. Livestock Marketing Ass’n*, however, the Supreme Court ruled that a requirement that businesses producing a specific product finance generic advertising by the government about the product does not raise any compelled speech or other First Amendment issues, even when the businesses object to the government’s message.⁵⁹ That ruling made a sharp

⁵⁷ See, e.g., *CTIA-The Wireless Association v. City of Berkeley, California*, ___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”].

⁵⁸ *CTIA-The Wireless Association v. City of Berkeley, California*, ___F.Supp.3d___ (USDC, ND CA, 2015). 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 could actually be subject to an even less restrictive test if it were clearly identified as coming from the government and not the manufacturer.

⁵⁹ *Johanns v. Livestock Marketing 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 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 onsert requirements that did not include any political or ideological messages. It also might not apply to required inserts or onserts 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.

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.⁶⁰

Following that same logic, a government-required insert or onsert clearly identified as being government speech, with no implied endorsement by the tobacco product manufacturer, would appear to raise no First Amendment issues, especially as the manufacturer's ability to deliver his own messages would not be restricted by the requirement.⁶¹

Even if the courts found that requiring what was clearly the government's own speech still raised First Amendment issues if it were required to be delivered with the manufacturers' own

⁶⁰ *Johanns*, 544 U.S. 550 (2005) 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 onserts would pass both the majority and the dissent opinions' tests for government speech. They pass the majority's test because: (a) product inserts and onserts have "long communicated messages from the [government]" (e.g., in prescription and over-the-counter drugs); (b) government-required inserts and onserts are "often closely identified in the public mind with the [government];" (c) the government "has sole control" over the content of the inserts or onserts; (d) inserts and onserts (or product packaging) are not "traditional public forums for private speech;" and (e) the inserts and onserts "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, 52. Similarly, they qualify as government speech under the dissent's test because: (a) governments have long used inserts and onserts "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 onserts "that do not express messages that the [manufacturers] wish to convey;" (c) product packages can accommodate "only a limited number" of inserts or onserts; and (d) neither manufacturers nor consumers could pay to have certain messages included in the inserts or onserts. 135 S. Ct. at 2258-59, 2261.

⁶¹ See, e.g., Sugarman, S.D., "Compelling Product Sellers to Transmit Government Public Health Messages," *Journal of Law & Politics* 29(557) (2014); and Berman, M., "Clarifying Standards for Compelled Commercial Speech," *Washington Journal of Law and Policy* (forthcoming). An argument might be made that requiring government-message inserts or onserts would impede the manufacturers' ability to communicate to consumers through their own inserts or onserts. But manufacturers would not be prohibited from using their own inserts or onserts, 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 onsert might reduce consumer attention to one or both, it might also increase consumer awareness because of the novelty. [On multiple inserts or onserts, see, also, *supra*, note 118, and corresponding text.] In any case, the insert-onsert situation is quite different from required government warning labels on cigarette package that require 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).

product, the Supreme Court's analysis in *Johanns* indicates that 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 is applied, to avoid being struck down the content of any government-required tobacco product inserts or onserts must be accurate and not misleading. To satisfy the *Zauderer* test, they must also be "purely factual and uncontroversial."⁶² In a recent DC Circuit case, the court stated that "'uncontroversial, as a legal test, must mean something different than 'purely factual,'" finding 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.⁶³

⁶² See, e.g., *Zauderer*, 471 U.S. at 651. See, also, *National Assoc. of Manufacturers v. S.E.C.* 800 F.3d 518, 527 (DC Cir. 2015), finding that *Zauderer* "'requires the disclosure to be of 'purely factual and uncontroversial information' about the good or service being offered" [quoting *American Meat Inst. v. U.S. Dep't of Agriculture*, 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. 800 F.3d at 528.

⁶³ *National Associations of Manufacturers v. S.E.C.*, 800 F.3d 518, 528, 528-31 (DC Cir. 2015). 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, *American Meat Inst. v. U.S. Dep't of Agriculture*, 760 F.3d 18, 27 (D.C. Cir. 2014) [finding compelled country-of-origin labeling factual and noncontroversial]; *Evergreen Association, Inc. v. City of New York*, F.3d 233, footnote 6 [noting that compelling pregnancy services centers to state the City's treatment preferences or to mention controversial pregnancy-related services some centers oppose would be "controversial" if the *Zauderer* test applied]; *CTIA-Wireless Association v. City and County of San Francisco*, 494 Fed.Appx. 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 Association v. Schwarzenegger*, 556 F.3d 950, 953, 966-67 (9th Cir. 2009)[compelled speech labeling video game as violent fails *Zauderer* test because it is controversial opinion not purely factual information]; *New York State Restaurant Ass'n v. New York City Board 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]; *Entertainment Software Association 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]. But see, also, *Discount Tobacco*

In the DC 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 or, at most, shock the viewer into retaining the information in the textural warning; are "not warnings but admonitions," and are "unabashed attempts to . . . browbeat consumers into quitting."⁶⁴ 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.⁶⁵

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."⁶⁶ Although that statement was only dicta (not part of the actual court ruling), 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. While the dissent in *R.J. Reynolds* noted that the "QUIT NOW" command in the 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.⁶⁷

The *R.J. Reynolds* ruling was not appealed to the Supreme Court, and it is not yet clear how the U.S. Supreme Court might handle a similar case. In the meantime, the Supreme Court's rulings

City & Lottery Inc. v. U.S., 674 F.3d 509, footnote 8 (6th Cir. 2012)[stating that to apply the *Zauderer* test the compelled speech need not be noncontroversial but only accurate and factual].

⁶⁴ *R.J. Reynolds*, 696 F.3d at 1211, 1216–17 (D.C. Cir. 2012). But see *Discount Tobacco City & Lottery Inc. v. U.S.*, 674 F.3d 509, 526, 560-61 (6th Cir. 2012)[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."].

⁶⁵ *R.J. Reynolds*, 696 F.3d (D.C. Cir. 2012) at 1216 [majority opinion: "'the '1-800-QUIT-NOW' number, when presented without any explanation about the services provided on the hotline, hardly sounds like an unbiased source of information"] and at 1234 [dissent: "the additional inclusion of the telephone number '1-800-QUIT-NOW' on each warning label does not directly disclose factual information about the health consequences of smoking"].

⁶⁶ *R.J. Reynolds* 696 F.3d (D.C. Cir. 2012) at 1218 footnote 13.

⁶⁷ *R.J. Reynolds* 696 F.3d (D.C. Cir. 2012) at 1236-37 (emphasis added).

in the *Zauderer* case remain controlling law, clearly establishing that any government compelled commercial speech (including inserts or onserts) must not only present “purely factual and uncontroversial information” but must also be “reasonably related” to a substantial government interest.”⁶⁸

Zauderer also notes that “unjustified or unduly burdensome [compelled speech] might offend the First Amendment by chilling protected commercial speech,” but 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;” and the Supreme Court followed that ruling in the *Milavetz* case, its most recent compelled speech case.⁶⁹

Even if there were a separate “unduly burdensome” test under *Zauderer*, warning labels that use large portions of the main display portions of product packaging have not been found to be overly burdensome.⁷⁰ Accordingly, required onserts that only temporarily obscured parts of a tobacco product package also should not be found unduly burdensome in that regard. It is possible, however, that required inserts or onserts, or other compelled speech, might still be found 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.

In sum, the existing case law discussed here suggest that government-required tobacco product inserts or onserts would almost certainly avoid First Amendment constraints if they:

- (a) Were purely factual, informative, and noncontroversial (which would also make them accurate and not misleading).⁷¹

⁶⁸ *Zauderer*, 471 U.S. at 651 (1985). See, also, *Milavetz, Gallop & Milavetz, P.A.*, 559 U.S. 229 (2010).

⁶⁹ *Zauderer* 471 U.S. at 651(1985). See, also, *Milavetz, Gallop & Milavetz, P.A.*, 559 U.S. 229, 250 (2010).

⁷⁰ 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 (D.C. Cir. 2012) 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. *Discount Tobacco City & Lottery Inc. v. U.S.*, 674 F.3d 509, 530-31 (6th Cir. 2012).

⁷¹ 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).

- (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.
- (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).⁷²
- (e) Were not extremely costly or difficult for manufacturers to implement.

As discussed previously, however, more rigorous First Amendment obstacles could arise if the required inserts or onserts 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.⁷³

At the same time, it should be perfectly acceptable under existing First Amendment law regarding compelled commercial speech to provide consumers with accurate, not misleading 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 - 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, requiring such inserts or onserts should readily fall under the relaxed *Zauderer* test, even if *Zauderer* were applied 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.⁷⁴ Moreover, it would be quite easy to show that disclosing the above-described information to consumers was "reasonably related" to the goal of reducing consumer misunderstandings and preventing consumer deception relating to such things as the health benefits from quitting or from using other harm reduction strategies instead of quitting completely, the health benefits from reducing one's use to

⁷² 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.

⁷³ For example, any use of the 1-800-QUIT-NOW phone number in the inserts or onserts could be switched to only listing the actual numbers in the phone number.

⁷⁴ See, e.g., *Discount Tobacco City & Lottery Inc. v. U.S.*, 674 F.3d 509, 526 (6th Cir. 2012), quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 527 (1992).

different degrees, and the health benefits from switching completely to using a less-harmful product compared to engaging in dual use.⁷⁵

If *Zauderer* were applied more broadly (beyond just preventing deception), it would be quite easy to establish that such purely informational disclosures were also “reasonably related” to various alternative government’s interests, as well, such as having adult consumers make more fully informed decisions about tobacco product use; preventing youth initiation and use, or even reducing overall tobacco use and harms.

If, however, the government wanted to use the tobacco product inserts or onserts to prevent and reduce youth tobacco use or reduce overall tobacco use harms as effectively as possible, the government might want to include 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, would likely trigger the application of the more restrictive *Central Hudson* test. Accordingly, the government 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 – 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, cutback, 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.⁷⁶

To satisfy the remainder of the *Central Hudson* test, the government would have to establish that there were no equally or more effective ways to promote that government interest that

⁷⁵ On consumer ignorance or misunderstandings relating to tobacco products and their use, risks, and harms, see, e.g., Wackowkski, OA & Delnevo, CD, “Young adults risk perceptions of various tobacco products relative to cigarettes: results from the National Young Adult Health Survey,” *Health Education & Behavior* 43(3): 328-36 (June 2015); Reditis, M, et al., “Adolescent (mis)perceptions about nicotine addiction: results from a mixed-methods study,” *Health Education & Behavior* 43(2): 156-64 (April 2015); Kivinlemi, MT & LT Kozlowski, “Deficiencies in public understanding about tobacco harm reduction: results from a United States national survey,” *Harm Reduction Journal* 12-21 (June 2, 2015); Masiero, M, et al., “Personal fable: optimistic bias in cigarette smokers,” *International Journal of High Risk Behaviors and Addiction* 4(1): e20939 (March 2015); Boynton, M, et al., “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,” *BMC Public Health* 16: 516, Epub (June 23, 2016).

⁷⁶ *Central Hudson*, 447 U.S. 557, 566 (1980); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001).

would interfere less with the manufacturer's protected commercial speech.⁷⁷ Doing that would not be too difficult because it would be readily apparent that onserts and, especially, inserts present a much smaller burden to manufacturers' commercial speech rights far less than advertising or labeling restrictions or compelled speech in product advertising or on product packaging or labels.⁷⁸ In particular, 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 compelled speech to deliver information or other messages to product consumers that could possibly be less burdensome to the manufacturers than product inserts.⁷⁹

Onserts that did not present any messages to consumers until they detached them from the package and opened them up would share these same characteristics as inserts (except for temporarily obscuring whatever part of the tobacco product package the onsert was affixed,

⁷⁷ *Central Hudson*, 447 U.S. 557, 566 (1980); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001); *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"]; *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653, 2674 (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)].

⁷⁸ See, e.g., the dissent in *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1236 (D.C. Cir. 2012) [suggesting that requiring cigarette package inserts is less burdensome, under First Amendment analysis, than requiring warning labels on the packs].

⁷⁹ 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, such government communications would not likely qualify as equally effective alternatives available to the government to promote the government's substantial interests because they 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. See, *supra*, note 34. 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 the court to say 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 in order to promote the government's substantial interests even more substantially and quickly.

which could be its warning label), making them easier to defend against First Amendment constraints, as well. But a required insert could be designed to be affixed to the front of the tobacco product package to obscure more of the manufacturer's commercial speech on the package label or to have text visible before purchase that directly contradicts the manufacturers' "Buy-Me" protected speech at point of sale (e.g., by the visible insert stating "QUIT NOW"), which would make the insert less easy to defend – unless there were research showing that such characteristics made the insert work more effectively to promote the government's substantial interests.

Clearly, FDA has the statutory authority to require tobacco product inserts or onserts and could structure such inserts or onserts 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 specific characteristics and elements that would work even more effectively to reduce tobacco use and its harms.

STATE-LOCAL TOBACCO PRODUCT INSERT OR ONSERT REQUIREMENTS AND POSSIBLE FEDERAL PREEMPTION

There do not appear to be any preemption threats from other federal laws, or any other statutory or constitutional impediments, that might apply to any efforts by FDA to require inserts or onserts for cigarettes or other tobacco products under its tobacco control authorities. But state or local efforts to require tobacco product inserts or onserts could be preempted in some situations by the Federal Cigarette Labeling and Advertising Act (FCLAA), the Comprehensive Smokeless Tobacco Health Education Act (CSTHEA), the federal Tobacco Control Act, or through implied federal preemption.

Scope of FCLAA and CSTHEA Preemption:

FCLAA preempts any "statement related to smoking and health" that a state or locality requires "on any cigarette package" and also preempts states and localities from imposing any requirement or prohibition based on smoking and health "with respect to the advertising or promotion of any cigarettes" (except for bans or restrictions on the time, place, or manner of cigarette advertising or promotion).⁸⁰ The Comprehensive Smokeless Tobacco Health Education Act (CSTHEA) includes a similar preemption provision regarding any statement "relating to the use of smokeless tobacco products and health" that a state or locality requires "on any package or in any advertisement (unless the advertisement is an outdoor billboard advertisement) of a smokeless tobacco product."⁸¹ No similar preemption provisions exist in federal law relating to cigars or any other tobacco products.

⁸⁰ 15 U.S.C. 1334.

⁸¹ 15 U.S.C. 4406(a) and (b).

Clearly, the CSTHEA preemption would not apply to any inserts required in smokeless tobacco products, as they would not be “on any package or in any advertisement.”⁸² Similarly, the FCLAA preemption would not apply to cigarette inserts because they would not be “on any cigarette package.” Although onserts would be affixed to cigarette or smokeless tobacco packaging, they should not be preempted, either, because they are not part of product packages or, therefore, “on any package.” As the DC Circuit has found, because cigarette onserts are not statements “on” the packages “but rather statements in a brochure attached to or included with a package” cigarette onserts are not preempted by the plain language of the Labeling Act.⁸³

In its consideration of whether onserts might be preempted by FCLAA, the DC Circuit did not even consider the possibility that the onserts at issue might still be subject to FCLAA preemption because they were requirements “with respect to the advertising or promotion of any cigarettes.” Indeed, “with respect to” typically means “about or concerning” or “in relation to” something;⁸⁴ and the phrase is defined even more narrowly by the U.S. Senate Report accompanying the amendments to FCLAA which established the “with respect to” preemption, stating that “it is limited entirely to State or local requirements or prohibitions in the advertising of cigarettes.”⁸⁵ Neither inserts nor onserts fit under either of these definitions because they are physically separate from any cigarette advertising or promotions, their content is not even seen by consumers until after they have already purchased the cigarettes (and inserts are not seen at all until the consumer opens the packaging), and onserts are affixed to the visible part of the packaging only temporarily, and would be removed by consumers when they first open the packages.⁸⁶

⁸² See, e.g., *Philip Morris, Inc. v. Harshbarger*, 122 F.3d 58, 77 (1st Cir. 1997); *U.S. v. Philip Morris USA Inc.*, 566 F.3d 1095, 1140-42 (DC Cir. 2009); and CSTHEA, at 15 USC §4408(4) [defining “package” only as “a pack, box, carton, pouch, or container of any kind”]. See, also, *Altria Group v. Good*, 555 U.S. 70, 77 (2008) [“when the text of a pre-emption clause is susceptible of more than one plausible reading, courts ordinarily ‘accept the reading that disfavors pre-emption’” (citations omitted)].

⁸³ *U.S. v. Philip Morris USA Inc.*, 566 F.3d 1095, 1140-42 (DC Cir. 2009). See, also, FCLAA at 15 USC §1332 [defining “package” only as “a pack, box, carton or container of any kind”]. The Tobacco Control Act, at 21 USC §387(13), has a parallel definition that also do not reference any attachments to a package as being part of the package, itself.

⁸⁴ See, e.g., Definition of “with respect to,” *Merriam-Webster Dictionary*, online at <http://www.merriam-webster.com/dictionary/with%20respect%20to>, accessed May 23, 2016.

⁸⁵ *Philip Morris, Inc. v. Harshbarger*, 122 F.3d 58, 64 (1st Cir. 1997) [quoting S. Rep. No 91-566 (1970), reprinted in 1970 U.S.C.C.A.N. 2652, 2663].

⁸⁶ See, e.g., *Philip Morris, Inc. v. Harshbarger*, 122 F.3d 58, 74 (1st Cir. 1997); *Cipolline v. Liggett Group, Inc.*, 505 U.S. 504, 520-30 (1992). The potential impact of onserts on the packaging’s advertising and promotional messaging prior to purchase and prior to removal by the consumer could be further reduced if the onserts were not required to be affixed to the front, display portions of the pack and did not include any publicly visible statements that could be seen prior to purchase. An even more precautionary approach would also ensure that the content of the inserts or onserts also did not directly refer to any cigarette advertising or promotion. In any case, the advertising and promotion aspects of

Because of these inherent characteristics, inserts and onserts also should not fall under the somewhat broader FCLAA preemption analysis of the Second Circuit in its 23-34 94th *St. Grocery Corp. v. New York City Board of Health* case, which struck down a City requirement that cigarette-selling retail outlets display signs with graphic images showing certain adverse effects of smoking that would be visible to consumers prior to purchase.⁸⁷ That case found that the required warning signs at retail were “with respect to” cigarette advertising or promotion because they were linked to and would affect cigarette product displays and, therefore, product promotion.⁸⁸ The Court confirmed that “[o]nly requirements or prohibitions directly affecting the *content* of the manufacturers’ promotional message to consumers are preempted” by FCLAA.⁸⁹ But it also found that “requiring a warning sign in close proximity to a cigarette display has practically the same effect as requiring a warning on the display itself, thereby directly affecting the content of the promotional message conveyed to consumers.”⁹⁰ This reasoning, however, should not extend to inserts or onserts, which are much more separate and remote, both temporally and physically, from cigarette advertising or promotion and have no impact on the content of that advertising or promotion.⁹¹

Even if onserts, or inserts, were found to be “on” cigarette or smokeless tobacco product packages (or, for cigarettes, “in respect to” the cigarette advertising or promotion), they still would not be subject to FCLAA or CSTHEA preemption if, for cigarettes, they were not “related to smoking and health” or “based on smoking and health” or, for smokeless products, they were not related “to the use of smokeless products and health.” That suggests that onserts not related to tobacco use and health but to such things as littering or other environmental harms, tax collection, economic costs, or other non-health harms (e.g., impacts on how one smells, looks, or is otherwise perceived by others) would not face FCLAA or CSTHEA preemption.⁹² A court could, however, find that such non-health messages were still related to “smoking and health” or to “the use of smokeless tobacco products and health” if the actual intent behind the state or local government requiring the inserts with such non-health messages was to prompt

cigarette labeling and packaging before they are in the consumer’s possession has been reduced by the federal prohibition against self-service displays of cigarettes and smokeless tobacco products, which makes the packaging (and any onserts) much less visible prior to purchase. 21 CFR 1140.16(c).

⁸⁷ 23-34 94th *St. Grocery Corp. v. New York City Board of Health*, 685 F.3d 174 (2nd Cir. 2012)

⁸⁸ 685 F.3d at 183.

⁸⁹ 685 F.3d at 184.

⁹⁰ 685 F.3d at 183.

⁹¹ See, also, *Philip Morris, Inc. v. Harshbarger*, 122 F.3d 58, 74 (1st Cir. 1997) [state law not preempted by FCLAA because, among other factors, it “does not make ‘reference to’ advertising and promotion. . . it does not ‘act[] immediately and exclusively’ upon advertising and promotion, and . . . the existence of such advertising is not ‘essential to the [state] law’s operation.’” (citations omitted)]; *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 520-30 (1992).

⁹² See, e.g., *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 520-30 (1992).

users to quit or otherwise change their smoking or smokeless use behaviors in order to improve their health or the public health.⁹³

In regard to FCLAA, it might also be relevant that the scope of its preemption of state-local action was sharply curtailed in the 2009 legislation establishing the Tobacco Control Act, which explicitly exempted state-local measures that restrict “the time, place, or manner, but not content, of the advertising or promotion” of the cigarettes or smokeless.⁹⁴ While not directly applicable to state-local insert or onsert requirements, this exclusion reflects an intent by Congress not to interfere with state-local measures – even if they were found to be “with respect to” cigarette advertising or promotion and based on smoking and health – if they did not have any impact on the content of any cigarette advertising or package labels. And insert and onsert requirements would not have any impact on the content of any cigarette advertising or package labels. At most, an onsert requirement might temporarily obscure some of a tobacco product label, which might temporarily obscure some of its advertising and promotional content. But the onsert would not change or restrict the content of the label (and could be seen more as temporarily restricting the post-purchase time and manner of its delivery to consumers).⁹⁵

Most generally, because inserts and onserts are not part of tobacco product labels or advertising and they or at least their content are not seen until after purchase, state-local insert or onsert requirements would not conflict with the core purpose of FCLAA or CSTHEA: to provide for uniform, nationwide content requirements and restrictions for cigarette and smokeless tobacco product labels and advertising relating to the use of the tobacco products and health.⁹⁶

⁹³ On the importance of the intent or purpose of the state or local requirements, see, e.g., *Altria Group v. Good*, 555 U.S. 70, 80-83 (2008) [FCLAA does not preempt application of state anti-fraud laws to light/low cigarette advertising because fraud laws based on duty not to deceive not on smoking or health]. Looking at it the other way, see, also, *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 548 (2001) [regulations targeted at reducing youth exposure to cigarette advertising were subject to FCLAA preemption because “intertwined with the concern about smoking and health”].

⁹⁴ 15 USC §1334(c). See, also, *National Association of Tobacco Outlets, Inc. v. City of Providence, R.I.*, 731 F.3d 71, 79-81 (1st Cir. 2013).

⁹⁵ It would, on the other hand, be difficult to characterize a cigarette insert as in any way restricting either the content or the time, place, or manner of cigarette labeling – which supports a finding that inserts are not actually “with respect to” and cigarette advertising or promotion in the first place.

⁹⁶ See, e.g., FCLAA, at 15 USC §1331, Congressional Declaration of Policy and Purpose, and 15 USC §1334(c), Preemption-Exception. The Second Circuit, however, has suggested an even broader, and more restrictive, purpose for FCLAA, stating that the purpose of FCLAA is that only the federal government will require manufacturers to issue warnings about cigarette smoking to educate consumers “without interference or supplementary efforts by state or local authorities.” *23-34 94th St. Grocery Corp. v. New York City Board of Health*, 685 F.3d 174, 185 (2012). Under that view, state or local inserts or onserts – if they were seen as warnings required of manufacturers -- could be preempted by FCLAA, despite being delivered to consumers separately from cigarette ads or promotions and only after purchase. But purely informational inserts or onserts might not be considered warnings. More

Scope of preemption by the Tobacco Control Act:

In general, the federal Tobacco Control Act does not preempt any state, local, or Tribal “law, rule, regulation or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under [the Act]”⁹⁷ (so long as compliance with the state-local measure does not constitute a violation of the Act). But the Tobacco Control Act could still preempt a state or local (or Tribal) insert or onsert requirement if it were seen to be “different from, or in addition to” any requirement established pursuant to the Tobacco Control Act “relating to tobacco product standards. . . [or] labeling.”⁹⁸

It is unlikely that any state-local insert or onsert requirements would be seen as product standards or as conflicting with any Tobacco Control Act or FDA rule requirements relating to product standards. In this regard, the Second Circuit has ruled that:

“To constitute a product standard subject to preemption, a local sales regulation must be ‘something more than an incentive or motivator,’ it must require manufacturers to alter ‘the construction, components, ingredients, additives, constituents . . . and properties’ of their products. A local sales regulation that does not clearly infringe on the FDA’s authority to determine what chemicals and processes may be used in making tobacco products does not fall within this description and is therefore not preempted.”⁹⁹

This ruling indicates that insert or onsert requirements would not be considered product standards subject to preemption - even if they specifically required manufacturers to package their tobacco products with inserts inside the package or with onserts affixed to the outside of the package - because they have no impact on the characteristics of the tobacco products, themselves, or on how they are manufactured.¹⁰⁰

importantly, the analysis presented here indicates that it would be very difficult, if not impossible, to interpret and apply the existing text of FCLAA to preempt inserts or onserts (unless they specifically referred to cigarette advertising or promotions), even if the inserts or onserts were characterized as consumer warnings – which suggests that the Second Circuit’s dicta about the purpose of FCLAA preemption is overly broad.

⁹⁷ Sec. 916. Preservation of State and Local Authority at (a)(1) [21 USC §387p(a)(1)].

⁹⁸ Sec. 916(a)(2)(A) [21 USC §387p(a)(2)(A)]: IN GENERAL.—No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this chapter relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.

⁹⁹ *U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York*, 708 F.3d 428 at 434 [internal citations omitted].

¹⁰⁰ To make the distinction between insert and onsert requirements and actual manufacturing product standards even clearer and more distinct, the state or local inserts and onserts could be required to be applied to the tobacco product packaging at the distributor level instead of when the product is manufactured. To apply state-required tax stamps, distributors regularly open up and then reseal cigarette cartons, also removing and then replacing the cellophane on the cartons and packs; and having to comply with state-local insert or onsert requirements would not be much different.

As discussed above, because they are inside the tobacco product package or only temporarily attached to its exterior, inserts or onserts required by state or local governments also are not likely to be characterized as relating to, much less conflicting with, tobacco product packaging or external labeling, or with any related requirements established by the Tobacco Control Act or an FDA rule. However, the Tobacco Control Act is a chapter in the federal Food, Drug, and Cosmetic Act, which formally defines “label” as “a display of written, printed, or graphic matter upon the immediate container of any article,” and defines “labeling,” to include “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.”¹⁰¹ Under those definitions, inserts and onserts still would not be labels, but could be characterized as part of a tobacco product’s “labeling.” Under this definition, state-local insert or onsert requirements would be labeling requirements, that could be found to be “different from, or in addition to” requirements established by the Tobacco Control Act or through FDA rules issued pursuant to the Tobacco Control Act relating to labeling.

It appears, however, that some, if not all, state-local insert or onsert requirements would not currently be found “different from, or in addition to” any requirements pursuant to the Tobacco Control Act relating to labeling. To start, the phrase or standard can be seen as “highly ambiguous,” which provides some flexibility for how it might be interpreted and applied, both by FDA and the courts.¹⁰² To date, however, its scope in the tobacco product context has not been clarified in any FDA guidelines or rules or through any court rulings.¹⁰³ But an FDA rule concerning what constitutes “different from, or in addition to” in preemption language relating to the agency’s regulation of medical devices states that no preemption occurs unless FDA has established “specific counterpart regulations or there are other specific requirements

¹⁰¹ 21 USC §321(k) and (m). This broad “labeling” definition applies only to the FDCA, as amended by the Tobacco Control Act, but does not apply to FCLAA or CSTHEA or their preemption provisions.

¹⁰² *Medtronic v. Lohr*, 518 U.S. 470, 506 (1996), Justice Beyer concurring in part and concurring in the judgement. For preemption analysis purposes, the broad FDCA definition of “labeling” and its use in the more expansive “related to labeling” phrase in the Tobacco Control Act’s preemption provision could also be seen as ambiguous.

¹⁰³ For example, the two major court rulings to date on the scope of the Tobacco Control Act’s preemption provisions did not specifically address the “different from, or in addition to” standard and rejected the tobacco industry’s preemption claims on other grounds. *U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York*, 708 F.3d 428, 433-34 (2nd Cir. 2013); *National Association of Tobacco Outlets, Inc. v. City of Providence, R.I.*, 731 F.3d 71, 79-81 (1st Cir. 2013). In response to comments submitted to FDA’s proposed deeming rule relating to the scope of preemption, FDA simply summarized what the Tobacco Control Act text states about preemption, without providing any additional interpretation – although FDA did also state that: “A State or local statute is facially preempted only if no set of circumstances exists under which the statute would be valid. (See *Comm. of Dental Amalgam Mfrs. & Distribs. v. Stratton*, 92 F.3d 807, 810 (9th Cir. 1996).)” U.S. FDA, Final Rule, “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,” *Federal Register* 81(90): 28973, 28989 (May 10, 2016).

applicable to a particular [product] under the act, thereby making any divergent State or local requirements. . . different from, or in addition to, the specific Food and Drug Administration requirements.”¹⁰⁴ Applying those clarifications to the parallel text relating to Tobacco Control Act preemption suggests that state-local tobacco product insert or onsert requirements should not be found “different from, or in addition to” FDA labeling requirements until FDA issued its own insert or onsert requirements applicable to the same tobacco products subject to the state-local requirement. Under this view, other FDA requirements relating to “labeling” that have nothing to do with inserts or onserts not only do not constitute specific counterpart regulations but are simply too different to provide the basis for any preemption analysis focused on state-local insert or onsert requirements or to justify any related preemption.

While medical products are quite different from tobacco products, a good argument can be made that the Tobacco Control Act, which specifically disfavors preemption, supports an even more permissive interpretation of the “different from, or in addition to” phrase in the context of FDA tobacco product regulation than in the context of its drug regulation.¹⁰⁵ In addition, applying FDA’s clarifications of the “different from, or in addition to” standard on the drug and medical device side, or an even more permissive interpretation, to prevent preemption of state-local tobacco product inserts would also be fully consistent with the core purpose of the Tobacco Control Act, to reduce tobacco use and its related harms. In the absence of FDA required inserts or onserts, state-local insert and onsert requirements would directly promote and protect the public health through a strategy not yet used by FDA, without interfering with the tobacco-related public health benefits promoted by any requirements the Act or FDA currently place on other “labeling.” Nor would state-local insert or onsert requirements (with or without FDA-required inserts or onserts) create any significant risk of conflicting with any lesser or subordinate federal interests reflected in any Tobacco Control Act or FDA requirements relating to “labeling,” such as educating consumers about tobacco product use

¹⁰⁴ 21 CFR Part 808, Exemptions from Federal Preemption of State and Local Medical Device Requirements, at §808(d). See, also, *Medtronic v. Lohr*, 518 U.S. 470 (1996) at 500 [“overarching concern” of “different from, or in addition to” preemption provision is that preemption occur only where a particular state requirement threatens to interfere with a specific federal interest” and they are “specific counterpart regulations”] and at 505-507, Justice Beyer concurring in part and concurring in the judgement [FDA has authority to clarify the ambiguous preemption text and 21 CFR §808 is helpful in that regard with its references to “specific” measures]. See, also, *Mitchell v. Collagen Corp.*, 126 F. 3d 902, 913 (7th Cir. 1997)[favorably quoting *Hernandez v. Coopervision, Inc.*, 691 So. 2d 639, 641 (FL.Dist.Ct.App0. 1997) on how FDA drug preemption requires “a conflict between the state and federal regulations of the [products] which threatens to interfere with a specific federal interest”].

¹⁰⁵ See, e.g., Sec. 916. Preservation of State and Local Authority at (a) and (b) [21 USC §387p(a) and (b)]; Sec. 4(a)(2) [21 USC 387 note]; Sec. 203 [amending 15 USC 1334 to reduce FCLAA preemption]. See, also, *U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York*, 708 F.3d 428, 436 (2nd Cir. 2013)[referring, in the context of interpreting the scope of Tobacco Control Act preemption, to the need to reflect “Congress’s explicit decision to preserve for the states a robust role in regulating . . . tobacco products” and to ensure that the interpretation does not directly conflict with the public health goals of the Act].

and related harms and risks or not subjecting tobacco product manufacturers to a crazy quilt of conflicting requirements relating to their products.¹⁰⁶

Even if FDA did issue its own insert or onsert requirements that overlapped with a state-local requirement, the FDA rule interpreting the “different from, or in addition to” standard indicates that state-local requirements would not be preempted if they were “equal to, or substantially identical to” the FDA requirements or not “divergent.”¹⁰⁷

In addition, even if the state-local insert or onsert requirements were found “different from or in addition to” requirements established pursuant to the Tobacco Control Act relating to product standards or labeling, they could still be exempted from any Tobacco Control Act preemption by the Act’s broad savings clause, which specifically exempts from preemption any state-local requirement “relating to the sale, distribution, . . . the advertising and promotion of, or use of, tobacco products by individuals of any age.”¹⁰⁸ As the First Circuit concluded in 2013, “this provision was intended to prohibit state regulation narrowly and only with respect to the ‘specified and limited areas’ listed in the statute.”¹⁰⁹ Accordingly, this savings clause could exempt state-local inserts and onserts from Tobacco Control Act preemption if they were

¹⁰⁶ For more on these points, see the discussion, below, on the scope of federal implied preemption in relation to state-local insert and onsert requirements. Also, in the medical product context a state-local requirement to increase product safety could upset FDA efforts to set standards or requirements that carefully balance a drug’s effectiveness against its safety (e.g., by the state-local requirement making the drug more safe but less effective). See, e.g., *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 325 (2008). But state-local tobacco product insert or onsert requirements would work directly to promote less complicated public health goals (such as educating consumers or reducing overall tobacco use and harms) without any significant risk of upsetting any careful balance or strategy that any FDA rules related to “labeling” are trying to achieve.

¹⁰⁷ 21 CFR §808(d) and (d)(2). See, e.g., also, *Wolicki-Gables v. Arrow Intern. Inc.*, 634 F.3d 1296, 1300 (11th Cir. 2011) [“In order for a state requirement to be parallel to a federal requirement, and thus not expressly preempted . . . the requirements [must be] ‘genuinely equivalent.’ State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law.” Quoting *McMullin v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005), citing *Bates v. Dow Argosciences LLC*, 544 U.S. 431, 454 (2005).].

¹⁰⁸ Sec. 916(a)(2)(B) [21 USC §387p(a)(2)(B)]: EXCEPTION.—Subparagraph (A) does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products. See, e.g., *U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York*, 708 F.3d 428, 433-34 (2nd Cir. February 26, 2013) [“The only [Tobacco Control Act preemption] prohibition relevant here forbids local governments to impose ‘any requirement relating to tobacco product standards. Even then, pursuant to the saving clause, local laws that would otherwise fall within the preemption clause are exempted if they constitute ‘requirements relating to the sale...of...tobacco products’”] See, also, *National Association of Tobacco Outlets, Inc. v. City of Providence, R.I.*, 731 F.3d 71 at footnote 11 (1st Cir. September 30, 2013).

¹⁰⁹ *National Association of Tobacco Outlets, Inc. v. City of Providence, R.I.*, 731 F.3d 71, 81-82 (1st Cir. September 30, 2013) [quoting H. Rep. 111–58, 2009 USSCAN 468, 493 (2009)].

specifically implemented as sale or distribution restrictions (e.g., to prohibit or restrict the sale or distribution of cigarettes that do not have certain inserts or onserts).¹¹⁰

Possible Application of Implied Preemption:

While it appears that state or local insert or onsert requirements could avoid preemption under the express preemption clauses of FCLAA, CSTHEA, and the Tobacco Control Act, they could still be preempted by “implied preemption,” especially if FDA had already implemented or proposed an insert or onsert requirement for the same subject tobacco products.

Implied preemption occurs in two situations:

- “First, the States are precluded from regulating conduct in a field that Congress, acting within its proper authority, has determined must be regulated by its exclusive governance. The intent to displace state law altogether can be inferred from a framework of regulation ‘so pervasive . . . that Congress left no room for the States to supplement it’ or where there is a ‘federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.’”
- “Second, state laws are preempted when they conflict with federal law. This includes cases where ‘compliance with both federal and state regulations is a physical impossibility,’ and those instances where the challenged state law stands ‘as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’”¹¹¹

As previously discussed, the explicit preemption provisions in FCLAA, CSTHEA, and the Tobacco Control Act appear, at most, to establish complete federal preemption of any state or local efforts to place direct content requirements or restrictions on cigarette or smokeless tobacco product labeling for health purposes or, through product standards, to regulate directly the content or characteristics of specific tobacco products, themselves. But these apparent areas of exclusive federal governance expressly created by statute do not appear to reach or prevent state or local inserts or onserts. Accordingly, state or local insert or onsert requirements would be preempted by the first form of implied preemption only if these or some other federal laws

¹¹⁰ Sec. 916(a)(2)(B) [21 USC §387p(a)(2)(B)]. To make it even clearer that a state-local restriction relating to inserts or onserts was a sale or distribution restriction (and not a “labeling” mandate for all subject tobacco products), it could allow the distribution and sale of tobacco products without inserts or onserts in certain situations (e.g., at adult-only tobacconists or when sales are made to adult consumers who verify that they are already familiar with the information provided in the inserts or onserts). See, e.g., *U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York*, 708 F.3d 428 (2nd Cir. 2013) at footnote 3 and at corresponding text. It is possible that inserts or onserts that provided users with information about how to use the tobacco products legally and to minimize related harms and risks to users and exposed nonusers might also be exempted from Tobacco Control Act preemption through the savings clause as “related to” the “use” of tobacco products. But the courts could interpret the “use” exemption to apply only to state-local laws that specifically restrict or regulate when, where, how, or by whom tobacco products may be used, or that prohibit their use altogether.

¹¹¹ *Arizona v. U.S.*, 132 S.Ct. 2492, 2495 (2012) [internal citations omitted].

could be seen as intending or implying any *other* areas of exclusive federal governance that would cover state or local insert or onsert requirements. But no such areas appear to exist.¹¹²

Pursuant to the second type of implied preemption, state or local inserts or onserts could still be blocked if they create a conflict between state-local and federal law because it is impossible to comply with both the state-local and federal law or because the state-local inserts or onserts stand as an “obstacle” to the accomplishment and execution of the full purposes and objectives of Congress.¹¹³ The Supreme Court has also stated that determining whether a state-local law creates a sufficient obstacle to merit conflict preemption “is a matter of judgment to be informed by examining the federal statute as a whole and identifying its purpose and intended effects.”¹¹⁴ In that regard, inserts or onserts that fully comply with the First Amendment and provide relevant, accurate, and not misleading information about tobacco products and their use to consumers who purchase them would directly support, rather than conflict with, the core purposes of the Tobacco Control Act: primarily to prevent and reduce tobacco use and its harms, and also to inform consumers about the health harms from tobacco product use.¹¹⁵

In addition, the Supreme Court has found that implied conflict preemption cannot occur when “it is not impossible for petitioners to comply with both federal and state law because there is simply no federal standard for a private party to comply with.”¹¹⁶ That suggests, at a minimum, that no implied conflict preemption could block state or local insert or onsert requirements

¹¹² One possibly might arise if existing federal laws and rules implied that all government-required messages from manufacturers relating to cigarette harms or risks, not just warnings on cigarette pack labels and in cigarette ads and promotions, should come only from the federal government. But there is nothing in the text of FCLAA (which explicitly relates only to the labeling and advertising of cigarettes and specifically allows state-local time, place and manner restrictions to conflict with each other and with federal law) or in the Tobacco Control Act (which explicitly states a general intent not to preempt and curtailed the preexisting FCLAA preemption) to support such a broad intent or implication. See, e.g., FCLAA, 15 USC §1331, Congressional Declaration of Policy and Purpose; and the Tobacco Control Act at Sec. 916. Preservation of State and Local Authority [21 USC §387p] and at Sec. 202, amending FCLAA at 15 USC §1333 and 1334. See, also, *Altria Group v. Good*, 555 U.S. 70, 78 (2008) [finding that FCLAA’s first of two stated purposes applies only to warning labels and that only the second purpose (which is explicitly limited to cigarette labeling and advertising) is relevant to federal preemption]. Moreover, the clear underlying goal of FCLAA, that supersedes stated purposes (1) and (2), is to inform consumers about smoking health harms and risks, and its intended effect is clearly to have more informed consumers - and relevant, accurate, not misleading state-local inserts and onserts would directly promote that underlying goal and those desired effects. See, also, *supra*, note 96.

¹¹³ *Arizona v. U.S.*, 132 S.Ct. 2492, 2495 (2012).

¹¹⁴ *Arizona v. U.S.*, 132 S.Ct. 2492, 2495 (2012).

¹¹⁵ That primary purpose is evident from the Act’s full title, the Family Smoking Prevention and Tobacco Control Act, and from text throughout the Act. See, e.g., Sec. 3, Purpose (9) [21 USC §387 note]. The secondary purpose of informing consumers is evident from, for example, Sec. 3, Purpose (6) [21 USC §387 note] and 15 U.S.C. §1333(e)(3) and Sec. 202(b), amending FCLAA at 15 USC §1333(d).

¹¹⁶ *Freightliner Corp. v. Myrick*, 514 U.S. 280, 289 (1995). See, also, *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 133 S.Ct. 2466, 2479 (2013).

until FDA actually issued its own insert and onsert requirements (which has not yet occurred).¹¹⁷

Even then, there would be no preemption so long as it were possible for manufacturers (or distributors) to comply with both the federal and state-local insert or onsert requirements. While it might be awkward or redundant, it would not be impossible or even difficult to have two tobacco product inserts or two onserts. Having greater multiples required might at some point make compliance impractical. But the chances of having more than two of either required at the same time would be very small given that no inserts or onserts are currently required and any new state-local insert or onsert requirements would apply only to cigarettes or other tobacco products sold within their specific jurisdictions. In addition, state and local governments are unlikely to require inserts or onserts that would directly duplicate versions that were already required by a higher level of government.¹¹⁸

Nor should state-local inserts or onserts that were required concurrent with an FDA insert or onsert requirement be seen as standing as an “obstacle” to the accomplishment and execution

¹¹⁷ It is also possible that FDA might implement some other rule or undertake some other activity (e.g., public education campaigns), other than implementing inserts or onserts, that would have the exact same purpose as the state-local inserts (e.g., to inform consumers about harmful constituents in cigarettes or about how to use cigarettes to reduce related harms and risks, or to provide information about where those smokers who want to quit can obtain related information or assistance). Here, too, it would be hard to imagine how accurate, not misleading state-local insert or onsert requirements would not complement and support the FDA measures, rather than somehow stand as an obstacle to accomplishing their full purposes and objectives. Nor would it be impossible for manufacturers to comply with both the state-local insert-onsert requirements and any such FDA measures directed at the same informational ends.

¹¹⁸ Multiple onserts might also occur if a Federal or state-local onsert requirement were implemented before or during the implementation of the court-ordered corrective-statement onserts on cigarette packs that are part of the remedies in the successful U.S. Government RICO case against the major U.S. cigarette companies. See, e.g., Craver, R., “Big 3 tobacco manufacturers file appeal on corrective statements,” *Winston-Salem Journal*, April 9, 2016; *United States v. Philip Morris USA Inc.*, ___ F.Supp3d___ (USDC, DC 2016); *U.S. v. Philip Morris USA Inc.* 801 F.3d 250 (DC Circuit 2015). The Court of Appeals upheld the ruling against the cigarette companies in that case back in 2009, but the defendant cigarette companies have been fighting the implementation of the remedies (which include the onsert requirements) ever since. The attacks on the remedies have not focused on any perceived problems with onserts as a communications device (and have focused primarily on the content of the corrective statements and whether they must be displayed in other ways at retail outlets). It is not clear when all the legal attacks and appeals on the remedies will be exhausted and the corrective onserts, in some form or another, will actually appear on the defendant companies’ cigarette packs. The court-ordered onserts would be applicable to the cigarettes of the major cigarette companies nationwide, but they would only be required for a fixed, temporary time period. Given their purpose (part of a lawsuit remedy), they could not be seen as intending to fill the field or otherwise preempt other onserts. But if they were on packs at the same time as an FDA required onsert, that could fortify an argument that adding on state-local onserts would be preempted as creating an obstacle to the purposes and objectives of the FDA onserts. But the same analysis presented above supporting having a state-local insert or onsert concurrently with an FDA insert or onsert applies in this situation, as well.

of the full purposes and objectives of the FDA inserts or onserts. If they were on the same topic, the state-local inserts or onserts would simply be redundant, but that could increase the chances that the messaging would get through to consumers rather than stand as an obstacle to their delivery. If they were on different topics, an argument might be made that the state-local inserts or onserts would distract consumers from the messages in the FDA inserts or onserts or split their attention between the FDA and state-local inserts or onserts. But that does not suggest the creation of an “obstacle” to the accomplishment of the purposes and objectives of the FDA versions. Moreover, even if they had different topics, both the FDA and state-local inserts and onserts would likely be directed at the same overarching purposes and objectives: to educate tobacco product users about the products and their use so they can make more informed decisions about their use of the products and/or to prevent and reduce overall tobacco use harms. And having two inserts or onserts directed at those same overarching purposes with two different types of information could promote them more effectively.

For these same reasons, a new FDA insert or onsert requirement, by itself, would not suggest that the federal government has determined that the “field” of inserts or onserts must be regulated by FDA’s exclusive governance, nor would it create a “framework of regulation ‘so pervasive . . . that [it leaves] no room for the States to supplement it.’”¹¹⁹ FDA could also eliminate this issue when it implements any such insert or onsert requirement by explicitly stating that it does not intend to fill the field or exclusively govern it.

On the other hand, if FDA explicitly stated that it did intend to fill the field and govern exclusively in relation to inserts or onserts, a good argument could be made that FDA does not have the authority to fill the field or exclusively govern in that way because that would directly conflict with the language and intent of the previously discussed savings clause and the rest of the preemption section in the Tobacco Control Act (titled “Preservation of State and Local Authority”) or with the language and intent of the savings clause in the FCLAA preemption subsection.¹²⁰

To summarize, the risks of any federal preemption of a state or local insert or onsert requirement are either non-existent or smallest when:

- The state-local requirement applies to tobacco products other than cigarettes or smokeless (no FCLAA or Comprehensive Smokeless Tobacco Health Education Act preemption issues).
- The inserts or onserts provide information that is not related to health and are not required for smoking or tobacco-related health purposes (no FCLAA or CSTHEA preemption issues).
- The state or locality requires only inserts (onserts more likely to be seen as interfering with federally required warning labels or other required disclosures on tobacco product packaging or labels).

¹¹⁹ *Arizona v. U.S.*, 132 S.Ct. 2492, 2495 (2012) [internal citations omitted].

¹²⁰ Tobacco Control Act, Sec. 916 [21 USC §387p]. FCLAA, Preemption, 15 U.S.C. §1334.

- Any required onserts do not obscure any federally mandated warning labels or other federally-required text or disclosures on the package or label.
- FDA has not yet issued any insert or onsert requirements for the same type of tobacco product.
- Any state-local onsert requirement does not apply to any cigarette packs sold in the state or locality during the time that any other onserts are required by a court order to be placed on the cigarette packs.
- The state-local inserts or onserts do not provide information that FDA already requires the manufacturers of the same type of tobacco product to disclose through inserts or onserts.
- The state-local inserts or onserts do not provide information that FDA already requires the manufacturers of the same type of tobacco product to disclose to consumers through other means.
- Any state-local insert or onsert requirement automatically terminates if FDA requires a parallel insert or onsert, or at least if FDA requires a parallel insert or onsert providing the same information or messaging.

OTHER LEGAL ISSUES

Tobacco product manufacturers could try to use the new insert or onsert requirements as shields against lawsuits brought against them for misleading consumers or failing to sufficiently educate or instruct them:

If FDA or a state or local government were to require inserts or onserts on cigarette packages or any other tobacco product packaging in order to provide consumers with information about product risks or harms or about how to use the product to reduce risks and harms to the user or others, tobacco product companies might argue (as they have in regard to government required warning labels)¹²¹ that the inserts or onserts had eliminated any legal duty the tobacco companies might otherwise have had to warn or consumers of any risks or harms from the products not mentioned in the inserts or onsert, to notify consumers about additional ways to reduce those harms and risks, or even not to mislead consumers through product packaging and labeling.

The possibility that insert or onsert requirements might eliminate or curtail the manufacturers' legal duties to consumers could be eliminated if any law establishing an insert or onsert requirement simply stated that nothing in the law establishing the inserts or onserts or in any related rules or requirements 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

¹²¹ See, e.g., *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (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 F3d 737 (9th Cir. 1997).

control rulemaking.¹²² Any state or local law establishing a new tobacco product insert or onsert requirement could include similar protective language.

In addition, any new law or rule establishing a tobacco product insert or onsert requirement could also provide a formal process that the tobacco product manufacturers could initiate to change the content of the inserts or onserts to make sure that the provided information or instructions provided to consumers are accurate and complete and not misleading.¹²³ The Tobacco Control Act already provides for ways that interested parties can try to initiate FDA action, including amendments to FDA rules.¹²⁴ But the process proposed here would provide tobacco manufacturers and others a more direct and dispositive tool (perhaps with related agency deadlines) for seeking and securing timely corrections and improvements. To place more responsibility on the tobacco product manufacturers, the process could also require that they provide FDA (or the state or local agency implementing the insert or onsert requirement) with any relevant new research or other information relating to the accuracy, completeness, or effectiveness of the information provided in the inserts or onserts that is developed by the manufacturers, or otherwise comes into their possession, and is not publicly available.

Tobacco companies could argue that new research or evidence that becomes available in the future shows that the compelled speech is not actually accurate, wholly informational, and not misleading, after all:

Establishing an administrative process that tobacco product manufacturers or others could use to correct and update any required inserts and onserts could also strengthen the insert or onsert requirement's defenses against First Amendment attacks. On the front end, if tobacco product manufacturers legally challenged the new law or final rule establishing an insert or onsert requirement (which is highly likely), the courts would likely look even more favorably on the requirement if it not only appeared to require inserts or onserts that were wholly accurate, purely informational, and not misleading, based on available research and other evidence, but also offered an explicit and effective process that manufacturers or others could initiate to get the compelled speech revised if any new research or other new information appeared that showed that the inserts or onserts were not accurate, purely informational, and not

¹²² Sec. 4(a) and 916(b) [21 USC §387p(b)], and Sec 908(b) [21 USC §387h(b)]. See, also, the Comprehensive Smokeless Tobacco Health Education Act (CSTHEA) at 15 USC §4406(c). For added protection, FDA could also explicitly state in any new insert or onsert rule that it did not intend to provide any new legal protections for any tobacco industry members by issuing the rule.

¹²³ See, e.g., *Wyeth v. Levine*, 555 U.S. 555, 572 (U.S. 2009) [failure-to-warn claim against drug manufacturer not preempted where manufacturer did not seek to update FDA label after learning of safety risks]; *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 800-801 (8th Cir. 2001)[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).

¹²⁴ See, e.g., Sec. 901(d) [21 USC §387a(d)]and the related provisions of the Administrative Procedures Act; and, for FDA product standard amendments, Sec. 907(c), (d)(4) [21 USC §387g(c), (d)(4)].

misleading.¹²⁵ On the back end, offering such a process would provide manufacturers a way to have the previously established insert or onsert requirements updated or otherwise corrected in a timely fashion when new evidence showed that was necessary for constitutional compliance – instead of taking the more extreme action of immediately bringing a new lawsuit to strike down the entire requirement.¹²⁶

The 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 would 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 that process to exhaust their administrative remedies before bringing any such constitutional challenges to the courts.¹²⁷

¹²⁵ 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. See, e.g., Sec. 901(d) [21 USC §387a(d)]and, for FDA product standard amendments, Sec. 907(c), (d)(4) [21 USC §387g(c), (d)(4)]. But the new administrative process suggested here would provide even stronger protections and procedures to account for that possibility.

¹²⁶ 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, 10089 (9th Cir. 2003).

¹²⁷ See, e.g., *McKart v. U.S.*, 395 U.S. 185, 194 (1969)[discussing the exhaustion of administrative remedies requirement in the context of agency regulatory action]; and, along the same lines, *Cutler v. Hayes*, 818 F.2d 879, 890-91 (DC Cir. 1987); *Rodrigues v. Donovan*, 769 F.2d 1344, 1349 (9th Cir. 1985). See, also, *Bradley v. Weinberger*, 483 F.2d 410 [requiring exhaustion in dispute over FDA-required drug labeling]. 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 (DC Cir. 1984) [citing, among other cases, *Aircraft & Diesel Equipment Corp. v. Hirsch*, 331 U.S. 752, 771-72 (1947)]. See, also, *Blackbear v. Norton*, 93 Fed.Appx. 192, 194 (10th Cir. 2004)[“constitutional 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.’ (Citations omitted.) In this case, plaintiffs' constitutional claims appear to be central, not collateral, rendering this exception to exhaustion inapplicable.”]. See, also, *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*,

The courts could consider the existing provisions in the Tobacco Control Act that allow interested third parties to petition FDA to amend an established rule¹²⁸ 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 onsert requirement in court.¹²⁹ But the more explicit and dispositive proposed new procedures discussed here, with specific agency deadlines, would even more easily 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 court¹³⁰ - especially if the final insert-onsert 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 onserts was inaccurate, not purely informational, or misleading so that the agency could make any necessary changes to the messaging.¹³¹

CONCLUSION

Tobacco product inserts or onserts provide an effective but rarely used way for governments to deliver information and guidance to consumers and to promote related public health goals.

The preceding information and analysis shows that FDA has statutory authority to implement tobacco product insert or onsert 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.

Such insert or onsert requirements would face weaker First Amendment obstacles than those confronting warning labels required on tobacco product labels, packaging or ads; and any

572 FedAppx. 107, 111 (3rd 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 re. 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).

¹²⁸ See, e.g., Sec. 901(d) [21 USC §387a(d)]and, for FDA product standard amendments, Sec. 907(c), (d)(4) [21 USC §387g(c), (d)(4)].

¹²⁹ See, e.g., *Association of American Physicians v. FDA*, 358 Fed.Appx. 179, 180-81 (DC Cir. 2009); *Biotics Research Corp. v. Heckler*, 710 F.2d 1375 (9th Cir. 1983).

¹³⁰ *Tutein v. Insite Towers, LLC*, 572 FedAppx. 107, 111 (3rd 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 re. 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).

¹³¹ 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 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. Sec. 912(a)(1)(A) [21 USC 387l(a)(1)(A)].

government insert or onsert requirements could readily be designed to be entirely consistent with First Amendment constraints on compelling or restricting the commercial speech of tobacco product manufacturers.

At least until FDA a federal tobacco product insert or onsert requirement (and perhaps even after that), State, local, and Tribal governments could establish their own insert or onsert requirements. But any such State, local, or Tribal insert or onsert requirements would need to be carefully structured to avoid federal preemption.

At the same time, additional research regarding the effectiveness of different types of inserts or onserts 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 State, local, and Tribal governments. Equally, or perhaps more, important, such new, additional research could also significantly strengthen the existing evidence that would support any new insert or onsert requirements against the likely First Amendment challenges and other legal attacks that members of the tobacco industry would bring to avoid compliance.