THE LEGAL FRAMEWORK FOR USING TOBACCO PRODUCT INSERTS AND ONSERTS TO HELP CONSUMERS

O’NEILL INSTITUTE WORKING PAPERS
The O’Neill Institute Working Papers are intended to provide a vehicle for quickly bringing new insights, ideas and analysis into circulation in unfinished, draft form to stimulate discussion and invite comments and questions on important national and global public health law and policy issues. Please direct any queries or comments on this working paper to O’Neill Institute Senior Scholar Eric N. Lindblom at enl27@law.georgetown.edu.

O’NEILL INSTITUTE
The O’Neill Institute for National and Global Health Law at Georgetown University was established in 2007 through the generous philanthropy of Linda and Timothy O’Neill to respond to the need for innovative solutions to the most pressing national and international health concerns. Housed at Georgetown University Law Center in Washington D.C., the O’Neill Institute reflects the importance of public and private law in health policy analysis. The O’Neill Institute draws upon the University’s considerable intellectual resources, including the School of Nursing & Health Studies, School of Medicine, the Public Policy Institute, and the Kennedy Institute of Ethics.

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.

Eric Lindblom is a Senior Scholar at the O’Neill Institute for National & Global Health Law, Georgetown University Law Center. James Thrasher is an Associate Professor, Department of Health Promotion, Education and Behavior, Arnold School of Public Health, University of South Carolina. All of the views, opinions, and analysis in the paper are the authors’ own.
INTRODUCTION

Governments often require 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. In the United States, however, the courts have blocked an effort by the U.S. Food and Drug Administration (FDA) to require new graphic health warnings on all cigarette packs as violating First Amendment protections for commercial speech. 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, 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, possibly making them more likely 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 be designed to complement any warnings required on the package labels, themselves, or to work independently to help consumers make more informed decisions about their tobacco product use or to promote other public health objectives.

So far, Canada is the only country or other major jurisdiction that has adopted an insert or onsert strategy as part of its tobacco control regulations, requiring cigarette inserts with cessation messaging since 2001. But tobacco companies have used inserts and onserts in the form of coupons, collectable cards, and other promotional material as part of integrated marketing strategies for over 100 years.

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

1. R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205 (D.C. Cir. 2012). But see American Meat Inst. v. U.S. Dept of Agriculture, 760 F.3d 18 (D.C. Cir. 2014) [overruling one of the core holdings the Reynolds v. FDA ruling was based on]. These rulings are discussed more fully, below.
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, either generally or specifically in regard to the agency’s possible implementation of tobacco product inserts or onserts. 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.

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.4 That text gives FDA authority to “prescribe disclosure requirements regarding the level of any cigarette or other tobacco product constituent including any smoke constituent . . . if the Secretary determines that disclosure would be of benefit to the public health, or otherwise would increase consumer awareness of the health consequences of the use of tobacco products.” 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,

---

4. A tobacco product “constituent” includes tobacco product additives and ingredients, as well as any new substances created during the product’s use (e.g., through the combustion of the original ingredients). That is expressly stated in Sec. 915(b)(2) and clearly implied in the FCLAA provision.
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 that increased awareness would not necessarily translate into any actual public health gains through related behavior changes. As noted above, any FDA determinations that the inserts or onserts would “benefit the public health” or “increase consumer awareness of the health consequences of the use of tobacco products” would simply need to avoid being “arbitrary or capricious.” As part of that, however, FDA would at least need to identify, respectively, either a specific public health benefit that would likely be produced (and not offset) or an increase in some specific type of consumer awareness of health consequences that would likely be produced by the disclosures of constituent levels in the inserts or onserts.

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.” While the Tobacco Control Act does not directly state the purpose of the required graphic health warnings, an adjacent provision in the Act provides FDA direct authority to adjust any 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.” Such “any other disclosures” could be done through FDA-required inserts or onserts; and this text also suggests that such additional disclosures could be used to complement the color graphic warnings that FDA must ultimately require (e.g., to ensure that they both depict the negative health consequences of smoking in an accurate and non-misleading manner and promote greater public understanding of the risks associated with the use of tobacco products).

5. 15 U.S.C. 1333(e)(3). It is possible that this ban on requiring constituent disclosures on the face of cigarette packs might be interpreted to block FDA from requiring, based on this section of the Act, that an onsert disclosing constituent levels be placed on the face of a cigarette package, even if it were readily removable by the consumer. But, even under such an interpretation, placing such an onsert on the back or side of the cigarette package would still be permitted. In addition, this pack-face restriction does not, on its face, 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).

6. Sec. 201(a), amending 15 USC 1333(d).
7. Sec. 202(b), amending 15 USC 1333(d).
8. 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.
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.”

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 ins 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.

Both Sec. 915(b)(2) and the Tobacco Control Act’s amendments to 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.

9. Sec. 915(b)(2); 21 USC 387o(b)(2).
10. 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.

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,\textsuperscript{12} 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.\textsuperscript{13} 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 unsubstanciated 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.\textsuperscript{14} Indeed, the FTC has concluded that the levels of tar and nicotine as measured by current testing protocols “are 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.”\textsuperscript{15}

Evidence from other countries outside the US also indicates that quantitative informa-
tion 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.16 Similar results have been found in Australia.17 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.18

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.19 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.”20

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 infor-

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 and their packaging and labeling.

Using FDA’s General Tobacco Control Authorities to Require Inserts or Onserts to Provide Information about Constituents or for Other Public Health Purposes

The Tobacco Control Act also provides FDA with much broader and extensive authorities to regulate the sale and promotion of cigarettes and other tobacco products, or to establish tobacco product standards (which could include warning labels or product inserts or onserts) when FDA finds that doing so would be “appropriate for the protection of the public health,” with 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.”

21. 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.
22. Sec. 906(d)(1); 21 USC 387f(d)(1).
23. Sec. 907(a)(3); 21 USC 387g(a)(3).
24. Sec. 906(d)(1); 21 USC 387f(d)(1).
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 offset those gains).  

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.

This same analysis applies to possible FDA tobacco product insert or onsert requirements for other purposes, beyond providing information about constituents, that would

---

25. 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 Sec. 915(b)(2).

26. Some might misconstrue the DC Circuit Court ruling in its R.J. Reynolds Tobacco Co. v. FDA graphic health warnings case rejected 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 this regard, however, the court stated only that, under its First Amendment analysis, it was inadequate for establishing that the warning labels would directly promote a government goal of reducing smoking for FDA to show only that the warnings would increase consumers’ desires or intentions to quit. The question of whether it was “appropriate for the protection of the public health” to increase consumer knowledge about tobacco product harms or about how to reduce them (or to increase smokers intentions to quit) was not at issue and was not decided by the court. R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205 (D.C. Cir. 2012) at 1218-19.
also be “appropriate for the protection of the public health.” For example, FDA might parallel 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; or also to provide information on such matters as dosage forms and strengths, contraindications, warnings and precautions, adverse reactions, drug interactions, use while pregnant, overdosage, and dependence.

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 labeling through color coding, certain descriptors, and other characteristics that make consumers inaccurately believe that some brands or subbrands are less harmful than others.

28. See, 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). For examples of FDA-required labeling, including inserts, for prescription and over-the-counter drugs, see the Drugs@FDA database at https://www.accessdata.fda.gov/scripts/cder/drugsatfda.
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.30 Research on the impact of the inserts suggests that they promote downstream self-efficacy to quit, increased quit attempts, and sustained abstinence from cigarettes.31

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.”32 Related case law firmly establishes that nothing close to scientific certainty is required in agency decisions 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.33

But even if FDA has clear authority to require such inserts or onserts as “appropriate for

32. Sec. 912(b); 21 USC 387l(b) [referencing the Administrative Procedures Act at 5 USC 706].
33. 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.
the protection of the public health” (or through any of its other authorities in the Tobacco Control Act), any such requirements must also fit within the constitutional constraints established by the First Amendment’s protections for “commercial speech.”

**First Amendment Constraints on Requiring Inserts or Onserts**

The First Amendment has already been used to strike down an FDA rule to establish external graphic health warnings on all cigarettes\(^{34}\) – 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 onserts, 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 onserts to survive any such constitutional attacks.

Any FDA or other government efforts to require tobacco product inserts or onserts would be considered “compelled commercial speech,” which 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.”\(^{35}\) The 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) is “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.”\(^{36}\)

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.

\(^{34}\) *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012). But see *American Meat Inst. v. U.S. Dept of Agriculture*, 760 F.3d 18 (D.C. Cir. 2014) [overruling one of the core holdings the *Reynolds v. FDA* ruling was based on]. These rulings are discussed more fully, below.


2. The government’s asserted interest in restricting the speech must be substantial.

3. The restriction must directly advance the government’s asserted interest.

4. The restriction must not be more extensive than necessary to serve the asserted government interest.\(^{37}\)

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.\(^{38}\) 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.\(^{39}\)

In the American Meat Institute case, the D.C. Circuit upheld government requirements that certain meat products disclosure their country of origin on their labeling, referencing the long history of country-of-origin labeling directed at enabling consumers to choose American-made products, especially in regard to health concerns.\(^{40}\)

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.\(^{41}\) Following that approach, it has upheld compelled commercial speech directed at purposes other than preventing consumer deception, including requirements to disclose that certain products contain mercury and to inform consumers how to safely dispose of the products to promote a government interest in protecting human health and the environ-

---

37. Central Hudson Gas & Electric Corp. v. Pub. Serv. Commission of N.Y., 447 U.S. 557, 566 (1980). This Central Hudson test was also applied in Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001), the last time the Supreme Court reviewed the constitutionality of government restrictions on tobacco product advertising.
39. Am. Meat Inst. v. U.S. Dept of Agriculture, 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 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.
ment from mercury poisoning;\textsuperscript{42} and the mandate of simple factual disclosures of caloric information on menus to promote a government interest in combating obesity.\textsuperscript{43}

The U.S. Supreme Court has not directly considered this question of whether the \textit{Zauderer} test should apply to compelled commercial speech cases directed at purposes other than preventing or reducing consumer deception or misunderstandings.\textsuperscript{44} But the 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.”\textsuperscript{45} 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 \textit{Zauderer} test, whether it addresses consumer deception or misunderstandings or not. As to what else might and might not be considered valuable product information beyond the above examples, the Second Circuit, in the \textit{International Dairy Foods Association v. Amestoy} case, found that “consumer curiosity alone is not a strong enough state interest to sustain the compulsion of even an accurate factual statement.”\textsuperscript{46}

Even if \textit{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 Fourth Circuit refused to apply strict scrutiny instead of the \textit{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

\textsuperscript{42. 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”].}
\textsuperscript{43. New York State Restaurant Ass’n v. New York City Board of Health, 556 F.3d 114, 118 (2d Cir.2009).}
\textsuperscript{44. But see, in regard to a more expansive application of the \textit{Zauderer} test: \textit{International Dairy Foods Ass’n v. Boggs}, 622 F.3d 628, 641 (6th Circuit, 2010) [\textit{Zauderer} test applies to disclosures to address not only inherently misleading commercial speech but also potentially misleading commercial speech]; and \textit{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 \textit{Zauderer} is limited to potentially deceptive advertising directed at consumers and that “we have found no cases limiting \textit{Zauderer} in such a way”). In regard to a more restrictive application of the \textit{Zauderer} test, see: \textit{Borgner v. Brooks}, 284 F.3d 1204, 1210–13 (11th Cir.2002) [applying Central Hudson test, instead of \textit{Zauderer}, to required disclosures without explanation].}
\textsuperscript{45. \textit{Zauderer} 471 U.S. at 651.}
that smoking is innocuous” and to prevent advertising that “represents the alleged pleasures or satisfactions of cigarette smoking” from being deceptive. As detailed above, there is also extensive research and court findings that certain ongoing characteristics of cigarettes and their packaging and labeling 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 Zauder test.

It is also possible that tobacco product inserts and onserts might actually be subject to an even more lenient standard than the Zauder test because they would not be seen by consumers prior to purchase and are not displayed as part of the manufacturer’s commercial speech of the manufacturer (i.e., they are not part of the actual product package or label or in the product advertising). While this analysis applies most clearly to inserts, which are inside the tobacco product package and completely invisible and separate from the package 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 labeling or packaging because they are not a part of the packaging or labeling but only affixed to the packaging.

As to whether inserts or onserts might, nevertheless, still be seen as interfering with a manufacturer’s commercial speech, the Supreme Court has defined commercial speech as “speech proposing a commercial transaction,” and tobacco product inserts and onserts, while clearly present in a commercial context, would not interfere with any such commercial speech. Moreover, a major consideration in the Zauderer ruling was that a business’s “constitutionally protected interest in not providing any particular factual information in his advertising is minimal.” That same reasoning suggests that any constitutionally protected interest a tobacco company has in not providing any particular factual information inside his product packaging or affixed to his product packaging (which is much less publicly visible than disclosures on the package labeling or in ads, and is seen by consumers only after they have purchased the company’s product) should be even less. The Zauderer and Central Hudson rulings and their progeny establish that less

48. Supra, note _28_.
51. Zauderer, 471 U.S. at 651 (last italics added).
52. In National Association of Manufacturers v. S.E.C. the DC Circuit makes a similar analysis, 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 Zau-
stringent First Amendment protections should apply to less burdensome requirements and restrictions relating to commercial speech, which indicates that the First Amendment scrutiny applied to product inserts should be less strict than for onserts, which should be less strict than the First Amendment scrutiny applied to warnings required on product labeling or in product advertisements.\(^{53}\)

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).\(^{54}\) 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.”\(^{55}\)

\(^{53}\) See, e.g., 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 in product 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. See, also, the dissent in *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1236-37 (D.C. Cir. 2012) [suggesting that requiring cigarette package inserts is less burdensome, under First Amendment analysis, than requiring warning labels on the packs].

\(^{54}\) 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”].

\(^{55}\) *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) not factual and noncontroversial information, and was from a third party not the government. Accordingly, it does not contradict the idea that
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.”\(^{56}\) In the DC Circuit’s *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 . . . brow-beat consumers into quitting.”\(^{57}\) 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.\(^{58}\)

In a more 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.\(^{59}\)

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.

56. 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 Circuit, 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. Dept 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.

57. *R.J. Reynolds*, 696 F.3d at 1211, 1216–17. But see *Discount Tobacco City & Lottery Inc. v. U.S.*, 674 F.3d 509, 526, 560-61 (6th Circuit, 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.”].

58. *R.J. Reynolds*, 696 F.3d 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”].

59. *National Associations of Manufacturers v. S.E.C.*, 800 F.3d 518, 528, 528-31 (DC Circuit, 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 adjoin-
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. However, the Supreme Court’s rulings regarding compelled commercial speech in the 1985 *Zauderer* case remain in full force, clearly establishing that any government compelled commercial speech (including inserts or onserts) must not only be “purely factual and uncontroversial information” but must also be “reasonably related” to a substantial government interest – and could still violate the First Amendment if the compelled speech were “unjustified” or “unduly burdensome.”

Raising a new issue, the *R.J. Reynolds* majority opinion also 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.” 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 companies that includes any direct encouragement for adults not to purchase or use their tobacco products as long as those tobacco products are legally

---


available for sale. While it did not go quite as far as the majority, the dissent in *R.J. Reynolds* similarly stated that the “QUIT NOW” command “directly contradicts the tobacco companies’ desired message at the point of sale, thereby imposing a significant burden on their protected commercial speech” and, consequently, cannot be sustained unless the government can explain why a less burdensome “alternative means of connecting smokers to cessation resources, such as a package insert,” would be inadequate.62

On the other hand, warning labels on the outside of product packaging that provide only relevant information about product harms and risks (without directly encouraging consumers not to buy or use the product) have not been found overly burdensome or otherwise in violation of First Amendment constraints, even if they permanently use large portions of the front or display portions of the product packaging.63 Accordingly, required onserts that only temporarily obscured parts of a tobacco product package also should not be found unduly burdensome or otherwise in conflict with the First Amendment (at least if they did not encourage consumers to not buy or use).

Compelled commercial speech could also be found overly burdensome and, therefore, in violation of the First Amendment if complying with the compelled speech requirement were extremely costly to the manufacturers. 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.

Based on the existing case law discussed here, 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).64

63. 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* at 696 F.3d at 1211, 1215. In an earlier case, members of the tobacco industry did challenge the size and placement of the required cigarette warning labels and similar requirements for new non-graphic smokeless tobacco product warning labels (covering 30% of the front and back of the packaging), arguing that they were unduly burdensome because they would effectively overshadow and dominate their own commercial speech; but the 6th Circuit ruled against them. *Discount Tobacco City & Lottery Inc. v. U.S.*, 674 F.3d 509, 530-31 (6th Circuit, 2012).
64. It is also likely that this standard would apply to the content of any website or other external
(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 to 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).

(e) Were not unduly burdensome on the manufacturers.

Required tobacco product inserts or onserts that followed the above criteria but were also directed at other substantial government interests, such as reducing smoking and other tobacco use harms, would also likely escape any First Amendment constraints. But, as discussed previously, possible First Amendment obstacles could arise if the inserts or onserts required to promote those broader or more ambitious goals were not purely informational but included graphic images that were subject to different interpretations or designed to provoke an emotional response, or that 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 products. At a minimum, including such elements in required tobacco product inserts or onserts especially in onserts with such messaging readily visible prior to purchase would likely subject them to First Amendment review under the more strict Central Hudson test rather than the more permissive Zauderer test.

Although there are no court rulings directly on point, 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 subjective graphic images, emotional appeals, or actual exhortations to quit or switch). 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 sources that the insert or onsert referred to or incorporated (e.g., by providing a website address or phone number).

65. 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.
consumer deception and related misleading commercial speech. 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 different degrees, and the health benefits from switching completely to using a less-harmful product compared to engaging in dual use.

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; reducing overall tobacco use harms; or even preventing youth initiation and use.

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 emotional appeals, not-purely-informational graphic images, or direct exhortations to quit, reduce use, or switch to less-harmful products as helpful tools for breaking through the addictive power of cigarettes and other tobacco products. Including such elements in the inserts and onserts would, however, almost certainly 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 determined that doing so would likely make the inserts or onserts significantly more effective – ideally basing that determination on sufficient available research and other evidence.

Moreover, if the government did go forward with required inserts or onserts that included these additional elements, having research and other evidence available to support their inclusion 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 in preventing and reducing youth tobacco use and reducing overall tobacco use harm.\(^{68}\)

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 would interfere less with the manufacturer’s protected commercial speech.\(^{69}\) 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 product labeling. 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. How to direct the insert messaging to consumers in ways that would be less burdensome to the manufacturer’s commercial speech is hard to imagine.\(^{70}\)

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, which could be its warning label), making them easier to defend against First Amendment constraints, as well. But a required onsert 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 onsert stating “QUIT NOW”), which would make the onsert less easy to defend – unless there were research showing that such characteristics made the onsert work more effectively than less burdensome inserts or onserts to promote the government’s substantial interests.

It is possible, however, that future business-favoring court rulings might follow the D.C. Circuit’s dicta in the \textit{R.J. Reynolds} case and find that, because of the First Amendment, the government cannot compel a manufacturer of a legal product to convey any messaging in any situation that explicitly encourages legal adult consumers not to purchase or consume the legally available product – even if that is necessary to promote a substantial


\(^{70}\) So far, the courts’ First Amendment tests have not required the government to consider entirely unrelated alternative ways to promote its substantial interests that might be less burdensome to commercial speech. Here, for example, the courts would not be likely to say that the government should raise tobacco product taxes, initiate a new public education campaign, or
government interest effectively.\textsuperscript{71} But if such a new restrictive court ruling appeared, the inserts or onserts could simply leave out any such exhortations to become compliant.\textsuperscript{72}

**Scope of Federal Preemption of State-Local Inserts or Onserts**

Any efforts by FDA to require inserts or onserts for cigarettes or other tobacco products under its tobacco control jurisdiction would be free of preemption threats and there do not appear to be any other statutory impediments. 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), or the federal Tobacco Control.

**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."\textsuperscript{73} 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.”\textsuperscript{74} No similar preemption provisions exist in federal law relating to cigars or any other tobacco products.

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.”\textsuperscript{75} It is also likely that the FCLAA preemption would not apply to cigarette inserts because they would not be “on any cigarette package” and would not likely be seen as being requirements “with respect to the advertising or promotion of any cigarettes.” The U.S. Senate Report accompanying the amendments to FCLAA that established the “with respect to” preemption states that “it is limited entirely to State or local requirements or prohibitions in the advertising of cigarettes.”\textsuperscript{76} But cigarette inserts would be entirely separate

\textsuperscript{71.} R.J. Reynolds at 1218 footnote 13.
\textsuperscript{72.} 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.
\textsuperscript{73.} 15 U.S.C. 1334.
\textsuperscript{74.} 15 U.S.C. 4406(a) and (b).
from the cigarette’s ads and promotions. They would not be attached to any labels or ads; and they could not even be seen by smokers until after they purchased the cigarettes and opened the packs. They also would not interfere with or otherwise relate to any cigarette promotions or ads (unless their content actually referred to the advertising or promotion).\textsuperscript{77} That indicates that product inserts could not be seen as “with respect to” any advertising or promotion of the cigarettes unless they were specifically designed to reference the ads or promotions.\textsuperscript{78}

Although onserts would be affixed to cigarette or smokeless tobacco packaging, the DC Circuit Court has found that because they are not statements “on” the packages “but rather statements in a brochure attached to or included with a package” cigarette onserts are not prohibited by the plain language of the Labeling Act.\textsuperscript{79} In addition, that case 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;\textsuperscript{80} and onserts would not fit that definition in regard to cigarette ads or promotions unless the onserts’ content actually referred to them.\textsuperscript{81}

\textsuperscript{77} Because of these characteristics, inserts and onserts do not fall under the FCLAA preemption analysis of the Second Circuit in 23-34 94th St. Grocery Corp. v. New York City Board of Health, 685 F.3d 174 (2012), which found that a City requirement that retail outlets which sell cigarettes display signs with graphic images showing certain adverse effects of smoking that would be visible to consumers prior to purchase. The Court found, first, that the requiring warning signs at retail was “with respect to” cigarette advertising or promotion because it was linked to and would affect cigarette product displays and, therefore, product promotion. 685 F.3d at 183. While the Court then confirmed that “[o]nly requirements or prohibitions directly affecting the content of the manufacturers’ promotional message to consumers are preempted” by FCLAA, it 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.” 685 F.3d at 184, 183. 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.

\textsuperscript{78} See, e.g., \textit{Philip Morris, Inc. v. Harshbarger}, 122 F.3d 58, 74 (1997) [state law not preempted by FCLAA because, among other factors, it “does not make ‘reference to’ advertising and promotion because 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)]; \textit{Cipolline v. Liggett Group, Inc.}, 505 U.S. 504, 520-30 (1992). See, also, \textit{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)].

\textsuperscript{79} \textit{U.S. v. Philip Morris USA Inc.}, 566 F.3d 1095, 1140-42 (DC Circuit, 2009).


\textsuperscript{81} See, e.g., \textit{Philip Morris, Inc. v. Harshbarger}, 122 F.3d 58, 74 (1997); \textit{Cipolline v. Liggett Group},
if “with respect to” were defined much more expansively to mean “having an impact on,” cigarette onserts are not seen by consumers until after they have already purchased the cigarettes, are affixed to the packaging only temporarily, and would be readily removed by consumers when they first open the packages, sharply reducing the extent to which onserts might be seen as affecting any advertising or promotional messaging on the packaging.82

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 promotion 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 smoking and smokeless tobacco use and littering or other environmental harms, tax collection, economic costs, or other non-health harms (e.g., impacts on one’s appearance or on how one is perceived by others) would not face FCLAA or CSTHEA preemption.83 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 users to quit or otherwise change their smoking or smokeless use behaviors in order to improve their health or the public health.84

Inserts and onserts could still be excluded from any FCLAA preemption – even if they were found to be “with respect to” cigarette advertising or promotion and based on smoking and health – if they were found to be measures that restrict “the time, place, or man-

---

82. 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 affixed to the front, display portions of the pack and did not include any publicly visible statements that could be seen prior to purchase and which might dissuade purchases. Moreover, the advertising and promotion aspects of 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).


84. 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”].
ner, but not content, of the advertising or promotion” of the cigarettes or smokeless.85 If this exclusion were needed, it should apply given that the inserts or onserts would not restrict the content of the cigarette labeling or any cigarette advertising or promotion. At most, an onsert requirement might temporarily obscure some of the advertising and promotional content of the cigarette label (which could be seen as restricting the time and manner of its delivery to consumers); but it would not change or restrict its content.86

As all of this analysis shows, any inserts and onserts required by state or local governments should not be preempted by FCLAA or CSTHEA because they would not conflict with those laws’ purpose, among others, of providing for uniform, nationwide content requirements and restrictions for cigarette and smokeless tobacco product labeling and advertising relating to the use of the tobacco products and health.87

**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].”88 It is still possible, however, that a state or local (or Tribal) insert or onsert requirement might still be preempted if it were seen to be “different from, or in addition to” any requirement

---

86. It would, on the other hand, be difficult to establish that a cigarette insert was a restriction of the time, place, or manner of cigarette advertising or promotion. But that simply supports a finding that inserts are not actually “with respect to” cigarette advertising or promotion in the first place.
87. See, e.g., FCLAA, at 15 USC 1331, Congressional Declaration of Policy and Purpose, and 15 USC 1334(c), Preemption-Exception; and text at supra, notes _86-87_. The Second Circuit, however, might see 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 -- should 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 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.
88. Sec. 916. Preservation of State and Local Authority at (a)(1) [21 USC 387p(c)(1)].
established pursuant to the Tobacco Control Act “relating to tobacco product standards. . . [or] labeling” and was not considered to be a requirement “relating to . . . the advertising and promotion of, or use of, tobacco products by individuals of any age.” But “this provision was intended to prohibit state regulation narrowly and only with respect to the ‘specified and limited areas’ listed in the statute.”

In fact, the savings clause in the TCA preemption provision indicates that state or local insert or onsert requirements would be completely free of the Tobacco Control Act’s preemption provisions if they were seen as “relating to the use of tobacco products” – and inserts or onserts providing information to consumers about a tobacco product’s harms and risks or about how to use the product to reduce related harms and risks certainly seems to relate to the use of tobacco products.

In that regard, the Second Circuit also addressed the concern that states or localities might try to evade the Tobacco Control Acts product standard preemption by disguising product standards as sales regulations, finding 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

---

89. Sec. 916(a)(2) [21 USC 387p(c)(2)]:

(a)(2) PREEMPTION OF CERTAIN STATE AND LOCAL REQUIREMENTS.—

(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.

(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.


91. Sec. 916(a)(2)(B) [21 USC 387p(c)(2)(B)].
therefore not preempted.”

That finding suggests that insert or onsert requirements would not be considered product standards subject to preemption, even if they 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. Moreover, state or local inserts and onserts could both be applied to the tobacco product packaging at the distributor level instead when the product is manufactured. Distributors regularly open up cigarette cartons to apply tax stamps to the individual packs inside and then reassemble them; and placing inserts under the cellophane of individual packs or cartons or affixing onserts onto the outside of individual packs or cartons would not be much different.

Even if the inserts or onsert requirements were somehow characterized as product standards subject to the Tobacco Control Act’s preemption provisions, they would still be protected by the Act’s savings clause if they were also found to be “relating to the sale of tobacco products.” As the Second Circuit found in its 2013 *U.S. Smokeless Tobacco Mfg. Co.* ruling:

“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.’”

Finally, even if required inserts and onserts were characterized as subject to the Tobacco Control Act’s preemption provision and not protected by its savings clause, it would be difficult to find them preempted as “different from, or in addition to” any product standard or labeling requirement issued by the Tobacco Control Act or a subsequent rule. As discussed above in the context of FCLAA preemption, inserts or onserts do not appear either to be labeling requirements or to affect the content of labels; and there is not yet any FDA insert or onsert product standard that state or local inserts or onserts could be different from or add to.


94. Supra at footnote _58_ and related text.

95. Even if there were an FDA insert or onsert requirement, a state or local insert or onsert requirement would not be preempted by the Tobacco Control Act, if the FDA requirement were not a product standard (e.g., was issued pursuant to non-product-standard authorities in the Tobacco Control Act or did not qualify as a preemption protected product standard pursuant to court rul-
Possible Application of Implied Preemption:

While it appears that state or local insert or onsert requirements could avoid preemption under FCLAA, CSTHEA, or 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 were ‘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.’”

As previously discussed, the explicit preemption provisions in FCLAA, CSTHEA, and the Tobacco Control Act appear to establish complete federal preemption of any state or local efforts to place direct requirements or restrictions on tobacco product labeling or on the content or characteristics of the tobacco products, themselves. But those areas of exclusive federal governance expressly created by statute do not appear to 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 those or any other federal laws could be seen as intending or implying any other areas of exclusive federal governance that would cover state or local insert or onsert requirements.

Currently, no such areas seem to exist. One possibly might be that existing federal laws and rules imply that all government-required messages from manufacturers relating to tobacco product harms or risks, not just warnings on cigarette pack labels and in cigarette ads and promotions, should come only from the federal government. In fact, the stated purpose of the FCLAA (which the Tobacco Control Act amended only in other subsections) is “to establish a comprehensive Federal Program to deal with cigarette labeling and was not seen to pertain to tobacco product labeling. Sec. 916(a)(2)(A) [21 USC 387p(c) (2)(A)].

and advertising with respect to any relationship between smoking and health, whereby—

(1) the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes; and

(2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.97

Purpose (1) indicates that Congress intended that the required warning labels on cigarette labeling and in cigarette ads to adequately inform consumers about any adverse health risks of cigarette smoking; and, in the Tobacco Control Act, Congress gave FDA extensive authority to revise the required warning labels to do that.98 But it does not necessarily follow that purpose (1) supports any related implied preemption of all non-federal, government efforts to require manufacturers to provide additional information about cigarette health effects to consumers, including state or local inserts or onserts. In fact, the U.S. Supreme Court, in its 2008 Altria Group v Good ruling, found that purpose (1) corresponds only to the federal warning label requirements, and it is only purpose (2) that is relevant in regard to federal preemption.99

Purpose (2) explicitly refers to preventing diverse, nonuniform, and confusing cigarette \textit{labeling and advertising} restrictions, which does not, by its words, reach state or local inserts or onserts. Nor could purpose (2) be readily interpreted – even in light of purpose (1)’s more expansive language -- to infer a Congressional intent to preempt state or local cigarette inserts or onserts. Most notably, the 2009 Tobacco Control Act’s amendments to FCLAA’s preemption provisions explicitly permitted states and localities to implement “specific bans or restrictions on the time, place, and manner, but not content, of the advertising or promotion of any cigarettes.”100 By making that change without amending purpose (2), Congress was saying that allowing such state or local health regulations, which could certainly be diverse and nonuniform, would not conflict with purpose (2). That makes sense only if requirements that manufacturers could readily comply with on a jurisdiction-by-jurisdiction basis – such as diverse and nonuniform time, place, and manner restrictions – would not be confusing and, in Congress’s view, do not need to be preempted. On the other hand, state or local measures that place requirements on

97. FCLAA, 15 USC 1331, Congressional Declaration of Policy and Purpose.
98. See, e.g., Sec. 202, amending 15 USC 1333 and 1334.
99. \textit{Altria Group v. Good}, 555 U.S. 70, 78 (2008) [“The requirement that cigarette manufacturers include in their packaging and advertising the precise warnings mandated by Congress furthers the Act’s first purpose. And the Act’s pre-emption provisions promote its second purpose.”].
100. FCLAA 15 USC 1334(c).
cigarette labels or on the content of cigarette ads could not readily be complied with on a jurisdiction-by-jurisdiction basis and consequently, would be confusing and need to be preempted. By extension, state or local insert or onsert requirements, which could readily be complied with on a jurisdiction-by-jurisdiction basis (similar to compliance with diverse and nonuniform state and local tax and tax stamping laws) also would not be confusing, and, consequently, should not be subject to any implied preemption based on purpose (2).

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.101 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.”102 In that regard, it is difficult to imagine, that 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 could conflict with the purposes of the Tobacco Control Act (primarily to prevent and reduce tobacco use and its harms) or with any other relevant purposes and objectives of Congress.103

As for whether it is possible to comply with both the state-local law and the federal law, 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.104 That suggests that no implied conflict preemption could block state or local insert or onsert requirements at least until FDA issues its own insert and onsert requirements.105

103. An argument might be made that state-local inserts that provide information about smoking harms and risks would be obstacles to purpose (1) of FCLAA, if that purpose were interpreted as providing that information only by federally required cigarette pack warning labels. But 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.
105. 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
Even after FDA implemented an insert or onsert requirement, it would likely be possible for manufacturers (or distributors) to comply with both the federal and state-local onserts. While it might be awkward or redundant to have two inserts or two onserts, it would not be impossible or even difficult. The chances of having more than two of either required at the same time would be very small given that state-local insert or onsert requirements would apply only to cigarettes or other tobacco products sold within their 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.106

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 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 would likely increase the chances that the messaging would get through to consumers—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.

106. Multiple onserts might also might 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.
ers 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 would likely 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.’” 107 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. 108

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 state-local requirement does not apply to any tobacco products under FDA’s tobacco control jurisdiction (until deeming is final, FDA has no tobacco control jurisdiction over cigars, e-cigarettes, or pipe/hookah tobacco).

- The inserts or onserts provide information that is not related to health (no FCLAA or CSTHEA preemption issues).

- The state or locality requires only inserts (no interference with labeling or advertising, as might be asserted in regard to onserts).

- Any required onserts do not obscure any federally mandated warning labels or other text or disclosures on the package or label (no even temporary physical conflict).

- 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.

- FDA has not yet issued any insert or onsert requirements for the same type of tobacco product (e.g., FDA could not be seen as completely occupying the field).

- 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 or other means.

Other Legal Issues

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)\(^\text{109}\) 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 or to notify consumers about additional ways to reduce those harms and risks. That possibility could be eliminated if the law or rule establishing the insert or onsert requirement also provided a process the tobacco product manufacturers could initiate to change the content of the inserts or onserts to make them more accurate and complete or to reflect new research and information.\(^\text{110}\) In addition, any law establishing an insert or onsert


\(^{110}\) See, e.g., *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 800-801 (Eighth Circuit, 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).
requirement could also simply state 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.111

Establishing a process to correct and update any required inserts and onserts could also strengthen the insert or onsert requirement’s defenses against any First Amendment attacks. If new research or other new information showed that the inserts or onserts were not accurate, purely informational, and not misleading, such a process would provide an administrative way that the tobacco product manufacturers would bring that information to the government’s attention and get any problems corrected (instead of taking the much more extreme action of bringing a lawsuit to strike down the entire requirement) – and the courts would likely require the tobacco companies to exhaust their administrative remedies before bringing any such First Amendment lawsuits.

111. For examples of such provisions, see, e.g., the federal Tobacco Control Act at Sec. 4(a) and 916(b) [21 USC 387p(b)], and the Comprehensive Smokeless Tobacco Health Education Act (CSTHEA) at 15 USC Sec. 4406(c). It is possible that such provisions to prevent insert or onsert requirements from providing any protections for tobacco product manufacturers and others from lawsuits could be established only through a law and not, for example, through an FDA rule (although FDA could still explicitly state in such a rule that it did not intend to provide any new legal protections for any tobacco industry members by issuing the rule). But, in the case of an FDA insert or onsert rule the other provisions in the federal Tobacco Control Act, itself, that limit preemption and, in some cases, explicitly establish non-interference with pending lawsuits would still apply. Sec. 916 [21 USC 387p], Sec 908(b) [21 USC 387h(b)].