

Communicating Tobacco Product Information to the Public

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ABSTRACT

The 2009 Family Smoking Prevention and Tobacco Control Act (TCA) requires tobacco companies to disclose information about the harmful chemicals in their products to the U.S. Food and Drug Administration (FDA). The law requires FDA, in turn, to communicate this information to the public "in a format that is understandable and not misleading to a lay person." But how should FDA comply with this requirement? What does it mean for information about complex chemicals to be "understandable and not misleading to a lay person"? These questions are not easy ones to answer. Disclosures about the amount of harmful chemicals (constituents) in different tobacco products may help to inform consumers, but may also conversely prompt consumers to reach incorrect or unsupported conclusions about products' relative health risks.

This paper first analyzes FDA's legal obligation to publish tobacco constituent information so that it is "understandable and not misleading to a layperson." Second, it discusses how that legal analysis has guided scientific research examining how members of the public interpret messages regarding tobacco constituents.

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Lastly, this paper concludes with policy recommendations for FDA as it considers how to comply with the law's constituent disclosure requirement while still furthering its overall objective of promoting public health.

INTRODUCTION

Over decades, tobacco companies carefully engineered their products—cigarettes in particular—to be more appealing to consumers to make them start smoking and more addictive to make it harder to quit.¹ Considerable evidence suggests that at least some of these product design changes also made the products more deadly.² In response, the 2009 Family Smoking Prevention and Tobacco Control Act (TCA) included provisions designed to stop tobacco companies from manipulating their products without oversight. One provision requires regulated tobacco companies to provide information on constituents (chemicals) in—and, if relevant, emitted by—their products to the U.S. Food & Drug Administration (FDA), which can make regulatory decisions based on that information. Prior to the TCA's enactment, neither the federal government nor the public had access to the companies' information about the constituents in each brand and subbrand of tobacco product.³

Using the information submitted by the tobacco companies, FDA is required to establish and publish a list of “harmful and potentially harmful constituents [HPHCs] in each tobacco product [and its smoke, if applicable] by brand and by quantity in each brand and subbrand.”⁴ This list, according to § 904(d) of the TCA, must be published “in a format that is *understandable and not misleading to a lay person.*”⁵ Though not explicitly stated, the requirement to consider the “lay person's” perspective appears to reflect Congress's judgment that information about the presence and quantity of harmful constituents in tobacco products—if communicated in an understandable and non-misleading manner—could provide consumers with important, useful information that would enable them to make more informed consumer choices (to the extent permitted by their tobacco product addiction). Such information could potentially prompt them to quit, reduce their use, or switch to less harmful and less risky forms of tobacco use.

¹ See, e.g., Gregory N. Connolly, et al., *Trends in Nicotine Yield in Smoke and its Relationship with Design Characteristics Among Popular US Cigarette Brands, 1997–2005*, 16 TOBACCO CONTROL e5, e8 (2007) (concluding that “tobacco manufacturers have increased nicotine levels, the addictive agent of cigarettes, in the smoke of their cigarettes by increasing the nicotine in the tobacco rod and by other design modifications”); Geoffrey F. Wayne & Gregory N. Connolly, *How Cigarette Design Can Affect Youth Initiation into Smoking: Camel Cigarettes, 1983–83*, 2002 Tobacco Control (Suppl. 1) i32, i37 (2002) (finding that “Camel's success among [younger adult smokers] in the late 1980s followed product design changes affecting the brand's smoothness and harshness attributes”).

² OFFICE ON SMOKING AND HEALTH, U.S. DEP'T. OF HEALTH AND HUMAN SERV., *THE HEALTH CONSEQUENCES OF SMOKING—50 YEARS OF PROGRESS: A REPORT OF THE SURGEON GENERAL* 186 (2014). (“The evidence is sufficient to conclude that the increased risk of adenocarcinoma of the lung in smokers results from changes in the design and composition of cigarettes since the 1950s.”).

³ “Kool” is an example of a cigarette brand. “Kool Blue” and “Kool Full Flavor” are examples of subbrands.

⁴ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31 (June 22, 2009), § 904(e) [Hereinafter TCA]

⁵ *Id.* § 904(d) (emphasis added).

Figure 1. Abbreviated List of Harmful and Potentially Harmful That Manufacturers Must Report to FDA⁶

HPHCs in Cigarette Smoke	HPHCs in Smokeless Tobacco	HPHCs in Roll-your-own Tobacco and Cigarette Filler
Acetaldehyde	Acetaldehyde	Ammonia
Acrolein	Arsenic	Arsenic
Acrylonitrile	Benzo[a]pyrene	Cadmium
4-Aminobiphenyl	Cadmium	Nicotine (total)
1-Aminonaphthalene	Crotonaldehyde	NNK
2-Aminonaphthalene	Formaldehyde	NNN
Ammonia	Nicotine (total and free)	
Benzene	NNK	
Benzo[a]pyrene	NNN	
1,3-Butadiene		
Carbon monoxide		
Crotonaldehyde		
Formaldehyde		
Isoprene		
Nicotine (total)		
NNK		
NNN		
Toluene		

To implement this requirement, FDA sought scientific input on which tobacco constituents are “harmful or potentially harmful,” and in 2012 it published a list of 93 known HPHCs. It then issued draft guidance instructing tobacco companies to provide FDA with quantity information for 20 of these HPHCs shown in Figure 1.⁷ FDA selected this abbreviated list of 20 because it constituted a “representative sample” of HPHCs for which “testing and analytic methods are well established and

⁶ NNK is 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone, and NNN is N-nitrosornicotine. The listed constituents include known or probable human carcinogens, as well as constituents with known or probable effects relating to addictiveness, cardiovascular health, respiratory health, and reproductive health.

⁷ U.S. Food & Drug Admin., Guidance for Industry: Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act: Draft Guidance 4 (2012) [hereinafter HPHC Guidance]. In 2016, FDA issued a “deeming rule” extending its TCA regulatory authority to cigars, little cigars, pipe tobacco, hookah tobacco, electronic cigarettes, and other previously unregulated products. Under the deeming rule, manufacturers of these categories of products will be required to disclose HPHC information to FDA beginning in August 2019. U.S. Food & Drug Admin., Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28980 (May 10, 2016) (to be codified at 21 C.F.R. 1100).

widely available.”⁸ FDA stated that it would expand the reporting requirement to cover the remaining HPHCs in the future.⁹

To date, however, FDA has not publicly disclosed the HPHC information it has received from tobacco companies.¹⁰ Instead, it has chosen, in partnership with the National Cancer Institute (NCI), to fund additional research on how FDA could disclose HPHC information to the public in a manner that is “understandable and not misleading” and also useful to consumers.¹¹ FDA’s major concern is that although the HPHC disclosure requirement is intended to help inform consumers, disclosure may mislead consumers into believing that there is a “lower risk [of] harm from a product that contains lower amounts of specific constituents or fewer overall constituents,”¹² even when no evidence supports such a conclusion.

An unfounded belief that some brands or subbrands of a product are less hazardous than others may in turn influence consumers to switch to an alternative brand (instead of quitting), to smoke more, to initiate tobacco use, or to engage in other behaviors that may be detrimental to health.¹³ This concern is not unfounded given past history with “light” and “low-tar” cigarettes. Starting in the 1950s, the tobacco industry made explicit and implicit claims that “light” or “low tar” cigarettes were less harmful alternatives for smokers, despite extensive internal research demonstrating that these products would not in fact reduce tobacco-related harms.¹⁴ In ensuing years, many smokers switched to “light” or “low tar” brands of cigarettes, likely instead of quitting smoking.¹⁵

⁸ HPHC Guidance, *supra* note 7, at 4.

⁹ *Id.* at 2 (“[W]e intend to move toward full implementation and enforcement of the statutory requirement to report quantities of *all* HPHCs on FDA’s established list, as appropriate.”) (emphasis added).

¹⁰ FDA has missed the statutory deadline for doing so, which was “[n]ot later than 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act,” i.e., June 22, 2012. TCA, *supra* note 4, § 904(d).

¹¹ In August 2013, FDA’s Tobacco Products Scientific Advisory Committee held a joint meeting with FDA’s Risk Communication Advisory Committee. The committees agreed that implementation of the HPHC disclosure requirement should be delayed until FDA could conduct additional research “about how well people understand such HPHC information and how their beliefs affect their behavior.” U.S. Food & Drug Admin., *Issue Snapshot: Harmful and Potentially Harmful Constituents (HPHCs) in Tobacco Products* (2015), <http://www.fda.gov/downloads/TobaccoProducts/Labeling/ProductsIngredients/Components/UCM435035.pdf>.

¹² *See id.*; see also Nat’l Inst. of Health, Administrative Supplements for Tobacco Regulatory Research on the Public Display of Harmful and Potentially Harmful Constituents (HPHC) Information (2014), <http://grants.nih.gov/grants/guide/pa-files/PA-15-046.html> [hereinafter Administrative Supplements].

¹³ Jessica K. Pepper et al., *How Risky Is it to Use E-cigarettes? Smokers’ Beliefs about Their Health Risks from Using Novel and Traditional Tobacco Products*, 38 J. BEHAV. MED. 318, 321–22 (2015).

¹⁴ *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 560 (D.D.C. 2006) (“It is clear, based on their internal research documents, reports, memoranda, and letters, that Defendants have known for decades that there is no clear health benefit from smoking low tar/low nicotine cigarettes as opposed to conventional full-flavor cigarettes. . . . Defendants also knew that . . . many smokers who were concerned and anxious about the health risks from smoking would rely on the health claims made for low tar cigarettes as a reason, or excuse, for not quitting smoking.”).

¹⁵ Gary A. Giovino et al., *Attitudes, Knowledge, and Beliefs about Low-Yield Cigarettes among Adolescents and Adults*, in NATIONAL CANCER INSTITUTE, SMOKING AND TOBACCO CONTROL MONOGRAPH NO. 7, 45–46 (1996).

Disclosure of constituent information could potentially be useful if it (a) is likely to discourage tobacco use, or (b) demonstrates the benefits of switching to a lower-risk *type* (as opposed to brand) of tobacco product, for those unwilling or unable to quit tobacco use entirely.¹⁶ However, to be useful in any of these ways (and to comply with the law), any such communication must still be “understandable and not misleading to a lay person”—and it may be difficult, if not impossible, to present the reported constituent information in a manner that is informative yet not simultaneously confusing and misleading. Indeed, two advisory committees to FDA determined in 2013 that FDA lacked any adequate means of doing so.¹⁷

In addressing this challenge, an important preliminary step is to conduct legal analysis to help clearly define the terms in the TCA’s phrase “understandable and not misleading to a lay person.” Such definitions, translated into language that is meaningful to behavioral scientists, can support the development of objective survey measures that correspond to the terms. Behavioral scientists can then use such measures to evaluate the impact of the format and content of potential disclosures to ensure that they increase knowledge and do not cause misunderstandings, both generally and among various sub-populations, including persons with low literacy and low numeracy.¹⁸ Basing this work in legal analysis is critically important given that any FDA effort to implement the HPHC disclosure requirement could be challenged in court by the tobacco industry.¹⁹ Accordingly, public health researchers must understand the legal parameters of § 904(d) in order to best assist FDA in designing an HPHC disclosure approach that will withstand legal scrutiny.

In 2015, FDA and NCI funded research projects to “operationalize what constitutes public display of HPHC information by brand and by quantity in each brand and subbrand in a format that is ‘understandable and not misleading’ to a lay person.”²⁰ One such research grant was awarded to the University of North Carolina

¹⁶ For example, switching *completely* from cigarettes to low-nitrosamine snus (a form of smokeless tobacco) would likely produce substantial health benefits. See David T. Levy et al., *The Relative Risks of Low-Nitrosamine Smokeless Tobacco Product Compared with Smoking Cigarettes: Estimates of a Panel of Experts*, 13 CANCER EPIDEMIOLOGY, BIOMARKERS & PREV. 2035 (2004). There is no evidence that switching between brands of cigarettes would produce health benefits, although this might be the case for other types of tobacco products. SEE WORLD HEALTH ORGANIZATION, TOBACCO: DEADLY IN ANY FORM OF DISGUISE (2006), http://apps.who.int/iris/bitstream/10665/43465/1/9241563222_eng.pdf (“[C]igarettes claimed to be without additives and made of ‘organic’ tobacco have never been demonstrated to be less dangerous or addictive than conventional cigarettes. In fact, tests on some brands indicate higher levels of tar and nicotine delivery than those produced by conventional cigarettes in smoking-machine studies.”).

¹⁷ U.S. Food & Drug Admin., Joint Meeting of the FDA Risk Communication Advisory Committee and Tobacco Products Scientific Advisory Committee (2013), <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/ucm380521.htm> [hereinafter FDA Joint Meeting].

¹⁸ “Numeracy” is the ability to interpret and understand numbers; it is an element of health literacy. Ellen Peters, et al., *Numeracy Skills and the Communication, Comprehension, and Use of Risk-Benefit Information*, 26 HEALTH AFF. 741, 742 (2007).

¹⁹ For examples of recent industry challenges to FDA regulatory actions, see, e.g., R.J. Reynolds Tobacco Co. v. Food & Drug Admin., 696 F.3d 1205 (D.C. Cir. 2012), *overruled in part by* Am. Meat Inst. v. U.S. Dep’t of Agric., 760 F.3d 18 (D.C. Cir. 2014) (cigarette graphic warning labels); R.J. Reynolds Tobacco Co. v. U.S. Food & Drug Admin., 810 F.3d 827 (D.C. Cir. 2016) (appointments to Tobacco Products Scientific Advisory Committee); Philip Morris USA Inc. v. United States Food & Drug Admin., No. 15-CV-1590, 2016 WL 4378970 (D.D.C. Aug. 16, 2016) (premarket review requirements); Nicopure Labs, LLC v. U.S. Food and Drug Administration, No. 16-cv-878 (D.D.C. 2016) (deeming rule).

²⁰ Administrative Supplements, *supra* note 12.

(UNC). To help inform its work—as well as FDA’s ultimate regulatory decisions regarding HPHC disclosures—the UNC researchers commissioned a legal review of what the terms “understandable,” “not misleading,” and “lay person” mean in the context of TCA § 904(d).

Part I of our paper summarizes the results of that legal analysis. Part II briefly outlines how the legal review informed the survey work of the researchers at UNC and Ohio State University (OSU), providing a promising model collaboration between legal experts and public health scientists. Finally, Part III concludes the paper by providing some policy considerations and recommendations relating to the HPHC disclosure requirement.

I. WHAT IS “UNDERSTANDABLE AND NOT MISLEADING TO A LAY PERSON”?

“The objective of statutory interpretation is to give effect to the intent of Congress.”²¹ Of course, as an initial matter, courts look to the plain language of the statute. In many cases, however, likely including this one, looking at the plain language alone is not sufficient to resolve all potential ambiguities. Thus, courts provide deference to administrative agencies, as the subject-matter experts designated by Congress, in interpreting a statute’s meaning when the language is unclear. Under the longstanding (though occasionally criticized) *Chevron* Test, if the words of a statute leave some ambiguity, the courts will defer to an agency’s interpretation, so long as it is based on a “permissible construction of the statute.”²² This is true even if the agency’s interpretation of the statute is different from the “reading the court would have reached if the question initially had arisen in a judicial proceeding.”²³ Thus, it is important to emphasize that when it interprets broad terms such as “understandable” and “misleading,” FDA has considerable flexibility, so long as its interpretations are reasonable and linked to Congress’s overall goals in enacting the TCA.²⁴

Because statutory interpretation focuses on the intent of Congress, one traditional tool of statutory interpretation is the examination of legislative history—contemporaneous statements in floor debates, committee reports, hearing testimony, etc. by members of Congress about a statute’s meaning. The statutory history, as well as the language of the TCA itself, makes clear that Congress’s overriding goal in enacting the TCA was to reduce the death and disease caused by tobacco

²¹ *Kirtsaeng v. John Wiley & Sons, Inc.*, 133 S. Ct. 1351, 1390 (2013) (Ginsburg, J., dissenting) (internal quotation marks omitted).

²² *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 843 (1984).

²³ *Id.* at 843 n.11.

²⁴ Furthermore, any legal challenge to actions under § 904(d) would have to allege that FDA’s decisions about how to disclose HPHC information were “arbitrary, capricious, and abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(1)(A). This is an exceedingly difficult standard for a plaintiff to meet, which again leaves FDA with a considerable amount of flexibility. Because § 904(d) relates to the government’s own presentation of information—rather than a requirement for tobacco companies to communicate information to consumers (as in the case where graphic warning labels for cigarettes were struck down by the courts)—the First Amendment is unlikely to impose any relevant limitations on FDA’s actions.

products.²⁵ Accordingly, FDA's actions to implement any part of the TCA should reflect this primary goal—at least where, as with § 904(d), no specific text directs otherwise.²⁶

Section 904(d) is only one small part of a much broader piece of legislation, and no legislative history specifically addresses this provision. However, it is notable that in the introduction to the TCA, Congress—in addition to mentioning its overarching goal of “address[ing] the public health crisis created by the actions of the tobacco industry”²⁷—also suggested that its additional goals included “ensur[ing] that consumers are better informed”²⁸ and “promot[ing] understanding of the impact of the product on health.”²⁹ Thus, in interpreting the meaning of § 904(d), it is reasonable to read that provision in light of these additional general purposes as well, which relate to both the perspective of individual consumers (including both current tobacco users and potential future users, including youth) and to the population-level viewpoint of public health. As the TCA emphasized throughout the TCA (though not specifically in § 904), Congress also instructed FDA to be sensitive to the differential effects that policy interventions may have on different segments of the population.³⁰

Another tool of statutory interpretation is to examine how identical or similar phrases in other statutes have been interpreted and applied.³¹ The § 904(d) phrase, “understandable and not misleading to a lay person” does not appear anywhere else in the U.S. Code.³² As discussed below, however, component terms of the § 904(d) phrase do appear in other contexts, which may provide some interpretive clues.

A final relevant interpretive tool is the legal maxim *noscitur a sociis*, the principle that “a word may be known by the company it keeps.”³³ That is, the terms in a phrase (particularly when the conjunctive “and” is used) inform the meaning of the other words in that phrase. Each word is presumed to have its own distinct meaning that adds something additional to the phrase, but the terms are also expected to relate

²⁵ See generally H.R. Rep. No. 111-58, pt. 1 (2009), 2-4 (explaining the need for federal regulation of tobacco and noting that “[a]ccording to the Institute of Medicine, smoking-related deaths account for more deaths than AIDS, alcohol, cocaine, heroin, homicide, suicide, motor vehicle crashes, and fires combined”); TCA, *supra* note 4.

²⁶ See Daniel Carpenter, Gregory N. Connolly & Lauren Kass Lempert, *Substantial Equivalence Standards in Tobacco Governance: Statutory Clarity and Regulatory Precedent for the FSPTCA*, 42 J. HEALTH, HEALTH POL. & L. __ (forthcoming 2017) (suggesting that the “findings” in the TCA that list the Act’s purposes should be “a central guide to any interpretation of legislative intent and the meaning of the law”), <http://jhpl.dukejournals.org/content/early/2016/11/18/03616878-3774188.full.pdf+html>.

²⁷ TCA, *supra* note 4, § 2(29).

²⁸ *Id.*, § 2(6).

²⁹ *Id.*, § 2(44).

³⁰ See, e.g., *id.*, § 907(a)(3)(B) (stating that when issuing product standards, FDA “shall consider scientific evidence concerning . . . the risks and benefits to the population as a whole, including users and nonusers of tobacco products . . .”).

³¹ See Hillel Y. Levin, *Contemporary Meaning and Expectations in Statutory Interpretation*, 2012 U. ILL. L. REV. 1103 (2012) (“If a court interprets one statutory phrase in a particular way, then the court assumes that if the same phrase appears in a different statute, it should be interpreted consistently with the court’s earlier interpretation.”).

³² In many cases, prior case law interpreting the statute serves as an additional (and very important) aid for interpreting a statute’s language. For this provision, however, there are no prior cases to examine.

³³ *Graham Cty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 287 (2010), (quoting *Russell Motor Car Co. v. United States*, 261 U.S. 514, 519 (1923)).

logically to one another. In this context, “understandable” and “not misleading” likely overlap to some extent, but their placement by Congress in the same phrase suggests that Congress intended them to establish separate, distinct requirements.

With these general principles and background in mind, the following sub-sections analyze the meaning of the terms “understandable,” “not misleading,” and “lay person” as the TCA uses them.

A. “Understandable”

“Understandable” is an ambiguous term not so much because it is unclear what “understandable” means, but because *what* must be understood and the required *depth* of understanding are uncertain. For example, what does it mean that someone “understands” that a certain cigarette brand’s smoke contains 100 µg of acrolein per cigarette? Is it enough that he or she can repeat that fact, or must there be a deeper level of comprehension? Black’s Law Dictionary—the definitive legal dictionary—defines “understand” as “to apprehend the meaning of; to know,” suggesting that the ability to simply repeat a fact does not, by itself, necessarily reflect *understanding*.³⁴ But what else must a person know to understand that fact about a specific brand’s acrolein levels? How much acrolein a “typical” cigarette’s smoke contains? What a µg is? What impacts acrolein has on health, and the relative likelihood of those impacts? The extent to which acrolein is absorbed by the lungs when inhaled in smoke? What a “safe” level of exposure would be? What he or she should do with this information?³⁵

FDA regulations in non-tobacco contexts also suggest that the term “understandable” implies a deeper level of comprehension. For example, in implementing the general requirement that labels on medical devices must be “understood by the ordinary individual,”³⁶ FDA requires the labeling for tampons not only to disclose that the use of tampons can cause toxic shock syndrome, and explain what that is, but also to include information about the extent of the risk of toxic shock syndrome, the common warning signs for the disease, what to do if its warning

³⁴ *Black’s Law Dictionary* (10th ed. 2014). Some FDA regulations implementing requirements that labeling be “understood” or “understandable” focus only the prominence and legibility of the labeling, rather than on consumer comprehension. See, e.g., 21 C.F.R. § 740.2 (2015) (cosmetics); 21 C.F.R. § 161.190 (2015) (canned tuna). Thus, some might similarly argue the term “understood” in § 904(d) should be read narrowly to refer only to whether consumers are able to see and identify various HPHCs and their levels. However, unlike the case of tobacco, these regulations tend to involve products that do not have significant safety risks or that involve third-party intermediaries (such as a doctor). For the reasons discussed in this section, we believe FDA is required to take a broader view of “understandable” in this instance, especially in light of the TCA’s overarching purposes and goals.

³⁵ To jump ahead to the conclusion, “understanding” that fact would include appreciating the health consequences of smoking a cigarette brand containing 100 µg of acrolein. To have such an appreciation, however, one would need a considerable amount of additional information. This would presumably include, but not be limited to: the health harms and risks caused by inhaling 100 µg of acrolein with every puff; whether those harms and risks vary with the number of cigarettes smoked each day; whether inhaling more or less deeply changes the acrolein health harms and risks; whether cigarettes are available with significantly higher or lower levels of acrolein; whether smoking such alternative cigarettes would produce higher or lower acrolein health harms and risks (risks (or other health consequences); the extent to which quitting all smoking reduces the acrolein harms and risks of those who have already been smoking cigarettes for different lengths of time; and whether there are other ways to reduce the acrolein health harms and risks.

³⁶ 21 U.S.C.A. § 352(c) (2010).

signs appear, and how to reduce the chance of the disease occurring.³⁷ These regulations suggest that ensuring that a disclosure is “understood” requires providing information to consumers about not only the harms and risks related to the disclosed information, but also about how to reduce and address them.³⁸

Another relevant FDA example is 21 U.S.C. § 343(H), enacted as part of the Patient Protection and Affordable Care Act, which requires chain restaurants to post calorie content information on menus. In addition to the calorie disclosure, the law requires “a succinct statement concerning suggested daily caloric intake . . . designed to enable the public to *understand*, in the context of a total daily diet, the significance of the caloric information that is provided on the menu.”³⁹ FDA rule implementing this requirement listed the following principles that should guide the development of such a statement:

- 1) The succinct statement should be in plain language that consumers can understand;
- 2) The total caloric value should be framed appropriately so that it is not viewed as a recommendation for daily intake for every consumer; and
- 3) The succinct statement should inform consumers that individual needs vary.⁴⁰

This statutory scheme is different than the § 904(d) HPHC disclosure requirements, but it nonetheless highlights a few important concepts that may be relevant to defining “understandable.” First, to be understandable, the information must be presented in “plain language” and avoid jargon or complex vocabulary.⁴¹ In the context of work by federal agencies, “plain language” has a specific technical meaning that includes the use of words and sentences that are easily understood by people with low educational attainment.⁴² Second, for information to be understandable, consumers must have a sense of what the information means *for them*. And third, consumers must recognize that not all people have the same needs (or risks).⁴³

³⁷ 21 C.F.R. § 801.430 (2015).

³⁸ These requirements do not appear to have ever been challenged in court; to the contrary, tampon companies have relied upon these federal regulations to defend against personal injury suits. *See Meyer v. International Playtex, Inc.*, 724 F. Supp. 288 (D.N.J. 1988); *Murphy v. Playtex Family Prods. Corp.*, 69 Fed. Appx. 140 (4th Cir. Md. 2003); *Ellis v. International Playtex, Inc.*, 754 F.2d 292 (4th Cir. Va. 1984). Of further note, recognizing “understood” as relating to both *the meaning of* and *what to do* in response to a disclosure suggests that an FDA disclosure may need to include the explicit message that smokers should quit and provide a link or phone number for cessation resources.

³⁹ 21 U.S.C. 343(1)(5)(H)(ii)(I)(bb) (emphasis added).

⁴⁰ Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71156-01 (Dec. 1, 2014). The final “succinct statement” required by FDA is “2,000 calories a day is used for general nutrition advice, but calorie needs vary.” FDA also set forth an alternative statement to be used on menus targeted to children. 21 C.F.R. § 101.11 (2014).

⁴¹ Some state laws use the Flesch reading ease test to implement requirements for forms to be “understandable” or “readable.” *See, e.g.*, N.Y. Ins. Law § 3102 (2015) (insurance forms); O.R.S. § 316.364 (2015) (income tax forms); N.C.G.S.A. § 58-66-25 (2015) (insurance forms). Cf. 21 C.F.R. § 161.175 (2015) (requiring that when preservatives are listed as ingredients for raw shrimp, they must be accompanied by the statement “added as a preservative,” so that consumers will be able to understand the purpose of the ingredient).

⁴² *See generally*, Federal Plain Language Guidelines (2011) <http://www.plainlanguage.gov/>.

⁴³ Like the tampon example, however, it does not appear that this section of the regulation has ever been challenged in court.

The three principles in the calorie disclosure regulations are important elements of what “understandable” means, but it is critical to note that they (especially the latter two principles) may be much more difficult to apply in the context of tobacco regulation. In comparison to calorie data, HPHC data are likely much tougher to understand and interpret. The number of calories in a donut, for example, can be calculated with some precision, and the calories consumed will be the same regardless of who eats it. And consumers likely have a general sense that calorie needs may vary depending on differences in body size, metabolism, and physical activity. By contrast, even the tobacco industry concedes that available methods for measuring HPHCs “do not accurately reflect the wide range of human smoking behavior of individual smokers such as variability in puff volume, puff duration, and puff frequency.”⁴⁴ And consumers are surely much less familiar with constituents such as crotonaldehyde and 1-aminonaphthalene than they are with calories. Thus, making the HPHC information “understandable” to the public poses a considerably more difficult challenge.

Given the major purpose of the TCA—to reduce the death, disease, and other health harms caused by tobacco use—one could also argue that whether any provided HPHC information is actually “understandable” can ultimately be determined only by examining how consumers change their behavior in response to receiving the information.⁴⁵ If an HPHC disclosure successfully increased consumer understanding of the tobacco product’s harms and risks and how to reduce or address them, at least some corresponding changes in consumer behavior would logically follow, despite consumer brand loyalties and the addictive power of tobacco use. Accordingly, as the American Cancer Society Cancer Action Network and other public health groups have suggested, before mandating any specific HPHC disclosures FDA must, at minimum, be satisfied that they will “more likely than not result in changes in consumer behavior that, on balance, have a positive impact on public health.”⁴⁶

Although the tampon regulation does not suggest that behavioral change (or anticipated behavioral change) should be a mechanism for evaluating “understanding,” that is likely because the tampon context is very different from that of tobacco product regulation. In approving tampons for sale in the United States, FDA determined that they were “safe and effective” for their intended purposes—i.e., that the toxic shock risks they presented users were not substantial enough to justify prohibiting potential users from choosing to use tampons instead of available

⁴⁴ Altria Comment, Re: Docket No. FDA-2011-N-0867 (Feb. 10, 2012). Puff volume, puff duration, and puff frequency are collectively referred to as “puff topography.” Puff topography studies have, for example, shown that “smokers take more, bigger, and/or longer puffs when they switch from full-flavor to low-yield brands.” Melissa D. Blank, et al., *Comparison of Methods for Measurement of Smoking Behavior: Mouthpiece-Based Computerized Devices Versus Direct Observation*, 11 NICOTINE & TOBACCO REV. 896, 896 (2009).

⁴⁵ See U.S. FOOD & DRUG ADMIN., COMMUNICATING RISKS AND BENEFITS : AN EVIDENCE-BASED USER’S GUIDE 26 (Baruch Fischhoff et al., eds.) (2011) (suggesting that users “understand” information if they “comprehend it well enough to incorporate it into their decision making”). Experimental research with samples of consumers to try to make this kind of determination prospectively is often too costly and protracted, in which case changes in behavioral intention may have to function as a proxy measure for actual behavioral change.

⁴⁶ American Cancer Society Cancer Action Network Comment, RE: Docket No. FDA-2011-N-0867 (Feb. 13, 2012).

alternatives (so long as adequate warnings were provided). Accordingly, when issuing the tampon regulation, FDA stated repeatedly that only purpose was “to provide adequate information to women so that they can make *informed decisions* about whether and how to use tampons.”⁴⁷ Influencing what product choices the women actually made was not a policy goal of the agency.⁴⁸ In sharp contrast, tobacco products are not “safe and effective” under any definition.⁴⁹ Although the Tobacco Control Act references “ensur[ing] that consumers are better informed,” it is not agnostic as to what product-use choices consumers should make. The Tobacco Control Act is clear FDA should “promote cessation to reduce disease risk and the social costs associated with tobacco-related disease,”⁵⁰ and that its regulatory interventions “should target all smokers to help them quit completely.”⁵¹ Thus, the unique nature of tobacco products—which, unlike all other FDA-regulated products, are inherently lethal without offering “the possibility of therapeutic benefit”⁵²—suggests that FDA must interpret the term “understandable” more comprehensively in the tobacco context.

B. “Misleading”

The Food, Drug, and Cosmetic Act (FDCA) FDA’s general governance statute—provides extensive general guidance on the meaning of the term “misleading,” especially in prohibiting “misleading” labeling or advertising. In determining whether labeling or advertising is misleading, Congress instructed FDA to consider not only representations made or suggested by [a] statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates . . . under such conditions of use as are customary or usual.⁵³

In other words, “misleading” is not limited to falsehoods, but also includes making affirmatively or implicitly misleading statements, as well as the failure to provide relevant information necessary to put the information or risks into context.

Regulations applying this requirement to prescription drug advertisements provide some examples of how accurate statements can be presented in ways that still mislead people to reach inaccurate conclusions:

⁴⁷ Menstrual Tampons; User Labeling, 47 Fed. Reg. 26982-01 (Jun. 22, 1982) (emphasis added).

⁴⁸ Nevertheless, whether FDA’s tampon labeling requirements were “understandable” could still be evaluated by seeing whether the disclosures prompted any risk-reducing responsible behavior changes.

⁴⁹ Food & Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 133-137 (2000) (concluding that if FDA were to regulate tobacco products under a “safe and effective” standard, it would have to remove them from the market, because “there are no directions that could make tobacco products safe for obtaining their intended effects”).

⁵⁰ TCA, *supra* note 4, § 2(24).

⁵¹ *Id.*, § 2(34).

⁵² Brown & Williamson, 529 U.S. at 134 (quoting *United States v. Rutherford*, 442 U.S. 544, 556 (1979)).

⁵³ 21 U.S.C. § 321(n) (2015). The definition of “misleading” now applies to the tobacco-related portions of the FDCA. It is important to note, however, that this definition was originally drafted with the regulation of drugs and medical devices in mind. Thus, it emphasizes the importance of disclosing risk from using presumable beneficial items – which is very different from the situation with tobacco products. Application of this language to tobacco products may therefore require some additional reinterpretation and reanalysis of this language, keeping in mind the broad purposes of the TCA.

- “Present[ing] information from a study in a way that implies that the study represents larger or more general experience with the drug than it actually does”;
- “Us[ing] a quote or paraphrase out of context to convey a false or misleading idea”; and
- “Us[ing] tables or graphs to distort or misrepresent the relationships, trends, differences, or changes among the variables or products studied [such as by failing to label the axes].”⁵⁴

In a recent federal court case from Florida, the court ruled that a label reading “100% Cranberry Pomegranate Flavored Juice Blend” was likely “misleading” in violation of the FDCA because, even though the drink was in fact 100 percent juice, only a small percentage of the juice was cranberry juice or pomegranate juice. Although everything on the label was technically true, it created a misleading impression that all of the juice in the drink was cranberry or pomegranate.⁵⁵ This ruling reinforces the general point that even 100 percent factually accurate communications can be “misleading” if incomplete or not situated in appropriate context.⁵⁶

Section § 904(d) is intended to provide useful information to consumers regarding the amounts of HPHCs in different brands and subbrands of different types of tobacco products so that they can better *understand* how harmful tobacco use is and make related behavior changes to reduce the health risks and harms they face. At the same time, there is a well-founded concern (and a distinct statutory requirement) that consumers not be *misled* by FDA’s disclosure of the HPHC information into taking actions they mistakenly think will reduce risks to their health, especially if those actions will actually increase their harms and risks.⁵⁷

To use the previous acrolein example, disclosures regarding the amount of acrolein in a tobacco product could increase consumer understanding of the harms and risks caused by the acrolein, thereby prompting efforts by consumers to reduce acrolein intake. But unless additional information was also provided about other tobacco-related risks unconnected to acrolein, consumers could be misled into taking actions that reduced their acrolein-related risks but either did not have any impact at all on their overall risk levels or actually *increased* them. For instance, some consumers might switch from their current brand with very high acrolein levels to a cigarette brand with substantially less acrolein without realizing that such a switch would have little or no impact on the overall health risks caused by their continued smoking. While their acrolein-induced health risks might decline, their overall smoking-related harms and risks might not because of the many other HPHCs in their new cigarette brand. More troublingly, smokers who had previously planned to

⁵⁴ 21 C.F.R. § 202.1(6),(7) (2015).

⁵⁵ *Reynolds v. Wal-Mart Stores, Inc.*, 2015 U.S. Dist. LEXIS 53405, 2015 WL 1879615 (N.D. Fla. Apr. 23, 2015).

⁵⁶ Outside of the FDA context, the term “misleading” is used in innumerable legal contexts, ranging from securities law to First Amendment law to criminal law to property law. A full review of these different areas of law is outside the scope of this article, but these other contexts tend to similarly reflect the idea that “misleading” is context-dependent and includes both affirmative misstatements and the failure to disclose relevant information. *See, e.g.*, 17 C.F.R. 230.145 (2015) (defining “misleading” in the context of sales literature for securities).

⁵⁷ As previously noted, the *noscitur a sociis* doctrine of construction suggests “understandable” and “not misleading,” as used in § 904(d), must mean somewhat different things and complement, rather than just repeat, one another.

quit all tobacco use could similarly be misled into switching to a different brand or different tobacco product with little or no acrolein, instead of continuing with their plan to quit, and any continued tobacco use would be far more harmful and risky than completely quitting. (And of course this is complicated by the fact that § 904(d) requires disclosures relating to all reported HPHCs, not just acrolein.)

Thus, the HPHC disclosures required by § 904(d), to avoid being misleading, should fully and fairly address the overall health pros and cons of switching from one brand or type of tobacco product to another, especially if switching occurs rather than quitting entirely. Furthermore, as with the “understandable” requirement discussed above, any FDA determination as to whether a specific HPHC disclosure scheme would be “misleading” (or “not misleading”) should be based on an analysis of whether it would prompt a significant number of consumers to change their behavior in ways that either produce no health benefits or increase overall health harms and risks.

C. “Lay Person”

Black’s Law Dictionary defines a “lay person” as one who is “not trained in or knowing much about a particular profession or subject; not expert, esp[ecially] with reference to law or medicine; nonprofessional.”⁵⁸ It appears that FDA regulations and case law use the term “lay person” sparingly, and it usually refers to someone who is not a health professional. However, in FDA-related (non-tobacco) litigation, “lay person” has on occasion been used interchangeably with the phrase “ordinary consumer.”⁵⁹

The concept of “lay person,” in most legal contexts, does not necessarily reflect consideration for those who have low levels of literacy or comprehension. But interestingly, the regulation detailing labeling requirements for over-the-counter (OTC) drugs requires warnings relating to unsafe use and side effects to be presented “in such terms as render them likely to be read and understood by the ordinary individual, *including individuals of low comprehension*, under customary conditions of purchase and use.”⁶⁰ This regulation implements a statutory requirement for OTC labeling to be “understood by the ordinary individual” (which is comparable to “understandable to a lay person”)—but the statute itself says nothing about individuals of low comprehension. It appears that FDA added consideration of low-comprehension individuals to the OTC regulation without any further statutory hook, which suggests that the agency could do the same for HPHC disclosures.⁶¹

More generally, this example suggests that FDA’s actions should also take into account those with lower levels of literacy, numeracy, or cognitive function (that may adversely affect comprehension), non-native English speakers, or other

⁵⁸ BLACK’S LAW DICTIONARY (10th ed. 2014).

⁵⁹ See, e.g., *United States v. Caronia*, 703 F.3d 149, 169 (2d Cir. 2012) (“a drug is misbranded is if its labeling lacks adequate directions for layperson use”); *United States v. Two Units, More or Less, of an Article or Device, Consisting of a Power Unit & a Chair*, 49 F.3d 479, 482 (9th Cir. 1995).

⁶⁰ 21 C.F.R. § 330.10 (2015) (emphasis added).

⁶¹ In practice, however, FDA labeling requirements do not always reflect sensitivity towards low comprehension individuals. See Lars Noah, *The Imperative to Warn: Disentangling the “Right to Know” from the “Need to Know” about Consumer Product Hazards*, 11 YALE J. REG. 293, 370 (1994) (“For example, suggestions that OTC products include warnings about possible carcinogenicity in animals will make little sense to persons of low or even ordinary comprehension.”).

populations that might respond differently to the presentation of HPHC information.⁶² In the tobacco context, it is also particularly important that FDA consider *youth* as a potential audience. As the TCA itself says, “Virtually all new users of tobacco products are under the minimum legal age to purchase such products.”⁶³ According to the 2012 Surgeon General’s Report, 88 percent of daily cigarette smokers began smoking before reaching the age of 18, often as 12-, or 13-, or 14-year-olds.⁶⁴ Thus, in order to have a meaningful impact on youth tobacco use, FDA should consider how its communications would likely influence adolescents—and even younger children—when determining how to implement § 904(d).

* * *

To summarize the discussion presented above, the following chart presents (somewhat simplified) definitions of “understandable,” “not misleading,” and “lay person” that could be used to inform both research and FDA regulatory decisions relating to HPHC disclosures.

⁶² Low levels of health literacy is a pervasive problem in the United States. In 2004, the Institute of Medicine concluded that “[n]early half of all American adults—90 million people—have difficulty understanding and acting upon health information.” INSTITUTE OF MEDICINE, HEALTH LITERACY: A PRESCRIPTION TO END CONFUSION 1, 1 (2004).

⁶³ TCA, *supra* note 4, §2(4).

⁶⁴ OFFICE ON SMOKING AND HEALTH, U.S. DEP’T. OF HEALTH AND HUMAN SERV., PREVENTING TOBACCO USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL 165 (2012).

Figure 2: Defining “Understandable,” “Not Misleading,” and “Lay Person” in § 904(d)

Term	Definition	Possible Considerations
<i>Understandable</i>	Communicated so that a lay person can comprehend and appreciate the meaning of the disclosed HPHC information for her or his health.	<ul style="list-style-type: none"> -Clear communication of the HPHC’s health impacts -Consumers’ (or viewers’) ability to take in the information (e.g., reading ability, vocabulary, numeracy, and cognitive function) -Explains scientific information and terms otherwise difficult to interpret -Places information in context -Suggests how information should (or should not be) used -Communicates that risk of harm varies among individuals
<i>Not Misleading</i>	Does not present facts in ways that result in viewers having inaccurate impressions, making inaccurate conclusions, or taking inappropriate or harmful actions.	<ul style="list-style-type: none"> -Does not omit or mischaracterize relevant facts -Does not overstate or understate health concerns -Fair presentation of graphics, if used -Communicates limits of what data shows and how it can be used -Does not reinforce common myths about smoking or tobacco -Does not lead people to believe different brands or subbrands vary in risk if they are similarly dangerous -Does not lead users to believe that switching brands or tobacco products will secure health benefits comparable to those from quitting all tobacco use
<i>Lay Person</i>	A member of the public with no relevant scientific or technical expertise.	<ul style="list-style-type: none"> -People who are not scientists -People who do not have medical training -Consumers’ (or viewers’) reading ability, vocabulary, numeracy, and cognitive function -Avoids jargon, acronyms, and technical terms -Considers different population groups, including youth and those with low literacy, numeracy, and cognitive functioning levels

II. USING LAW TO INFORM BEHAVIORAL RESEARCH: TESTING CONSTITUENT DISCLOSURE OPTIONS

Researchers at UNC and OSU used the legal review outlined above to inform studies of consumer responses to different options for presenting information about HPHCs. In accordance with FDA's previous work to develop a website to implement § 904(d),⁶⁵ the research team believed that the constituent information would be most efficiently presented through a website, and they conducted a series of experiments that manipulated webpage design features.⁶⁶ Participants evaluated static versions of potential webpages, which varied in overall layout look and feel, the number of constituents presented, the format used to communicate the health effects of the constituents, the format used to present quantity of constituents, and the use of a visual risk indicator. Participants then answered questions about the webpage they saw. The full design of these experiments is described elsewhere.⁶⁷

To examine the *understandability* of the disclosures, researchers asked questions—based on the definition in Figure 2—designed to examine whether study participants could read, comprehend, and appreciate the significance (or lack thereof) of the constituent information presented. For example, items designed to evaluate whether the participants could understand the constituent information presented included:

- Does cigarette smoke contain [specific constituent]? (Possible responses: yes, no, don't know.)
- Does smoking cause [specific health effect]? (Possible responses: yes, no, don't know.)
- This webpage clearly shows whether the amount of each chemical is harmful. (Five possible responses ranging from strongly agree to strongly disagree.)

As suggested by these items, the challenge inherent in designing *understandable* HPHC disclosures is in determining what information the public needs to learn from the webpage. Is it awareness of the names of chemicals, the resulting health effects, chemical quantities, or something more fundamental? Certainly, an important fact for viewers to understand is that constituent information—whether the amount of a given constituent or the overall number of HPHCs present—cannot be used to determine whether some brands or subbrands of cigarettes (or other tobacco products) are less harmful than others. As it is natural for consumers to compare

⁶⁵ FDA's previous work included conducting focus groups, an experimental study that examined the effect of enhancing the HPHC list with additional information, and another study that sought to identify potential strategies for ensuring the public's understanding of an HPHC list. FDA Joint Meeting, *supra* note 17.

⁶⁶ Some of the limitations of presenting HPHC information through a website should be noted. Accessing a website requires proactive steps by consumers, not all consumers have access to the Internet, and consumers may be unlikely to access the website at the point-of-sale when purchasing decisions are being finalized.

⁶⁷ M. Justin Byron, et al., *Designing a Tobacco Constituent Website to be Understandable and Not Misleading* (forthcoming 2017) (on file with authors).

brands on the relevant amount of constituents and to (perhaps even unconsciously) make judgments about safety based on this information, this will be a major challenge for FDA.⁶⁸

Also based on the legal review, in designing survey questions to test whether disclosures are “not misleading,” the research team selected questions that focus on the overall impression taken away by the viewer. For example, survey items included:

- It’s much safer to smoke cigarettes with fewer chemicals. (Five possible responses ranging from strongly agree to strongly disagree.)
- If you can’t quit, you should switch to brands/styles with fewer chemicals. (Five possible responses ranging from strongly agree to strongly disagree.)
- A cigarette is much safer to smoke if it has a third less [specific constituent] than other cigarettes. (Five possible responses ranging from strongly agree to strongly disagree.)
- If a website had information like this for all cigarette brands, I would use it to see which cigarettes are safer than others. (Five possible responses ranging from strongly agree to strongly disagree.)

These survey items focus on ensuring that the viewer is not left with misleading impressions, i.e., that the viewer does not draw unsupported conclusions from the information presented. Somewhat oddly, this means that in order to show that the HPHC information is not misleading, studies must find that such information does *not* help people to make health-related decisions about the relative harm of different brands/subbrands of cigarettes. Because no currently available brand or subbrand of cigarette is significantly more or less harmful and risky than another,⁶⁹ the only consumer response to the provided HPHC information that indicates a lack of being misled is a conclusion that there are no meaningful differences between brands and thus one must quit smoking to secure significant health benefits.⁷⁰

This desired response is problematic, however, because psychological theory and research suggest that people expect that information provided to them is intended to be useful.⁷¹ This includes the expectation that information is designed to be truthful, relevant, and understandable. If consumers are presented with brand and subbrand information, they may rightfully expect that all of this information must be important and not redundant. They are likely to assume that important differences therefore must exist between brands/subbrands, or FDA would not provide this

⁶⁸ See generally Daniel Kahneman & Amos Tversky, *Prospect Theory: An Analysis of Decision Under Risk*, 47(2) *ECONOMETRICA* 263 (1979); Elke U. Weber & Eric J. Johnson, *Mindful Judgment and Decision Making*, 60 *ANNUAL REV. PSYCH.* 53 (2009).

⁶⁹ World Health Organization, *supra* note 16, at 20.

⁷⁰ Whether tobacco use risks can be substantially reduced by lowering consumption, as opposed to quitting completely, is beyond the scope of this article. But it is notable that even those who report smoking less than one cigarette per day can benefit substantially from quitting smoking entirely. Maki Inoue-Choi, et al, *Association of Long-term, Low-Intensity Smoking with All-Cause and Cause-Specific Mortality in the National Institutes of Health-AARP Diet and Health Study*, 177 *JAMA INTERN. MED.* 87 (2017),

⁷¹ This theory is based on so-called Gricean maxims that include that contributed information must be relevant, designed to be understood, and believed to be true (by the individual contributing it). See generally Norbert Schwartz, *Judgment in a Social Context: Biases, Shortcomings, and the Logic of Conversation* 26 *ADV. EXPERIMENTAL SOC. PSYCH.* 123 (1994); H. P. Grice, *Logic and Conversation*, 3 *SYNTAX & SEMANTICS* 41 (1975).

information. Thus, the very nature of the communication may be misleading, when viewed through the lens of psychological theory, given that study participants are supposed to conclude that brand/subbrand differences are not meaningful in terms of their impact on health.

It is important to emphasize one uncommon feature of the research approach taken here: use of an in-depth legal review to inform the design of a research study. Although FDA considers the relevant statutory framework and the advice of its own attorneys when making regulatory decisions, it is rare for researchers to incorporate legal research directly into the design of their research studies. Doing so, however, has at least two important advantages. For one, it helps to ensure that the resulting research can directly inform FDA's decision-making process. Too often, researchers conduct their studies without a nuanced awareness of the relevant legal framework, and as a result, the research (though perhaps scientifically valuable) is of limited utility to policymakers. Although we have decades of research on whether people have heard of some cigarette smoke constituents, little of the information was gathered in such a way that it can inform FDA decisions.⁷² Secondly, such an approach makes it more likely that FDA's regulatory decisions, if based on the resulting research, can withstand potential legal challenges. FDA will be able to demonstrate that its decisions were guided by a careful analysis of which HPHC disclosure formats are "understandable and not misleading to a lay person," based on research into how regulatory agencies and the courts have previously understood those terms.⁷³

III. POLICY CONSIDERATIONS AND RECOMMENDATIONS

FDA finds itself in a difficult position due to the two separate requirements of § 904(d): (1) to publish a listing of HPHC information, by brand and subbrand, and (2) to ensure that the list is "understandable and not misleading to a lay person." As suggested above, given the limited utility of HPHC information for lay people, it is not clear that FDA will ever be able to meet the latter requirement. It may be that *any* presentation of constituent information by brand and subbrand inevitably produces confusion and inaccurate impressions of relative harm.

If that is the case, what should FDA do? Publishing the information in a way that *is* misleading would contradict the statute and also run counter to the general goals of the TCA (reducing the public health harms caused by tobacco use and better informing consumers about tobacco product health consequences). At the same time, however, the statute says that FDA "shall publish" HPHC information. Indeed, it provides FDA with a deadline to do so that has already passed: "not later than 3 years after the date of enactment of the [TCA]."⁷⁴ Ignoring this statutory mandate

⁷² See Jennifer Morgan, et al., *Up in Smoke: Knowledge and Perceptions of Constituents in Cigarette Smoke*, 49 ANN. BEHAV. MED. 233 (2015).

⁷³ The importance of this approach was highlighted by the federal appellate court decision striking down FDA's proposed graphic health warnings for cigarette packages and advertisements. *R.J. Reynolds Tobacco Co. v. U.S. Food & Drug Admin.*, 696 F.3d 1205 (D.C. Cir. 2012). Although FDA had conducted a large-scale research study to guide its selection of warning images likely to have the largest public health impact, it did not devote similar resources to research establishing that its proposed warnings were "factual and uncontroversial," as the applicable legal test required.

⁷⁴ TCA, *supra* note 4, § 904(d).

entirely is not an attractive option, as it would both set a troublesome precedent⁷⁵ and open up FDA to a potential *mandamus* lawsuit.⁷⁶ FDA could try to defend itself in any such lawsuit by showing that, despite its good faith efforts, it has been unable to develop a way to disclose the required information in a manner that would not be misleading to laypersons and would not risk serious adverse public health consequences. But it is likely that the courts would still require FDA to comply with the disclosure requirement to the extent it could do so without misleading consumers in ways that would likely cause public health harms. Additionally, even if potentially misleading to some members of the public, disclosure of the constituent information (and ingredient information more generally) could be valuable to tobacco control researchers, and could spur the development of new research that would inform other possible FDA efforts to prevent and reduce tobacco-related harms.⁷⁷

Thus, to comply with § 904(d) FDA must “publish” at least some HPHC data in some “format.” Returning to the public health goals of the TCA, however, it must still ensure that its publication of any such information benefits public health in the aggregate (or, at the very least, does not harm public health). Recognizing that the *collection* of HPHC data and the *publishing* of such data are distinct requirements suggests how FDA might interpret the language of § 904(d) in line with the statute’s overriding purposes:

(1) If it is possible for FDA to publish HPHC information by brand and by subbrand in a manner that is “understandable and not misleading to a layperson” (as defined above), then it must do so. This will almost certainly require providing additional context and clarifying information.

(2) If it is not possible to provide such detailed information in a manner that is “understandable and not misleading to a layperson,” then FDA should determine *what* information about HPHCs it can publish in certain formats that would be “understandable and not misleading to a layperson,” and publish such information accordingly. This might require reporting HPHC levels in a more aggregate manner, rather than by brand or subbrand, in addition to adding supplemental contextual information.⁷⁸ At the same time, FDA could make more detailed brand and subbrand information available upon request for confidential research and other appropriate purposes, so as to facilitate research and transparency without undermining the TCA’s public health goals.

⁷⁵ Cf. Jacob E. Gersen & Anne Joseph O’Connell, *Deadlines in Administrative Law*, 156 U. PA. L. REV. 923 (2008) (discussing positive and negative consequences of Congress imposing deadlines on administrative agencies).

⁷⁶ A *mandamus* lawsuit seeks a court order directing a government actor to comply with a legal duty. In October 2016, eight public health groups filed a *mandamus* lawsuit in federal court seeking to compel FDA to issue a rule requiring graphic warning labels for cigarettes, as required by the TCA. That lawsuit is currently pending. *American Academy of Pediatrics v. U.S. Food and Drug Administration*, Case No. 1:16-cv-11985 (D. Mass.), filed Oct. 4, 2016.

⁷⁷ For example, FDA recently held a public workshop on risk assessment. U.S. Food & Drug Admin., *Risk Assessment—A Public Workshop*, (Nov. 15–16, 2016), <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm515442.htm>. Information on HPHC levels could be helpful to research seeking to develop and apply risk assessment methodologies for tobacco.

⁷⁸ Note that even aggregate information about constituent levels in products could be misleading if it is used to make inaccurate health judgments about the relative risks of different types of tobacco products (e.g., cigarettes vs. cigars).

The second option could be defended against any potential legal challenge by noting that the law gives FDA flexibility to determine the “manner” of the HPHC data publication, and that releasing data in a way that is *not* understandable or is misleading would plainly violate the statute’s requirements. If pursuing this option, FDA should issue a formal notice that explains how it is interpreting and applying the language of § 904(d) to promote the core goals of the TCA most effectively, thereby putting its interpretation in the strongest possible position to withstand any legal challenges.⁷⁹

Two additional policy considerations merit mention. First, even though § 904(d) focuses only on the disclosure of HPHC information, FDA has broad authority to educate the public about the harms of tobacco use. Placing the HPHC disclosures within this broader context may help to minimize any potentially adverse effects of publishing the information.

Secondly, although FDA should make its best effort to comply with the requirements of § 904(d), it should also be mindful of the allocation of its resources. If it appears from ongoing research that disclosure of HPHC is unlikely to produce significant public health gains (in whatever form presented), then FDA should not devote too much more time and research funding to this provision of the TCA. Although additional research may help make a disclosure website incrementally more effective, the cost may not be worth the effort if the public health benefits are likely to be negligible in any event. Given its limited resources, FDA should prioritize research and regulatory efforts most likely to further its core mission of reducing the public health harms of tobacco use.

CONCLUSION

Though it appears logical that disclosing more information about the levels of harmful and potentially harmful constituents in different tobacco products would lead to improved health-related decision making, that is not necessarily what happens in practice.⁸⁰ Thus, FDA should ensure that in implementing § 904(d)’s requirement to provide constituent information in a manner that is “understandable and not misleading to a layperson,” it interprets those terms in a manner that does not contradict or impede the TCA’s primary purpose of reducing death and disease caused by tobacco use. The legal review outlined in this paper is intended to support FDA’s effort to do so. If it is impossible to deliver detailed HPHC information to the public in a manner that is “understandable and not misleading,” FDA should exercise its discretion to limit the amount of information presented.

⁷⁹ Though not a hard-and-fast rule, courts may decline to afford *Chevron* deference to agency’s statutory interpretation if the interpretation was not developed through a formal rulemaking process. *United States v. Mead Corp.*, 533 U.S. 218, 229 (2001).

⁸⁰ See Ellen Peters et al., *More is not Always Better: Intuitions about Effective Public Policy Can Lead to Unintended Consequences*, 7 SOC. ISSUES & POL’Y REV. 114 (2013); Omri Ben-Shahar & Carl E. Schneider, *The Failure of Mandated Disclosure*, 159 U. PA. L. REV. 647 (2011) (providing an extensive review of why mandated disclosures—particularly those that are complex and include a lot of information—often fail to achieve their policy objectives).