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Comments on the Food and Drug Administration's Regulatory Impact Analysis and Cost Estimate for the Menu Labeling Final Rule

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In its Regulatory Impact Analysis[1] of the menu labeling Final Rule,[2] the Food and Drug Administration (FDA) underestimated the costs for regulated businesses to comply with the Final Rule. This analysis provides a more accurate estimate focused principally on the FDA's shortcomings in analyzing costs to the convenience store industry. Convenience store estimation problems serve as a reliable proxy for the estimation problems FDA's analysis has with respect to grocery and general merchandise stores.

Key Findings

- Actual costs of compliance and enforcement of the FDA Final Rule for all covered industries are estimated to be more than 3.6 times FDA's estimates and for the convenience store industry 7 times FDA's estimates;
- Annual costs of compliance and enforcement of the FDA Final Rule are estimated to exceed $306 million;
- Actual costs of compliance and enforcement of the FDA Final Rule for the convenience store industry alone are almost equal to the total cost that FDA estimated for all covered industries;
- Because the Final Rule makes no allowances for normal calorie and nutrition variations in foods, more than 93% of foods subject to the rule are likely to be in violation of the Final Rule no matter how much businesses spend attempting to comply; and
- Enforcement costs (including fines, legal fees, and negative publicity) alone of the Final Rule are likely to vastly exceed FDA's total estimate of the compliance costs of the Final Rule.

[1] Food and Drug Administration, Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Final Regulatory Impact Analysis, November 2014, available at https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/LabelingNutrition/UCM423985.pdf.

[2] Food and Drug Administration, Final Rule, Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Calorie Labeling of Articles of Food in Vending Machines, 79 Fed. Reg. 71156 (Dec. 1, 2014), https://www.gpo.gov/fdsys/pkg/FR-2014-12-01/pdf/2014-27833.pdf; Final Regulatory Impact Analysis, Department of Health and Human Services, Food and Drug Administration, *Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments*, Docket No. FDA-2011-F-0172, at 7 (Nov. 2014), *available at* https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/LabelingNutrition/UCM423985.pdf.

Introduction

The convenience store industry operates in a very decentralized manner (i.e., stores tend to differ from one another even if they are part of the same chain) that does not fit well with the way that FDA's rule is written. FDA's analysis of the rule does not match the way that the modern convenience store industry operates. FDA also based its cost estimates for all of the industries covered by the Final Rule on a model that best fits restaurants. In restaurants there is one menu or one menu board and food is offered to customers at one location – the counter or the table. Unlike fast food restaurant chains with identical and limited offerings usually in only one portion size, convenience stores offer different items in different stores (even stores that are a part of the same chain) and often in three or more different portion sizes. Convenience stores also offer food to consumers at many points around a store rather than at one central location.

This analysis allows FDA to understand the impact of the rule on the convenience store industry as it operates. The way that the Final Rule is written makes it almost certain that convenience stores will face enforcement actions no matter how hard and diligently they try to comply. Yet, FDA's analysis of the rule does not include enforcement costs that will inevitably occur. This analysis accounts for the cost of enforcement actions. In addition, most of the data used for FDA's cost analysis of the rule date back to 2007. This analysis makes use of much newer and more detailed data that is available. This analysis assists FDA with updating the impact of the rule using the federal government standards of OMB Circular A-4 for economic analyses.[3]

FDA estimated that the costs for convenience stores to comply with the rule would be $12.1 million[4] on an annualized basis. **As this analysis shows in the sections that follow, the actual cost of compliance and enforcement by convenience stores is $84.2 million on an annualized basis – or 7 times the FDA estimate for convenience stores and almost equal to the $84.5 million that FDA estimated for all chain stores covered by the rule**.

Because of the similarity of convenience stores to grocery stores and general merchandise stores, and because FDA estimated the costs for all three of those types of stores in the same way, it is likely that the actual cost of the rule to those stores for compliance and enforcement is 7 times FDA's estimate of $17.7 million[5] on an annualized basis – $123.9 million.

The analysis shows that assuming FDA estimated the compliance (non-enforcement) costs of the rule *correctly* for all restaurants; managed food service; lodging; and sports, recreation, and entertainment establishments (so that the only underestimates are for the compliance costs by grocery, convenience and general merchandise stores and the enforcement costs in all

[3] Office of Management and Budget, Circular A-4, 68 Fed. Reg. 58366 (Oct. 9, 2003); *see also* Circular A-4, *https://www.whitehouse.gov/omb/circulars_a004_a-4.*

[4] This is FDA's estimate when 20 years of costs are annualized at a 7% discount rate. Unless otherwise noted, all annualized estimates in this analysis are calculated on that basis.

[5] FDA does not report its complete estimate of the cost of the rule to the various industry segments. The $17.7 million estimate comes by multiplying the annualized cost estimate of the full rule by the 21% of the initial costs of the rule associated with grocery, convenience, and general merchandise stores.

establishments), then the actual costs of the rule are $306 million on an annualized basis. If FDA underestimated the compliance costs to any restaurants; managed food service; lodging; or sports, recreation, and entertainment establishments, then the actual costs would be even higher than $306 million on an annualized basis.

Enforcement Costs for Imperfect Declaration of Calorie Content[6]

The biggest shortcoming of FDA's analysis is that it ignores a serious flaw in FDA's Final Rule. The regulation provides no allowance for normal variation from one serving of food to the next in the number of calories and nutrition content. This effectively makes full compliance impossible. FDA's policy on how the rule will be enforced has several features that make enforcement costs inevitable.[7]

1) FDA's guidance for the rule provides only a 5-calorie deviation (for foods with over 50 calories) for unit to unit variability of the same product. For example, a slice of cheese pizza declared at 270 calories is misbranded if it contains 264 calories or less, or if it has 275 calories or more.[8] A difference of just 2 grams (0.07 ounces) of cheese on a typical slice of pizza would make it misbranded.

2) The rule does not permit declared calories to be given in ranges to account for variability from one unit to the next or the same unit over time.[9] The caloric content of some foods can change over a short amount of time. For example, the calorie content of a single sausage held on a roller grill will go down as fats drip off.

3) Research has repeatedly revealed that calorie declarations are never perfect.
   a. Urban, et al., 2010[10] tested the caloric content of 29 restaurant meals and 10 frozen packaged meals. None of the calorie declarations matched the tested amount exactly. Twelve of the 29 (41%) restaurant meals tested within 10% of the declared calories, and even 3 of the 10 (30%) packaged meals tested outside of 10% of the declared calories.

[6] This analysis identifies as "enforcement costs" the costs that regulated entities incur to deal with enforcement actions. Costs include fines, legal fees and negative publicity.

[7] The estimate of enforcement costs in this analysis is an incomplete estimate of the full enforcement costs that face covered establishments. For example, beyond imperfect calorie declarations, establishments would face enforcement costs if they are found not to have the nutrition information (beyond calorie content) that is required by the rule.

[8] Guidance for Industry: A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods - Part II (Menu Labeling Requirements in Accordance with 21 CFR 101.11), at 22.

[9] Ranges are only allowed to account for different customer choices for combination meals of three items or more.

[10] Lorien E. Urban, MS, Gerard E. Dallal, PhD, Lisa M. Robinson, RD, Lynne M. Ausman, DSc, RD, Edward Saltzman, MD, and Susan B. Roberts, PhD, "The Accuracy of Stated Energy Contents of Reduced-Energy, Commercially Prepared Foods." *J Am Diet Assoc*. 2010 January; 110(1): 116–123. doi:10.1016/j.jada.2009.10.003.

b. Urban, et al., 2011[11] tested 269 restaurant food portions. Only seven percent of the portions tested within 10 calories per portion of the declared amount, and 19% of the portions tested differed from the declared amount by more than 100 calories.

c. Jumpertz, et al., 2013[12] tested the caloric content of 24 common packaged snack foods. Of the 24, 10 (42%) had the declared calorie content within the 95% confidence interval of the test results.

4) Portion and ingredient control issues pose problems in a foodservice setting that are absent in a food manufacturing setting for packaged foods where automation can more easily control for many variable factors. Therefore, it is unlikely that caloric declarations in a foodservice setting could ever reach the 42% accuracy found for manufactured packaged foods by Jumpertz, et al. After all, if a convenience store were to open packages of the snack foods tested by Jumpertz, et al. and offer them for sale with the calorie declarations from the packages, we can say, with 95% confidence, that those calorie declarations could be found to be in violation of FDA's rule 58% of the time. But it is more likely that even the 93% violation estimate in found by Urban, et al., 2011 is aspirational because that study accepts a 10-calorie variation, whereas FDA's guidelines accept only a 5-calorie variation (related to rounding).

Using this peer-reviewed research it is possible to estimate the cost of enforcement actions against convenience stores under FDA's rule. If calorie declarations for restaurant-type foods remain only as accurate as found by Urban, et al., 2011, then if 1 food item in 1% of the 47,200[13] covered convenience stores were to be tested per year, and if 93% were found to be misbranded (as Urban, et al., 2011 implies),[14] then about 439 stores would be found to be in violation annually. If fines, legal fees, and negative publicity cost covered establishments $50,000 per occurrence, then the total cost for the convenience store industry to deal with enforcement and non-compliance would be at least $21.9 million per year.[15]

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[11] Lorien E. Urban, PhD, Megan A. McCrory, PhD, E. Dallal, PhD, Krupa Das, PhD, Edward Saltzman, MD, Judith L. Weber, PhD, RD, and Susan B. Roberts, PhD, "Accuracy of Stated Energy Contents of Restaurant Foods." *JAMA*. 2011 July 20; 306(3): 287–293. doi:10.1001/jama.2011.993.

[12] Reiner Jumpertz, Colleen A Venti, Duc Son Le, Jennifer Michaels, Shannon Parrington, Jonathan Krakoff, and Susanne Votruba, "Food Label Accuracy of Common Snack Foods." *Obesity* (Silver Spring). 2013 January; 21(1): 164–169. doi:10.1002/oby.20185.

[13] This estimate of the number of convenience stores covered by the rule will be explained later. There are good reasons to believe that the actual number of stores covered by the rule is much higher.

[14] Note that the Urban, et al., 2011 interpretation of compliance (accepting 10-calorie variance) is more lenient than FDA's guidance permits (5-calorie variation related to rounding). Therefore, more than 93% of tested foods are likely to be found to be misbranded.

[15] Note that the regulation allows for enforcement of many other issues than the one issue (accuracy of the declaration of calorie content) identified and quantified here. Moreover, the FDA will not be the only institution that may enforce the rule. Therefore, the estimates made here are almost certainly a conservative underestimate of the actual costs.

This enforcement jeopardy is not unique to convenience stores. If the same probabilities of misbranding are extended to all of the roughly 309,600 establishments covered by the rule (47,200 convenience stores + 262,400 other establishments), then the annual cost of fines, legal fees, and negative publicity associated with enforcement of the rule would be about $144 million. **In other words, the enforcement cost of the rule alone likely exceeds by 70% the annualized costs of nutrition analysis, signage and training as estimated by FDA**.[16]

How Convenience Stores Differ Dramatically from Restaurants

FDA modeled the cost of convenience stores to comply with the rule in the same way that it modeled the cost of quick service restaurants to comply – with one or two new menu boards being sufficient to meet the requirements of the rule. However, convenience stores are almost nothing like quick service restaurants.

The convenience store industry is primarily the retail sector of the motor fuel industry. What most people call "gas stations" are usually convenience stores that sell gasoline. Convenience stores sell 80% of the motor fuel sold in the United States.[17] For the convenience store industry as a whole, 75% of stores sell fuel.[18] For chains with 26-500 stores, 98% of stores sell fuel, and for chains with over 500 stores, 80% sell fuel.[19] On average, from 2006 to 2015, fuel pump revenue accounted for 69% of total convenience store industry sales.[20] That percentage can fluctuate significantly from year to year as fuel prices fluctuate. As fuel prices become more volatile, convenience stores increasingly depend on revenue from the sale of merchandise and from food service to provide a stable source of income.

Although the most identifiable product that a convenience store sells is gasoline and/or diesel fuel (half of the all of the stores that sell fuel, sell fuel from one of the major refiners[21]), almost none of the stores are owned by the major refiners. The 5 largest oil companies only own less than one-half of 1% of the convenience stores that sell fuel.[22] So, although many convenience stores may do business under the name of one of the major fuel refiners and the refiners exercise some contractual control over the fuel-related aspects of the stores, the refiners have nothing to do with the nonfuel items sold in the convenience store.

[16] Similar problems were present in the packaged food space and addressed by FDA in the regulations. *See* 21 C.F.R. §101.9(g)(4), (5).

[17] NACS 2015 Retail Fuels Report, at 30.

[18] NACS State of the Industry Annual Report 2015 Data, at 7.

[19] NACS State of the Industry Annual Report 2015 Data, at 7.

[20] Calculations based on data from NACS State of the Industry Annual Report 2015 Data, at 12.

[21] NACS 2015 Retail Fuels Report, at 30.

[22] NACS 2015 Retail Fuels Report, at 29.

For the most part, there are two types of convenience store "chains."[23]

1) The 20 largest chains that are unrelated to the major fuel refiners and sell gasoline under their own brands (if the stores sell gasoline at all). These chains operate nationally or regionally. These 20 chains account for a total of about 29,000 stores.[24]

2) The smaller chains that sell branded or unbranded motor fuel and operate over smaller geographical areas than the largest chains. These chains have between 2 and 500 stores each and account for about 56,800 stores in total.[25] There are between 1,400 and 2,400 such chains. About 380 (possibly as few as 239 and as many as 521) of these smaller chains are chains operating 20 or more stores (about 18,200 stores belong to smaller chains with 20 or more locations).[26]

This estimate of the number of convenience stores covered by the rule is almost certainly a large underestimate of the number of stores covered by the rule. It is based on the best data available from TDLinx. However, the definition of chain that is commonly used within the industry and recorded by TDLinx differs from the definition of chain used by FDA in the Final Rule. FDA considers an establishment to be part of a chain if the establishment is visibly branded to customers with a common name. For example, if an independent convenience store (whose owner owns and operates only a single store) sells ExxonMobil gasoline and prominently displays the Exxon sign at the store, FDA considers that store to be part of a chain, which (given the scale of ExxonMobil) would have over 20 establishments. However, within the convenience store industry, that independent convenience store owner would never consider herself to be part of the ExxonMobil Corporation or its chain of establishments. Therefore, to the extent that this analysis underestimates the number of convenience stores covered by the rule, the cost estimates made here are lower than the actual cost of the rule.

Foodservice in Convenience Stores

More convenience stores sell food or beverages covered by FDA's rule than sell motor fuel. Seventy-five percent of convenience stores sell gasoline. But 99% sell hot dispensed beverages, 98% sell cold dispensed beverages, 95% sell food prepared at an off-site commissary, 83% sell food prepared on site, and 75% sell frozen dispensed beverages.[27] Due to the nature of the business, stores in larger chains are more likely than single-store, independent operations to offer

[23] Data on the number of convenience stores were collected by TDLinx, a service of Nielsen. TDLinx is the industry-accepted standard channel database of retail locations providing universal coverage for every store in retail trade channels and for every outlet in on-premise trade channels. Data on products offered come from the CSX database. CSX provides business intelligence and benchmarking tools for reporting and financial analysis in the petroleum marketing and convenience store industry. See NACS State of the Industry Annual Report 2015 Data, at 4.

[24] NACS State of the Industry Annual Report 2015 Data, at 140.

[25] NACS State of the Industry Annual Report 2015 Data, at 7.

[26] Calculations based on data from NACS State of the Industry Annual Report 2015 Data, at 7.

[27] NACS State of the Industry Annual Report 2015 Data, at 50.

restaurant type foods. Therefore, FDA's rule will apply to all stores in all chains operating 20 or more stores, not 60% of stores as estimated by FDA.

Within each of these broad categories of products (hot dispensed beverages, cold dispensed beverages, food prepared at an off-site commissary, food prepared on site, and frozen dispensed beverages) convenience stores commonly sell a wide variety of products placed throughout the store. For example, coffee islands are in one area, cappuccino and hot chocolate machines are in a different area, cold fountain sodas are in another area, pastries are in a separate area, and hot lunch and breakfast foods each have their own areas. Separate signs will be needed in each location to comply with the rule (contrary to FDA's estimates, 2 menu boards per store will not be sufficient).

Additionally, convenience stores offer customers a much wider range of food service choices than do many other food service retailers. For example, a typical convenience store will offer at least 8 varieties of cold fountain drinks in 4 different sizes. Each variety-size combination is likely to contain a different number of calories. Providing calorie content for each variety in each size will require an enormous sign just for cold fountain drinks. The same is true for the range of frozen beverages offered in a separate location from the cold beverages, thereby requiring a separate sign. Convenience stores also employ a wide range of promotional displays for food in places like the fuel pumps, the windows and doors, and hanging from the ceiling. All those promotional displays will need to be redesigned and replaced under the rule if FDA or other enforcers of the regulation interpret promotional displays as menus (an issue which FDA has not yet definitively addressed).

With hundreds of different chains covered by the rule, it is no surprise that there are different ways that convenience store chains operate. Some chains may establish a uniform set of foodservice items across all stores, while other chains (for example, those that are primarily focused on motor fuel brand and sales) may have no established standards for what foodservice items are offered. So, some chains may only offer specific brands and sizes of cold fountain sodas and hot coffee throughout the entire chain of stores, while other chains may have stores that offer different brands and sizes of cold fountain sodas and hot coffee across the chain. Also, some chains may have established standards for some foodservice items offered but not for others. This leads to a situation where all stores in the chain must offer a specific brand and sizes of cold fountain sodas and hot coffee, but may choose to offer different pastries, snacks, hot dogs, breakfast sandwiches, and other meal items.

At the same time, some chains may have a single supplier for every foodservice item sold in the chain, while other chains may have multiple suppliers of many of the foodservice items sold in the chain. An example of the latter case would be where a chain has multiple suppliers of items like sausage, pastries and self-serve ice cream. Therefore, although two different suppliers may offer the same "product" by name (e.g., "hot dog"), the caloric content of those products with the same name are unlikely to be identical.[28]

[28] Even products for which FDA has established standards of identity will have variations in calorie content.

For over a decade the trend in foodservice has been toward increasing customization and localization.[29] Chain stores increasingly customize their offerings in different stores to appeal to local tastes, to offer items sourced locally or nearby, and to coincide with seasonal trends. It would be very unusual today for most of the foodservice offerings in a chain store in the upper Midwest to be identical to most of the foodservice offerings of another store in the same chain in the Southwest. Likewise, summer offerings will differ from winter offerings. And offerings will change over time as new products are brought in to replace existing products.

All of these operational factors reveal why the costs of the rule cannot be modeled (as FDA did) primarily on a per product and per chain basis. Large chains are more likely to have different stores offering different products from multiple suppliers of the same product. A two-tiered cost model will be closer to reality than FDA's one-size-fits-all cost model (although even this two-tiered model is an extreme oversimplification). The following tables provide a detailed explanation of the basis for the cost estimates in this analysis.

Table 1 details the cost model for the rule (based on food offerings in typical convenience store chains of different sizes) versus FDA's cost model for nutrition analysis.[30]

Table 1. Convenience Store Costs for Nutrition Analysis

	20 Largest Chains	**380 Smaller Chains**	**FDA's Estimate for All 450 Chains[31]**
Stores in Chains with 20+ Stores Needing Signage	29,000 (avg 1,450 per chain)	18,200 (avg 50 per chain)	36,200 (avg 80 per chain
Stores with Food for Immediate Consumption	100%	100%	60%
Distinct Products Sold Over Course of Year Common Throughout Chain	122[32]	34[33]	40
Distinct Products That Need Analysis Over Course of Year Common Throughout Chain	0[34]	0[35]	40
Suppliers per Product for Products Common Throughout Chain	1	1	1
Distinct Products Sold Over Course of Year Not	88[36]	52[37]	5

[29] Howard Riell, "Revitalized Roller Grill Sales," Convenience Store Decisions, August 24, 2011.
[30] Estimates are rounded to the nearest $1,000.

[31] For its estimate of the number of chains, FDA uses data from the 2007 Economic Census. This analysis uses data from the NACS State of the Industry Report 2015. The NACS report mentions on page 19 that "consolidation among chains remained an ongoing strategy." This likely explains why FDA's estimate of the number of chains is larger than the estimate made in this analysis.

[32] 16 varieties of cold fountain drinks @ 4 sizes of cups + 16 varieties of frozen beverages @ 3 sizes of cups + 6 varieties of flavoring syrup for coffee + 2 varieties of chicken nuggets + 2 varieties of frankfurters. Some fountain drinks, frozen beverages and flavoring syrups for coffee change seasonally.

[33] 8 varieties of cold fountain drinks @ 3 sizes of cups + 4 varieties of frozen beverages @ 2 sizes of cups + 2 varieties of frankfurters.

[34] All products have known caloric content per serving and will be provided by the suppliers.

[35] All products have known caloric content per serving and will be provided by the suppliers.

Common Chainwide			
	20 Largest Chains	**380 Smaller Chains**	**FDA's Estimate for All 450 Chains[38]**
Distinct Products That Need Analysis Over Course of Year Not Common Chainwide	64[39]	44[40]	5
Suppliers per Product for Products Not Common Chainwide	2.5	1.25	1
Distinct Products from All Suppliers That Need Analysis Over Course of Year Not Common Chainwide	160	55	5
Price to Analyze Each Product	$800[41]	$800	$660
Cost per Chain for Analysis	$128,000	$44,000	$26,400
First Year Cost for Nutrition Analysis per Size Category of Convenience Store Chain	**$2,560,000**	**$16,720,000**	**$11,880,000**
Distinct New Products from All Suppliers Introduced Annually that Need Analysis[42]	32	11	12
Recurring Annual Cost for Nutrition Analysis per Size Category of Convenience Store Chain	**$512,000**	**$3,344,000**	**$3,564,000**

[36] 32 varieties of pastries + 8 varieties of sausage + 16 varieties of savory snacks + 8 varieties of self-serve ice cream @ 2 sizes of bowls + 8 varieties of pizza + 4 varieties of sweetened hot beverages @ 2 sizes of cups.

[37] 32 varieties of pastries + 4 varieties of sausage + 4 varieties of savory snacks + 2 varieties of self-serve ice cream @ 2 sizes of bowls + 4 varieties of pizza + 2 varieties of sweetened hot beverages @ 2 sizes of cups.

[38] For its estimate of the number of chains, FDA uses data from the 2007 Economic Census. This analysis uses data from the NACS State of the Industry Report 2015. The NACS report mentions on page 19 that "consolidation among chains remained an ongoing strategy." This likely explains why FDA's estimate of the number of chains is larger than the estimate made in this analysis.

[39] 32 varieties of pastries + 8 varieties of sausage + 16 varieties of savory snacks + 8 varieties of pizza.

[40] 32 varieties of pastries + 4 varieties of sausage + 4 varieties of savory snacks + 4 varieties of pizza.

[41] A June 2016 internet search of prices for the nutrition analysis needed for menu labeling revealed a median cost of about $800.

[42] Estimated annual introduction of new products (including changes in suppliers of existing products) of 20% of products that are not common to all stores in the chain.

Table 2 details the cost model for providing nutrition information (based on food offerings in typical convenience store chains of different sizes) versus FDA's cost model.[43]

Table 2. Costs for Convenience Store Signage and Pamphlets

	20 Largest Chains	**380 Smaller Chains**	**FDA's Estimate for All 450 Chains**
Stores in Chains with 20+ Stores	29,000 (avg 1,450 per chain)	18,200 (avg 50 per chain)	36,200 (avg 80 per chain)
Number of Signs Positioned with Products and Promotional Displays per Store for Compliance per Year	15[44]	11[45]	2
Price for Design of Each Sign and Promotional Display	$3,700	$3,700	$3,700
Cost for Design of Signs and Promotional Displays per Chain	$55,500	$40,700	$7,400
Initial Cost for Design of Signs and Promotional Displays per Size Category of Convenience Store Chain	**$1,110,000**	**$15,466,000**	**$3,330,000**
Cost of Point of Sale Signs[46] and Labor to Place New Signs	$591	$591	$591
Number of Signs per Store	1	1	2
Initial Cost of New Point of Sale Signs per Size Category of Convenience Store Chain	**$17,139,000**	**$10,756,000**	**$42,552,000**
Cost of Signs and Labor to Order Appropriate Signs and Place New Food Display Signs[47]	$20	$20	0
Number of Signs per Store	8	6	0
Initial Cost of New Food Display Signs per Size Category of Convenience Store Chain	**$4,640,000**	**$2,184,000**	**0**
Hours of Verifying, Maintaining and Replacing Food Display Signs per Store per Year	26	26	0
Average Hourly Wage[48]	$15	$15	
Annual Labor Cost of Verifying, Maintaining and Replacing Food Display Signs per Size Category of	**$11,310,000**	**$7,098,000**	**0**

[43] Estimates are rounded to the nearest $1,000.

[44] 8 food display signs + 6 promotional displays + 1 point of sale sign

[45] 6 food display signs + 4 promotional displays + 1 point of sale sign

[46] The regulation requires calorie content declarations wherever covered food and beverage items are listed for sale and also wherever the foods are displayed. Point of sale signs are those menu-board-type signs located near the checkout registers.

[47] The regulation requires calorie content declarations wherever covered food and beverage items are listed for sale and wherever the foods are displayed. Food display signs are small relatively inexpensive signs placed very near every place in the store where covered food and beverage items are displayed. Because of their proximity to food and customers, they are likely to have to be replaced frequently due to loss and damage. Modeling this cost on a per store basis is a serious oversimplification that ignores the cost of handling, storing and transporting the signs throughout the company's distribution chain. So even the estimates in this analysis underestimate the true cost of the Final Rule.

[48] NACS State of the Industry Annual Report 2015 Data, at 144.

Convenience Store Chain			
Annual Cost of Replacing Food Display Signs on a Quarterly Basis due to Damage, Loss or Out of Date	**$18,560,000**	**$8,736,000**	**0**
Cost per Store for Nutrition Pamphlets per Year[49]	$22	$22	$22
Annual Cost per Category of Nutrition Pamphlets per Size Category of Convenience Store Chain	**$638,000**	**$400,000**	**$792,000**

Table 3 details the cost model for training employees to maintain compliance versus FDA's cost model for training.

Table 3. Cost for Convenience Stores of Training Employees to Maintain Compliance[50]

Average Employees per Store Needing Training[51]	18	18	
Average Hourly Wage	$15	$15	
Hours of Training per Employee per Year	0.5	0.5	
Cost of Employee Compliance Training per Store per Year	$135	$135	$103
Annual Cost of Employee Compliance Training per Size Category of Convenience Store Chain	**$3,915,000**	**$2,457,000**	**$3,708,000**

[49] Modeling this cost on a per pamphlet/per chain basis is a serious oversimplification that ignores the cost of updating, handling, storing and transporting the pamphlets throughout a company's distribution chain.

[50] Estimates are rounded to the nearest $1,000.

[51] NACS State of the Industry Annual Report 2015 Data, at 144.

Summary of Compliance and Enforcement Costs for Convenience Stores

Table 4 summarizes the first-year costs of compliance and enforcement versus FDA's estimate of first-year costs.

Table 4. Summary of Convenience Store First Year Costs of Compliance and Enforcement

	20 Largest Chains	**380 Smaller Chains**	**FDA's Estimate for All 450 Chains**
Stores in Chains with 20+ Stores	29,000 (avg 1,450 per chain)	18,200 (avg 50 per chain)	36,200 (avg 80 per chain)
First Year Cost for Nutrition Analysis per Size Category of Convenience Store Chain	$2,560,000	$16,720,000	$11,880,000
Initial Cost for Design of Signs and Promotional Displays per Size Category of Convenience Store Chain	$1,110,000	$15,466,000	$3,330,000
Initial Cost of New Point of Sale Signs per Size Category of Convenience Store Chain	$17,139,000	$10,756,000	$42,552,000
Initial Cost of New Food Display Signs per Size Category of Convenience Store Chain	$4,640,000	$2,184,000	0
Annual Labor Cost of Verifying, Maintaining and Replacing Food Display Signs per Size Category of Convenience Store Chain	$11,310,000	$7,098,000	$0
Cost of Replacing Signs Quarterly in the 2nd, 3rd and 4th Quarters of the First Year due to Damage, Loss or Out of Date (75% of the annual cost)	$13,920,000	$6,552,000	$0
Annual Cost per Category of Nutrition Pamphlets per Size Category of Convenience Store Chain	$638,000	$400,000	$792,000
Annual Cost of Employee Compliance Training per Size Category of Convenience Store Chain	$3,915,000	$2,457,000	$3,708,000
Total Cost of Compliance in First Year for All Convenience Store Chains		**$116,865,000**	**$62,262,000**
Total Annual Cost of Enforcement for All Convenience Store Chains		**$21,900,000**	**$0**
Total Cost of Compliance and Enforcement in First Year for All Convenience Store Chains		**$138,765,000**	**$62,262,000**

Table 5 summarizes the recurring costs of compliance and enforcement versus FDA's estimate of recurring costs.

Table 5. Recurring Convenience Store Costs of Compliance and Enforcement

	20 Largest Chains	380 Smaller Chains	FDA's Estimate for All 450 Chains
Stores in Chains with 20+ Stores	29,000 (avg 1,450 per chain)	18,200 (avg 50 per chain)	36,200 (avg 80 per chain)
Recurring Annual Cost for Nutrition Analysis per Size Category of Convenience Store Chain	$512,000	$3,344,000	$3,564,000
Annual Labor Cost of Verifying, Maintaining and Replacing Food Display Signs per Size Category of Convenience Store Chain	$11,310,000	$7,098,000	$0
Annual Cost of Replacing Food Display Signs on a Quarterly Basis due to Damage, Loss or Out of Date	$18,560,000	$8,736,000	$0
Annual Cost per Category of Nutrition Pamphlets per Size Category of Convenience Store Chain	$638,000	$400,000	$792,000
Annual Cost of Employee Compliance Training per Size Category of Convenience Store Chain	$3,915,000	$2,457,000	$3,708,000
Total Annual Recurring Cost of Compliance for All Convenience Store Chains		**$56,970,000**	**$7,272,000**
Total Annual Cost of Enforcement for All Convenience Store Chains		**$21,900,000**	**$0**
Total Recurring Cost of Compliance and Enforcement for All Convenience Store Chains		**$78,870,000**	**$7,272,000**

Table 6 summarizes the annualized cost of compliance and enforcement versus FDA's estimate of annualized cost.

Table 6. Annualized Convenience Store Costs of Compliance and Enforcement

	400 Chains	FDA's Estimate for All 450 Chains
Total Cost of Compliance and Enforcement in First Year for All Convenience Store Chains	**$138,765,000**	**$62,262,000**
Total Recurring Cost of Compliance and Enforcement for All Convenience Store Chains	**$78,870,000**	**$7,272,000**
Annualized Cost of Compliance and Enforcement over 20 Years at 7% for All Convenience Store Chains	**$84,154,000**	**$12,123,000**
Annualized Cost of Compliance and Enforcement over 20 Years at 3% for All Convenience Store Chains	**$82,779,000**	**$10,861,000**

Conclusion

FDA estimated that the costs for convenience stores to comply with the rule would be $12.1 million on an annualized basis. **As this analysis showed, the actual cost of compliance and enforcement by convenience stores is $84.2 million on an annualized basis – or 7 times the FDA estimate for convenience stores and almost equal to the $84.5 million that FDA estimated to be the cost for the universe of chains covered by the Final Rule**. Due to the similarity of convenience stores to grocery stores and general merchandise stores, and because FDA estimated the costs for all 3 of those types of stores in the same way, it is likely that the actual cost of the rule for those stores is, similarly, 7 times FDA's estimate of $17.7 million[52] on an annualized basis – $123.9 million.

FDA estimated that the total cost of compliance with the rule for all covered establishments was $84.5 million ($17.7 million for grocery, convenience, and general merchandise stores plus $66.8 million for all other 248,000 covered establishments). Adding $115.3 million for enforcement costs for the 248,000 establishments that are not grocery, convenience, or general merchandise stores to the compliance cost of $66.8 million estimated by FDA for those 248,000 establishments yields an estimate of $182.1 million for the cost of the rule for stores that are not grocery, convenience or general merchandise stores. Therefore, the total cost of the rule is $306 million ($182.1 million + $123.9 million), assuming that FDA correctly estimated the costs of the rule to all of the establishments beyond those that are in the grocery, convenience, or general merchandise industries.

[52] FDA does not report its complete estimate of the cost of the rule to the various industry segments. The $17.7 million estimate comes by multiplying the annualized cost estimate of the full rule by the 21% of the initial costs of the rule associated with grocery, convenience, and general merchandise stores.