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Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2009-N-0569
Comments from the Campaign for Tobacco-Free Kids

To Whom It May Concern:

The Family Smoking Prevention and Tobacco Control Act (FSPTCA) establishes weaker penalties for retailers that make prohibited sales of tobacco products to youth if the retailers have in place an FDA-approved training program for staff to prevent any such sales. The idea behind this provision is that retailers that make solid investments of time and resources that reduce staff sales to youth should not be subject as high penalties if, despite their qualifying good faith efforts, prohibited sales are somehow still made.

Weaker penalties, however, inevitably produce weaker financial incentives for compliance. Accordingly, this training program provision can work as intended only if requirements and procedures are in place to make sure that the retailer training programs are actually structured and implemented in ways that will effectively prevent and reduce retail sales of tobacco products to youth.

Accordingly, FDA's guidance regarding the training program provision should make it clear that a retailer cannot benefit from the provision unless, prior to any enforcement actions against the retailer, the retailer has notified FDA that it has implemented a training program to trigger the application of weaker penalties and FDA has certified that the training program, as described by the retailer, complies with the standards FDA has developed for such programs. But whether a training program that satisfied this initial threshold requirement would actually protect a retailer that sells tobacco products to kids against the regular penalties in the law should also depend on whether the retailer had actually fully implemented the approved training program, as described, effectively and in good faith before the subject violations. In particular, the retailer should be required to show that all staff involved in the violations, including the managers of the sales staff, had previously received the initial training, as well as any required refresher sessions, and had passed all related tests.

More generally, no training program should qualify to reduce the penalties for retailers selling tobacco products to kids until all of the retailer's sales staff, including managers, had gone

through the FDA-approved training program. No new staff should be allowed to make any tobacco product sales until they also successfully completed the training; and periodic refresher training sessions should be required for all sales staff.

In addition, no staff should be certified as successfully completing the initial training or any refresher sessions simply through attendance. Successful completion should depend on passing related tests showing a full understanding of the applicable laws and procedures, including successful participation in simulated sales transactions.

Along the same lines, retailers with FDA approved training program should be required to periodically test staff to ensure they are following all procedures for preventing tobacco product sales to youth by having “customers” under the age of 27 not known to the staff attempt to purchase tobacco products without showing the required identification and otherwise trying to persuade the staff to make the sale without following legal requirements or the retailer’s established practices and procedures. Staff that fail such real-world tests should, at a minimum, be required to go through the training again prior to making any tobacco product sales, with repeated failings being grounds for firing the employee. FDA might also encourage retailers to reward staff that pass such tests to provide an additional inducement to staff compliance with the law and the related retailer procedures.

Similarly, the retailer programs for training staff and preventing tobacco product sales to youth should include related penalties for the managers of the staff or the retail outlets based on how the staff they manage do regarding the training sessions, related tests and performance on state and federal compliance tests. Here, too, FDA might also encourage retailers to provide managers with incentives for strong staff performances and zero sales to youth.

Special attention should also be given to the likelihood that sales staff who are under the minimum age for purchasing tobacco products might be more likely to make sales to friends and peers who are below the legal age, as well. To avoid this problem, all staff that sell tobacco products should be at or above the minimum age. Toward that end, FDA could require that all graduates of the retailer training programs be at or over the minimum legal age for tobacco product purchases. Retail chains and most other retailers could readily comply with such a requirement, but FDA might offer an exemption to those small and independent, owner-operated retail outlets that rely on younger family members for staffing.

Although there is little formal research on how to structure, implement or oversee effective retailer staff training programs to block sales to minors, it is very clear that voluntary, industry-sponsored programs have been ineffective and even counterproductive.

For example, a 2000 study by the California Department of Health Services showed that the much publicized “We Card” program, promoted by the tobacco industry as a voluntary means to keep underage kids from purchasing tobacco products, had little or no effect on underage tobacco sales. The California data demonstrated that the rate of illegal underage sales for stores with “We Card” and other tobacco industry signs was much higher than stores with state

government signs about prohibiting illegal sales to minors; and retailer compliance increased only when the tobacco industry signs were coupled with the government signs.¹

An audit of another industry-sponsored "Action Against Access" program in the mid to late 1990's found that retailers did not take the program seriously and that it was not implemented completely. For example, after the program had been in place for two years Philip Morris had penalized only sixteen retailers for selling to kids.² Before that, the tobacco industry launched the "It's the Law" program, which provided retailers with educational materials about not selling to kids. Beyond sending decals and signage to retail stores, this program was never effectively implemented. Studies published in the *American Journal of Public Health* in 1992 and 1996 found that compliance with the program was extremely low and it was not effective.³ A Philip Morris email document revealed the true purpose of the "It's the Law" program by stating:

"We have two objectives for the ITL [It's the Law] program -- 1) To provide an alternative to legislative/mandated policy actions; and 2) To improve PM's image regarding the youth issue."⁴

At the same time, there is abundant evidence that retailers can and do reduce their sales to youth when faced with strong laws and effective enforcement.⁵ More specifically, a 2004 study found that the behavior of retailer sales clerks, rather than the behavior of youth trying to make the underage purchases, was the strongest predictor of cigarettes sales to youth.⁶

¹ Cowling, DC & Robins, DG, "Rate of Illegal Tobacco Sales to Minors Varies by Sign Type in California," Research Letters, *American Journal of Public Health* 90(11): 1792-1793, 2000.

² Kirshenbaum, M, et al., *Smoke & Mirrors: How the Tobacco Industry Buys and Lies Its Way to Power and Profits*, an Advocacy Institute report, August 1998.

³ DiFranza, JR & Brown, LJ, "The Tobacco Institute's 'It's the Law' Campaign: Has It Halted Illegal Sales of Tobacco to Children," *American Journal of Public Health* 82(9):1271-73, September 1992; DiFranza, JR, et al., "Youth Access to Tobacco: The Effects of Age, Gender, and 'It's the Law' Programs," *American Journal of Public Health* 86(2):221-24, February 1996. See also, DiFranza, JR & Godshall, WT, "Tobacco Industry Efforts Hindering Enforcement of the Ban on Tobacco Sales to Minors: Actions Speak Louder than Words," *Tobacco Control* 5(2):127-31, Summer 1996.

⁴ Crawford, D, email to Slavitt, J, "RE: Sting Operations," May 9, 1994, Tobacco Industry Document Bates No. 2023587951.

⁵ See, e.g., Gray, Bradley & Frank J. Chaloupka, "State Policies and Community Characteristics Affect Tobacco Sales to Minors? An Analysis of over 100,000 FDA Compliance Check," *Policy Forum* 16:1 (2003); Forster J., et al., "The Effects of Community Policies to Reduce Youth Access to Tobacco." *American Journal of Public Health* 88: 1193-1198 (1998); Chaloupka, F., Paper presented at 3rd Biennial Pacific Rim Allied Economic Organizations Conference, Bangkok, Thailand, January, 14, 1997. Jason, L.A.; et al., "Active Enforcement of Cigarette Control Laws in the Prevention of Cigarette Sales to Minors," *Journal of the American Medical Association* 266:22:3159-3161, December 11, 1991; Stead, L. & T. Lancaster, "Interventions for preventing tobacco sales to minors," *Cochrane Database of Systematic Reviews* (1), January 25, 2005 [update of Stead, L. & T. Lancaster, "A Systematic Review of Interventions for Preventing Tobacco Sales to Minors," *Tobacco Control* 9: 169-176, Summer, 2000].

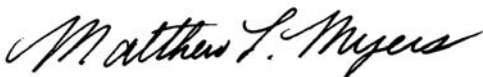
⁶ Klondoff, A. and H. Landrine, "Predicting Youth Access to Tobacco: The Role of Youth Versus Store-clerk Behavior and Issues of Ecological Validity," *Health Psychology* 23(5): 517-524, September 2004.

These studies show that it is critical that FDA not accept any training programs sponsored or administered by the tobacco industry or by tobacco product retailer organizations. Moreover, no public or private training programs should qualify under the new law to reduce applicable penalties unless the program satisfies strict FDA requirements and is subject to rigorous FDA and public oversight, including ongoing independent studies to evaluate and ensure the effectiveness of the training program for actually reducing tobacco product sales to youth and increasing retailer compliance.

Existing research indicates that unless true retailer compliance exceeds 90 percent, it will remain too easy for youth to purchase cigarettes and other tobacco products and there will be no significant related reductions to overall youth smoking and other tobacco use rates.⁷ That means that FDA must be especially vigilant in its oversight and enforcement of the new federal law prohibiting sales to youth, including the provisions providing for weaker penalties for retailers that sell to kids but also have FDA-approved staff training programs. Done right, FDA's requirements will ensure that the training programs operate effectively to make any sales to youth by retailers with training programs quite rare, and the weaker penalties will seldom come into play.

When the weaker penalties are triggered, the retailer making the illegal sales to kids, despite its training program, should be required to make a thorough internal review of its training program, in light of the violations, and correct any discovered problems or weaknesses in the program or its administration. Even more important, if in the future any significant number of retailers make illegal tobacco product sales to youth, despite having implemented training programs that qualify to reduce their penalties, FDA should carefully review and strengthen its training program standards and related requirements.

Sincerely,



Matthew L. Myers
President

⁷ See, e.g., DiFranza, JR, "Are the Federal and State Governments Complying With the Synar Amendment?," *Archives of Pediatrics & Adolescent Medicine* 153(10):1089-1097, October, 1999 ["All of the studies that have demonstrated a decreased availability of tobacco to minors, as evidenced by a reduced prevalence of tobacco use, have achieved violation rates below 10%."]].