



March 4, 2019

Richard Ashworth  
President of Operations  
Walgreen Co.  
200 Wilmot Rd.  
MS #2244  
Deerfield, IL 60015

Dear Mr. Ashworth,

Last month, the Food and Drug Administration (FDA or the Agency) filed a complaint seeking a No Tobacco Sale Order against a Walgreen Co. (Walgreens) retail outlet in Miami, Florida, for repeated violations of restrictions on the sale and distribution of tobacco products to minors. FDA took this action following the most recent inspection of the retail outlet during which a minor was able to purchase a package of Newport Box cigarettes. This was the fifth time in three years that the store had been cited by FDA for violating the law.

Sadly, these violations are – for Walgreens – not an isolated episode. Since FDA began its retailer inspection program in 2010, FDA inspectors have found nearly 1,800 instances in which Walgreens stores failed to follow the law. Among pharmacy chains that sell tobacco products, Walgreens is the top violator, with 22 percent of the stores inspected having illegally sold tobacco products to minors.

These illegal sales must stop. I would like to personally meet with you and the leadership team of Walgreens to discuss this corporate-wide issue related to your stores' noncompliance. Nearly 9 out of 10 smokers start before the age of 18.<sup>1</sup> The public health effects of tobacco use are well documented. Tobacco product use – particularly use of combustible cigarettes – is the leading cause of preventable death and disease.<sup>2</sup>

The Family Smoking Prevention and Tobacco Control Act (TCA) gave FDA the authority to regulate tobacco products to prevent use by minors and reduce the impact of nicotine addiction on public health. FDA regulations prohibit any retailer from selling tobacco products, including cigarettes, smokeless tobacco, and e-cigarettes, to any person younger than 18 years of age,<sup>3</sup> and FDA conducts inspections of tobacco product retailers to determine a retailer's compliance with the law.

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<sup>1</sup> See, e.g., U.S. Department of Health and Human Services, "Preventing Tobacco Use Among Youth and Young Adults," A Report of the Surgeon General; 2012, available at <https://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/full-report.pdf>.

<sup>2</sup> See, e.g., U.S. Department of Health and Human Services, "The Health Consequences of Smoking—50 Years of Progress," A Report of the Surgeon General; 2014, available at [https://www.cdc.gov/tobacco/data\\_statistics/sgr/50th-anniversary/index.htm](https://www.cdc.gov/tobacco/data_statistics/sgr/50th-anniversary/index.htm).

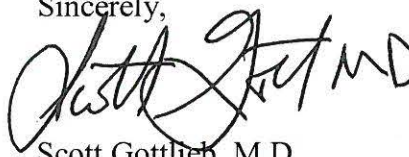
<sup>3</sup> 21 C.F.R. § 1140.14(a), (b).

Both the rate and sheer volume of violative inspections of Walgreens stores are disturbing, particularly since the company positions itself as a health-and-wellness-minded business. These statistics about violations at Walgreens retail outlets cannot possibly come as a surprise to corporate leadership. In addition to issuing a warning letter, civil money penalty, or no-tobacco-sale order, as applicable, to violating retailers, FDA also publicizes the results from compliance check inspections of tobacco retailers in a searchable database that can be accessed by any member of the public, including by the corporate management of retailers themselves.<sup>4</sup>

Violating the law preventing sales of tobacco products to minors, and paying associated fines and penalties, should not simply be viewed as a cost of doing business. The stakes are too high for our young people and our country's decades-long fight to reduce the morbidity and mortality that accompanies tobacco product use. Retailers are on the frontlines of these efforts to reduce the health consequences of tobacco use and nicotine dependence. I hope that Walgreens, like other national pharmacy chains, will take seriously not only your legal obligations, but also the substantial public health impact that you can make by preventing tobacco product sales to minors at your stores.

I would like to discuss with you the high rate of violations by Walgreens stores and what steps the company will take to address these corporate-wide failures. Given the importance of this issue, I request an acknowledgement of receipt of this letter within 15 days and a proposed timeline for meeting with FDA.

Sincerely,

A handwritten signature in black ink, appearing to read "Scott Gottlieb M.D.", written in a cursive style.

Scott Gottlieb, M.D.

Commissioner of Food and Drugs

cc: Elena Kraus,  
Senior Vice President, General Counsel

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<sup>4</sup> The retailer inspection database is accessible at [https://www.accessdata.fda.gov/scripts/oc/inspections/oc\\_insp\\_searching.cfm](https://www.accessdata.fda.gov/scripts/oc/inspections/oc_insp_searching.cfm).