October 15, 2019

Ned Sharpless  
Acting Commissioner  
Food and Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20993  

Re: Comments on Tobacco Products; Required Warnings for Cigarette Packages and Advertisements (Docket ID No. FDA-2019-N-3065)

Dear Dr. Sharpless:

The Big Cities Health Coalition (BCHC) appreciates the opportunity to provide comments on the Food and Drug Administration’s (FDA) proposed rule “Tobacco Products; Required Warnings for Cigarette Packages and Advertisements” (Docket ID No. FDA-2019-N-3065), which would establish new required health warnings for cigarette packages and advertisements. BCHC is a forum for the nation’s largest metropolitan public health departments, who together serve nearly 62 million, or one-in-six, Americans. Our member departments work every day to keep their communities healthy and safe. BCHC wholeheartedly supports FDA moving forward with finalizing the graphic warnings.

Our cities have a long history — and extensive experience — regulating tobacco products at the local level. We are proud of the sustained decreases we have seen in the number of Americans who report regular use of cigarettes. However, in the ever-evolving tobacco market, we must remain vigilant to not lose ground on traditional tobacco product use, while at the same time, stem the tide of emerging products, like e-cigarettes and other vaping devices. While many local health departments continue to take steps to curb the sale and use of all types of tobacco/vaping products, not all localities have this regulatory authority. Because of this, it is so incredibly important that FDA continue to act to protect the public’s health, particularly in areas such as graphic health warnings, where only FDA can fill existing regulatory gaps to create uniform nationwide regulations.

Tobacco use is the leading cause of preventable death in the United States, killing more than 480,000 Americans each year—more than the total number killed by AIDS, alcohol, motor vehicles, homicide, illegal drugs and suicide combined. Despite tremendous progress in reducing smoking, there are still approximately 34.3 million adult smokers in the United States today, about half of whom will die prematurely as a result of their addiction. Each day, more than 300 children under the age of 18 become regular, daily smokers and almost one-third will eventually die from smoking. The 2014 Report of the Surgeon General projected that, if current trends continue, 5.6 million of today’s youth will die prematurely from a smoking-related illness.
In enacting that landmark legislation, Congress determined that the current Surgeon General warnings on the sides of cigarette packages were largely ignored and utterly ineffective in communicating the health hazards of cigarettes to the public. Those warnings remain just as ineffective today. Over 120 countries have adopted graphic health warnings; 81 in the ten years since enactment of the Tobacco Control Act. The evidence is overwhelming that such warnings substantially increase public understanding of the dangers of smoking. Yet, in the U.S., cigarette packages and advertising today remain devoid of effective health warnings. Given the length of time that the Congressional mandate of graphic health warnings has remained unfulfilled, and the strong support for the proposed warnings in the administrative record, FDA must ensure that a final rule is issued by the March 15, 2020 deadline established by order of the United States District Court for the District of Massachusetts in Am. Acad. of Pediatrics v. FDA, No. 1:16-cv-11985-IT, Dkt. No. 56 (March 5, 2019).

There is no question that the graphic warnings in the proposed rule would effectively promote greater public understanding of the negative health consequences of cigarette smoking. The administrative record supporting the proposed rule establishes:

1. That the current Surgeon General’s warnings on cigarette packs are wholly inadequate because they are not noticed and fail to address many of the health harms of smoking of which the public has little knowledge;
2. Research from across the globe demonstrates that large, pictorial health warnings enhance the effectiveness of textual warnings in increasing public understanding of the health harms of smoking;
3. The FDA’s own research supporting the development of the proposed textual and graphic elements in the proposed rule strongly supports the conclusion that the proposed warnings will lead to greater public understanding of the health harms of smoking;
4. The proposed rule and supporting justification are responsive to the First Amendment concerns that led the U.S. Court of Appeals, in R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205 (D.C. Cir. 2012) to strike down the final rule issued by FDA in June, 2011 (the 2011 rule) and remand the matter to the agency; and
5. The various textual and graphic elements in the proposed rule should be considered severable and workable on their own and, should portions of the rule be invalidated by the courts, the implementation of other portions would nevertheless promote greater public understanding of the health harms of smoking.

As is persuasively summarized in the proposed rule, the current health warnings on cigarette packs are wholly inadequate because they have been unchanged for nearly 35 years, are small, and do not contain a color image. As the FDA notes, the current warnings do not effectively inform the public or promote greater understanding of the negative health effects because they do not attract attention, are not remembered, and do not prompt thoughts about the risks of smoking. In the 35 years since the implementation of these warnings, their effect on smokers has drastically weakened. While health warnings on cigarette packs have remain unchanged for nearly 35 years, the science base has grown substantially.
The FDA’s revision of the textual warnings relied on research generated from a large sample including adolescent smokers, adolescents at risk for smoking, and adult smokers, ensuring that the warnings chosen would increase knowledge and understanding among these critical populations. As described in the proposed rule, FDA assessed whether the revised textual warnings provided new information to participants and whether participants reported learning something from the warning statements.\textsuperscript{10} As noted in the proposed rule, “communications science research has found that people are more likely to pay attention to information that is new, and attention plays a vital role in message comprehension and learning.”\textsuperscript{11}

In closing, the Big Cities Health Coalition supports full implementation of FDA’s proposed graphic warnings for cigarette packages and advertisements that will more sufficiently educate the public about the dangers of tobacco use. It is time that the warnings be updated, and we thank the Administration for doing so. If you have any questions, please do not hesitate to contact me at juliano@bigcitieshealth.org or 301-664-2989.

Sincerely,

Chrissie Juliano, MPP
Executive Director
Big Cities Health Coalition


\textsuperscript{6} See also \textit{Am. Acad. of Pediatrics, Inc. et al. v. FDA}, 330 F.Supp.3d 657 (2018) (finding FDA had “unlawfully withheld” and “unreasonably delayed” issuance of a final rule mandating graphic health warnings).

\textsuperscript{7} Proposed Rule, 84 Fed. Reg. at 42759-61.

\textsuperscript{8} Id. at 42760.

\textsuperscript{9} Id. at 42766.

\textsuperscript{10} Id. at 42768.

\textsuperscript{11} Id.