CITIZENS AGAINST GOVERNMENT WASTE

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Food and Drug Administration
Dockets Management Staff (HFA-305)
5630 Fishers Lane, Rm. 1061,
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Docket No. FDA–2019–N–3065
Proposed Rule
Tobacco Products; Required Warnings for Cigarette Packages and Advertisements

Background

Citizens Against Government Waste (CAGW) is a private, nonpartisan, nonprofit organization representing more than one million members and supporters nationwide. CAGW's mission is to eliminate waste, mismanagement, and inefficiency in the federal government. CAGW was founded in 1984 by the late industrialist J. Peter Grace and syndicated columnist Jack Anderson to implement the recommendations of President Ronald Reagan's Private Sector Survey on Cost Control, also known as the Grace Commission.

Comment

The proposed rule is the Food and Drug Administration's (FDA) second attempt to change the 1984 warning label for cigarettes as required under the Family Smoking Prevention and Tobacco Control Act (TCA). The first attempt occurred and failed when a final rule was issued in June 2011 establishing colored pictorial graphics showing the negative effects of smoking that would accompany the nine textual warning statements found in Section 201(a) of the TCA. The images, along with the textual messages, were to appear on every pack of cigarettes sold and advertisement in the U.S. The rule was challenged in August 2011 by four tobacco companies in *R.J. Reynolds Tobacco Company, et al. v. Food and Drug Administration, et al.*, which was argued in April 2012, and found to be a violation of the First Amendment in August 2012 by the U.S. Court of Appeals of the District of Columbia.

The Court of Appeals determined that while the tobacco companies did not dispute the FDA's authority to require health warnings on cigarettes packages or ads, or the substance of the nine textual messages, there are "elements of compulsion and forced subsidization. The Companies contend that, to the extent the graphic warnings go beyond the textual warnings to shame and repulse smokers and denigrate smoking as an antisocial act, the message is ideological and not informational. '[B]y effectively shouting well-understood information to consumers,' they explain, 'FDA is communicating an ideological message, a point of view on how people should

live their lives: that the risks from smoking outweigh the pleasure that smokers derive from it, and that smokers make bad personal decisions, and should stop smoking.' In effect, the graphic images are not warnings, but admonitions: '[D]on't buy or use this product.'"

The Court of Appeals noted, "no one doubts the government can promote smoking cessation programs; can use shock, shame, and moral opprobrium to discourage people from becoming smokers; and can use its taxing and regulatory authority to make smoking economically prohibitive and socially onerous. And the government can certainly require that consumers be fully informed about the dangers of hazardous products. But this case raises novel questions about the scope of the government's authority to force the manufacturer of a product to go beyond making purely factual and accurate commercial disclosures and undermine its own economic interest—in this case, by making 'every single pack of cigarettes in the country [a] mini billboard' for the government's anti-smoking message."

The Court of Appeals cited *Central Hudson Gas & Electric v. Public Service Commission of New York*, in which the Supreme Court held, "The government can regulate commercial speech under the First Amendment if there is a substantial government interest that is directly advanced by the regulation, and if the regulation is not broader than necessary to achieve that goal." The Court of Appeals stated, "Because FDA bears the burden of justifying its proposed restraint on speech, it cannot claim—rather perversely—that its own analysis was irrelevant because it lacked precision and was based on insufficient data. Central Hudson requires FDA to find and present data supporting its claims prior to imposing a burden on commercial speech."

The conclusion in *R.J. Reynolds v FDA* was, "The First Amendment requires the government not only to state a substantial interest justifying a regulation on commercial speech, but also to show that its regulation directly advances that goal. FDA failed to present any data—much less the substantial evidence required under the APA [Administrative Procedure Act]—showing that enacting their proposed graphic warnings will accomplish the agency's stated objective of reducing smoking rates. The [FDA] Rule thus cannot pass muster under Central Hudson."

As a result, the FDA said it would create a new set of warning levels that would not violate the First Amendment. In 2016, eight groups and doctors sued the FDA *in American Academy of Pediatrics et al. v. U.S. Food and Drug Administration* for delaying the release of new labels. The FDA was ordered by the U.S. District Court for the District of Massachusetts to produce a proposed rule by August 15, 2019 and a final rule by March 15, 2020.

Even though the FDA has had seven years to come up with a proposed rule that would pass constitutional muster, the new proposed labels are neither better nor more informative then the labels proposed in 2012. While the FDA claims that pictorial cigarette warnings promote increased information and an understanding of the negative health consequences of smoking, there is no information or data on how much the pictorial labels would reduce smoking.

In its comment regarding the proposed regulation, King and Spalding, LLP, said there are no "records and documentation pertaining to FDA's qualitative and quantitative testing concerning graphic images and textual warnings, including the agency's final study" even though the firm submitted a FOIA request in June 2017.

The World Health Organization admits that while pictorial warnings are "cited by former smokers as an important factor in their attempt to quit and have been associated with increases in the use of effective cessation services, such as toll-free telephone 'helplines,' … all warnings are subject to wear-out over time," although "pictorial warnings have also been shown to sustain their effects longer than text-only warning labels."

Australia's pictorial health warnings, which were created in 2006, have had some of the harshest and most vivid graphics on its tobacco products packaging, covering 75 percent of the front surface and 90 percent of the back surface. Australia was also the first country to require brown packaging with no company logos. The country's smoking rate for daily smokers was 13.8 percent from 2017 to 2018.

Canada was the first country to implement pictorial health warnings. In 2001, the warnings were required to cover 50 percent (increased to 75 percent in 2012) on the front and back of cigarette packages. A message is included on a slider or leaflet inside the package that provided information on quitting. On the sides of the packages, there was information on tar, nicotine, carbon monoxide, formaldehyde, hydrogen cyanide, and benzene emission numbers. The country is in the process of implementing plain packaging. Canada's smoking rate in 2017 was 15 percent, an increase from 13 percent in in 2015. Daily smokers were at 11 percent.

In the United States, with its "ineffective" smoking warning labels, the smoking rate among adults is at 14 percent with the daily rate at 10.5 percent.

CAGW remains unconvinced that the pictorial graphics reduce smoking rates over the long term any more than the standard warning currently on cigarette packaging or ads.

In addition, the products that have been shown to be very successful in helping people reduce or quit smoking, electronic nicotine delivery systems (ENDS), are being threatened by FDA regulations. Between ongoing threats to ban flavors, which make ENDS attractive to smokers and help them to wean themselves off combustible cigarettes, and FDA's onerous and cumbersome marketing applications, the availability of a variety of ENDS will be greatly reduced.

Fueling these proposed restrictions is recent evidence of increased use of vaping products by teenagers. Currently, it is illegal to sell them a tobacco product. Statistics show that teenage youth who smoke cigarettes on a continuing basis also practice other risky behavior such as drinking alcoholic beverages or using drugs. The best way to tackle the problem of youth use is not by banning flavors that help smokers move away from combustible cigarettes and maintain their abstinence, but for parents and teachers to be vigilant about youth use of tobacco products and other risky behaviors.

Currently, the FDA appears to be taking advantage of the deaths and illnesses from vaping in spite of the fact the evidence is growing day-by-day that the cause is illicit products containing tetrahydrocannabinol (THC). It is disappointing that the FDA is moving at lightning speed to ban flavors that will do great damage to the vaping industry, hurting people who may go back to

smoking as a result or purchase black-market vaping products. This is a complete reversal from former FDA Commissioner Gottlieb's July 2017 announcement that the agency would encourage innovation to help smokers quit cigarettes.

On October 3, 2019 the Centers for Disease Control (CDC) announced that among patients who first experienced the symptoms of lung disease, 78 percent reported using THC-containing products and 37 percent reported exclusive use of THC-containing products about three months prior to onset. According to the CDC, while no specific product has been linked to the problems, the agency did warn people who vape not to buy vaping products with THC or Cannabidiol oils from informal sources, such as friends or off the street, and should not modify or add any substances to vaping products. The New York Health Department reported in early September that black market cannabis products may be the cause of the illnesses.

The FDA should wait until all the data is in regarding the recent spate of lung illnesses, which seem to be caused by illicit products. If the FDA should ban vaping flavors and products that have been sold legally for more than 10 years, as it currently seems inclined to do, the agency and the CDC should be prepared for additional health problems caused by increased black-market production.

Instead of looking for any opportunity to destroy the production of ENDS harm reduction products, the FDA, as well as the CDC, should take the lead as Public Health England is doing, and that is to encourage smokers to switch to vaping to help them quit smoking or use this less harmful product.

CAGW appreciates the opportunity to provide comments on the proposed rule for tobacco products and express our concerns over the proposed regulation of the ENDS industry.

Sincerely,

Thomas Schatz