# Food, Drugs, *and* Consumer Freedom

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*A Pro-Growth Agenda for the 117th Congress*

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# Food, Drugs, and Consumer Freedom

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Few matters are as important to individuals as the foods they eat, how they pursue personal health, and how they choose to spend their time and money. Fortunately, the number of choices for consumers has never been greater. Additionally, the quality and accessibility of many consumer goods have only increased. Nevertheless, self-appointed advocates continue to pressure governments to control, restrict, or even ban products and services consumers want. Rarely do such restrictions result in better options or health for consumers. On the contrary, they typically raise the cost of living for those least able to afford it, while causing other perverse and potentially hazardous consequences.

Consumers have exacting demands that, free from interference, private businesses have proved capable and willing to meet. Government regulation of food, drugs, and other consumer products is generally intended to protect consumers, but one-size-fits-all regulation is often poorly suited for ensuring safety for a wide range of consumers with highly individualized needs. Some rules are intended to reduce choices or to discourage consumers from choosing particular goods or services. Whatever the intent, government regulation necessarily imposes costs on producers and consumers, reduces choice, and alters consumer behavior—not always for the better.

Legislators and regulators respond to political pressures. Often, rules are not based on basic principles of science, but on activist agendas and the belief that controlling consumers' choices is "for their own good." In such cases, governments myopically

focus on regulating or prohibiting controversial or novel products without considering how they fit into the range of options and alternatives consumers have. Government may attempt to restrict the use of products and technologies that activists consider risky, but that are nevertheless safer than the alternatives. When that happens, genuine safety can be compromised as consumers pursue riskier alternatives. The result of such politically driven regulation is not a safer, more secure, and more prosperous world, but one that is poorer, less fair, and often more dangerous. Consumers are best helped not by heavy-handed restrictions, but by producers competing with one another to supply consumer demands and needs.

It is essential that government regulation of consumer choices be limited to policing the marketplace to ensure that consumers are not misled by false claims or exposed to adulterated products. Product safety and labeling regulations should be designed with maximum flexibility to allow producers to offer the products and use the production methods that best meet their customers' demands. Where safety restrictions are truly needed to protect consumers or the environment, quality standards should be based on the best available scientific data, while allowing producers and consumers the widest possible range of choice.

## PROTECT CONSUMERS' ACCESS TO TOBACCO SUBSTITUTES AND VAPING PRODUCTS

After more than a decade of intense research, there is no doubt that noncombustible tobacco products are a valuable tool in reducing the harms associated with smoking. Although not harmless, the evidence incontrovertibly demonstrates that they are vastly safer than combustible tobacco and are effective in helping smokers quit their deadly habit. The availability of affordable and satisfying noncombustible alternatives to smoking would be beneficial to public health—a fact tacitly endorsed by the U.S. Food and Drug Administration (FDA) when it granted Swedish Match the right to market snus (a smokeless tobacco powder) as a "modified risk" product in 2019 and Philip Morris International to market its IQOS (which heats, but doesn't burn tobacco) as a "modified exposure" product in 2020. Yet the continued existence of products that are arguably even more beneficial for adult smokers—nicotine vapor—is threatened by FDA regulation.

Although many health experts now recognize that using nicotine vapor, or "vaping," is a safer alternative to smoking and some nations now promote those products for smoking cessation, anti-smoking activists in the United States have persuaded many that vapor products are no different than combustible tobacco. They scored a major victory in 2014 by convincing the FDA to "deem" e-cigarettes as tobacco products and issue regulations that, despite e-cigarettes' different risks and purposes, treat nicotine vapor as functionally no different from combustible cigarettes. In fact, because traditional tobacco cigarettes are grandfathered in and not required to submit premarket tobacco applications (PMTAs) with the FDA, the rules are now *more* onerous for e-cigarette manufacturers than for traditional tobacco. Without immediate action, consumers will lose access to this potentially life-saving technology and many will return to smoking, a habit that kills hundreds of thousands of Americans every year.

**Congress should:**

- Amend the Tobacco Control Act (TCA) to direct the Food and Drug Administration to create a streamlined approval process for lower-risk tobacco products that can be reasonably assumed to have a net positive effect on public health.
- Amend the TCA to allow less harmful nicotine products to be advertised as such. Despite the mountains of evidence, consumers remain largely unaware

that noncombustible tobacco poses fewer risks than combustible cigarettes. Allowing the makers of lower-risk alternatives to communicate honestly with consumers will provide smokers with accurate information about alternatives and may convince more smokers to switch.

- Modify the TCA's "predicate" date (the grandfather date) to 2018 so that products currently available to consumers can remain on the market. In the 114th Congress, Reps. Tom Cole (R-OK) and Sanford Bishop (D-GA) introduced an amendment to the agriculture appropriations bill to change the predicate date to August 2016, which could serve as a model.

As of September 9, 2020, manufacturers of all vaping products and components—including every flavor and nicotine concentration level—are required to file premarket tobacco applications with the FDA. In addition to receiving approval to stay on the market, manufacturers will also have to conform to new labeling requirements and adhere to restrictions on sales and advertising. Together, those rules will cost the makers of vapor products millions of dollars, which only the largest manufacturers will be able to afford. By the agency's own admission, that process will result in the near-total elimination of the nicotine vapor industry, leaving just 1 percent of the currently available products on the market. With fewer options, the nicotine vapor products left available for consumers will be more expensive, less attractive, and less satisfying for adult smokers' individual tastes. As a result, fewer smokers will switch to those products and many who have switched will return to smoking, increasing the burden of death and disease caused by smoking—unless Congress intervenes.

## Amend the Tobacco Control Act

In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act, which vested the U.S. Food and Drug Administration with the authority to regulate the manufacture, sale, and advertising of tobacco products (Pub. L. No. 111-31, 114th Congress). In 2014, without direction from Congress, the FDA announced it would begin regulating all nicotine products as tobacco products under the TCA. That "deeming rule" essentially lumped all nicotine products under the same onerous rules as traditional tobacco cigarettes—rules designed to reduce and ultimately eliminate the use of traditional cigarettes—without accounting for relative risks or benefits of the various product categories.

The premarket tobacco applications that companies must now file for every product will cost upward of $1 million each. For the vast majority of companies, those

compliance costs will force them to either exit the market or drastically reduce their product lines. Most likely, only big tobacco companies will be able to successfully move their products through the FDA's PMTA process, leading one public health expert to deem the rule "the Cigarette Protection Act of 2015."

For any vapor product that does receive FDA approval, companies will also have to comply with sales and advertising restrictions and feature new warning labels. Because of the huge compliance costs and reduced competition, products that remain on the market likely will be much more expensive and less attractive to adult smokers, causing many to simply continue smoking and some to return to smoking.

The effects of these new rules were not what Congress intended when it enacted the Tobacco Control Act. In addition to giving the FDA oversight of tobacco products, the TCA instructed the agency to promote cessation in order to "reduce disease risk and the social costs associated with tobacco-related diseases." Nicotine vapor products have proved to be exactly the type of technology capable of reducing the disease burden, but the FDA's onerous, one-size-fits-all approach to regulating this novel market will effectively eliminate access to these safer alternatives.

### Base Regulations on the Relative Risk of Products

Putting the same regulatory burden on nicotine vapor as the FDA applies to cigarettes—regulations intended to reduce tobacco use—runs contrary to the agency's mission of protecting public health. In its May 10, 2016, final rule deeming e-cigarettes to be tobacco products, the FDA insisted that no long-term studies yet existed to support claims that "vaping" would have a net benefit on public health. Since then, however, the research—including long-term studies—has inconvertibly confirmed that fact. Nicotine vapor products have far fewer harmful and potentially harmful chemicals and significantly improve the health of smokers who switch to these noncombustible products.

Initially, there were fears that e-cigarettes would "renormalize" smoking and lead to increases in adolescent and adult smoking. However, that has not happened. Only a negligible percentage of nonsmokers habitually use nicotine vapor products, and the smoking rate for both youths and adults has reached historic lows every year since they entered the market. In contrast, many smokers attest—and studies confirm—that e-cigarettes are popular and effective for smoking cessation. One randomized

controlled trial from 2019, published in the *New England Journal of Medicine*, confirmed that e-cigarettes were twice as effective for long-term smoking cessation than other nicotine replacement therapies.

## Allow Noncombustible Products to Advertise Reduced Harm

Not only are e-cigarettes now required to acquire FDA sanction, but also manufacturers are prohibited from telling customers that their products are less risky than cigarettes, contain fewer toxins than cigarettes, contain no tobacco, and produce no smoke—all of which are true.

The Tobacco Control Act's subsection 911—which prevents one tobacco product from advertising its relative safety compared with others—was intended to stop dishonest cigarette marketing using such terms as "light" or "low tar" to mislead consumers into thinking they were safer. But that same subsection now also bars nicotine vapor companies from communicating accurate information to consumers, like the fact that e-cigarettes contain fewer toxins than combustible cigarettes. The reason is that the TCA explicitly prohibits companies from claiming that their products are "free" of a certain ingredient or have "less" of a particular ingredient, even if that is true.

Thus, in addition to being more expensive, less customizable, and less appealing, the nicotine vapor market may not even attempt to attract adult smokers away from cigarettes by *truthfully* advertising their products as less harmful.

## Move the "Grandfather" Date to 2018

When Congress enacted the Tobacco Control Act in 2009, it included a "predicate date," which grandfathered in products on the market before February 15, 2007 (a date left over from a previous version of the TCA). Grandfathered products and new products that are substantially equivalent to those already grandfathered in do not have to submit premarket tobacco applications. But because e-cigarettes entered the U.S. market after that date, all nicotine vapor products must go through the PMTA process, making the regulation more onerous for safer nicotine vapor products than it is for traditional combustible cigarettes. Congress can ameliorate the disproportionate effects of the regulation by changing that predicate date to 2016 or 2018—when the law went into full effect—thereby reducing the number of products eliminated from the market.

However, that solution is far from perfect. Grandfathering in many of the products on the market will bring innovation in this market to a screeching halt, preventing the competition and improvements that might make them even safer and more effective for adult smokers. But at least it will not throw innovation back by nearly a decade.

The FDA's mission is to protect and enhance consumer health. The agency asserts the new regulations on vapes will "improve public health and protect future generations from the dangers of tobacco use," but nothing could be further from the truth. The wide variety of flavors, styles, levels of nicotine, and customizability provided by the current nicotine vapor market are what make e-cigarettes so popular and effective. Almost any smoker can find a device, flavor, and nicotine concentration to satisfy his or her needs and preferences. That makes switching from cigarettes easier, cheaper, and more likely to result in permanent smoking cessation. The current state of FDA regulation will eliminate this vibrant and beneficial market. At the very least, it will eliminate consumers' ability to acquire those products *legally*.

Already, states that have banned, heavily taxed, and restricted e-cigarette products are discovering that simply passing laws does not eliminate products. Reports of large-scale bootlegging, illicit manufacturing, and overseas purchasing of banned nicotine vapor products are widespread. Cities that banned products and flavor options in an attempt to reduce youth vaping, like San Francisco, are also reporting increases in youth *smoking*. Whatever risks may be associated with e-cigarettes, it is hard to argue that they would be worse than the harms lurking in the unregulated black market or the harms associated with smoking.

It is long past time for both Congress and the FDA to recognize that nicotine vapor products are not cigarettes. They have different ingredients, risks, and purposes. Regulation should be tailored accordingly, based on the scientific evidence and the needs of consumers—adults and adolescents—not exaggerated media stories, unfounded fears, and wishful thinking.

Expert: Michelle Minton

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## STRENGTHEN COOPERATIVE FEDERALISM BY REMOVING CANNABIS FROM THE CONTROLLED SUBSTANCES ACT

The year 2020 marks the 83rd anniversary of Congress' prohibition on the sale and possession of *Cannabis sativa*. Since 1937, however, public opinion on the subject has changed dramatically. Polls in 2019 show that 91 percent of American adults now believe that cannabis should be legal for recreational or medical use—or both. Only 32 percent of Americans now oppose legalization. But while the public's views have shifted, the federal stance on cannabis has remained largely unchanged since the Great Depression. Under federal law, the possession or sale of cannabis, whether for medical or recreational purposes, is punishable by fines of up to $1 million and as much as life in prison, even if the parties charged are in full compliance with the laws of their state.

To date, only eight states continue to fully criminalize cannabis, with all other states and Washington, D.C., democratically enacting laws to legalize the sale and possession of medical or recreational marijuana. Legalization across the states is the result of changing attitudes and the will of voters, which Congress ought to respect.

Congress has been slow to respond to the public will. On the other hand, the federal government has generally and appropriately taken a stance of noninterference regarding that conflict between state and federal cannabis laws. However, recent actions within the executive branch demonstrate that this entente is tenuous.

In January 2018, the Department of Justice ended the decades-long hands-off position taken by both Congress and the executive branch. In addition to the difficulties that already exist for legal state-based marijuana businesses and consumers because cannabis is federally criminalized, the DOJ's stance put them at even greater risk for legal consequences.

**Congress should:**

- Protect the principle of cooperative federalism, voters' rights, and consumer safety by removing cannabis from the Controlled Substances Act.
- At the very least, amend the Act to decriminalize the business of selling or the act of using cannabis (preferably both) in states where such activity is legal.

In April 2019, a bipartisan group of lawmakers introduced the Strengthening the Tenth Amendment through Entrusting States (STATES) Act (S. 1028, H.R. 2093, 116th Congress). Sponsored in the Senate by Sens. Cory Gardner (R-CO) and Elizabeth Warren (D-MA) and in the House by Reps. Earl Blumenauer (D-OR) and David Joyce (R-OH), the STATES Act is a modest amendment to the Controlled Substances Act (21 U.S.C. 801 *et seq*.). Rather than remove cannabis from the federal drug law, the legislation would make the Controlled Substances Act inapplicable to any person acting in compliance with state law related to the substance. At its heart, the Act does not require Congress to legalize cannabis. Rather, it merely affirms that state legislatures are the government units best equipped to decide whether and how cannabis ought to be regulated in their states.

Our Constitution wisely limits federal power and leaves most issues of law enforcement to the individual states. Given that we are a nation of diverse populations and opinions, state legislatures and local law enforcement must be free to decide how best to use their limited resources to protect public health and safety and direct resources toward those priorities. What works for Colorado may not be appropriate for Alabama, and vice versa. The STATES Act would not prevent the federal government from enforcing federal laws criminalizing the sale or use of marijuana. It merely requires the federal government to enforce those laws in a way that respects states' authority to legislate in this area.

The STATES Act can serve as a model for a modernized approach to marijuana regulation. Perhaps more than any other issue in Congress, it has true bipartisan support, with cosponsors evenly distributed between Democratic and Republican members. Clearly, America is ready to see an end to the longstanding and untenable conflict between state and federal drug policy. All that remains is for Congress to act.

Experts: Michelle Minton

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