Food, Drugs *and* Consumer Freedom

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A Pro-Growth Agenda for the 116th Congress

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Food, Drugs, and Consumer Freedom

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Few matters are as important to consumers as the foods they eat, the medicines they put in their bodies, and the ways they choose to spend their time and money. Fortunately, the number of choices we have as consumers has never been greater. The quality and affordability of foods, medicines, and other consumer products have never been better. Nevertheless, many self-described consumer activists insist that government do more to control the availability, safety, and cost of the products we want and need. Consumers have exacting demands for the products they buy and use, and they—not government—are generally the best judges of the value and quality of the products and services they choose.

Consumers want products that are safe and effective, along with a broad range of choices and affordable prices. Government regulation of food, drugs, and other consumer products is generally intended to ensure safety, 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 explicitly intended to reduce choices or to discourage consumers from choosing particular goods or services. Whatever the rationale, government regulation necessarily reduces choice and imposes costs on producers and consumers, which leads to higher prices in the marketplace.

Legislators and regulators also respond to political pressures, so rules are often driven by activist agendas rather than basic principles of science, or by a desire to control the choices consumers make "for their own good." In such cases, government too often

tends 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. The result of politically driven regulation is not a safer, more secure, and more prosperous world but one that is poorer, less fair, and often less safe. 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, then, that government regulation of consumer choices be limited to policing the marketplace to ensure that consumers are not misled by false claims. 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. When 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 a decade of intense research, there is no doubt that vaping, although not harmless, is vastly less harmful for smokers than combustible tobacco products and are effective in helping smokers quit their deadly habit. Yet, the U.S. Food and Drug Administration is threatening to regulate vaping products out of existence. That can only result in higher incidences of cancer and more smoking-related deaths as more people find it harder to quit smoking tobacco.

Congress should:

- Amend the Tobacco Control Act (TCA) to direct the FDA to create an easier path to approval for tobacco products that are demonstrably less harmful or that can be reasonably assumed to have a net positive effect on public health.
- For noncombustible nicotine-delivering products, instruct the FDA to create a system whereby manufacturers submit ingredients and safety disclosures but are not forced to wait for approval from the agency before selling their products on the market.
- Amend the TCA to allow less harmful nicotine products to be advertised as such. Despite the increasing evidence that noncombustible nicotine is vastly less harmful than cigarettes, consumers remain largely unaware of that fact. Allowing producers of tobacco alternatives to communicate their lower risk 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-Okla.) 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.

Although many other countries' health experts now promote vaping as a safer alternative to smoking and encourage regulators to ease the regulatory burden on vape manufacturers, U.S. health advocates are working overtime to portray vaping as similarly dangerous to traditional tobacco cigarettes and to make those products harder and more expensive for consumers to purchase. Anti-vaping activists scored a major victory last year, when the FDA issued onerous new regulations for vaping products. Despite the much lower risk, the new rules treat vapes—which help millions quit smoking and seem to have minimal, if any, long-term health risks—

functionally the same way as regular cigarettes, which kill almost half a million Americans each year.

Between now and 2022, the manufacturers of all vaping products and components—including every flavor and nicotine level of vaping liquid—will be required to file premarket tobacco applications (PMTAs) and receive approval from the FDA, conform to new labeling requirements, and adhere to restrictions on sales and advertising. Those requirements will cost producers millions of dollars in compliance, which only the largest will be able to afford. By the agency's own admission, this process will eliminate 99 percent of currently available products. The options that remain for vapers will be more expensive and less attractive, meaning that fewer smokers will make the switch and more Americans will die from smoking-related illnesses 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, the FDA, without direction from Congress, announced that 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 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 upwards of $1 million for each application. For the vast majority of companies, the compliance costs will force them to either exit the market or drastically reduce their product lines. Most likely, only large 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." But there is no guarantee that the FDA will approve *any* PMTAs at all. In the agency's history, it has only ever approved eight such products—all of them tobacco "dip" products from one large Swedish company that submitted an application that was more than 100,000 pages long.

If any vape products manage to receive FDA approval, they still will 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 will likely be much more expensive and less attractive to smokers—many of whom will continue to use much deadlier traditional cigarettes.

Clearly, the effects of those new rules were not what Congress intended when it enacted the TCA. In addition to giving the FDA oversight of tobacco products, the TCA instructed the agency to promote cessation to "reduce disease risk and the social costs associated with tobacco-related diseases." Instead, the FDA's actions will reduce access to safer tobacco alternatives.

Modify regulations based on the relative harm of a product

Putting the same regulatory burden on vapes as the FDA applies to traditional tobacco—for which the goal is to reduce use—runs counter to the agency's purported goal of protecting public health. Although the FDA insisted in its May 10, 2016, final rule that "there have not yet been long-term studies conducted to support" the claim that vaping either will have a net benefit on or will harm public health, most of the existing research indicates that the availability of vaping products will significantly *improve* public health.

Although some advocates fear that vaping will "renormalize" smoking, evidence shows that, at most, only 2.3 percent of vapers were "never smokers." Of those who vape, about 35 percent quit tobacco entirely, with another 32 percent significantly reducing tobacco use. According to a July 2017 study led by Georgetown University oncologist David T. Levy, the presence of vaping could lead to a 21 percent decline in deaths from smoking-related diseases for people born after 1997, even after accounting for any potential negative health effects from vaping by people who would otherwise not have smoked at all. (The study was funded by the National Institute on Drug Abuse, the National Cancer Institute, and the Cancer Intervention and Surveillance Modeling Network.)

Allow noncombustible products to advertise reduced harm

Not only are vapes now required to acquire FDA sanction, manufacturers also are prohibited from telling customers that vapes are safer than cigarettes, contain no tobacco, and produce no smoke, and that vapor has been shown to have fewer toxins than cigarette smoke—all of which are true.

The Tobacco Controls Act's Subsection 911, which prevents one tobacco product from advertising its relative safety compared to other tobacco products, was intended to stop companies from using such terms as "light" or "low tar" that falsely contend that the products are safer than regular cigarettes. Subsection 911 also bars manufacturers from advertising that vapes have fewer toxins than do traditional cigarettes because the TCA, which vapes must now comply with, also explicitly bars companies from advertising products as being "free" of a certain ingredient or having "less" of a particular ingredient.

The result will be a vaping market in which products are more expensive, consumers have access to fewer customizable options and fewer flavors, and manufacturers are barred from trying to attract consumers away from cigarettes by *truthfully* advertising products as significantly less harmful.

Move the "grandfather" date to 2016

When Congress enacted the Tobacco Control Act in 2009, it included a "predicate date" that allowed tobacco products already on the market—or similar products on the market before February 15, 2007—to bypass the FDA's prior approval process (the 2007 date was a leftover from a previous version of the TCA). As the FDA itself noted, before 2007 there were no vaping products on the market comparable to today's products. If Congress changes that date to 2016 or 2018—when the law is fully in effect—it will reduce the number of products that its new rules will eliminate from the market.

Although not a perfect solution, grandfathering in most of the products now on the market would only bring innovation in the tobacco substitute market to a screeching halt, instead of throwing it back a decade. The FDA's mission is to protect and enhance consumer health. The agency asserts that 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 limitless flavors, styles, levels of nicotine, and general customizability provided by the current vape market are what has made them so popular—almost any smoker can find a device and juice combination to satisfy his or her needs, making switching from cigarettes easier, cheaper, and more likely to result in permanent smoking cessation.

By the FDA's own admission, the new rules will eliminate almost all of those products, which even FDA experts recognize are "good for public health." It seems that the FDA would rather eliminate life-saving products than allow them to be available without its explicit permission.

Preserve noncombustible nicotine products' advantage over traditional tobacco

Under Commissioner Scott Gottlieb, the FDA has thankfully delayed the decision of his predecessor to regulate less harmful vapor products like it does traditional combustible cigarettes until 2022. However, the FDA and other federal agencies are considering proposals to regulate e-cigarettes in a way that would eliminate their comparative advantage over traditional cigarettes and thus eliminate incentives for current smokers to switch to the less harmful alternatives. For example, the FDA is currently considering a proposal to limit the flavors that e-cigarette makers could offer to tobacco and menthol.

The purported targets of such a ban are candy- and fruit-flavored varieties of e-cigarettes. The agency claims that those varieties can attract nonsmoking minors to use e-cigarettes and thus lead to later smoking. However, data collected by the Centers for Disease Control and Prevention (CDC) show that even as e-cigarettes have risen in popularity, cigarette use among teenagers has declined dramatically. Research, such as a 2015 paper led by University of Pittsburgh oncologist Saul Shiffman, also shows that nonsmoking minors are not attracted by e-cigarette flavors. Instead, those flavors seem to help smoking adults switch to vaping, and stay with it, instead of returning to smoking. Eliminating those flavors would have no effect on minors, but it could have potentially disastrous consequences for smoking adults.

The FDA is charged with protecting consumers from dangerous products. Thus far, none of the scientific evidence indicates that e-cigarette use is harmful either in the short or long term, and almost all of the evidence indicates that vaping is significantly less harmful than cigarette smoking.

One of the FDA's fundamental roles is to provide information about risk to consumers. By focusing on the hypothetical harms that e-cigarettes may or may not pose, the agency has altered public perception about the relative risk of e-cigarettes, with an increasing number of adults reporting that they believe e-cigarettes are as harmful as or even more harmful than traditional smoking—a demonstrably false

belief. The FDA must not only base its regulations on sound science but also be more careful about how it addresses and discusses concerns to avoid misinforming the public.

For Further Reading

Michelle Minton, "CEI Comments on the Regulation of Flavors in Tobacco Products," Regulatory Comments and Testimony, Competitive Enterprise Institute, July 16, 2018, https://cei.org/content/cei-comments-regulation-flavors-tobacco-products.

Michelle Minton, "Prop E Win in San Francisco would be Loss for Public Health," OpenMarket (blog), Competitive Enterprise Institute, June 1, 2018, https://cei.org/blog/prop-e-win-san-francisco-would-be-loss-public-health.

Michelle Minton, "FDA's Asinine Vaping Rule Costs Lives," *Las Vegas Sun*, August 14, 2016, https://www.congress.gov/bill/111th-congress/house-bill/1256/text.

Centers for Disease Control and Prevention, "Tobacco Product Use among Middle and High School Students—United States, 2011–2017," Morbidity and Mortality Weekly Report, June 8, 2018, https://www.cdc.gov/mmwr/volumes/67/wr/mm6722a3.htm.

David T. Levy et al., "The Application of a Decision-Theoretic Model to Estimate the Public Health Impact of Vaporized Nicotine Product Initiation in the United States," *Nicotine and Tobacco Research*, Vol. 19, No. 2 (February 1, 2017), pp. 149–159, https://academic.oup.com/ntr/article/19/2/149/2631691.

Public Health England, "E-Cigarettes Around 95% Less Harmful than Tobacco Estimates Landmark Review," news release, August 19, 2015, https://www.gov.uk/government/news/e-cigarettes-around-95-less-harmful-than-tobacco-estimates-landmark-review. For the study, see A. McNeill, L. S. Brose, R. Calder, and S. C. Hitchman, "E-Cigarettes: An Evidence Update: A Report Commissioned by Public Health England," https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/457102/Ecigarettes_an_evidence_update_A_report_commissioned_by_Public_Health_England_FINAL.pdf.

Saul Shiffman, Mark A. Sembower, Janine L. Pillitteri, Karen K. Gerlach, and Joseph G. Gitchell, "The Impact of Flavor Descriptors on Nonsmoking Teens' and Adult Smokers' Interest in Electronic Cigarettes," *Nicotine & Tobacco Research*, Vol. 17, No. 10 (October 2015), pp. 1255–1262, https://academic.oup.com/ntr/article-abstract/17/10/1255/1028251?redirectedFrom=PDF.

Michael Siegel, "FDA Is Out of Its Mind: Deeming Regulations Should Be Called 'The Cigarette Protection Act of 2015'; Regs are an Embarrassment to Public Health and

Will Decimate the Vaping Industry," The Rest of the Story: Tobacco and Alcohol News Analysis and Commentary (blog), November 9, 2015, http://tobaccoanalysis.blogspot.com/2015/11/fda-is-out-of-its-mind-deeming.html.

Michael Siegel, "First PMTA Approvals by FDA Demonstrate Why Treating E-Cigarettes like Tobacco Products Makes No Sense and Will Decimate the Industry," Tobacco Analysis (blog), November 12, 2015, http://tobaccoanalysis.blogspot.com/2015/11/first-pmta-approvals-by-fda-demonstrate.html.

Jeff Stier, "Comment on the Food and Drug Administration (FDA) Proposed Rule: Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products," National Center for Public Policy Research, September 2, 2014, https://www.regulations.gov/document?D=FDA-2014-N-0189-79941.

PROTECT FEDERALISM AND AMERICAN ADULTS' ACCESS TO ONLINE GAMBLING PLATFORMS

The morality of gambling is an issue that has long been settled in the United States. All but one state has some form of gambling, all but six have lotteries, and four states have legal casino-style gambling online. Without exception, the regulation of intrastate gambling has been left to the states under the Tenth Amendment of the Constitution. That was confirmed in May 2018, when the Supreme Court ruled that a federal law barring states from legalizing sports betting was unconstitutional. For the few antiquated federal gambling statutes that do exist, modern technologies and business models, unanticipated by previous Congresses, have provoked legal conflicts and regulatory uncertainties for state lawmakers and businesses.

Congress should:

- Protect the principle of federalism, Internet freedom, and consumer safety by rejecting any proposals to enact new legislation or amend existing legislation that would prohibit states from legalizing online gambling within their own borders, and between other states where such gambling is legal.

Although states have traditionally regulated intrastate gambling, some members of Congress continue to push for federal laws that would block or otherwise hamstring states from fully legalizing gambling, especially online. Beginning in the 114th Congress, some lawmakers, led by Rep. Jason Chaffetz (R-Utah), have proposed amending the Federal Wire Act of 1961, a law meant to prevent criminal organizations from using the "national wire" to profit from illegal interstate sports gambling. The law was originally enacted because of fears that states would be unable to keep such gambling within their borders. Yet for a number of years, states have had online gambling—including online lotteries, casino-style games, and daily sports betting. State regulation has proved effective, with few, if any, violations of age or geographic restrictions and no evidence of using licensed online gambling sites being as conduits for money laundering or other crimes. But some in Congress would rather push such activities back into the black market.

Proponents of federal restrictions on state gambling, whether or on- or offline, argue that such legislation is necessary to protect consumers. In reality, creating barriers to

legal gambling merely encourages the black market to flourish, putting consumers at greater risk, and undermines state sovereignty.

After the Supreme Court struck down a federal law prohibiting states from legalizing sports betting in May 2018, some members of Congress advocated for new laws to regulate the burgeoning sports gambling market. Sen. Orrin Hatch (R-Utah), who helped enact the original federal sports betting laws, has said that a free market for sports betting in the states would create a "patchwork race to the regulatory bottom" and has announced his intention to introduce new legislation to protect the integrity of sports.

Proponents of federal gambling restrictions worry that Internet gambling will lead to increased rates of problem gambling, but a series of studies conducted at Harvard Medical School's Division on Addiction shows that online gambling is no more addicting than traditional forms of gambling and that its availability will not increase problem gambling. In fact, the rate of gambling addiction has remained stable or has slightly declined, despite the increase in the availability of gambling—including on the Internet, which is legal in most developed nations. In fact, online gambling sites may be better equipped to identify and help players who exhibit signs of problem behavior, because unlike at a brick-and-mortar casino, a person's online behavior can be monitored and analyzed by sophisticated algorithms.

Another common argument used by gambling opponents is that online gambling is necessarily interstate and therefore impossible to contain within state boundaries. Should some states legalize the practice, other states wishing to prevent their residents from gambling online will be unable to block access. That concern is without merit. Should that argument prevail, it would help set a dangerous precedent for other forms of online commerce. Technology exists to track users' location and block them if necessary, as states and countries with legal online gambling have shown.

States have proven that they are more than capable of regulating those activities over the past five years, when online casino-style gambling has been legal in U.S. states. Federal laws and mechanisms already exist to regulate or prosecute operators that violate the laws of other states or nations. Should Congress eventually enact restrictions on Internet gambling, Americans will no doubt simply return to using

foreign-operated sites, which have few, if any, protections for American consumers, or illegal sites, which have none.

Clearly, there is no justification or pressing need to rewrite a 25- or 50 year-old law to protect consumers. States already are doing so by allowing legal, well-regulated gambling online. Congress should stay out of their way. Federal interference will merely strengthen the online gambling black market and weaken the principle of federalism that protects states from federal overreach. Congress should reject any attempts to constrain states from passing gambling laws that serve and protect citizens within their own borders.

For Further Reading

Michelle Minton, "Legalizing Sports Betting in the United States: A Playbook for State Liberalization and Regulation," *OnPoint* No. 243, Competitive Enterprise Institute, March 15, 2018, https://cei.org/content/legalizing-sports-betting-united-states.

Michelle Minton and Steven Titch, "Game Changer: Rethinking Online Gambling Regulation in the Age of Daily Fantasy Sports," *Issue Analysis* 2016 No. 2, Competitive Enterprise Institute, May 10, 2016, https://cei.org/content/game-changer.

Michelle Minton, "The Original Intent of the Wire Act and Its Implications for State-Based Legalization of Internet Gambling," Center for Gaming Research, Occasional Paper No. 29, University of Nevada, Las Vegas, September 2014, http://gaming.unlv.edu/papers/cgr_op29_minton.pdf.

Howard J. Shaffer, Allyson J. Peller, Debi A. LaPlante, Sarah E. Nelson, and Richard A. LaBrie, "Toward a Paradigm Shift in Internet Gambling Research: From Opinion and Self-Report to Actual Behavior," *Addiction Research & Theory*, Vol. 18, No. 3 (2010), pp. 270–283, https://www.tandfonline.com/doi/abs/10.3109/16066350902777974.

STRENGTHEN COOPERATIVE FEDERALISM BY DESCHEDULING CANNABIS FROM FEDERAL DRUG PROHIBITIONS

The year 2019 marks the 82nd anniversary of Congress prohibiting the sale and possession of marijuana. Since 1937, however, public opinion on the subject has changed dramatically. Polls in 2017 showed that 64 percent of Americans support legalization of marijuana, including 51 percent of Republicans and 72 percent of Democrats. But while Americans' views on cannabis have shifted, the federal stance has remained frozen in the Great Depression era. 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 sentences as long as life in prison, even if the parties charged are in full compliance with the laws of their state.

Congress should:

- Protect the principle of cooperative federalism, voters' rights, and consumer safety by un-scheduling marijuana from the Controlled Substances Act or amend the Act to decriminalize marijuana selling or buying in the CSA in states where such activity is legal.

To date, 30 states and Washington, D.C. have democratically enacted laws to legalize the sale and possession of medical marijuana, and nine states and D.C. allow legal recreational marijuana use. Legalization across the states is the result of changing attitudes and the will of voters, which Congress ought to respect. Unfortunately, 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 new stance puts them at even greater risk for legal consequences.

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.

In June 2018, a bipartisan group of lawmakers introduced the Strengthening the Tenth Amendment through Entrusting States (STATES) Act (S. 3032, 115th Congress). Sponsored by Sens. Cory Gardner (R-Colo.) and Elizabeth Warren (D-Mass.), the STATES Act is a modest amendment of the Controlled Substance Act (21 U.S.C. 801 *et seq*). Rather than remove marijuana from federal drug laws, the legislation would make the Controlled Substance Act inapplicable to any person acting in compliance with state law related to marijuana. At its heart, the Act does not require Congress to answer the question of whether marijuana should be legalized. Rather, it affirms that state legislatures are the governmental unit best equipped to decide whether and how marijuana ought to be legalized in their respective states. 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, this one has true bipartisan support, with cosponsors evenly distributed between Democratic and Republican members. President Trump has also stated that he would sign such a bill if it were to pass in Congress. 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 take action.

For Further Reading

Jonathan H. Adler, "Is Morrison Dead? Assessing a Supreme Drug (Law) Overdose," *Faculty Publications*, Paper 174, Case Western Reserve University School of Law, 2005, http://scholarlycommons.law.case.edu/faculty_publications/174.

Angela Dills, Sietse Goffard, and Jeffrey Miron, "Dose of Reality: The Effect of State Marijuana Legalizations," *Policy Analysis* No. 799, Cato Institute, September 16, 2016, https://www.cato.org/publications/policy-analysis/dose-reality-effect-state-marijuana-legalizations.

John Hudak, *Marijuana: A Short History* (Washington, DC: Brookings Institution Press, 2016).

Alex Kreit, "Beyond the Prohibition Debate: Thoughts on Federal Drug Laws in an Age of State Reforms," *Chapman Law Review*, Vol. 13, No. 3 (2010): 555, https://digitalcommons.chapman.edu/chapman-law-review/vol13/iss3/3.

Jeffrey Miron, "The Budgetary Effects of Ending Drug Prohibition," *Tax and Budget Bulletin,* No. 83, Cato Institute, July 23, 2018, https://www.cato.org/publications/tax-budget-bulletin/budgetary-effects-ending-drug-prohibition.