

# Food, Drugs *and* Consumer Freedom

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*A Pro-Growth Agenda for  
the 115th Congress*



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# Food, Drugs, and Consumer Freedom

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 individual products and services.

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. Other 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, leading to higher prices in the marketplace.

Legislators and regulators also respond to political pressures, so rules are often motivated by fear-driven 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,

governments too often tend to restrict the use of products and technologies that activists consider risky, but 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 vigorous competition in the marketplace 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. 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 CONSUMER FREEDOM BY ENSURING ACCESS TO GENETICALLY ENGINEERED FOODS

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The safety of genetically engineered organisms—also known as biotech, bioengineered, and genetically modified organisms (GMOs)—has been studied extensively by dozens of the world’s leading scientific bodies. Every one of them has concluded that the techniques give rise to no new or unique risks compared with conventional breeding methods, and that the ability to move individual genes between organisms makes the characteristics of genetically engineered (GE) products more precise and predictable, and therefore safer, than comparable products developed with more conventional breeding methods. Furthermore, the consensus among scientists who have studied genetic engineering holds that the evaluation of these products “does not require a fundamental change in established principles of food safety; nor does it require a different standard of safety” than those that apply to conventional foods (Institute of Food Technologists, *IFT Expert Report on Biotechnology and Foods* [Chicago: Institute of Food Technologists, 2000], p. 23).

Nevertheless, genetically engineered plants and animals, and foods derived from them, have been subject to extensive regulatory requirements imposed by three different agencies in the United States: the U.S. Department of Agriculture (USDA), Environmental Protection Agency (EPA), and Food and Drug Administration (FDA). Nearly all new GE crop plants must undergo rigorous testing and be vetted by those agencies before they can be put on the market, even though conventionally bred plants with identical characteristics are subject to no regulation at all.

The expensive and lengthy review process is scientifically unjustified, but it adds millions of dollars to the development costs for each new GE variety. The cost and complexity of complying with these regulatory strictures have concentrated GE product development in the hands of just six major seed corporations, and has made it uneconomical to use genetic engineering to develop improved varieties of all but major commodity crops, such as corn and soybeans. Small startup firms and university-based researchers can rarely afford the regulatory costs associated with bringing a new GE crop to market.

The unfounded concerns that some GE products may not be regulated stringently enough prompted the Obama administration, in July 2015, to initiate a comprehensive review of the way the USDA, EPA, and FDA regulate GE organisms. Although

**Congress should:**

- ◆ Monitor the Biotechnology Working Group’s review of existing genetically engineered product regulations, and reject any recommendation to add regulatory hurdles.
- ◆ Reform the USDA and EPA approval processes for GE plants to exempt low-risk GE traits from premarket regulation and to focus regulatory scrutiny solely on traits known to pose potential hazards to humans or the environment, as well as traits that are genuinely novel, but for which the risks are unknown.

the memorandum ordering that review notes that one of its purposes is to “prevent unnecessary barriers to future innovation,” most observers expect the Biotechnology Working Group of senior government officials that is conducting the review to recommend increased regulatory scrutiny, even as the scientific community is calling for regulatory reduction and streamlining.

Despite the overwhelmingly positive record of environmental and human safety, and the substantial burden of mandatory testing and regulatory review, some critics have demanded special labeling for GE foods. They argue that, even if GE foods are safe and nutritious, consumers want the additional information and have a right to choose products that are not produced using genetic engineering.

By 2014, Vermont, Connecticut, and Maine had enacted legislation that would require labeling certain GE foods as containing genetically engineered ingredients—and several other states have considered such laws. Such mandatory labeling would create a patchwork of conflicting, onerous, and expensive labeling rules throughout the country, needlessly raising the cost of all foods, whether or not they contained GE ingredients. Mandatory labels also send a false signal to consumers that they should be concerned about eating GE foods. They are unnecessary because a thriving market exists for voluntarily labeled non-GE foods, providing plenty of choices to those who wish to avoid genetically engineered ingredients. And mandatory labeling laws also raise First Amendment questions, if they are not enacted to advance a government interest more substantial than satisfying consumer curiosity.

To head off the threat of conflicting state laws, in July 2016, Congress enacted the National Bioengineered Food Disclosure Standard to create a uniform national labeling policy for genetically engineered foods and ingredients (Pub. L. No. 114-216, en-

acted as S. 764, 114th Cong., amending 7 U.S.C. 1621 *et seq.*, <https://www.congress.gov/114/bills/s764/BILLS-114s764enr.pdf>). The law instructs the U.S. Department of Agriculture to require food producers to disclose whether their products include GE ingredients. Producers will be given an option to disclose the information with on-package labeling or by directing consumers to a website or telephone number, from which they can learn about individual products.

Despite creating a new nationwide regulatory burden, the bill received overwhelming support from food and agriculture interests, because it also preempts state labeling requirements that differ from the national standard, thereby alleviating some of the concerns about inconsistent state laws. Unfortunately, this uniform national standard will prove to be little better than state mandates. Although it will prevent states from enacting multiple, conflicting policies, it (a) will still prove expensive for food producers to implement, (b) will falsely suggest that there is some reason for consumers to be concerned about GE ingredients, and (c) may run afoul of the First Amendment's prohibition on compelled speech that does not further a substantial government interest.

At the very least, Congress should monitor the USDA's implementation of the National Bioengineered Food Disclosure Standard to ensure that the rule it promulgates provides for the greatest amount of flexibility and the lowest burden for producers. Better still, Congress should in future years consider eliminating the disclosure requirement altogether, while still preempting state labeling laws. Instead, Congress should codify the FDA's longstanding policy that reserves mandatory labeling for food products with characteristics that have been changed in a way that affects safety and nutrition. Where a food product has been changed in a material way—such as an

### **Congress should:**

- ◆ Monitor the implementation of the National Bioengineered Food Disclosure Standard to ensure that the USDA rule provides for the greatest amount of flexibility and the lowest burden for producers.
- ◆ Lay the groundwork for repealing the National Bioengineered Food Disclosure Standard by codifying the FDA's longtime labeling policy for food products, under which special labeling is necessary only when a food's characteristics have been altered in a material way.

increase or decrease in vitamins, the addition of an allergen, or some other change that affects safety or nutritional value—the product label must note the specific change.

Expert: Gregory Conko

### ***For Further Reading***

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## STREAMLINE REGULATION OF GENETICALLY ENGINEERED PLANTS AND FOODS

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Dozens of scientific organizations—including the U.S. National Academy of Sciences, American Association for the Advancement of Science, and Institute of Food Technologists—have carefully studied the safety of genetic engineering for consumers and the environment. All have concluded that the use of modern biotechnology, or gene-splicing techniques, gives rise to no new or unique risks compared with more conventional forms of breeding. In fact, say the experts, GE plants and foods derived from them will in many cases be safer than their conventionally bred counterparts, because the tools of genetic engineering are more precise and predictable.

In each of six studies conducted from 1989 to 2016, the National Research Council of the U.S. National Academy of Sciences, Engineering, and Medicine concluded that no scientific justification exists for regulating genetically engineered organisms any differently from conventionally bred varieties. The safety of a new plant variety has to do solely with the characteristics of the plant that is being modified, the specific traits that are added, and the local environment into which it is being introduced, regardless of whether genetic engineering or a more conventional breeding method is used to modify the plant. Nevertheless, to ameliorate public concerns about gene splicing, the U.S. Department of Agriculture and the Environmental Protection Agency each developed regulatory frameworks during the 1980s that require premarket approval for nearly all new GE plant varieties, regardless of the safety of traits incorporated into individual plants (7 CFR Parts 340 and 360; and 40 CFR Parts 152 and 174).

In 2015, the Obama administration established a Biotechnology Working Group to conduct a comprehensive review of the way the USDA, EPA, and FDA regulate genetically engineered organisms, in part to ensure that no “gaps” existed that would allow products to go unregulated.

The working group would be wise to recommend streamlining and reducing the regulatory burdens facing genetically engineered products and to promote a revised regulatory framework that focuses only on new plant traits known to or suspected of posing unique risks, rather than subjecting all GE products to the same level of heightened scrutiny. However, many scientists fear that the working group’s recommendations will reinforce the current, flawed regulatory framework and will lead to increased regulation for many,



**Congress should:**

- ◆ Monitor the Biotechnology Working Group's review of existing GE product regulations, and reject any recommendation to add unnecessary regulatory hurdles.
- ◆ Reform the USDA and EPA approval processes for GE plants to exempt low-risk GE traits from premarket regulation, and focus regulatory scrutiny solely on traits known to pose potential hazards to humans or the environment.

if not all, engineered plants and foods. Specifically, they fear that the working group will recommend bringing more products under the USDA's and EPA's regulatory purview and increase regulatory scrutiny for many or all GE products.

Under the Plant Protection Act, the USDA treats essentially all GE plants as potential plant pests—organisms that may be harmful to agriculture—until they have been extensively tested under stringent rules, found not to be pests, and then “deregulated” by the department (7 CFR Part 340). New GE plants may also be regulated under the USDA's authority to restrict the planting of so-called noxious weeds if the department believes they may be injurious to public health, agriculture, recreation, wildlife, or property (7 CFR Part 360). The EPA, on the other hand, regulates the testing and cultivation of GE plants modified to prevent, destroy, repel, or mitigate a pest under the same legal authority it uses to regulate chemical pesticides (7 U.S.C. §§ 136–136r). Note that weeds and plant diseases are considered pests. So even plants modified to resist diseases but that produce no new substances that could be considered pesticides are regulated as pesticides by the EPA.

Two decades of practical, commercial experience with GE crops has shown early concerns about genetic engineering to be unwarranted, and that approved varieties have an admirable record of consumer and environmental safety. But regulatory hurdles add years of unnecessary delay to the development process and an estimated \$6 million to \$15 million or more to development costs for each new variety, a burden that can be justified only for major commodity crops bred by large corporate seed companies. Small startup firms and university-based researchers can rarely afford even to test new GE varieties in field trials, let alone bring them to market.

The current regulatory system for GE crop varieties cannot be justified scientifically. It singles out the more precise techniques of genetic engineering for added scrutiny,

even as crops bred using less precise, and arguably less safe, methods—such as induced DNA mutation and forced hybridization of different plant species—go entirely unregulated. Crops bred to withstand herbicides or with added resistance to certain pests are heavily regulated if they are produced with genetic engineering techniques. But the very same traits are not regulated at all if the crop was, for example, exposed to radiation in order to mutate the plant’s DNA in unknown and unpredictable ways.

Four decades’ worth of formal risk assessments and observations of real-world use by millions of farmers on hundreds of millions of acres around the world have failed to show any new or incremental risks associated with GE crops. The time is ripe for significant rationalization and reduction of the regulatory burden placed on GE products. Nevertheless, because breeders are beginning to use innovative techniques that, in some cases, allow GE crops to escape regulation under the USDA’s plant pest authority, some critics are calling for new rules that would increase the stringency of agency oversight. That was the primary motivation for the Obama administration’s decision to reevaluate the adequacy of current regulations for GE organisms.

The Biotechnology Working Group established to conduct this review of genetic engineering regulation should recommend comprehensive reform of the USDA and EPA approval processes for GE plants. It should recommend exempting low-risk GE traits from premarket regulation entirely and should advise the agencies to focus solely on traits known to pose potential hazards to humans or the environment, as well as traits that are genuinely novel, and for which the risks are unknown.

Expert: Gregory Conko

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## REPEAL THE NATIONAL BIOENGINEERED FOOD DISCLOSURE STANDARD

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When the first food products developed with genetic engineering were introduced in the United States in the early 1990s, the Food and Drug Administration, following the advice of major scientific bodies, determined that special labeling for GE foods and ingredients was unnecessary. What determines the safety, wholesomeness, and nutritional value of a food is its characteristics, not the breeding method used to develop it. All breeding methods—from simple hybridization to the most modern biotechnology-based techniques—have the potential to introduce significant changes in the composition of foods. But well-known and simple-to-perform testing methods are sufficient to determine a food’s nutritional value and safety.

According to the FDA’s longstanding policy, food producers have a legal obligation to note on labels any time a food has been changed in a way that might be material to consumer safety or nutrition. Such changes might include a higher or lower level of vitamins or other nutrients, fats, carbohydrates, and other components beyond the normal variability present in conventional counterparts. Material changes could also include the introduction of an allergen or other potentially harmful substance, or even a change in a food’s taste, smell, or texture or its storage, handling, or preparation requirements.

If a new food product has been changed in any of those ways, its label must alert consumers to the modification, regardless of whether that change was made using genetic engineering or another breeding method. Importantly, under the FDA’s policy, it is not sufficient merely to state what breeding method was used to develop the product; the label must state what change has been made, so consumers are informed of relevant information about the foods they eat.

Because the agency relies on mandatory labeling to alert consumers about important safety and nutritional changes, it concluded that mandatory GE-specific labeling would falsely lead consumers to believe there is an important safety concern regarding genetic engineering when there is none. As the American Association for the Advancement of Sciences points out, “Legally mandating such a label can only serve to mislead and falsely alarm consumers.”

Mandatory GE labeling also raises food costs, both for products that include genetically engineered ingredients and for those that do not. Adding information to labels is only one source of cost. When such labeling policies are implemented, all producers must track the provenance of every ingredient, bear the burden of segregating GE and non-GE ingredients, and take special precautions to ensure that every product they sell carries an accurate label. For that reason, mandatory GE labeling would raise the cost of producing nearly every food product—including costs for producers who wish to sell only non-GE products.

Such laws are also unnecessary because a thriving market exists for voluntarily labeled non-GE foods, providing those who wish to avoid genetically engineered ingredients a choice of many thousands of affirmatively labeled “non-GMO” foods. Nevertheless, by 2014, the states of Vermont, Connecticut, and Maine had enacted special labeling laws, and public support for labeling mandates in several other states appeared strong. To prevent the proliferation of a patchwork of burdensome and potentially conflicting state laws, in 2016, Congress enacted and President Obama signed S. 764, legislation that will create a National Bioengineered Food Disclosure Standard (Pub. L. No. 114-216, 114th Congress).

The new law instructs the U.S. Department of Agriculture to develop a uniform national labeling policy by 2018 that will require food producers to disclose whether their products include GE ingredients. Unlike the state laws, producers will not be required to indicate on package labels whether a product includes GE ingredients, although they have the option to do so. Instead, producers will be given the option to use text, a symbol, an electronic or digital link—such as Web address or QR (quick response) code—or a telephone number from which consumers can learn whether individual products contain such GE ingredients.

### **Congress should:**

- ◆ Monitor the implementation of the National Bioengineered Food Disclosure Standard to ensure that the USDA rule provides for the greatest amount of flexibility and lowest burden for producers.
- ◆ Lay the groundwork for repealing the National Bioengineered Food Disclosure Standard by codifying the FDA’s longtime labeling policy for food products, under which special labeling is necessary only when a food’s characteristics have been altered in a material way.

Like the state labeling laws, the new national labeling standard does not cover every food product produced with genetic engineering. It specifically exempts milk, meat, eggs, and other foods derived from animals given GE feed. The disclosure requirement applies only to foods that contain “genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques,” which should exempt many other products, such as cheeses made with the GE enzyme chymosin, beer and wine fermented with GE yeasts, and processed foods like corn and canola oil from GE plants. The processing of such foods removes or denatures DNA and proteins added by the genetic engineering, so they no longer “contain” such genetic material.

Although the National Bioengineered Food Disclosure Standard will create a new nationwide regulatory program, the bill received overwhelming support from food and agriculture interests, because it also preempts state labeling requirements that differ from the national standard, thereby alleviating some of the concerns about inconsistent state laws. Unfortunately, this national standard will still be quite burdensome. Like the state laws it replaces, it will still prove expensive for food producers to implement, it will falsely suggest that some reason exists for consumers to be concerned about GE ingredients, and it may run afoul of the First Amendment’s prohibition on compelled speech that does not further a substantial government interest.

Federal courts have held that government cannot compel commercial speech merely to satisfy consumer curiosity. Although a federal district court refused to stop or delay implementation of the Vermont labeling law, concluding that it did not violate the First Amendment, the U.S. Second Circuit Court of Appeals has ruled in the past that states could not require labeling of GE foods merely because some consumers wished to have the information. Absent a more substantial government interest, states cannot overcome a producer’s First Amendment rights not to include the information on labels. Enactment of the national law preempts the Vermont labeling law, so the legal challenge to it is now moot. However, it is possible that the National Bioengineered Food Disclosure Standard may one day be declared unconstitutional.

Expert: Gregory Conko

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## PROTECT CONSUMER FOOD CHOICE BY OPPOSING FDA OVERREGULATION OF FOOD ADDITIVES

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Fueled by hubris and demands by public health advocates to “do something,” federal agencies—primarily the Food and Drug Administration and Department of Agriculture—have imposed a flurry of rules designed to control Americans’ dietary choices, going beyond the bounds of their authority to protect public health. Most of those policies qualify as “nudges” rather than outright directives, but the goal is the same: to guide consumers and industry to make the “right” food choices by making it as difficult and expensive as possible to go against government dietary wisdom. Yet most of the government’s programs have proved ineffective and misguided. Individuals and their health professionals are better at determining what is best for their health than government bureaucrats.

In June 2015, the FDA revoked the “generally recognized as safe” (GRAS) status of partially hydrogenated vegetable oils, more commonly known as trans fats. Without GRAS status, producers need to prove their products are “safe” before the FDA will allow them to use trans fats as an additive—a hurdle that is likely impossible, given that the agency has indicated that it believes there is no safe level of trans fat consumption. Thus, it constitutes a de facto ban on this ingredient. Since finalizing the trans fat rule, it has become clear that activists have no intention of stopping there and have already moved on to pressuring the FDA into using its GRAS authority to restrict additional ingredients, including sugar, sodium, caffeine, and others.

In 2002, Americans consumed an average of 4.6 grams of trans fats per day. But by 2012, that number had fallen to 1 gram a day (0.5 percent of daily calories). Although

### **Congress should:**

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- ◆ Stop the FDA’s march toward invasive control by amending the Federal Food, Drug, and Cosmetic Act to clarify that the agency has authority to limit or ban only those ingredients that:
  - Are either acutely harmful to human health or have health risks that are cumulative;
  - Cannot be identified by consumers; and
  - Cannot be mitigated through other dietary and lifestyle choices.



evidence shows that very high levels of trans fat consumption (much higher than typical consumption in the U.S.) may increase the risk of cardiovascular disease, little research has examined risks associated with low-level consumption, and those that have found no adverse effects. Yet the FDA contends that any level increases the risk of death, and therefore it is justified in eliminating trans fats from the American diet.

Under the Federal Food, Drug, and Cosmetic Act, the FDA has the authority to approve additives for use in food if it determines that they are safe. Revoking the GRAS status of trans fats because long-term overuse may lead to an increased risk of developing certain health conditions would be a significant shift in policy. By attempting to stop individuals from consuming ingredients that could be unhealthful if overused, the agency is trying to protect consumers not from dangerous foods, but from what it sees as bad choices.

The FDA appears to have based its policies on the wishes of extremist public health activists rather than on sound scientific evidence. Beginning almost immediately after the trans fat ban, activists and the FDA began to push for policies that would limit added sugars and sodium in foods. It seems that trans fats were a test case in the agency's broader effort to establish its authority to limit or ban ingredients that are not harmful, but that may be unhealthful if overconsumed.

Expert: Michelle Minton

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## PROTECT CONSUMER FOOD CHOICE BY OPPOSING THE FDA'S "VOLUNTARY" SODIUM LIMITS

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Fueled by hubris and demands by public health advocates to “do something,” federal agencies—primarily the Food and Drug Administration and Department of Agriculture—have imposed a flurry of rules designed to control Americans’ dietary choices, going beyond the bounds of their authority to protect public health. Most of those policies qualify as “nudges” rather than outright directives, but the goal is the same: to guide consumers and industry to make the “right” food choices by making it as difficult and expensive as possible to go against government dietary wisdom. Yet most of the government’s programs have proved ineffective and misguided. Individuals and their health professionals are better at determining what is best for their health than government bureaucrats.

For decades, activists have fixated on lowering salt intake as the key to addressing our worryingly high rates of hypertension. Apparently convinced by their rhetoric, in May 2016, the Obama administration announced plans to set limits on the amount of salt in processed foods. A few weeks later, the FDA unveiled proposed “voluntary” sodium limits for food manufacturers, hoping that reducing sodium in processed foods will reduce total consumption and improve health. Instead, this obsession with sodium has diverted energy and resources away from strategies that could actually work.

### **Congress should:**

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- ◆ Hold hearings to examine the FDA’s authority to issue these guidelines, seeking information on whether such guidelines would result in improved public health outcomes, on the compliance costs for food manufacturers, and on alternative approaches. Specifically, Congress should ask FDA officials:
  - To justify whether their agency, which is charged with protecting the public health from adulterated foods and drugs—not their own dietary choices—has the authority to attempt to limit the use of a generally recognized as safe (GRAS) food ingredient.
  - Whether the FDA plans to revoke the GRAS status of added salt or other ingredients currently recognized as safe, so that it may implement mandatory restrictions in prepared foods.
  - To explain the possible unintended side effects of, scientific basis for; and
  - Offer possible alternatives to the FDA’s approach regarding salt.

Although the theory that excess salt leads to hypertension seems like long-settled science, in reality, sodium reduction has a negligible effect for the vast majority of people. Yet for the 25 percent who are “salt sensitive,” large reductions can moderately reduce blood pressure. So lowering salt in processed foods—from which Americans get 75 percent of their sodium—is an attractive plan, but one that hinges on people not adding the salt back in or seeking out sodium in other salty foods. Clinical studies have shown that people unconsciously alter their diets in order to satisfy their salt appetite, the physiologically set level of sodium they crave. And for the vast majority of the human population, that level is remarkably similar.

Recent worldwide surveys of salt intake found that, apart from a few remote tribes, most people consume between 2,600 and 4,800 milligrams (mg) of sodium a day for an average of 3,700 mg. That is almost the exact amount the average American consumes, at 3,400 mg, a level that has been stable for at least 50 years, despite the fact that we consume more processed foods now than ever before.

Even if we assume that people won't add salt or eat other salty foods, would the proposed sodium reduction in processed foods make Americans healthier? The answer is unclear. Numerous large population studies have shown that death is more likely for populations that consume excessively high or excessively low levels of salt, with the best outcomes associated in the middle range that most of us eat. In 2013, an Institute of Medicine panel found no evidence of health benefits from reducing sodium below the FDA-recommended 2,300 mg a day.

Certainly, salt reduction can be one aspect of hypertension control for some, but additional approaches might be more effective for a wider range of individuals. For example, increasing vitamins from fruits and vegetables, particularly potassium, can be nearly as effective at lowering blood pressure as halving daily salt intake, in addition to having other health benefits. And of course, exercise helps as well.

The FDA appears to be basing its policies not on sound scientific evidence but on the wishes of extremist public health activists. For example, in 2012, Robert Lustig, a pediatric endocrinologist at the University of California, San Francisco, declared that sugar was a toxin and that the agency should consider removing its GRAS status, thus treating it like an additive that companies would need to prove is safe before they can add it to their products. If the FDA continues on this path unchecked, public health

advocates will continue to push toward greater control of our diets. Congress should remind the agency that its charge is to protect the public from acutely dangerous products—not to protect us from our own choices. What constitutes a healthy diet should be left to individuals to decide.

Expert: Michelle Minton

### **For Further Reading**

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## PROTECT CONSUMERS' ACCESS TO LIFE-SAVING DRUGS AND MEDICAL DEVICES

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Patients benefit from the thousands of available medical drugs and devices on the market today. But the Food and Drug Administration's overly cautious testing and approval requirements, and demands that such treatments meet a near-perfect level of safety, are often counterproductive. That approach often leads to extensive delays in the availability of new treatment options and high prices.

Patients can be injured if the FDA approves a treatment that is later found to be unsafe, but they can also be harmed when needed treatments are delayed by regulatory hurdles, or when the cost and complexity of securing approval mean that promising new treatments are never presented for agency evaluation. Safety concerns that arise after a drug or device is approved result in startling headlines and congressional hearings. That incentivizes the FDA to be overly cautious in its decision making, demanding more trials with more patients, raising costs, and prolonging development times. Far too little attention is paid to sick patients who are denied treatment options that may save their lives or improve their quality of life. And the combination of high development costs and lengthy approval times contributes to high prices for the drugs and devices that do make it to market.

Fortunately, many of these concerns are now recognized by a bipartisan group of legislators, who began to address them during the 113th and 114th Congresses. Reps. Fred Upton (R-Mich.) and Diana DeGette (D-Colo.) assembled a comprehensive list of reform proposals into the 21st Century Cures Act, which was approved by the full House in 2015. The Senate considered a package of 19 bills addressing many of the same proposals, but none of that legislation has been enacted into law. Congress should make comprehensive FDA reform a priority in the 115th Congress. Although real reform would require changes much more substantial than those contained in the 21st Century Cures Act, that legislation would be a good place to start.

The bill's proposals include much-needed updates to the FDA's decades-old rules for evaluating the safety and effectiveness of new drugs. Updates include (a) a requirement that the agency consider patients' views on the desirability of a new drug's benefits and their willingness to tolerate certain risks associated with the treatment, (b) the evaluation of evidence from real-world clinical use when considering new indications

**Congress should:**

- ◆ Modernize the FDA's rules for evaluating new drugs and medical devices by enacting the 21st Century Cures Act.
- ◆ Encourage the use of adaptive clinical trial designs, which let researchers incorporate active learning into study methodologies, by making the rules governing their use more flexible.
- ◆ Consider evidence from real-world clinical use when evaluating new indications for already-approved drugs.
- ◆ Consider patients' views on the risks and benefits of new drugs when making approval decisions.

for already-approved drugs, and (c) encouragement of more adaptive clinical trial designs that let researchers modify ongoing studies to reflect what they are learning during the course of a given trial.

The FDA's one-size-fits-all approval process means that some decisions will be too cautious for some and not cautious enough for others. Individual patients disagree about how much risk they are willing to tolerate in order to obtain a new treatment's potential benefits. But those who view the FDA's approval process as too quick may freely choose to use only products that have been on the market for several years with a well-established record of safety and efficacy. Those who seek access to medical products before the agency has approved them have little or no choice.

In theory, the FDA's expanded access, or "compassionate use," program provides an option for terminally ill patients who cannot be enrolled in a clinical trial to access treatments that have not yet been approved. In practice, however, the process for seeking a compassionate use exemption is complicated, time-consuming, and burdensome, which means that many patients are denied a genuine opportunity to choose. More must be done to expand patients' access to not-yet-approved drugs when they cannot enroll in a clinical trial.

**Congress should:**

- ◆ Reform the Expanded Access process by streamlining the paperwork burden and removing the FDA's discretion to deny compassionate use to patients who meet basic qualifications.
- ◆ Explore other options for giving patients access to not-yet-approved drugs and devices.

Expert: Gregory Conko

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## MODERNIZE THE RULES FOR EVALUATING NEW DRUGS AND MEDICAL DEVICES

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First developed more than 50 years ago, the U.S. Food and Drug Administration’s approach to clinical testing—which relies on multiple trials in three phases of testing—is premised on the belief that most patients will have similar responses to medical interventions and that a drug’s benefits and side effects will be easy to identify, given a large enough test population of patients with similar health and physical characteristics. However, we now know that similar patients often respond quite differently to the same medications, and that the homogeneous patient pools and tightly controlled clinical environments associated with randomized trials do not reflect real-world practice and outcomes very well. Such methods are ill-suited for detecting and testing subtle differences that occur in small patient subpopulations, which makes them poor tools for fast-paced, adaptive learning.

A 2007 report by the FDA Science Board concluded that “FDA’s evaluation methods have remained largely unchanged over the last half-century,” and that the agency’s “inadequately trained scientists are generally risk-averse, and tend to give no decision, a slow decision or even worse, the wrong decision on regulatory approval or disapproval.”

To minimize the occurrence of hindsight bias in data analysis, clinical trials begin with a hypothesis and a carefully constructed methodology for testing that hypothesis. When an unexpected or idiosyncratic effect is detected among a subpopulation of the test group, the FDA typically demands that the manufacturer form a new hypothesis and initiate an entirely new trial. In the process, adaptive learning is short-circuited, the development process is prolonged, and the costs of drug development rise. The FDA must be more willing to allow flexibility in trial designs and conduct and to approve new drugs based on fewer trials with fewer patients.

Today, new computational tools, a better understanding of disease pathways, the development of biomarkers to predict drug effects, and other technological advances are enabling the use of innovative methods that could improve clinical trial quality. Those tools, combined with adaptive clinical trial designs—which allow researchers to learn as trials are in progress and, in turn, change dosing regimens or isolate patient subpopulations that respond especially well or poorly to the test drug—could help trial



sponsors collect better, more robust data from fewer patients and in a shorter amount of time. Thus, use of adaptive trial methodologies could lead to significant efficiencies in drug development, accelerate testing, and reduce the cost and time it takes to bring a new medicine to market.

In theory, the FDA has been open to adaptive trial proposals, but it insists that such trials be designed more carefully than conventional ones in order to prevent biases from being introduced into the statistical analysis. Among other things, the agency asks trial sponsors to predict what idiosyncratic results may occur during the course of a trial and decide at the outset how they will change the trial's direction when those results occur. Such rigid constraints have prevented researchers from reaping the full benefits of the innovative methodologies, and many have been reluctant to experiment with adaptive trials until they have greater assurance that the FDA will accept their results and not penalize researchers for using them. It is imperative, then, that the FDA develop more flexible guidelines for using adaptive trial methods and encourage drug developers to use them.

Similarly, the FDA has long been reluctant to consider evidence of a drug's safety or efficacy derived from real-world use in treating patients outside the tightly controlled confines of a clinical trial. When the FDA approves new drugs, they are approved at a specific dosage to treat a specific condition, such as a particular type of cancer. But once approved for any indication, physicians may legally prescribe drugs in varying doses for other safe and effective uses. These "off-label" uses are very common, and for many diseases, the first line treatment is an off-label drug. But doctors and patients often lack sufficient information about off-label indications because manufacturers may not disseminate certain kinds of information about unapproved uses. Consequently, both the FDA and the medical community encourage manufacturers to pursue supplemental FDA approvals for off-label uses.

However, testing approved drugs and pursuing a supplemental FDA approval is expensive. It is also difficult, and in some cases unethical, to enroll patients in placebo-controlled trials when doctors are already free to prescribe the drugs. Furthermore, in many cases, the expense of securing a new FDA approval would not prove economical—such as when a drug is off patent and available from many generic firms. In such cases, a manufacturer that paid tens or even hundreds of millions of dollars for clinical trials to support a supplemental approval application would not be ensured of recoup-

ing the costs. Therefore, the FDA should consider real-world evidence from clinical use to support approvals for supplemental indications for drugs.

The FDA already considers real-world evidence to support medical device approval decisions, as a supplement to other evidence generated through clinical trials. And it relies almost exclusively on evidence of adverse effects from clinical use to justify decisions to withdraw, or recommend withdrawing, a drug from the market. It makes little sense then for the FDA to refuse to consider real-world clinical evidence in evaluating drugs for supplemental approvals.

Nor are the views of patients given adequate consideration when the FDA makes approval decisions. No drug is perfectly safe, in the sense that it has no negative side effects. Patients facing critical illnesses and those with otherwise unmet treatment needs are often willing to tolerate significant side effects in order to receive the life-saving or quality-of-life-improving benefits of new drugs and devices. Historically, patient views regarding the value of new treatment options have been given short shrift in the drug and biologics approval process.

For patients, medicines do more than simply treat or cure disease. They can produce uncomfortable, disabling, or embarrassing side effects, but they can also improve patients' quality of life by reducing pain, discomfort, or other symptoms caused by the underlying medical condition. New or improved products can improve mental function or physical performance compared with alternative treatment options. And even a seemingly simple change in dosing frequency should not be discounted as trivial if it improves patient compliance with prescribed treatment protocols. Formally incorporating patients' views into the agency's evaluation of the safety and efficacy of drugs and devices will result in improved FDA decision making and give patients more and better treatment options.

Enacting the 21st Century Cures Act with the proposals above would vastly improve the conduct of clinical trials and FDA approval decisions, and it would help bring the agency's decades-old rules for evaluating the safety and effectiveness of new drugs into the modern age.

**Congress should:**

- ◆ Modernize the FDA's rules for evaluating new drugs and medical devices by enacting the 21st Century Cures Act.
- ◆ Encourage the use of adaptive clinical trial designs, which let researchers incorporate active learning into study methodologies, by making the rules governing their use more flexible.
- ◆ Consider evidence from real-world clinical use when evaluating new indications for already approved drugs.
- ◆ Consider patients' views on the risks and benefits of new drugs when making approval decisions.

Expert: Gregory Conko

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## EXPAND PATIENT ACCESS TO EXPERIMENTAL TREATMENTS

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When making safety evaluations, the U.S. Food and Drug Administration is required, by statute, to determine the appropriate balance between patient safety and medical product effectiveness. The FDA cannot know what the optimal risk–benefit balance is for every patient. Each patient will have different views about how much risk and how many side effects he or she is willing to bear in order to use a new treatment that could alleviate symptoms or cure a disease. Therefore, it is important that individual patients have more opportunities to choose a medical treatment that meets their unique health status and risk tolerance. Currently, however, few patients ever have the option of choosing a drug or medical device that has not satisfied the FDA’s risk–benefit preferences.

Some patients with unmet medical needs may be eligible to enroll in a clinical trial to test a new medicine or medical device. But because of the need for homogeneous patient populations in clinical trials, many simply do not qualify for enrollment because of their age, comorbidities, prior treatments, and/or the progression of their disease. Under current law, the FDA may grant expanded access, known as compassionate use exemptions, for patients with serious or life-threatening diseases and no other viable treatment alternatives to use experimental treatments outside of a clinical trial (Expanded Access to Investigational Drugs for Treatment Use, 21 C.F.R. § 312 subpart I, 2013). But the process for seeking expanded access is complicated and time-consuming.

Although guidance documents published by the FDA in June 2016 purport to “facilitate the availability” of expanded access use by clarifying the procedures for obtaining the FDA’s authorization, they do little to streamline the process. Such permission requires the patient’s physician to submit a detailed application, which, before the issuance of the FDA’s 2016 guidance, was estimated to take 100 hours to complete. Under the terms of this guidance, physicians may satisfy some of the submission requirements by referring to information in the drug manufacturer’s Investigational New Drug (IND) application to conduct clinical trials—which would reduce the amount of time it takes to complete the submission—but only if the manufacturer consents and provides a letter authorizing the FDA to reference that IND.

The manufacturer must also consent to provide the drug for close to zero price, while still agreeing to fulfill burdensome paperwork and monitoring requirements. Manufacturers may charge patients only the direct costs “incurred by a sponsor that can be specifically and exclusively attributed to providing the drug,” so many are understandably reluctant to agree to expanded access use (Charging for Investigational Drugs under an Investigational New Drug Application; Expanded Access to Investigational Drugs for Treatment Use; Final Rules, 21 CFR Parts 312 and 316, August 31, 2009). In addition, many manufacturers are concerned that granting expanded access to large numbers of patients could jeopardize their ability to enroll in the clinical trials needed for FDA approval.

Although the FDA does eventually grant nearly all expanded access requests that are submitted by patients and manufacturers, that authorization often comes months after the process is initiated, jeopardizing the patient’s best opportunity to treat the disease at a stage early enough to be effective. In the end, the hurdles involved with seeking such an expanded access exemption mean that few patients ever even try to use this route. Despite substantial demand for early access to not-yet-approved drugs, only about 1,000 to 2,000 patients each year navigate the process and complete an expanded access request.

The FDA’s standard response to demands for broader preapproval availability is that critically ill patients will grasp at straws trying to seek access to drugs that remain experimental and about which too little is known. But individual patients and their doctors are in a far better position than the FDA to judge whether the uncertain risk and benefit of new treatments are warranted. The FDA should focus on providing them with the information on what is and is not known about experimental treatments and permit patients and their doctors to weigh the potential risks on their own, rather than on restricting patient choice.

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**Congress should:**

- ◆ Reform the Expanded Access process by streamlining the paperwork burden and removing the FDA’s discretion to deny compassionate use to patients who meet basic qualifications.
- ◆ Explore other options for giving patients access to not-yet-approved drugs and devices.

Congress has previously examined proposals to reform the expanded access process by streamlining the paperwork burden and removing the FDA's discretion to deny compassionate use to patients who meet basic qualifications. One such example is the Compassionate Access Act (H.R. 4732), introduced in 2010 by Rep. Diane Watson (D-Calif.). That bill, and others like it, have never reached a floor vote, but they provide Congress with a template to use as the starting point to develop legislation to make it easier for patients to be granted Expanded Access exemptions. Congress should consider that proposal and other options for giving patients access to not-yet-approved drugs and devices.

Expert: Gregory Conko

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

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After nearly a decade of intense research, there is no doubt that vaping—while maybe not harmless—is vastly less harmful for smokers than combustible tobacco products and is an effective aid in helping smokers quit their deadly habit. Yet the U.S. Food and Drug Administration is threatening to regulate vaping products out of existence—which can only result in higher cancer incidences and more smoking-related deaths as more people find it harder to quit.

Although 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 created new onerous regulations for vaping products. Despite the massive difference in risk, the new rules treat vapes—which help millions quit smoking and appear 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.

### **Congress should:**

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- ◆ 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 can be reasonably assumed to have a net positive effect on public health. Rather than forcing companies to wait for prior approval, the agency should create “file-and-use” rules that require companies to submit ingredient and safety disclosures to the agency, but not force them to wait for prior approval before bringing products to market.
- ◆ Amend the TCA to allow less harmful nicotine products to be advertised as such.
- ◆ Modify the TCA’s “predicate” date (the grandfather date) to 2016 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 that would change the predicate date to August 2016, which could serve as a model.

Over the next two years, 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, to conform to new labeling requirements, and to 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 result in the near total destruction of the market, eliminating 99 percent of currently available products. The options that remain for vapers will be more expensive and less attractive, meaning 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, without direction from Congress, the FDA announced it would begin regulating all packaged nicotine products as tobacco 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 upward 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. Only large tobacco companies will likely 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 products—all 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 add new warning labels to their products. 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, who will continue to use much more deadly traditional cigarettes.



Clearly, the effects of these new rules were not what Congress intended when it enacted the TCA—which, in addition to giving the FDA oversight of tobacco products, instructed the agency to promote cessation in order to “reduce disease risk and the social costs associated with tobacco-related diseases.” Instead, the FDA’s actions will reduce access to and use of safer tobacco alternatives and thus result in some number of Americans who will continue to smoke and who will become ill and die prematurely.

**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. Though 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 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. According to a July 2016 study by David T. Levy and other tobacco control experts, 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.

Though some advocates fear 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.

**Allow noncombustible products to advertise reduced harm.** Not only are vapes now required to acquire FDA sanction, manufacturers are also prohibited from telling customers that they 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 with others—was intended to stop companies from using such terms as “light” or “low tar” that falsely contend that the products are safer than normal cigarettes. It also bars manufacturers from advertising that vapes have fewer toxins than 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. So in addition to being more expensive, having fewer customizable op-

tions, and having fewer flavors, the new vaping market will not even be able 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 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, there were no vaping products on the market comparable to today’s products before 2007. If Congress changes that date to 2016 or 2018—when the law is fully in effect—it will reduce the number of products 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 nine years.

The FDA’s mission is to protect and enhance consumer health. Although it asserts the new regulations on vapes will “improve public health and protect future generations from the dangers of tobacco use,” 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. The new rules will, by the FDA’s own admission, eliminate almost all of these products, which even experts within the FDA recognize are “good for public health.” It seems the FDA would rather eliminate life-saving products than allow them to be available without its explicit permission.

Expert: Michelle Minton

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## IMPROVE OVERSIGHT OF THE CONSUMER PRODUCT SAFETY COMMISSION'S REGULATION OF PHTHALATES

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Actions by the Consumer Product Safety Commission (CPSC) related to plasticizers designed to make soft and pliable plastics—collectively known as phthalates—should raise concerns among members of Congress. In 2015, the CPSC released the Chronic Hazard Advisory Panel (CHAP) report, which was designed to assess the risks of those chemicals, which the agency may use to issue regulations.

The CPSC's process for assessing the risks of phthalates has proved highly suspect. Key concerns include:

- ◆ A lack of transparency in regard to the peer review process of the CHAP report;
- ◆ The refusal to allow public comment on a draft version of the CHAP report; and
- ◆ Reliance on outdated exposure data, and questionable approaches employed for a cumulative exposure assessment.

The CHAP report authors did not adequately consider the public health effects that might result from inferior substitute products. In any case, the science outlined in the CHAP report and elsewhere does not support regulatory action on any of the phthalates.

Such regulatory actions will have unanticipated effects on the markets for a variety of products beyond those regulated under this rule. Forced reformulations of children's products regulated under the rule, along with resulting market deselection of other products, threaten to undermine the public health, innovation, and economic well-being. In the case of children's toys, the CPSC did not consider whether product failures associated with substitute products might increase risks for children. For example,

### **Congress should:**

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- ◆ Conduct oversight hearings regarding the Consumer Product Safety Commission's regulatory actions on phthalates.

substitute products might increase choking hazards because they make many plastics more brittle and prone to breaking into small parts.

Expert: Angela Logomasini

***For Further Reading***

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## IMPROVE OVERSIGHT OF THE CONSUMER PRODUCT SAFETY COMMISSION'S RESPONSE TO CALLS TO BAN ORGANOHALOGEN FLAME RETARDANTS

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In July 2015, a coalition of environmental activist groups petitioned the Consumer Product Safety Commission to ban the use of all organohalogen flame-retardant products in upholstered furniture sold for home use, in mattresses and mattress pads, and in the plastic casing of all electronic devices. The CPSC has received comments and held hearings. It is now deliberating on whether such bans are necessary.

The petitioners claim that trace exposures of these chemicals pose health risks, and that products that contain them provide no benefits. Both claims fall apart under scrutiny. Evidence is scant that trace human exposures to organohalogens through consumer products pose a significant public health risk, whereas fire risks are real, verifiable, and substantial. Moreover, because not all organohalogens are the same, banning that entire class of chemicals makes no scientific sense.

Banning even a limited number of uses for an entire category of flame-retardant chemicals not only is unwarranted but will eliminate currently valuable uses and market development of future uses. The regrettable result could be unnecessary and preventable loss of life from fires that expand faster in the absence of these products.

### **Congress should:**

- ◆ Conduct oversight hearings on regulatory actions by the Consumer Product Safety Commission related to organohalogen flame-retardant chemicals.

Expert: Angela Logomasini

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## IMPROVE OVERSIGHT AND DEFUND ACTIVIST RESEARCH

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Although we all would like to believe that researchers' motives are unbiased and pure, the reality is that incentives and personal opinions can have a huge effect on study design and results. When researcher bias combines with political agendas, it can evolve into "activist science" designed to achieve political objectives, rather than provide valid information. Unfortunately, politically active researchers are also adept at lobbying for government-funded activist research, and the resulting activist research can have adverse effects on public policy.

Some of the worst examples of government-funded activist science are found within the National Institute of Environmental Health Sciences (NIEHS). Consider the agency's research program related to the chemical bisphenol A (BPA), which is used to make clear hard plastics and the resins that line metal food containers. The activist campaigns against BPA have been fueled by taxpayer-funded research of questionable value, much of it supported by NIEHS grants. Between 2000 and 2014, the National Institutes of Health doled out \$172.7 million for BPA research grants, according to a tally compiled by Citizens against Government Waste. That group estimated that 70 percent of those funds were spent between 2010 and 2014, coinciding with the appointment of Linda Birnbaum as director of NIEHS. Birnbaum and other anti-BPA activists have lobbied for and distributed government funds as part of a coordinated effort to promote bans.

Although this government-funded activist science is weak and runs contrary to comprehensive research that has demonstrated BPA's safety, those faulty studies promote alarming news headlines and generate unwarranted fear. As a result, state governments

### **Congress should:**

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- ◆ Conduct oversight hearings on activist science in the federal government, particularly at the National Institute of Environmental Health Sciences (NIEHS) within the National Institutes of Health.
- ◆ Defund activist science to save taxpayer dollars, or reallocate funds to more worthy causes, such as research to develop cures for cancer.

are advancing bans and other regulations, while industry is voluntarily removing BPA from its products.

Unfortunately, replacement products may prove more dangerous. For example, elimination of BPA resins in food packaging could lead to food waste, spoilage, and food-borne illnesses. BPA is just one example of how activist science undermines consumer freedom and public welfare, which underscores why Congress should work to prevent government-funded activist science.

Expert: Angela Logomasini

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## PROTECT FEDERALISM AND AMERICAN ADULTS' ACCESS TO ONLINE GAMBLING PLATFORMS

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The morality of gambling has long been decided in the United States. All but one state has some form of gambling, all but six have lotteries, and as of 2016, 28 states have gambling online. With a few exceptions, the regulation of intrastate gambling activities has been left to the states, as is their right under the Tenth Amendment of the Constitution. Yet 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. States have moved swiftly to modernize their laws in response to changing market conditions and the attitudes of their populations, taking illegal activities out of the shadows, implementing consumer protections, and bringing in new revenue for the states. However, some in Congress want the federal government to impose and maintain unconstitutional national prohibitions on some gambling activities.

Although states have traditionally regulated intrastate gambling, some members of Congress are trying to block state laws regarding online gambling. They are doing so by amending the Wire Act, a law from the 1960s that was only ever meant to regulate *sports* betting, over fears that states will 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 as conduits for money laundering or other crimes. But some in Congress would rather push such activities back into the black market, where between 2003 and 2010, Americans spent more than \$30 billion gambling on foreign-operated websites.

The Restoration of America's Wire Act (RAWA), sponsored by Rep. Jason Chaffetz (R-Utah) in the 114th Congress, would rewrite the 1961 law, creating a sweeping online gambling prohibition. Proponents claim that RAWA is necessary to “restore” the Wire Act to its original intent—to protect consumers and preserve federalism. In reality, it would do exactly the opposite. Amending a 53-year-old law to create a national prohibition now would do profound damage to the principle of federalism, undermine state sovereignty, and undercut the protections for online gamblers instituted by states, thereby forcing players into the black market.

**Congress should:**

- ◆ Protect the principle of federalism, Internet freedom, and consumer safety by rejecting the Restoration of America’s Wire Act or any other proposals to prohibit or limit Internet gambling or that interfere in any way with state-based regulation of online gambling.

The original intent of the Wire Act is unambiguous. Attorney General Robert Kennedy, his assistants, and Congress understood that the law was meant to target organized crime, “to assist the various States in enforcement of *their* laws,” and only to prohibited wire transmissions of “certain gambling information in interstate and foreign commerce,” not *all* gambling information. Furthermore, subsequent Congresses recognized that the Wire Act did not prohibit online gambling, as evidenced by the fact that between 1995 and 2003, Congress considered no fewer than 23 bills to establish such a ban, and none were accused of being unnecessary because a ban already existed. In 2011, the Justice Department’s Office of Legal Counsel restored that original understanding of the Wire Act—a move some in Congress saw as a “unilateral” reinterpretation. In 2013, a group of mostly Republican members of Congress, led by Rep. Chaffetz, introduced RAWA in response.

RAWA proponents claim to worry about online gambling increasing 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 Western nations. Online sites may even be better equipped to identify and help players who exhibit signs of disordered behavior, because unlike at a brick-and-mortar casino, a person’s online behavior can be monitored and analyzed by sophisticated algorithms.

RAWA proponents also insist that the nature of the Internet makes it impossible to contain online gambling within state boundaries. Should some states be allowed to offer online gambling, those wishing to prevent residents from gambling online will be unable to block access. Therefore, Internet gambling is necessarily interstate, they claim. That concern is without merit, and such logic—should it prevail—sets a

dangerous precedent for other forms of online commerce. Technology exists to track users' location and block them if necessary, as the states with legal online gambling and the dozens of countries with legal online gambling have shown.

States have proved that they are more than capable of regulating these activities. Federal laws and mechanisms already exist to regulate or prosecute operators that violate the laws of other states or nations. And should Congress eventually enact a prohibition on Internet gambling, there is no doubt that Americans will simply return to the foreign-operated illegal market, with few or no consumer protections.

Clearly, there is no justification or pressing need to rewrite a 50-year-old law and to create a national Internet gambling prohibition that 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.

Expert: Michelle Minton

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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>.

## REPEAL THE PROFESSIONAL AND AMATEUR SPORTS PROTECTION ACT

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Although Washington generally defers to states on matters of intrastate gambling, as is states' prerogative under the Tenth Amendment to the Constitution, a notable exception is the regulation of sports gambling. The 1992 Professional and Amateur Sports Protection Act (PASPA) prevents states from legalizing and regulating sports gambling. As a dozen states considered laws regulating sports gambling in the late 1980s and 1990s, some members of Congress feared that betting on amateur and professional games jeopardized the integrity of sports—and the public perception thereof. PASPA, endorsed by the major sports leagues, thwarted the expansion of sports betting and created a government-granted monopoly on sports betting, exempting from the ban only the four states that had some form of sports gambling prior to the law.

Since then, a robust black market has emerged with Americans spending hundreds of billions on illegal sports gambling even as states sue for the right to regulate it. PASPA clearly violates the spirit of the Tenth Amendment, and many scholars believe that should the U.S. Supreme Court ever take up a challenge to the law, it likely would not survive.

Apart from four states—Delaware, Nevada, Montana, and Oregon—federal law prohibits states from sponsoring, operating, advertising, promoting, licensing, or authorizing sports gambling unless they had already done so by 1993 (Professional and Amateur Sports Protection Act, 1992, 28 U.S. C. Chapter 178, <https://www.law.cornell.edu/uscode/text/28/part-VI/chapter-178>). The law, however, has not stopped Americans from wagering on sports, online or off. It is estimated that Americans illegally wager upward of \$400 billion on sports annually. Unsurprisingly, in the wake of the late-2000s economic downturn, lawmakers grasping for new sources of revenue to fill gaps in state budgets would like to tap into the billions being wagered illegally in their states, with at least five—California, Delaware, New Jersey, New York, and Pennsylvania—challenging the federal statute. As New Jersey phrased it in its recent court

### **Congress should:**

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- ◆ Repeal the Professional and Amateur Sports Protection Act to reverse the damage done to the principles of federalism and individual rights, and allow states to regulate intrastate gambling activities as they see fit.

challenge to the law, it would “conscript and commandeer states into instrumentalities of the federal government.”

In addition to its unconstitutionality, the ban is also counterproductive. Although lawmakers hoped the ban would protect the perceived integrity of sports, all it really did was protect illegal sports bookies and gambling rings. In contrast, allowing states to legalize and regulate the activity would give regulators and sports leagues the ability to track betting behavior and identify signs of corruption. More important, it would give states the opportunity to establish consumer protections, prevent fraud, protect privacy, and institute safeguards for minors and those with addiction.

If the purpose of PASPA was to protect the integrity of sports and uphold the nation’s moral values by preventing a “culture of gambling” among our youth, it has utterly failed. In 1991, illegal sports betting was just a \$40 billion a year industry, but 23 years later, the market for illegal sports betting is nearly 10 times that amount.

America’s perspective on the morality of gambling has shifted. Where once there was reluctance to expand legal gambling, surveys now indicate that an overwhelming majority do not oppose or strongly favor the legalization of sports betting. Regardless of the outcome of any future Supreme Court case on the constitutionality of PASPA, it is high time Congress rectified the damage it did to federalism when it enacted the Professional and Amateur Sports Protection Act in 1992.

Expert: Michelle Minton

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