BRIEFLY NOTED

Legislating Drug Price Transparency

BY THOMAS A. HEMPHILL

The U.S. pharmaceutical industry has once again become a target of consumers' and politicians' ire. In the past few years, public outcry ensued after a new, blockbuster drug was marketed at a seemingly exorbitant price and an older, off-patent generic drug underwent a progression of price hikes.

The former controversy was over the drug Harvoni, first released by Gilead Sciences in 2014. Harvoni can completely cure many people of the most common type of hepatitis C (and with few side effects), resulting in its being hailed by the medical community as a major breakthrough. However, the patient cost of this "miracle drug"—$94,500 for a 12-week treatment—elicited a firestorm of condemnation. By late 2014, both Democrats and Republicans on the U.S. Senate Finance Committee were demanding detailed cost data on Harvoni from Gilead Sciences because the new drug was already placing an additional strain on the budgets of state and federal health care assistance programs.

The latter controversy was over Turing Pharmaceutical's marketing of Daraprim, a medication used to treat protozoal infections in AIDS and cancer patients. Daraprim is on the World Health Organization's List of Essential Medicines. In the summer of 2015, Turing announced that the drug's price would rise from $13.50 to $750 per tablet—a 5,500% increase.

Public and employer concern / A recent national survey shows that the average American consumer is alarmed at these skyrocketing prescription and brand-name pharmaceutical prices. Just over three-fourths of those surveyed believe that brand-name prescription drug prices are unreasonably high today, including 80% of Democrats and 70% of Republicans. Although media attention has focused on a small number of very high-priced medicines to treat debilitating diseases, a majority of survey respondents report greater concern for future rising prices for more routine brand-name drugs. This concern is fueling support for major governmental action to negotiate or set future drug prices.

American consumers aren't alone in their concern about rising drug prices; so are their employers. Willis Towers Watson, a leading global workforce advisory firm, surveyed employers about their top health coverage concerns heading into the 2017 open enrollment season. The firm found that nearly nine in 10 employers identified managing prescription drug expenses—especially for specialty drugs—as their top priority.

State action / According to Aaron Kesselheim, an associate professor of Medicine at Harvard Medical School, transparency initiatives may be more palatable than tackling price caps or patent protection. "Who could be opposed to transparency?" asked Kesselheim rhetorically, speaking at a March 2017 American Medical Association advocacy conference. "To the extent that all of them are difficult hills to climb, that one might be easier because we're not changing anything, we just want things to be more open. So that seems more doable in the short term."

According to the National Conference of State Legislatures (NCSL), at least 14 states considered legislation involving prescription drug manufacturer price transparency in their 2015–2016 legislative sessions. In essence, such legislation would require drug makers to report and justify price increases that lawmakers consider questionably large. The NCSL also found that eight states considered bills that would place drug pricing transparency requirements on health insurers, with Arkansas, South Dakota, and Texas adopting such legislation. Ten states and Puerto Rico considered legislation requiring pharmacy benefit managers (PBMs)—third-party administrators of prescription drug programs—to provide price transparency, with Delaware and Maine signing those bills into law.

The NCSL reports that 15 states have legislation pending related to drug price transparency as of early March of this year. One such state is Maryland, which has two bills, one to require drug manufacturers to explain price hikes, and a second to allow legal action for excessive price increases.

Vermont / The first state to implement drug price transparency legislation was Vermont in June of 2016. "This bill is about accountability," explained Gov. Peter Shumlin of the enacting legislation. He continued:

> The reality is that we have pharmaceutical companies raising prices on lifesaving drugs 5,000%. When asked about those outrageous increases, CEOs are literally laughing in front of Congress. That needs to change.

Under the legislation, the Green Mountain Care Board—a Vermont health care regulator—works in conjunction with the Department of Vermont Health Access to develop an annual list of either (1) the 15 drugs for which "significant health care dollars are spent and where list (i.e., 'wholesale acquisition cost') prices rose by 50 percent or more over the previous five-year period," or (2) 15 medicines whose list prices rose 15% or more over a 12-month period for the state's Medicaid program. Also, the 15 drugs identified by these agencies must represent different drug classes. The Green Mountain Care Board then provides the state attorney general the

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compiled list, including the percentage of the wholesale acquisition cost increase for each drug. The drug cost information is made publicly available on the Green Mountain Care Board's website.

Under the law, pharmaceutical manufacturers need to disclose "all the factors that have contributed to a price increase," including detailed cost breakdowns, and justify the increases to the attorney general in a format that is "understandable and appropriate." The attorney general can seek injunctive relief, costs, and attorney fees if these companies decline to provide the requested information, where each civil violation carries a $10,000 civil penalty.

Congress Acts? / On September 14, 2016, a bipartisan bill, the Fair Accountability and Innovative Research (FAIR) Drug Pricing Act, was introduced in Congress by cosponsors Sen. John McCain (R-Ariz.) and Sen. Tammy Baldwin (D-Wisc.) in the Senate, and by Rep. Jan Schakowsky (D-Ill.) in the House. This legislation was not enacted in the 114th Congress, and has yet to be re-introduced in the 115th Congress.

Under the legislation, drug manufacturers would have been required to report in advance to the U.S. Department of Health and Human Services (HHS) a price increase of more than 10% over a 12-month period for certain drugs. As part of their reports, the manufacturers would have had to provide a justification for each price increase, manufacturing and research and development costs for the qualifying drug, net profits attributable to the drug, marketing and advertising spending on the qualifying drug, and other information as deemed appropriate.

The bill would not have prohibited manufacturers from increasing prices, but it would have given taxpayers notice of price increases and would have brought a basic level of transparency to the market for prescription drugs. The HHS would have made the information from these reports (excluding any proprietary and confidential information) publicly available in an understandable online format within 30 days. Moreover, the HHS would have been required to submit an annual report to Congress summarizing the information and reports submitted by drug manufacturers.

In a June 15, 2016 *Stat News* article, an unnamed spokeswoman for the Pharmaceutical Research & Manufacturers Association, the drug industry's trade association, said that the FAIR Drug Pricing Act "will not benefit patients" or provide information that they could use. "Instead it focuses on isolating research and development costs for the few medicines that make it to patients in a thinly veiled attempt to build a case for government price setting," the spokeswoman argued. Moreover, she maintained that drug manufacturers already disclose "extensive information" about R&D costs, "a wealth of information about effectiveness and safety" before clinical research that is published on public websites, and "aggregated information about negotiated and required rebates is included in company financial filings."

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Will greater transparency work? /Returning to Vermont, the state has been a bellwether for legislation addressing alleged "excesses" of the pharmaceutical industry. The recent legislation continues that trend. It will most likely capture popular generic drugs (and increase compliance costs for those companies) among the state's list of the top 15 drugs, because it focuses on *percentage* price increases where this category of pharmaceutical has a low list price. Conversely, because the legislation focuses on price increases, Vermont's legislation will not capture newly introduced drugs initially offered to the public at seemingly exorbitant prices. Yet, the new legislation will provide information for the state's Medicaid program and the Green Mountain Care Board will have to decide whether the state will pay for certain drugs.

A December 2016 report issued by the Vermont attorney general's office identified 10 drugs of concern. While manufacturers were asked to submit explanations of all factors that contributed to price increases and estimate percentages attributable to each factor, none of those specific answers are explained in the report. Rather it merely summarizes some of the reasons given, including the industry's need to invest in research and development. As required in the state's legislation, the law has a confidentiality provision that does

not allow for companies' written responses to be made publicly available. Thus, the efficacy of this transparency legislation is being called into question by many of the legislation's original critics.

An issue with many of the proposed state bills is that they offer percentage thresholds in annual (or multi-year) price increases that must be exceeded before a drug manufacturer is required to justify its cost to a state government's satisfaction. These percentage thresholds will offer visible targets for pharmaceutical manufacturers to consider when making their pricing decisions. While providing an annual price increase ceiling for some pharmaceutical manufacturers who do not want to make a state's list, these laws could perversely entice other drug manufacturers to raise prices yearly rather than risk one large (and reportable) increase in the future. Also, if other states pass legislation similar to Vermont, the lowest percentage price increase will likely establish a national threshold for pharmacy manufacturers concerned with such transparency legislation—unless the FAIR Drug Pricing Act is re-introduced and enacted in the 115th Congress, which would result in a 10% annual ceiling. The net result could conceivably be an overall increase in the price of prescription drugs.

Another legitimate criticism of these laws concerns the use of "list price" terminology. These wholesale prices are simply starting points for negotiations with PBMs and health care insurers. For example, according to data compiled in 2015 by the Drug Channels Institute, a pharmaceuticals consultancy, the combined top three PBMs (Express Scripts, CVS/Caremark, and United Health Group/OptimumRx/Catamarin) controlled 75% of market share by total equivalent prescriptions in 2014, worth an estimated $263 billion annually. These large buyers will negotiate a final price for a pharmaceutical, and that price often includes substantial rebates. Depending on competition in the market for a drug, a pharmacy manufacturer may provide steep rebates, i.e., discounts, on their product to the increasingly concentrated PBM industry. For insulin, which is a highly competitive market, Eli Lily reportedly offered rebates off its list price in 2014 averaging 56% to PBMs and health insurers. As a result, the net price of insulin increased by only 3% over the previous five years.

Another area of concern to the pharmaceutical industry is the public release of trade secrets. In a May 30, 2016 letter to the editor in the *Pittsburgh Post-Gazette,* Robyn Boerstling, a vice president for the National Association of Manufacturers, noted the industry's concerns about the recently enacted Vermont legislation:

> Manufacturers understand the need to reduce health care costs, but we have serious concerns related to the long-term implications of pharmaceutical pricing transparency proposals. Protection of trade secrets and intellectual property is a necessity for manufacturers to succeed in today's intensely competitive global marketplace. No industry should be forced to turn over highly sensitive, proprietary information to any government—state or federal.

Boerstling goes on to note, "Trade secrets, which include pricing information, are protected by both federal and state laws."

Whether the Vermont legislation improperly asks for proprietary information that is part of the overall drug development process, and whether this request would cause competitive harm to a pharmaceutical manufacturer, is yet to be decided by the Vermont judiciary. At this time, the pharmaceutical industry has not challenged the lawfulness of the Vermont law—but that situation could change quickly. R

Populism and Protectionism

BY PIERRE LEMIEUX

The recent French election illustrated what may look to many like an intriguing fact: the rejection of free trade by both extreme-left and extreme-right populism. The extreme-right candidate, Marine Le Pen, presented herself as an opponent of globalization, promising a "smart protectionism" and vowing to "reject free-trade agreements," to establish a "reindustrialization plan," and to hire 6,000 new customs agents. "We need protectionism," claimed a press release by the vice-president of the National Front, Le Pen's party. Jean-Luc Mélenchon, the extreme-left candidate, criticized "deindustrialization" and promised "solidary protectionism," "industrial sovereignty," and French exit from the World Trade Organization.

Both programs would undermine free trade and freedom to work within the European Union. In practice, there is little difference between Le Pen's "smart protectionism" and Mélenchon's "solidary protectionism."

Today's populists oppose free trade even when they don't stand at the extremes of the political spectrum. In the United States, both Donald Trump and Bernie Sanders campaigned for protectionism. Many other examples could be given, including most if not all populist third parties in Europe.

Authority and "the people" / The *Encyclopedia Britannica* defines "populism" as a "political program or movement that champions the common person," noting that it "usually combines elements of the left and the right." Authoritarian populism is "typically critical of political rep-

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resentation and anything that mediates the relation between the people and their leader or government."

A number of reasons account for the marriage between populism and protectionism.

First, the common person does not understand how free trade benefits the vast majority of people. This ignorance is not surprising if only because the typical voter remains "rationally ignorant" of such matters. At least on this topic, ignorance is more prevalent among the less educated. There is evidence, including in a recent WSJ/NBC opinion poll, that individuals without a college degree are more likely to think free trade is detrimental (*Wall Street Journal,* February 26, 2017). But even among the educated, only a small minority understand the economic theory of trade.

A second reason why populists naturally favor protectionism is that the common person is more likely to fear foreigners, if only because he travels less and meets fewer strangers. As the word says, strangers are strange.

The third reason is that populism needs much state power, which free trade undermines. A populist leader may say he is working on behalf of "the people," but at best he can only impose the preferences of the majority (or a large plurality) on the rest of the citizenry. "The people" do not have identical preferences and unanimous opinions. However much the populist leader wants to be loved, he will only be able to satisfy the preferences of some people. He will only satisfy his supporters—and then only some of their preferences. Power is required to steamroll minority preferences. Given the real or fictitious crises that typically spark and fuel populism, additional power will be needed. You don't satisfy a mob by throwing roses to minorities.

When Trump said in a campaign advertisement, "We will be unified, we will be one, we will be happy again," he was dreaming or uttering balderdash. No more unity would have been generated under Sanders; it would have been just another majority (or plurality) denying the preferences of another minority.

Free trade is an obstacle to any sort of government authoritarianism, including populist authoritarianism. Under free trade, domestic policies that would increase the cost of goods and services (say, by maintaining inefficient manufacturing) will be circumvented by imports. The free movement of capital, which is part of free trade, is also a powerful restraint on authoritarian governments. If your savings are threatened, you can transfer them to another country. If worse comes to worse, you can leave and bring your money with you—or, today, telecommute from a foreign abode and receive payments from your customers over the border. Needing more power, populist leaders will favor protectionism.

Dual (or multiple) citizenship is an interesting case study. Populist or authoritarian governments don't like dual citizenship because it allows their citizens to escape more easily. The more authoritarian the state is, the more captive a citizenry it wants. It is significant that Le Pen has voiced her opposition to dual citizenship.

These reasons are reinforced by a fourth one: the establishment—the populists' bête noire—has come to side with institutions that appear to favor free trade—that is, with "globalization." Established international organizations such as the World Trade Organization, the World Bank, the International Monetary Fund, and the Organisation for Economic Co-Operation and Development have acquired a bias against protectionism. The fact that many economists work for these organizations has reinforced their free trade orientation.

This is the result of seven decades of trade liberalization. Members of the political and economic establishment are typically more cosmopolitan than others: they travel more, are more likely to have dual citizenships, and so forth.

Yet, we are still very far from having truly free trade. Not only has the liberalization movement been stalled for two decades, but much of what passes for free trade is partially managed trade and is viewed as a concession from national states. The establishment's free-trade bias is only a matter of degree. But it is apparently sufficient to provoke the populist ire.

These observations are not meant to depreciate common people, but to emphasize why they easily fall for populist rulers from whom, to borrow from H.L. Mencken, they will "get it good and hard." R

BRIEFLY NOTED

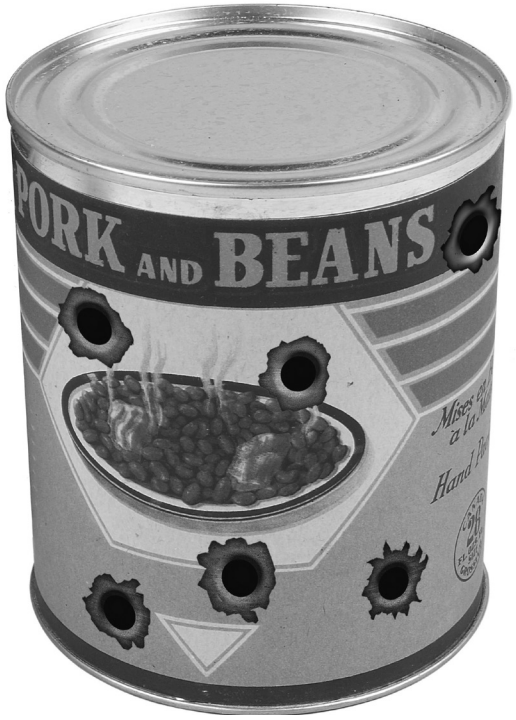
Fearless Fosdick and Trump's Immigration 'Pause'

BY BRUCE YANDLE

The Trump administration's efforts to bar entry into the United States of people from several Muslim-majority countries have been justified as necessary to reduce Americans' risk of death from terrorism. Though these travelers—especially refugees—already are scrutinized before receiving entry visas, President Trump and his staffers claim this scrutiny is insufficient and must be "paused" so that "extreme vetting" mechanisms can be drawn up and implemented.

The Trump White House considers risk reduction of terrorism to be of paramount importance and no counterweighing concern—including the harm that could befall refugees attempting to flee to the United States, or the negative effects of such a ban on the United States' reputation, or the loss to American society and the economy from losing these immigrants—are adjudged important enough to offset the value of that risk reduction.

But removing risk is itself risky business. Through the travel ban and ensuing "extreme vetting," President Trump hopes to avoid a false negative or "Type II" error—mistakenly considering "safe" a traveler with lethal intentions. However, strong sensitivity to Type II errors increases the likelihood of Type I errors, which in this case would be the turning away (whether temporarily or permanently) of benign travelers at a cost to both those travelers and the United States. Showing disregard for holders of travel visas (and in the ban's original form, U.S. green cards) generates costly uncertainty for a large category of people who contribute to the nation's well-being. When these and other costs are imposed on tens of thousands of innocent people, the cost becomes quite large.



This point was made memorably years ago by Al Capp, the creator of the legendary comic strip *Li'l Abner*. Though the strip primarily dealt with the exploits of Li'l Abner, Daisy Mae, and the other denizens of Dogpatch, Capp would sometimes take a break from that storyline to tell tales (or in some cases, just a panel or two) of L'il Abner's favorite comic book character, police detective Fearless Fosdick.

Fosdick was a parody of Dick Tracy, a combination of Barney Fife and Roscoe P. Coltrane (without the corruption), with Tracy's square jaw. One of Fosdick's nemeses was Anyface, a master of disguise who could appear at first as, say, an innocent old woman, but then transform into a gasoline pump if Fosdick appeared to be on his trail. Anyface was determined to unleash mayhem on the unnamed metropolis Fosdick protected—in today's words, he was a terrorist.

In one episode, Anyface let it be known that he had poisoned a can of Old Faithful Pork-n-Beans, which happened to be the community's favorite delicacy. Hardly a meal was enjoyed without a serving of the beans, and Anyface knew that.

Wrestling with the problem and what to do about it, Fosdick's boss, The Chief, gathered together his inner circle to form a strategy. A bunker mentality prevailed. It was law and order against terrorism, good against evil, right against wrong.

After some deliberation, The Chief had a revelation: he simply instructed trusty Fosdick to make certain no one would die from eating Old Faithful beans. Fosdick took his orders seriously. To avoid a Type II error, he immediately went to the Old Faithful factory, shut it down, and impounded all the beans in the warehouse. He likewise impounded all the beans in grocery stores and at wholesalers.

But then he realized: what if someone had already purchased the poisoned can and the beans were simmering on the stove or in bowls ready to serve? Heaven forbid, what if people in some restaurant were lifting a forkful of the lethal beans to their lips at that very moment? Remembering his charge from The Chief—don't let anyone die from eating poisoned beans—Fosdick knew what to do.

Rushing from house to house and from café to restaurant, when Fosdick saw people about to heat up a can of beans, he shot them. If people appeared to be ready to eat some of the beans, he shot them, too.

When the episode ended, no one had died from Anyface's can of poisoned beans, but many had died from Fosdick's gun.

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Still, with the terrorist Anyface held at bay, Fosdick smiled. He had made the classic Type I/Type II tradeoff. He had made sure that no one would fall ill or die from poisoned beans. Problem is, he had wiped out part of the population in doing so.

Our nation is exposed to terrorism risk. Because our president is sworn to protect us, extreme vetting and even more costly actions may be imposed on innocent people. While none will be shot in an effort to avoid allowing terrorists to enter the country, an abrupt slamming of the door on foreign travelers imposes a cost on each innocent traveler denied at the threshold. There is also a cost imposed on the rest of us when chastened, foreign opportunity-seekers decide to seek their fortunes elsewhere.

President Trump, like Fosdick, may be successful in preventing death in this country from the hands of terrorists. But depending on how he does this, he can erode the wealth-creating process as well as bruise some precious ideas that define this nation.

Sadly, there is no such thing as free protection from terrorist harm. Knowing that, we should move cautiously when tightening the screen that, while guarding us from harm, limits the entry of the ultimate resource: creative and productive human beings who wish to pursue the American dream. R

Sorry Mr. Ruckelshaus, But Your Old Agency Is a Shambles

BY HENRY I. MILLER

William Ruckelshaus, who served twice as head of the U.S. Environmental Protection Agency, recently took to the opinion pages of the *New York Times* to defend his old agency ("A Lesson Trump and the E.P.A. Should Heed," March 7, 2017). He claimed the EPA has achieved cleaner air and water for the nation and posited that it "represents one of the clearest examples of our political system listening and responding to the American people."

Ruckelshaus, who is now in his mid-80s, has been away from the EPA for 32 years and the rosy picture he paints of expert, efficient bureaucracy is very different from the reality of recent decades. I know first-hand that it was different even during his second, short stint there from 1983 to 1985.

Blocking innovation / When I joined the U.S. Food and Drug Administration in 1979, I was essentially apolitical and knew next to nothing about federal regulation. A science nerd, I had spent the previous 16 years in college, graduate school, medical school, and post-doctoral training. It didn't take long until I learned about the jungle of government bureaucracies. And one of the darkest and most dangerous parts of that jungle was the perfidious and incompetent EPA, one of the FDA's siblings.

I found the EPA, several of whose major programs I interacted with, to be relentlessly anti-science, anti-technology, and anti-industry. The only thing it seemed to be *for* was the Europeans' innovation-busting "precautionary principle," the view that until a product or activity has been proven safe definitively, it should be banned or at least smothered with regulation. (See "The Paralyzing Principle," Winter 2002–2003.) In fact, during international discussions and negotiations over the harmonization of biotechnology regulations in which I participated, the EPA often seemed allied with the European Union and committed to working against U.S. interests. At home, its officials seemed to be taking their marching orders from the most radical elements of the environmental movement.

The EPA has unilaterally killed off entire, once-promising sectors of U.S. research and development. The use of genetically engineered microorganisms for bioremediation—that is, the biological cleanup of toxic wastes, including oil—is one.

Accidents that result in oil spills are inevitable as long as they can be caused by human or mechanical failures or the vagaries of weather. During the 1980s, microorganisms genetically engineered to degrade spilled oil were developed in laboratories. But draconian EPA regulations discouraged their testing and commercialization, ensuring that the techniques available for responding to these disasters remain low-tech and marginally effective. Those measures include such archaic methods as deploying booms to contain the oil, burning or spraying chemicals to disperse it, and spreading absorbent mats.

At the time of the catastrophic 1989 Exxon Valdez spill in Alaska, there were great expectations for modern biotechnology applied to bioremediation. William Reilly, then head of the EPA, later recalled, "When I saw the full scale of the disaster in Prince William Sound in Alaska ... my first thought was: Where are the exotic new technologies, the products of genetic engineering, that can help us clean this up?"

He of all people should have known. Innovation had been stymied by Reilly's own agency's hostile policies toward the most precise new genetic engineering techniques.

Another biotech sector that the EPA relegated to oblivion was protection of crops from frost damage. Peaches, plums, citrus, and other crops are regularly threatened by frost in the Southeast, resulting in losses that can total in the billions of dollars. California is also susceptible: A January 2007 freeze there cost farmers more than $1 billion in losses of citrus, avocados, and strawberries, and a 1990 freeze caused

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about $800 million in damage to agriculture, resulting in the layoff of 12,000 citrus-industry workers, including pickers, packers, harvesters, and salespeople.

Farmers fight freeze damage with pathetically low-tech methods. These include burning smudge pots, which produce warm smoke; running wind machines to move the frigid air; and spraying water on the plants to form an insulating coat of ice.

In the early 1980s, scientists at the University of California, Berkeley and in industry devised a more ingenious approach. They knew that a harmless bacterium, *Pseudomonas syringae*, which normally lives on many plants, contains an "ice-nucleation" protein that promotes frost damage. They produced a variant of the bacterium that lacked the ice-nucleation protein, reasoning that spraying this variant bacterium (dubbed "ice-minus") on plants might prevent frost damage by displacing the common, damage-promoting kind. Using precise genetic engineering techniques, the researchers deleted the gene for the ice-nucleation protein and planned field tests with ice-minus bacteria.

Then the EPA stepped in and that was the beginning of the end. Regulators classified as a *pesticide* the innocuous ice-minus bacterium, which was to be tested in Northern California on small, fenced-off plots of potatoes and strawberries. How could it be a pesticide? Because the regulators considered the naturally occurring, ubiquitous "ice-plus" bacterium a pest because its ice-nucleation protein promotes ice crystal formation that damages plants. Therefore, they reasoned, other bacteria intended to displace it would be a pesticide. This is the kind of absurd, sophistic reasoning that could lead the EPA to regulate trash-can lids as pesticides because they deter or mitigate a pest, namely raccoons.

At the time, scientists inside and outside the EPA were unanimous that the test posed negligible risk. (I wrote the FDA's opinion.) No new genetic material had been added; only a single gene, whose function was well-known, had been removed, and the organism was obviously harmless. Nonetheless, the field trial was subjected to an extraordinary long and burdensome review only because the organism was created with modern genetic engineering techniques.

It is noteworthy that experiments using bacteria with identical traits but constructed with older, cruder techniques require no governmental review of any kind. When tested on less than 10 acres, nongenetically engineered bacteria and chemical pesticides are exempt from regulation. Moreover, there is no government regulation of the use of vast quantities of the ice-plus organisms, which are commonly blown into the air during snowmaking at ski resorts.

Policy by policy and decision by decision, the EPA has damaged the nation's competitiveness, ability to innovate, and capacity to create wealth.

Although the ice-minus bacteria proved safe and effective at preventing frost damage in field trials, further research was discouraged by the combination of onerous government regulation, the inflated expense of doing the experiments, and the prospect of huge downstream costs of pesticide registration. As a result, the product was never commercialized and plants cultivated for food and fiber throughout much of the nation remain vulnerable to frost damage. We have the EPA to thank for putting farmers' livelihoods in jeopardy, jobs lost, and inflated produce prices for consumers.

Flawed decisions / During the two decades since I left government service, I've continued to watch the EPA's missteps and excesses with a mixture of awe and vexation. Policy by policy and decision by decision, the EPA has damaged the nation's competitiveness, ability to innovate, and capacity to create wealth.

The EPA's ever-expanding regulation imposes huge costs on American businesses and ultimately on consumers. An analysis by the Competitive Enterprise Institute estimates that the annual cost of compliance with EPA regulations is more than a third of a trillion dollars.

The EPA is the prototype of agencies that spend more and more to address smaller and smaller risks. In one analysis by the Office of Management and Budget of the 30 least cost-effective regulations throughout the government, the EPA had imposed no fewer than 17.

One of the EPA's most controversial recent actions was to redefine "navigable waters" for the purpose of regulating them under the Clean Water Act. Under the new definition these include virtually every body of water in the nation right down to the smallest of streams, farm ponds, and ditches. (Pursuant to an order from President Trump, this travesty is now being reversed.)

Another example of flawed EPA decisionmaking was the imposition of overly stringent ambient air standards under the Clean Air Act. Clean air is desirable, of course, but an EPA rule finalized in February 2012 that created new emissions standards for coal- and oil-fired electric utilities was ill-conceived. According to an analysis ("Government Regulators Were Too Busy in 2012," Dec. 28, 2012) by Diane Katz and James Gattuso of the Heritage Foundation:

> The benefits are highly questionable, with the vast majority being unrelated to the emissions targeted by the regulation. The costs, however, are certain: an estimated $9.6 billion annually. The regulations will produce a significant loss of electricity generating capacity, which [will] undermine energy reliability and raise energy costs across the entire economy.

Transgressions / Regulatory excesses are one thing; dishonesty and mendacity are something else. An EPA subterfuge that has received attention from the U.S. Senate's Environment and Public Works Committee is the "sue-and-settle" maneuver the EPA uses frequently to advance

its agenda in a way that substitutes a judicial mechanism for the customary, prescribed interface between legislation and agency rulemaking.

The way this works is that environmental groups (some of which receive government grants) sue the federal government on the grounds that agencies are failing to meet their regulatory obligations, and then—behind closed doors—the activists and regulators concoct a settlement agreement that furthers activists' (and regulators') extra-statutory goals. Thus, sue-and-settle is a strategy that circumvents both congressional intent and the rulemaking process.

Last year, investigators found two flagrant transgressions of federal law by the EPA: engaging in "covert propaganda" and "grassroots lobbying." The Government Accountability Office discovered that the EPA illegally used Thunderclap, a social media site, "to correct what [the EPA] viewed as misinformation." Government use of social media is not unlawful per se and many agencies use it to communicate their actions and policies to the public. But the EPA crossed the line when it asked members of the public to share EPA-composed propaganda on Facebook or Twitter without attributing it to the government. Neglecting to reveal the source was the basis of the "covert propaganda" violation because the law says that citizens must know when messages presented to them were created by their government.

Federal agencies are supposed to be apolitical and federal law prohibits lobbying for or against proposed legislation. But an EPA blog post contained links to websites that encouraged the public to, for example, "urge your senators to defend Clean Water Act safeguards for critical streams and wetlands." This "grassroots lobbying" was a violation of federal law because, at the time, Congress was considering a number of pieces of legislation to derail the EPA's "waters of the United States" regulation. Not surprisingly, the EPA wanted those bills to be defeated.

The above examples are by no means an exhaustive list. For at least the past three decades, the EPA has been a rogue agency—ideological, poorly managed, dishonest, and out of touch with sound science and common sense. It is emblematic of what *Wall Street Journal* columnist Bill McGurn has condemned as the "soft despotism" of the "unelected and increasingly assertive class that populates our federal bureaucracies and substitutes rule by regulation for the rule of law."

The new head of the EPA, Scott Pruitt, made clear in a recent interview that things are about to change. According to Pruitt:

> This past administration didn't bother with statutes.... They displaced Congress, disregarded the law, and in general said they would act in their own way. That now ends.

About time.