CEI PLANET
ADVANCING LIBERTY FROM THE ECONOMY TO ECOLOGY
COMPETITIVE ENTERPRISE INSTITUTE VOLUME 25, NUMBER 1 JANUARY/FEBRUARY 2012

The FDA vs. Commercial Speech

BY GREGORY CONKO AND HENRY I. MILLER

The ability of physicians to prescribe approved medicines for purposes not sanctioned by the Food and Drug Administration (FDA) is one of the most important elements of medical care in the United States. Not only are these "off-label" uses perfectly legal, doctors rely on them extensively. However, the FDA views off-label prescribing as an attempt to circumvent its control over the nation's pharmaceutical supply, so it maintains a number of regulations that make it difficult for doctors to learn about and prescribe drugs off-label.

The most prominent such rule entirely forbids drug manufacturers from promoting off-label uses. That might change soon, however, as two different federal courts are now considering lawsuits challenging the constitutionality of the off-label promotion ban. And given a string of recent Supreme Court cases affirming commercial free speech rights, one of those cases may at least partially invalidate the FDA's restrictions.

Before a drug can be sold in the United States, it must be certified by the FDA as safe and effective for a specific, or "on-label," use. However, once a drug is approved, physicians may legally prescribe it for any other purpose. And because medical research regularly discovers new treatment options years before the FDA can approve them, off-label prescribing enables patients to benefit from the most up-to-date knowledge.

The practice is ubiquitous in cancer treatment, cardiology, and neurology, and by some estimates, at least 20 percent of all prescriptions written are off-label. The American Medical Association says that many off-label uses are considered "reasonable and necessary medical care, irrespective of labeling." In fact, doctors can be subject to malpractice liability if they do not use drugs for off-label indications when doing so constitutes the standard of care. That's one reason Medicare, Medicaid, and most private health insurance plans with prescription drug benefits cover various off-label uses.

The FDA acknowledges this in theory. According to the agency's website, "Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment." But the agency doesn't make it easy for doctors or patients to learn about new off-label uses.

Doctors learn about some off-label uses in medical school, and later by reading medical journals articles or hearing about them from colleagues or at conferences. But the FDA uses its authority over drug labeling and "promotion"—which includes not just advertising but virtually any communication with health professionals or patients—to prevent manufacturers

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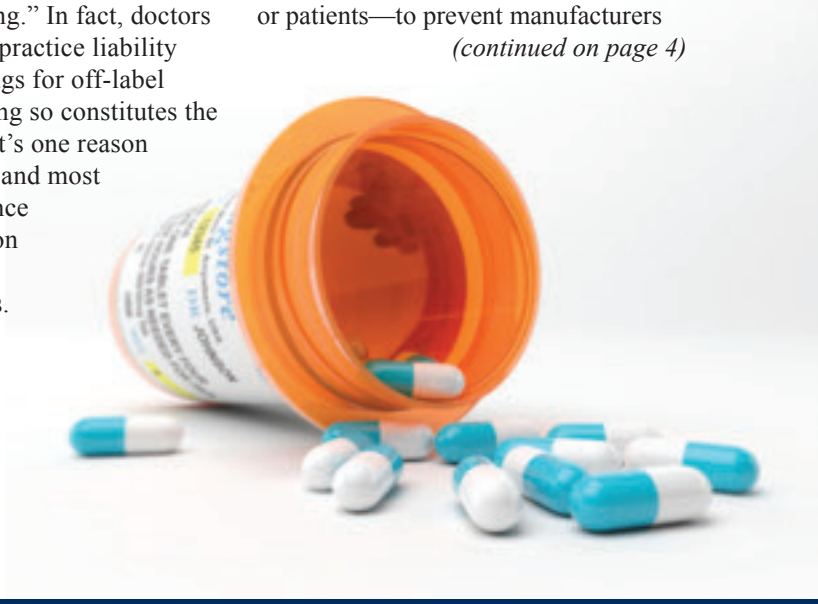

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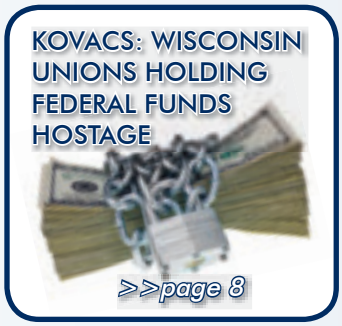

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>>FROM THE VICE PRESIDENT FOR STRATEGY

The Euro Crisis Sends Lessons to America

By Iain Murray

Even as the American economy begins to show some signs of recovery, we should all be wary of what is happening in Europe. If economic disaster strikes there, as is still possible, the United States could be dragged into a worldwide recession. Yet if we heed what is going on in Europe, we will learn lessons that could be applied to make our economy stronger.

The crisis in the European Union (EU) has three dimensions: First, decades of overspending on welfare states. Second, the EU itself has done much to promote harmful anti-competitive regulation in the name of harmonization. Finally, the adoption of the euro compounded these problems in some countries, triggering the current crisis.

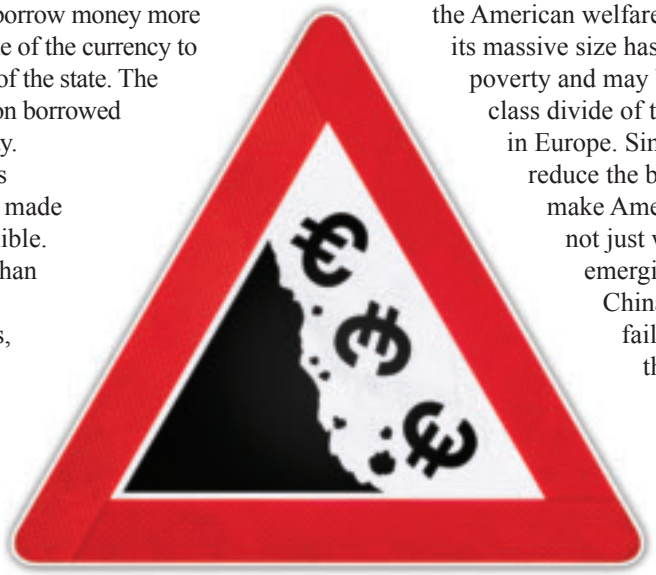
The poster child for overspending is, of course, Greece. That country instituted a massive welfare bureaucracy, with vast numbers of public servants and state-provided retirement pensions beginning as early as age 50. When I was at business school in London in the 1990s, there were many Greeks taking the same course, and all of them had an expression, "Lazy like a public servant." Yet the bureaucracy continued to grow, and the private sector that was paying the bills found ways to leave the country or stopped paying taxes altogether. When the country adopted the euro, the government found it could borrow money more easily given the greater value of the currency to pay for a further expansion of the state. The result was a country that soon borrowed more than it could ever repay.

Meanwhile, the EU was promoting regulations that made labor forces much less flexible. Working weeks of longer than 40 hours were banned, for example. Other regulations, such as the REACH directive on chemicals, made innovation much more expensive. Some countries took the principles of the regulatory state and ran with them. In Italy, as our Adjunct Analyst Matthew Melchiorre has pointed out, employment regulations make it next to impossible to fire an employee under any circumstances. As a result, unemployment rose—in turn placing even more burdens on the welfare state.

With the adoption of the euro, nations that had not made their workforces as flexible as possible, like Germany did, found themselves rendered uncompetitive. Germany prospered, while Greece and Italy suffered. Spain found that it could no longer afford to pay massive subsidies to its green energy sector, which collapsed. Ireland's housing bubble collapsed with similar effects as in the U.S.

With Germany unwilling to pay for the other countries' debts and refusing to countenance monetizing euro debt, the uncompetitive economies look doomed to years of recession as austere policies at once reduce the size of the bloated public sectors yet simultaneously raise tax rates above their already high levels, while doing little or nothing to address the regulatory burden.

American leaders should take time to look across the Atlantic and learn from what is happening. They should take steps to reduce the size of the American welfare state, which despite its massive size has done little to alleviate poverty and may be helping to create a vast class divide of the sort that is common in Europe. Simultaneously, they should reduce the burden of regulation to make America more competitive not just with Europe but with the emerging economies of Brazil, China, and India. If Americans fail to heed these warnings, they will have no one but themselves to blame for their future troubles.



CEI PLANET

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The CEI Planet is produced by the Competitive Enterprise Institute, a pro-market public interest group dedicated to free enterprise and limited government.

CEI is a non-partisan, non-profit organization incorporated in the District of Columbia and is classified by the IRS as a 501 (c)(3) charity. CEI relies upon contributions from foundations, corporations and individuals for its support. Articles may be reprinted provided they are attributed to CEI.

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ISSN#: 1086-3036

Moisturizing the EPA

BY ROBERT J. SMITH

Property rights advocates had reason to be optimistic in early January, as the Supreme Court heard arguments in *Sackett v. U.S. Environmental Protection Agency.* At stake is landowners' right to challenge bureaucratic control of their lands without redress or any meaningful right to appeal. The Justices seemed receptive to arguments on behalf of the plaintiffs, Mike and Chantell Sackett. A ruling in their favor would help restore some of the property rights protections that have been eroded over the past century.

The Sacketts had purchased a small lot in Priest Lake, Idaho, to build their home. The lot was in a residential area and they obtained all the necessary permits, graded the lot, and dumped gravel for the foundation. Then the U.S. Environmental Protection Agency (EPA) suddenly declared their lot a federally protected wetland under the Clean Water Act, and told the Sacketts they must restore it to pristine condition or face a fine of $37,500 per day.

They were told they could not appeal until they had exhausted all administrative remedies. Therefore, they must restore the land at considerable cost and then appeal for a permit, a process that could take years and cost tens of thousands of dollars—and likely result in a denial of their appeal. Only then would they be able to go to court—by which time they might be facing bankruptcy.

The Sackett case provides the Court an opportunity to revive the orphan child of the Bill of Rights—the Fifth Amendment, specifically due process and the takings clause. For much of the past century, various advocates of big government have run roughshod over property rights. Green activists have consistently used environmental legislation not to protect the environment but rather to impose land use controls at no cost to the government. For property owners, the costs can be staggering—complete loss of the use of their property.

From the day the Clean Water Act was passed, giving the federal government the authority to protect navigable waters, the bureaucrats at the EPA and the Army Corps of Engineers have stretched the definition of navigable water beyond all rational bounds to include almost any surface that is ever wet—no matter how seldom, for how short a time, or to what degree or depth. As one attorney has put it, the government is now trying to regulate the "moistures of the United States."

Rather than work to reduce fill and pollution in the nation's genuine navigable waters, agency regulators have spent ever-increasing amounts of time harassing small landowners, functionally "taking" their lands by preventing their use, entangling them in costly permit battles that often stretch out over several years, and even imprisoning some of them.

Consider the case of Gaston Roberge, a retiree in Old Orchard Beach, Maine. He owned a commercial lot where he had allowed the town to dump clean fill. Attempting to sell the lot for his retirement, the Army Corps charged him with illegally filling a wetland. After six years and tens of thousands of dollars in legal fees fighting to get a permit, it turned out he didn't need the permit after all, as his lot was finally designated as not a wetland. He then sued for a temporary taking of his property. During the proceedings, a Corps memo was discovered, saying, "Roberge would be a good one to squash and set an example."

That is how the Clean Water Act is being used—to set an example in order to prevent citizens from using their own land. The EPA may well be trying to set another example at Priest Lake to slow development. Mike Sackett is in the construction business—who better to make an example of?

At the Supreme Court hearing, the Sacketts' attorney seemed to make a strong argument. Most of the justices seemed somewhat angered by the government's actions, some strongly so. Justice Alito asked: "[D]on't you think most ordinary homeowners would say this kind of thing can't happen in the United States?" Justice Scalia said, "It shows the high-handedness of the agency." Even Justices Sotomayor and Breyer appeared irritated at times.

Rather than wasting taxpayer money to regulate farmers' stock ponds, the federal government should concentrate on the original goals of the Clean Water Act. Those who believe in a free society and a healthy environment can only hope for a wise decision from the Court—one that will protect landowners' rights to challenge arbitrary agency designations of dry land as navigable waters. Perhaps we are on the verge of seeing a return to the protection of people's inalienable rights, which the Constitution is intended to protect.

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Commercial Speech, *continued from page 1*

from disseminating information about off-label uses, even to doctors.

Drug makers may engage in a limited range of so-called educational activities, such as speaking about research on off-label uses at medical conferences. And in some circumstances, they may send peer-reviewed medical journal articles and excerpts from medical textbooks to physicians—but not if the firm has any financial ties to the underlying research. Almost everything else is forbidden, though the regulations are so unclear that even experts cannot always tell what is permitted.

National surveys commissioned by CEI found that a large majority of physician specialists believe the FDA's policies have made it more difficult for them to learn about new uses, and that the agency should not restrict information about off-label use. Nevertheless, the FDA and federal prosecutors regularly hit violators with both civil and criminal sanctions. In November, drug maker GlaxoSmithKline pled guilty and paid a record $3 billion to settle allegations that it illegally promoted several of its products for off-label uses. Similarly, Merck agreed to pay $950 million to settle claims that it illegally promoted Vioxx off-label.

But it isn't just big manufacturers that have been targeted. In January 2010, the FDA threatened to prosecute a Florida dermatologist for mentioning in interviews with *Elle* and *Allure* magazines and on NBC's "Today" show that an anti-wrinkle drug she was testing had shown positive results and that, "early data shows it may last longer and kick in faster than Botox."

The FDA's aggressive enforcement has attracted the attention of constitutional scholars who argue that restrictions on truthful and non-misleading speech violate the First Amendment. Well-established case law holds that government may not categorically bar truthful and non-misleading speech simply because its purpose is to promote a commercial transaction. Instead, the government must have a substantial interest in regulating the speech in question, and the regulation must directly advance that governmental interest and be no more extensive than necessary.

The agency and its supporters say the ban prevents snake oil salesmen from peddling unproven fixes, and the courts agree that preventing false or fraudulent speech is a substantial governmental interest. But the rules do not merely forbid false or misleading claims; they ban all promotion of off-label uses, even if they have been proven to be safe and effective in clinical trials.

Over the past decade, a handful of challenges have been brought in federal courts, with limited success. But none has resulted in an unambiguous ruling that the restrictions are unconstitutional.

> ***"Well-established case law holds that government may not categorically bar truthful and non-misleading speech simply because its purpose is to promote a commercial transaction."***

For example, prior to 1999, FDA regulations prohibited even the distribution of peer-reviewed medical studies unless the manufacturer had already submitted a supplemental application for approval of the off-label use in question. But in a case brought by the nonprofit Washington Legal Foundation, a federal district court held that a ban on disseminating truthful and non-misleading information contained in medical journal articles was unconstitutional.

On appeal, the FDA tweaked its interpretation of the law and claimed the rules governing journal articles merely established a "safe harbor" under which manufacturers would be automatically deemed in compliance. The regulations did not prevent all off-label promotion, according to agency lawyers. And they conceded that drug manufacturers do have some First Amendment rights, including the right to distribute journal reprints. That rendered the constitutional question moot. But in the intervening years, the FDA has declined to say what else is permitted.

The U.S. 2nd Circuit Court of Appeals in New York and the U.S. District Court for Washington, D.C. will each have an opportunity to shed some light on the matter in the coming months.

In January 2011, the 2nd Circuit heard the appeal of a drug salesman named Alfred Caronia who was convicted of conspiracy to misbrand his company's narcolepsy drug Xyrem. Caronia arranged a meeting between a paid medical consultant named Peter Gleason and another physician who was later revealed to be a confidential government informant. At that meeting, the informant asked Gleason about using Xyrem off-label to treat other forms of drowsiness and chronic fatigue. When Gleason answered the questions—providing truthful information about the drug's safe and effective but unapproved uses—both he and Caronia became criminals in the FDA's eyes.

Caronia choose to have his day in court, while Gleason pled guilty to a misdemeanor charge, and Orphan Medical agreed to a $20 million criminal and civil settlement. Gleason's medical licenses were suspended, and his life fell apart. He committed suicide in February 2011. Ironically, the FDA has since approved the off-label uses in question, indirectly validating Gleason's claims.

During oral arguments in January 2011, the 2nd Circuit seemed inclined to agree that the FDA rules are unclear, ambiguous, and overbroad. At one point, Justice Department attorney Douglas Letter tried to explain that off-label promotion "is not a crime" per se, but is merely evidence of Caronia's and Gleason's intent to "introduce a misbranded drug into commerce," which is illegal. But the only way the drug was "misbranded" was

Gleason's claim that it was safe and effective for off-label uses. The judges had difficulty following Letter's argument and questioned why such speech should be considered illegal.

The other ongoing challenge, in the D.C. District Court, is even more bizarre. New Jersey-based drug maker Par Pharmaceutical argues that off-label promotion regulations could subject manufacturers to prosecution for wholly lawful on-label promotion.

Par manufactures an appetite stimulant called Megace, approved for treating anorexia, severe malnutrition, and sudden weight loss in AIDS patients. It is also widely recommended by major treatment guidelines for off-label use to stimulate the appetite of geriatric and cancer patients.

Par's most potent argument is that the prohibition of off-label promotion of Megace also precludes a substantial amount of on-label promotion. The facilities that commonly treat patients suffering from anorexia and late-stage AIDS also tend to treat geriatric and cancer patients. Unfortunately for Par, the FDA prohibits drug makers from promoting fully-approved on-label uses in environments where off-label prescribing is likely to occur. In filings with the district court, Par provides examples of similarly situated drug companies having been prosecuted for what otherwise appeared to be fully legal speech.

Surely the U.S. Constitution must preclude criminal prosecution for engaging in explicitly lawful conduct, Par asks? The fact that the FDA's rules cast even this in doubt shows just how confusing the regulations have become.

The U.S. Supreme Court has held on several occasions, most recently in June 2011, that truthful speech used in pharmaceutical marketing is entitled to the same level of First Amendment protection as other commercial speech. And a recent decision on a related issue by the 7th Circuit Court suggested in non-binding dicta that the FDA's off-label speech restrictions are likely to be "unconstitutional in at least some applications." There is good reason, therefore, to believe that the 2nd Circuit or the D.C. District Court will strike down the off-label promotion ban, at least in part.

Few would argue that the government may not regulate commercial speech to ensure it is truthful and not fraudulent. But the First Amendment would mean little if it did not protect the right to say and hear truthful information. As the Supreme Court concluded in a landmark 2002 case involving advertising by pharmacists, "The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good."

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Biggest Hidden Cost of Fuel Economy Mandates is to Democracy

The Obama administration's executive actions have circumvented Congress yet again, undermining the will of the people and threatening our Republic

BY MARLO LEWIS, JR.

The biggest hidden cost of the Obama administration's fuel economy agenda, is the damage it does to the separation of powers and democratic accountability. Unfortunately, it is a prime example of the administration's approach to environmental rulemaking.

In the press release announcing their proposed fuel economy standards for model years (MY) 2017-2025, Environmental Protection Agency (EPA) Administrator Lisa Jackson and Transportation Secretary Ray LaHood actually boast about bypassing Congress: "Today's announcement is the latest in a series of executive actions the Obama administration is taking to strengthen the economy and move the country forward because we can't wait for congressional Republicans to act."

Indeed, legislation boosting average fuel economy to 54.5 miles per gallon would not pass in the 112th Congress. Note also that the National Highway Traffic Safety Administration (NHTSA) need not propose fuel economy standards for MY 2017 until 2014. "We can't wait" really means, "We won't let the people's rep–resentatives decide, either now or after the 2012 elections."

Circumventing Congress is the administration's standard modus operandi. Under the statutory scheme created by Congress, one agency, NHTSA, regulates fuel efficiency through one set of standards, Corporate Average Fuel Economy, under the Energy Policy Conservation Act (EPCA). Yet today, three agencies—EPA, NHTSA, and the California Air Resources Board (CARB)—regulate fuel efficiency via three sets of standards under three statutes—EPCA, the Clean Air Act (CAA), and California Assembly Bill 1493 (AB 1493).

The EPA and CARB claim they are regulating greenhouse gas emissions, not fuel economy. But greenhouse gas emission standards implicitly regulate fuel economy. As EPA and NHTSA's May 2010 Tailpipe Rule explains (pp. 25424, 25327), carbon dioxide (CO_2) constitutes 94.9 percent of vehicular greenhouse gas emissions, and the only feasible way to decrease CO_2 emissions per mile is to decrease fuel consumption per mile—that is, increase fuel economy.

The CAA provides no authority to regulate fuel economy, and EPCA preempts state laws or regulations "related to" fuel economy standards. California's standards are highly "related to" fuel economy.

Automakers support this "triplification" of fuel economy regulation, but only as the price they must pay to avoid outright regulatory chaos—a peril of the EPA's own making.

In February 2009, EPA Administrator Jackson reconsidered California's request for a waiver to implement AB 1493. In effect, Jackson threatened to balkanize the nation's auto market. The waiver would allow other states to adopt California's standards and thereby implicitly regulate fuel economy, forcing automakers to reshuffle the mix of vehicles delivered for sale in each "California" state to achieve the same average fuel economy.

Under the so-called "historic agreement" of May 2009, negotiated by then-Obama environment czar Carol Browner, California and

other states agreed to deem compliance with the EPA's greenhouse gas standards as compliance with their own—but only if automakers pledged to support the EPA's standards and the California waiver. The administration may also have tied its offer of bailout money to automakers' acceptance of those terms, making the historic agreement an offer GM and Chrysler could not refuse.

We may never know the details because, in apparent violation of the Presidential Records and Federal Advisory Committee acts, Browner imposed a vow of silence, instructing participants to "put nothing in writing, ever."

The payoffs for the EPA were huge. In 2010, Alaska Senator Lisa Murkowski introduced a resolution to overturn the EPA's Endangerment Rule, the prerequisite for all of the agency's greenhouse gas regulations. The auto industry lobbied against it, warning that the resolution would undo the historic agreement and expose auto makers to a regulatory patchwork.

Also in 2010, the EPA parlayed the Tailpipe Rule into a mandate to regulate stationary sources of greenhouse gases under CAA permitting programs. Having taken that step, the EPA predictably consented to establish greenhouse gas performance standards for coal power plants and oil refineries, with more such standards sure to follow. The EPA is now effectively legislating climate policy for the nation.

The EPA claims its greenhouse gas regulations derive from the CAA as interpreted by the Supreme Court in *Massachusetts v. EPA*. But only last year, Congress declined to give the EPA explicit authority to regulate greenhouse gases when Senate leaders mothballed cap and trade legislation. A bill authorizing the EPA to do exactly what it is doing now—regulate greenhouse gases under the CAA as it sees fit—would have been dead on arrival.

The notion that Congress gave the EPA such authority when the Clean Air Act was passed in 1970, years before global warming emerged as a public concern, defies common sense.

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CEI Events Update

January was a busy month at CEI, with our analysts coordinating and appearing at four events on a variety of issues.

January 14: Americans for Prosperity Michigan Prosperity Forum

Labor Policy Counsel F. Vincent Vernuccio spoke before the Michigan Prosperity Forum in Grand Rapids to Americans for Prosperity activists. Vinnie's talk focused on right-to-work legislation and President Obama's Big Labor agenda. Conservative commentators Michelle Malkin and Andrew Breitbart also spoke to the group of activists.

January 19: Unintended Consequences of the Rogue Website Crackdown

CEI co-hosted a lunch event with TechFreedom and the Cato Institute on then-pending rogue website legislation– the Stop Online Piracy Act (SOPA) in the House and the Protect Intellectual Property Act (PIPA) in the Senate. The event featured a panel of leading technology policy experts, moderated by CEI Associate Director of Technology Studies Ryan Radia, on the implications of SOPA and PIPA for entrepreneurship, free speech, Internet governance, and holders of copyrights and trademarks.

January 30: Preserving the User-Pays Highway Funding Principle in the Highway Bill

CEI held a Capitol Hill briefing on a funding mechanism proposed in the House's current surface transportation reauthorization legislation. The proposal would direct royalty revenues from expanded onshore and offshore oil and gas production into the Highway Trust Fund, breaking with the longstanding user-pays/user-benefits principle. A panel was moderated by Marc Scribner, transportation policy analyst at CEI, and was composed of transportation policy experts from the Reason Foundation, Taxpayers for Common Sense, and the Natural Resources Defense Council.

January 30: Previewing the Farm Bill: A Discussion of the Sugar Program

On the same day, Fran Smith, CEI Adjunct Fellow and Board Member, participated in a discussion on the upcoming farm bill and the future of the U.S. sugar program. CEI has long opposed government protectionism of sugar growers, both cane and beet, as harmful to both downstream industries and consumers. Former Texas Rep. Henry Bonilla moderated the panel, which also featured representatives from the sugar industry and the sugar-users industry.

Wisconsin Union Holding Federal Funds Hostage

BY TREY KOVACS

Federal health care funds are being held hostage by the Wisconsin Education Association Trust (WEA Trust), a nonprofit health insurance company created by the state's largest teachers' union. The union trust is doing this in a bid to retain its dominant position as the state government's largest health care insurance provider.

The funds in question derive from the much-maligned Early Retiree Reinsurance Program (ERRP). Obamacare created ERRP as a taxpayer-funded subsidy intended to lower the cost of early retiree health care.

Instead, the Obama administration has used ERRP funds to give political payback to preferred special interest groups. Top ERRP recipients include the United Auto Workers ($206.8 million), state governments and government unions ($5 billion), and General Electric ($36.6 million). The WEA Trust received a total of $18 million.

The WEA Trust is preemptively suing the state to withhold ERRP funds from school districts that drop it as their health care contractor, essentially acknowledging that the ERRP is a taxpayer-funded union bailout.

The lawsuit is in response to Governor Scott Walker's labor reform, enacted last year, which decreased the collective bargaining power of Wisconsin government unions and dissolved the WEA Trust's government health care monopoly.

Previously, WEA Trust provided health insurance to two-thirds of Wisconsin school districts under exclusive agreements made possible by the unions' collective bargaining power. The law enabled school districts the freedom to choose their health insurance providers.

To counter school districts' newfound freedom, the WEA Trust attempted to strong-arm them into renewing their contracts. In a letter, the WEA Trust informed school districts that it would withhold ERRP funds from any district that switched health care insurance providers.

In the end, such threats failed to persuade the majority of school districts from switching, and for good reason. The MacIver Institute reports that the newly competitive health care insurance market has helped yield an estimated $16.8 million in total savings. A new MacIver study reports, "25 districts have reported switching providers or lowering their costs through competitive bids. Amongst these districts, the average savings have been $730,634.99. That comes out to $211.45 per student."

One would think that the WEA Trust, a non-profit created by the Wisconsin Education Association Council (WEAC), would be thrilled at such savings to union members' health insurance costs. However, the WEA Trust seems more concerned with retaining its privileged status.

The threats led 14 Wisconsin school districts that dropped the WEA Trust last year to sue to recoup the nearly $3 million in ERRP funds being withheld. The Hartland-Lakeside school district is leading the charge to recoup ERRP funds. Hartland-Lakeside superintendent David Schilling stated at least 30 school districts have expressed interest in joining the lawsuit. The school districts lawsuit contends members of WEA Trust in 2010-2011, when the WEA Trust applied for ERRP, are entitled to the funds.

To resolve the lawsuit the WEA Trust continues to use questionable tactics. The Associated Press reported comments of WEA Trust spokesman Steve Lyons, "that any of the 14 school districts that choose not to litigate against WEA could be dropped from the lawsuit."

Worse, this scenario could be repeated in other states, as state and local governments cut budgets to get their finances in order, and unions, seeing their member dues flow decrease, use ERRP funds to bail out their dwindling coffers at taxpayer expense. The WEA Trust's parent, WEAC, cut 40 percent of its staff after the passage of Governor Walker's bill.

Having lost their privileged status, government unions in Wisconsin are now opposing reforms that lower health care costs for union members. That makes it worth asking: Who is WEAC really looking out for?

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STOKING FEARS ABOUT "NO MORE TEARS"

BY DANA JOEL GATTUSO

For as long as there have been cosmetics, they've been part of the holidays. They're popular Christmas gifts and part of looking good at big New Year's Eve parties, yet if you believe the Campaign for Safe Cosmetics, personal care products—from skin creams to popular fragrances to baby shampoo—contain a "minefield of toxins." But the campaign's claims amount to a minefield of misinformation that could have far more dangerous repercussions than any of the chemicals it demonizes. Its latest target is Johnson & Johnson's "No More Tears" baby shampoo, which parents use to help their children look their best in holiday photos.

"This is the story of a world obsessed with stuff. It's the story of a system in crisis. We're trashing the planet, we're trashing each other, and we're not even having fun." So begins the shocking video produced by the Campaign for Safe Cosmetics, a coalition of enviro-activists on a crusade to terrify consumers away from using personal care products that contain any trace of "unnatural" ingredients.

Our bathroom is loaded with toxins "that seep into our lives every day," the campaign tells us. We are polluting our bodies with products containing chemicals that cause cancer, learning disabilities, asthma, and sperm damage, it says.

The activists—who will not rest until all man-made chemicals have been regulated out of existence—target women, particularly mothers of young children, who they claim are unknowingly "poisoning" their babies by using soaps and baby shampoos loaded with chemicals. "Babies across America are sitting in bubbles tainted with cancer-causing chemicals and other toxins linked to serious health effects," they wrote

Not surprisingly, their fear-mongering may have a big impact on consumer behavior. Increasingly, women are afraid to buy skin care products they have used for years, turning instead to products we know much less about because they promise natural, organic and chemical-free ingredients—though those promises are often broken. Not only are the campaigners doing the public a grave disservice by inciting panic over preservatives, they are subjecting consumers to serious health risks.

Most recently, the campaign has directed a witchhunt attack at Johnson & Johnson for using a "known human carcinogen" in its baby shampoo. At issue is a widely used formaldehyde-releasing preservative called quaternium-15, which is used in trace amounts to prevent contamination.

Water-based personal care products such as shampoos, skin creams and makeups, stored in warm and humid bathrooms, are breeding grounds for mold, fungi, and even deadly bacteria. Preservatives are essential to prevent microorganisms from growing in our skin care products. Formaldehyde releasers are particularly effective in fighting dangerous bacteria such as E. coli and Pseudomonas aeruginosa that can cause serious and even deadly infections.

Only small concentrations of preservatives are needed to keep products safe from contamination. Quaternium-15 typically releases 100 to 200 parts per million of formaldehyde. To put that in perspective, many foods we ingest contain natural formaldehyde. Shiitake mushrooms, for example, contain up to 400 parts per million. Yet activists with the Campaign for Safe Cosmetics accuse Johnson & Johnson of using a "cancer-causing chemical" in its baby shampoo and demand that it remove the preservative.

The campaign is being dishonest with the American people and abusing consumer trust. It is fully aware the debate over formaldehyde as a carcinogen does not pertain to traces of formaldehyde-releasing preservatives in cosmetics. Rather it refers to risks associated with long-term exposure in industrial settings among workers who breathe in formaldehyde vapors day in and day out. Fortunately, these risks can be managed through worker-safety measures. In fact, stringent Occupational Safety and Health Administration standards ensure that worker exposures pose little health concern.

But most relevant to cosmetics, the European Commission's scientific committee on cosmetics—one of the world's most stringent regulators of chemicals—has found that formaldehyde-releasing ingredients such as quaternium-15 are safe in shampoos and other personal care products as long as they do not exceed 2,000 parts per million. The campaign's own lab tests found shampoos containing formaldehyde at levels ranging from 54 to 610 parts per million—including Johnson's baby shampoo at 200 parts per million. These are well within the range of safety.

No matter. Johnson & Johnson broke under pressure and assured the campaign that it would remove the preservative. The winners are the campaign extremists who have successfully bullied the makers of "No More Tears" into submission. The losers are American consumers, who will pay a lot more for a product whose ingredients we know a lot less about.

Dana Joel Gattuso is a Senior Fellow at The National Center for Public Policy Research and author of the recent CEI study, "The True Story of Cosmetics." A version of this article originally appeared in The Washington Times.

THE GOOD

Sponsors Withdraw Flawed "Rogue Website" Bills; CEI Urges New Approach

After an uproar from Internet users and prominent protests from major websites such as Google and Wikipedia, the House's Stop Online Piracy Act (SOPA) and the Senate's Protect Intellectual Property Act (PIPA) were shelved by their respective sponsors in mid-January. While much of the rhetorical outrage relied on false assumptions about what this legislation would actually do, CEI had long opposed the bills as written, going back to our first event on the issue back in April 2011. The day prior to their withdrawal, CEI Associate Director of Technology Studies Ryan Radia moderated a panel of leading free-market technology policy experts to discuss problems with the legislation and how to appropriately handle the very serious problem of foreign rogue websites. "While I'm relieved that the flawed SOPA and PIPA bills seem unlikely to pass in their current forms, I also think it would be unwise for Congress to dither on rogue sites legislation for years in search of 'credible data' about how such sites impact our economy," said Radia. For our part, CEI has offered policies that could better address this issue while maintaining Internet freedom.

THE BAD

Presidential "Recess" Appointments Violate Separation of Powers

On January 4, President Obama ignored the Senate confirmation process and appointed Richard Cordray as director of the new Consumer Financial Protection Bureau, in addition to making three appointments to the National Labor Relations Board. While the president is constitutionally permitted to make appointments while the Senate is in recess, the Senate was technically in a pro forma session, which meant is was not in fact in recess when Obama made his appointments. While the president can refer to pro forma sessions "procedural gimmicks" all he wishes, the fact is that this longstanding parliamentary tool is real and that his unprecedented, anti-democratic appointments were unconstitutional. The Justice Department's defense of the presidential "recess" appointments has been attacked as "simply fashioning rules to reach to the outcomes it wishes" by a former federal judge, as well as by a number of prominent law professors and constitutional scholars. Several groups have already filed legal challenges.

THE UGLY

Obama Administration Rejects Keystone XL Pipeline

On January 18, President Obama denied a permit to begin construction of the Keystone XL pipeline, saying it was not in the "national interest." Keystone XL would have carried oil from Canada's extremely productive Alberta Tar Sands to American refineries along the Gulf Coast. CEI blasted the president's pandering to the radical environmental lobby, arguing that he was betraying his promises to allow for more domestic energy production, as well as fostering a pro-job economic environment. "As oil production in Venezuela and Mexico likely declines dramatically in the next few years, the Obama administration's claim that importing more oil from Canada is not in the national interest is preposterous," said Myron Ebell, director of CEI's Center for Energy and Environment. "Contrary to his phony rhetoric, President Obama's real goals are to reduce energy supplies, raise energy prices for American consumers, and destroy jobs."

MediaMENTIONS

Compiled by Nicole Ciandella

Director of the Center for Investors and Entrepreneurs John Berlau and Policy Analyst Trey Kovacs respond to claims the tax rate on investment is too low:

Massachusetts [G]overnor [Mitt Romney] caused a brouhaha last week when he estimated the tax rate on his investment income at 15 percent. "How unfair!" pundits exclaimed, noting that the top marginal rate for wage income is more than 30 percent.

The tax rate on investors is unfair, but for the opposite reason. Our tax code layers taxation of dividends and capital gains on top of a top corporate tax rate of 35 percent—which even President Obama acknowledges is one of the highest in the world.

This is, ironically, the embodiment of the "corporate personhood" legal doctrine otherwise so decried by the left. The law taxes corporations as if they were separate beings from the shareholders who own them and then levies a separate tax on shareholder payouts and gains. This double taxation brings the effective tax rate on investment income to as much as 44.75 percent.

-January 24, *The Wall Street Journal*

Vice President for Strategy Iain Murray and Research Associate David Bier argue that President Obama is as secretive as former Vice President Dick Cheney when it comes to energy policy:

When Vice President Dick Cheney held secret meetings for his energy task force in the early days of President George W. Bush's first term, he was excoriated by the left and even some on the right. Both Judicial Watch and the Sierra Club sued, but the Supreme Court found the proceedings were protected by executive privilege.

President Barack Obama came into office pledging to end such secrecy, saying, "The way to make government accountable is to make it transparent."

On his own energy agenda, however, the president has been as opaque as Cheney, repeatedly holding closed-door meetings, anonymously courting lobbyists, dodging Freedom of Information Act requests, and ignoring subpoenas from Congress.

-January 16, *The Sacramento Bee* and *The Miami Herald*

Vice President for Strategy Iain Murray argues that both the U.S. and Britain would benefit from increased cross-Atlantic trade:

The ongoing euro crisis will not be resolved any time soon, and America will continue to be impacted by bank write-downs and declines in U.S.-European trade. Increasing U.S.-UK trade would be one relatively quick and effective way of taking up some of the slack.

Up to now, however, the U.S. has pursued a policy of propping up the euro while discouraging British independence from Brussels. This is incredibly short-sighted. Using the vehicles of the Federal Reserve and the International Monetary Fund to try to fill the gaping hole in Europe's finances will get everybody nowhere. Instead, British, American and Canadian policy makers (along with their NAFTA partners in Mexico) should be taking the long view and preparing for a future in which the unsustainable euro zone inevitably collapses. Welcoming Britain back into the North Atlantic economic community would be a win-win for all involved.

-December 29, *The Wall Street Journal Europe*

Fellow in Technology and Entrepreneurship Bill Frezza explains how tax dollars are corrupting scientific integrity:

Science and the scientific method are the jewels in the crown of Western civilization. The ascertainment of facts, construction of reproducible experiments, development of falsifiable theories, impartial training and meritocratic advancement of practitioners, and—most importantly—integrity of the publication process by which a well established body of truth can be confidently assembled all underpin the respect accorded to science by the citizenry. In modern times, this respect translates into tax dollars.

Unfortunately, today those tax dollars are corrupting the process. Unprecedented billions are doled out by unaccountable federal and state bureaucracies run by and for the benefit of a closed guild of practitioners. This has created a moral hazard to scientific integrity no less threatening than the moral hazard to financial integrity that recently destroyed our banking system.

-December 5, RealClearMarkets

Warren Brookes Fellow Matt Patterson explains why deregulation at the federal level is slow going:

If we lived in a constitutional republic—that is to say, one of limited and clearly defined powers—perhaps eliminating whole swaths of government would be possible. Maybe that's [Texas Governor Rick] Perry and Republican primary voters' problem: They believe, beyond all evidence, that we live in such a nation. But we don't, and haven't for a long time.

America was born such a creature, or at least that was the Founding Fathers' hope for the government they brought into this world. But as the nation grew, it matured into something quite different. Especially over the past century, Americans collectively and repeatedly voted for politicians and supported policies that transmogrified the Old Republic into what could best be described as an imperial bureaucracy. Ever since the New Deal, we have effectively been living in post-republic America.

-November 25, *The Baltimore Sun*

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...END NOTES

Look Before You Try to Lie

When a *Boston Herald* reporter sought employee compensation data from the head of the Rose Kennedy Greenway Conservancy, a quasi-government entity set up by the city, state, and former toll authority to manage the network of parks, Executive Director Nancy Brennan probably should have contacted her human resources department to respond to the query. Instead, Brennan mistakenly replied to the reporter while trying to email her publicist, asking for help in concealing her and others' salary information. While state Transportation Secretary Richard Davey said he was "concerned about the Conservancy's transparency," other public officials apparently were not. Attorney General Martha Coakley and Auditor Suzanne Bump declined to comment, while Govenor Deval Patrick told reporters, "I don't run the Conservancy" and that he intended to continue funding it.

Clogged Drain? Papers, Please!

If you have a sluggish drain and you live in Illinois, the government wants to keep track of you. Under one of the 40,000 new laws across the country that took effect on January 1, 2012, the state of Illinois now requires consumers to show valid ID to buy drain cleaner. Retailers are then required to log the name of the customer, customer's address, date and time of purchase, product brand, and net weight. The bill was passed in response to a Taliban-style acid attack on two Chicago women. It is also an anti-drug law, as drain cleaner can be used to make methamphetamine. But it is still unclear how showing ID and putting pen to paper would physically prevent either planned acid attacks or illegal drug manufacturing.

Sledding: Unsafe at Any Speed

If you live in a part of the country where the winters are cold and snowy, some of your most cherished childhood memories probably involve sledding down a snow-covered hill. But in Beaver Borough, Pennsylvania, regulators guard that activity very carefully. For one, children under 12 are required to wear helmets while sledding. That is not particularly onerous, though there is an argument to be made about parental discretion. Sledding is also banned in some parks, though it is allowed in others. The Borough recently circulated a newsletter to confused residents explaining what is allowed where. The real kicker is that out-of-town children are not allowed to go sledding in Beaver Borough, on pain of a $25 fine. If out-of-towners are in Beaver Borough to visit friends or relatives, they will need to find something else to do for a family outing.

New York Nanny Statists Busted for Scare-Brush Tactics

New York City's Health Department recently began running anti-obesity ads in the subway system designed to scare straphangers straight—or rather, thin. One ad featured a photograph of a one-legged man sitting on a stool, with accompanying text that read, "Portions have grown. So has Type 2 diabetes, which can lead to amputations." It was soon revealed, however, that the photo was a fake. *New York Times* reporters uncovered the original stock photo of the man seated on a stool. It turns out he still had two legs at the time of photographing, meaning that the Health Department engaged in some pretty serious Photoshopping. At press time, *The New York Times* was unable to identify the model, so it is possible the man is now a diabetic amputee and that NYC's wellness-watchers were airbrushing in accuracy. But I doubt it.