



Promoting open government,
accountability, and citizen
participation since 1983

[Subscribe](#)

[Blog](#)

[Donate](#)

The Watcher

November 27, 2012

Vol. 13, No. 22

In This Issue

Fiscal Stewardship

[Multiple CRS Reports Show Return to Clinton-Era Tax Rates for Rich Will Not Harm Economic Growth](#)

Government Openness

[New Bill Will Strengthen Transparency and Accountability by Protecting Federal Whistleblowers](#)
[New Website Makes Information on Fracking Chemicals More Accessible to the Public](#)

Protecting the Public

[The Future of Long-Awaited Public Protections in Obama's Second Term](#)
[State Regulation of Compounding Pharmacies Is Inadequate](#)

Multiple CRS Reports Show Return to Clinton-Era Tax Rates for Rich Will Not Harm Economic Growth

The New York Times recently [reported](#) that a Congressional Research Service (CRS) report was "withdrawn from circulation" at the behest of Senate Republicans. The CRS report finds no relationship between upper-income tax rates and economic growth, undercutting Republican claims that an extension of the Bush tax cuts for the wealthy is necessary for economic growth. Senate Republicans called the report's validity into question, and CRS eventually withdrew it. However, the report's findings are only the latest in a series that suggest only a tenuous relationship between the economy and upper-income and capital gains tax cuts.

CRS Findings Undercut Conservative Approach to Tax Policy

[CRS](#) is a part of the Library of Congress and provides Congress with unbiased analyses of legislative topics to help members craft public policy. The report that was withdrawn by CRS, [Taxes and the Economy: An Economic Analysis of the Top Tax Rates Since 1945](#), analyzes the connection between tax rates on upper-income taxpayers (and capital gains tax rates) and economic indicators, including saving, investment, productivity growth, and income inequality. The report concludes:

The results of the analysis suggest that changes over the past 65 years in the top marginal tax rate and the top capital gains tax rate do not appear correlated with economic growth. The reduction in the top tax rates appears to be uncorrelated with saving, investment, and productivity growth. The top tax rates appear to have little or no relation to the size of the economic pie.

However, the top tax rate reductions appear to be associated with the increasing concentration of income at the top of the income distribution. The *Times* article quoted a spokeswoman for the Senate Finance Committee's Republicans who said that "[t]here were a lot of problems with the report from a real, legitimate economic analysis perspective." (Jared Bernstein, former Chief Economist and Economic Adviser to Vice President Joe Biden, [refutes](#) these complaints from an "economic analysis perspective.") CRS, against the advice of its economics division, withdrew the report. However, it is only one of several reports from CRS that blunt claims that a return to Clinton-era upper-income tax rates would be detrimental to the current economic recovery.

Three Percent of Small Businesses Affected by Upper-Income Tax Cuts

In October, referring to the expiration of the upper-income Bush tax cuts, House Speaker John Boehner (R-OH) [wrote](#):

Proponents of the looming tax hike don't call it a tax increase on small business, of course; they frame it as a tax increase on 'the wealthy.' But the fact of the matter is it will dramatically impact small businesses in America.

One year prior to this statement, CRS released a report entitled [Small Business and the Expiration of the 2001 Tax Rate Reductions: Economic Issues](#) that contradicts this assertion. That report examines the available data on small businesses and how the expiration of the upper-income Bush tax cuts would impact them. It notes that "the empirical evidence suggests that tax rates have small, uncertain, and possibly unexpected effects on the formation of small business" and concludes: "...lowering the top tax rates benefits only a small share (3% or so) of businesses, and 80% or more of the tax cut's benefits do not accrue to business."

Capital Gains Tax Cuts Unlikely to Expand Economy

Thomas L. Hungerford, the author of the withdrawn report, wrote a June 2010 analysis that examines the relationship between capital gains taxes and the economy. This report, [The Economic Effects of Capital Gains Taxation](#), did not draw similar criticism from Senate Republicans, but it has similar findings as his withdrawn report. Hungerford indicates that:

Many economists note that capital gains tax reductions appear to have little or even a negative effect on saving and investment....Consequently, capital gains tax rate reductions are unlikely to have much effect on the long-term level of output or the path to the long-run level of output (i.e., economic growth).

[...]

An effective short-term economic stimulus, however, will have to increase aggregate demand, which requires additional spending. A tax reduction on capital gains would mostly benefit very high income taxpayers who are likely to save most of any tax reduction. Economists note that a temporary capital gains tax reduction possibly could have a negative impact on short-term economic growth.

Economic Growth Factors "Insensitive" to Tax Rates

[*Tax Rates and Economic Growth*](#), released in December 2011, is another CRS report that looks at the relationship between tax rates and economic growth. It finds that "[a] review of statistical evidence suggests that both labor supply and savings and investment are relatively insensitive to tax rates." That is, labor supply, savings, and investment, which are key components of economic growth, would be minimally impacted, if at all, by an expiration of the upper-income Bush tax cuts. In fact, the report notes that lower savings are associated with lower tax rates.

That report separates out the long-term and short-term effects of taxation on the economy. In terms of short-term economic-boosting activity, "the smallest effects [on employment and economic output] are from cutting taxes of high-income individuals or businesses," whereas policies that impact lower-income families have the largest impact. In the long term, the evidence "suggests that past changes in tax rates have had no large clear effect on economic growth and selected factors commonly associated with economic growth."

Tax Cuts Least Efficient Policy to Maintain Recovery

The urgency to address the expiration of the Bush tax cuts and the \$1 trillion across-the-board spending cuts set to start in January comes from concern that such rapid fiscal contraction could push the nation into a recession. The Congressional Budget Office (CBO) [*projects*](#) that if all of the Bush tax cuts expire, the automatic cuts are fully enacted, and other fiscal policies scheduled to expire take place, the economy will shrink and unemployment will increase from today's 7.9 percent to 9.1 percent.

A CRS report issued in September, [*The 'Fiscal Cliff': Macroeconomic Consequences of Tax Increases and Spending Cuts*](#), details the impacts of these fiscal policies. The report suggests that between the trade-off of allowing the national debt to grow or pushing the economy into recession from too-severe deficit reduction measures, Congress could allow the "less robust" tax provisions (e.g. upper-income Bush tax cuts) to expire and replace them with federal spending programs, like expanded unemployment insurance.

When Congress reconvenes for its lame-duck session, it will begin debating the merits of allowing the upper-income Bush tax cuts to expire. The health of the economy and the millions of families that are affected by it will be central to that debate. Despite the attacks on the most recent CRS report, a raft of other analyses supports its conclusions: raising upper-income tax rates will have little, if any, negative impact on economic growth.

New Bill Will Strengthen Transparency and Accountability by Protecting Federal Whistleblowers

Today, President Obama [signed a bill](#) that will bring stronger protections for federal whistleblowers. The bill, the [Whistleblower Protection Enhancement Act](#) (S. 743), will improve government transparency and accountability by safeguarding public servants who report misconduct.

Whistleblowers make the public aware of lawbreaking, waste, or threats to health and safety. By protecting public servants who report problems from professional retribution, the public will learn more about government activities in need of attention and improvement. Furthermore, protecting and rewarding whistleblowers can strengthen a culture of transparency and accountability in government and deter wrongdoing from occurring in the first place.

This update was needed because current whistleblower protections are riddled with loopholes from court rulings over the years that leave individuals at risk of retaliation from their supervisors, including being fired. The new bill will close loopholes, clarify protections, and strengthen the agencies charged with protecting whistleblowers. Its passage represents the fulfillment of an intensive, years-long effort by the government accountability community, as well as congressional leaders and whistleblowers themselves.

How Federal Whistleblowers are Protected Now

Under existing law, federal employees are protected from retaliation for disclosing information that they reasonably believe demonstrates a violation of law or regulation, waste or abuse, or a danger to public health or safety. Employees may disclose to officials within their agency, members of Congress, or journalists. Classified information can be disclosed to the agency inspector general or the independent Office of Special Counsel (OSC). Agencies cannot fire, demote, or otherwise punish an employee because he or she blew the whistle.

If an employee feels retaliated against for blowing the whistle, he or she can file a complaint with OSC. OSC investigates to determine if the complaint has merit and requests the agency correct anything improper. Cases can also go before the Merit Systems Protection Board (MSPB), an independent agency which adjudicates personnel appeals for federal employees if OSC believes an agency is not taking corrective action or if a whistleblower disagrees with a decision by OSC to not seek corrective action.

An administrative judge at the MSPB decides appeals. If the MSPB holds that the agency retaliated against the whistleblower, it can order the agency to undo the punishment and pay the whistleblower's attorney fees. If the employee or agency disagrees with the judge's decision, either the individual or the agency can appeal to the full board. Decisions by the judge or board can, in turn, be appealed to a federal appellate court.

Chinks in the Armor

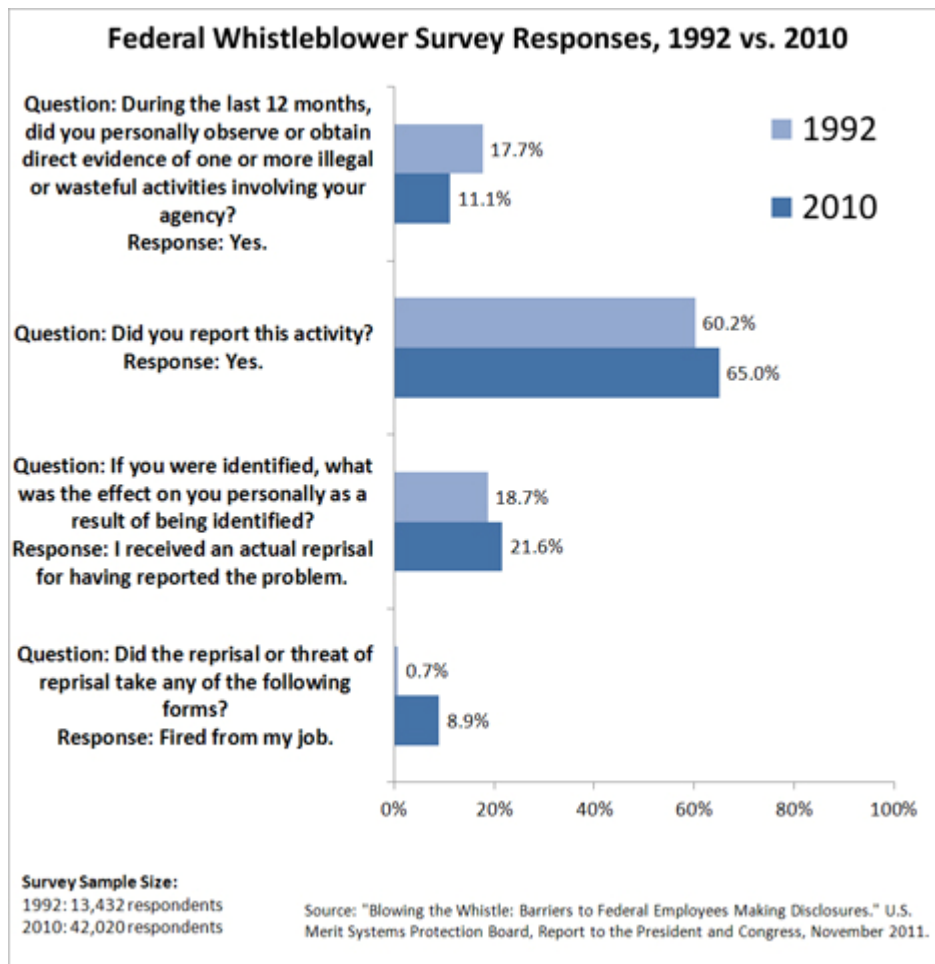
Over the years, this complex system developed a number of weaknesses that left whistleblowers exposed. In particular, the U.S. Court of Appeals for the Federal Circuit, which is the appellate court with jurisdiction over MSPB decisions, has a "consistent track record of [narrowing the law's protections](#)," according to the Government Accountability Project.

Under these judicially created loopholes, a federal employee is not protected from retribution under a number of common scenarios, including if he or she:

- Is not the first person to report the incident;
- Discloses related information to a co-worker or supervisor;
- Shares the results of a policy decision; or
- Reports the issue while carrying out job duties.

The results of a [recent study by the MSPB](#), which surveyed more than 42,000 employees, suggest that these loopholes may have contributed to an atmosphere of impunity within federal agencies. A larger percentage of whistleblowers reported suffering reprisal in 2010 compared to 1992. Whistleblowers appear to be 13 times more likely to be fired from their job than in 1992, according to the survey.

Thankfully, the percentage of employees who perceive wrongdoing has declined from 17.7 percent in 1992 to 11.1 percent in 2010. And despite the risks, a larger percentage (65 percent in 2010 compared to 60.2 percent in 1992) reported blowing the whistle when they saw wrongdoing. Many of these respondents reported problems to their immediate supervisors in 2010 (33.4 percent), and relatively few reported issues to their agency's Office of Inspector General (5.1 percent), OSC (1.1 percent), a member of Congress (1.8 percent), or their union representative (7.2 percent). Those numbers varied only slightly from 1992.



click image to enlarge

Strengthening protections for whistleblowers may help to further reduce wrongdoing, while at the same time ensuring fairer treatment for whistleblowers. As the MSPB report notes, "The most important step that agencies can take to prevent wrongdoing may be the creation of a culture that supports whistleblowing."

Enhancing Protections

The new bill is aimed at clarifying and strengthening protections, closing loopholes, and enhancing the authorities of offices that protect whistleblowers. Key provisions of the bill:

- Fix the aforementioned harmful judicial precedents by making the protections more broadly applicable;
- As a two-year experiment, allow whistleblowers to appeal to the other appellate courts, rather than only the Court of Appeals for the Federal Circuit, which created the harmful loopholes;
- Clarify that scientists who blow the whistle on censorship are protected;
- Extend whistleblower protections to Transportation Security Administration employees;
- Allow the MSPB to make agencies pay compensatory damages for retaliating against a whistleblower;

- Increase MSPB's ability to take disciplinary action against a manager for illegal retaliation against a whistleblower; and
- Require agencies to better inform employees of their whistleblower rights, including creating ombudsmen within each agency's inspector general office.

The bill's passage was [hailed as an advance](#) by the Make It Safe Coalition, whose members range across the political spectrum and include OMB Watch. The coalition's statement explained "though it does not include every reform that we have sought and will continue to seek, the bill will restore and modernize government whistleblower rights by ensuring that legitimate disclosures of wrongdoing will be protected, increasing government accountability to taxpayers, and saving billions of taxpayer dollars by helping expose fraud, waste and abuse."

Building the Culture of Accountability

The new law will be an important step forward for transparency and accountability in government. The next step will be for agencies to responsibly implement the law.

Despite the bill's many helpful reforms, advocates admit that intelligence and national security workers have been left out – the bill does not provide them with the protections other federal employees have. To address this concern, in October, President Obama [issued a directive](#) to improve protection of intelligence community whistleblowers. While praiseworthy, the presidential directive cannot provide the same legal protections that including these workers in the law would have.

Nevertheless, the bill's passage represents Congress' acknowledgement that whistleblowers are important to ensuring the integrity and efficiency of government operations. The new protections will be a significant advance for strengthening a culture of accountability within government.

New Website Makes Information on Fracking Chemicals More Accessible to the Public

On Nov. 14, an environmental organization, SkyTruth, launched a [website](#) to give the public improved access to information on the chemicals used in a natural gas extraction process commonly referred to as fracking. The Fracking Chemical Database makes data from FracFocus.org (the industry-funded chemical disclosure site) easier to search and download for research and analysis.

Fracking is a process that pumps sand, water, and toxic chemicals into gas wells at very high pressure to cause fissures in shale rock that contains methane gas. Fracking fluid is [known](#) to contain benzene (which causes cancer), toluene, and other harmful chemicals, but the exact substances and amounts in fracking fluids are typically kept secret because companies invoke "confidential business information" exemptions to right-to-know laws and rules.

The Fracking Chemical Database

Founded in 2002, SkyTruth is a West Virginia-based group that uses remote-sensing and digital mapping technologies to investigate a wide range of environmental issues, such as mountaintop removal mining, the 2010 oil spill in the Gulf of Mexico, and gas drilling. The organization extracted the fracking data from chemical disclosure reports submitted voluntarily by well operators to FracFocus.org.

"Unfortunately for researchers who want to analyze data to determine patterns and better understand fracking nationwide, FracFocus is difficult to use," [said](#) Paul Woods of SkyTruth. The organization hopes that the database "will facilitate credible research" and "promote discussion about effective public disclosure."

The database allows users to explore more than 27,000 industry chemical disclosure reports for gas and oil wells that were hydraulically fractured (or fracked) between January 2011 and August 2012 in 24 states. The reports cover 26,938 unique wells, but almost 700 wells were fracked more than once in that time period and have submitted multiple reports. Users can download the entire dataset or specific search results for deeper analysis or mashups with other data. The site also offers a large dataset, which includes more than 800,000 records, of all listed chemicals at each well. In addition to offering the data for review, SkyTruth has been collaborating with FracTracker.org to publish maps, analysis, and visualizations using the dataset.

However, because the dataset relies on information voluntarily provided by companies, the fraction of the fracking industry's activities being reported is unclear. SkyTruth has been researching the disclosure rate to estimate how much data is missing. In Pennsylvania, the group estimates that [only 43 percent](#) of chemicals used in fracking operations have been disclosed. In West Virginia, SkyTruth estimates that well operators provided information on [0-32 percent](#) of the chemicals they use in fracking.

Nonetheless, despite the incomplete character of the information, the search and sort capabilities of the site, as well as the opportunity to download the database, represents a significant step forward in the public's ability to understand the fracking industry's activities. SkyTruth and FracTracker have used the data to calculate that the 27,000 wells in the dataset have used [at least 65.9 billion gallons of water](#) to frack for oil and gas – more water than goes over Niagara Falls in a day. The organizations also found that diesel fuel is still used in fracking fluid despite an explicit ban on its use under the Safe Drinking Water Act. Additionally, they found that two-thirds of all industry reports omit chemical information, claiming it to be trade secrets.

The Limits of the Industry-Funded Data Repository, FracFocus.org

Launched in April 2011 amid increased demand for public disclosure, FracFocus.org was created as a voluntary disclosure program for drilling companies to report the chemicals used in fracking fluid. The site is managed by the Ground Water Protection Council (GWPC) and the Interstate Oil and Gas Compact Commission (IOGCC), nonprofit intergovernmental organizations comprised of state agencies that promote oil and gas development. However, the site is paid for by the American

Petroleum Institute and America's Natural Gas Alliance, industry associations that represent the interests of member companies.

Though originally designed as a voluntary program, several states (including Colorado, Louisiana, Montana, North Dakota, Pennsylvania, and Texas) have begun *requiring* drilling companies to report to the site as a means of online public disclosure. The move by states to require online disclosure is encouraging, but the choice of FracFocus as the vehicle is problematic. The site was developed in cooperation with industry associations, and its independence has been questioned. Because FracFocus is a third-party website, state agencies would have little to no authority to stop those recording the data from limiting functionality or use of the data.

Also, when electronic data is posted on a third-party site, it may not be available under state open records laws. The IOGCC has already declared that it is not subject to federal or state open records laws. "IOGCC is an interstate compact of its member states and is neither a state nor federal agency," Commission Director Car Michael Smith wrote in his July [response](#) to a data request from *EnergyWire*, a media company. "IOGCC is not subject to either the federal Freedom of Information Act or the Oklahoma Open Records Act," Smith said.

Government-mandated reporting information should be made available to the public on a government website, where access and capabilities are ensured and access to data cannot be limited by industry representatives.

The FracFocus website has several functional limits that also make it difficult for researchers to use for any significant analyses. For one, it does not include a comprehensive or specific list of all the chemicals used in fracking. The website also limits what users can search for in the database. But Colorado and Pennsylvania both require the FracFocus.org registry to be searchable by geographic area, ingredients, Chemical Abstracts Service Registry number, time period, and well operator by January 2013. If FracFocus does not contain this information and functionality by that time, state regulators have to develop their own searchable public websites. The IOGCC and the GWPC plan to improve the search function of the database to meet states' criteria by January 2013, but we believe this information should also be available on public websites.

Downloading data is another difficulty on the FracFocus website. Currently, users can only download reports of fracked wells as PDF files, which makes it very difficult for researchers to extract data (they have to scan or re-enter the data in the PDF files). Despite the plans to improve searching, there has been no indication if the site will provide data in a spreadsheet format for easy downloading and analysis.

Both the GWPC and the IOGCC [contend](#) (subscription required) that FracFocus was designed only for use by people who live near oil and gas wells – to allow them to find what chemicals were used to frack those wells – and "not for broader analysis." In general, the oil and gas industry does not support making chemical ingredient data available to the public in a downloadable format for fear that the public or anti-fracking activists "might misinterpret it or use it for political purposes."

Next Steps

SkyTruth plans to update its site with new data as it is added to FracFocus.org. By Dec. 1, the organization will have software in place that automatically updates the SkyTruth database any time new data is added to the FracFocus.org site. The group also plans to integrate the fracking data into its [Alerts System](#). This service allows the public to receive an e-mail alert or use an RSS feed to be notified whenever a new chemical report is added in a state or geographic area. Currently, the alerts are only available by state, but by Dec. 1, SkyTruth will have the capacity to send its audience more geographically refined data. This is a valuable and time-saving service, and we applaud the availability of new data in user-friendly and useful formats.

The Future of Long-Awaited Public Protections in Obama's Second Term

A number of high-profile rules that would strengthen health, safety, and environmental protections failed to move through the regulatory review process in the first term of the Obama administration. Many [speculate](#) that the administration avoided publishing controversial rules during the election season. With the election settled, some overdue rules may finally see the light of day. However, corporate interests that have been fighting against stronger standards continue to do so, and advocates for stronger protections are waiting to see if the administration will act more aggressively to protect public health and the environment in its second term.

Rules Caught in the Regulatory Review Logjam

The regulatory process is a lengthy one, and it often takes agencies years to adopt public protections. A significant source of delay for many protective rules is mandatory review by the Office of Information and Regulatory Affairs (OIRA). Under Executive Order 12866, OIRA review is limited to 90 days with a possible 30-day extension, but rules are routinely delayed beyond the 120-day deadline. As of Nov. 20, 129 of the 156 regulatory actions (and 20 of 24 economically significant rules) [pending at OIRA](#) had been waiting for more than 90 days. In fact, the average time that the 20 economically significant rules have been under review at OIRA is 264.8 days – more than twice the time allowed by executive order.

One long-delayed proposal is an effort by the Occupational Safety and Health Administration (OSHA) to strengthen workplace exposure limits for crystalline silica, a known cancer-causing substance that is linked to fatalities and disabling respiratory illnesses. The silica rule has been at OIRA since Feb. 14, 2011 – almost two years. During this time, OSHA estimates that more than 100 workers have died from silica-related illnesses. This [unreasonable delay](#), which came after OIRA held a number of closed-door meetings with industry groups, sparked an outcry from 300 occupational health experts, public safety advocates, and labor officials, who sent the White House a [letter](#) on Jan. 25, 2012, urging President Obama to release the rule for public comment. Almost a year after the letter was sent, the rule remains at OIRA.

Another proposed rule long past due is the U.S. Environmental Protection Agency's (EPA) proposed Chemicals of Concern List, which would identify chemicals that may present unreasonable human health risks. Under the Toxic Substances Control Act (TSCA), EPA would add a number of chemicals, including bisphenol A (BPA), to a list of substances that present or may present an unreasonable risk of injury to human health or the environment. The rule would have important health and safety benefits and is not economically significant, yet it has been stalled at OIRA since May 2010. Over a year ago, Sens. Frank Lautenberg (D-NJ) and Sheldon Whitehouse (D-RI) wrote OIRA a [letter](#) asking that the *proposed* rule be released. OIRA has yet to release the rule or explain the reason for the delay.

Environmental regulations were targeted by an increasingly anti-regulatory, [anti-environmental House of Representatives during the 112th Congress](#), and a number have been delayed by Obama administration officials. (For a more complete list of environmental rules that could be on the horizon, see this [article](#) by Kate Sheppard.)

In September 2011, [the president ordered](#) the EPA to withdraw a rule establishing a new standard for ground-level ozone pollution, directing the agency to wait and update the standard in 2013. Industry and environmental advocates alike are waiting to see how stringently the administration will regulate ozone pollution. In the face of intense opposition from business interests and some of their allies in Congress, EPA Administrator Lisa Jackson had proposed a rule that would strengthen the previous ozone standards of the George W. Bush administration, following the recommendations of the agency's scientific advisory panel. The Bush ozone standards were not sufficiently protective in the scientists' view and were [overturned](#) by a federal court in 2010. Environmentalists viewed the White House action as inappropriate political interference in agency rulemaking. [Evidence](#) shows that the standards scientists recommended to the agency would save thousands of lives every year. EPA is to review the ozone standard next year, and hopes are that a tougher standard will prevail.

Another environmental rule under review would regulate coal ash, a toxic waste produced when coal is burned. This December will mark the four-year anniversary of a massive spill in Tennessee that sparked new calls for the regulation of coal waste. While EPA [proposed new standards](#) for the regulation of coal ash in 2010, [little progress](#) has been made toward issuing comprehensive national standards. There are [new reports](#) that the agency will likely default to the less stringent regulatory option preferred by the coal and waste recycling sectors, but there is no official word yet from EPA.

Getting Rules Moving

When OIRA blocks publication of the rules proposed by federal agencies, the regulatory process grinds to a halt, the public officials and scientists who have worked on the standards are demoralized, reforms are delayed, and most importantly, public agencies are unable to implement the safeguards and protections that Congress wrote into law.

In the coming months, President Obama will be appointing a new OIRA administrator and some new agency heads. These staffing decisions will no doubt be important in determining whether stronger environmental and health standards are part of the Obama administration's legacy. But even before new candidates are nominated and confirmation hearings take place, the administration could move

the rules already under review at OIRA forward. They should do so. Promptly.

State Regulation of Compounding Pharmacies Is Inadequate

Over the past several weeks, 36 people have died and more than 500 others have been infected with fungal meningitis from tainted steroids obtained from a compounding pharmacy in Massachusetts. This industry prefers state regulation of its practices and has been fighting Food and Drug Administration (FDA) oversight for more than a decade. Some, including [Rep. Ed Markey](#) (D-MA) and [FDA Commissioner Margaret Hamburg](#), are now calling for clear FDA oversight authority over compounding pharmacies.

Traditionally, compounding pharmacies mixed medicines specifically for individual patients, following the instructions in a health care provider's prescription. For example, they would eliminate an allergen from a medicine or put cherry flavoring in foul-tasting medicine based on an individual patient's needs. States oversee these compounding practices. But 42 states permit a practice known as "compounding for office use" where a pharmacist prepares multiple doses of a medicine without a prescription for a specific patient and sells those doses to providers. At some point, a compounding pharmacy produces so many doses of a medicine that its practices begin to look like manufacturing rather than compounding.

Generally, states have regulated pharmacy practices, and the compounding industry prefers to leave it that way. Markey's [recent report on the industry](#) suggests the reason why. Only six states have a record of taking enforcement action against compounding pharmacies since 2001. As Markey's report notes, "State regulators are not, or cannot, perform the same sort of safety related oversight of compounding pharmacy practices that FDA has historically undertaken." In other words, effective FDA standards might have safeguarded the public from the meningitis outbreak.

FDA's authority to regulate the *manufacture* of drugs is clear. It must approve new drugs as "safe and effective" before they can be marketed, and it may seek a court order to shut down any drugmaking activity if substances are misbranded or adulterated. Before doing so, the FDA will usually send a warning letter to the manufacturer seeking voluntary compliance.

But FDA's authority over compounding pharmacies is unclear. The agency describes its authority as "more limited" compared with its authority over traditional drug manufacturers. As far back as 1996, then-FDA Commissioner David Kessler warned that unregulated compounding pharmacies could harm the public, and the agency has repeatedly urged Congress to give it clearer oversight authority.

Despite the ambiguity about its regulatory authority over compounding pharmacies, the FDA has issued 60 warning letters about unsafe compounded drugs since 2001. FDA takes this action when it believes compounding pharmacies are manufacturing misbranded or adulterated products. But because the compounding industry vigorously contests FDA's authority over its practices in court, if the agency sought a court order to shut down these practices, it would need to invest significant resources (at the expense of other priorities). Given past court decisions, it might not be successful. Of

course, these ambiguities were created by the compounding industry and allow it to profit with little effective oversight – at either the state or federal level.

The compounding industry has vigorously fought congressional efforts to increase federal regulation of its practices. At the behest of compounding pharmacies, courts struck down portions of legislation that would have increased FDA's oversight role, and in 2007, industry lobbying helped defeat a bipartisan bill to grant FDA clear authority over compounding pharmacies. The latest meningitis outbreak ensures that legislators will revisit the issue in the 113th Congress.

Time after time, the story is the same: Industry opposes federal oversight of potentially dangerous practices and argues that state regulation is preferable. In fact, industry prefers state regulation because state standards are often weaker than federal standards, and/or enforcement at the state level is less effective.

A few states are known for rigorously protecting public health, but effective state standards, adequately enforced, are the exception, not the rule. Markey and others hope the current outbreak will spur Congress to finally take action to improve federal oversight of these facilities.

[Comments Policy](#) | [Privacy Statement](#) | [Standards of Quality](#) | [Press Room](#) | [OMB Watch Logos](#) | [Contact OMB Watch](#)

OMB Watch • 1742 Connecticut Avenue, N.W. • Washington, D.C. 20009
202-234-8494 (phone) | 202-234-8584 (fax)

© 2012 | Please credit OMB Watch when redistributing this material.



Combined Federal Campaign #10201