GOVERNMENT MATTERS

April 9, 2013 Vol. 1, No. 7

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Food Safety Rules the Latest to be Weakened During Regulatory Review

Recently disclosed documents show that the Office of Information and Regulatory Affairs (OIRA) weakened a proposed Food and Drug Administration (FDA) food safety rule. During the regulatory review process, OIRA removed important safety testing requirements from the "preventative controls" rule, which were intended to prevent foodborne pathogens from entering the food supply. Unfortunately, this is nothing new. OIRA has a long track record of changing the draft rules it reviews, often weakening them to appease regulated entities. In this case, the public was made aware of the rule revisions only because FDA followed the requirement to disclose changes made during OIRA review.

Congress tasked the FDA with issuing a set of new food safety standards when it passed the Food Safety Modernization Act (FSMA) in 2011. The FDA finally released some of these proposals in January 2013, including one rule that would require food facilities to develop and implement controls to significantly minimize or prevent hazards. FDA had included in the draft rule requirements to conduct environmental monitoring for pathogens and finished product testing. In the published proposal, these requirements were removed from the text of the rule and only mentioned in an appendix.

Later, when FDA published both the draft it submitted to OIRA for review and the proposal that was ultimately published for public comment, it became clear that testing requirements had been stripped from FDA's original draft. This is not the first time an agency's original idea was supplanted by a weaker version during OIRA review.

Track Record of Rule Changes and Lackluster Transparency

Executive Order 12866 requires agencies to submit all significant proposed and final rules to OIRA, housed within the Office of Management and Budget (OMB) at the White House, for review before they are published for public comment or finalized. It also requires agencies to "[i]dentify for the public, in a complete, clear, and simple manner, the substantive changes between the draft submitted to OIRA for review and the action subsequently announced." The agency must also identify those changes that were made at the suggestion or recommendation of OIRA. Despite this requirement, agencies rarely disclose what changes OIRA makes to rules.

Even when agencies disclose the changes made to the original draft during review, it is not always clear which changes were made at the behest of OIRA, and it can be nearly impossible to determine exactly when the changes were made and the reasons or motivations for the changes. This lack of adequate disclosure and thorough explanation is especially disconcerting given OIRA's tendency to weaken rules.

The documents that FDA disclosed illustrate this pattern. It was apparent from the drafts that "FDA thought testing was critical to effective preventive control programs and OMB made them take it out," David Plunkett of the Center for Science in the Public Interest told *The Huffington Post*. "It's OMB once again protecting corporate bottom lines at the expense of protection for public health," Plunkett also explained to *Food Safety News*.

Other important health and safety rules have suffered a similar fate during OIRA review. A rule regulating hazardous coal ash, proposed by the U.S. Environmental Protection Agency (EPA) in 2010, was significantly changed while under OIRA review. EPA's original draft offered one strong regulatory option but asked for public comment on alternatives. By the time the rule was published in the *Federal Register*, it included two co-proposals – EPA's original proposal and a weaker, presumably OIRA-supplied alternative proposal. Not surprisingly, industry continues to push for the weaker option, and there has still been no final action on the coal ash rule.

The Center for Progressive Reform issued a report in 2011 citing a number of recent examples of rules being weakened after industry groups lobbied OIRA. In one instance, the EPA dropped a key testing provision from its 2010 proposed lead paint rule after the home-renovation industry complained to OIRA. In another, air pollution standards were significantly weakened compared to EPA's original proposal to reduce costs.

Despite OIRA's dominating influence over agency rulemaking, its review process has been historically opaque. In a 2003 report, the U.S. Government Accountability Office (GAO) found that OIRA often made substantial changes to rules under review, but the review process was not well documented or clear. Although 400 rules were changed, returned, or withdrawn during the one-year period examined, GAO focused on 85 rules from health, safety, and environmental agencies. Of those 85 rules, 25 were significantly affected while undergoing OIRA review. For many rules, OIRA recommended that agencies remove or delay regulatory provisions and add compliance flexibility.

For example, at the behest of OIRA, the EPA:

- Removed a substance from a list of hazardous constituents in a rule intended to identify hazardous wastes;
- Delayed the compliance date for states to report pollution emissions; and
- Added compliance alternatives and exemptions to rules seeking to minimize the adverse environmental impacts at power facilities that withdraw water from U.S. water bodies.

OIRA also returned a number of rules to agencies within the Department of Transportation, and others were withdrawn at OIRA's suggestion.

GAO also found that agencies often could not explain why changes were made to rules and observed that "agencies' docket files did not always provide clear and complete documentation of the changes made during OIRA's review or at OIRA's suggestion, as required by the executive order."

Conclusion

The public has a right to know how and why government agencies craft the standards they issue, especially when the process is being influenced by political and industry interests. FDA's release of documents for the preventative controls rule allowed the public to see how the rule the agency ultimately proposed differed from the draft rule it submitted to OIRA, but this is not enough. To truly improve accountability, agencies and OIRA should provide clear, complete explanations of what was changed, who recommended or influenced the change, and why.

EPA's Proposed Gasoline Standards Benefit Public Health, the Environment, and Automakers

On March 29, the U.S. Environmental Protection Agency (EPA) proposed a new rule setting stricter emissions standards for cars and trucks and requiring a reduction in the sulfur content of gasoline beginning in 2017. The proposal addresses health risks posed by breathing hazardous vehicle pollution, such as asthma and other respiratory infections that can cause premature death. Together, the more stringent sulfur limit and new emissions standards will lead to rapid improvements in air quality nationwide.

On Jan. 29, EPA submitted the proposed rule to the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget (OMB) for review. To the surprise of many, OIRA completed its review in only two months.

EPA's Harmonized Standard Clears OIRA Review in 60 Days

Under the Clean Air Act, EPA is tasked with setting emissions standards for vehicles to address air pollution that might endanger public health. The proposed rule sets a more stringent limit on the amount of sulfur permitted in gasoline, reducing the standard from 30 parts per million (ppm) to 10 ppm. By harmonizing the national standard with California's existing emissions limits, auto manufacturers now only have to follow one standard in all 50 states, a change that the auto industry widely supports.

Under Executive Order 12866, agencies must submit proposed major rules and an analysis of costs and benefits to OIRA for review. OIRA is given 90 days to complete all initial reviews; however, as we reported in an earlier article, OIRA often misses this deadline, delaying crucial standards and safeguards. In this case, however, OIRA completed its review in only 60 days, leading some experts to question why OIRA review was so fast. Since OIRA has now demonstrated that it can complete its review of a complex, controversial rule in 60 days, these experts wonder what really causes the lengthy, sometimes indefinite delays faced by many agency rules.

Some sources have suggested that OIRA's speedy review may have been prompted by the upcoming confirmation hearing on the nomination of Gina McCarthy to head EPA. By releasing the rule, McCarthy is now free to tout it as a widely supported and cost-effective measure that creates jobs and addresses health concerns associated with air pollution.

Benefits of Reducing Sulfur Emissions Outweigh Costs by 7-to-1

EPA's emission standard will result in huge benefits. EPA estimates that by 2030, the total annual health benefits from the new standards will range from $8 billion to $23 billion. Each year, the rule will prevent 820 to 2,400 premature deaths, 3,200 asthma-related hospital admissions and visits to the emergency room, and 22,000 cases of respiratory ailments in children. The rule will also protect approximately 50 million people exposed to air pollution near roadways, such as cyclists, joggers, and other pedestrians.

Description of Quantified Costs and Benefits	Anticipated for Year 2030
Vehicle Program Costs	$2.1 billion ($130 per vehicle)
Fuels Program Costs	$1.3 billion (1 cent per gallon)
Total Estimated Costs	$3.4 billion
Total Estimated Health Benefits	
3% discount rate	$8 billion - $23 billion
7% discount rate	$7.4 billion - $21 billion
Annual Net Benefits (Benefits - Costs)	
3% discount rate	$4.6 billion - $20 billion
7% discount rate	$4.0 billion - $18 billion

Source: EPA's Draft Regulatory Impact Analysis, tbl. I-7, Summary of Annual Benefits and Costs Associated with the Proposed Tier 3 Program (billions, 2010 dollars)

EPA estimates that these benefits far exceed the cost of the vehicle emissions standards and limit on sulfur content of gasoline. The total annual cost of EPA's proposed rule is approximately $3.4 billion – only a fraction of the annual benefits. The more stringent sulfur standard is projected to increase the price of gasoline for refineries by less than one cent per gallon; the vehicle emissions standards require new technology that will cost $130 per vehicle per year. These amounts are unlikely to affect demand for either gasoline or new cars.

Oil industry opponents have exaggerated the costs of the standard; *The Washington Post* editorial board recently explained how the industry ignores the flexibility EPA's proposal provides oil refineries by allowing them to average the sulfur content across the pool of gasoline they produce and to make needed capital improvements over many years.

Moreover, the EPA sulfur standard is identical to standards already in place in California, as well as Japan and Europe, which means many oil refineries already comply with EPA's proposed rule. In fact, of all 111 U.S. oil refineries, EPA found that 29 already meet the new sulfur standard or would require only minor improvements, 66 would require moderate changes, and only 16 refineries would have to make significant upgrades and invest in new equipment capable of meeting the stricter standard.

Industry Opponents Likely to Increase Pressure on Policymakers to Delay Rules

Oil industry lobbyists and industry allies in Congress are already pressing the agency to delay the rule for a full year while EPA recalculates the rule's cost. EPA may grant a request to extend the notice-and-comment period and allow the public more time to review the approximately 900-page rule and the accompanying 500-page regulatory analysis. And OIRA will have another opportunity to delay these public protections when it reviews EPA's final rule.

Take Action on EPA's Proposed Rule

EPA's new standard for reducing sulfur content in gasoline and setting stricter limits on vehicle emissions is an important part of the agency's nationwide program to improve air quality and protect public health and our quality of life. Citizens can make their voices heard by filing comments supporting EPA's effort to reduce auto emissions.

House Budget Plans Do Not Reflect Americans' Views on Public Investments

Job Creation and Protecting Societal Protections Should Be Priority Now, Not Deficits

Sequestration's automatic cuts to federal spending are beginning to sting in communities across the country, and two of the four major congressional budget plans put forth this year are at odds with public opinion on specific areas of public investments, according to a Center for Effective Government analysis. As the Pew Research Center found in a pre-sequestration poll in February, most Americans say they support maintaining or increasing funding for specific federal programs, including education, Social Security, and Medicare.

Two of the congressional plans, both offered by House Republicans, would cut spending even more deeply than it has already been. Two other plans, from Senate Budget Committee Chair Patty Murray (D-WA) and the Congressional Progressive Caucus (CPC), track more closely with the views of the American people.

- ***Education***. While 89 percent of Americans polled support maintaining or increasing spending on education, both Rep. Paul Ryan's (R-WI) and the Republican Study Committee's (RSC) budget blueprints cut the purchasing power of Pell Grants to pay for tuition and slash funding for improving teacher quality and student achievement. By contrast, the Murray and Congressional Progressive Caucus plans would expand support for education.

- ***Social Security*** is extremely popular with 87 percent of Americans who support maintaining or increasing spending in this area. Most of the plans do not propose changing it in any way, except for the Republican Study Committee's plan, which proposes decreasing benefits.

- ***Transportation and infrastructure*** spending to maintain, repair, and build roads, bridges, and other public infrastructure – critical to the broad economic success of the nation – is another area of spending with significant popular support, with some 81 percent polled stating that they want spending maintained or increased. The two Democratic plans increase spending here, with especially large increases in the Congressional Progressive Caucus plan. The Ryan and RSC plans cut this part of the budget.

- ***Defense*** is among the most "popular" major budget categories that Americans think should be cut back. But even then, defense spending is still seen by a majority as an area that should be shielded from spending reductions. Only 24 percent of Americans polled by Pew say defense should be cut. Defense is the only major area where the Ryan and RSC budgets appear to line up with the public's views, as they would essentially do nothing to cut defense spending. Murray's plan seeks only modest amounts of savings in defense. The sole plan that seeks relatively deep cuts to defense is the Congressional Progressive Caucus's.

- ***Aid for the poor***. A majority of Americans – 71 percent – also want to increase or maintain aid for the needy here in the U.S. Slightly more Americans (27 percent) want this aid increased than those that want it cut (24 percent). The Ryan and RSC budgets deeply cut food assistance programs and Medicaid. The Murray plan maintains them, whereas the Congressional Progressive Caucus plan greatly expands spending.

Although Americans consistently state that reducing the deficit should be a priority, repeated polling by Pew and others have shown that the majority of Americans reject reductions in the vast majority of specific areas of spending. A plurality of Americans supports maintaining most programs at their current levels, according to Pew's poll.

Why Americans Say They Are So Concerned About the Deficit Right Now

One of the greatest paradoxes in American politics is the conflation Americans have made between the state of the economy and government deficits. There is a relationship between the two, but the seemingly intuitive understanding many Americans have of their connection is backwards. A campaign by conservatives over several decades, coupled with a media that hasn't been willing to aggressively challenge savvy public relation efforts enough, have contributed to this confusion.

When economic times are good with strong employment and growing wages, tax revenue increases because there is greater income, assuming everything else such as tax rates remain the same. At the same time, these taxes generally feel like less of a burden. Meanwhile, expenditures on unemployment insurance and other types of assistance to the needy, such as the Supplemental Nutrition Assistance Program (SNAP), drop. Combined, these revenue and expenditure changes make it easier to shrink the annual deficit and even generate surpluses as the U.S. government had in the late 1990s.

During times of economic distress, expenditures on unemployment insurance, SNAP, and other programs increase and tax revenue drops – this tends to exacerbate deficit spending.

So there is a relationship between the economy and the deficit, but it's an inverse one. As the *American Prospect* noted, "Voters associate high deficits with poor economic performance—the public might say that it wants more action to lower the deficit, but what it means is that it wants Washington to improve the economy."

Part of this is due to confusion that has been carefully cultivated by conservatives and business leaders, such as Peter G. Peterson through his numerous organizations like "Fix the Debt," in a decades-long campaign to strangle the government. As Robert Reich, labor secretary in the Clinton administration, recently wrote, "The piles of money spent by billionaire Pete Peterson to persuade Americans that the budget deficit is the nation's most urgent economic problem is now paying off.

Recent polls show greater concern about the deficit now than was expressed a few years ago when the deficit represented a much larger percentage of the total economy."

With effective tax rates on major corporations at record lows and a larger share of the tax burden being placed on wages, even as corporations rake in record profits and average wages are lagging, lower overall tax revenue – especially in our country's weak economic situation – means there will be greater deficits, assuming spending stays the same. Conservatives, in turn, use this as an opportunity to argue more strenuously for cutting spending even more.

This is what anti-tax crusader Grover Norquist meant when he famously said, "I don't want to abolish government. I simply want to reduce it to the size where I can drag it into the bathroom and drown it in the bathtub." He wants to starve government of revenue, creating deficits and hysteria over debt, in order to further cut the size and role of government.

Why We Want the Government to Make More Public Investments in Economic Hard Times

When the economy is bad and people are uncertain about their future employment prospects, they tend to save more and consume less. This is completely rational. Similarly, when a businessperson assesses whether she should hire more workers and sees weak consumer demand, she is unlikely to hire more employees – whom she may have to lay off – and otherwise expand her operations. That businessperson is more likely to try to get more out of the workers she has until there is enough reason to believe she needs to hire more.

Multiply these dynamics across the economy, and it's easy to see how an economic shock can be hard to recover from. Why would anyone want to be the first business to expand during uncertain times when there's a high risk of losing money because everyone is pulling back on their spending? Similarly, why would a bank want to take a risk with loans to unproven businesses – or even proven ones?

Enter government spending. Often, government is the only major player that can move the economy up and out of this otherwise mutually reinforcing morass of slow growth and high unemployment – this undoubtedly happened during the massive expansion of government spending in World War II. The key is government can make up for, or at least mitigate, the drop in demand in the economy when most everyone else is retracting, such as individuals paying off their credit card debt instead of spending and banks sitting on large pools of money that they are loathe to loan out.

This is why folksy but misleadingly dangerous attempts to compare the federal budget to family budgets should be ignored. Even President Obama has fallen into this trap, saying, "Small businesses and families are tightening their belts. Their government should, too." As University of Oregon economist Mark Thoma wrote in response, "Reducing the deficit in a recession – Obama's belt-tightening analogy – reinforces the decline in private sector demand instead and makes an already bad situation worse."

The government should expand public investments when economic times are bad generally (and work on paying down the debt when things are good).

Government can do this by investing in projects that lay the groundwork for growth in the private sector: repairing and building infrastructure, such as roads, bridges, and high-speed Internet connectivity, and funding basic research that allows the U.S. to maintain its technological lead in fields such as aerospace, biotechnology, medicine, robotics, defense, and computers.

Spending in general will create jobs. That does not mean there are not legitimate concerns about what actually gets funded – spending that predominantly benefits the wealthy and powerful corporations is not very justifiable – and about potential waste and fraud – public dollars should be used effectively on projects that are successful. After all, funding for a bridge that gets wasted by contractors isn't of much use. Yet those challenges can be overcome with vigorous oversight, competent front-end planning, and appropriate resources. Unfortunately, there have been numerous examples of waste and fraud, which the media rightfully reports on, that have been seized by anti-government ideologues as arguments against government spending. However, the larger story is that these societal investments mostly have been successful in laying the groundwork for a healthy, growing economy. While there is some disagreement about what kinds of spending are worthwhile, there is a broad understanding among Americans of the need to invest in ourselves and country to help America compete as a nation.

An effective government can play a large role in improving the state of the middle class and helping the private sector get back on its feet. To do that, the government needs to maintain a key role in nursing the economy back to health.

Shortcomings in Transparency Performance Point to the Need for Reforms of Freedom of Information Act

The Center for Effective Government's recent analysis, *Freedom of Information Act Performance, 2012: Agencies Are Processing More Requests but Redacting More Often*, highlighted some troubling trends in agencies' performance in providing information to the public under the Freedom of Information Act (FOIA) and found wide disparities among agencies. These shortcomings show that legislation will be needed to repair the current weaknesses in the FOIA system.

One bill is already moving through the House. On March 20, the House Oversight and Government Reform Committee approved the FOIA Oversight and Implementation Act (H.R. 1211), which includes several provisions that would make FOIA easier for requesters to use and require more consistency in agency responses. However, in its current form, the bill would make little progress in improving the problems identified in our latest FOIA performance analysis.

Findings from the Analysis

Requests Rose, but Processing Increased and Backlogs Fell

After a steady decrease in the number of requests for public information during the George W. Bush era, the 25 agencies covered in the analysis began to receive more FOIA requests during the first term of the Obama administration. In fiscal year 2012, agencies received 11,000 more requests than in the previous year but were able to process 39,000 more requests. The fact that agency processing is catching up to demand is a positive indication of agencies' capacity to meet the law's requirements. However, most major agencies are still not in full compliance, as discussed below.

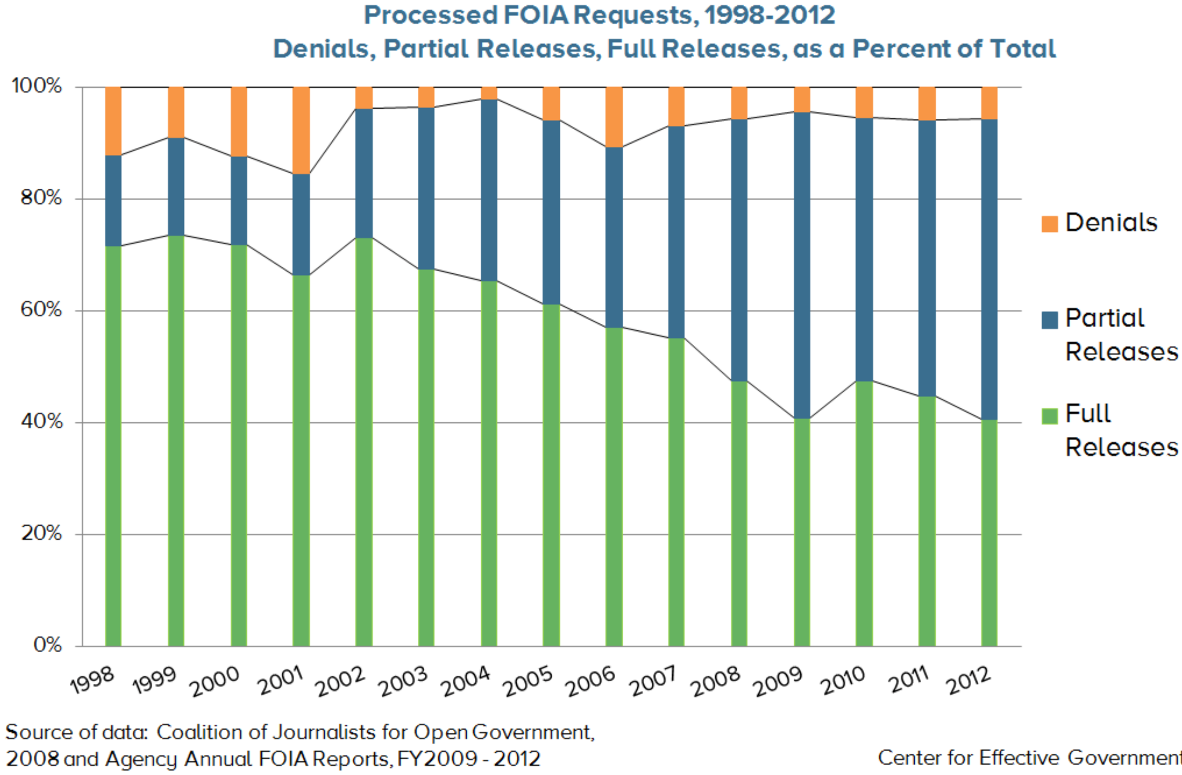
The number of unprocessed, or pending, requests has generally been falling since 2006, and in the last year alone, the number of pending requests was reduced by 12 percent. Most of this progress was due to one agency: the Department of Homeland Security (DHS). DHS receives far more requests than the other federal agencies examined in our analysis and reduced its pending requests by 30 percent.

Overall, the Obama administration has made an intentional effort to reduce backlogs: at the end of 2009, President Obama ordered the heads of federal agencies to reduce their backlogs of FOIA requests by 10 percent per year. However, out of 11 agencies that had 500 or more backlogged requests, only two met the reduction goal each year: the Departments of the Interior and the Treasury. Two agencies, the Central Intelligence Agency and the National Archives and Records Administration, failed to meet the backlog reduction goal in all three years.

Yet the House bill that passed out of committee, H.R. 1211, would do little to directly address the issue of backlogs. Stiffening the penalties for agency non-compliance and encouraging agencies to develop robust plans for managing their FOIA requests are required.

Fewer Releases Include All the Information Requested

The practice of “redacting” information (not releasing all of the information requested) has been increasing since George W. Bush took office. President Obama has failed to halt this trend. In fact, the proportion of fully granted requests fell in 2012 to the lowest level on record – just under 41 percent of FOIA requests processed provided full and complete information to the requester.



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Unfortunately, H.R. 1211 would not do much to directly address this, and without more information, we don't know how serious this problem is. Available data do not indicate the extent of withholding under partial releases, so it is not possible to know whether agencies are redacting small amounts of sensitive information or withholding dozens of documents per request. Congress should require reporting of the quantity of records released as a way to permit fuller analysis and oversight of the issue of partial releases.

Federal Agencies Are Using Exemptions to Deny More Requests

In 2012, agencies used exemptions to withhold information markedly more often than in 2011. This increase occurred despite the fact that the use of the internal rules exemption, once among the most highly-used exemptions, was almost entirely eliminated after a 2011 U.S. Supreme Court decision that limited the applicability of this exemption. However, a significant increase in the use of the interagency memos exemption suggests that some agencies may have been using it to withhold records that had previously been claimed as internal rules. The exemption on internal and interagency information allow agencies to claim that disclosing information would negatively impact how government functions and how agencies interact with each other; the safety or rights of American citizens are not directly at stake if such information is released. Several other exemptions were also claimed more often in 2012 than in the previous year.

H.R. 1211 would partially address this issue by prohibiting an agency from withholding information unless it can show "foreseeable harm" resulting from release of the information. This would roughly codify a similar standard found in Attorney General Eric Holder's FOIA guidelines.

Instituting tighter standards for withholding would be an important step in the right direction and would follow emerging international norms for access to information laws.

However, it is difficult to know how effective the provision would be as currently written because the bill does not explain how the foreseeable harm standard for withholding should be applied. Without more details, it is not clear how the provision would affect agency procedures or judges' decisions. Congress should make clear that the burden should fall squarely on agencies to show that harm would result from disclosure and that judges should be able to review these decisions.

Congress should also address the interagency information exemption (Exemption 5) in particular, given its tremendous growth and its discretionary nature. Congress could require agencies to consider the public interest in releasing the information, rather than only the potential harm to governmental functions. In addition, Congress could limit the length of time that agencies can claim this exemption, comparable to provisions under the Presidential Records Act that allow a former president to restrict access to his or her records for only 12 years after leaving office.

Moving Toward Stronger Disclosure

Reps. Darrell Issa (R-CA) and Elijah Cummings (D-MD), the sponsors of H.R. 1211, have taken the lead on fixing the FOIA system and have shown their willingness to work toward constructive reforms to increase transparency. As the legislation moves to the floor of the House and on to the Senate, there will be opportunities to improve its limitations. We would also like to see open government advocates in the White House work to ensure the bill gets better as it moves through congressional negotiations. Effective improvements in FOIA would be a fitting legacy for a president who wants to be the most transparent in history.

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