In This Issue

Congress Delays Spending Bill, Tackles Tax Return Provision

Although it was widely believed Congress would pass and the President would sign the $388 billion omnibus spending bill before Thanksgiving, it appears now the must-pass legislation will remain on hold until Dec. 6 when Congress will reconvene for a second lame-duck session to work on its passage. The bill, H.R. 4818, includes the nine remaining appropriations bills Congress left unfinished when the fiscal year ended, as well as numerous other riders and provisions.

The bill was not passed as expected because of a controversial rider that threatened the privacy of U.S. taxpayers' records by allowing some Congressional staffers the power to enter Internal Revenue Service (IRS) facilities and examine taxpayers' returns. The staff of Senator Kent Conrad (D-ND) discovered the provision, and in his floor statement on the subject Conrad stated, "That is an outrage. That is absolutely beyond the pale to allow staffers here the access to tax returns of any American citizen, of any American company with absolutely no civil or criminal penalties for the release of that private information. What is going on here that we have a stack of paper that has a little nugget like that stuck in?" House Minority Leader Nancy Pelosi (D-CA) echoed Conrad's sentiments, saying "The Republican leadership forced through a so-called 'martial law' rule that required a same-day vote, preventing members of Congress from having enough time to read legislation that spent hundreds of billions of dollars and was thousands of pages long." She proposed requiring that lawmakers have a minimum of three days to read legislation before voting on it.

The House will reconvene Dec. 6 and the Senate Dec. 7 to pass a correcting bill. Meanwhile, Congress passed a continuing resolution that will fund all government programs and agencies through Dec. 8, extending the current CR, which runs through Dec. 3. It is undetermined how long the second lame-duck session will last. The spending bill process is further described in a *New York Times* article Nov. 24.

The $388 billion spending bill includes funding for thousands of faith-based and community organizations and other agencies and programs. The Compassion Capital Fund will receive $55 million to provide social service grants to charitable and religious organizations. That amount is half of what President Bush requested, but 15.3 percent more than in fiscal year 2004. The bill also funds abstinence programs, job training for the unemployed, education and substance abuse programs. For more information see *Highlights of the Conference Report*.

Congress Raises Debt Limit, Fails To Pass Intelligence Bill

While members of Congress were unable to complete work on the omnibus spending bill or the intelligence bill during the lame-duck session, they did manage to complete their work on the debt limit.

Both the House and the Senate approved measures that will raise the debt ceiling by $800 billion, bringing the debt limit to $8.18 billion dollars. This marks the third time since 2001 that Congress has had to increase the debt limit to keep up with both federal spending and tax cuts. The failure of Congress to reinstate PayGo restrictions demonstrates a severe lack of fiscal discipline; and in essence gives the president a blank check to continue running large deficits.

Raising the debt ceiling, while necessary to fund U.S. agencies and programs, has profound implications for our nation's fiscal house. A *Washington Post* article raises some concerns. Yet little is being done to address the long-range structural problems we now face.

While Congress acted to raise the debt ceiling, it was unable to reach agreement on the bill to overhaul U.S. intelligence agencies. After weeks of debate, Republican lawmakers blocked it from going to the floor on the last day of the lame-duck session, even as President Bush urged its passage. There is hope that an agreement will be reached before January, in which case the 108th Congress will reconvene one more time for a vote, possibly during the Dec. 6 lame-duck.

White House Rejects Overtime Rules Amendments

In both versions of the FY 2005 Labor-HHS spending bill, the House and Senate approved amendments intended to block the White House from implementing new and harmful overtime rules. Those amendments, sponsored by Rep. David Obey (D-WI) and Sen. Tom Harkin (D-IA), would have reinstated old overtime eligibility rules for some workers, and were seen as a major victory for labor.

Although the amendments were successfully passed in October, a conference committee deleted the language from the bill during last week's lame-duck session because the White House threatened to veto the entire omnibus spending package if it included such amendments. Read more about overtime rules and the economic effects of changing them in a briefing paper from the Economic Policy Institute.

While it can be considered a theoretical victory that both Houses supported the amendments, it is a significant loss that they were ultimately stripped from the spending bill. However, when the appropriations process is reduced to Congress passing most of the bills through an omnibus, it is not surprising important policy amendments do not receive the attention they deserve. For more on this, read this *Washington Post* article.

EPA Releases Early TRI Data, Usability Limited

On Nov. 23, the Environmental Protection Agency (EPA) began early access to the 2003 Toxics Release Inventory (TRI), but in a limited manner. This early release is seven months faster than last year's release. While this earlier access represents a step in the right direction, the data format significantly limits its use. Additionally, EPA will not make the underlying data available to the public at this time.

EPA typically releases the entire database for a new year about 18 months after that reporting year ends. For example, the 2002 data, which companies had to report to EPA by July 1, 2003, was released June 24, 2004. Public interests groups have continually pushed for earlier release of the data so the public can use the information before it is relatively out of date. As part of EPA's efforts to remedy these concerns and speed up the process, this year the agency is releasing facility data earlier, but in a special Electronic-Facility Data Release format. This earlier release is prior to several steps EPA takes to cross check the quality of the information submitted by companies, most of which is now submitted electronically.

Unfortunately, the information's format makes it difficult for users to manipulate or analyze the data. EPA usually presents the information in a database format that allows users to examine totals, averages, and trends. In other words, users can aggregate and disaggregate data in different ways. The Electronic-Facility Data Release, however, only allows users to view the individual forms facilities submitted for each chemical release. The system does not, for example, permit users to add these releases together to examine the total releases from a facility or total amount of chemicals released in a town.

Moreover, EPA has been unwilling to provide the underlying data to the public even though it is making the data available through its website in a limited format. EPA says it will continue making the underlying data available once it makes the full data set available on its website in the spring. Groups such as Environmental Defense and OMB Watch make such data available for free on Scorecard and RTK NET, respectively.

The early data release is available at http://www.epa.gov/tri-efdr/.

Court Dismisses First Data Quality Act Case

In the first Data Quality Act case to be handled by the courts, a U.S. District Court has ruled that challenges under the DQA and its subsequent guidelines to agencies are not judicially reviewable. A previous court decision addressed the issue of reviewability, but the legal claim in that case was not limited to data quality.

On Nov. 15, the U.S. District Court for the Eastern District of Virginia dismissed a case brought by the Salt Institute and the U.S. Chamber of Commerce against the National Heart, Lung and Blood Institute (NHLBI) over statements about the health benefits from lower sodium diets. In reviewing the government's motion to dismiss the suit, the judge, Gerald Bruce Lee, ruled that the Salt Institute and the U.S. Chamber of Commerce lacked legal standing to claim injury in a federal court, concluded that the DQA provides "no private right of action," and determined that the key data is not subject to judicial review under the Administrative Procedure Act.

See OMB Watch's full analysis of the court decision.

CSX Refuses to Disclose Hazardous Waste Re-Routing

Rail companies that operate in and around Washington, DC, refuse to reveal whether or not hazardous chemicals are being re-routed around the city. Rail companies may be voluntarily re-routing trains, but the public will not be informed.

During a D.C. City Council meeting last Monday, CSX Transportation, the owner of a rail line that runs near downtown D. C., refused to disclose any details in security changes including whether they are re-routing trains. Both CSX and the Department of Homeland Security (DHS) refrained from discussing plans, citing security concerns. DHS did disclose that a working group called the D.C. Rail Corridor Project has developed measures to heighten security along the rail lines. Specific information on the working group and its plans is not publicly available.

Calculations have determined that an attack on a 90-ton rail car containing chlorine inside the nation's capital could kill up to 100,000 people. While only a small number of the 8,000 cars that pass through the city each year contain such volatile chemicals, the threat remains significant. The irony is that if hazardous shipments are being re-routed then the companies and DHS are promoting secrecy for a problem that has already been fixed. Some believe that the secrecy may be an attempt to prevent or delay other major cities from pursuing similar re-routing procedures, which would cost the rail companies money.

In response to the concerns about hazardous shipments, the D.C. Council voted on an emergency bill Nov. 9 that would have banned the shipment of any hazardous materials through the city. CSX and the Department of Transportation opposed the bill. Support from D.C. Council members and the mayor shifted and the bill ultimately failed.

Jersey to Withhold Hazardous Waste Records

A proposed rule in New Jersey would keep important health and safety information secret, possibly endangering residents that live near chemical plants, or workers that are employed at a number of different facilities.

On Oct. 18, the state's Attorney General's Office published proposed regulations modifying access to records, which, according to the proposal, is intended to "strike a balance between the need to allow read access to government records and the need to deny access to government records where such access would materially diminish the State's ability to protect and defend the State and its people against sabotage and terrorism."

New Jersey's Open Public Records Act, which took effect on July 7, 2002, requires all government records be disclosed unless specifically exempted. Around the same time, former Gov. James E. McGreevey issued Executive Order No. 21 (on July 8, 2002) to provide exemptions to the new Open Public Records Act. The executive order excludes from disclosure at any level of government:

> Any government record where the inspection, examination or copying of that record would substantially interfere with the State's ability to protect and defend the State and its citizens against acts of sabotage or terrorism, or which, if disclosed, would materially increase the risk or consequences of potential acts of sabotage or terrorism.

The executive order also requires the Attorney General, in consultation with the Domestic Security Preparedness Task Force, to develop more specific rules on what "government records shall be deemed to be confidential." The proposed rule issued on Oct. 18 is to implement this directive.

The proposed rule would limit access to information providing details about buildings including airports, tunnels, stadiums, and emergency-response and hazardous waste storage facilities. The information could range from security plans for existing sites to proposed development plans. The rule could also restrict workers and concerned citizens from knowing what chemicals are stored in their workplaces and neighborhoods.

The proposed rule also provides exemptions to disclosure in nine other areas, ranging from information about contagious diseases in livestock to security of computer networks to various uses of geographic information systems (GIS). Additionally, the rule proposes to exempt from disclosure sensitive but unclassified information described under Section 892 of the Homeland Security Act.

Under the proposed rule, records identified as exempt from disclosure would only be released if the head of a cabinet-level

agency and the state's Domestic Security Preparedness Task Force determine that the recipient has a "bona fide need for public access to the records and imposes appropriate limitations or conditions upon such authorized disclosure."

Rick Engler, the director of New Jersey work Environment Council, believes, "[t]he rules will do more to hurt public safety than to minimize the impact of terrorists." Many public interest groups assert that maintaining a right to know environment best ensures public safety. The government should be required to disclosure information except when information falls within clearly defined categories such as national security and privacy information. This method informs the public and allows them to participate in the effort to make their communities safer.

The proposed rule is open for public comment until Dec. 17.

Committee Releases Clarke's Declassified Testimony

The Senate Committee on Intelligence Chairman Pat Roberts (R-KS) finally released declassified testimony from former White House Counterterrorism Chief Richard Clarke regarding the 9/11 investigation. As reported in a previous *OMB Watcher* article, Roberts refused to release the testimony publicly, even though officials declassified it earlier this year. The testimony gained attention after critics asserted that Clarke made statements this past March regarding pre-9/11 intelligence that conflicted with the earlier testimony.

Several Senators called for disclosure of the declassified testimony earlier this year, but Roberts refused, leading many to speculate that the information was being withheld until after the elections for political reasons. The Intelligence Committee posted the testimony on its website on Nov. 17, just two weeks after the election. A copy of the testimony can also be found on the Project on Government Secrecy's website.

Intelligence Bill Erodes Right To Know

When House Speaker Dennis Hastert (R-IL) refused to bring the intelligence reform bill to a vote because Republicans in the House of Representatives opposed it, some open government advocates breathed a sigh of relief. As the bill moved through Congress, lawmakers dropped or severely limited the 9/11 Commission's recommendations to strengthen openness throughout the federal government.

In the last week of negotiations, Sen. Susan Collins (R-ME) acceded to pressure from the White House and other House Republicans to keep the total intelligence budget secret. Other language to encourage federal agencies to keep fewer secrets was narrowed from its already humble starting point. A proposal from several senators to let the public appeal decisions by government agencies to keep information secret was narrowed so only the chairmen of already powerful congressional committees could make such appeals. The Center for National Security Studies expressed concern that the legislation would expand intelligence agencies' ability to withhold documents from the public. And finally, congressional staff appeared unsure how to address the need for Congress to exercise stronger oversight over the way the new National Intelligence Director would control the flow of information.

While the 9/11 Commission and families of the 9/11 victims pushed for passage of the bill, in the end the bill may have enshrined bad policy into a law that could increase government secrecy for years if not decades.

It is still possible for Congress to complete work on the bill and schedule a vote next week. But it is more likely that intelligence reform will not be voted on until next year. If so, that could provide open government advocates an opportunity to regain some ground or clarify what problems really exist.

FEC Schedules New Rulemaking in 2005

Beginning in January 2005 the Federal Election Commission (FEC) will begin an intense seven-month series of proceedings to amend rules implementing the Bipartisan Campaign Reform Act of 2002 (BCRA) rejected by a federal court this fall, and take up new issues generated by this year's election. Among those with greatest impact on nonprofits will be expansion of regulation into Internet communications, reconsideration of the electioneering communications exemption for 501(c)(3) groups and party donations to nonprofits.

At its Nov. 18 meeting the FEC approved a schedule for the new rules along with a requirement for quick final action once public comment periods have closed. Nonprofits will be most impacted by consideration of:

- Party donations to tax-exempt organizations. The FEC staff have drafted a proposed rule for the Commissioners to consider at their Dec. 2 meeting. If the Notice of Proposed Rulemaking is approved, it will be published in the *Federal Register* for public comment likely in January.
- Internet exclusion from rules on coordination between campaigns and outside groups and the definition of a public communication. That proceeding will begin in March 2005.
- Electioneering communications. The FEC will consider exemptions for 501(c)(3) groups and documentary ads, as well as unpaid broadcasts. The federal district court overturned the unpaid broadcast exemption, but the FEC has appealed. This proceeding will begin in June 2005.

At the FEC meeting Vice-Chair Ellen Weintraub said substantive changes in the exemption for Internet communications are likely. Some of the other issues, such as the 501(c)(3) exemption for electioneering communications, were overturned on technical grounds and may not be radically changed.

For information on the court decision being appealed see the Oct. 4 OMB Watcher. More background is also available on the FEC webpage on rulemaking proceedings.

IRS Initiates Pay, Reporting Enforcement Effort

As part of a stepped-up enforcement effort, the Internal Revenue Service Exempt Organizations division (EO) is sending letters to approximately 2,000 charities asking them to detail their method of determining executive compensation. EO Director Martha Sullivan estimates 25 percent of organizations receiving the letter will be examined further.

In a related issue, the IRS is contacting charities that have not answered question 89B of Tax Form 990. Question 89B deals with excess benefit transactions, and is considering the use of penalties up to $50,000.

In April 2005 the IRS will open a Fraud and Financial Transaction Unit (FFTU) to scrutinize charities for possible transactions with terrorists and will begin examinations of U.S. charities that make foreign grants. A team devoted solely to examining charities that send money overseas has been created to study whether changes to current enforcement procedures are necessary. This effort appears to duplicate or conflict with the Treasury Department's Voluntary Best Practice Guidelines for U.S. Based Charities. These guidelines are inconsistent with current IRS regulations and have been criticized for being overbroad and ineffective to prevent diversion of funds to terrorists. Currently a working group of nonprofits and foundations is working on alternatives to the guidelines. See OMB Watch website for more information.

OMB Watch Launches Nonprofit Issues Blog

OMB Watch's nonprofit advocacy project is pleased to announce the launch of its new "Nonprofit Issues Blog." "Weblog," and "blog," are popular terms to denote a website (or a portion of a website) that contains short, frequent posts and Web links. The entries are usually sorted in reverse chronological order and archived by category and date. OMB Watch's new blog will cover a wide range of nonprofit issues, and will be updated throughout the week by OMB Watch staff. We are confident you will find it a valuable resource.

Court Narrows Faith-Based Suit

A law suit claiming sweeping constitutional problems with the Bush administration's faith-based initiative has been largely defanged by a court's decision that the plaintiff does not have standing to file the suit. The dismissal of all but a small portion of a lawsuit means the merits of the case remain undecided in the courts.

On June 17, the Freedom of Religion Foundation (FRF) filed suit in the United States District Court for the Western District of Wisconsin against Jim Towey, the Director of the White House Office for Faith-Based and Community Initiativesand the head of every federal agency that has a connection with the Faith-Based Initiative.

The complaint alleges the government violated the Establishment Clause of the First Amendment by: endorsing religion; favoring religious over secular organizations; directly funding services that include religious content; and funding intermediary faith-based organizations that prefer religious subgrantees to secular ones.

On Nov. 12, FRF voluntarily dropped eight of their ten claims focused on specific grants made under the initiative. On Nov. 16, the District Court also dismissed the claims against Jim Towey, all of the Faith-Based Initiative directors at various agencies, and Education Secretary Rod Paige after determining that FRF lacked standing to sue. The District Court felt that the taxpaying members of FRF are not considered injured parties eligible to file suit, leaving the merits of the claims undecided.

As a result, the complaint has been narrowed to two grants, one sponsored by the Department of Health and Human Services and the other by the Department of Labor. Further pre-trial motions on the remaining parts of the complaint were due in District Court by Nov. 23. FRF may still appeal the dismissal of their claims.

- For more on the Faith-Based Initiative, read this recent article in the *OMB Watcher*
- For a legal analysis of the court's decision see the Roundtable on Religion and Social Policy Nov. 22 Legal Update.

CFC Issues Terror List Check Guidance

After months of silence the Combined Federal Campaign has issued guidance on how charities participating in this workplace-giving program for federal employees should implement its requirement that they certify they do not knowingly employ persons on various government terrorist watch lists. The CFC Memorandum 2004-12 provides background information and clarification, but does not change the interpretation that led a dozen nonprofits to file suit to block the policy.

The CFC guidance, issued on Nov. 24, cites the Treasury Department's Voluntary Best Practice guidelines and Executive Order 13224 as authority for its action. But the Treasury guidelines themselves have been criticized for being overbroad, ineffective at combating terrorism, and inconsistent with existing law, and OMB Watch has called for their withdrawal. OMB Watch also sent a letter Sept. 7 to Mara Patermaster, the head of the CFC, asking a series of questions about how to implement the new requirements. While Patermaster did not respond, this memo provides some of the answers to questions we had. However, it does not resolve the fundamental problems with the list-checking requirement.

The memo modifies the requirements in the 2005 CFC application to only checking two government watch lists -- one operated by the Treasury Department (the Office of Foreign Assets Control Specially Designated Nationals List) and the other by the State Department (the Terrorist Exclusion List). CFC "continues to encourage" organizations to also consult a United Nations list, but it is not required.

The memorandum states that the list-checking requirement applies to employees, not volunteers, consultants or vendors. It also applies to direct contributions to any organization, but does not include non-cash contributions, and does not include tracking the regranting of such contributions. The memo indicates it "does not intend...to encompass the procurement of goods or services... unless the organization has reason to believe that a vendor of such goods or services commits or supports terrorist acts." This caveat is not described further.

If a match is found at the time of submitting the CFC application — even if it is an incorrect match — the group "may not complete the certification and will be denied participation in the CFC." If at a time subsequent to certification, the group finds a person it employs or an organization it contributes to on the watch lists, it must notify CFC "immediately." CFC will take "appropriate" steps, which could include suspension from the program, retraction of funds already disbursed, and notifying "investigative and/or enforcement authorities."

The memo does not provide information on how often to check the lists, but clearly indicates that the list must be checked when applying. The memo is less clear when it describes what it means by "knowingly" employ individuals or contribute funds to groups on the watch lists. The memo creates an ambiguous standard where CFC "determines that an organization in fact has exercised appropriate care to check the lists." CFC continues: "Intentional ignorance... is not an excuse for not knowing...."

OMB Watch is among the plaintiffs in the lawsuit challenging the policy. For more information see the Nov. 16 OMB Watcher. A full analysis of the guidance will be released soon.

Post Election Analysis of 527s, Other Issues Begins

Now that the first election since passage of the Bipartisan Campaign Reform Act of 2002 (BCRA) is over, analysis of its impact on campaigns, parties, donors and independent groups is underway. Overall, there was a huge increase in the number of small donors to both campaigns and independent groups and elimination of soft money donations to parties and federal candidates. While much more needs to be learned before further reform efforts go forward, initial reports provide an indication of long-term trends.

An Top 25 Individual Donors to Federal Oriented 527 Committees, 2004 Election Cycle that indicates $126.4 million of the total raised came from these donors. This represents 44 percent of all contributions. More research will be needed to identify characteristics of the remaining 56 percent of donors.

Democracy 21 found "The most important long-term campaign finance development of the 2004 elections may turn out be the breakthrough made in Internet fundraising", in its report Campaign Finance Successes and Problems in the 2004 Elections. The Internet helped make the significant increase in small donations possible. For example, America Coming Together (ACT) raised $3.3 million online, $7 million by direct mail and $16 million from concerts. This represents 51.5 percent of its total receipts of $51 million (based on data from October 2004).

The growth in small donors was most significant after the primaries were over. The Campaign Finance Institute's Wrap-Up Analysis of Primary Funding found that small donations quadrupled from 2000 levels. The report defines small donors as those giving under $200. However, the report found that donations of $1000 or more were the largest category of individual contributions.

The controversial independent groups spent heavily on broadcast ads, with Republican-leaning groups outspending Democratic-leaning groups near the end of the campaigns, according to the Center for Public Integrity. The *New York Times* reported that corporate political committees gave to Republican candidates over Democrats at a rate of 10-1.

The rise in small donors was a counterbalance to the breakdown of the Presidential public financing system. Both candidates rejected public financing. A task force of experts and reform advocates has called for a revamping of presidential primaries, with more realistic spending limits and a three-for-one match for donations of $100 to promote competition and participation.

Activists Assess Needs, Trends for 'Progressive Politics and Technology'

Collaboration, innovation and integration -- those were the keys to advancement for progressive advocacy groups during the recent electoral season, according to presenters at the November "Roundtable on Progressive Politics and Technology." These will no doubt remain key watchwords for progressives as they strive to keep up with evolving technologies, and use them to make their outreach strategies, programs and messaging more effective in the years ahead.

The forum packed more than 100 activists into a room at the AFL-CIO's Washington headquarters, for a program featuring prominent leaders from nearly 30 organizations and firms. In rapid-fire, panelists shared observations and lessons from their recent experiences with both national and grassroots campaigns. Each offered advice and predictions for building on their movements' accomplishments, and expressed optimism that progressives will realize significant success using the new tools and findings.

Among the technologies speakers touted were: weblogs, open source software for managing lists of supporters and donors, and digital media such as Flash and online video that take advantage of increasing broadband capabilities. Some echoed the view of Michael Warren of the firm Limbic Systems, who said, "What progressives most need now is detailed research -- focused information gathering" and the wisdom to use it for the greatest impact. Bob Fertik of Democrats.com challenged conventional political wisdom when he pronounced, "TV is the enemy [of progressives] ... money spent on TV ads is totally wasted." Other speakers expressed the related conviction that broadcast media's once dominant influence is quickly being eclipsed by the Internet. They agreed with Microsoft founder, Bill Gates, that the Internet will change history on the same scale as the invention of the printing press or the industrial revolution.

Sources for more information:

- Roundtable Series on Politics and Technology
- Pop and Politics
- MovingIdeas.org
- Democracy In Action
- Institute for Politics, Democracy and the Internet

NAS Biases Panel With Industry Interests

The National Academies biased a panel to study the risks from disposing coal wastes in abandoned mines by appointing six members with ties to the mining, coal, and electric utility industries, of whom two have subsequently stepped down after criticism from public interest groups.

Congress requested the National Academies to impanel a committee to study the health, safety, and environmental risks of disposing wastes from coal combustion wastes, millions of tons of which are stored in coal mines. These wastes, the product of coal burning power plants, can leach toxic chemicals such as mercury, arsenic, and lead when the coal ash makes its way into the water.

The Center for Science in the Public Interest and a large coalition of public interest groups sent a letter to the National Academies identifying six members of this panel who have strong ties to industries opposed to regulation of coal combustion wastes:

- **Patricia A. Buffler**, a paid consultant for the Electric Power Research Institute, has been a paid consultant for Pacific Gas & Electric Company and sits on the board of a company whose holdings link it with surface mining. Buffler's association with EPRI is particularly problematic because that company advocates the use of coal combustion wastes as backfill for mine reclamation.

- **Y. P. Chugh** holds patents related to coal combustion wastes that could mean he has a financial stake in any future regulation of the disposal of these wastes in coal mines.

- **Edward M. Green** worked for 16 years as general counsel of the mining industry's lobbying association. Green receives a substantial income from mining companies. As a lawyer at Crowell and Moring, he has litigated or filed amicus briefs in a number of cases opposing federal regulations of the mining industry.

- **Thomas O'Neil** recently retired as president and CEO of Cleveland Cliffs Iron Company and Cliffs Mining Company, and he spent years as an executive and board member of several mining industry enterprises.

- **Robin Mills Ridgeway** works for Purdue University's coal-fired electric plant, which annually generates 30,000 tons of coal combustion wastes. Purdue is currently using these wastes, among others, to reclaim a large gravel pit on university property, and one purpose of that project is to develop a commercial process converting coal combustion wastes into soil substitute products for mine reclamation and fill projects.

- **Richard Sweigard** sits on the advisory board of the University of Kentucky's Center for Applied Energy Research, which sponsors a biennial symposium to help industry work with coal combustion wastes.

After the public interest groups called for an investigation of the potential conflicts of interest and imbalance on the panel, Buffler resigned from the committee and the National Academies announced that Green "is no longer serving on the committee."

This committee is not the first National Academies panel imbalanced with pro-industry bias. In one case the National Academies stacked mining interests on a panel charged with investigating the clean-up of the Superfund site in Coeur d'Alene, Idaho. Other recent panels that the National Academies stacked with biased industry representatives include a committee to investigate the health consequences of perchlorate ingestion and one assessing plants genetically modified for pest protection.

Conclusions from the National Academies are given great weight in federal policymaking. "Highly influential scientific assessments" must be subjected to arduous peer review procedures under likely forthcoming guidance from the Office of Management and Budget -- unless they are produced by the National Academies, in which case they are deemed trustworthy, even if the assessments come from panels stacked with industry representatives.

Graham Defiant in Hearing, Dems Probe Mercury Rule

The last regulatory policy hearing of a House Government Reform subcommittee was split into two disconnected halves, as committee Republicans considered the White House's policy of inviting industry to suggest rollbacks of regulatory protections while Democrats assailed the Environmental Protection Agency's pending rulemaking for mercury pollution.

The final hearing this term of the Energy Policy, Natural Resources, and Regulatory Affairs subcommittee of the House Committee on Government Reform was marked by cheerleading from industry representatives of White House anti-regulatory policy, stonewalling from White House regulatory czar John Graham, and completely unrelated criticism from House Democrats and their witnesses of EPA's handling of its still-developing mercury policy.

Committee Republicans focused in the Nov. 17 hearing on the White House's approach to regulatory policy -- in particular Graham's use of the annual report on the cumulative costs and benefits of regulation as a vehicle for soliciting suggestions from industry for a "hit list" of regulations to be rolled back or weakened. A succession of industry groups praised the process. All witnesses ignored the embarrassment of the 2001 hit list, in which Graham sent agencies a selection of "high priority" nominations to reform -- at least two of which Graham had prompted agencies to create just months before.

Graham came under fire from Rep. Doug Ose (R-Cal.), who has consistently pushed an even more vigorously anti-regulatory position than Graham. After repeating an exchange from previous hearings -- Ose prodding Graham to identify the cost of all pre-existing regulations, and Graham demurring -- Ose pointed out that Graham failed to follow up on a specific request to submit a catalogue of all hit-list reform nominations from the current and previous regulatory accounting reports. Ose had requested that Graham list the individual nominations, identify which were screened out and which were forwarded to agencies, and chart their current status.

In response, Graham simply declared that his office had not been given sufficient time to prepare a response. In fact, two agencies had been given the same request for reform nominations submitted to them, and those agencies were able to comply with the request. Although Graham could conceivably have asked other agencies to do the same and then simply supplemented their responses with information exclusively available to his office, he offered no excuse for failing to do so.

Moreover, Graham specifically refused Ose's request for further information. Graham reminded Ose that his office is compiling information about the current hit-list solicitation for reforms to benefit the manufacturing sector in the final version of the annual regulatory accounting report, which will be published at the end of 2004. Graham declared that he would not release information about the hit list solicitation in advance of that final report, calling it "pre-decisional."

Although pre-decisional information can be excluded from Freedom of Information Act requests, it is not clear how these outside communications from industry constitute pre-decisional information, nor is it clear why Graham would cite FOIA exemptions to justify refusing to give information to Congress in response to a specific request from the committee charged with overseeing his office.

Committee Democrats, meanwhile, used the hearing not to line up witnesses with information that would counter industry cheerleading of the hit list project but, instead, to attack EPA's mishandling of pending mercury regulation. Compressed scheduling had ruled out a separate hearing on mercury, so the Democratic members essentially conducted their own one-sided hearing on mercury while the Republican members held a one-sided hearing on anti-regulatory policy.

Critics Diagnose Systemic Maladies of FDA

A Senate Finance Committee hearing on Vioxx and a series of studies by a leading medical journal reveal systematic breakdowns in FDA's evaluation of drug safety, prompting advocates to call for an independent agency to review drug safety.

Drug Researcher Testifies: The System is 'Broken'

In testimony before the Senate Finance Committee Nov. 18, FDA researcher David Graham said the current system for testing the safety of drugs is "broken" and incapable of preventing unsafe drugs from entering the marketplace. Graham's testimony came in response to an investigation into the agency's handling of Vioxx, which was pulled from the market last month after it was found that use of Vioxx led to increased risk of heart failure. Graham's research had found that users of Vioxx were 3.7 times more likely to suffer heart attack or sudden death compared to users of its competitor Celebrex. Though Graham presented these findings at a conference in France this summer, the FDA would not act on his findings here and instead asked Graham to soften his conclusions.

A Culture of Suppression

Vioxx is Not Alone

Although the Vioxx case prompted the hearing, Graham charged that the FDA's failure to serve the public extends beyond that one drug. Graham pointed to a systematic failure to warn the public about the dangers of drugs when such warnings go against the interests of the Office of New Drugs. Graham used the historical examples of Lotronex, which studies had shown caused severe constipation and ischemic colitis, and Rezulin, a diabetes drug that caused acute liver failure. In both cases, Graham stated, the FDA knew of problems with the drugs but stalled, allowing countless individuals to suffer needlessly before finally withdrawing the drugs.

Graham listed five other drugs that he believed had been proven to present a serious health risk that FDA was failing to act on:

- AstraZeneca's cholesterol drug **Crestor**, which has been linked to muscle degeneration and kidney failure;
- Abbott Laboratories' weight loss drug **Meridia**, which has been associated with high blood pressure;
- GlaxoSmithKline's **Serevent** for asthma, which can cause life-threatening lung spasms;
- Roche Pharmaceutical's **Accutane** for acne, which has been shown to cause serious birth defects; and
- Pfizer's **Bextra**, an arthritis drug similar to Vioxx, that may cause heart failure or stroke.

When questioned Graham asserted that the failure of FDA to protect the public is inherent in the current system. As Graham stated in his testimony, when FDA approves a new drug, "it is also saying the drug is 'safe and effective.' When a serious safety issue arises post-marketing, their immediate reaction is almost always one of denial, rejection and heat." Graham's charges were echoed as other news surfaced suggesting that top officials at the FDA are more concerned with industry profits and their own image than in protecting the public.

Killing the Messenger

FDA officials may have attempted to discredit Graham before the hearing took place, leading Senate Finance Committee Chairman Charles Grassley (R-IA) to call for the Department of Health and Human Services Inspector General to investigate the matter. According to the *New York Times*, when Graham realized he was potentially vulnerable to retaliation as a whistleblower, he contacted Tom Devine at the Government Accountability Project to seek protection. While considering whether to take on the case, Devine began to receive anonymous phone calls trying to discredit Graham's reputation. Devine was able to deduce through their phone numbers and documents they sent him that they were high-level FDA officials. The officials were never able to back up their claims against Graham.

Moreover, news is surfacing that FDA officials tried to discredit Graham's study before it was published in a medical journal. *USA Today* reported that Steven Galson, acting director of the agency's Center for Drug Evaluation and Research, contacted the editors of the London medical journal *The Lancet* while the editors were reviewing Graham's article for possible publication. Among other things, Galson charged Graham with manipulating the data in his study--a charge that the study itself lacks sufficient integrity to warrant publication in any serious scholarly journal. In fact, according to Graham, the basis of that charge was a "discrepancy" between an abstract of the study as published in materials for a conference and the final study itself. That "discrepancy" was the product of an error that he corrected before addressing that conference and before submitting the paper itself for publication.

The attack on Graham coincided with the FDA's decision to exclude from an advisory panel a scientist who has compiled evidence that yet another drug may, like Vioxx, be harmful to users. Curt D. Furberg, a professor at Wake Forest University, was booted from an FDA committee to review the safety of the Cox-2 inhibitors after he made public statements questioning the safety of Bextra, a Cox-2 inhibitor painkiller produced by Pfizer, Inc. Furberg, a leading expert on drug analysis, told the *New York Times* that he believed Bextra appeared to be similar to Vioxx. The statement prompted FDA to rescind his invitation to the advisory panel. Furberg told the *Wall Street Journal*, "I collected the evidence to contribute to the debate, I drew a conclusion, and I'm off."

Broader Failures in Drug Safety Evaluation

In a series of studies, the *Journal of the American Medical Association* (JAMA) illustrated the failures of FDA's current system of drug evaluation. Evidence of the failures of the current system revolved around the drug Baycol, which was pulled from the market in 2001. While one study demonstrated that the cholesterol-lowering drug had substantial risk of serious side effects, another pointed to evidence that the makers of Baycol had information in early 2000 that the drug was more dangerous than competing drugs but did not make the information known. Patients on Baycol were far more likely to be hospitalized with a rare, serious muscle disorder than those on Lipitor, Pravachol or Zocor.

Drug makers are largely responsible for evaluating the dangers of their own drugs. FDA may perform some drug evaluations, but it relies largely on the makers of the drug to evaluate the drugs safety and then report the information to the agency. The agency also relies on voluntary reporting from doctors, so the majority of cases go unreported or the reports are not thorough enough to accurately determine the potential side effects.

The editors of *JAMA* concluded that this system, too, is broken:

> For instance, it appears that fewer than half of the post-marketing studies that manufacturers have made commitments to undertake as a condition of approval have been completed and many have not even been initiated. Moreover, despite the mandatory adverse event reporting system for companies subject to the FDA's post-marketing safety reporting regulations, drug manufacturers may be tempted to conceal available data that may signal the possibility of major risks. In some cases, the FDA and drug manufacturers may fail to act on that information and fail to conduct appropriate studies to examine a potential risk rigorously and promptly.

The Agency Responds to Criticism

The day before the hearing, FDA Acting Commissioner Lester Crawford issued a statement countering Graham's testimony. Crawford responded to criticism that the agency mishandled the Vioxx case, saying, "FDA has a well-documented and longstanding commitment to openness and transparency in its review of marketed drugs." Graham had contended that he was forced to revise the conclusions of his study, but Crawford countered that all revisions to Graham's study were done by Graham with his approval and without compromising his "deeply held convictions."

Sandra Kweder at the Office of New Drugs defended FDA's actions on the Vioxx case, saying, "FDA worked actively and vigorously with Merck to inform public health professionals of what was known regarding [cardio-vascular] risk with Vioxx, and to pursue further definitive investigations to better define and quantify this risk." Kweder also said that the FDA described by Dr. Graham "was not the FDA [she] know[s]."

Crawford also responded to statements that Dr. Curt Furberg had been removed from an advisory panel for publicly questioning the safety of Bextra. Backing away from the previous FDA position, Crawford said, "The advisory committee preparation process is still under way, so it was premature for any FDA official to suggest that Dr. Furberg could not participate in the upcoming meeting."

Crawford and Kweder also pointed out that FDA has taken steps to evaluate weaknesses in their current drug evaluation system. Early this month, FDA called on the National Academies' Institute of Medicine to review the agency's drug safety system. Responding to criticism that controversial scientific opinions of the agency's top scientists were suppressed or weakened by superiors, FDA is also establishing an internal appeals process. Through the appeals process, individuals within the agency who feel that superiors have allowed an unsafe drug to enter the market may present their case before an expert committee.

Calls for Change

In response to its findings that the public/private relationship in the drug evaluation system is deeply flawed, *JAMA* called for an independent agency to look at drug safety. The editors contended that it was unreasonable to have the same agency both approve drugs and "also be committed to actively seek evidence to prove itself wrong."

Other advocates have echoed the journal's request for an independent review of drugs, including Grassley. The Vioxx hearing before the committee pointed to mounting tensions between the FDA's Office of Drug Safety and the Office of New Drugs. Though the two offices are theoretically independent of one another, testimony revealed that the Office of New Drugs exerts considerable influence over the Office of Drug Safety. Many advocates believe such influence is inevitable when the same agency both approves drugs and evaluates their post-market safety. The agency is often reticent to release criticism of drugs already on the market, leaving patients at risk for side effects that can do serious harm.

Not everyone agrees that an independent group is necessary. University of Pennsylvania School of Medicine's Brian Strom, a consultant to major pharmaceutical manufacturers, countered the editorial staff with a commentary in *JAMA*. Strom argued that pre-market clinical trials will account for common side effects but may not catch rare side effects, which may only be detected through post-marketing surveillance. The current system "reflects a deliberate societal decision to balance delays in access to new drugs with delays in information about rare adverse reactions." Senate Health Committee Chairman Judd Gregg (R-NH) also disagreed with the need for an independent group to evaluate drug safety, saying Nov. 24 that "another layer of bureaucracy at the FDA is probably the last thing we need."

Gregg is set to step down as committee chairman in January. A new chair has yet to be announced.

Public interest groups have begun to take action against the host of problems within FDA. Among them, Consumers Union has launched a national grassroots advocacy campaign, Prescription for Change, which seeks reforms to ensure safe, effective and affordable prescription drugs. Echoing recent cries from Congress and several medical journals, the group calls "for a mandatory, public registry of drug companies' clinical trials to ensure that drug safety and effectiveness information is readily available to researchers, physicians and consumers." Over 25,000 citizens have already used the website to send emails to their representatives calling for action.

Reg Round-Up

How to stay on top of appointments news and rumors • Learn about the mad cow scare — and the unaddressed weaknesses in safeguards against mad cow disease • EPA rollback killing children • And more news briefs and alerts!

Do the Cabinet Shuffle: Who will be running the agencies in the next term of the Bush administration? Stay on top of the latest news and rumors in **REG•WATCH**, our regulatory policy weblog.

Mad Cow Scare: The false positive result in the potential mad cow case that made the news is, nonetheless, a stark reminder of the need for improvements to the regulatory safeguards intended to protect us all from BSE. Learn more in this OMB Watch analysis.

Deadly EPA Rollback: Learn more about recent news that EPA's decision to reverse a Clinton-era regulatory safeguard of rat poison is proving to have deadly consequences for poor children. (from REG•WATCH)

Astroturf Group Exposed: Learn about an industry-funded nonprofit that claims to address the safety of America's railways -- with a safety message that lets the rail industry off the hook. (from REG•WATCH)

What Bush Rollbacks Mean for You: Check out this great new feature from the Center for American Progress: **My Backyard**, a source for state-by-state data underscoring the deadly consequences of Bush administration anti-regulatory policy for you and people you care about.

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