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In This Issue

Investigation of United Church of Christ Shows IRS Rules Need Fixing

On Feb. 20, the Internal Revenue Service (IRS) sent the United Church of Christ (UCC) national office a letter announcing the agency has launched an investigation because there is "reasonable belief" that the church violated the ban on partisan electioneering, based on a June 23, 2007, speech by Sen. Barack Obama☼ (D-IL) at the church's 50th General Synod. The investigation has generated strong reactions, and as details emerge, it is clear that this case highlights the inherent weakness of the IRS's facts and circumstances test as a regulatory standard defining what is and is not partisan electioneering.

On Feb. 26, the United Church of Christ released a statement that denied any wrongdoing. UCC President Rev. John H. Thomas called the investigation "disturbing" and said it will likely have "a chilling effect on every religious community." The statement said Obama had been invited to speak a year before he became a candidate for president and that he spoke as a 20-year member of the UCC on the topic of the intersection of faith and public life. He was one of

60 speakers at the annual event, which was held at the civic center in Hartford, CT.

The IRS letter said the agency's concerns were based on articles on the Web that described Obama's speech to nearly 10,000 church members attending the event, and it noted that "40 Obama campaign workers staffed campaign tables outside the center to promote his campaign." The IRS did not mention a complaint filed with the IRS in August 2007 that said Obama did not speak as a non-candidate because he referred to his candidacy once during his 45-minute speech and pledged to sign a universal health care bill by the end of his first term. The identity of the person filing the complaint was redacted, and the complaint was anonymously sent to James Hutchins, who posted it on UCC Truths, a blog that is critical of the UCC denomination's leadership and positions. Hutchins said he did not file the complaint.

The IRS gave the UCC 15 days to respond to a list of specific questions and said the church has the right to request a meeting with IRS representatives "to discuss our concerns." There is no deadline on when the IRS must conclude its investigation.

The UCC statement listed several factors it said indicate there was no partisan campaigning at the event. These include the following facts:

- Obama was invited to speak in his capacity as a church member and elected official a year before he became a presidential candidate
- Before the speech, church officials warned the crowd that the event was not about the campaign and no signs, buttons, leaflets, or other campaign material would be allowed in the civic center
- Obama campaign volunteers were not allowed into the civic center, but set up outside, in public space where the UCC had no control
- There were 60 speakers at the Synod, including Obama, who addressed the intersection of faith with their vocation
- Obama has been a member of Trinity United Church of Christ in Chicago for over 20 years
- Church leaders got legal advice before the event

Strong Reactions

In addition to denying wrongdoing, the UCC criticized the IRS for failing to seek any information from them prior to launching the investigation. The Rev. Davida Foy Crabtree of the Connecticut Conference UCC wrote a letter to the editor of the *Hartford Courant* and said, "I believe the agency needs to change its process. A simple dialog with our leaders would have established that the facts contradict the complaint. Instead, given the facts in this case, by issuing this letter the agency risks encumbering the free practice of religion."

Others have been equally critical. The *Hartford Courant* reports that Hartford mayor Eddie Perez has asked Connecticut's congressional delegation to investigate an "intimidation tactic aimed at preventing churches and people of faith from hearing from public officials about the important issues of the day." Americans United for Separation of Church and State Executive

Director Rev. Barry Lynn released a press statement saying, "We looked into the situation and did not see a violation of IRS rules. We saw no evidence of UCC officials seeking to appear to endorse his candidacy."

The Huffington Post's John Wilson posted an analysis on Feb. 28 with the headline "IRS Probe of Obama's Church Underscores Anxieties For Nonprofits". Wilson wrote, "What's at stake here is not just religious freedom, but the freedom of speech of all nonprofits. The danger is that when nonprofit groups are silenced, corporate America will be able to dominate even more thoroughly the public debate." Wilson noted that the threat of IRS enforcement has "already caused fearful reactions from nonprofit organizations," citing the example of the School of the Art Institute of Chicago, which banned a documentary about Obama from being shown in January.

But Wilson's biggest objections center around the apparent IRS interpretation of standards for appearances by candidates, noting that there were nearly 50 presidential candidates in the field in June when the speech occurred, and that to require the UCC or any nonprofit to invite all these candidates or none at all "would effectively mean that every nonprofit organization in the country is now banned from having any politician speak at an event at any time."

The UCC Truths blog argues that the entire speech was a campaign speech because Obama made one mention of being a candidate. One article on the blog says, "One could argue that Obama spoke of his work as a US Senator, not as a candidate. But in declaring himself a candidate, how does one deny that his take on the issues doesn't represent his presidential values? When Obama said he was a candidate, his whole speech became a candidate speech." It is not clear that the IRS interprets the law this way.

Finally, the Street Prophets blog said that although there "was no foul" in this case, "anyone who thought that having a single presidential candidate come to speak at a denominational convention wasn't going to draw some kind of fire had to be smoking the wacky tabacky."

IRS Revenue Ruling 2007-41, Candidate Appearances, and the Complaint

The IRS uses an undefined "facts and circumstances test" to enforce the ban on partisan intervention in elections by 501(c)(3) organizations. IRS Revenue Ruling 2007-41 was published last year to provide better guidance, but it leaves many questions unanswered. One section addresses candidate appearances at 501(c)(3)-sponsored events, including those where the candidate is appearing in a non-candidate capacity. It says, in part, "If the candidate is invited to speak, factors in determining whether the candidate's appearance results in political campaign intervention include the following:

- "Whether the individual is chosen to speak solely for reasons other than candidacy for public office;
- Whether the individual speaks only in a non-candidate capacity;
- Whether either the individual or any representative of the organization makes any mention of his or her candidacy or the election;

- Whether any campaign activity occurs in connection with the candidate's attendance;
- Whether the organization maintains a nonpartisan atmosphere on the premises or at the event where the candidate is present; and
- Whether the organization clearly indicates the capacity in which the candidate is appearing and does not mention the individual's political candidacy or the upcoming election in the communications announcing the candidate's attendance at the event."

The complaint against the UCC only addresses some of these factors and does not indicate factors that show the church took steps to ensure the speech was not a campaign event. For example, it says the UCC "selectively provided convention facilities for Sen. Obama to speak in support of his campaign" and "campaign activity occurred in connection with the speech." It even cites the UCC's disclaimer of any endorsement as an indication of partisanship, saying the UCC "referenced his candidacy" before the speech.

What Next

On Feb. 27, the UCC announced a legal fund to help defray the costs of the investigation, so that "money given for mission will not be needed to pay legal bills, instead of ministry needs." By March 3, a new UCC announcement said that that former Solicitor General Seth Waxman, now with the firm WilmerHale, will lead their legal defense and waive hourly fees. The legal fund had already raised $59,564, which the UCC said should be enough to cover other expenses relating to their defense. As a result, the fundraising effort has been suspended.

House Committee Hearing Highlights Lax Enforcement of Voting Rights

The House Judiciary Subcommittee on the Constitution, Civil Rights and Civil Liberties held a hearing on Feb. 26 to examine the problems of voter suppression and poor enforcement of voting rights. The hearing largely focused on the U.S. Department of Justice's (DOJ) lax enforcement of voting rights mandates in the National Voter Registration Act (NVRA). Evidence of tactics to prevent people from voting (voter suppression) was also presented.

A press release from Subcommittee Chairman Jerrold Nadler (D-NY) said, "The right to vote is the cornerstone of our democracy — a right that must be protected and defended ... However, under the current Administration, the Department of Justice has a remarkably poor record of protecting that fundamental right. Laws that protect voters from discrimination on the basis of race, language or disability have not been properly enforced. Indeed, it would seem that political pressures have deterred the Justice Department from fulfilling its mandate."

The hearing's first panel included testimony from Asheesh Agarwal, Deputy Assistant Attorney General at the Department of Justice Civil Rights Division, which is charged with enforcing civil rights and voting rights laws. Agarwal's testimony defended DOJ against criticism that it has not adequately prosecuted voter suppression cases. However, Gerry Herbert, Executive Director of the Campaign Legal Center and former attorney with the Civil Rights Division,

testified that "professionalism and nonpartisan commitment to the historic mission of the Division has been replaced by unprecedented, political decision making. The result is that the essential work of the Division to protect the civil rights of all Americans is not getting done."

Other voter suppression tactics addressed during the hearing include voter caging, an illegal process of purging people from the voter rolls if they fail to answer registered mail sent to a place where they are not currently living. This strategy works to suppress votes by minorities, college students, people in the military, and others. Testimony also addressed excessively strict voter identification requirements, strict rules to purge voter rolls because of administrative errors, and lax enforcement of NVRA.

Two nonprofits, Project Vote and Demos, submitted written testimony in advance of the hearing detailing DOJ's failure to enforce provisions of NVRA that would increase the number of low-income registered voters. Section 7 of NVRA requires public assistance agencies to offer voter registration services to all individuals when they apply for benefits, recertify benefits, or change of address (otherwise known as the motor voter provision). Project Vote found that these agencies failed to offer voter registration, and voter registration from public assistance agencies has decreased 79 percent since the provision was first implemented. "Specifically, we are concerned that Mr. Agarwal's statement fails to acknowledge or explain DOJ's record of largely ignoring evidence of state non-compliance with the NVRA's requirements for registering low-income voters, while focusing selectively instead on urging states to purge more voters from their rolls."

Barnard College professor Lorraine Minnite, author of a Project Vote report *The Politics of Voter Fraud*, testified that "the alleged epidemic of voter fraud sweeping the country is a fabricated myth. It can not compare to the massive challenges the states face in administering elections in ways that open up the process and make voting easier for all Americans, but especially for our most vulnerable citizens for whom the barriers to access to the vote are still too high."

Before the hearing began, the committee voted to issue a subpoena for former Ohio Secretary of State Kenneth Blackwell for testimony about the 2004 election. On Jan. 29, Judiciary Committee Chairman John Conyers (D-MI) and Nadler wrote a letter to Blackwell to "explore the state of voting rights and the allocation of resources to end voter suppression and voter fraud." Blackwell has refused to appear voluntarily. The Associated Press quoted Conyers as saying, "Mr. Ken Blackwell, wherever you are in North America today, please know that we are not sending the gendarme for you this moment." Conyers added, "I do not like to issue subpoenas. ... The only problem is we can never reach him."

Federal Meat Inspectors Spread Thin as Recalls Rise

The federal regulator of meat, poultry, and egg products, the Food Safety and Inspection Service (FSIS), faces resource limitations that make it more difficult for the agency to ensure the safety of the food supply. Although the agency's budget has risen since it was created,

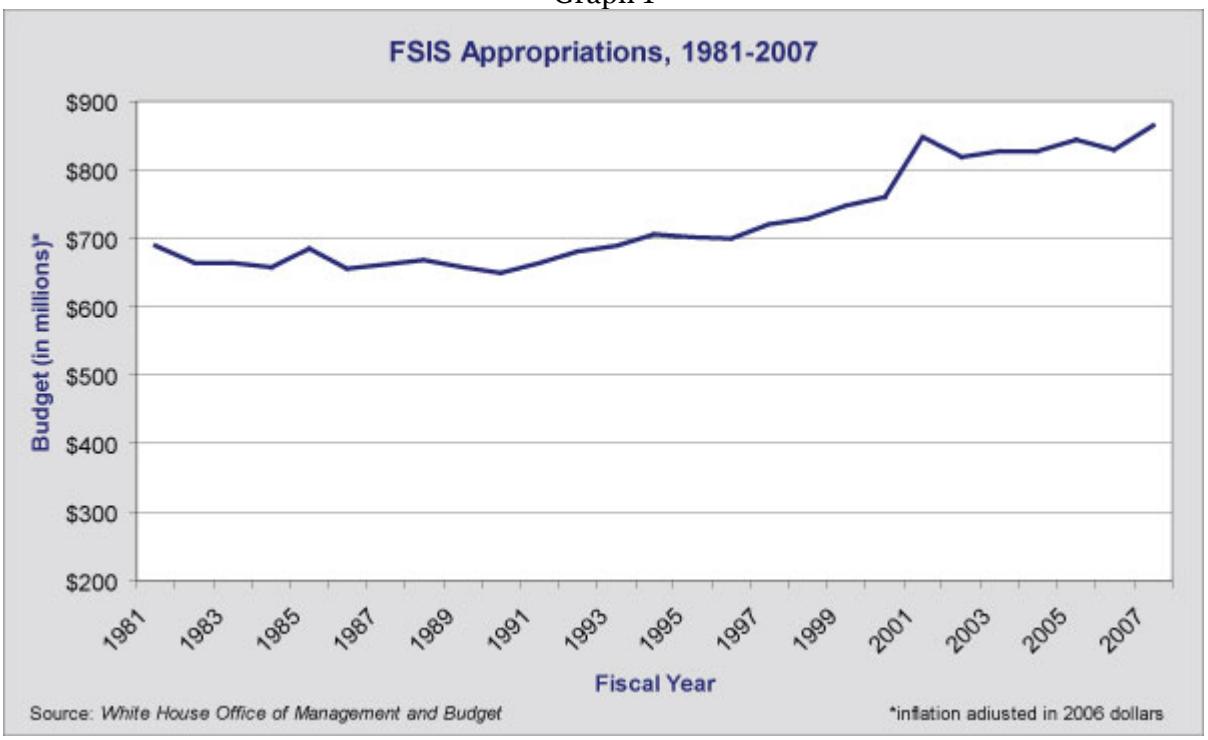
staffing levels have dropped steadily. Widespread vacancies in the agency have spread FSIS's inspection force too thin. Meanwhile, the number of meat, poultry, and egg product recalls has risen, and a recent recall of 143 million pounds of beef is the largest in the nation's history.

The U.S. Department of Agriculture created FSIS in 1981. Federal law requires the agency to monitor the slaughter, processing, and labeling of all meat and poultry and to inspect meat and poultry to ensure products are not contaminated or adulterated. Egg products also fall under the agency's jurisdiction. The agency is responsible for ensuring the safety and wholesomeness of the billions of pounds of meat, poultry, and egg products that enter the market each year.

Budget Increases Fail to Keep Pace with Size of Mandate

Unlike many other federal regulatory agencies, the budget for FSIS has seen a marked increase since its inception. From FY 1981 to FY 2007, appropriated funds for the agency increased 25 percent when adjusted for inflation. The bulk of that growth has occurred in the last 12 years. (See Graph 1.)

Graph 1

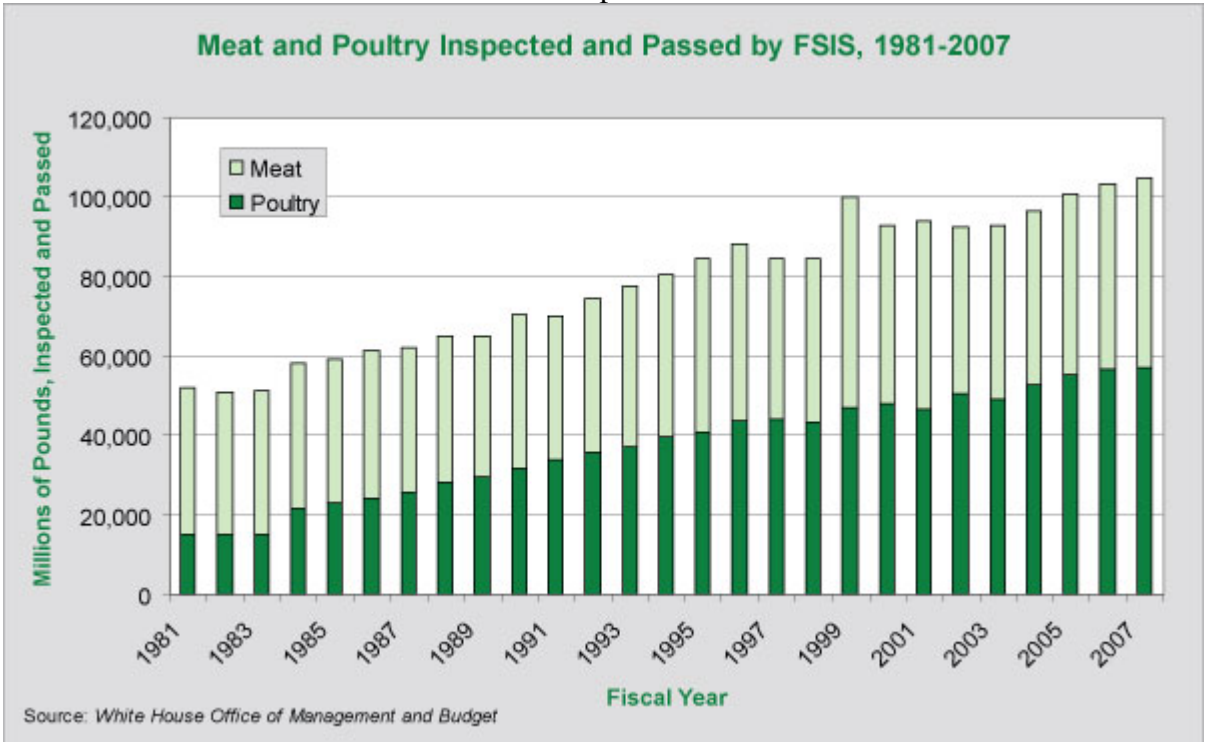


In particular, the agency has enjoyed significant budget increases over the past three fiscal years. In FY 2006, FSIS was appropriated $830 million; in FY 2007, $890 million; and in FY 2008, $930 million — a two-year increase of 7.5 percent when adjusted for inflation. President Bush's proposed FY 2009 budget calls for another increase of $22 million, to $952 million. When adjusting for inflation, the proposed increase will likely be negligible — holding funding for FSIS level.

Meanwhile, meat and poultry consumption in the U.S. has increased sharply. Since FSIS began

operations, pounds of slaughtered meat and poultry inspected and approved by the agency have doubled — from about 52 billion pounds in 1981 to about 104 billion pounds in 2007. Much of the increase is due to the expanding U.S. poultry market. Pounds of poultry approved by FSIS nearly quadrupled during that time. (See Graph 2.)

Graph 2

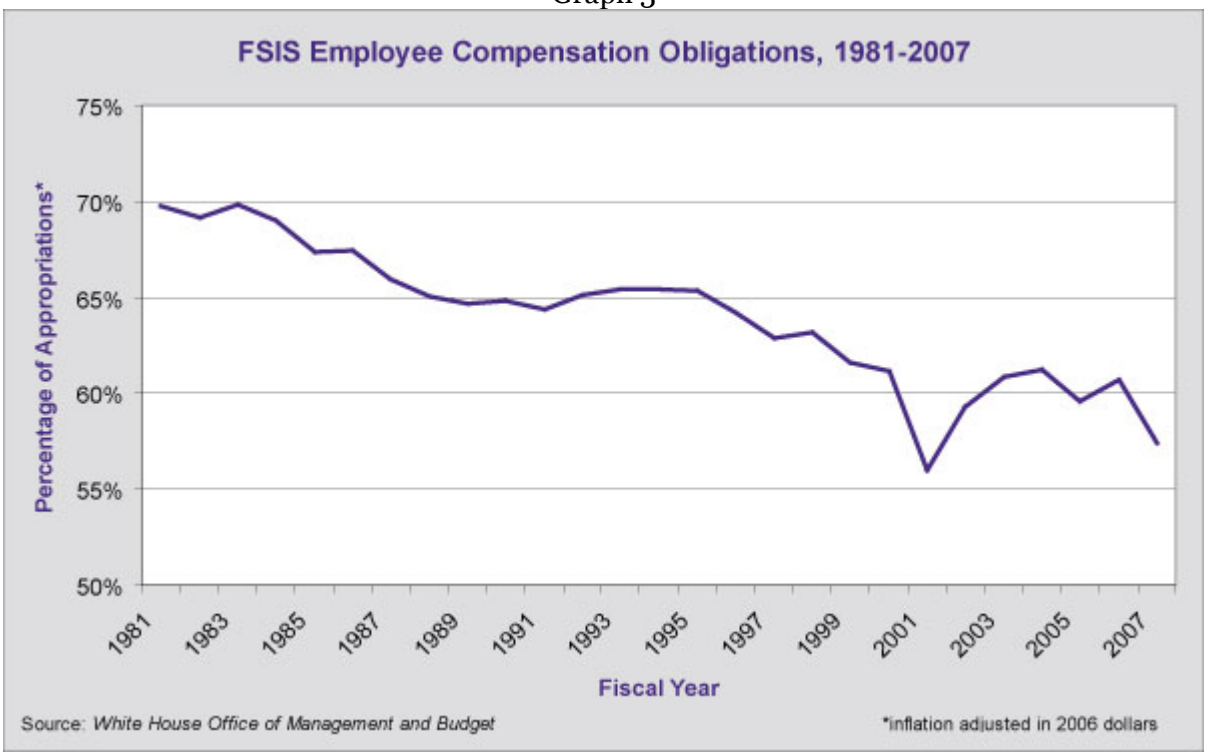


Because of the increase in production, FSIS staff and resources become increasingly smaller when compared to the scope of the industry it regulates. Even though FSIS's budget has increased, the growth is dwarfed by the expansion of the meat and poultry industry. Of its appropriated funds, in FY 1981, FSIS spent $13.22 per thousand pounds of meat and poultry inspected and passed. By FY 2007, the figure had fallen to $8.26 per thousand pounds — a drop of almost 40 percent.

Spending on FSIS Workers Slows

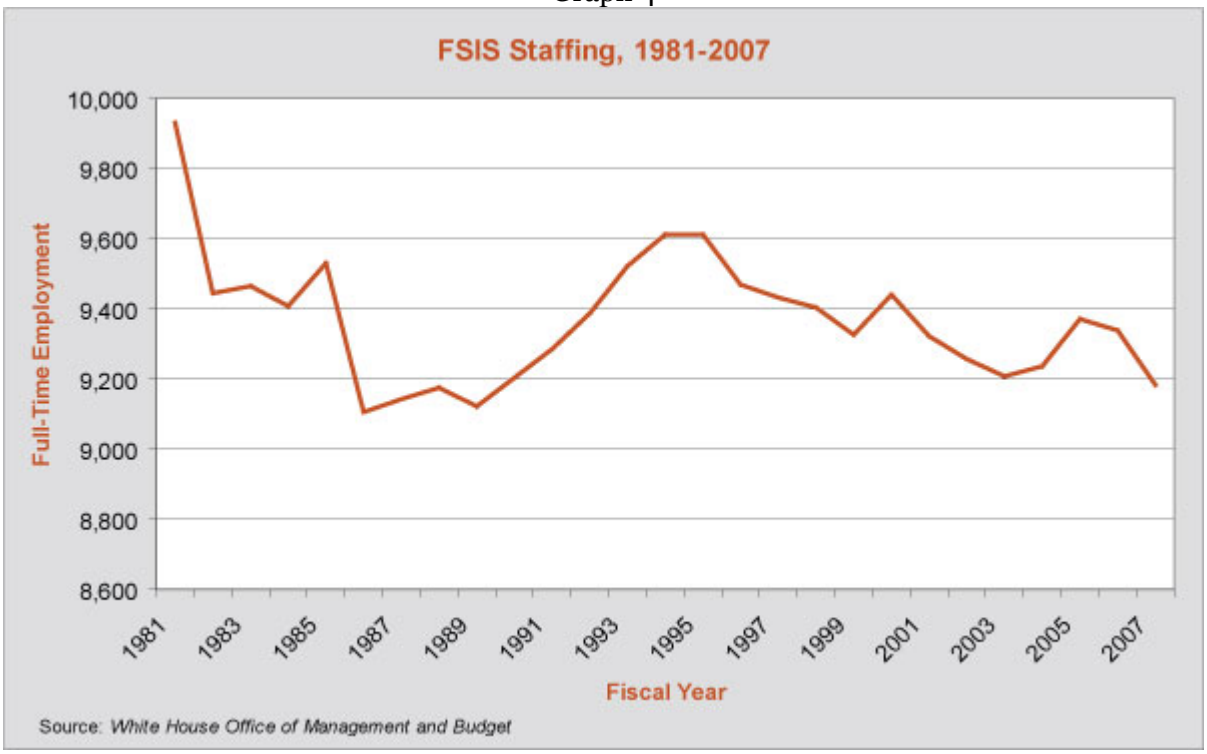
While Congress has appropriated significantly more money since the early 1980s, the agency has not spent proportionally for personnel. In the early 1980s, FSIS spent about 69 percent of its appropriated funds to pay its employees. However, the percentage has steadily dropped. By FY 2007, the agency only spent 57 percent on employee compensation. (See Graph 3.) And correlated with this decline is a drop in the number of agency workers.

Graph 3



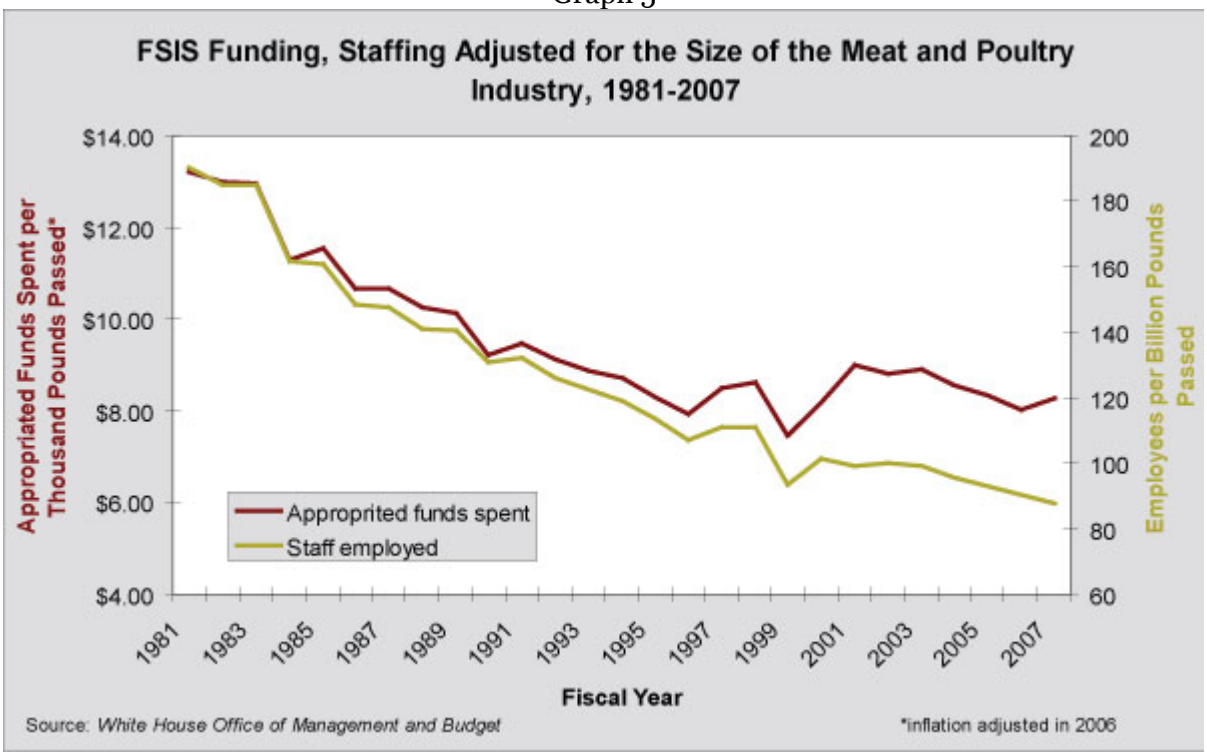
From FY 1981 to FY 2007, the number of full-time employees at FSIS fell from 9,932 to 9,184 — a 7.5 percent drop. Despite robust funding increases in the 2000s, FSIS's staffing level has dropped nearly three percent during this time. FSIS's staffing is now at its lowest level since FY 1989. (See Graph 4.)

Graph 4



The situation appears even worse when comparing the size of the meat and poultry industry to the size of FSIS's workforce. In FY 1981, FSIS employed about 190 workers per billion pounds of meat and poultry inspected and passed. By FY 2007, FSIS employed fewer than 88 workers per billion pounds, a 54 percent drop. (See Graph 5.)

Graph 5



Where's the Inspector?

For FSIS and consumers, the consequences are real. The increasing disparity between the size of FSIS and the size of the regulated community means FSIS inspectors face difficulty performing their duties and fulfilling the mission of the agency.

Other agencies that focus on product inspection, such as the Consumer Product Safety Commission or the food division of the Food and Drug Administration, conduct risk-based inspections. In risk-based inspection, managers, analysts, and field officers focus on those products or firms that they determine pose the greatest risk to consumers.

Under federal law, FSIS must inspect all meat, poultry, and egg products intended for commercial use. According to the FSIS website, "Slaughter facilities cannot operate if FSIS inspection personnel are not present," and, "Only Federally inspected establishments can produce products that are destined to enter commerce." Theoretically, FSIS's comprehensive inspection regime means that the physical presence of inspectors is essential to both plant operations and product safety.

In reality, inspection activity manifests itself differently. Recent media accounts have reported that slaughterhouse and processing plant employees use radios to signal the comings and goings of FSIS inspectors. According to *The Los Angeles Times*, "They even assign the pretty talkative woman to work next to the inspector to distract him from his mission to safeguard the nation's food supply."

The ability of processors and manufacturers to circumvent the FSIS inspection process is aided by widespread inspector shortages. According to *The Baltimore Sun*, "inspectors interviewed said that because of vacancies in the ranks, inspectors are often forced to do the work of two or three staff members, making it all the more difficult for them to catch signs of disease either in animals before slaughter, or in meat that has been butchered."

In multiple media accounts, FSIS officials claim the agency employs more than 7,000 inspectors nationwide. However, FSIS's inspection force has an average national vacancy rate of at least ten percent. In June 2007, the rate spiked to 12.2 percent. Three of the agency's 15 districts — Denver, Dallas, and Chicago — consistently carried vacancy rates of about 15 percent. One district, Albany, consistently carried a vacancy rate of more than 20 percent. These high vacancy rates continue to erode the ability of FSIS to properly carry out a robust inspection regime of the nation's beef, poultry, and egg stocks.

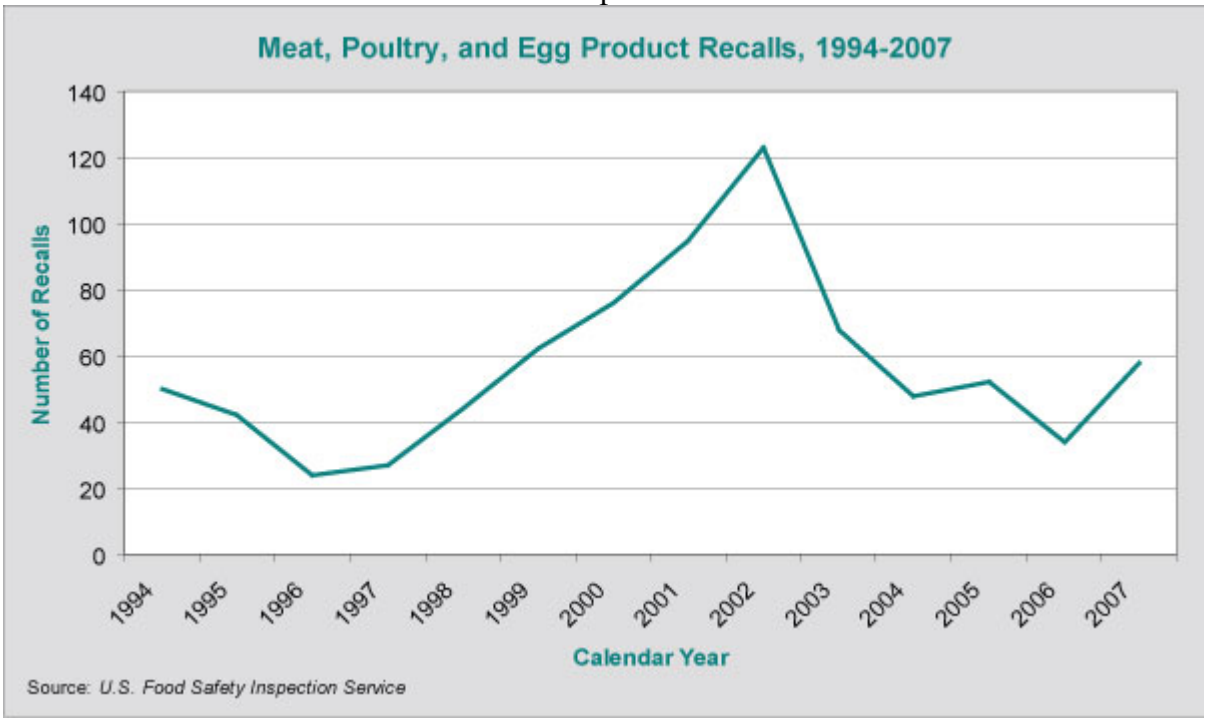
Recalls and Right to Know

Less thorough inspections raise the chance that processors may have to conduct recalls. Although recalls present an opportunity for FSIS and processors to keep tainted meat, poultry, or egg products away from consumers, recalls are far less effective in protecting public health than proper inspections, which keep those products from entering the market in the first place.

First, all recalls are conducted by manufacturers or distributors and are completely voluntary. FSIS may request a recall, but it cannot force a recall. (FSIS does have the authority to seize products in commerce.) Second, manufacturers and distributors frequently recover only a small fraction of the product for which the recall was announced. Lastly, and most importantly, FSIS does not release the names or locations of retail outlets where tainted products may end up, stripping consumers of their ability to make informed decisions and their right to protect themselves and their families.

Meat, poultry, and egg product recalls have spiked in the 2000s. In 2001, FSIS announced 95 recalls of the products under its jurisdiction. In 2002, the agency announced 123 recalls. (See Graph 6.)

Graph 6



Although the number of recalls has declined since 2002, their severity has increased. Two of the three biggest meat recalls in U.S. history have occurred in the past four months. In October 2007, Topps Meat Co. announced the recall of 21.7 million pounds of ground beef used for frozen hamburgers due to *E. coli* contamination. At the time, the Topps recall was the second largest in U.S. history. The *E. coli*-contaminated meat sickened at least 40 people in eight states.

On Feb. 17, Hallmark/Westland Meat Packing Co. announced the recall of more than 143 million pounds of beef, the largest recall in U.S. history. The company announced the recall after an investigation by the Humane Society of the United States showed that nonambulatory (or "downer") cows were slaughtered and allowed into the market. Federal regulations prohibit companies from processing and selling meat from downer cows without explicit FSIS inspector approval because downer cows have a higher probability of being infected with mad cow disease. However, USDA officials say the health risks posed by the Hallmark/Westland beef are low.

Outlook

In 2005, FSIS began considering switching to risk-based inspection practices. FSIS says it would move additional inspectors to processing plants determined to have a high risk. The agency has also proposed virtual inspection — a process by which cameras would monitor facilities' compliance with food safety regulations — for lower-risk plants, according to sources familiar with the issue. FSIS hopes to finalize the switch before the end of the Bush administration.

Critics believe the transition to a risk-based inspection model is directly tied to agency resources. According to a report by the nonprofit group Food and Water Watch, "Far from a minor adjustment intended to maximize food safety, this plan is really being used as a way to reduce the USDA's budget." The report adds, "The changes in the way inspectors are assigned to meat and poultry plants would make current inspector shortages permanent, effectively shrinking the size of the agency's frontline inspection workforce."

Recent failures of the meat inspection regime have provided the public and Congress a window into the breakdown of FSIS's ability to safeguard a large part of the nation's food supply. And although resource allocation within the agency may be open to criticism, it is clear that Congress has failed to maintain funding levels for FSIS comparable to the size of the meat, poultry, and egg industries. Restoring and enhancing FSIS's capacity to protect consumers is not restricted to a single-dimension policy change, but it does require that Congress provide adequate levels of funding that would allow FSIS to keep up with its responsibilities and fulfill its mission.

Endnotes:

All budget and staffing data for Fiscal Years 1981-2007 are from the Budget of the U.S. Government appendices, Fiscal Years 1981-2009. These volumes are the president's request to Congress and contain final budget numbers and program data from two fiscal years prior.

* All inflation-adjusted figures are expressed in 2006 dollars. Inflation adjusting is based on the Bureau of Labor Statistics Consumer Price Index, available at: ftp.bls.gov/pub/special.requests/cpi/cpiai.txt

Environmental, Worker Safety Rules Targeted by Industry Groups

The Small Business Administration's (SBA) Office of Advocacy has finalized a list of ten rules it will encourage federal agencies to modify. The Office of Advocacy compiled the list after receiving recommendations from small businesses and industry lobbyists.

The Office of Advocacy announced the list Feb. 28 as a part of its Regulatory Review and Reform Initiative (R3). The Office of Advocacy undertook the R3 initiative in 2007; the program is "designed to identify and address existing federal regulations that should be revised because they are ineffective, duplicative, or out of date."

The Office of Advocacy acts as a liaison between the business community and the federal government, particularly the executive branch. Although the Office of Advocacy purports to be the voice of small business in the federal government, it often appears to cater to the wishes of national trade groups and anti-regulatory lobbyists when it comes to regulatory issues.

The final list targets public health and safety regulations. Of the final ten rules, four are U.S. Environmental Protection Agency (EPA) rules, one is an Occupational Safety and Health Administration (OSHA) regulation, and one is a Mine Safety and Health Administration

(MSHA) rule. The Office of Advocacy winnowed the final list from a preliminary tally of 82 rules nominated by small businesses, industry lobbying groups, and think tanks.

The Office of Advocacy recommended EPA update a rule that requires dry cleaners to test their machines for air pollutant emissions. According to the Office of Advocacy, "The testing method requires an operator to open the machine to sample the emissions. However, most modern machines are closed-loop machines that will automatically shut down if any of the components are disconnected." The Office of Advocacy also recommends EPA ease requirements on the devices that test dry cleaning machine emissions by reducing their sensitivity. Easing the requirement would make it more difficult for operators to discover the presence of air pollutants. The Small Business Environmental Assistance Program and Small Business Ombudsman National Steering Committee nominated the rule.

The Office of Advocacy also targeted a rule on community drinking water systems. The Office of Advocacy recommended EPA make it easier for small communities to receive an affordability variance from EPA. Affordability variances allow small communities to adopt alternative pollution control technologies in their drinking water systems. The National Rural Water Association nominated the rule.

The third EPA rule concerns the recycling of solid waste. Currently, solid waste deemed to be a hazardous material must undergo special treatment. EPA has been in the process of revising definitions for solid waste policy since 2003.

The Office of Advocacy is pushing EPA to adopt a definition of hazardous materials that is as narrow as possible, stating, "Currently many useful materials that could otherwise be reused are required to be handled, transported, and disposed of as hazardous wastes." EPA, the Office of Advocacy, and the White House Office of Management and Budget (OMB) have attempted to portray the rule change as environmentally friendly by claiming it would increase recycling.

Leading environmentalists are critical of the proposed definition change. According to the Sierra Club, "If the rule were adopted, an estimated three billion pounds of hazardous waste annually would no longer be regulated as waste under certain conditions." The group added, "If the waste is no longer regulated, it will be much easier for these still toxic substances to make it onto our land and into our waters."

An environmental consulting firm (iSi Environmental Services), the Synthetic Organic Chemical Manufacturers Association, and the National Paint and Coatings Association nominated the rule.

The fourth EPA rule concerns oil spill prevention. The Office of Advocacy is asking EPA to clarify the definition of oil under federal regulations that require facilities to adopt oil spill prevention and clean-up plans. According to the Office of Advocacy, "Many facilities are unsure whether a given product is considered 'oil' or not, and therefore whether the [prevention and clean-up] rules apply." The American Chemistry Council and the National

Paint and Coatings Association nominated the rule.

The OSHA rule protects laboratory and medical workers from exposure to bloodborne pathogens by, for example, requiring facilities to reduce the risk of needlestick. The Office of Advocacy is asking OSHA to revise the rule to allow smaller facilities or facilities where the risk of blood exposure is low to be held to less stringent requirements. Scott George, president and CEO of the Mid-America Dental and Hearing Center in Missouri, nominated the rule.

The MSHA rule sets standards on the use of explosives in mines. According to the Office of Advocacy, MSHA has not updated the standards since 1996. The Office of Advocacy recommended MSHA update the standards to reflect industry best practices and to more closely resemble federal standards for general industry, which OSHA is currently in the process of updating. The Institute of Makers of Explosives and the International Society of Explosives Engineers nominated the rule.

Another nominated rule places restrictions on flights around the Washington, DC, metropolitan area. The Federal Aviation Administration (FAA) issued the rule as an interim rule in the wake of the September 11 attacks and plans to finalize it, according to the Office of Advocacy.

Of the remaining three rules, one is an IRS rule regarding home office deductions, and the other two relate to federal procurement and contracting.

The Office of Advocacy consulted with OMB's Office of Information and Regulatory Affairs (OIRA) in finalizing the list of rules. SBA's Office of Advocacy and the White House's OIRA often work together under a memorandum of understanding signed in 2002 in which both offices pledged to "achieve a reduction in unnecessary regulatory burden for small entities." Although the memorandum expired in 2005, the offices continue to work together closely. OIRA serves as the clearinghouse for most regulations developed by executive branch agencies. In President Bush's White House, OIRA has often sought to weaken or delay environmental and worker safety regulations.

The Office of Advocacy's attempt to push for agencies to review the rules duplicates a statutorily required process under the Regulatory Flexibility Act (RFA). Under RFA, agencies must review every ten years rules they find to impact small entities. A recent Government Accountability Office report found agencies often conduct regulatory reviews even more frequently under individual internal policies.

The Office of Advocacy will post and update the status of each rule on its website at www.sba.gov/advo/r3/.

High Court Expands Federal Preemption in Medical Cases

The U.S. Supreme Court has taken up a series of cases that addresses the issue of whether federal agency approval of medical devices and drugs shields manufacturers of those products from liability under state laws. In a case decided Feb. 20, the Court held that federal law preempts state liability claims if certain medical devices received U.S. Food and Drug Administration (FDA) approval. The Court also considered if that same protection should be extended to drug manufacturers.

In *Riegel v Medtronic Inc.*, the Court held that the 1976 Medical Device Amendments (MDA) contained express preemption language. Congress intended to create a federal oversight responsibility and, therefore, intended to limit the rights of those injured by medical devices. Allowing state law liability claims would create a conflict between federal and state law requirements, according to the Court. The preemption language, the Court held, "bars common-law claims challenging the safety or effectiveness of a medical device marketed in a form that received premarket approval from the FDA."

FDA's premarket approval process is its most rigorous medical device review and is applied only to certain medical devices — in this case, a balloon catheter used in angioplasty. "These devices may enter the market only if the FDA reviews their design, labeling, and manufacturing specifications and determines that those specifications provide a reasonable assurance of safety and effectiveness. Manufacturers may not make changes to such devices that would affect safety or effectiveness unless they first seek and obtain permission from the FDA," according to the opinion.

In a Feb. 21 article, BNA (subscription required) quotes the attorney arguing on behalf of the plaintiff as saying that this decision curtails patients' ability to receive compensation when they are harmed by medical devices that fail. Justice Ruth Bader Ginsburg, the lone dissenter in the case, argued Congress had no intent to curtail the public's right to compensation when injured because "a legislative design to preempt state common-law tort actions" does not exist in MDA and because FDA did not provide any federal compensation remedy.

According to a Feb. 26 BNA article, the Court denied review Feb. 25 of another medical device liability suit from Texas involving a heart valve that was voluntarily recalled after a supplemental FDA premarket approval process concluded the valve needed an infection-resistant coating. The Court was asked to overturn a Texas appeals court ruling that the state claim was preempted by the MDA language.

The same day, the Court heard arguments in a similar case from Michigan involving drug manufacturers. According to another Feb. 26 BNA article, in *Warner-Lambert Co. v Kent*, a lawyer representing pharmaceutical companies argued that Michigan's tort-reform law, which allows liability suits against drug makers in cases where the company has misled FDA during or after the approval process, is preempted by federal law. The basis for the argument is the same conflict between state and federal requirements as found in *Riegel*.

The drug makers were supported in their arguments, according to the article, by the Solicitor General's office of the U.S. Justice Department. In an amicus curiae brief, the Bush administration argued that FDA and the drug makers have a relationship that is "inherently federal." What is unique about the administration's position, according to a Feb. 26 *New York Times* article, is that FDA has historically argued these liability lawsuits protected patients; under the Bush administration, the lawsuits are generally regarded as conflicting with FDA's ability to do its job and with FDA's discretion about whether it was misled.

The New York Times reported in its March 4 edition that the Court voted 4-4 on the case March 3. Chief Justice John Roberts recused himself because he owns stock in the drug maker Pfizer Inc., the parent company of Warner-Lambert. The tie vote means that the suit against Warner-Lambert may proceed in Michigan courts.

According to the *Times* article, the Court agreed to hear yet another drug liability case in the October term, *Levine v. Wyeth*, that could extend preemption even further if products have received FDA approval.

There are at least three implications from this line of cases. First, the Court seems to be moving toward extending preemption over state tort law to a broader category of products under FDA's jurisdiction. Since *Riegel* was decided by an 8-1 vote, it seems clear that the Court is interpreting the MDA language to be clearly preemptive. This gives manufacturers liability protection via FDA approval and removes citizens' ability to receive compensation for injuries from faulty products — at least under the most rigorous FDA reviews.

Second, this is also an instance in which the law fails the public. The Court is ignoring FDA's inability to regulate these products effectively. Two recent studies point out how severely limited the FDA is in carrying out its mission after years of staffing losses and budget cuts. One is a 2006 report from the Institute of Medicine. The other report is from FDA's own Subcommittee on Science and Technology, which was asked to assess "whether science and technology at the FDA can support current and future regulatory needs." The reports are scathing indictments of governmental failure.

Third, both Congress and the executive branch have an obligation to make sure the FDA can regulate effectively these products if indeed the responsibility is "inherently federal." In addition, it is incumbent upon both branches to ensure that patients harmed by ineffective or dangerous drugs and faulty medical devices have a way to hold manufacturers responsible. If the Court finds that federal law removes liability suits as one incentive to industry to produce safe products, the other branches must restore protections to American citizens.

Bush Administration to Alter Employee Leave Protections

The Department of Labor (DOL) has announced a proposed rule that would alter federal protections for workers who need to take leave to care for themselves or their families. DOL

chose to pursue the rule changes after hearing complaints from industry lobbyists.

The Family and Medical Leave Act of 1993 (FMLA) allows employees to take up to 12 weeks of unpaid leave in a 12-month period without risking their pay, benefits, or position. According to DOL, employees can apply for FMLA leave "for the birth of a child; for the placement of a child for adoption or foster care; to care for a newborn or newly-placed child; to care for a spouse, parent, son or daughter with a serious health condition; or when the employee is unable to work due to the employee's own serious health condition."

According the National Partnership for Women and Families, a nonprofit organization that works on workplace fairness issues and has expertise on FMLA, seven provisions in the proposed rule would make it more difficult for workers to take FMLA leave. The proposed rule would:

- Make it more difficult for workers to use paid vacation or personal time during FMLA leave. Because FMLA leave is unpaid, this may mean more workers will be unable to use FMLA leave time if they cannot afford to miss work.
- Require employees to notify their employers before their shift starts for unforeseeable leave except in emergency situations. Conversely, employers would have more time (five days, from the current standard of two days) to determine whether an employee will be granted FMLA leave.
- Allow employers to speak directly to an employee's health care provider after receiving permission from the employee. Currently, employers must use a medical professional as an intermediary.
- Require chronic condition sufferers to visit their doctors every six months in order to recertify their condition. Currently, employees must only visit their doctors "periodically."
- Allow employees to waive their FMLA claims without review. Currently, DOL or courts must review such claims. Because employees may not have access to legal counsel, the rule change would increase the chance that employees may waive their rights under duress or may be coerced into doing so.
- Allow employers to count FMLA leave against the attendance record of an employee. Currently, employers cannot withhold attendance rewards based on time missed under FMLA.
- Make little progress in educating workers about the benefits of FMLA. Many workers do not utilize FMLA because they are unaware of the benefits or the process for requesting leave, according to the National Partnership.

Two provisions of the proposed rule would strengthen FMLA for workers, according to the National Partnership. The proposed rule would:

- Allow employees to take "light duty" assignments without counting the time worked toward FMLA leave. Currently, light duty time is subtracted from the 12 weeks of FMLA leave allowed.
- Improve employer disclosure of FMLA policy, including notification of how much

FMLA leave time an employee is being charged and written notification of why an employer finds a medical excuse insufficient and what can be done to correct it.

The proposed rule would also expand FMLA's provisions to military families. As part of the 2008 Defense Authorization Bill (P.L. 110-181), which President Bush signed into law on Jan. 28, Congress amended the FMLA to assist members of the military and their families. The legislation expands the FMLA in two significant ways: It adds a Caregiver Leave section that allows up to 26 weeks of unpaid leave for employees to provide care to a close relative who is a member of the Armed Forces undergoing outpatient treatment, recuperation, or therapy for a serious injury or illness. This provision was implemented immediately. The law also adds an Active Duty Leave section that allows up to 12 weeks of unpaid leave for employees who have an immediate family member who is on active duty or is called to active duty to serve in a military operation and who experience "any qualifying exigency." This provision does not go into effect until DOL issues final regulations. The proposed rule addresses the Active Duty Leave section by defining "any qualifying exigency."

By DOL's own admission, FMLA is working: "No employment law matters more to America's caregiving workforce than [FMLA] of 1993. Since its enactment, millions of American workers and their families have benefited from enhanced opportunities for job-protected leave..."

But business groups and industry lobbyists have been complaining about some of the FMLA's provisions for years. According to the National Partnership, "The organized business community has been pushing hard for a number of changes in the FMLA."

In December 2006, DOL solicited the public for their views on FMLA with a potential modification in mind. According to DOL's report on the comments, "There is broad consensus that family and medical leave is good for workers and their families, is in the public interest, and is good workplace policy." The Department received more than 15,000 comments from public interest groups, lobbyists, businesses, academics, and the general public.

Nonetheless, DOL began working on a rule change in late 2007. DOL published the proposed rule in the *Federal Register* on Feb. 11.

Some of the provisions of the proposed rule that the National Partnership and others find objectionable mirror the complaints of industry lobbyists who submitted comments in response to the Department's December 2006 request. For example, the National Association of Manufacturers urged a change in the rules to allow an opportunity for "unambiguous employee authorization for the employer — not necessarily a health care provider — to make inquiries of the employee's health care provider, as needed." The Department heeded that recommendation in the proposed rule.

Other industry suggestions, such as those to narrow the definition of "serious medical condition," have not been taken up in the proposed rule.

DOL is accepting public comments on the proposed rule until April 11. Comments can be

submitted here: www.regulations.gov, Docket identifier: ESA-2008-0001.

EPA Releases 2006 TRI Data

The U.S. Environmental Protection Agency (EPA) released the 2006 Toxics Release Inventory (TRI) data on Feb. 21. This is the fastest data release in the history of the program, although it still constitutes more than a year of lag time from the period the data refers to, and it still takes four months longer than Canada's National Pollutant Release Inventory. The 2006 data, which marks the first year that facilities are allowed to stop detailed reporting on chemical waste of less than 5,000 pounds, indicates that nationwide, 4.25 billion pounds of toxic pollution were released, which was a two percent decrease from 2005.

TRI Program

TRI is a database that tracks the release and management of over 650 toxic chemicals by industry, including manufacturing, waste handling, mining, and electric utility facilities. Facilities report to EPA on an annual basis, and EPA provides public electronic access to this information so that users can determine where, how, and in what amounts chemicals are released or managed in their communities and who is responsible for them. Pollution is divided into "releases," in which chemicals are discharged directly into the environment, and "waste," which adds waste management processes such as treatment, recycling, and energy recovery to the releases. Both can be on or off site of the reporting facility.

Facilities can opt out of providing such specific information — using the short Form A — if releases or total waste fall beneath a certain threshold, which was recently raised from 500 to up to 5,000 pounds, so long as less than 2,000 pounds are released directly to the environment. This sparked a controversy that is still unresolved: congressional legislation is pending to return the thresholds to the original 500 pounds, and 12 states are suing EPA over the change.

The 2006 data is the first year of the new threshold levels, and there is concern that a reduction of releases and/or waste management might be partially a consequence of the policy change rather than actual pollution reduction. Facilities filed 12,365 Form A reports in 2006, which was a 13 percent increase (1,435 more) from 2005. However, the overall reduction figures underscore that U.S. pollution in the TRI industrial sectors has steadily declined over the past 20 years. When considering chemicals and industries that have reported to the program since it began in 1988, annual releases are down are 59 percent.

2006 Releases and Waste

EPA has not provided a definitive cause for the two percent decrease in releases from 2005, but the three percent fewer facilities reporting for 2006 could be a factor. Electric utilities had the largest decrease in chemical releases, with a drop of 1.02 billion pounds from 2005. Metal mining remained the largest polluting industry, claiming all top five polluting facilities, and

had the largest increase in releases and disposal (47 million pounds).

Of the 4.25 billion pounds of releases in 2006, 88 percent of the releases were on site of the facility, and 12 percent were off site. Of on-site pollution:

- 49 percent was released into land
- 33 percent was released into air
- Six percent was released into water

Of the 24.4 billion pounds of total waste produced:

- One-third was recycled
- One-third was treated
- 13 percent was burned for energy recovery

2006 PBTs

A total of 455 million pounds of persistent bioaccumulative toxics (PBTs) were released in 2006, accounting for 11 percent of total releases. These included:

- 446 million pounds of lead and lead compounds, a five percent decrease from 2005
- 5.1 million pounds of mercury and mercury compounds, a 17 percent increase
- 130,277 grams (287 pounds) of dioxin and dioxin-like compounds, a 52 percent increase

Dioxin and related compounds are extremely toxic and have a reporting threshold of 0.1 grams. Three chemical manufacturers account for almost two-thirds of the reported releases.

2006 Carcinogens

The TRI program tracks 179 known or suspected carcinogens, including many of the PBTs. In 2006, approximately 820 million pounds of carcinogens were released, mostly to land. Ninety-one percent of them were on-site releases. Lead and arsenic were the largest contributors, and both of them decreased since 2005. Overall, carcinogens decreased by 11 percent in 2006.

In the last five years, releases reported by TRI facilities have decreased by 24 percent, sustaining the reduction trend since the program's inception. As previously mentioned, EPA has not provided an explanation for this significant progression, and the public is left to wonder whether it is predominantly due to increased efficiency, alternative practices, reduced production, fewer reporting facilities, and/or less detailed reporting. Such an analysis could be useful for determining how to decrease pollution even more.

The Next New Chemicals for TRI?

A recent analysis by the Project on Emerging Nanotechnologies (PEN) proposed adding

nanomaterials to the list of toxic chemicals tracked under the TRI program. The PEN report considered TRI only a possible avenue for advancing nanotechnology disclosure and acknowledges that more toxicological research needs to be done to determine whether or not nanomaterials constitute a health hazard. The last major overhaul to the TRI chemical list was in 1995, and PBTs were added in 2000. The new use of nanotechnology raises the question of how EPA can increase an older pollution program's relevancy in the face of current and emerging technologies.

2006 Data Available on RTK NET

Just one day after EPA released the 2006 TRI data, OMB Watch made the new information available on the Right-to-Know Network (RTKNET.org), which provides the public with search capabilities for a number of environmental databases. OMB Watch also launched new formats for presenting TRI data, such a new summary page that provides a concise snapshot of a search, including release/waste breakdown graphs, trend charts, and Top 5 lists of polluting companies, industries, and chemicals. Improved low- and medium-detail views allow users to easily sort results by releases or waste amounts, facility names, parent companies, chemicals, industry sectors, and geographic locations. The core chemical option in searches provides meaningful chemical comparisons by isolating chemicals consistently reported across any range of years being searched. Additional new features include links to street maps for facility addresses, an XML output, updated industry codes, and estimate amounts for the new Form A thresholds.

Inspectors General Need More Independence

A new study by the Project on Government Oversight (POGO) found that many Inspector General (IG) offices do not have sufficient independence to effectively discharge their responsibilities to investigate agencies for possible mismanagement, waste, fraud, or abuse.

Congress established the modern IG system with the Inspector General Act of 1978 in reaction to Watergate and other governmental scandals of the time. The IG offices have served as a vital check and balance against many of government's biggest reoccurring problems — excessive spending, abuse of power, and misleading the public. Currently, there are 64 IGs, 30 of which are appointed by the president, while the remaining 34, mostly at smaller agencies, are appointed by the heads of their respective agencies.

POGO surveyed IG offices throughout the federal government, receiving replies from 49 of the 64 offices. The report, *Inspectors General: Many Lack Essential Tools for Independence*, highlights patterns and issues contained in the responses and offers recommendations to improve the IG process.

The study reviewed several key factors that affect the level of independence of an IG office including:

- IG Candidate Selection
- Budget Line Items and Authority
- Staffing and Spending Authority
- In-House Counsel
- Ease of Website Access and Use
- Unfettered Investigative Authority

The responses from agencies revealed troubling trends among the IG offices. POGO concluded that many IG offices lacked the resources, staff, and money necessary to operate effectively. Some must even receive agency approval before spending funds, creating a potential conflict of interest when permission for investigations could lead to embarrassments for the agency. Similarly, few IG offices have their own in-house counsel and are required instead to use the general counsel of the agency, whose responsibility it is to protect the agency.

Another pattern noted in the report was the greater difficulties faced by the 34 IGs not appointed by the president. For instance, based on legislation, the fund for the 30 presidential appointed IGs must be separated out in the agency budgets and overseen by Congress. The agency-appointed IG funds are not listed separately and therefore are subject to administrators of those agencies. Since agency-appointed IGs are mostly at smaller agencies, commissions, and boards, the lack of funding and staff are more pronounced and many are unable to bring in contract help or post reports of their findings to agency websites.

The POGO study offered a number of recommendations for all IG offices to improve the level of independence and effectiveness. The recommendations included the idea of creating a council of all IGs to encourage greater coordination and sharing of resources, such as a pool of professional employees for smaller IG offices or consultation with IG counsel of another agency for those offices that lack their own in-house counsel. POGO also urged that the internal vetting process previously used by the IG community be revived to help ensure that only well qualified candidates are granted IG positions. Additionally, each IG office should have separate budget authority and transparent public budgets and should be allowed to spend the funds without additional agency approval. The POGO report also included several recommendations specific to individual agencies based upon unique issues indicated in their responses.

Congress is currently considering several bills that seek to improve the IG system. On Oct. 3, 2007, the House passed the Improving Government Accountability Act (H.R. 928), sponsored by Rep. Jim Cooper☼ (D-TN), which seeks to enhance the independence of the Inspectors General and create a Council of the Inspectors General on Integrity and Efficiency. The bill now moves on to the Senate for consideration. The Senate also has another bill, the Inspector General Reform Act of 2007 (S. 2324), introduced by Sen. Claire McCaskill☼ (D-MO), that seeks to address many of the same Inspector General issues. On Nov. 14, 2007, the Senate Committee on Homeland Security and Governmental Affairs passed S. 2324 by unanimous voice vote, and the bill has been scheduled for debate.

In the last several months, OMB Watch has on several occasions reported troubling activities

concerning IG offices in federal agencies, including the Central Intelligence Agency conducting an investigation of its own IG while that office reviewed the agency's detention practices; the General Services Administration dramatically cutting its IG office's budget; and the IG for NASA destroying documents and interfering in a federal investigation. These ongoing problems across several agencies serve to reinforce the problems outlined in the POGO report. Many of the recommendations contained in the POGO report, as well as the improvements sought by the pending legislation, would directly address many of these problems.

POGO plans to release another study that will address questions of IG accountability, performance, and effectiveness.

FY 09 Budget Resolution: Goals, Strategies, and Challenges

The House and Senate Budget Committees will soon turn to the congressional budget resolution for Fiscal Year 2009. The draft versions of the budget resolution, to be offered by House Budget chief Rep. John Spratt☼ (D-SC) and Senate Budget head Kent Conrad (D-ND), are likely to be considerably different from President Bush's unrealistic budget proposal submitted to Congress in February.

The budget resolution is a non-binding blueprint in which Congress charts out a fiscal direction for the federal government over a five-year period, but it also sets the rules for debate on fiscal issues and establishes tax and spending parameters for the year ahead. In 2008, on crucial issues such as balancing the budget, war funding, the reach of the alternative minimum tax (AMT), or whether revenue can be boosted without raising taxes, Democrats will be challenged to explain why their budget is more realistic than what the White House offered.

The president's FY 09 budget proposal to Congress showed a balanced budget, with a $48 billion surplus, by FY 2012. Democrats and some Republicans in Congress rightly criticized the proposal, arguing it was based on some improbable assumptions:

- Hundreds of billions of dollars in federal revenue from allowing the AMT to go "un-patched" — thereby affecting tens of millions of middle-class taxpayers
- Only $70 billion in future war funding for Iraq, Afghanistan, and other fronts in the global war on terror — far less than current spending requests
- Stagnant or even reduced domestic discretionary spending in real terms

Spratt and Conrad have indicated their budget blueprints both set a goal of a balanced budget by FY 2012, often using the same spending and revenue assumptions. Regarding war costs, for example, Conrad says the $70 billion makes more sense "in the context of our policy than [Bush's] policy because he intends to stay in Iraq. Some of his people told us, 'Think Korea,' when we asked how long might we stay... So the President has played hide the ball in the budget on war cost with respect to his policy."

On the AMT, the Democrats will likely assume passage of a fully offset patch in FY 09. The

assumption of an extended AMT patch is politically warranted, but there is no reason to expect the GOP to permit it to be paid for with tax increases elsewhere in the budget. Democrats will also assume, like last year, that they can balance the budget without allowing all of the 2001 and 2003 tax cuts to expire in 2010. Few experts, however, think sufficient revenue can be raised from the limited roll-backs the Democrats have proposed to balance the budget.

Another budget resolution strategy for Congress to achieve fiscal goals is through budget reconciliation instructions. Democrats' fiscal goals were stymied in 2007 due to Republican senators whose filibuster threats regularly killed legislation intended to reduce the deficit. Many of these legislative proposals had support from more than half the Senate, but the rules of that chamber require 60 votes to defeat a filibuster. To overcome this deadlock, Democrats can use special instructions contained in a budget resolution directing committees to move legislation that would reduce the deficit and be protected from filibusters.

This means that securing offsets for the AMT legislation and the renewable energy tax package that has passed the House three times already would be far easier. But this strategy has its risks. Democrats, with their one-vote majority in the Senate, have no room for error.

Sen. Mary Landrieu☼ (D-LA), for example, opposes offsetting renewable energy tax breaks by raising taxes on oil and gas companies, as was tried in an energy bill last year; she does not want that proposal included as a reconciliation instruction. And Senate Finance Chair Max Baucus (D-MT) calls trying to pass an offset AMT patch "a waste of time" because the Senate proved in 2007 that such an approach was futile. Baucus might be right, as even if fully offset energy tax or AMT bills are cleared, President Bush would likely veto them.

The antagonism over budget priorities witnessed in 2007 will likely repeat itself in 2008, especially since the president has already threatened to veto any spending bills exceeding his requests. Almost no one in Washington expects Congress and the president to agree on an FY 09 budget anytime this year. As has been typical of the debate over the federal budget recently, House Appropriations Chair Rep. David Obey☼ (D-WI) has vowed to wait "until a new president is in office who will act like an adult" before negotiating an FY 09 federal budget.

Under these circumstances, there is little reason for Democrats not to include "message" instructions that highlight differences in fiscal priorities with their GOP colleagues and the president. Among the message instructions under consideration are:

- Spending $20 billion to prevent a 10 percent cut in Medicare payments to physicians as well as other Medicare changes
- Adding $35 billion for another stimulus package featuring additional money for the unemployed, food stamps, and heating subsidies for the poor
- Providing $40-60 billion for the highway trust fund and other infrastructure projects
- Expanding the State Children's Health Insurance Program

Recent election-year history points up the challenges facing budget-makers in Congress in 2008. Republicans failed to produce a House-Senate agreement in 2004 and 2006, while in

2002, Democrats in the Senate and Republicans in the House could not overcome their differences to pass a budget.

Even if a resolution is enacted, it may not produce a realistic roadmap to a balanced budget in the next few years. Indeed, it may not even produce a viable budget for the next fiscal year. But it will quite likely serve as a proxy fight for the post-election battle over the future of President Bush's tax cuts, most of which expire at the end of 2010, as well as other fiscal issues that will be played out over the course of the 2008 election year. These issues, like the FY 09 budget, will ultimately be resolved in 2009 by the next Congress and the next president.

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