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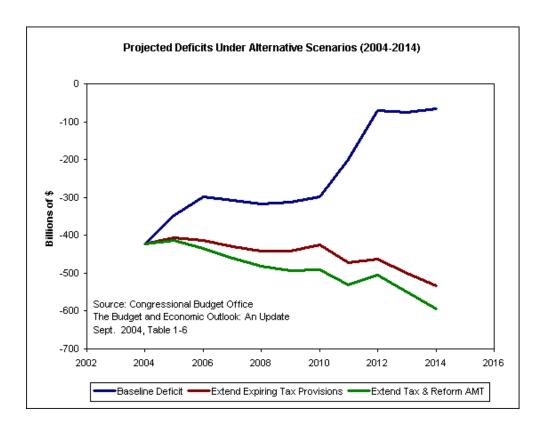
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CBO Updates Budget Estimates: Massive Deficits to Grow

The Congressional Budget Office today released its semi-annual update on the nation's budget situation. The report confirms massive deficits for the current year and beyond. In addition, the report shows that deficits will not be "cut in half" in the next five years, as projected by the Bush administration.

To the contrary, if the president's tax changes are made permanent, deficits will continue to increase over the next 10 years and reach nearly \$600 billion in 2014. The chart below uses data from the CBO report to show the effect on the baseline deficit if the tax changes are extended and if a modest reform of the Alternative Minimum Tax is enacted.

This recent experience contrasts sharply with the surpluses that reached over 2 percent of GDP just a few short years ago. The alternative scenarios produced in the report also highlight the devastating impact the tax changes will have on the budget if they continue unchecked. Extending the planned tax changes over the next 10 years will cost more than \$2.2 trillion.



'State of Working America' Calls Economy Unbalanced

On Labor Day, the Economic Policy Institute (EPI) released its 2004 "State of Working America" report, showing that performance of the economy throughout the recovery has been unbalanced. "After almost three years of recovery, our job market is still too weak to broadly distribute the benefits of the growing economy," it found. "Unemployment is essentially unchanged, job growth has stalled, and real wages have started to fall behind inflation."

The annual study measures a range of economic indicators, including: employment, unemployment and underemployment; wages and job quality; and poverty, income, and wealth. An excerpt from the study, as well as many interesting facts sheets, are at EPI's *The State of Working America*

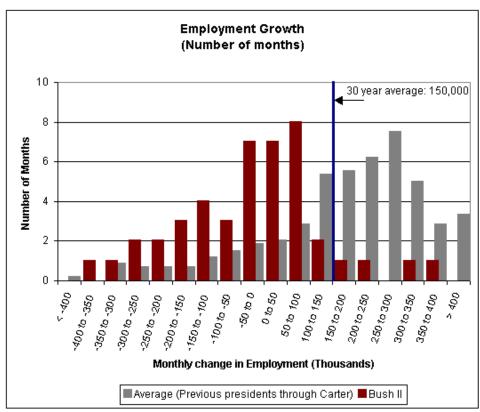
Labor Day Finds Little to Celebrate in Recent Trends

Yesterday we celebrated Labor Day. Unfortunately, there has not been much to celebrate in the labor market over the last 4 years. A look at the recent record shows an extremely under-performing labor market economy.

Employment

Since the start of 2001, the economy has lost nearly a million jobs. Part of the job-loss was due to the recession, however, even after 2001 the labor market has just barely crept along. Measuring from the end of the recession, the economy has added an average of only 18,000 jobs a month.

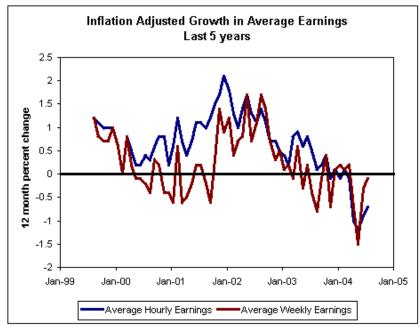
This stands in stark contrast with previous administrations and recent historical experience. Over the last 30 years, employment growth has averaged a healthy 150,000 jobs. Looking at the past six 4-year terms, on average, a 4-year term will contain 30 months with growth above this level. Under the Bush administration, there have only been 4 months with satisfactory levels of growth. (See figure below). The Bush Administration will be the only administration since Herbert Hoover in the 1930's to have a net job loss during its term in power.



Data: Bureau of Labor Statistics

Earnings

In addition to a weak labor market as measured by the number of jobs, it also appears that even those with jobs are not doing well. Average inflation adjusted weekly and hourly earnings have slowed to a crawl, and even declined over the past year. (See figure below).



Data: Bureau of Labor Statistics

Policy

The record of the last 4 years appears clear. The economy and the labor market have underperformed under the policies of this administration. While the labor market weakness has been emphasized, in fact, the average growth rate of the overall economy has been weak as well. Real gross domestic product has grown on average just around 2.5 percent under

Bush -- which is lower than past administrations, including the 3.3 percent average rate experienced during the Carter administration.

Administration economic policies, which were sold as economic and jobs stimulus, have obviously not had their claimed impact.

In the meantime corporate profits have soared, from \$767 billion in 2001, to \$1,167 billion in the most recent reporting period (2004, 2nd Quarter) -- an increase of more than 50 percent. It seems clear who is currently benefiting from the current economy as well as current policy.

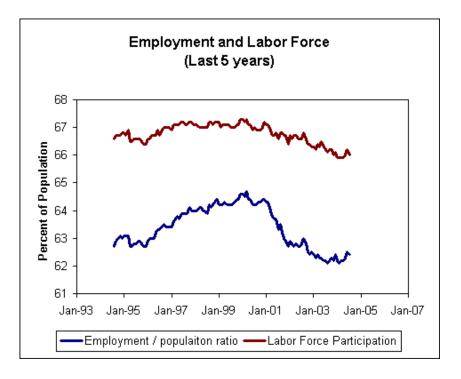
Economy and Jobs Watch: Sluggish Growth Continues

Employment growth continues to be below average. In August, the number of new jobs added was just 144,000, according to the Bureau of Labor Statistics (BLS). This is the third straight month that the data has been below its historical average -- over the last 30 years, the economy has added about 150,000 per month.

During the Bush term, there have only been 4 months in which employment growth has been above this average threshold. By contrast, looking over the 6 previous 4-year terms, administrations have averaged 30 months of employment growth per term above the 150,000 mark. (See Labor Day article this issue.)

In addition, the BLS also announced that the unemployment rate fell one tenth of a percentage point to 5.4 percent, primarily because of a decline in the labor force -- of the 174,000 decline in unemployed workers, 152,000 was due to workers leaving the labor force. This continues the trend of declining employment and declining labor force participation, which began in early 2001.

These signs continue to point to a weak labor market and the continuing failure of current policy to address the macroeconomic situation.



Appropriations: A Look Ahead

As Congress reconvenes today, the Defense Bill remains the only completed appropriation bill for FY 2005. The \$417.5 billion bill was approved only just prior to the August recess. Members of Congress have a lot of work ahead of them if they wish to complete their appropriations work before the end of the fiscal year, which ends on September 30th, as only three other bills -- Homeland Security, Legislative Branch, and Military Construction -- have even made it through a full Senate committee.

If Congress is unable or unwilling to pass the other twelve appropriations bills before the end of the month, they may be forced to combine the remaining bills into a massive omnibus bill. The lack of time to adequately address the bills individually, along with both an extremely partisan political environment and a tight budget cap makes the omnibus route very likely. Resorting to an omnibus bill is somewhat detrimental because this process not only reduces bill discussion and debate, but it also makes way for bill sponsors to attach numerous pieces of unrelated legislation in order to gain needed Congressional support. Last year, seven spending bills were rolled into one omnibus bill for FY 2004, and as a result \$10.7 billion worth of earmarks were passed along with the appropriation bills. Lawmakers passed thousands of provisions with most people not knowing where the money went. The same situation could very well occur again with the appropriation

bills for FY 2005. There is also a possibility that the bills -- either individually or as a group -- will not pass and that Congress would be forced to take up the issue in a lame-duck session after the November elections.

In addition to following a flawed process, the bills also reflect flawed domestic priorities. The budget bills are set to embody the domestic discretionary spending cuts proposed and supported by the current administration. Looking towards the future, domestic discretionary programs will see cuts based on the administration's funding request over the next five years, according to a recent report released by the Center on Budget and Policy Priorities. By 2009, the report claims, overall funding for all domestic discretionary programs besides Homeland Security will be cut by 10.4percent, or approximately \$45 billion, when taking into account adjustments for inflation. This action will reduce funding for many basic services that citizens across the country rely upon.

Congress thus has a huge challenge ahead of them, not only in the next few weeks, but also in the upcoming years. The annual appropriations process requires time for both intelligent debate, committee testimony, and the opportunity for amendments to be proposed and decided upon. A rushed omnibus bill reflects a lack of congressional effectiveness in passing a responsible federal budget, and only makes it easier for the current administration to slip in spending cuts that affect multiple discretionary programs.

Senate Approves FOIA Exemption for Satellite Images

The Senate has approved a broad new Freedom of Information Act (FOIA) exemption that would restrict public access and use of commercial satellite imagery.

The proposal entitled "Nondisclosure of Certain Products of Commercial Satellite Operations," would impose strong restrictions on the dissemination of unclassified information that is relied upon for reporting to the public on disasters, international incidents, wars, and other news items. The provision would not only exempt the imagery from disclosure under FOIA but would actually prohibit the government from releasing the information. It also preempts any state or local disclosure laws that require access to such imagery information.

The Senate placed the information restriction in the National Defense Authorization Act for FY 2005, even though no national security issue appears to be involved. A House-Senate conference committee will consider the FOIA exemption proposal this month.

Various groups concerned with the vague and undiscussed provision are signing onto a letter urging the Committee Chairman to drop the FOIA exemption from the bill. For organizations interested in signing on to the letter contact Patrice McDermott with the American Libraries Association.

Coalition Reports Massive Classification Abuse, Secrecy Rose 60%

Testimony from two government officials before the House Subcommittee on National Security, Emerging Threats & International Relations confirmed that federal agencies are massively abusing their classification powers. The experts estimated that half of the classified information is wrongly restricted. The same week, OpenTheGovernment.org, a diverse coalition of more than 30 organizations, released a Secrecy Report Card quantifying the expansion of secrecy as well as the growing costs to taxpayers.

The subcommittee of the House Government Reform Committee held a hearing at the end of August to investigate the 9/11 Commission's conclusion that government secrecy is actually impeding anti-terrorism efforts. Overuse of classification prevents information from being more widely discussed or shared with either the public or government officials who lack sufficient clearance, including many law enforcement officials. The commission cited such obstructions to timely sharing of intelligence information among law enforcement agencies as a significant factor in their failure to prevent the 9/11 attacks.

J. William Leonard, Director of the National Archives' Information Security Oversight Office, told the subcommittee that in the past year over-classification has been "disturbingly increasing." Leonard also estimated that when officials have discretionary choices of whether or not to classify information they get it wrong more than half the time. This estimate was corroborated by testimony from Carol A. Haave, Undersecretary of Defense for Counter Intelligence and Security. Haave described the problem as extensive and projected that overuse of classification occurs 50 percent of the time.

According to data from Leonard's office compiled in OpenTheGovernment.org report card, the government spent \$6.5 billion last year -- more than it has for at least the past decade. The study also found that the federal government spent at least \$120 creating new secrets and maintaining them for every dollar it spent declassifying documents. This figure is a dramatic increase over recent years.

Examples discussed in the hearing indicated both the absurdity and seriousness of excessive secrecy. Harmless information clearly not warranting any security restrictions, such as the humorous plot against Santa Claus and the drinking preferences of a former dictator, are sometimes classified. Other examples demonstrate the serious danger from inappropriate classification. One study that found 40 percent of Army gas masks leak was classified, which delayed discussion and action to correct the life-threatening problem for six years.

Perhaps most serious is the intentional abuse of over-classification as a self-serving deception. Prior to the U.S. war on Iraq, the Central Intelligence Agency restricted figures on the amount Iraqi agents paid for aluminum tubes from a prewar intelligence report in order the hide the inaccuracy of the agency's conclusion that Iraq's willingness to pay high costs suggested the intention to use the tubes in a special national interest project. The amounts were between \$10 and \$17.50 per tube.

Rep. Christopher Shays (R-CT), Chairman of the Subcommittee, noted that as a contributing factor the increased number of officials that have the authority to classify information. Currently almost 4,000 government officials may categorize documents as secret, top secret, or confidential. Participants also cited the complex variety of rules that allow different agencies to restrict information under numerous categories as another obstacle to effective information sharing. These the number of restricted information categories has grown considerably since the 9/11 attacks, only making the problem worse and more confusing for officials.

OpenTheGovernment.org is a coalition of more than 30 organizations co-chaired by OMB Watch and the National Security Archive. Weekly updates from the coalition are available at www.openthegovernment.org.

On the Web, subscribe to Secrecy News. You can get policy updates from the coalition by registering here.

Industry Data Quality Challenge Weakens Dietary Guidelines: Deadline for Comments Sept. 27

An industry data quality challenge appears to have succeeded in weakening new U.S. Department of Agriculture (USDA) dietary guidelines.

Last year, the Center for Regulatory Effectiveness, an industry advocacy group, filed data quality challenges with USDA and the Department of Health and Human Services (HHS) over a World Health Organization (WHO) Report on Diet, Nutrition and the Prevention of Chronic Diseases. The agencies announced their intention to use the WHO report and its recommendation as a significant base for the pending 2005 Dietary Guidelines. The CRE challenge disputed two of the WHO report's recommendations which propose healthy levels for sugar and carbohydrates.

The WHO report recommended that for a healthy diet sugar consumption should remain below 10 percent of the total energy goal. The report also recommended that carbohydrates should comprise 55-75 percent of the diet. The CRE's challenge asserted that other studies placed maximum healthy sugar intake as high as 25 percent and that many successful low carbohydrate diets contradict the WHO recommendation. The group insisted that the WHO should not be used as basis for the new U.S. dietary quidelines.

Every five years the USDA and HHS review and update the dietary guidelines, famous for their food pyramid chart. A 13-member scientific panel recently released the recommended dietary guidelines, which acknowledge the link between sugar and weight gain, but do not specifically recommend that Americans limit sugar consumption. The panel claimed that more research was necessary before a clear position on sugar could be taken.

Consumer groups had hoped the panel would follow the WHO report and recommend clear limits on consumption of sugary foods such as soft drinks, candy, and cookies. Beverage makers and the sugar industry strongly opposed such a position and would likely support the data quality challenge. Concerns have also been raised about the USDA's objectivity, given the agency's role in promoting agricultural products. Last year, consumer groups requested the removal of seven panel members because of close ties to the food industry, but none of them were removed.

The new recommended dietary guidelines are now open for review. The USDA and HHS are accepting public comments until Sept. 27 and will hold a public meeting Sept. 21. Written comments can be submitted online or mailed into the address provided in the Federal Register notice.

Security Measures Invoked to End Safety Measures

A large sign in New York City, indicating the location of a natural gas pipeline to prevent accidents, was taken down after a website posted a photograph of the sign. John Young, the owner of www.cryptome.org, posts information on his site to draw attention to places needing increased security. Although federal regulations require that the location of natural gas lines be made as obvious as possible to the public for safety reasons, the company that owns the pipeline asserted that local laws allowed the sign's removal.

This incident illustrates how secrecy in the name of security increasingly overrides safety protections and the public's right-to-know, while doing little or nothing to improve security. The regulations requiring that natural gas pipelines be clearly marked were established to prevent accidental rupture that often causes injuries and deaths to residents, contractors, and emergency responders. Ironically, removing such information puts the public in greater danger of lethal accidents.

Reports by the Council on Foreign Relations and the National Academy of Sciences identify city power gates and compressor stations as the most vulnerable points to a potential attack that would leave a local power system down for several weeks. Since 9/11 some utility companies, such as Consolidated Edison, have addressed this threat by increasing fencing, security cameras, patrols around facilities, and inspections of pipelines.

Yet public disclosure of information is also a key part of the solution. A public that understands the risks around them can take steps to reduce them. Firefighters understood this when they opposed recent proposals by the U.S. Departments of Homeland Security and of Transportation to remove placards from hazardous materials containers. They noted that such placards help prevent accidents and inform first responders so they can properly assess and address emergencies involving toxic, explosive and hazardous materials.

National security is best enhanced, and harm from potential attacks minimized, by fixing problems and reducing risks at potential target sites. Moreover, while terrorist threats remain hypothetical, lethal accidents are certain to increase should safety warnings be eliminated. Foregoing safety in an elusive quest for security seems pennywise and pound-foolish. Policies must address both safety and security, and inform the public to improve the net protection of the public.

City Cites Terrorism in Secret Meeting on Gangs

The City Council of Staunton, Va., questionably used a terrorism provision to hold a secret meeting on gang activities. Using homeland security policies to hide non-terrorism information appears to be an increasing problem.

Amendments to Virginia's Freedom of Information Act (FOIA) allow secret sessions if the information is related to terrorist activity. In this instance, the City Council held a closed session to discuss "particular investigative and other preventive initiatives regarding gang activity." City Manger, Bob Stripling, asserted that this closed session fell into that category because "some type(s) of gang activity are terrorism because you are terrorizing the public."

This overly broad interpretation of the FOIA exemption, which grants the use of secrecy in limited circumstances, abuses the trust granted to the government. More and more often the government blocks public access to safety information in the name of security. Limitations were placed on these secrecy policies specifically to assure that only legitimate homeland security issues would be withheld and that other safety information would continue to be accessible to the public.

"There is criminal gang activity within a few hundred miles of Staunton," the city's customer relations coordinator stated. "Although there does not appear to (be) a significant problem with such activities in or near the city at this time, it's only prudent for us to be prepared in case that situation changes." But Councilman Richard P. Bell disagreed, saying much of what was covered could have been safely disclosed. Other Council members agreed the issue should be opened to public discussion.

This case brings into question how governments at all levels are using security issues to hide information of concern to the public.

Commission Finds Muslim Charities Shutdown Without Cause

A report published by the independent commission to investigate the 9/11 attacks has raised "substantial civil liberty concerns" regarding the government's shutdown in December 2001 of two Chicago-area Islamic charities. Since then, the government has neither proven either group was guilty of any terrorism-related crimes, nor convicted anyone involved.

Authorities closed the Global Relief Foundation (GRF) of Bridgeview and Benevolence International Foundation (BIF) of Palos Hills before any official finding that they were aiding terrorist organizations. Both had been under FBI scrutiny for years because of apparent ties to terrorist organizations. The report found that the concerns were "not baseless," but goes to say, "Despite these troubling links, the investigation of BIF and GRF revealed little compelling evidence that either of these charities actually provided financial support to al Quaeda -- at least after al Quaeda was designated a foreign terrorist organization in 1999. Indeed, despite unprecedented access to the U.S. and foreign records of these organizations, one of the world's most experienced and best terrorist prosecutors has not been able to make any criminal case against GRF and resolved the investigation of BIF without a conviction for support of terrorism."

The finding calls into question the government's claims to success in fighting terrorism and highlights the issue of the continued abuses of civil liberties towards Muslim charities in the name of 9/11. The FBI raids on the foreign, then the Illinois offices of both charities, were authorized under the post 9/11 Patriot Act, and required the approval of only one Treasury Department official.

The charities assets were frozen for about 10 months before the Treasury Department officially deemed them supporters of terrorism. As a result, both charities closed their doors permanently -- leaving over a million dollars suspended indefinitely. The director of Benevolence International pled guilty to diverting money to Islamic fighters in Bosnia and Chechnya but prosecutors later dropped charges that he aided terrorists. A co-founder of Global Relief was deported after an immigration judge deemed him a security risk.

The report concludes that these cases demonstrate the government's dramatic shift from pre-9/11 investigating and monitoring terrorist financing to actively disrupting suspect entities through freezing their assets. It also found many suspects are denied due process and organizations have been closed without formal evidence that they actually funded al Qaeda or other terrorist groups. The question becomes what is the threshold of information for the government to take disruptive action against suspect charities. For more background see OMB Watch's September 2003 report *The USA Patriot Act and its Impact on Nonprofit Organizations*.

IRS Audits Nonprofits, Lets Big Business Slide

The Internal Revenue Service (IRS) has begun a major effort to examine internal financial issues of charities and foundations. IRS Announcement 2004-206, issued August 10, said nearly 2,000 charities and foundations will be contacted and asked for information about their salary practices and procedures. The effort will include a broader review of foundations that will eventually include examinations of over 400 organizations, and conclude in July 2005.

The Senate Finance Committee has held public hearings this year focusing on excessive compensation; involvement in joint ventures and tax shelters; participation in fundraising activities; and participation in political campaigns. Its staff released draft proposals for reform during the summer, and nonprofit groups have provided input and responses.

While nonprofits are enduring increased audits, a study done by Syracuse University Transactional Records Access Clearinghouse concluded that the IRS audited fewer corporations and small businesses in 2004 than in previous years. The declining audits of businesses exposes a flaw in the administration's tough stance on corporate wrongdoing.

Unlike large corporations, most of whom operate with far larger budgets, 70 percent of charities have annual budgets of under \$500,000. Tougher regulations and enforcement procedures could be overly burdensome to organizations so that people are discouraged from working for nonprofits or giving to charitable organizations, a development clearly not in the government's, or the public's interest.

FEC Seeks Comments on Electioneering Rule

The Federal Election Commission (FEC) has issued a Notice of Availability of a rulemaking petition filed in July that seeks to exempt promotion of political films, books and other materials that refer to federal candidates from the electioneering communications rule. Comments in support or opposition to the proposal are due September 27. During August a federal court turned down Wisconsin Right to Life's (WRLC) request for an injunction that would allow it to run ads mentioning Sen. Russell Feingold (D-WI), who is running for re-election.

The Petition notes "substantial uncertainty" about how the ban on broadcasts referring to federal candidates within 60 days of an election or 30 days of a primary or party convention apply to promotion of films like Fahrenheit 9/11. It proposes these ads be exempted, saying "These legal questions are precisely the kind that Congress did not anticipate and that the Commission is authorized to settle decisively by promulgation of an exception to the general rule. Legal sanctions should not loom over, much less be pursued against, the promotion of political documentary films -- however controversial"

The FEC is currently considering an advisory opinion request from Citizens United, (see AO 2004-30) which seeks permission to air broadcasts publicizing a book about Presidential candidate John Kerry. The same group has previously filed a complaint against advertisements for Michael Moore's film Fahrenheit 9/11. On August 6, the FEC dismissed that complaint based on stipulations from Moore and the film's distributor that it had already planned to delete references to federal candidates from advertising during the blackout period.

The Wisconsin Right to Life Committee lawsuit challenged application of the electioneering communications rule to grassroots lobbying ads it wants to run this fall. The ads urge the public to contact Democratic Senators Russ Feingold and Herb Kohl to end the filibuster against President Bush's judicial nominees. Wisconsin Right to Life is a 501(c)(4) organization that has endorsed Republican candidates.

The three-judge panel ruled that the Supreme Court's decision in *McConnell v. FEC* upheld the law and does not allow for challenges to its application in specific circumstances. The court also said the ads "May fit the very type of activity" the law was meant to prevent. WRLC said it would appeal, and has taken the ads off the air. The court noted that the ads could continue airing if WRLC used money subject to FEC fundraising restrictions and filed disclosure reports.

Bush Campaign Files Suit to Force FEC to Shut Down 527s

On September 1, President Bush and Sen. John McCain (R-AZ) filed a lawsuit against the Federal Election Commission (FEC) to force FEC action on a complaint the Bush campaign had filed last March against Democratic leaning independent political committees. Based on their announcement August 26, Trevor Potter, a campaign reform advocate and former FEC chairman, said he had anticipated the two would file a second suit as well seeking to force stricter regulation of *all* independent political committees, but they did not.

The new suit asks the U.S. District Court for the District of Columbia for an injunction forcing the FEC to act within 30 days and for an expedited hearing. The FEC said it will oppose the request.

The law allows parties that file FEC complaints and feel they are "aggrieved" if there is no action after 120 days to file a petition in federal court. In order to prevail the party must show that the FEC acted "contrary to law". The court will examine the credibility of the allegations in the complaint, the severity of the threat, resources available to the FEC and other factors, including whether Congress has provided guidance on the question. These types of suits are unusual and courts do no usually intervene.

The complaint charges that the groups are violating the law by spending soft money to defeat President Bush. The legal issues are the same as those debated throughout the year in FEC rulemakings and Advisory Opinions. See www.nonprofitadvocacy.org for more information.

On August 31 the Campaign Legal Center, Democracy 21 and the Center for Responsive Politics sent a letter to the FEC urging them to act on complaints the groups filed against The Media Fund, the Progress for America Voting Fund and Swift Boat Veterans for Truth.

Politics over Science: Change in Recovery Plan for Salmon Smells Fishy

The National Marine Fisheries Service (NMFS) announced August 31 it will not consider removing dams in the Columbia and Snake rivers in order to save the endangered salmon population. The announcement contradicts twenty years of research by both environmental groups and government agencies that supports breaching the dams as the most effective way to save the endangered fish population.

The NMFS announcement precedes their upcoming biological opinion (BiOp) due out November 30, which will provide a strategy for "how the basin's hydroelectric system must be operated to minimize harm to the 13 populations of salmon that the federal environmental law protects," according to an NMFS press release. A federal district court determined in June 2003 that the agency's previous BiOp did not adequately detail the mechanisms for protecting the ESA-listed salmon, ordered NMFS to develop a new BiOp, and ordered NMFS to rework the draft plan as required by the federal Endangered Species Act. See National Wildlife Fed. v. National Marine Fisheries Serv., 254 F. Supp. 2d 1196 (D. Or. 2003). Although the previous plan did include dam breaching as an option, the one scientists identified as most effective, that strategy is notably absent from the revised version.

In its announcement, NMFS cited recent increases in the wild salmon population as evidence that current methods are effective in protecting the endangered fish, making the breaching of the dams unnecessary. "NOAA Fisheries credits measures to restore hundreds of miles of in-river and estuary salmon habitat, state-of-the-art technological upgrades to hydroelectric dams and other facilities, aggressive predator control, better hatchery and harvest practices, and favorable ocean conditions with boosting returns over the past four years."

The new findings contrast starkly with the 2000 NMFS report which considered the chance of salmon survival bleak without severe intervention: "[A]II the Columbia River Basin salmon stocks are in a state of perilous decline, especially Upper Columbia Spring Chinook and Steelhead throughout its range. Put in starker terms: without substantial intervention, there is a greater than 50:50 chance that most of these ESUs will be extinct by the next century, some much sooner."

Earthjustice attorney Steve Mashuda told the BNA that the agency's draft biological opinion may not be scientifically or "probably even legally defensible." Close to an election time the policy seems to reflect voter concern over jobs provided by the hydroelectric plants in the area rather than the obligations of the Endangered Species Act. John Kober of the National Wildlife Federation told the Washington Post that "President Bush, on campaign swings through the region, has repeatedly insisted that dams on the Snake River are crucial to the economic life of the Pacific Northwest and that he would never allow them to be breached."

FDA Quietly Drops Rule to Protect Recipients of Contaminated Blood

The Food and Drug Administration (FDA) quietly abandoned work on a proposal to protect recipients of plasma-derived products, according to the agency's most recent statement of its regulatory priorities for the next six months.

The proposal was initially placed on the FDA's regulatory agenda, a semiannual publication of the agency's recent activities and upcoming regulatory priorities, back in 1999 in response to a House committee report identifying weaknesses in the FDA's efforts to protect the nation's blood supply from infectious agents.

Specifically, the proposal would have created enforceable standards mandating a tracking system and notification process for alerting, in cases of contamination or risk of contagion, persons who receive batches of products derived from blood plasma and self-administer the products over time.

The FDA argued at the time that voluntary industry programs for notification were inadequate to ensure the protection of these recipients. "[V]oluntary programs for notifying recipients ... are fairly new," the agency explained. "Thus the success of the voluntary programs cannot yet be fully assessed. However, the success of such voluntary programs will always depend on the continued voluntary support by manufacturers of blood products and the continued vigorous recruitment of patients/recipients to encourage full participation. FDA is concerned that the continued success of patient notification cannot be assured without regulatory standards ... and without a clear mechanism of enforcement in the event a notification program is found deficient."

The FDA dropped the item from its June 28, 2004 agenda, without any explanation.

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