

Regulation Digest Weekly

April 24th, 2013

Vol. 2 No. 17

Opinion

- Compounding pharmacies can be regulated by FDA
- Regulation by Tweet and Other CFPB Follies
- Thank You for Smoking

Marketplace of Ideas

American Action Forum

- Regulation Review: Final Transformer Regulations, *Dan Goldbeck*
- The Week in Regulation: April 15-19, *Sam Batkins*

American Bird Conservancy

- Ask Secretary Sally Jewell to Say "No" to Weakened Protections for Eagles

Center for Effective Government (Formerly OMB Watch)

- We Need Protection from Industrial Hazards in Our Communities, *Randy Rabinowitz*
- Blogger Gets Debate over Regulations Right, *Randy Rabinowitz*
- Texas Fertilizer Plant Explosion Raises Important Questions, *Sofia Plagakis*

Center for Progressive Reform

- Blistering Comments on State's Draft Keystone XL Environmental Impact Statement, *Sandra Zellmer*

Competitive Enterprise Institute

- Costs Rise In Obama's New 2013 Draft Report To Congress On The Benefits And Costs Of Federal Regulations, *Wayne Crews*
- Why FAA's Child Seat Campaign Is Deadly, *Adam Sandberg*
- CEI's Battered Business Bureau: The Week In Regulation, *Ryan Young*
- Costs Rise In Obama's New 2013 Draft Report To Congress On The Benefits And Costs Of Federal Regulations, *Wayne Crews*

Feature Story

OMB Releases Draft Report of Benefits and Costs of Regulation

Last week, the Office of Information and Regulatory Affairs within the Office of Management and Budget released its draft [2013 Report to Congress on the Benefits and Costs of Regulations](#). The draft report, which tracks regulatory benefits and costs over a 10 fiscal-year window, indicated that in fiscal year 2012, two rules in particular dominated both the total cost and benefit figures: EPA's Mercury and Air Toxics Standards (MATS) rule, and the joint EPA-DOT CAFÉ standards for light-duty vehicles. According to data from OMB's report, the MATS and CAFÉ rules alone contributed 89% of the costs and 94% of the benefits reported by OMB in fiscal year 2012.

According to analysis from the [Regulatory Studies Center](#), OMB's reported 2012 regulatory costs exceed the costs of all rules issued in Clinton's and Bush's first terms combined. OMB's figures are based on agencies' estimates of the benefits and costs of the major regulations (generally, regulations with impacts of \$100 million or more per year) reviewed by OMB during the fiscal year. The current figures cover 14 rules, 5% of the 278 rules OMB reviewed during FY2012. OMB reports that these rules will have annual costs ranging from \$14.8 to \$19.5 and benefits ranging from \$53.2 to \$114.6 (all in 2001 dollars).

In the News

4/17/13

[Co-author of Obama health care law sees 'huge train wreck' in implementation](#), *Washington Post*

[GOP lawmakers accuse SEC of bending rules for lobbyists](#), *The Hill*

[Legislators endorse FDA action against OxyContin generics](#), *The Hill*

[Oil-and-gas lobby talks biofuel rule with White House, EPA, senior lawmakers](#), *The Hill*

[Fed proposes charging banks \\$440M to fund Dodd-Frank oversight](#), *The Hill*

[House GOP: Obama regs slowing oil-and-gas development](#), *The Hill*

[Former Consumer Bureau Deputy Date Starts Consulting Firm](#), *Bloomberg*

[Labor Pick Faces Backlash Over His Aggressive Record](#), *Wall Street Journal*

[Fed Officials Back Higher Capital](#), *Wall Street Journal*

[Fed's Stein Favors Staying the Course on Regulation](#), *Wall Street Journal*

4/18/13

[Immigration bill calls for slew of regulations, new bureaucracy](#), *The Hill*

[White House Said Near Decision on Leader of Fannie Mae Regulator](#), *Bloomberg*

[SEC Sues Schottenfeld Trader Mancuso Over Goffer Tips](#), *Bloomberg*

[SEC to Move Past Financial Crisis Cases Under New Chairman White](#), *Bloomberg*

[Power Plants Brace for New EPA Rules Adding to Coal Woes](#), *Bloomberg*

[FAA: Expect long delays at major airports as air traffic controller furloughs kick in Sunday](#), *Washington Post*



Consumer Financial Protection Bureau

- Testimony of Richard Cordray at the US Senate Committee on Banking, Housing, and Urban Affairs, *Richard Cordray*

Federal Regulations Advisor

- Homeland Security & Labor Issue H-2B Regulations: Authority Solved?, *Leland Beck*
- Monday Morning Regulatory Review – 4/22/13, *Leland Beck*

Federalist Society

- What is the Effect of Renewable Fuels Mandates?, *Susan E. Dudley*
- OMB Report to Congress on the Costs and Benefits of Regulations issued in FY 2012, *Susan E. Dudley*

The George Washington University Regulatory Studies Center

- Costs of New Regulations issued in 2012 Dwarf those of Previous Years, according to OMB Report, *Susan Dudley*

Government Accountability Office

- Continued Management Attention Would Strengthen Internal Supervisory Controls, *Angela Clowers*
- OSHA Can Better Respond to State-Run Programs Facing Challenges, *Revae Moran*

Heritage Foundation

- Congress Wants to Tell Americans How to Be More Efficient? Really?, *Nicolas Loris & Katie Tubb*

The Mercatus Center

- Public Interest Comment - Federal Aviation Administration: Unmanned Aircraft System Test Site Program, *Jerry Brito, Eli Dourado, & Adam Thierer*
- Evaluating OSHA's Effectiveness and Suggestions for Reform, *John Leeth & Nathan Hale*
- Deregulate the Skies: Why We Can't Afford to Fear Drones, *Eli Dourado*

Penn Program on Regulation

- President Obama's Budget Sets Regulatory Priorities Too, *Sam Batkins*
- Shifting OSHA's Priorities to Protect Public Health, *Brady Sullivan*
- The Regulatory Week in Review: April 19, 2013, *RegBlog*
- Supreme Court Reaffirms Agency Discretion in Interpreting Regulations, *Eric Lorber*

[EPA faulted over years of delays in studies of dangers in Montana town where hundreds killed](#), *Washington Post*

[FDA panel split over safety of Endo's long-acting testosterone injection](#), *Washington Post*

[Federal regulators fined Texas fertilizer plant in 2012 for safety violations](#), *Washington Post*

[Labor nominee Perez pledges open mind, willingness to work with business, labor to create jobs](#), *Washington Post*

[Lawmakers fear new regulatory burdens on organic farmers](#), *The Hill*

[FDA given green light to ask docs about drug advertising](#), *The Hill*

[Fertilizer industry worries explosion will lead to new regs](#), *The Hill*

[Industry balks at 'food safety tax' to hit consumers](#), *The Hill*

[Consumer bureau: Senior citizens need help with financial advisers](#), *The Hill*

[With Warren absent, lawmakers take it easy on housing agency chief](#), *The Hill*

[Food Illness-Dieback Stalls as Safety Rules Arrive Late](#), *Bloomberg*

[Obama Said Near Decision on Leader for Fannie Mae Regulator](#), *Bloomberg*

[Texas Explosion Seen as Sign of Weak U.S. Oversight](#), *Bloomberg*

[U.S. Treasury's Miller Says Too-Big-To-Fail Bailouts Are Over](#), *Bloomberg*

4/19/13

[U.S. FAA Prepared to Approve Boeing's 787 Battery Fix](#), *Bloomberg*

[FAA approves resumption of Boeing 787 Dreamliner flights with revamped battery system](#), *Washington Post*

[Regulators close small lenders in Florida, Kentucky; brings US bank failures this year to 8](#), *Washington Post*

[US EPA: California has failed to spend \\$455 million on safe drinking water improvements](#), *Washington Post*

[Supreme Court asked to hear EPA greenhouse gas challenge](#), *Reuters*

[Fed's Stein backs putting price on bank access to liquidity](#), *Reuters*

[EPA proposes water pollution rules for power plants](#), *The Hill*

[Power Plants Get Water-Discharge Limits in 4 EPA Options](#), *Bloomberg*

[CFTC Sought Oil Trading Data Tied to BP, Canadian Natural](#), *Bloomberg*

4/20/13

[In small Texas towns, people live close to fertilizer plants with limited safety regulation](#), *Washington Post*

[EPA proposes rules to curb power-plant waste in waterways](#), *Washington Post*

4/21/13

[Md. congressman says he is concerned about impact of federal regulation on local business](#), *Washington Post*

4/22/13

[U.S. Swaps 'Reach,' Iosco Proposal, SEC Fee: Compliance](#), *Bloomberg*

[EEOC to argue that disabled workers at Iowa turkey plant were abused and deserve damages](#), *Washington Post*

[Former foreman at asbestos-removing project at Virginia Tech admits violating Clean Air Act](#), *Washington Post*

[House panel refuses to hear testimony from chief of consumer financial bureau](#), *The Hill*

[Regulators to request information about chemicals in tobacco products](#), *The Hill*

[Feds nix 'duplicative' fuel efficiency stickers](#), *The Hill*

[Former prosecutor picked to lead SEC's enforcement division](#), *The Hill*

[Interior chief Jewell: 'One size doesn't fit all' on fracking](#), *The Hill*

[Deloitte Loses Bid to Delay SEC Suit Over China Documents](#), *Bloomberg*

[Coal-Ash Recyclers Seen Aided in EPA's Water-Discharge Plan](#), *Bloomberg*

[FDA Breaks Food Safety Law With Rule Delays, Judge Finds](#), *Bloomberg*

[Fed Rule on Overseas Bank Units May Spark Reprisal, EU Says](#), *Bloomberg*



[FINRA names new regulatory operations head](#), *Reuters*
[Justices decline to hear challenge to tobacco law](#), *Reuters*
[Wall Street watchdog names new regulatory operations head](#), *Reuters*

4/23/13

[Too-Big-to-Fail Bill Increases Big Banks' Capital Standards](#), *Bloomberg*
[Boeing 787 Battery Approval Examined by U.S. Safety Board](#), *Bloomberg*
[Keystone Foes Say 1 Million Comments Show Grassroots Power](#), *Bloomberg*
[Bernanke Warned by Barnier That Bank Unit Rules Risk Retaliation](#), *Bloomberg*
[Report: 2012 Regulatory Rules More Costly than All Rules in 'Entire First Terms of Presidents Bush and Clinton, Combined'](#), *The Weekly Standard*
[Homeowners defaulting in loan modification program, report says](#), *Washington Post*

[US safety regulators seek voluntary limits on car touch screens to curb driver distraction](#), *Washington Post*

[Privacy groups urge FTC to reject delay in children's privacy rules](#), *The Hill*
[OMB identifies up to \\$800 billion in benefits from regulations since 2002](#), *The Hill*
[Court backs EPA veto of mountaintop mining project](#), *The Hill*

[S.E.C. Gets Plea: Force Companies to Disclose Donations](#), *New York Times*

[Judge Orders FDA to Proceed on Food-Safety Rules](#), *Wall Street Journal*

[GOP criticizes EPA comments on Keystone XL path](#), *The Hill*

[Court rejects challenge to EPA pollution rules](#), *The Hill*

[White House Lawyer Anne Small Returns to SEC as General Counsel](#), *Bloomberg*

[FDIC Said to Join OCC in Plan to Curb Payday Loans by U.S. Banks](#), *Bloomberg*

[U.S. Regulators to Warn Against Payday-Style Loans](#), *Wall Street Journal*

[Too-Big-to-Fail Bill Due Today Faces Opposition in U.S. Senate](#), *Bloomberg*

[CBOE Said to Consider Separation of Regulatory Unit From Company](#), *Bloomberg*

4/24/13

[Regulators to rein in on bank payday lending](#), *Washington Post*

[Watchdog: Banks Are Still Too Intertwined](#), *Wall Street Journal*

[TARP Watchdog Says Closely Connected Banks Remain Financial Risk](#), *Bloomberg*

Bloomberg

[Watchdogs Warned of Chemical-Plant Oversight Before Blast](#), *Bloomberg*

Rulemaking

Department of Health and Human Services

HHS Seeks Comments on HIPAA Revisions to Allow Mental Health Checks for Gun Ownership

The Department of Health and Human Services published an [advanced notice of proposed rulemaking](#) announcing that the Department is seeking comments on how to restructure HIPAA privacy requirements to allow some entities access to mental health histories. As part of President Obama's executive actions to reduce gun violence, the National Instant Criminal Background Check System (NICS) will check for individuals who are prohibited from gun ownership during the sale or transfer of firearms by licensed dealers. Going forward, the NICS checks required for gun ownership will include whether individuals are prohibited from owning a gun based on mental health status, which currently could be prohibited by privacy requirements.

"Concerns have been raised that, in certain states, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule may be a barrier to States' reporting the identities of individuals subject to the mental health prohibitor to the NICS. The Department of Health and Human Services (HHS or "the Department"), which administers the HIPAA regulations, is issuing this Advance Notice of Proposed Rulemaking (ANPRM) to solicit public comments on such barriers to reporting and ways in which these barriers can be addressed. In particular, we are considering creating an express permission in the HIPAA rules for reporting the relevant information to the NICS by those HIPAA covered entities responsible for involuntary commitments or the formal adjudications that would subject individuals to the mental health prohibitor, or that are otherwise designated by the States to report to the NICS. In addition, we are soliciting comments on the best methods to disseminate information on relevant



HIPAA policies to State level entities that originate or maintain information that may be reported to NICS. Finally, we are soliciting public input on whether there are ways to mitigate any unintended adverse consequences for individuals seeking needed mental health services that may be caused by creating express regulatory permission to report relevant information to NICS. The Department will use the information it receives to determine how best to address these issues.” [Comments](#) are due on June 7th.

Federal Reserve System

Fed Board Proposes Assessments and Fees for Bank and Loan Holding Companies

The Federal Reserve Board published a [proposed rule](#) establishing assessments and fees for bank holding companies and loan holding companies subject to supervision by the Financial Stability Oversight Council (FSOC). “This proposed rule outlines the Board’s assessment program, including how the Board would: (a) Determine which companies would be subject to an assessment for each calendar-year assessment period, (b) estimate the total expenses that are necessary or appropriate to carry out the supervisory and regulatory responsibilities to be covered by the assessment, (c) determine the assessment for each of these companies, and (d) bill for and collect the assessment from these companies.”

“Under the proposal, each calendar year would be an assessment period. Companies would be covered by this rule if the total consolidated assets for the company meets or exceeds \$50 billion or the company has been designated for Board supervision by the Council during the assessment period. The Board proposes to notify those companies of the amount of their assessment no later than July 15 of the year following each assessment period. After an opportunity for appeal, assessed companies would be required to pay their assessments by September 30 of the year following the assessment period. The Board is proposing to collect assessments beginning with the 2012 assessment period. The Board believes that initiating the assessment program with the 2012 assessment period is appropriate as the Board has completed the development of a framework for the estimation of appropriate expenses and the collection of assessments. Additionally, the 2012 assessment period would be the first full calendar-year assessment period subsequent to the effective date of section 318 of Dodd-Frank.” [Comments](#) are due on June 15th.

Department of Energy

DOE Finalizes \$3 Billion Energy Efficiency Standards for Distribution Transformers

The Department of Energy published a [final rule](#) setting energy efficiency standards for distribution transformers. “The Energy Policy and Conservation Act of 1975 (EPCA), as amended, prescribes energy conservation standards for various consumer products and certain commercial and industrial equipment, including distribution transformers. EPCA also requires the U.S. Department of Energy (DOE) to determine whether more-stringent standards would be technologically feasible and economically justified, and would save a significant amount of energy. In this final rule, DOE is adopting more-stringent energy conservation standards for distribution transformers. It has determined that the amended energy conservation standards for this equipment would result in significant conservation of energy, and are technologically feasible and economically justified.” DOE estimates that this standard will reduce CO₂ emissions by 264.7 million metric tons between the years 2016 and 2045, with incremental installed costs of between \$2.9 billion and \$5.22 billion.

Securities and Exchange Commission

SEC, CFTC Finalize Identity Theft Red Flags Rules

The Securities and Exchange Commission and the Commodity Futures Trading Commission jointly published a [final rule](#) requiring regulated entities to enact programs to address identity theft. “These rules and guidelines implement provisions of the Dodd-Frank Wall Street Reform and Consumer Protection Act, which amended the Fair Credit Reporting Act and directed the Commissions to adopt rules requiring entities that are subject to the Commissions’ respective enforcement authorities to address identity theft. First, the rules require financial institutions and creditors to develop and implement a written identity theft prevention program designed to detect, prevent, and mitigate identity theft in connection with certain existing accounts or the opening of new accounts. The rules include guidelines to assist entities in the formulation and maintenance of programs that would satisfy the requirements of the rules. Second, the rules establish special requirements for any credit and debit card issuers that are subject to the Commissions’ respective enforcement authorities, to assess the validity of notifications of changes of address under certain circumstances.”



Department of Housing and Urban Development

HUD Proposes Rule Streamlining Reporting Requirements for Some Lenders, Mortgagees

The Department of Housing and Urban Development published a [proposed rule](#) streamlining reporting requirements for smaller lenders and mortgagees. “This proposed rule would streamline the [Federal Housing Administration] FHA financial statement reporting requirements for lenders and mortgagees who are supervised by federal banking agencies and whose consolidated assets do not meet the thresholds set by their supervising federal banking agencies for submission of audited financial statements (currently set at \$500 million in consolidated assets). HUD's regulations currently require all supervised lenders and mortgagees to submit annual audited financial statements as a condition of FHA lender approval and recertification. Through this proposed rule, in lieu of the annual audited financial statements, small supervised lenders and mortgagees would be required to submit the unaudited financial regulatory reports that align with their fiscal year ends and are required to be submitted to their supervising federal banking agencies. Small supervised lenders and mortgagees would only be required to submit audited financial statements if HUD determines that the supervised lenders or mortgagees pose heightened risk to the FHA insurance fund.” [Comments](#) are due on June 17th.

Food and Drug Administration

FDA Proposes Rule Allowing Use of Symbols, Images on Medical Device Labels

The Food and Drug Administration published a [proposed rule](#) allowing for the use of certain symbols and images instead of words on medical devices and biological products as a part of FDA's labeling requirements. “The Food and Drug Administration (FDA) is proposing to revise medical device and biological product labeling regulations to explicitly allow for the inclusion of stand-alone graphical representations of information, or symbols, if the symbol has been established as part of a standard developed by a nationally or internationally recognized standards development organization (SDO) (referred to in this document as a “standardized symbol”) and such standardized symbol is part of a standard recognized by FDA for use on the labeling of medical devices (or on a subset of medical devices), provided that such symbol is explained in a symbols glossary that contemporaneously accompanies the medical device. FDA is also proposing to revise prescription device labeling regulations to authorize the use of the symbol statement “Rx only” on the labeling of prescription devices.” [Comments](#) are due on June 18th.

Post Office

Post Office Proposes Rule Requiring Special Handling for Shipments Containing Live Animals

The Post Office published a [proposed rule](#) that would require special handling and fees for shipments containing live animals, with particular standards for bees, amphibians, reptiles, and birds. “The Postal Service consistently accepts, transports, and delivers live animals with additional care in handling, regardless of the mail class or the extra service being purchased. This additional care ensures safe and effective processing for mail containing live animals through the mailstream to its destination. Consequently, the Postal Service incurs additional expense to isolate and protect live shipments even when sent by air transportation, such as with Express Mail[®] or Priority Mail[®]. If this proposal is adopted the Postal Service will require special handling service for all parcels containing bulk shipments of bees (e.g. a queen bee packaged with an attending swarm), day-old poultry and adult birds, regardless of the class of mail used... To assure prompt or expedited delivery and to minimize the chances of animals dying in transit, the Postal Service is also proposing to require shipments containing amphibians and reptiles to be limited to the following products: Express Mail, Priority Mail (excluding Critical Mail[®]), First-Class Mail (parcels only) or First-Class Package Service. If this proposal is adopted, shipments of live amphibians and reptiles would no longer be permitted for use with any Package Services, Standard Post, or Parcel Select[®] products.” [Comments](#) are due on May 24th.

Agencies

Department of State

State Dept. Seeks Expert Reviewers for Kyoto Good Practice Guidance

The State Department published a [notice](#) seeking experts to review the Second Order Draft of the *2013 Revised Supplementary Methods and Good Practice Guidance Arising from the Kyoto Protocol* (the *KP Supplement*). The Intergovernmental Panel on Climate Change (IPCC) is preparing a series of guidance documents for the preparation of national greenhouse gas inventories. The Good Practice Guidance for Land Use, Land-Use Change



and Forestry (GPG-LULUCF) contains estimates of anthropogenic greenhouse gas emissions by sources and removals by sinks resulting from land use, land-use change and forestry. “The need to review and update Chapter 4 of the GPG-LULUCF arises for two reasons. Firstly, the methodologies contained in Chapter 4 provide the link between IPCC's general greenhouse gas inventory guidance, and reporting requirements under the KP. CMP7 agreed rules for LULUCF for the second commitment period under the KP which differ in some respects significantly from the rules agreed for the first commitment period, implying the need to update. Secondly, since Chapter 4 was intended to be used with the latest IPCC LULUCF guidance updating is needed to take account of the decision of the CMP to use the 2006 IPCC Guidelines for the purposes of the second commitment period under the KP. The new rules referred to and agreed by CMP7 on LULUCF contain, amongst other things, new provisions on forest management, emissions and removals associated with natural disturbances in forests, harvested wood products, and wetland drainage and rewetting, which are not covered in the existing Chapter 4.” [Comments](#) are due on May 23rd.

Department of Transportation

FAA Gives Notice of Furlough Implementation

The Federal Aviation Administration published a [notice](#) announcing FAA’s implementation of furloughs pursuant to the across-the-board cuts required by the Budget Control Act of 2011 and the American Taxpayer Relief Act of 2012. “[The Aviation Safety Office] and its Services/Offices will implement the required 11 days of furlough beginning April 21, 2013 and continuing through September 30, 2013. AVS will continue to focus resources on those initiatives that would have the highest safety and economic value for the American public and aviation industry. The furlough days vary, with each office scheduling those days in accordance with mission requirements, workload considerations, and applicable collective bargaining agreements.” More information on FAA’s sequestration actions can be found [here](#).

Federal Communications Commission

FCC Reconsiders Broadcast Indecency Standards for Nudity, Expletives

The Federal Communications Commission published a [notice](#) seeking comment from the public on whether to change its existing broadcast indecency policies or keep them as they are. “For example, should the Commission treat isolated expletives in a manner consistent with its decision in *Pacifica Foundation, Inc.* or instead maintain the approach to isolated expletives set forth in its decision in *Complaints Against Various Broadcast Licensees Regarding Their Airing of the “Golden Globe Awards” Program*? As another example, should the Commission treat isolated (non-sexual) nudity the same as or differently than isolated expletives? Commenters are invited to address these issues as well as any other aspect of the Commission's substantive indecency policies.” [Comments](#) are due on May 20th.

Export-Import Bank

Ex-Im Bank Receives Application for \$100+ Million to Support Boeing Exports to Canada

The Export-Import Bank published a [notice](#) announcing the receipt of an application for a long-term loan or financial guarantee in excess of \$100 million to support the export of commercial Boeing aircraft to Canada. These exports would be used for “Canadian domestic passenger air service and Canadian cross-border passenger air service between Canada and Mexico, the U.S. or the Caribbean.” [Comments](#) are due on May 17th.

