

Regulation Digest Weekly

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Opinion

- U.S. Should Act Unilaterally on Climate Change
- OPM plans to shake up charity program raise concerns about reduced donations
- Financial Rule-Makers Must Learn to Use Their Calculators
- The EPA's Lisa Jackson: The Worst Head of the Worst Regulatory Agency, Ever

Marketplace of Ideas

American Action Forum

- Individual and Small Group Insurance Premiums and the Affordable Care Act: Analytic Results, *Douglas Holtz-Eakin*
- Regulation Review: HHS's January Regulation Push: Regulations Could Cost Small Farms \$13,000 Annually, *Sam Batkins*
- The Week in Regulation: January 21-25, *Sam Batkins*
- When a Recess Appointment Is Not a Recess Appointment, *Dan Goldbeck & Sam Batkins*
- What the Unified Agenda Tells Us About Regulation's Impending Burdens, *Sam Batkins*

American Enterprise Institute

- Personalized regulation: More than just personalized medicine — and urgently required, *David Shaywitz*

Center for Effective Government (Formerly OMB Watch)

- The Obama Administration's Regulatory Agenda: Many Overdue Rules Need to Be Finalized to Fulfill Legislative and Public Safety Promises
- Three Reasons the REINS Act Must Be Stopped (Again)
- Small Businesses, Public Health, and Scientific Integrity: Whose Interests Does the Office of Advocacy at the Small Business Administration Serve?, *Randy Rabinowitz, Katie Greenhaw, & Katie Weatherford*

Feature Story

DOJ Proposes Rule Enhancing the National Instant Criminal Background Check System

The Department of Justice published a [proposed rule](#) to improve the operation of the National Instant Criminal Background Check System (NICS), which was created following the Brady Handgun Violence Prevention Act of 1993 and mandated background checks for any firearm transfer from a federal firearms licensee (FFL) to any unlicensed person. According to the FBI's website, "NICS is used by Federal Firearms Licensees (FFLs) to instantly determine whether a prospective buyer is eligible to buy firearms or explosives. Before ringing up the sale, cashiers call in a check to the FBI or to other designated agencies to ensure that each customer does not have a criminal record or isn't otherwise ineligible to make a purchase. More than 100 million such checks have been made in the last decade, leading to more than 700,000 denials."

The NICS index can be accessed only for purposes related to the Brady Act, excepting 1) in response to an inquiry from the Bureau of Alcohol, Tobacco, Firearms, and Explosives, and 2) for use by Federal, state, or local criminal justice agencies in connection with the issuance of a firearm-related or explosives-related permit or license. The amendments proposed in this rule would "add tribal criminal justice agencies to those entities authorized to receive information in connection with the issuance of a firearm-related permit or license; [a]uthorize access for criminal justice agencies to the FBI-maintained NICS Index to permit background checks for the purpose of disposing of firearms in the possession of those agencies; and... permit NICS to retain in a separate database its Audit Log records relating to denied transactions beyond 10 years, rather than transferring them to a Federal Records Center for storage." [Comments](#) are due on March 29th.

In the News

1/23/13

[Sickening fog smothers Salt Lake City area; doctors call for lower speeds, free mass transit](#), *Washington Post*

[US officials defend their review of Boeing 787 battery mishaps, promise data-driven probe](#), *Washington Post*

[Q&A: FAA approval may need rethink, House aviation leader says](#), *Reuters*

[Critics sweep election at futures-industry regulator](#), *Reuters*

[Former officials tell hedge funds: Be ready for the regulators](#), *Reuters*

[Obama Could Bypass Congress to Fulfill Climate Pledge](#), *Bloomberg*

[FDA Won't Appeal Free-Speech Marketing Decision](#), *Wall Street Journal*

[Vitter: Obama administration hiding the ball on regulatory agenda](#), *The Hill*

[GOP lawmaker pushes bill to reduce federal regulations](#), *The Hill*

1/24/13

[Obama to nominate Mary Jo White as SEC chair](#), *Washington Post*



Center for Progressive Reform

- Distorting the Interests of Small Business: How the Small Business Administration Office of Advocacy's Politicization of Small Business Concerns Undermines Public Health and Safety, *Sidney Shapiro & James Goodwin*

Competitive Enterprise Institute

- REINS Act Introduced in House: CEI Experts Applaud Regulatory Reform That Holds Administration and Congress Accountable, *CEI Staff*

Federal Regulations Advisor

- D.C. Circuit finds "Recess Appointments" Invalid: NLRB Lacked Quorum, *Leland Beck*
- Monday Morning Regulatory Review – 1/28/13, *Leland Beck*

Free State Foundation

- Comments of the Free State Foundation Before the Federal Communications Commission in the Matter of AT&T and NTCA Petitions on Transition from Legacy Transmission Platforms to Services Based on Internet Protocol, *Randolph May*

The George Washington University Regulatory Studies Center

- GAO Report: Agencies Circumvent Public Comment on Major Rules, *Susan Dudley*

Government Accountability Office

- Regulators Have Faced Challenges Finalizing Key Reforms and Unaddressed Areas Pose Potential Risks, *Angela Clowers*
- Expiration of the Health Coverage Tax Credit Will Affect Participants' Costs and Coverage Choices as Health Reform Provisions Are Implemented, *John Dicken*

Heritage Foundation

- Climate Change: How the U.S. Should Lead, *Nicholas Loris & Brett Schaefer*
- CFPB Servicing Rules Are Excessive and Unauthorized, *Diane Katz*

The Mercatus Center

- Why Dodd-Frank Is Pushing the US Towards Impending Financial Crisis, *Hester Peirce*
- Evaluating Risk-Based Capital Regulation, *Thomas Hogan, Neil Meredith, & Xuhoa Pan*

National Bureau of Economic Research

- Bank Regulation and Supervision in 180 Countries from 1999 to 2011, *James Barth, Gerard Caprio, Jr., Ross Levine*

[IRS seeks to lift injunction on tax-preparer regs after losing suit challenging its authority](#), *Washington Post*

[Boeing 787 to stay grounded as U.S. can't find battery flaw](#), *Washington Post*

[US IRS asks judge to let tax return preparer regulation proceed](#), *Reuters*

[SEC Delays Ruling on Nasdaq's Payout Proposal for Facebook IPO](#), *Bloomberg*

[Obama Will Name Former Prosecutor Mary Jo White SEC Chairman](#), *Bloomberg*

[Banks May Face Limits on Risk Calculations, Basel Chief Says](#), *Bloomberg*

[Boeing 787's Grounding Highlights Threat to Innovation](#), *Bloomberg*

[Boeing 787 to Stay Grounded as U.S. Can't Explain Fires](#), *Bloomberg*

[Basel Chief Says Basel III Delays 'Not Critical' This Year](#), *Bloomberg*

[Facebook Friends Fronting Debt Collectors Draw U.S. Regulation](#), *Bloomberg*

[Community banks back latest mortgage lending rules](#), *The Hill*

[GOP tries again to require congressional approval of 'major' regulations](#), *The Hill*

[Federal appeals court denies EPA bid to reopen case on downwind pollution from power plants](#), *Washington Post*

[Boeing 787 battery in fire shows short-circuiting but cause unclear, NTSB chairman says](#), *Washington Post*

[Obama picks former US attorney to head SEC; first prosecutor ever to lead the agency](#), *Washington Post*

[Mary Jo White named as new SEC chairman; ex-prosecutor won convictions of terrorists, mob boss](#), *Washington Post*

[Federal court won't review decision that struck down EPA pollution rule](#), *The Hill*

[Conservative group: New healthcare rules add \\$9B in costs, 10M hours in paperwork](#), *The Hill*

[Cordray Nomination Shows Consumer Bureau Battle Lines Unmoved](#), *Bloomberg*

[Energy Swaps Migrating to Futures on Dodd-Frank Rules](#), *Bloomberg*

[Tough-as-Nails Prosecutor White to Tackle SEC Policy Stalemates](#), *Bloomberg*

[Focus Media Says SEC Probes Possible Securities Violation](#), *Bloomberg*

1/25/13

[CFTC Commissioner Jill Sommers Will Resign After First Quarter](#), *Bloomberg*

[Boehringer's Lung Drug's Benefits Questioned](#), *Bloomberg*

[Court: Obama recess appointments unconstitutional](#), *Washington Times*

[Appeals Court rules Obama recess appointments unconstitutional](#), *Politico*

[Appeals court panel rules Obama recess appointments to labor board are unconstitutional](#), *Washington Post*

[FDA head and company CEOs cheer bumper haul of new drugs](#), *Reuters*

[F.D.A. Panel to Vote on Restricting Drugs Like Vicodin](#), *New York Times*

[Poll: 72 percent of small businesses say regulations are hurting them](#), *The Hill*

[FDA moves to thwart drug-induced liver problems](#), *The Hill*

[Regulator says unavoidable cuts will cripple New England fishing industry, says rules 'failed'](#), *Washington Post*

[For SEC nominee Mary Jo White, a shift in enforcement strategy](#), *Washington Post*

[Appeals court says Obama violated constitution with recess appointments to labor board](#), *Washington Post*

[Mary Jo White, Obama's SEC pick, used to represent Morgan Stanley. Is that a problem?](#), *Washington Post*

[Tougher Limits on Most-Used Pain Pills Backed by Panel](#), *Bloomberg*

[Contagion Thesis Once Derided Proven by Kristin Forbes](#), *Bloomberg*

[EU Regulator: OK for U.S. to Delay Basel Rules](#), *Wall Street Journal*

1/28/13

[News bites: Panel urges FDA to seek tougher restrictions on painkillers](#), *The Hill*

[Washington and business brace for an Obama wave of regulations](#), *The Hill*

[Obama: Executive action necessary](#), *The Hill*

[Study: More than one-third of major regulations begin without public input](#), *The Hill*



National Labor Relations Board

- Statement by Chairman Pearce on recess appointment ruling

Penn Program on Regulation

- Exempting Climate Mitigation from OIRA Review, *David M. Driesen*
- A Prescription for the FDA, *Nicolle Strand*
- The Regulatory Week in Review: January 25, 2013, *RegBlog Staff*
- Improving Drug Safety Regulation after the Meningitis Outbreak, *Cary Coglianese & Theodore Ruger*
- What the Unified Agenda Tells Us About Regulation's Impending Burdens, *Sam Batkins*

Hill

[Drag seen on smokeless-tobacco regulations](#), *The Hill*

[Report: More than half of Dodd-Frank rules still in the works](#), *The Hill*

[“A Rigged Game”: The FTC Calls Fortune Hi-Tech A Pyramid Scheme](#), *Wall Street Journal*

1/29/13

[US investigators ask Boeing for full operating history of lithium-ion batteries in 787s](#), *Washington Post*

[FDA warns Florida company over false, misleading ads for GermBullet cold and flu remedy](#), *Washington Post*

[Reports: Big business using obscure office to kill federal regulations](#), *The Hill*

[Banks Worry CFPB May Be Weakened](#), *Wall Street Journal*

1/30/13

[New England fishermen face grim news as regulators meet to consider steep cuts in catch limits](#), *Washington Post*

[News bites: Regulators increase scrutiny on Boeing 'Dreamliner' battery](#), *The Hill*

[Dems to Obama: Pick EPA chief with 'vision,' use 'available tools' on climate](#), *The Hill*

[Delayed auto pollution rules land at White House for review](#), *The Hill*

Rulemaking

Department of Health and Human Services

HHS Finalizes Omnibus Rule Strengthening HIPAA Privacy Requirements

The Department of Health and Human Services published a [final rule](#) modifying the Health Insurance Portability and Accountability Act (HIPAA) Privacy, Security, and Enforcement Rules. According to the final rule language, these modifications will strengthen the privacy and security protection for individuals' health information, strengthen the privacy protections for genetic information, and otherwise modify HIPAA to improve its effectiveness and decrease the burden on regulated entities. This final rule is an “omnibus” rule, combining elements of four previously proposed rules pertaining to HIPAA requirements. “The total cost of compliance with the rule’s provisions is estimated to be between \$114 million and \$225.4 million in the first year of implementation and approximately \$14.5 million annually thereafter.” Despite this calculation of costs, the Agency was unable to provide quantitative benefits: “We are not able to quantify the benefits of the rule due to lack of data and the impossibility of monetizing the value of individuals' privacy and dignity, which we believe will be enhanced by the strengthened privacy and security protections, expanded individual rights, and improved enforcement enabled by the rule.”

Environmental Protection Agency

EPA Finalizes \$840 Million NESHAPs Rule for Reciprocating Internal Combustion Engines

The Environmental Protection Agency published a [final rule](#) providing amendments to the National Emission Standards for Hazardous Air Pollutants (NESHAPs) for stationary reciprocating internal combustion engines, and New Source Performance Standards (NSPS) for stationary internal combustion engines. “The final amendments include alternative testing options for certain large spark ignition (generally natural gas-fueled) stationary reciprocating internal combustion engines, management practices for a subset of existing spark ignition stationary reciprocating internal combustion engines in sparsely populated areas and alternative monitoring and compliance options for the same engines in populated areas. The EPA is establishing management practices for existing compression ignition engines on offshore vessels. The EPA is also finalizing limits on the hours that stationary emergency engines may be used for emergency demand response and establishing fuel and reporting requirements for certain emergency engines used for emergency demand response.” This rule has a capital cost of \$840 million, with a recurring annual cost of \$490 million.

EPA Denies Petition to Reconsider GHG Standards for Light-Duty Vehicles

The Environmental Protection Agency published a [proposed rule](#) denying a petition by the Pacific Legal Foundation (PLF) to reconsider EPA's 2010 final rules establishing greenhouse gas emissions standards from light duty motor vehicles for model years 2012-2016. Section 307(d)(7)(B) of the Clean Air Act (CAA) requires that



“Only an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review.” Because PLF’s petition for reconsideration did not satisfy the requirements of CAA Section 307(d)(7)(B), EPA is denying the petition.

Presidio Trust

Presidio Trust Proposes Rule Restricting Dog Walking in Presidio of San Francisco

The Presidio Trust, a federal agency entrusted with the preservation of the Presidio of San Francisco as an enduring resource for the American public, published a [proposed rule](#) limiting the permissible activities of commercial dog walkers while in the Presidio of San Francisco. “The limit will require any person walking four or more dogs at one time for consideration in Area B to possess a valid Commercial Dog Walking permit obtained from the City and County of San Francisco (City). Commercial Dog Walkers with four or more dogs at one time in Area B will be required to comply with the terms and conditions of the City permit as well as those rules and regulations otherwise applicable to Area B. The Trust is also proposing that throughout Area B, all pet walkers, whether or not for consideration, shall remove pet excrement and deposit it in refuse containers.” [Comments](#) are due on February 25th.

Consumer Financial Protection Bureau

CFPB Finalizes Ability-to-Repay and Qualified Mortgage Standards (Regulation Z)

The Consumer Financial Protection Bureau published a [final rule](#) amending Regulation Z and implementing the standards required by the Dodd-Frank Act amendments to the Truth in Lending Act (TILA). “The final rule implements sections 1411 and 1412 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act), which generally require creditors to make a reasonable, good faith determination of a consumer’s ability to repay any consumer credit transaction secured by a dwelling (excluding an open-end credit plan, timeshare plan, reverse mortgage, or temporary loan) and establishes certain protections from liability under this requirement for “qualified mortgages.” The final rule also implements section 1414 of the Dodd-Frank Act, which limits prepayment penalties. Finally, the final rule requires creditors to retain evidence of compliance with the rule for three years after a covered loan is consummated.” Publication of this final rule was followed with publication of a CFPB proposed rule amending this final rule, providing exemptions for some non-profits and homeownership stabilization programs.

CFPB Proposes Amendments Exempting some Parties from the Ability to Repay Rule (Regulation Z)

The Consumer Financial Protection Bureau published a [proposed rule](#) amending the final Regulation Z rule, which was [simultaneously published](#) in the Federal Register today and implements the Truth in Lending Act (TILA). This proposed rule would incorporate amendments to TILA that were included in the Dodd-Frank Act: “Among other things, the Dodd-Frank Act requires creditors to make a reasonable, good faith determination of a consumer’s ability to repay any consumer credit transaction secured by a dwelling (excluding an open-end credit plan, timeshare plan, reverse mortgage, or temporary loan) and establishes certain protections from liability under this requirement for “qualified mortgages.” The Bureau is proposing certain amendments to the final rule implementing these requirements, including exemptions for certain nonprofit creditors and certain homeownership stabilization programs and an additional definition of a qualified mortgage for certain loans made and held in portfolio by small creditors. The Bureau is also seeking feedback on whether additional clarification is needed regarding the inclusion of loan originator compensation in the points and fees calculation.” [Comments](#) are due on February 25th.

CFPB Delays Effective Date for Electronic Fund Transfers Rule (Regulation E)

The Consumer Financial Protection Bureau [announced](#) a delay of the February 7th, 2013 effective date of the Bureau’s 2012 Electronic Fund Transfers Rule (Regulation E). Regulation E implemented the Dodd-Frank Act’s amendments to the Electronic Fund Transfers Act (EFTA) “to create a new comprehensive consumer protection regime for remittance transfers sent by consumers in the United States to individuals and businesses in foreign countries.” The amended rule requires cancellation and refund rights, the provision of disclosures prior to and at the time of payment by the sender for the transfer, the investigation and remedy of errors by remittance transfer providers, and liability standards for remittance transfer providers for the acts of their agents. “The Bureau is delaying the effective date of the 2012 Final Rule pending the finalization of a proposal, published on December 31, 2012 (December 2012 Proposal), that would address three narrow issues in the 2012 Final Rule. The Bureau will determine the new effective date when it finalizes the December 2012 Proposal.”



Social Security Administration

SSA Proposes Rule Replacing the Term “Mental Retardation” with “Intellectual Disability”

The Social Security Administration published a [proposed rule](#) that would replace the term “mental retardation” with “intellectual disability” in the SSA’s Listing of Impairments used to evaluate claims for mental disorders in children and adults under titles II and XVI of the Social Security Act. In 2010, Rosa’s Law required some federal agencies to change existing references to “mental retardation” to “intellectual disability.” Rosa’s Law did not apply to titles II and XVI of the Social Security Act; “However, consistent with the concerns expressed by Congress when it enacted Rosa’s Law, and in response to numerous inquiries from advocate organizations, we propose to revise our rules to use the term “intellectual disability” in the name of our current listings and in our other regulations. In so doing, we would join other agencies that have responded to the spirit of the law, even though Rosa’s Law did not require them to change their terminology.” [Comments](#) are due on February 27th.

Agencies

Environmental Protection Agency

EPA Seeks Comment on National Enforcement Initiatives for FY 2014 – 2016

The Environmental Protection Agency [announced](#) that it is seeking public comments and recommendations on the Agency’s national enforcement initiatives for fiscal years 2014 – 2016. “EPA selects these priority areas every three years in order to focus federal resources on the most important environmental problems where noncompliance is a significant contributing factor and where federal enforcement attention can make a difference. For the FY 2011-2013 time period, the U.S. Environmental Protection Agency, Office of Enforcement and Compliance Assurance, has six national enforcement initiatives. These initiatives are (1) Municipal Infrastructure—addressing sewage discharges from combined sewer systems, sanitary sewer systems, and municipal separate storm sewer systems; (2) Mineral Processing—addressing hazardous waste at phosphoric acid facilities and high risk mineral processing sites; (3) New Source Review—controlling emissions from coal fired utility sector, cement plants, glass plants, and acid production plants; (4) Air Toxics—addressing toxic emissions from high risk facilities by examining leak detection and repair (LDAR), flares, and excess emission sources; (5) Energy Extraction—addressing land-based natural gas extraction facilities, including corporate-wide evaluations; and (6) Concentrated Animal Feeding Operations—addressing animal waste discharges from large animal feeding facilities.” EPA is seeking comment on whether to continue these six priorities as national enforcement initiatives, or whether EPA should focus on other sectors or important strategic areas. [Comments](#) are due on February 27th.

Food and Drug Administration

FDA Seeks Comment on Smokeless Tobacco Product Warning Statements

The Food and Drug Administration published a [proposed rule](#) announcing the establishment of a public docket and seeking comment from the public “regarding what changes to the smokeless tobacco product warnings, if any, would promote greater public understanding of the risks associated with the use of smokeless tobacco products.” Currently, smokeless tobacco products are required to include one of four warning statements which inform the user of that the product is addictive or that warn of the risk of mouth cancer, gum disease and tooth loss posed by the product. “We are interested in comments, supported by scientific evidence, regarding what changes, if any, to the smokeless tobacco product warnings would promote greater public understanding of the risks associated with the use of smokeless tobacco products. The “public” includes both tobacco users and nonusers (i.e., never users and former users). Comments and supporting evidence should address how any changes in the warnings would affect both users’ and nonusers’ understanding of the risks associated with the use of smokeless tobacco products.” [Comments](#) are due on April 1st.

FDA Releases Guidance for Industry on Premarket Evaluation & Labeling of Clinical Pharmacogenomics

The Food and Drug Administration published a [notice](#) announcing the availability of a [guidance](#) for industry entitled *Clinical Pharmacogenomics: Premarket Evaluation in Early-Phase Clinical Studies and Recommendations for Labeling*. “This guidance is intended to assist the pharmaceutical industry and other investigators engaged in new drug development in evaluating how variations in the human genome, specifically DNA sequence variants, could affect a drug’s pharmacokinetics (PK), pharmacodynamics (PD), efficacy, or safety. The guidance provides recommendations on when and how genomic principles should be considered and applied in early-phase clinical studies to address questions arising during drug development and regulatory review.” [Comments](#) on this guidance document will be accepted by the Agency at any time.



Export-Import Bank

Ex-Im Bank Receives Application for \$100+ Million to Fund Boeing Exports to Turkey

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 fund the export of commercial Boeing aircraft to Turkey. These exports would be used to facilitate short- and medium-haul passenger air service within Turkey and between Turkey and other countries. [Comments](#) are due on February 19th.

Ex-Im Bank Receives Application for \$225 Million to Fund Export of Equipment to United Arab Emirates

The Export-Import Bank published a [notice](#) announcing the receipt of an application for a direct long-term loan of \$225 million to fund the export of \$173 million in U.S. aluminum manufacturing equipment to the United Arab Emirates. “The U.S. exports will enable the foreign buyer to increase its production capacity of aluminum by about 574,000 metric tons of aluminum per year. Available information indicates that the majority of this new foreign production will be sold in the following markets: Netherlands, Japan, United Arab Emirates, United States, South Korea, and Thailand. The balance of the foreign production will be sold to China, Cyprus, Egypt, France, Germany, Greece, Hungary, Indonesia, Italy, Kenya, Malaysia, Philippines, Poland, Romania, Slovakia, South Africa, Spain, Sri Lanka, Taiwan, Turkey, and United Kingdom.” [Comments](#) are due on February 13th.

