

# Regulation Digest Weekly

December 12<sup>th</sup>, 2012

Vol. 1 No. 39

## Opinion

- The regulatory cliff awaits
- It's Time For the FDIC To Stop Playing "TAG"
- How much can the EPA cut carbon emissions? It depends on the courts
- Regulation Vs. Jobs: Assessing The Employment Impact Of Rules and Regulations

## Marketplace of Ideas

### American Action Forum

- The Week in Regulation: December 3-7, *Sam Batkins*

### American Enterprise Institute

- Today's ruling on commercial speech will rein in FDA's regulatory overreach, *Scott Gottlieb*
- The US Department of Justice's targeting of medical speech and its public health impacts, *Scott Gottlieb*

### Competitive Enterprise Institute

- CEI's Battered Business Bureau: The Week In Regulation, *Ryan Young*

### Consumer Financial Protection Bureau

- Fair Lending Report of the Consumer Financial Protection Bureau
- Consumer Financial Protection Bureau halts alleged nationwide mortgage loan modification scams
- Memorandum of Understanding between the Consumer Financial Protection Bureau and the United States Department of Justice Regarding Fair Lending Coordination

### Department of Health and Human Services Office of the Inspector General

- Compendium of Unimplemented Recommendations, December 2012 Edition

## Feature Story

### FRA Proposes Expanding Exceptions to Positive Train Control Rule

The Federal Railroad Administration published a [proposed rule](#) in response to a petition from the Association of American Railroads (AAR) requesting that the Agency expand the exceptions to existing positive train control requirements. In 2005, FRA promulgated a rule allowing voluntary application of processor-based train control systems, but did not make the standard mandatory because the costs "far outweighed" the benefits. Positive train controls (PTC) are statutorily required for trains carrying certain hazardous materials through the 2008 Rail Safety Improvement Act, which also allows FRA to extend these requirements to other train lines as necessary. Currently, there are exceptions to the implementation of PTC in instances where the regulatory burdens would not yield an actual benefit and for passenger trains or segments over which limited freight railroad operations occur. In response to AAR's petition: "FRA proposes to add a yard movement *de minimis* exception that would authorize movements by unequipped locomotives over PTC-equipped main line track segments for the purpose of switching service or transfer train movements. FRA does not propose to create an additional limited operations exemption, nor does FRA propose to remove oversight from signal system discontinuances or modify the default rules for resolving en route failures of a PTC system."

"The proposed revisions to the existing *de minimis* risk exception under 49 CFR § 236.1005(b)(4)(iii) will allow railroads to avoid installing PTC systems' wayside equipment on affected segments. FRA is unsure of the mileage of wayside that will be affected, in part because the railroads have indicated that they intend to reroute PIH materials traffic from many miles of their systems. FRA analyzed the impact of extending the *de minimis* risk exception to cover an additional 1,000 miles of wayside, as well as two sensitivity cases—one where the mileage affected was higher (1,900 miles) and one where the mileage affected was lower (100 miles). *The estimated savings per mile was \$50,000 per mile.*" [Comments](#) are due on February 11<sup>th</sup>, 2013.

## In the News

12/5/12

- [New net rules would hit digital economy - US diplomat](#), *Reuters*
- [Nasdaq attorney calls on SEC to review proxy rules](#), *Reuters*
- [U.S. House Democrats introduce new meningitis legislation](#), *Reuters*
- [SEC: Investment banker in NC, then NYC passed along inside info on 4 mergers that earned \\$11M](#), *Washington Post*
- [Three top SEC officials to leave agency](#), *Washington Post*
- [Wells Fargo Banker Sued by SEC in Probe of Insider Trading](#), *Bloomberg*
- [FDA Approves 35 Drugs in Fiscal 2012 to Match 2011 Tally](#), *Bloomberg*

12/6/12

- [Investor advocates press SEC to finish "bad actor" rule](#), *Reuters*



## Federal Regulations Advisor

- Monday Morning Regulatory Review – 12/10/12, *Leland Beck*
- Administrative Conference Approves Three New Recommendations, *Leland Beck*

## Federal Trade Commission

- Mobile Apps for Kids: Disclosures Still Not Making the Grade, *FTC Staff Report*

## Food and Drug Administration

- FY 2012 Innovative Drug Approvals: Bringing Life-saving Drugs to Patients Quickly and Efficiently

## Government Accountability Office

- OSHA's Accreditation Process Needs Reexamination, *Revae Moran*

## Penn Program on Regulation

- The Regulatory Week in Review: December 7, 2012, *RegBlog Staff*
- EPA Bars BP from Bidding on Government Contracts, *Lauren-Kelly Devine*
- How Do Industry Insiders View Regulations?, *Mima Mohammed*

## Securities and Exchange Commission

- Response to Questions Posed by Commissioners Aguilar, Paredes, and Gallagher, *Division of Risk, Strategy, and Financial Innovation*

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WASHINGTON, DC  
REGULATORY STUDIES CENTER

[Big Lots CEO Probed by U.S., SEC Over Stock Trades](#), *Bloomberg*

[Feds File Suit Against Nap Nanny Maker After 5 Infant Deaths, 70 Complaints](#), *ABC News*

[Netflix and CEO Reed Hastings face SEC scrutiny about July announcement made on Facebook](#), *Washington Post*

[Netflix says CEO's Facebook post triggered SEC notice](#), *Reuters*

[Dodd-Frank Swap Rules Delayed as Agency Eases Transition](#), *Bloomberg*

[FDA's Two-year Approval Record Marks 15-Year Best, Report Finds](#), *Regulatory Focus*

[Government Report Details FDA's Progress, Failures in Implementing Improvements](#), *Regulatory Focus*

**12/7/12**

[Critic questions whether regulators ensure proper construction, expansion of coal slurry ponds](#), *Washington Post*

[With regulators poised to propose black boxes in all new cars, privacy concerns go unaddressed](#), *Washington Post*

[Netflix CEO Hastings Faces SEC Action Over Facebook Post](#), *Bloomberg*

[SEC Urged to Update Disclosure Rules on Netflix Warning](#), *Bloomberg*

[Groups back EPA, try to join W.Va. farmer lawsuit](#), *Wall Street Journal*

[For Netflix and the SEC, a Facebook Share Should Be Public Enough](#), *All Things D*

[SEC wrestles with Internet age in Netflix case](#), *Reuters*

[CFTC fines Goldman \\$1.5M for failing to supervise ex-trader who hid trade, cost firm \\$118M](#), *Washington Post*

[Following report, SEC board member is more willing to revamp money market fund](#), *Washington Post*

[SEC's Aguilar Open to Proposals for Overhauling U.S. Money Funds](#), *Bloomberg*

**12/8/12**

[USDA to allow more meat, grains in school lunches after administrators, students complain](#), *Washington Post*

[In a quirky corner of the government, analyzing snake-infused liquor and counterfeit smokes](#), *Washington Post*

**12/9/12**

[Lobbyists see powerful opportunities in second term](#), *Washington Post*

[Breathing uneasy: Wood smoke, particulate make winter air dangerous in frigid Alaska city](#), *Washington Post*

[Basel Liquidity Rule May Be Watered Down Amid Crisis](#), *Bloomberg*

**12/10/12**

[Technical Fixes Prompt Suspicion From Dodd-Frank Backers](#), *Bloomberg*

[Pay for Delay, Dodd-Frank, Broker Bonuses: Compliance](#), *Bloomberg*

[Many Apps for Children Fall Short on Disclosure to Parents, Report Says](#), *New York Times*

[FTC looks at mobile apps firms over child privacy concerns](#), *Washington Post*

**12/11/12**

[Small business pessimism should spur regulatory overhaul: Blanche Lincoln](#), *The Hill NY*, 6 other states plan to sue EPA over methane emissions from oil and gas drilling, *Washington Post*

*Washington Post*

[FTC looking at new regulations for targeting children with ads on mobile technology](#), *Washington Post*

*Washington Post*

[U.S. Chamber calls for trade officials to review Volcker rule](#), *Reuters*

[SEC Sues Consultant Who Arranged Chinese Reverse Mergers](#), *Bloomberg*

[Dish Wireless Proposal by FCC Said to Have Votes to Pass](#), *Bloomberg*

[Pakistan Hounding, SEC Sanctions, Basel, ECB: Compliance](#), *Bloomberg*

[Eight Ex-Morgan Keegan Fund Directors Sanctioned by SEC](#), *Bloomberg*

[Money market funds come to their own rescue, SEC report shows](#), *Washington Post*



## Contact Us

www.regulatorystudies.gwu.edu

Twitter: @RegStudies

Email: regulatorystudies@gwu.edu

[JPMorgan Pressed by SEC on Prop Trading Before Whale Loss](#), *Bloomberg*  
12/12/12

[Dish Smartphone Service Wins Approval by U.S. Regulators](#), *Bloomberg*

[U.S. CFTC to Face Critics of Swaps Market Rules](#), *Bloomberg*

[SEC Chief's Exit May Stall Dodd-Frank Rules Including Volcker](#), *Bloomberg*

[Bond Disclosure Before Debt Sales Considered by U.S. Regulators](#), *Bloomberg*

## Rulemaking

### Treasury Department

#### IRS Finalizes Rule Providing Guidance on Taxable Medical Devices through Affordable Care Act

The Internal Revenue Service published a [final rule](#) providing guidance on the taxation of medical devices, a provision required by the Patient Protection and Affordable Care Act. A medical device that is subject to taxation is a device that is listed with FDA as a device under section 510(j) of the Federal Food, Drug Cosmetic Act. The final IRS rule also states that if a device is not listed with the FDA, but the FDA later determines that the device *should have been* listed as a device, the device will be deemed to be subject to taxation through the PPACA. The rule includes a “retail exemption” for medical devices that can be purchased by the general public for individual use, such as eye glasses, contact lenses, and hearing aids, exempting these products from taxation.

### Department of Health and Human Services

#### HHS Proposes 102-Page Rule on PPACA Loss Ratio Program, Risk Adjustment, Risk Corridors

The Department of Health and Human Services published a [proposed rule](#) implementing the Patient Protection and Affordable Care Act by providing parameters related to: “the risk adjustment, reinsurance, and risk corridors programs; cost-sharing reductions; user fees for a Federally-facilitated Exchange; advance payments of the premium tax credit; a Federally-facilitated Small Business Health Option Program; and the medical loss ratio program. The cost-sharing reductions and advanced payments of the premium tax credit, combined with new insurance market reforms, will significantly increase the number of individuals with health insurance coverage, particularly in the individual market. The premium stabilization programs—risk adjustment, reinsurance, and risk corridors—will protect against adverse selection in the newly enrolled population.” The Department is seeking comments on how best to meet the requirements established in the PPACA while maintaining affordable levels for premiums. In addition, HHS is “soliciting comments on the nature and magnitude of these costs and benefits to issuers, and the potential effect of the provisions of this rule on premium rates and financial performance.” [Comments](#) are due on December 31<sup>st</sup>.

#### HHS Final Rule Modifies Opioid Treatment Program Restrictions

The Department of Health and Human Services published a [final rule](#) modifying the existing requirements for patients receiving narcotic medications to treat opiate addiction. “This final rule will modify the way that the narcotic treatment medication buprenorphine will be dispensed by treatment programs to individuals who are dependent on heroin or on certain prescription pain relievers by reducing the requirements for dispensing treatment medications for “take home” use. Currently, patients in treatment must wait one year before treatment programs may dispense a two week supply of medication. These types of requirements impart a burden on patients and may affect their adherence to treatment...This change will increase flexibility in treatment and is justified by the experience to date with buprenorphine addiction treatment products, together with buprenorphine's safety profile.”

### Consumer Product Safety Commission

#### CPSC Rule Requires Child-Proof Packaging for Eye Drops, Nasal Sprays

The Consumer Product Safety Commission published a [final rule](#) requiring manufacturers of products containing imidazoline—such as eye drops and nasal sprays—to sell these products in a child-resistant packaging to prevent their ingestion by children under the age of 5. Imidazoline constricts blood vessels when applied topically, relieving nasal congestion and eye irritation; however, if consumed, the imidazoline could cause central nervous system depression, decreased heart rate, and depressed ventilation in a child. The Commission disagreed with commenters who argued that ingestion of an aerosol would result in a low oral dose of imidazoline that would not pose risks to children under the age of 5. The final rule applies to any products containing more than 0.08 milligrams of imidazoline; nasal sprays and eye drop products can hold around 15 milliliters of fluid,



## Department of Labor

### OSHA Seeks Comment on Proposed Retrospective Review of Construction Safety, Health Standards

The Occupational Safety and Health Administration published a [proposed rule](#), *Standards Improvement Project—Phase IV (SIP-IV)*, implementing President Obama’s Executive Order 13563 on improving regulation and regulatory review. The purpose of this proposed rule is to “improve and streamline OSHA standards by removing or revising requirements that are confusing or outdated, or that duplicate, or are inconsistent with, other standards. The purpose of the regulatory review is to reduce regulatory burden while maintaining or enhancing employees’ safety and health. SIP-IV will focus primarily on OSHA’s construction standards. The purpose of this notice is to invite the public, including employers, employees, and employee representatives involved in the construction industry, to submit recommendations for revisions to existing construction standards, including the rationale for these recommendations.” [Comments](#) are due on February 4<sup>th</sup>, 2013.

## Small Business Administration

### SBA Proposes Rule Expanding “Small Business” Size Standards for Coal and Metal Mining Businesses

The Small Business Administration published a [proposed rule](#) increasing the size threshold for which mining businesses will be considered “small entities” by the Small Business Administration. Previously, Support Activities for Oil and Gas Operations, Support Activities for Coal Mining, Support Activities for Metal Mining, and Support Activities for Nonmetallic Minerals were considered small entities below a \$7 million annual receipts threshold. SBA is proposing new standards of \$35.5 million, \$19 million, and \$19 million respectively, leaving the threshold for Support Activities for Nonmetallic Minerals at \$7 million.

Determination of which businesses are “small businesses” is necessary because the purpose of the Small Business Act is to help small businesses compete in the marketplace, necessitating standards to define which businesses qualify as small businesses. Businesses that will acquire small business status because of this rule will become newly eligible for Federal small business assistance programs, including the SBA’s financial assistance programs, economic injury disaster loans, and Federal procurement programs intended for small businesses. [Comments](#) are due on February 4<sup>th</sup>, 2013.

## Environmental Protection Agency

### EPA Withdraws Direct Final Diesel Sulfur Rule

The Environmental Protection Agency officially [withdrew](#) a [direct final rule](#) that would have “amended requirements under EPA’s diesel sulfur program related to the sulfur content of locomotive and marine diesel fuel produced by transmix processors, and the fuel marker requirements for 500 ppm sulfur locomotive and marine (LM) diesel fuel to allow for solvent yellow 124 marker to transition out of the distribution system. Because EPA received adverse comments on the heating oil definition and transmix amendments, we are withdrawing those portions of the direct final rule. Because EPA did not receive adverse comments with respect to the yellow marker amendments, those amendments will become effective as indicated in the direct final rule.”

## Department of Agriculture

### FSIS Policy Statement Withholds Meat and Poultry Products from Commerce until Test Results are Received

The Food Safety Inspection Service gave [notice](#) that the Agency is altering its procedures for the inspection and approval of meat and poultry products, disallowing meat and poultry products from entering into commerce until all test results have been received indicating that the products have not been adulterated. Previously, Agency practice had been to allow products to enter commerce bearing the mark of FSIS inspection before the results of the adulteration tests had been received. Establishments making the products undergoing FSIS inspection had been asked, but not required, to withhold entering the meat and poultry products into commerce until test results had been received by FSIS.

### FSIS Proposes New Hazard Analysis for Ground Turkey and Chicken Producers

The Food Safety Inspection Service published a [proposed rule](#) instructing establishments that produce not-ready-to-eat (NRTE) comminuted chicken and turkey products to reassess their Hazard Analysis and Critical Control Points (HACCP) plans to address recent salmonella outbreaks. “Because the recent outbreaks discussed above have been directly associated with illness in many unrelated individuals in multiple states, these outbreaks, in the Agency’s view, represent evidence of a material change in the effectiveness of what heretofore had been regarded as necessary and appropriate sanitary conditions required to manufacture safe and wholesome product. As such, the



occurrence of these outbreaks is a change that could affect the hazard analysis or alter the HACCP plans for such products and like products. Therefore, establishments that produce NRTE comminuted turkey or chicken poultry products (including ground, mechanically separated, or hand- or mechanically-deboned poultry that is further chopped, flaked, minced, or otherwise processed to reduce particle size but not battered or breaded) in final form or as an intermediary product must evaluate the information discussed above to determine whether their HACCP plans for these products adequately address biological hazards, particularly Salmonella.” [Comments](#) are due on March 6<sup>th</sup>.

## Agencies

### Export-Import Bank

#### Ex-Im Bank Announces Application for \$100 Million to Fund Boeing Exports to Indonesia

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 Indonesia and/or Malaysia. If funded, these exports would provide short- and medium-haul airline service in Indonesia and Malaysia, and between Indonesia and Malaysia and other countries in Asia. [Comments](#) are due on December 31<sup>st</sup>.

#### Ex-Im Bank Announces Application for \$100 Million to Fund Boeing Exports to the United Arab Emirates

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 the United Arab Emirates. If funded, these exports would be used for long-haul passenger air service between Abu Dhabi and destinations in the Middle East, Africa, Europe, Asia and North America. [Comments](#) are due on January 7<sup>th</sup>, 2013.

