

Regulation Digest Weekly

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- Federal Regulations A Red-Tape Wreck For Manufacturing
- Regulation should be more accountable
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- Mistakes, and meningitis
- The judicial jihad against the regulatory state
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- Compounding pharmacies need FDA oversight
- U.S. coal industry would face decline even without Obama's policies
- Basel III Is Simpler and Stronger
- Fed Should Push to Cut Biggest Banks Down to Size
- Refreshing the Clean Water Act
- Deadly meningitis outbreak was completely avoidable

Marketplace of Ideas

American Action Forum

- Regulation Review: Final Stress Test Rule, *Dan Goldbeck*
- The Week in Regulation: October 8-12, *Sam Batkins*

American Energy Alliance

- The New "Benefits" of Environmental Regulation, *Dan Sutter & Scott Beaulier*

American Enterprise Institute

- Compounding a Crisis, *Scott Gottlieb*
- Hoenig and Haldane are right about Basel III, *Alex Pollock & Bert Ely*

Competitive Enterprise Institute

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

Federal Regulations Advisor

- Monday Morning Regulatory Review – 10/15/12, *Leland Beck*

Feature Story

FDIC Final Rule Allows FDIC to Enforce Subsidiary Contracts for Covered Financial Companies

The Federal Deposit Insurance Corporation promulgated a [final rule](#) allowing the Corporation, when acting as a receiver “for a financial company whose failure would pose a significant risk to the financial stability of the United States (a “covered financial company”), to enforce contracts of subsidiaries or affiliates of the covered financial company despite contract clauses that purport to terminate, accelerate or provide for other remedies based on the insolvency, financial condition or receivership of the covered financial company. As a condition to maintaining these subsidiary or affiliate contracts in full force and effect, the Corporation as receiver must either: Transfer any supporting obligations of the covered financial company that back the obligations of the subsidiary or affiliate under the contract (along with all assets and liabilities that relate to those supporting obligations) to a bridge financial company or qualified third-party transferee by the statutory one-business-day deadline; or provide adequate protection to such contract counterparties.” This regulation is being promulgated because of the belief of the FDIC that the orderly liquidation of covered financial companies requires that the key operations, contracts, and services of the covered financial company continue to operate in FDIC receivership. “The Final Rule makes clear that the effect of this enforcement authority is that no party may exercise any remedy under a contract simply as a result of the appointment of the receiver and the exercise of its orderly liquidation authorities as long as the receiver complies with the statutory requirements.”

In the News

10/10/12

- [Conservative think tank says health law compliance has cost \\$27 billion](#), *The Hill*
- [Pharmacies under scrutiny over US meningitis outbreak](#), *Reuters*
- [JPMorgan's Dimon says annual regulation costs to top \\$1 billion](#), *Reuters*

10/11/12

- [Food Sickens Millions as Company-Paid Checks Find It Safe](#), *Bloomberg*
- [Hatch 'implores' EPA to reduce ethanol production mandate](#), *The Hill*
- [In meningitis scare, charges firm misled U.S. regulators](#), *Reuters*
- [CDC says 14,000 people at meningitis risk amid call for criminal probe](#), *Reuters*
- [Factbox: Obama, Romney positions on energy policy](#), *Reuters*
- [Fed's Tarullo warns on passing the buck on money-fund reforms](#), *Reuters*
- [Wyoming Water Tests in Line With EPA Finding on Fracking](#), *Bloomberg BusinessWeek*
- [FDA Considers Faster Approval Process for Obesity Drugs](#), *Bloomberg BusinessWeek*
- [Officials say they lacked authority over pharmacy involved in meningitis outbreak](#), *Washington Post*



Free State Foundation

- AllVid Regulation Risks Harm to Next-Generation Video Innovation, *Seth Cooper*

The George Washington University Regulatory Studies Center

- EVENT: Enhancing Science and Policy for Chemical Risk Assessments

Government Accountability Office

- Additional Federal Actions Could Help Protect Consumer Privacy, *Mark Goldstein & Gregory Wilshusen*
- Most DOE Cleanup Projects Are Complete, but Project Management Guidance Could Be Strengthened, *Mark Gaffigan*

The Heritage Foundation

- The Affordable Care Act's Rulemaking Process: What the Research Shows, *Diane Calmus*

The Mercatus Center

- In the Post Dodd-Frank Derivatives World, October 12th Matters, *Hester Peirce*
- The Industry-specific Regulatory Constraints Database: A Numerical Database on Industry-specific Regulations for All U.S. Industries and Federal Regulations, 1997-2010, *Omar Ahmad Al-Ubaydli & Patrick McLaughlin*
- A NEW WAY TO QUANTIFY REGULATION: The Industry-specific Regulatory Constraint Database (IRCD), *Patrick McLaughlin*

Penn Program on Regulation

- Penn Conference Dissects the Impact of Regulation on Jobs, *Alisa Melekhina*
- The Regulatory Week in Review: October 12, 2012

Think Progress

- As Meningitis Outbreak Spreads, FDA Implores Congress To Strengthen Safety Regulations, *Tara Culp-Ressler*



THE GEORGE
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[In meningitis scare, charges firm misled U.S. regulators](#), *Reuters*
[FDA Considers Faster Approval Process for Obesity Drugs](#), *Bloomberg Sens. Cardin, Lugar slam oil industry's Dodd-Frank lawsuit*, *The Hill*

10/12/12

[Report: FDA Considering New Approval Paradigm for Socially Beneficial Drugs](#), *Regulatory Focus*

[FDA approves Celgene's Abraxane for lung cancer](#), *Reuters*

[FDA OKs use of Actemra for earlier-stage arthritis treatment](#), *Reuters*

[Restaurant Registration Under FSMA Delayed](#), *Food Safety News*

[Meningitis outbreak triggers calls for tighter FDA regulation; previous attempts fell short](#), *Washington Post*

[Reports: US regulators moving closer to suing Google over alleged abuse of search dominance](#), *Washington Post*

[CFTC grants last-minute relief on CME commodity swaps](#), *Reuters*

10/13/12

[FTC investigators pushing Google antitrust suit, memo says](#), *Washington Post*

[Company linked to meningitis scare besieged as deaths rise](#), *Reuters*

10/14/12

[On The Campaign Trail, Regulations Dominate The Environmental Debate](#), *NPR*

[Coal ash decision stymied in election year](#), *Washington Post*

10/15/12

[Home Loans May Get Shield](#), *Wall Street Journal*

[FDA Identifies Two Additional Compounded Drugs as Potentially Contaminated](#), *Regulatory Focus*

10/16/12

[CFPB Issues Safe Harbor Countries List for Remittance Transfer Providers](#), *RegBlog*

[Regulator says student loan complaints resemble mortgage woes](#), *Reuters*

[Fed's Raskin cites limits of bank self-regulation](#), *Reuters*

[California defends greenhouse gas regulation for fuels](#), *Reuters*

[Insight: How compounding pharmacies rallied patients to fight regulation](#), *Reuters*

[Fed's Raskin: Regulators don't have "gotcha mentality"](#), *Reuters*

[Romney adviser dismisses capping bank size](#), *Reuters*

[Goldman takes less risk, executives strike cautious tone](#), *Reuters*

[Lawmakers ask Department of Justice to investigate Mass. pharmacy linked to meningitis cases](#), *Washington Post*

[Experts say the story behind meningitis outbreak may be one of dirty shoes or high volume](#), *Washington Post*

[Regulators let cable companies encrypt all TV signals to foil moochers](#), *Washington Post*

[FTC declines to join European criticism of Google](#), *Washington Post*

[FDA: More drugs may be linked to meningitis outbreak](#), *Washington Post*

[Fed's Raskin Cites Need for Blend of Self, Government Regulation](#), *Wall Street Journal*

[Charles Schwab: Banks need to reduce risk more aggressively](#), *Fox News*

[Crackdown on Cosmetic Marketing Claims Expands as Avon Sent Warning Letter](#), *Regulatory Focus*

[FDA Releases Guidance Document on Soon-To-Be-Mandatory Device Submission Program](#), *Regulatory Focus*

[Regulators Scramble to Contain Compounding Crisis as Industry Scrutinized](#), *Regulatory Focus*

[Suit says California hasn't looked at fracking's risks](#), *Washington Times*

[New call for probe of meningitis-linked company on addictive drugs](#), *Reuters*



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[Discussion of Securities Market "Kill Switch" Dominates SEC Roundtable, RegBlog](#)

[Amid drilling boom, U.S. states rush to update laws: Kemp, Reuters](#)

[FDA's Power to Prosecute, Food Safety News](#)

[Republicans press HHS on malpractice reform, The Hill](#)

Rulemaking

Environmental Protection Agency

EPA Finalizes \$60 Billion Greenhouse Gas CAFE Standards for Light-Duty Vehicles

The Environmental Protection Agency published a [final rule](#) establishing Corporate Average Fuel Economy Standards (CAFE Standards) for light-duty vehicles model year 2017 and later. "These standards apply to passenger cars, light-duty trucks, and medium-duty passenger vehicles, and represent the continuation of a harmonized and consistent National Program. Under the National Program automobile manufacturers will be able to continue building a single light-duty national fleet that satisfies all requirements under both programs while ensuring that consumers still have a full range of vehicle choices that are available today... The National Program is estimated to save approximately 4 billion barrels of oil and to reduce GHG emissions by the equivalent of approximately 2 billion metric tons over the lifetimes of those light duty vehicles produced in MYs 2017-2025. The agencies project that fuel savings will far outweigh higher vehicle costs, and that the net benefits to society of the MYs 2017-2025 National Program will be in the range of \$326 billion to \$451 billion (7 and 3 percent discount rates, respectively) over the lifetimes of those light duty vehicles sold in MYs 2017-2025.

The National Program is projected to provide significant savings for consumers due to reduced fuel use. Although the agencies estimate that technologies used to meet the standards will add, on average, about \$1,800 to the cost of a new light duty vehicle in MY 2025, consumers who drive their MY 2025 vehicle for its entire lifetime will save, on average, \$5,700 to \$7,400 (7 and 3 percent discount rates, respectively) in fuel, for a net lifetime savings of \$3,400 to \$5,000. This estimate assumes gasoline prices of \$3.87 per gallon in 2025 with small increases most years throughout the vehicle's lifetime."

Federal Trade Commission

FTC Finalizes Guidance for Industry on the Use of Environmental Marketing Claims

The Federal Trade Commission [announced](#) the release of a [final guide](#) for industry on the use of environmental claims in marketing materials. The Guide, first made by the FTC in 1998, is being updated to add Carbon Offsets, Certifications and Seals of Approval, Free-of, Non-toxic, Made with Renewable Energy, and Made with Renewable Materials to the "environmental marketing claims" covered in this Guide. Because this is simply an industry guide, FTC reminds readers that the guide is an administrative interpretation of the law, and is not independently enforceable. "The final Guides caution marketers not to make unqualified general environmental benefit claims because "it is highly unlikely that marketers can substantiate all reasonable interpretations of these claims." The claims to which FTC is referring occur not only in the marketing text itself, but also in the images accompanying the text and how such text and images are perceived by consumers. "The Guides further provide that marketers may be able to qualify general environmental benefit claims to focus consumers on the specific environmental benefits that they can substantiate. In doing so, marketers should use clear and prominent qualifying language to convey that a general environmental claim refers only to a specific and limited environmental benefit(s). In addition, this section cautions marketers that explanations of specific attributes, even when true and substantiated, will not adequately qualify general environmental marketing claims if an advertisement's context implies other deceptive claims. Moreover, the Guides advise marketers not to imply that any specific benefit is significant if it is, in fact, negligible. Finally, the Guides state that if a qualified general claim conveys that a product is more environmentally beneficial overall because of the particular touted benefit, marketers should analyze trade-offs resulting from the benefit to substantiate this claim."

Federal Deposit Insurance Corporation

FDIC Provides Initial Reg Flex Analysis for Risk-Weighted Assets Standardized Approach Capital Rules

The Federal Deposit Insurance Corporation [published](#) the initial regulatory flexibility analysis for a proposed FDIC rule that "would revise and harmonize the agencies' rules for calculating risk-weighted assets to enhance risk-



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sensitivity and address weaknesses identified over recent years, including by incorporating certain international capital standards of the Basel Committee on Banking Supervision...the agencies are proposing to revise their capital requirements to promote safe and sound banking practices, implement Basel II (as later revised), and harmonize capital requirements across charter type. The [proposed rule] also proposes alternatives to the use of credit ratings consistent with section 939A of the Dodd-Frank Act by revising regulatory capital requirements to remove all references to, and requirements of reliance on, credit ratings. Federal law authorizes each of the agencies to prescribe capital standards for the banking organizations it regulates.” FDIC estimates that for the small entities affected by this rule, the average burden will be an initial \$39,000 and after that an annual \$17,500 in lost tax benefits. [Comments](#) are due on November 16th.

Department of the Treasury

OCC Proposes Rule Amending Dodd-Frank Capital Requirements for Retail Foreign Exchange Transactions

The Office of the Comptroller of the Currency issued a [proposed rule](#) to amend its retail foreign exchange rule (retail “forex” rule) for transactions with bank common trust funds, bank collective investment funds, and insurance company separate accounts. Dodd-Frank requires that no U.S. financial institutions for which there are Federal regulatory agencies may enter into a transaction described in section 2(c)(2)(B)(i)(I) of the Commodity Exchange Act (CEA) with a person who is not an eligible contract participant (ECP). These transactions include foreign currency futures, options on foreign currency futures, and options on foreign currency. Retail forex rules “must treat similarly all such futures and options and all agreements, contracts, or transactions that are functionally or economically similar to such futures and options. Retail forex rules must prescribe appropriate requirements with respect to disclosure, recordkeeping, capital and margin, reporting, business conduct, documentation, and such other standards or requirements as the Federal regulatory agency determines to be necessary.”

OCC is amending the retail forex rule it finalized in July of last year. “First, the OCC proposes to clarify the capital requirements applicable to Federal branches and agencies of foreign banks that offer or enter into retail forex transactions. The current retail forex rule requires these Federal branches and agencies to be *well capitalized*,” [defined](#) as having “a total risk-based capital ratio of 10.0 percent or greater; [a] Tier 1 risk-based capital ratio of 6.0 percent or greater; and [a] leverage ratio of 5.0 percent or greater.” The OCC is proposing to amend the capital requirements so that all Federal branches and agencies entering into retail forex transactions must instead satisfy the requirements of [12 CFR 4.7\(b\)\(iii\)\(A\) and \(iv\)](#): “The foreign bank's most recently reported capital adequacy position consists of, or is equivalent to, Tier 1 and total risk-based capital ratios of at least 6 percent and 10 percent, respectively, on a consolidated basis... [The foreign bank is] not subject to a formal enforcement action or order by the Federal Reserve Board, the Federal Deposit Insurance Corporation, or the OCC.”

The OCC also proposed to “clarify that instruments that Congress or the CFTC have excluded from regulation under the CEA are not retail forex transactions. Because these instruments are excluded from regulation under the CEA, section 2(c)(2)(E) of the CEA, which prohibits retail forex transactions except under a retail forex rule, does not apply to them. Because this amendment refers to transactions that are already excluded from regulation under the CEA, it would simply clarify how the OCC's retail forex rule interacts with established law.” [Comments](#) are due by November 13th.

Federal Reserve System

Fed Board Finalizes Annual Stress Test Requirements for Banks Bigger than \$10 Billion

The Federal Reserve System Board promulgated a [final rule](#) implementing the Dodd-Frank requirement that the Board “issue regulations that: (i) Define the term “stress test”; (ii) establish methodologies for the conduct of the company-run stress tests that provide for at least three different sets of conditions, including baseline, adverse, and severely adverse conditions; (iii) establish the form and content of the report that companies subject to the regulation must submit to the Board; and (iv) require companies to publish a summary of the results of the required stress tests.” The proposed rule, which the Board is finalizing, requires “each bank holding company, state member bank, and savings and loan holding company with more than \$10 billion in total consolidated assets to conduct an annual company-run stress test using data as of September 30 of each year and the three scenarios provided by the Board. In addition, each state member bank, bank holding company, and savings and loan holding company would be required to disclose a summary of the results of its company-run stress tests within 90 days of submitting the results to the Board.”



Fed Board Finalizes Supervisory and Company-Run Stress Test Requirements for Banks Bigger than \$50 Bil.

The Federal Reserve System Board promulgated a [final rule](#) implementing the Dodd-Frank requirement that the Board require annual stress tests of bank holding companies with total consolidated assets of \$50 billion or more. “The Board has long held the view that a banking organization, such as a bank holding company or insured depository institution, should operate with capital levels well above its minimum regulatory capital ratios and commensurate with its risk profile. A banking organization should also have internal processes for assessing its capital adequacy that reflect a full understanding of its risks and ensure that it holds capital commensurate with those risks. Moreover, a banking organization that is subject to the Board's advanced approaches risk-based capital requirements must satisfy specific requirements relating to their internal capital adequacy processes in order to use the advanced approaches to calculate its minimum risk-based capital requirements. Stress testing is one tool that helps both bank supervisors and a banking organization measure the sufficiency of capital available to support the banking organization's operations throughout periods of stress. The Board and the other federal banking agencies previously have highlighted the use of stress testing as a means to better understand the range of a banking organization's potential risk exposures... Together, the supervisory stress tests and the company-run stress tests are intended to provide supervisors with forward-looking information to help identify downside risks and the potential effect of adverse conditions on capital adequacy at covered companies. The stress tests will estimate the covered company's net income and other factors affecting capital and how each covered company's capital resources would be affected under the scenarios and will produce pro forma projections of capital levels and regulatory capital ratios in each quarter of the planning horizon, under each scenario. The publication of summary results from these stress tests will enhance public information about covered companies' financial condition and the ability of those companies to absorb losses as a result of adverse economic and financial conditions.”

Agencies

Environmental Protection Agency

SAB Seeks Expert Nominations for Clean Air Scientific Advisory Committee NAAQS NO_x Review Panel

The Environmental Protection Agency's Science Advisory Board (SAB) is [seeking](#) nominations of technical experts to staff the Clean Air Scientific Advisory Committee (CASAC) ad hoc panel on National Ambient Air Quality Standards for nitrous oxides. “CASAC provides advice, information and recommendations on the scientific and technical aspects of air quality criteria and National Ambient Air Quality Standards (NAAQS) under sections 108 and 109 of the [Clean Air] Act... The SAB Staff Office is seeking nominations of nationally and internationally recognized scientists in the science of air pollution related to nitrogen oxides. Experts are sought in atmospheric science, human exposure, dosimetry, toxicology, epidemiology, medicine, public health, biostatistics and risk assessment.” [Nominations](#) are due on November 7th.

EPA Seeks Nomination of Scientific Experts for Pentachlorophenol Carcinogen Report

The Environmental Protection Agency is [seeking](#) nominations of scientific experts to act as speakers for an upcoming meeting on the evaluation of human epidemiologic studies on exposure to pentachlorophenol and cancer risk. This meeting will help to inform the development of a monograph on pentachlorophenol for the National Toxicology Program Report on Carcinogens (RoC). “To inform development of that monograph, the Office of the RoC (ORoC) will hold a web-based meeting to obtain information related to evaluating human epidemiologic studies on exposure to pentachlorophenol and cancer risk and invites the nomination of speakers. Nominees should have expertise in cancer epidemiology and knowledge of studies related to exposure to pentachlorophenol.” [Nominations](#) are due December 3rd.

Food and Drug Administration

FDA Announces Public Meeting of the Risk Communication Advisory Committee

The Food and Drug Administration [published notice](#) of a public meeting on November 2nd from 8:00am – 3:00pm to discuss “general factors in risk communication about FDA regulated products, including approaches to avoid message fatigue and related communication barriers such as prevention or warning fatigue or inaccurate risk perception... Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 25, 2012.”



Export-Import Bank

Ex-Im Bank Receives Application for \$100 Million to Fund Boeing Aircraft Exports to Russia

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 Boeing aircrafts to Russia. These aircraft will be used to provide passenger service between Russia and other countries. [Comments](#) are due November 6th.

Ex-Im Bank Receives Application for \$100 Million to Fund Gasification Plant Exports to India

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 U.S. services and equipment for the construction of a gasification plant and the improvement of petrochemical manufacturing in India. Among the equipment intended for export are gas turbines, compressors, centrifuges, technology licenses, and engineering services. [Comments](#) are due on November 5th.

Ex-Im Bank Receives Application for \$100 Million to Fund Satellite Exports to Hong Kong

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 a U.S.-manufactured satellite, ground equipment, and associated services to Hong Kong. These exports will be used to provide video and data communication services. [Comments](#) are due on November 5th.

Ex-Im Bank Receives Application for \$100 Million to Fund Boeing Satellite Export to Hong Kong

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 Boeing satellites, ground equipment, and launch services to Hong Kong to be used for the provision of video and data communication services. [Comments](#) are due on November 5th.

