

# Regulation Digest Weekly

July 11<sup>th</sup>, 2012

Vol 1. No 18

## Opinion

- The Wise Way to Regulate Gas Drilling
- Barclays Bank Bash
- The Invisible Tsunami
- Banks Prove That They Are Not Too Big To Fail By Saying “We Can Fail” On A Piece Of Paper, Moving On
- What price clean air?
- What Happens in Real Bureaucracies
- Blame Barclays, not capitalism
- Better Regulations, Not Fancy Kitchen Tools, Are the Key to Food Safety

## Marketplace of Ideas

### American Action Forum

- The Week in Regulation: July 2-6, *Sam Batkins*
- Regulation Review: FDA Unique Device ID System, *Dan Goldbeck*

### Center for Progressive Reform

- Environmental Justice and Chemical Security: Why EPA Should Use the General Duty Clause to Protect Vulnerable Communities, *Nicholas Vidargas*

### Competitive Enterprise Institute

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

### The George Washington University Regulatory Studies Center

- Testimony Before the Social Security Subcommittee of the House Ways and Means Committee, *Richard Pierce*

### Government Accountability Office

- Securities Regulation: Factors That May Affect Trends in Regulation A Offerings, *Angela Clowers*

### The Hudson Institute

- The Regulatory State, *Chris DeMuth*

## Feature Story

### FDIC Cautions Banks Against Passing Deposit Insurance Assessment Fees on to Customers

The Federal Deposit Insurance Corporation published a [letter of caution](#) to all FDIC-insured deposit institutions (IDIs), regardless of total asset size, warning against passing deposit insurance fees on to banking customers and expressing expectations for IDIs when calculating and implementing these fees on customers. “The FDIC has become aware that certain IDIs are charging customers an “FDIC fee” or similarly described fee, apparently to compensate the IDI for some or all of its FDIC deposit insurance assessment costs. In some cases, IDIs have advised customers to contact the FDIC if they have questions about these fees. In the past, the FDIC has advised IDIs in published advisory opinions that the FDIC does not preclude them from passing deposit insurance costs to depositors with notice that the cost is for that purpose, as long as the cost is calculated accurately and the charge does not exceed the actual cost of insurance for a customer’s deposits. These advisory opinions pre-date risk-based pricing and are obsolete; they are withdrawn and superseded by this [letter].”

FDIC reverses its previous position, and now requires that IDIs not identify these fees as “deposit insurance fees,” “FDIC fees,” or other similar descriptions which refer to the role of the FDIC; additionally, FDIC is asking that customers not be referred by IDIs to the FDIC for an explanation of fees to recoup mandatory deposit insurance costs.

## In the News

7/3/12

[US Regulators Approve First Over-the-counter HIV Test Kit](#), *Regulatory Focus*

[Small bankers fear Dodd-Frank rules](#), *Marketplace Business*

[FDA Issues New Draft Guidance for Products Containing Acetaminophen](#), *Regulatory Focus*

[For-Profit Colleges Score a Victory](#), *Wall Street Journal*

7/5/12

[Delay Seen \(Again\) For New Rules on Accounting](#), *Wall Street Journal*

[No apologies from outgoing Nuclear Regulatory Commission chairman](#), *The Hill*

[Big Board's New Dark-Pool Ammo: Sub-Penny Quotes](#), *Wall Street Journal*

[Nitrogen Pollution Changing Rocky Mountain National Park Vegetation](#), *Science Daily*

[J.P. Morgan Pressed on Withheld Email in FERC Probe](#), *Wall Street Journal*

[Why So Few Sought Foreclosure Redress: It Was Too Complicated, Watchdog Says](#), *Wall Street Journal*

## Journal of Environmental Management

- Nitrogen critical loads for alpine vegetation and soils in Rocky Mountain National Park, *William D. Bowman, John Murgel, Tamara Blett, & Ellen Porter*

## The Mercatus Center

- Overriding Consumer Preferences with Energy Regulations, *Kip Viscusi & Ted Gayer*
- To Regulate or to Tax, *Matt Mitchell*
- THE PATHOLOGY OF PRIVILEGE: The Economic Consequences of Government Favoritism, *Matt Mitchell*

## National Taxpayers Union

- The Left, the Right, and the Debate over Regulation, *Manzanita McMahon*

## OMB Watch

- The Land of the Free and the Home of Overdue Food Safety Rules, *Jessica Randall*
- The Right to Know, the Responsibility to Protect: State Actions Are Inadequate to Ensure Effective Disclosure of the Chemicals Used in Natural Gas Fracking, *Sean Moulton & Sofia Plagakis*
- Searching for a Regulatory "Tsunami" in Calm Seas, *July 10*

## Penn Program on Regulation

- The Regulatory Week in Review: July 6, 2012, *Mima Mohammed*
- James Q. Wilson: An Appreciation, *Robert Katzmann*

## Contact Us

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[US Regulators Reclassify Pacemaker Electrodes as Higher-Risk Devices](#), *Regulatory Focus*

[FDA Releases Draft Guidance Changing Blood Donation Criteria](#), *Regulatory Focus*

[Regulators seize bank in Georgia, bringing the number of US bank failures this year to 32](#), *Washington Post*

[FDA: Stop Manufacturing Unapproved Oxycodone Products](#), *Regulatory Focus*

[Pharmaceutical Manufacturer Sues FDA Over Use of Enforcement Discretion](#), *Regulatory Focus*

[DEA to Increase Supply of ADHD, Opioid Ingredients in Light of Shortages](#), *Regulatory Focus*

7/9/12

[SEC Approves Rules and Interpretations on Key Terms for Regulating Derivatives](#), *SEC Press Room*

[This at-Home HIV Test Looks Simple, but Is It Accurate?](#), *The Atlantic*

[SEC finalizes derivative definition rules](#), *Chicago Tribune*

[FDA Wants Industry Input on New Drug Review Process](#), *Regulatory Focus*

[Daily Environment Report: The Week Ahead for July 9](#), *Bloomberg BNA*

[OVERNIGHT ENERGY: Federal officials to defend EPA air rules](#), *The Hill*

[As Mine Protections Fail, Black Lung Cases Surge](#) (Part I), *NPR*

7/10/12

[Black-Lung Rule Loopholes Leave Miners Vulnerable](#) (Part II), *NPR*

[Almost age 2, Dodd-Frank is still learning to crawl](#), *Politico*

[Regulators' vote to define swaps will bring reforms to risky market](#),

*Washington Post*

[Park Service loses ground on Canyon air noise](#), *Politico*

[U.S. regulator finally defines a swap, starts reform countdown](#), *Chicago Tribune*

[Lawsuit: FDA Tissue Donation Regulations 'Unconstitutional'](#), *Regulatory Focus*

[US regulators list financial transactions that would be subject to new derivative rules](#), *Washington Post*

[Feds send message by fining Google](#), *Politico*

[Google would pay record FTC fine under tentative Apple Safari settlement](#), *Washington Post*

[Proposed Legislation Would Require FDA to Develop Guidelines to Ensure Scientific Quality](#), *Regulatory Focus*

[NTSB blames Enbridge, 'weak' regulations in Kalamazoo oil spill](#), *Washington Post*

[Panel hears testimony on regulations requiring best available technology for septic systems](#), *Washington Post*

[In New Rules to Shine Light on Derivatives, Regulators Also Allow Exemptions](#), *DealBook*

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[Bipartisan group of senators calls for tough action on flame retardants](#), *Chicago Tribune*

[Swaps Regulation Still Fuzzy After CFTC Vote](#), *Wall Street Journal*

[The Morning Ledger: Trading Scandal Heaps Pressure on Regulators](#), *Wall Street Journal*

## Rulemaking

### Food and Drug Administration

#### FDA Proposes \$588 Million Rule Requiring Medical Device ID Systems

The Food and Drug Administration published a [proposed rule](#) establishing a “unique device identification system for medical devices” in order to implement a new requirement to the Federal Food, Drug, and Cosmetic Act. Requiring a unique device identifier (UDI) on medical devices and packages seeks to simplify data systems, provide rapid identification in an urgent event, and allow for easier recall of faulty devices. A UDI would not be required in situations where devices are low-risk or sold over the counter. The FDA would be responsible for tracking UDIs and making a database available to the public. The majority of costs of this regulation will be incurred by labelers who include “manufacturers, reproprocessors, specification developers, repackagers and relabelers” at \$499.4 -571.5 million over ten years. Large one-time costs would be necessary to integrate UDI into information systems, install, and train employees. Costs to the FDA over 10 years to maintain the program are \$13.7-16.1 million over ten years. [Comments](#) on this proposed rule are due on November 17<sup>th</sup>, 2012.

### Department of Commerce

#### NOAA Proposes Rule Expands Shark Conservation to Waters Outside National Jurisdiction

The National Oceanic and Atmospheric Administration issued a [proposed rule](#) establishing the procedures required by the Shark Conservation Act to promote shark conservation in water outside of U.S. jurisdiction. This rule would also change the definition of *illegal, unreported, or unregulated fishing* to be more consistent with the Moratorium Protection Act. The new definition would include fishing activity that threatens conservation from nations that are non-parties to an international fishery management agreement and fishing activity by foreign vessels in United States water without permission from the United States. [Comments](#) are due on August 9<sup>th</sup>.

### Department of Health and Human Services

#### CMS Proposes Rule Increasing Payment Rates for Dialysis Treatments

The Centers for Medicare & Medicaid Services (CMS) issued a [proposed rule](#) that would update the End-Stage Renal Disease (ESRD) payment system by increasing the payment rates for dialysis facilities starting in January 2013. The CMS estimates that payment rates for dialysis treatment will increase by 2.5 percent. The rule also proposes changes to the ESRD Quality Incentive Program (QIP), which aims to improve patient care by establishing incentives for dialysis facilities to meet CMS performance standards. Under this program, facilities that do not meet a percentage of the performance standards would receive reduced payment rates. The rule would also implement a reduction in bad debt reimbursement to all Medicare providers, which is estimated to save \$10.9 billion over ten years. [Comments](#) are due on August 31<sup>st</sup>.

## Agencies

### Food and Drug Administration

#### FDA Releases Draft Guidance for Industry to Reduce Malaria Spread Through Blood Donations

The Federal Drug Administration issued a nonbinding draft [guidance](#) document for industry recommending steps concerning blood donor questioning and deferral to prevent the risk of transmitted malaria. These recommendations apply to “Whole Blood and all blood components with the exception of Source Plasma” and, once finalized, will supersede the FDA memorandum issued July 26, 1994. These recommendations update definitions of terms like *residence, malaria-endemic, and travel* to standardize potential blood donor interviews. These recommendations also include specific timelines of deferrals given different situations. More suggestions are given on quarantining blood from donors that should have been deferred and the appropriate labeling for such blood so it may be used for research. The “FDA will continue to monitor the situation of malaria transmission in Mexico” as studies by two blood donor organizations have shown that 41 percent of blood donors deferred were people who had traveled malaria-endemic places in Mexico. [Comments](#) can be made on this draft guidance document until September 4, 2012.

## **Environmental Protection Agency**

### **EPA Guidance Document Sets Air Quality Monitoring Standards for “Exceptional Events”**

The Environmental Protection Agency has issued a [guidance](#) document concerning monitoring air quality explaining requirements about reporting data influenced by exceptional events. These events are situations where obtaining air quality data is difficult because of four crucial components: “(1) not reasonably controllable or preventable (2) if the event was caused by human activity, that human activity is unlikely to recur at a particular location (3) clear causal relationship between specific event and monitored concentration and (4) no exceedance or violation but for the event” among two other minor qualities. These requirements are in-line with the “Treatment of Data Influenced by Exceptional Events Final Rule” which was promulgated on March 22, 2007. Demonstration packages are submitted by air agencies concerning these data problems, and the EPA clarifies the timing and review of these packages in an attempt to put a lesser burden and reduce the amount of resources required to submit this information. The document contains frequently asked questions and an excerpt on High Winds guidance. Although the guidance is still available for comment and EPA is open to suggestions, the air quality requirements therein are effective immediately. Final [comments](#) can be made until September 4, 2012.

## **Internal Revenue Service**

### **IRS Announces Open Meeting of Taxpayer Advocacy Panel**

The Internal Revenue Service [announced](#) a public open meeting of the Taxpayer Burden Reduction Project Committee of the Taxpayer Advocacy Panel on Wednesday, August 15<sup>th</sup>. “The Taxpayer Advocacy Panel is soliciting public comments, ideas and suggestions on improving customer service at the Internal Revenue Service.” Members of the public are invited to either submit written comments for consideration or to make oral statements at the public meeting on improving IRS customer service.

## **Export-Import Bank**

### **Ex-Im Receives Application for \$694 Million Guarantee for Exports to Germany**

The Export-Import Bank [published notice](#) in the Federal Register of receipt of a petition for a long-term \$694 million guarantee supporting \$612 million in semiconductor manufacturing equipment exports to Germany. The U.S. exports would be directed to a dedicated foundry, enabling the foundry to “increase existing 300mm (non-DRAM) production capacity of logic semiconductors by approximately 34,000 wafers per month.” Existing information also indicates that semiconductors made possible by this long-term guarantee would be consumed globally.

## **Department of Transportation**

### **NHTSA Seeks Input on Vehicle Lighting Technical Report**

The National Highway Traffic Safety Administration is [seeking comments](#) on a technical report that examines methods of regulating motor vehicle lighting performance. The NHTSA is searching for new approaches to meet the standards set forth in the Federal Motor Vehicle Safety Standard No. 108, *Lamps, reflective devices, and associated equipment*, which exists “to reduce crashes and injuries by increasing the conspicuity of motor vehicles and adequately illuminating the roadway.” [Comments](#) are due on September 10, 2012.