

Regulation Digest Weekly

June 20th, 2012

Vol 1. No 15

Opinion

- Is Obama the pro-regulation candidate? Not exactly
- Incoming Regulator Promises No More Coddling of Banks
- The FDA Chomps Down on Cigars
- FDA Approvals Are a Matter of Life and Death
- Banking's Tangled Web

Marketplace of Ideas

American Action Forum

- What Does an Hour of Regulatory Compliance Cost?, *Sam Batkins*
- Regulation Review: Revised Soot Standards, *Sam Batkins*

Committee on Oversight and Government Reform

- FDA's Contribution to the Drug Shortage Crisis, *U.S. House of Representatives Staff Report*

Competitive Enterprise Institute

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

The George Washington University Regulatory Studies Center

- New Dishwasher Standards Will Save Water, Electricity...But Money?, *KEYE-TV, Austin TX*

The Mercatus Center

- STATE REGULATORY REVIEW: A 50 State Analysis of Effectiveness, *Russ Sobel & John Dove*

- Video Marketplace Deregulation: The Battle Over Spectrum Policy & Retransmission Consent Reform, *Adam Thierer*

OMB Watch

- Farming Out the Story on EPA Regulations, *Jessica Randall*

Penn Program on Regulation

- The Regulatory Week in Review: June 15, 2012, *Mima Mohammed*
- Understanding the Regulatory Process, *John Cooney*
- Working with Regulatory Agencies, *John Cooney*
- What is it Like to be a Regulatory Practitioner?, *John Cooney*

Feature Story

Office of the Comptroller of the Currency Announces Interim Final Rule Broadening Application of Lending Limits

The Office of the Comptroller of the Currency [announced](#) the pending publication of an [interim final rule](#) revising the statutory definition of loans and extensions of credit for purposes of the lending limit, which would subject new financial products to preexisting lending limits. Current regulations provide that “the total loans and extensions of credit by a national bank to a person outstanding at one time shall not exceed 15 percent of the unimpaired capital and unimpaired surplus of the bank if the loan is not fully secured, plus an additional 10 percent of unimpaired capital and unimpaired surplus if the loan is fully secured.” Pursuant to the Dodd-Frank Act, the OCC final rule revises the existing definition of loans and extensions of credit to include: “any credit exposure to a person arising from a derivative transaction, repurchase agreement, reverse repurchase agreement, securities lending transaction, or securities borrowing transaction between a national bank and that person.” This expanded definition will restrict the ability of banks to make loans and extend credit.

“The revised lending limit rule continues to provide that loans and extensions of credit, including those that arise from derivative and securities financing transactions, must be consistent with safe and sound banking practices.” The new applications of this lending limit extend to national banks and state savings associations, per section 312 of the Dodd-Frank Act. The rule, which will be open for comment until August 6, is effective July 21.

In the News

6/13/12

[U.S. House members visit Hannibal, hear about business concerns](#), *Quincy Herald-Whig*

[Jamie Dimon on How He Would Regulate the World](#), *Wall Street Journal*
[Geithner: J.P. Morgan's 'Pretty Significant Failure' Makes Case for Regulation](#), *Wall Street Journal*

6/14/12

[Congressional Hearing Highlights EPA Oversight of Hydraulic Fracturing](#), *RegBlog*

[Pressured, E.P.A. Proposes Soot Limit](#), *New York Times Green Blog*
[Panel Endorses Guidelines for 'Midnight Rulemaking'](#), *Roll Call*

6/15/12

[EPA to propose tougher rules on soot](#), *The Hill*

[Is 'Smart Regulation' Not? GRAPHIC](#), *National Journal*

[House: Obama's FDA causing drug shortages](#), *Washington Examiner*
[U.S. approves Glaxo meningitis vaccine for children](#), *Reuters*
[Study: FDA's Risk Communications and Warnings Not as Effective as Hoped](#), *Regulatory Focus*
[Regulators Shut Banks in Three States](#), *Wall Street Journal*

6/18/12

[IIF Says Regulation Will Lead to More Shadow Banking](#), *NASDAQ*
[FCC may re-examine cell phone safety standards](#), *IT Pro Portal*
[Government Report Blames Drug Shortages on FDA, Calls for Change in Warning Letter Policy](#), *Regulatory Focus*
[FCC takes up phone safety ahead of GAO report](#), *Washington Post*
[AP Exclusive: US regulators suspect design caused tube trouble at idled Calif. nuclear plant](#), *Washington Post*
[FDA review of Onyx Pharmaceuticals cancer drug focuses on toxic side effects](#), *Washington Post*
[New Dishwasher Standards Will Save Water, Electricity...But Money?](#), *KEYE TV*
[Former FDA Commissioner Calls for Agency Reforms](#), *Regulatory Focus*
[Small Banks Put Up 'For Sale' Sign](#), *Wall Street Journal*
[Five Take-aways on Dodd-Frank's Impact on Stress Testing](#), *CFO Journal*

6/19/12

[Criminal Inquiry Focuses on EPA Email](#), *Wall Street Journal*
[US regulators blame botched computer analysis for tube trouble at idled Calif. nuclear plant](#), *Washington Post*
[FDA Releases Draft Guidance for Veterinary Trials](#), *Regulatory Focus*
[CFTC Moves to Brake High-Speed Traders](#), *Wall Street Journal*
[Poll Finds Public Backs EPA, Not GOP, on Mercury](#), *National Journal Daily*
[FDA Policies Erode Minnesota MedTech Industry, Leaders Likely to Move Jobs, Invest Overseas, According to an Industry Study](#), *Business Wire*

6/20/12

[W.Va. farmer sues over Chesapeake pollution order](#), *Wall Street Journal*
[Reports: FDA to Overhaul New Dietary Ingredient Guidance](#), *Regulatory Focus*
[EPA wears the bull's-eye](#), *Politico*
[House GOP reverses position, won't block FCC political ad rule](#), *The Hill*
[House to Vote Wednesday on FDA User Fee Legislation](#), *Regulatory Focus*
[House panel urges Obama to fight UN regulation of the Internet](#), *The Hill*
[Prison Rape Regulations to Cost \\$7 Billion](#), *Weekly Standard*

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Rulemaking

Department of Justice

DOJ Finalizes \$6.9 Billion Prison Rape Rule

The Department of Justice issued a [final rule](#) “adopting national standards to prevent, detect, and respond to prison rape, as required by the Prison Rape Elimination Act of 2003 (PREA).” By statute, the immediately binding standards are not permitted to “impose substantial additional costs compared to the costs presently expended by Federal, State, and local prison authorities.” Additionally, a state that is not in compliance with the new standards is eligible to lose 5 percent of DOJ grant funds it receives that are directed toward prison uses. “Notably, the standards are generally not outcome-based, but rather focus on policies and procedures. While performance-based standards generally give regulated parties the flexibility to achieve regulatory objectives in the most cost-effective way, it is difficult to employ such standards effectively to combat sexual abuse in confinement facilities, where significant barriers exist to the reporting and investigating of such incidents.” DOJ is promulgating separate standards for adult prisons and jails, community confinement facilities, and juvenile detention facilities, including

minimum staffing levels and video monitoring requirements. In juvenile facilities, DOJ is requiring a minimum 1:8 staff-to-resident ratio during the day and 1:16 at night; minors who are placed in an adult holding facility will not be permitted to make contact with adult inmates in a common space, shower area, or sleeping quarters, nor are they permitted to be in isolation. Additionally, the Department is phasing-in a requirement for all pat-downs of female inmates to be conducted by female members of the staff, without restricting female inmates' access to programming and out-of-cell opportunities.

The Department estimates that implementing these standards will cost [\\$6.9 billion](#), or \$468.5 million annually, with an “annualized cost per facility of compliance with the standards [of] approximately \$55,000 for prisons, \$50,000 for jails, \$24,000 for community confinement facilities, and \$54,000 for juvenile facilities.” The start-up cost of implementing these standards in 2012 will be \$745.8 million for all applicable facilities in the U.S. The Department monetizes the avoidance of an incidence of prison sexual misconduct between \$310,000 – \$480,000 per victim (and \$675,000 for juveniles), and estimates that the “breakeven” point for this rule is avoidance of 1,671 incidences of prison sexual misconduct.

Department of Transportation

FMCSA Direct Final Rule Reduces Regulatory Burden for Some Interstate Truckers

The Federal Motor Carrier Safety Administration released a [direct final rule](#) amending regulations on the interstate transportation of household goods, removing obsolete requirements from the existing regulations, and reducing the regulatory burden on for-hire household goods motor carriers. The final rule clarifies the definition of a “household goods motor carrier” to explicitly exclude motor carriers that transport household goods from a store or factory to a household, meaning that these motor carriers need not obtain the nonrefundable [\\$300](#) operating authority registration that is requisite for household goods motor carriers.

Environmental Protection Agency

EPA: NY, NJ, CT Meet 8-hour Ozone NAAQS Determinations

The Environmental Protection Agency issued a [final rule](#) this week determining that that New York-New Jersey-Connecticut (NY-NJ-CT) ozone area is currently meeting the eight-hour ozone nonattainment area standards set forth in the National Ambient Air Quality Act. The [National Ambient Air Quality Standards](#), established under the Clean Air Act, require nonattainment areas to implement plans to reduce pollutants or risk losing federal funds. The EPA is withdrawing proposed disapprovals of Connecticut and New Jersey's stated plans to meet the eight-hour ozone standards. The EPA also determined that the NY-NJ-CT area is currently meeting the revoked one-hour ozone nonattainment area standards.

EPA Final Rule Tightens Emissions Standards for Aircraft Engines

The Environmental Protection Agency issued a [final rule](#) this week requiring aircraft engine manufacturers to reduce engine emission of oxides of nitrogen (NO_x). The first round of reductions requires manufacturers to reduce NO_x emissions by 12 percent. The second round, which takes effect in 2014, requires manufacturers to reduce NO_x emissions by 15 percent. These standards were developed by the United Nations' International Civil Aviation Organization, and “by adopting such similar standards, therefore, the United States maintains consistency with these international efforts.”

Agencies

Environmental Protection Agency

EPA Releases Benchmark Doses Technical Guidance

The Environmental Protection Agency [released](#) the final version of its [technical guidance](#) on benchmark doses to update risk assessment methodologies used when developing dose response values and determining a point of departure for toxicological studies. “Dose-response analysis is one of the four components of a chemical risk assessment as defined by the National Research Council. Historically, for cancer assessments EPA assessors have used linear methods to determine a dose response while noncancer assessments have relied on identifying the dose at which no adverse effects are detected. As EPA moves toward harmonization of approaches for cancer and noncancer risk assessment, the dichotomy between cancer and noncancer health effects is being replaced by consideration of mode of action and whether the effects of concern are likely to be linear or nonlinear at low doses.

This guidance document addresses the computation of the BMDs and benchmark concentrations and their confidence limits; data requirements; dose-response analysis, and recommendations for reporting the results.”

EPA Announces Public Meeting on Draft Diesel Fuel Fracking Guidance

The Environmental Protection Agency [announced](#) a public meeting on June 29th to facilitate discussion of the Agency’s [draft permitting guidance](#) on hydraulic fracturing using diesel fuels. EPA is hosting two sessions, from 8:30 to 12:00pm and from 1:30 to 5:00pm, during which participants will be presented with the basics of the guidance by EPA’s Office of Ground Water and Drinking Water and allowed to present comments on the guidance. Seating will be limited; interested participants can pre-register [here](#).

Food and Drug Administration

FDA Releases Draft Guidance on New Animal Drug Approval for Companion Animals

The Food and Drug Administration [released](#) a [draft guidance](#) advising industry on the use of active controls, or therapies that are known to be effective, in studies intended to provide substantial evidence of effectiveness of new animal drugs for use in companion animals (dogs, cats, and horses). “The intent of the guidance is to provide information to clinical investigators who conduct studies using active controls and have a basic understanding of statistical principles.” The guidance provides comparisons of studies to illustrate the advantages and disadvantages of using a study with an active control to provide substantial evidence of animal drug effectiveness. [Comments](#) on this draft are due on August 20th.

Export-Import Bank

Ex-Im Receives Application for \$22.5 Million Capital Guarantee for Kazakh Titanium Production

The Export-Import bank [published notice](#) of receipt of an application for a capital guarantee for \$22.5 million worth of U.S. titanium refining and production equipment for a titanium production facility in Kazakhstan. “The U.S. exports will enable the Kazakh firm to establish a maximum production capacity of 7,000 metric tons of titanium per year. Available information indicates that all of the new Kazakh titanium production will be sold in South Korea.”