



THE MONTH IN WASHINGTON

A Federal Report Provided by LGV&A

AUGUST 2014

August is traditionally the most uneventful month in the nation’s capital, with much of official Washington out of town. Congress began a five-week recess on August 1, and President Obama took a 15-day vacation to Martha’s Vineyard in the middle of the month. The rest of the world was not exactly accommodating to these attempts at some downtime, however, as Islamic militants from ISIS continued to tear apart much of Iraq and Syria while making a show of their brutality, and Russian involvement in the rebellion in eastern Ukraine appeared to deepen. Closer to home, the shooting of an unarmed 18-year-old black man by a white police officer in Ferguson, Mo., stoked racial tensions in that city and beyond.

ISSUES AND EVENTS

GOP Senators Press for FDA Guidance on Biosimilars

Five Republican senators on August 1 urged the Obama administration to release guidance regarding the approval of generic versions of biologic drugs, known as biosimilars.

Biologic drugs are highly advanced medicines derived from biological, rather than chemical, processes. They are among the most innovative of drug treatments and, as such, are also among the most expensive, potentially costing tens, even hundreds of thousands of dollars each year for a single patient. Generic biopharmaceuticals would offer lower-cost alternatives – as with generic versions of traditional drugs – but there was no “pathway” allowing their approval by the Food and Drug Administration (FDA) until passage of the 2010 health care reform law.

Despite the inclusion in the reform law of the “Biologics Price Competition and Innovation Act,” the senators wrote in the letter to Health and Human Services Secretary Sylvia Burwell, “The FDA has not yet issued guidance on some of the key scientific policy questions related to biosimilars, such as naming, labeling, indication extrapolation, and interchangeability.”

“We still have seen no draft proposal on the naming issue, or guidance on demonstrating interchangeability,” they wrote. “We have heard there is some difference of opinion on

these matters, making it even more important that these policies, which are integral to the success of the biosimilar pathway, be released in draft form as soon as possible.”

The letter was signed by Senators Lamar Alexander of Tennessee, Orrin Hatch of Utah, Michael Enzi of Wyoming, Richard Burr of North Carolina and Pat Roberts of Kansas.

CalPERS has weighed in on the naming issue, signing on to a July 1 letter that was also supported by 31 other groups that urged the FDA not to require biosimilars to have a different International Nonproprietary Name (INN) from the brand-name drug. This could become a significant issue because some states require that a generic can only be substituted for a brand-name drug if the two products have the same name.

“Requiring different INNs for biologics and biosimilars could lead to patient and prescriber confusion, increasing the possibility of medication errors, and would also effectively separate the biosimilar from existing safety information about the underlying molecule,” the letter stated.

The American Consumer Institute made a similar request in a July 10 letter, stating that requiring different INNs “would impede biosimilar competition in the United States and limit access to life-saving care for millions of consumers. ... At a minimum, the FDA should put the naming issue on hold and, instead, accelerate its rulemaking to encourage market entry and heighten industry price competition.”

On July 24, the FDA accepted its first application for a biosimilar – Zarzio from Sandoz, which is intended to decrease the incidence of certain infections during chemotherapy. The reference product is NEUPOGEN by Amgen.

Biologics have been in the news lately because of Sovaldi, a brand-name drug that cures hepatitis C in most patients at a cost of \$84,000 for a treatment regimen of 84 pills over 12 weeks.

The FDA has made available some documents and draft guidance related to biosimilars.

AMA Seeks Delay of ‘Sunshine Act’ Website Launch

The American Medical Association (AMA) is asking the Centers for Medicare & Medicaid Services (CMS) to delay the online publication of information concerning drug company payments to doctors.

The 2010 Patient Protection and Affordable Care Act requires manufacturers of drugs and medical equipment that are covered by Medicare, Medicaid or the Children’s Health Insurance Program (CHIP) to submit records of their payments to physicians and teaching hospitals to CMS, which will then post them on a public “Open Payments” website. Required disclosures involve payments for food, entertainment, gifts, consulting fees, honoraria, research funding or grants, education or conferences, royalties or licenses, and

charity. CMS released a rule implementing the “Sunshine Act” in February 2013, 16 months after it was due.

The website is now being used only to collect information from companies and to allow doctors and representatives of teaching hospitals to review the submitted data. CMS took the site offline from August 3-15 to “resolve a technical issue.” The public launch of the site – at which point the submitted information will be made available to all – is scheduled for September 30.

On August 15, the AMA, citing “continued poor functionality of the government website and poor communication to physicians and the public,” asked CMS to push back the public launch until March 31, 2015. The six-month delay, CMS stated, would give doctors more time to register on the site and review information. Physicians now have until September 8 to register and seek to have inaccurate data corrected. The deadline had been August 27, but CMS extended it because of the website being down for 12 days.

“In order for the Sunshine Act to be effective, physicians need enough time to review and correct any inaccurate data that may be reported,” AMA President Robert Wah said. “The issues that resulted in the system being taken offline further underscore the need for more time than CMS proposes to ensure the system is actually ready and that physicians have adequate time to register, review, and seek correction of inaccurate data.”

On August 5, the AMA and more than 100 other medical associations wrote to CMS Administrator Marilyn Tavenner to request a six-month delay.

“There are widespread concerns that the implementation of this new system for data collection – without minimally a six month period to upload the data, process registrations, generate aggregated individualized reports, and manage the dispute communications and updates – will not be ready and will likely lead to the release of inaccurate, misleading, and false information,” the associations wrote. “The Agency has not provided effective notification to the vast majority of physicians nor provided a reasonable amount of time for the undersigned organizations to engage and educate physicians on the registration and dispute process.”

CMS Provides More Flexibility in Electronic Health Records Program

The Centers for Medicare & Medicaid Services (CMS) on August 29 adopted a rule aimed at increasing the flexibility that health care providers have this year in transitioning to electronic health records (EHR).

The Health Information Technology for Economic and Clinical Health (HITECH) Act, which was included in the 2009 stimulus legislation, provided for tens of billions of dollars in incentive payments to expand the “meaningful use” of digital health records.

Implementation is divided into three stages, each with a higher threshold for meaningful use. The new rule pushes back the beginning of Stage 3 from 2016 to 2017 and also allows providers to continue to use the 2011 version of EHR software this year. Without this rule, they would be required to transition to the 2014 version this year.

“We listened to stakeholder feedback and provided ... flexibility for 2014 to help ensure providers can continue to participate in the EHR Incentive Programs [going] forward,” CMS Administrator Marilyn Tavenner said. “We were excited to see that there is overwhelming support for this change.”

The increased flexibility comes as many providers are having difficulty moving beyond the most basic EHR implementations. CMS reported in June that only 106 health care professionals and just four hospitals have made it to Stage 2.

SEC to Examine Municipal Advisors

The Securities and Exchange Commission (SEC) has announced that it is launching a two-year initiative to examine a “significant percentage” of newly-registered municipal advisors.

A rule that went into effect on July 1 implements a provision of the 2010 Dodd-Frank Act requiring municipal advisors to register with the commission. In the absence of registration, according to the SEC, many municipalities have been left “relying on advice from unregulated advisors, and they were often unaware of any conflicts of interest a municipal advisor may have had.” (The commission released interpretive guidance for the rule this year.)

During the examination initiative, the SEC’s Office of Compliance Inspections and Examinations (OCIE), will, according to a letter sent on August 19 to municipal advisors, “conduct focused, risk-based examinations of [municipal advisors] that are registered with the SEC, but are not registered with [the Financial Industry Regulatory Authority (FINRA)].” The office intends to look at, among other things, municipal advisors’ compliance with rules related to registration, fiduciary duty, disclosure, fair dealing, supervision, books and records, and training/qualifications.

“The municipal advisor examination initiative will focus on the areas that are most important to protecting issuers, investors and municipal taxpayers,” said Kevin Goodman, national associate director of OCIE’s broker-dealer examination program. “We also will promote compliance by engaging these new municipal advisor registrants through outreach.”

The OCIE intends to conduct a “compliance outreach program” with FINRA and the Municipal Securities Rulemaking Board (MSRB) this year to help municipal advisors “learn more about the examination process and their obligations under the Dodd-Frank Wall Street Reform and Consumer Protection Act and related rules.”

Lawsuit Challenges SEC's Anti-'Pay-to-Play' Rule

A pair of state Republican parties are suing to overturn a Securities and Exchange Commission (SEC) rule that limits political contributions by investment firms.

The rule prohibits donations from such firms to candidates for political offices that have influence over state contracts with investment companies. Firms that make such donations are barred from managing a state's investments for two years.

The SEC enacted the rule to address concerns over "pay-to-play" arrangements in which campaign contributions could be used to seek government contracts, but the New York and Tennessee Republican parties argue in the lawsuit that the rule violates the companies' rights to free speech.

The lawsuit charges that firms are forced to make "an impermissible choice" between "exercising a First Amendment right and retaining the ability to engage in professional activities," and that the SEC is improperly encroaching upon the jurisdiction of the Federal Election Commission.

"As an institution, the SEC has no specialized knowledge of, or insight into, campaign finance and elections," the lawsuit states.

Bank of America Reaches \$17 Billion Settlement; CalPERS, CalSTRS to Receive \$300 Million

Bank of America has agreed to pay nearly \$17 billion to settle charges related to mortgage investments offered by the firm and its subsidiaries before and during the financial crisis of the late 2000s.

The settlement grew out of investigations of transactions in the subprime mortgage market, the collapse of which is generally considered to be a major factor that contributed to the financial crisis and recession. Regulators charged that Bank of America and its subsidiaries, including Merrill Lynch and Countrywide, misled investors about the quality of the mortgages behind certain asset-backed securities.

"It's kind of like going to your neighborhood grocery store to buy milk advertised as fresh, only to discover that store employees knew the milk you were buying had been left out on the loading dock, unrefrigerated, the entire day before, yet they never told you," Associate U.S. Attorney General Tony West said. "And, just like you might be in for an unpleasant surprise when you got home and poured yourself that glass of milk, investors – such as public pension funds and federally insured financial institutions – were unpleasantly met with billions of dollars in losses when those securities investments soured."

In the largest civil settlement involving a single entity in the nation's history, Bank of America reached a deal with the U.S. Justice Department in which it will pay \$16.65 billion

to settle outstanding federal and state claims against it and its subsidiaries. That amount includes \$7 billion “in relief to struggling homeowners, borrowers and communities affected by the bank’s conduct.” That relief is expected to come in various forms, including principal reduction loan modifications to help homeowners who are underwater on their mortgages, new loans to credit-worthy borrowers who have been unable to get a mortgage, donations to assist communities in recovering from the financial crisis, and financing for affordable rental housing.

The remaining \$9.65 billion “will be paid to settle federal and state civil claims by various entities related to [residential mortgage-backed securities (RMBS), collateralized debt obligations (CDOs)] and other types of fraud.” This includes a \$5 billion penalty under the Financial Institutions Reform, Recovery and Enforcement Act, \$1.8 billion to settle federal fraud claims related to the bank’s origination and sale of mortgages, and \$1.03 billion to settle federal and state securities claims by the Federal Deposit Insurance Corporation (FDIC). Funds will also go to several states to settle claims, including \$300 million to California to reimburse CalPERS and the California State Teachers’ Retirement System (CalSTRS) for their losses.

“Bank of America profited by misleading investors about the risky nature of the mortgage-backed securities it sold,” California Attorney General Kamala Harris said. “This settlement makes our pension funds whole for the financial losses caused by these misrepresentations and brings help to hard-pressed homeowners and communities in California.”

Bank of America also reached a \$245 million settlement with the Securities and Exchange Commission (SEC) in which the firm “acknowledges that its conduct violated the federal securities laws” related to disclosures.

“Bank of America failed to make accurate and complete disclosure to investors, and its illegal conduct kept investors in the dark,” said Rhea Kemble Dignam, regional director of the SEC’s Atlanta office. “Requiring an admission of wrongdoing as part of Bank of America’s agreement to resolve the SEC charges filed today provides an additional level of accountability for its violation of the federal securities laws.”

Regulators Reject ‘Living Wills’ from 11 Banks

The nation’s largest banks have not impressed regulators with their living wills.

The 2010 Dodd-Frank Act requires banks with assets of \$50 billion or more, as well as nonbank financial companies designated by the Financial Stability Oversight Council for additional oversight, to annually draft plans – known as living wills – that outline how the firm is to be dissolved if it encounters major financial problems. The provision is intended to address concerns that “too big to fail” firms will inevitably be bailed out by the federal government, if necessary.

Eleven banks that are in the “first wave” of filers subject to the provision submitted living wills in 2013, and the Federal Reserve and the Federal Deposit Insurance Corporation (FDIC) announced on August 5 that, after reviewing the plans, they had rejected all 11.

The Fed and the FDIC identified several common failings in the plans, including assumptions that the agencies regard as unrealistic or inadequately supported, such as “assumptions about the likely behavior of customers, counterparties, investors, central clearing facilities, and regulators; and the failure to make, or even to identify, the kinds of changes in firm structure and practices that would be necessary to enhance the prospects for orderly resolution.”

The FDIC stated that the submitted plans “are not credible and do not facilitate an orderly resolution under the U.S. Bankruptcy Code,” while the Federal Reserve determined that the banks “must take immediate action to improve their resolvability in bankruptcy.” Regulators sent a letter to each of the 11 banks that identified “the specific and concrete steps the firm must take to improve its resolvability under bankruptcy.”

“The agencies will require that the annual plans submitted by the first-wave filers on or before July 1, 2015, demonstrate that the firms are making significant progress to address all the shortcomings identified in the letters, and are taking actions to improve their resolvability under the U.S. Bankruptcy Code,” the Fed and the FDIC stated.

Resolution plans that were filed for 2014 are still under review.

The 11 banks that submitted plans in 2013 were Bank of America, Bank of New York Mellon, Barclays, Citigroup, Credit Suisse, Deutsche Bank, Goldman Sachs, JPMorgan Chase, Morgan Stanley, State Street Corp., and UBS.

RELATED NATIONAL AND INDUSTRY NEWS

New Treasury Office to Examine Public Pensions

A new Treasury Department office that focuses on state and local finance will take a close look at public pensions, the office’s director said in early August.

Maryland State Retirement and Pension System CIO A. Melissa Moye has been appointed a senior policy advisor within the Treasury Department’s Office of State and Local Finance and will focus on state and local pensions.

State and Local Finance Office Director Kent Hiteshew said at an August 4 meeting of the Council of State Governments that Moye “will substantially strengthen our office’s understanding of the critical challenges facing a system upon which approximately 23 million Americans depend ... for their retirement security.”

Hiteshew noted during his speech that the aggregate funding level for public pensions is down to 72 percent, largely because of “both market forces and trying fiscal times during the last few years.”

The Treasury Department announced in April that it was creating the Office of State and Local Finance to “serve as Treasury’s liaison to state and municipal officials and associations, monitor developments in municipal bond markets, support policies to improve the management of public pensions and other liabilities, and develop potential federal policy responses to issues that emerge in municipal financing markets.”

CALIFORNIA CONGRESSIONAL DELEGATION NEWS

U.K. Unveils Draft Payment Disclosure Rules

The United Kingdom on August 21 released drafts of rules requiring oil and gas companies to disclose payments they make to foreign governments.

The drafts would require companies to disclose such payments – whether in the form of taxes, royalties, permit fees, etc. – starting January 1, 2015. Noncompliant companies could face criminal penalties.

The proposed regulations are expected to be introduced to Parliament for its approval this year.

In June 2013, the European Union passed a directive requiring its member states to enact disclosure mandates by 2015. The U.K. would be the first E.U. member to implement the rules.

A similar rule is supposed to be enacted in the United States. Section 1504 of the 2010 Dodd-Frank Act directed the implementation of the rule in order to increase the transparency of money flowing to regimes that may be more likely to pocket it than use it for the good of their nations.

After its first rule was struck down in federal court last year, the SEC did not include development of a new version of the rule in its original list of priorities for the coming year, but an update to the list projects completion of the rule by March 2015.

Royal Dutch Shell and Exxon Mobil wrote to the SEC on May 1 to ask the commission to make development of the rule a priority this year in the hope that the U.K. would postpone its implementation until 2015, so that it could take the SEC approach into account. This, the companies wrote, would be “especially important for purposes of ‘equivalency’ between the EU and U.S. reporting regimes.”

Critics, however, say that the companies are less interested in equivalency than in “playing both sides off against each other” in order to weaken and slow implementation of any rule.

Oxfam, an international organization that works on poverty issues, wrote in a July 14 letter to the SEC that the commission is well past the April 17, 2011, deadline for issuing a final rule that implements Section 1504 and that Oxfam members are concerned about “the recent non-binding announcement that the Commission may propose a new rule in March 2015 and strongly believe that this delay is both unwarranted and inconsistent with the Commission’s legal obligations.”

The group stated in the letter that, “If by August 1, 2014, the Commission has not committed to finalizing the rule by year’s end or agreed to the terms of a Consent Decree, Oxfam intends to promptly return to court to enforce the Commission’s legal obligations.”

The August 1 deadline passed with no action on the matter by the SEC, and Oxfam officials said on August 12 that the organization “intends to promptly return to court to enforce the SEC’s legal obligations to issue a final rule for Section 1504 of the Dodd-Frank Act.”

Oxfam filed a lawsuit in May 2012 demanding that the SEC issue a Section 1504 rule. Three months later, the commission released the rule that was later struck down in a case brought by the American Petroleum Institute, the U.S. Chamber of Commerce, the National Foreign Trade Council and the Independent Petroleum Association of America. The commission’s analysis of the rule’s potential impact, the judge concluded, “was arbitrary and capricious and independently invalidates the Rule.”

In June, 58 Democrats signed on to a letter organized by House Financial Services Committee Ranking Democrat Maxine Waters of California that advised SEC Chairman Mary Jo White that, “we believe that the rulemaking for section 1504 should be on a swifter, more definite time line. We strongly urge you, therefore, to issue a proposed rule for public comment no later than the end of this year.”

Sen. Barbara Boxer, D-Calif., signed on to a May 1 letter from 13 senators – 12 Democrats and one independent who caucuses with them – to White urging the commission to “prioritize the issuance of a new rule for Section 1504 by 2015.”

CalPERS, in February 2011, wrote to the SEC to support the rule, which was then under consideration by the agency, stating that it “is especially vital for companies operating in countries where governance is weak resulting in corruption, bribery and conflict that could negatively impact the sustainability of a company’s operations and our ability to more effectively make investment decisions.”