Legal/Regulatory Outlook

Experts See Biosimilars, Marketing, Patent Settlements Among Year’s Key Topics

In the new year, the key concerns for drug and biotech companies will include how they can promote their products, how the government implements a new pathway for approving biosimilar drugs, what the courts may do to curtail patent litigation settlements, and whether the Food and Drug Administration will have sufficient funding to review product applications.

BNA contacted stakeholders and interviewed members of the advisory board for the Pharmaceutical Law & Industry Report to identify the important 2013 issues for drug and biotech companies in the courts, Congress, and regulatory agencies.

Other key issues to watch will be how FDA responds to safety concerns over pharmacies’ compounding of drugs, the enforcement of fraud laws affecting companies’ domestic and overseas marketing, implementation of the FDA Safety and Innovation Act, changes to government program payment policies, and implementation of the health care reform law.

Biosimilars. Jim Greenwood, president and chief executive officer of the Biotechnology Industry Organization (BIO), told BNA that FDA will issue more guidance on biosimilars at some point. The 2010 health reform law, through its Biologics Price Competition and Innovation Act (BPCIA), created a pathway for FDA to approve follow-on biologic drugs, or biosimilars, but the agency still is working on implementation.

Specifically, Greenwood said the agency has been quiet on the issue of naming biosimilars. BIO’s stance on naming is that biosimilars should have unique names, but generic companies want biosimilars to have the same name as the brand product, he said. “The naming issue will need to be resolved,” he said.

The naming and interchangeability of biosimilars will be the big challenges for FDA in 2013, Michael Reilly, executive director of the Alliance for Safe Biologic Medicines (ASBM), told BNA.

“FDA is still struggling with how they address unique names” for biosimilars and needs to determine what unique names will entail, Reilly said.

Reilly said the big challenge for FDA is going to be pressure to approve an interchangeable biosimilar. The guidance the agency issued in February 2012 (10 PLIR 173, 2/10/12) “punted on the issue of interchangeability,” he said. The interchangeability issue is still being studied within FDA, Reilly said.

ASBM plans to bring in other countries that have worked on the interchangeability issue to provide a reference point for FDA, Reilly said. “FDA will be cautious on interchangeability and automatic substitution,” he said.

Reilly said FDA will come out with more guidance in some form on the naming and interchangeability issue. Additionally, Reilly said he expects that FDA will approve the first biosimilar product by the end of 2013, which will answer questions and “give a blueprint” for the approval of biosimilars.

“Biosimilars are both a threat and an opportunity for companies that have branded products,” Dan Mendelson, chief executive officer of the consulting firm Avalere Health, told BNA. “As biosimilars emerge, this is not going to look like a generic pharmaceutical marketplace.”

Mendelson said Avalere Health is closely following how the biosimilars pathway is defined.

A majority of the BNA advisory board members mentioned the FDA’s implementation of the new biosimilars law as a top issue for 2013.

“The FDA still has work to do related to the implementation of the biosimilars provisions of the Affordable Care Act,” advisory board member Linda D. Bentley, of Mintz Levin Cohn Ferris Glovsky and Popeo PC, in Boston, said.

Indeed, industry is waiting for further FDA guidance on a host of issues involving biosimilar entry, said advisory board member Terry Mahn, of Fish & Richardson, in Washington.

Industry is interested in how FDA will implement the pathway for approval of biosimilar drugs.

FDA needs to develop rules for biosimilar applications addressing important issues such as reference product exclusivity and the extent to which applicants can rely on studies of similar approved products, Donna Lee Yesner, an advisory board member and attorney with Morgan Lewis & Bockius, in Washington, said. “Companies investing in biosimilar research must know what the rules will be for obtaining FDA approval,” she added.

“This is probably the year that the BPCIA framework will be tested,” said advisory board member Daniel A. Kracov, with Arnold & Porter LLP in Washington. “We likely can expect expanded FDA guidance, and litigation relating to FDA’s interpretation of the BPCIA ex-
clusivity framework . . . and whether biosimilar applicants must respect the statutory patent dispute framework with respect to disclosures to patent owners.”

Advisory board members said to watch for whether companies take advantage of the abbreviated pathway.

Advisory board member Bruce C. Belzak, of Marsh USA Inc., in Philadelphia, said that, in 2013, biosimilars may “finally get traction, with generics and biotechs looking at partnership arrangements such as recently announced between Watson and Amgen.”

In 2011, Amgen Inc entered into a collaboration agreement with Watson Pharmaceuticals Inc. to develop and commercialize oncology antibody biosimilar products. Several other companies also have announced agreements to develop biosimilars (10 PLIR 23, 1/6/12).

And advisory board member L. Scott Burwell, with Finnegan Henderson Farabow Garrett & Dunner LLP’s Reston, Va., office, said that 2013 could bring the first patent litigation involving biosimilars.

**Patent Settlements.** Board members said the face of pharmaceutical patent litigation itself may change, pending the outcome of the U.S. Supreme Court’s decision in the reverse payments case involving the testosterone drug AndroGel.

Reverse payment or pay-for-delay settlements generally involve payments from companies that hold patents on drugs to settle patent infringement litigation against companies that want to sell a generic. These settlements have been criticized for delaying generic drug entry in the market.

**The U.S. Supreme Court will examine whether “pay-for-delay” pharmaceutical patent settlements violate antitrust law.**

In December 2012, the high court agreed to review the Watson Pharmaceuticals case (FTC v. Watson Pharmaceuticals Inc., U.S., No. 12-416, review granted 12/7/12). In that case, the U.S. Court of Appeals for the Eleventh Circuit found that a branded drugmaker did not violate federal antitrust laws in paying two generic drugmakers to delay introduction of their generic version of AndroGel as part of a patent litigation settlement. The high court is likely to hear oral argument in the case in March, board members said. The Supreme Court’s ruling in the case could resolve a long-standing circuit split on whether such “pay-for-delay” deals are anticompetitive.

According to board member James M. Burns, of Dickinson Wright in Washington, “This case . . . will undoubtedly be the most significant pharmaceutical industry-related antitrust development of 2013.”

“In fact,” Burns said, “it could very well also be the most significant antitrust development of the year.”

Burwell agreed. “This case will likely affect how litigants approach Hatch-Waxman litigation, as it will determine whether settlement is a realistic alternative to trial,” he said.

“The circuits are now split and the Supreme Court will be forced to set guidelines for when payment (or other consideration) from a patent holder to delay generic entry violates the antitrust laws,” Mahn observed.

Advisory board member James N. Czaban, of Wiley Rein LLP in Washington, said if the Supreme Court rules that reverse payment settlements of Hatch-Waxman patent cases violate the antitrust laws, the number of Hatch-Waxman patent cases may drop.

“If generic and innovator drug companies cannot settle patent cases on terms similar to what they have been using in recent years, the risk/reward calculus for a generic applicant to challenge a patent may be significantly negatively altered leading to even fewer challenges,” he said. Or, he said, “if there is no early-out settlement approach that provides more benefit for generics and consumers than simply waiting for the patent to expire, smaller generics may be priced out of the litigation market despite the potential upside of 180-day exclusivity.”

**Patents, Safe Harbor.** Multiple board members also mentioned the impact of the U.S. Supreme Court’s forthcoming decision on the patentability of human genes in the Myriad case (Association for Molecular Pathology v. Myriad Genetics Inc., No. 12-398, U.S., review granted 11/30/12).

“This case has the potential to change what has been settled law for decades,” Burwell said.

Board members said earlier that they were waiting to see whether the Supreme Court would hear Classen Immunotherapies Inc. v. Biogen Idec, 659 F.3d 1057 (Fed. Cir. 2011) concerning the scope of the “safe harbor” provision of the Hatch-Waxman Act (9 PLIR 1104, 9/9/11). GlaxoSmithKline petitioned the high court for review, but review was denied Jan. 14 (see related item in the Court Proceedings section).

In Classen, the U.S. Court of Appeals for the Federal Circuit considered the safe harbor issue in the context of a patent covering methods of immunizing a patient using an immunization schedule that poses a lower risk of inducing a chronic immune disorder than other tested schedules. The panel held that the safe harbor clause of the Hatch-Waxman Act did not protect GlaxoSmithKline from infringement claims when it infringed on Classen Immunotherapies’ patents for vaccination scheduling methods during postmarket safety studies. The panel held that the safe harbor that shields generic drugmakers from claims of patent infringement during the generic drug development process did not apply to “information that may be routinely reported to the FDA, long after marketing approval has been obtained.” The panel further suggested that the safe harbor would not protect any post-approval activities.

But shortly after Classen was handed down, the Federal Circuit decided Momenta Pharmaceuticals Inc. v. Amphastar Pharmaceuticals Inc., 686 F.3d 1348 (Fed. Cir. 2012), (10 PLIR 1021, 8/10/12), a case involving two manufacturers of generic Lovenox (enoxaparin), Momenta Pharmaceuticals Inc. and Amphastar Pharmaceuticals Inc.

Momenta accused Amphastar of infringing its patent claiming a method for analyzing the chemical composition of enoxaparin. Specifically, Momenta alleged that the patent infringement occurred during Amphastar’s post-approval batch testing.

But, in Momenta, in contrast to Classen, the Federal Circuit held that the safe harbor did apply, because Am-
phastar was using the method to ensure that the enoxaparin it produced met FDA standards.

**Off-Label Promotion.** John Kamp, executive director of the Coalition for Healthcare Communication, told BNA that his group will be focused on the follow-up to the *Caronia* decision on off-label promotion of FDA-approved products.

On Dec. 3, 2012, the U.S. Court of Appeals for the Second Circuit found that the criminalization of truthful, nonmisleading promotion of FDA-approved pharmaceuticals violates the First Amendment (*United States v. Caronia*, 2d Cir., No. 09-5006-cr, 12/3/12) (10 PLIR 1525, 12/7/12). “We conclude simply that the government cannot prosecute pharmaceutical manufacturers and their representatives under the [Federal Food, Drug, and Cosmetic Act] for speech promoting the lawful, off-label use of an FDA-approved drug,” the majority opinion said. The appeals court also reversed the conviction of pharmaceutical company sales representative Alfred Caronia for promotion of an unapproved use of a drug.

**Industry and attorneys are interested in the impact of a 2012 appeals court decision supporting off-label speech about FDA-approved products.**

The decision “introduces a lot of uncertainty about the future of FDA marketing regulation,” Kamp said.

Kamp said FDA will uphold the current regulations on off-label marketing until all appeals are decided but he believes the opinion will be affirmed. Additionally, Kamp said he expects FDA soon will issue more guidance on social media but the Coalition believes that the opinion will be affirmed. Additionally, Kamp said he expects FDA soon will issue more guidance on social media but the opinion will be affirmed.

“While Caronia’s holding is limited to the Second Circuit,” Bentley said, “it has gotten vocal responses on both sides of the issue.” In particular, she said, “FDA has responded much more than it typically does to a one-circuit court decision.”

“I think that the FDA will have to quickly determine its strategy going forward, which could include looking for ‘good’ cases in other circuits with the goal of eventually taking the issue to the U.S. Supreme Court,” she said.

Kracov said that, after *Caronia*, “the Department of Justice and FDA have to be considering their options both from both a policy and enforcement perspective.” While ‘off-label enforcement isn’t going away . . . there will be a continuing shift in focus toward false and misleading claims, including comparative effectiveness claims, and safety-related issues, as well as the traditional focus on kickback allegations.”

In addition, Kracov observed, “FDA will need to walk a fine line in providing new guidance on scientific exchange, unsolicited requests, social media and other topics.”

“How far the courts are ultimately willing to go on pharmaceutical off-label speech remains to be seen, but the implications for the current commercial and regulatory models are potentially transformative, and could result in a significant Congressional reevaluation of the Federal Food, Drug, and Cosmetic Act framework for drugs and devices,” he said.

Mahn predicted that the Second Circuit’s decision in the *Caronia* case “will reverberate and confuse until the Supreme Court clarifies how FDA’s misbranding rules can be enforced consistently with the First Amendment.”

The *Caronia* decision raises “serious implications for regulating ‘speech’ and associated compliance processes for the dissemination of truthful off-label information by pharmaceutical company representatives,” advisory board member L. Stephan Vinceze, of Deloitte & Touche LLP in Boston said. The *Caronia* case, he said, “could significantly alter current interactions and associated compliance processes with regard to the dissemination and discussion of off-label materials.”

“The full impact of *Caronia* remains to be seen,” Czaban added, “but the biggest downstream issue to watch is whether it impacts the government’s ability to continue to extract massive legal settlements from pharmaceutical companies under the dubious guise of inducing False Claims Act violations.”

**Product Safety.** The Supreme Court also will be the focal point for product liability matters, another big issue confronting the pharmaceutical industry, board members told BNA.

In 2013, the high court is set to review the First Circuit decision finding no preemption of a design defect claim against a generic manufacturer (*Mutual Pharmaceutical Co. v. Bartlett*, U.S., No. 12-142, review granted 11/30/12) (10 PLIR 1529, 12/7/12). That decision departed from the Supreme Court’s 2011 decision in *Pliva Inc. v. Mensing*, 131 S. Ct. 2567 (2011), in which the high court held that federal drug regulations applicable to generic drug manufacturers directly conflict with, and thus preempt, state-law claims.

“The First Circuit in *Bartlett* found the *Mensing* pre-emption rationale inapplicable, reasoning that compliance with federal law did not make it impossible for a generic company to prevent the plaintiff’s alleged harm because the company could simply choose not to sell the drug,” Czaban said. “This decision created a circuit split on the issue and overtly challenged the Supreme Court’s reasoning in *Mensing*.”

Belzak said because the decision in *Mensing* may be tested, underwriters are closely following the potential impact of any change. “In general,” he said, “underwriters are still very uncertain about the future of the generic industry, how the Supreme Court will view the *Bartlett* case, will the *Mensing* decision stand, and what laws Congress may attempt to impose.”

Also on the product liability front, Czaban said, so-called *Conte* theories of liability continue to be asserted. In the *Conte* decision (*Conte v. Wyeth Inc.*, 85 Cal. Rptr. 85 Cal. Rptr. 85 Cal. Rptr. 85 Cal. Rptr. 85 Cal. Rptr. 85 Cal. Rptr. 85 Cal. Rptr. 85 Cal. Rptr.
3d 299 (Cal. App. 2008)), a state appellate court held a branded company liable for injuries to patients who took only generic drugs and never took the branded product.

While so far, most state and federal courts have rejected the reasoning in Conte, Czaban said that the Alabama Supreme Court still has a pending case, Weeks v. Wyeth, 2011 WL 6980897 (Ala. 2011), in which it will decide whether Conte claims are viable under Alabama law.

“This will be the first time any state’s highest court rules on Conte and the decision could prove pivotal even outside of Alabama, regardless of the outcome,” Czaban said.

Indeed, on Jan. 11, the Alabama high court released its ruling in the Weeks case, adopting the Conte theory and finding that Pfizer Inc. could be liable for injuries to a patient who took a generic version of the branded heartburn medication drug Reglan (metoclopramide).

Enforcement in Life Sciences Area to Continue. With regard to the False Claims Act, the Foreign Corrupt Practices Act, and other areas of pharmaceutical enforcement, advisory board members expect 2013 will continue to see a slew of federal and state enforcement actions.

“Because of the huge amounts of money that states and the federal government can receive from enforcement actions as well as the positive press that results from the perceived recovery of waste in the healthcare system and the positive effects on the political aspirations of many of the prosecutors, I expect that enforcement activities will continue to be a hot topic for 2013,” Bentley said. “These may take the form of alleged violations relating to the False Claims Act, fraud and abuse, off-label promotion and other violations alleged by government prosecutors or whistle blowers.”

And Belzak said enforcement of the Foreign Corrupt Practices Act against life sciences companies will continue apace in 2013. “The DOJ [Department of Justice] and SEC [Securities and Exchange Commission] are vigorously conducting hundreds of civil and criminal investigations into alleged FCPA violations and the life sciences industry is a target for this,” he observed.

The FCPA, which covers companies that list their securities in the United States, prohibits offering or paying bribes to foreign government officials at any level of government. DOJ and SEC enforce the statute, and drug companies’ overseas marketing activities have been the subject of recent enforcement actions under the law.

In addition, Belzak said, government agencies have heightened their usage of the responsible corporate officer (RCO) doctrine and “have targeted healthcare and life science firms which will continue in 2013.”

Under the RCO doctrine, certain individuals can be held responsible for fraud and abuse at their companies even if they had no personal knowledge of the fraud.

David L. Rosen, of Foley & Lardner LLP in Washington, said to look for whether FDA will bring a criminal prosecution against company executives in 2013, and whether the use of consent decrees will continue.

And Vincze said that corporate integrity agreement (CIA) requirements from the U.S. Department of Health and Human Services’ Office of Inspector General “continue to raise the bar for companies entering into CIAs and, as a result, for the industry as a whole.”

Regulating Compounders? The role of the federal government in regulating compounding pharmacies is expected to be a high-profile topic in 2013. Compounders typically produce a small amount of custom-made medications for consumers who have a prescription. The large-scale production of drugs by compounding pharmacies, and associated safety problems, has drawn the attention of lawmakers due to a recent outbreak of fungal meningitis caused by compounded drugs that were contaminated.

On Dec. 19, 2012, FDA met with state boards of pharmacy to discuss what role FDA and the states should play in overseeing compounding pharmacies in light of the meningitis outbreak tied to the New England Compounding Center (NECC). Traditional compounding is overseen by state boards of pharmacy. During the meeting, FDA Commissioner Margaret A. Hamburg said there is a need for additional legislation to strengthen and clarify the existing laws, and she is “guardedly optimistic” that Congress will act. Specifically, she said a uniform set of standards for nontraditional pharmacies should be created at the federal level. Additionally, Hamburg suggested that working groups be held to come up with clear definitions of traditional compounding and manufacturing.

The safety concerns arising from pharmaceutical compounding by pharmacies have policymakers contemplating what FDA’s exact role in regulating such pharmacies should be.

At the end of the previous Congress in 2012, House members introduced two bills on compounding. Reps. Rosa DeLauro (D-Conn.) and Nita Lowey (D-N.Y.) introduced a bill (H.R. 6638) to improve the regulatory framework governing compounding pharmacies, and Rep. Edward J. Markey (D-Mass.) introduced a bill (H.R. 6634) that aims to strengthen federal regulations for compounding pharmacies. Markey said Jan. 4 that he is preparing to reintroduce a new version of his bill in the 113th Congress.

The issue of compounding “may come to a head as Congress, FDA, CMS [the Centers for Medicare & Medicaid Services] and state agencies all scramble to flex their muscles trying to deal with the aftermath of the NECC situation,” Belzak said.

“FDA is begging Congress for new legislation to ‘clarify’ the legal status of alleged ‘compounders’ and the FDA’s authority to regulate them,” Czaban said. “Unfortunately, with respect to ‘compounding,’ politics has thus far trumped public health; the question is whether the right priorities will emerge on top in light of the recent tragedy.”

And Yesner noted, compounding “is a longstanding issue but nothing spurs legislative action more than a safety crisis.”

“The most likely approach,” she said, “will be one in which pharmacies operating as manufacturers will be subject to FDA standards and inspections while traditional compounding activities will be regulated by the states.”
Sunshine Rule. Industry is waiting to see the final rule from CMS implementing the Physician Payments Sunshine Act, part of the 2010 health reform law, board members said. The formal name of the rule is Transparency Reports and Reporting of Physician Ownership of Investment Interests (CMS-5060-F). It will require companies to report on payments to health care providers, and the information will be made available to the public. A proposed rule was issued in late 2011.

“Another issue is the long-awaited patient definition guidance for 340B, Slafsky said. In 2007, HRSA proposed new guidance in this area but has not published guidance for 340B, Slafsky said. In 2007, HRSA proposed new guidance in this area but has not published guidance for 340B, Slafsky said. In 2007, HRSA proposed new guidance in this area but has not published guidance for 340B. Slafsky said that some orphan drugs are used in treating rare diseases. Slafsky said that some orphan drugs are used in treating rare diseases. Slafsky said that some orphan drugs are used in treating rare diseases. Slafsky said that some orphan drugs are used in treating rare diseases.

Kracov noted that because transparency reporting requirements also are proliferating globally, along with a focus on anti-bribery/anti-corruption, it is critical that companies develop effective systems and controls. “We are seeing clients focusing on creating sustainable global approaches to compliance, with deviations for certain local requirements and issues. That process will accelerate in the coming year,” he said.

Medicaid, 340B. Board members also mentioned CMS’s actions regarding Medicaid to be a hot issue.

CMS must decide whether to allow partial expansion of Medicaid, Yesner said. “Integrated coverage of dual eligibles also bears watching as CMS could waive Medicare Part D formula requirements, and mandatory minimum rebates for dual eligibles are likely to be on the table again.”

In addition, she said, “important issues necessary to implement State and Federally-facilitated Exchanges include what constitutes essential health benefits and how restrictive formularies can be.”

“CMS has already indicated it would not apply Medicare Part D protected therapeutic classes to exchanges,” she said.

Advisory board member Wells Wilkinson, project director of Prescription Access Litigation at Boston’s Community Catalyst group, said the extension of drug rebates to dual Medicare/Medicaid eligibles under Medicare Part D is a likely budget balancing move for 2013.

And Short said the implementation of entitlement cuts and their potential impact on the prescription drug marketplace, particularly if rebates on utilization by dual eligibles or Low Income Subsidy enrollees in Part D are implemented, could undermine the free-market management of the benefit to date.

Ted Slafsky, president and chief executive officer of the trade group Safety Net Hospitals for Pharmaceutical Access (SNHPA) told BNA Dec. 19, 2012, that there will be a lot of activity on the 340B program on Capitol Hill and by federal regulatory agencies in 2013.

Created in 1992, the 340B program requires pharmaceutical manufacturers participating in the Medicaid program to enter into an agreement with HHS under which the manufacturer agrees to provide discounts on covered outpatient drugs purchased by safety-net providers such as disproportionate share hospitals and federally qualified health centers.

The Health Resources and Services Administration (HRSA) has begun to audit the entities in the 340B program to ensure that they are complying with the program, Slafsky said. The audits began in 2012 but will continue in 2013, he said. In fiscal year 2012 there were 50 audits and there will be up to 400 audits in FY 2013. “This is a significant increase in the amount of oversight,” he said.

The Government Accountability Office, in a September 2011 report, said HRSA’s Office of Pharmacy Affairs—a part of the Department of Health and Human Services—had not conducted any audits of the 340B program since it began in 1992 (9 PLIR 1231, 9/30/11).

Slafsky said SNHPA supports the increased oversight but requests that HRSA also ensure that drug manufacturers are complying with the program. “We hope there is some balance and the agency also looks at manufacturers to ensure they are complying with the law,” he said.

The issue of orphan drugs also will be big in 2013, Slafsky said. The Affordable Care Act (ACA) expanded the 340B program to certain rural health care facilities, such as critical access hospitals. However, at the last minute, a provision was added to the law that exempts pharmaceutical manufacturers from having to provide discounts on “orphan drugs” to the new types of facilities eligible for the program, he said. Orphan drugs are used in treating rare diseases. Slafsky said that some drug manufacturers are interpreting the law “very broadly.”

In May 2011, HRSA published a proposed rule designed to clarify the way in which orphan drugs can be purchased under the 340B program (76 Fed. Reg. 29,183) (9 PLIR 641, 5/27/11). Under the proposed rule, orphan drugs are excluded from the program for the newly eligible entities, if the drugs are used to treat the rare ailment for which they received the orphan-drug designation. Under the proposal, the covered entities (safety-net providers) could purchase medications designated as orphan drugs at the 340B discounted prices “when using them for common conditions for which they are approved or any other lawful use except” the rare condition or disease for which the FDA granted an orphan designation.

“HRSA’s proposed rule balances the interests of both providers and the industry and we encourage the agency to expedite the publication of the final regulations,” Slafsky said.

“Another issue is the long-awaited patient definition guidance” for 340B, Slafsky said. In 2007, HRSA proposed new guidance in this area but has not published the final guidance on patient definition. Currently, a 1996 guidance is used to determine patient eligibility
for the program but there still is some confusion around who is eligible, Slafsky said. HRSA may publish a new guidance on patient eligibility in 2013, he said.

On the legislative front, Slafsky said SNHPA plans to work with lawmakers on legislation to make some reforms to the 340B program to make the program more effective. Currently, the legislation is in the early stages of development, so details could not be provided.

**FDASIA.** Other issues expected to be on the table in 2013 include implementation of the FDA Safety and Innovation Act (FDASIA), and social media.

BIO’s Greenwood told BNA that his group will be focused on the regulatory process around implementing FDASIA, a law signed by President Obama in mid-2012 that renews user fee programs. “There is a lot of work to do around implementation,” Greenwood said.

Greenwood said BIO wants to make sure the accelerated approval pathway in FDASIA “is done well.” FDA-SIA included new user fees, as well as commitments by the agency on the review of drugs and devices.

“The successful implementation of FDASIA will be critical for the industry in the United States, and it will also be an important test of FDA’s ability to expand upon recent efforts to accelerate the review of important new products and indications,” Kracov said.

“Global GMP [good manufacturing practices] compliance will be an important issue for the FDA as more and more manufacturing is performed offshore requiring foreign inspections,” Yesner said. “Track and trace and supply chain issues will also likely remain in the forefront.”

Kracov said to expect serious consideration of legislation in the new Congress relating to track-and-trace issues. To address drug distribution security issues, some legislators have proposed a national drug track-and-trace system that would create a national traceability system for pharmaceuticals (10 PLIR 1405, 11/2/12).

On the social media front, Rosen said industry is still waiting to see if FDA will develop and release a coherent policy regarding the use of social media in advertising and promotion of health care products.

**Drug Reimbursement.** Greenwood of BIO told BNA that “the agenda for us is going to be focused on reimbursement and protecting incentives for innovation.”

Greenwood said we’ve been living beyond our means in the United States, and “Congress will get serious about putting the country on a more sustainable path” but it needs to be done right so innovation is protected.

“We think that Medicare is on an unsustainable footing right now” and “it is the primary driver in increases in federal spending,” Greenwood said.

Greenwood said Medicare tends to be looked at as paying for doctor bills, drugs, and devices and this could cause reimbursement to be decreased and more pressure to be put on “a tenuous investment environment” for biopharmaceuticals.

BIO suggests that Medicare be looked at in terms of treating specific chronic diseases such as cardiovascular disease and diabetes. “The real solution is to have fewer people in the program with chronic diseases” and to do this, investment in the biopharmaceutical industry should be encouraged so that innovation will continue, Greenwood said.

Another big issue in 2013 will be comprehensive tax reform, and BIO will encourage Congress to create tax policies that will promote innovation in the biotech industry, Greenwood said.

**Health Care Reform.** Mendelson also told BNA that 2013 is going to be the key year for implementation of health care reform. Specifically, he said preparation will begin for 30 million new people to enter the health care system, half of which will come through insurance exchanges and half through Medicaid.

As such, the pharmaceutical industry will see new purchasers coming into the marketplace, Mendelson said. Formulary designs will contain tools such as four tiers and prior authorization “to keep costs low,” and there will be “more insurance with a skinnier design,” he said.

For cancer drugs and biologics, there will be more aggregation of the buyers and this will change the customer mix for pharmaceutical companies, Mendelson said.

Additionally, Mendelson said in 2013 there will be more focus on bundled payments and quality metrics. The focus on quality will change the way manufacturers are developing new drugs and companies will need to deliver quality metrics, he said.

**Drug Shortages.** Drug shortages also will continue to get a lot of attention on Capitol Hill in 2013, Slafsky said.

In November 2012, Rep. Bill Cassidy (R-La.) introduced a bill (H.R. 6611) that aims to prevent shortages of generic drugs by altering payment policies in Medicare (10 PLIR 1538, 12/7/12). The bill also would exempt drug manufacturers from providing discounts on generic sterile injectibles to 340B health care providers and to the Medicaid program. Cassidy said in a statement that the artificially low Medicare reimbursement rate for generic sterile injectable drugs discourages their production. The bill is intended to increase production by pegging the reimbursement rate to a figure that accurately reflects the value of those drugs, he said.

“While the reimbursement changes proposed in the bill could be helpful, we are very concerned about legislation that would exempt more drug products from discounted pricing,” Slafsky said.

FBI escaped sequestration cuts at the start of 2013, but concerns remain about the agency’s funding level.

**FDA Funding.** The fiscal cliff legislation (H.R. 8, Pub. L. No. 112-240) cancels for two months—until March—the sequestration cuts mandated under the Budget Control Act of 2011 (Pub. L. No. 112-25). The measure cleared the Senate by an 89-8 vote and the House by a 257-167 vote, and President Obama signed it into law Jan. 2.

The Alliance for a Stronger FDA said Jan. 4 said the legislation “kicks the spending issues down the road” and if the sequester cuts were to go into effect, it estimates that FDA would need to find about $250 million to $270 million in savings in fiscal year 2013.

“This delay gives us additional time to work with Congress on alternatives that protect FDA and the vital
services it provides the American people,” the Alliance said. “We want Congress to abandon across-the-board cuts and allow the Appropriations Committee to do their job: determine national priorities and make sure they are funded. In such an environment, we are confident that FDA will be adjudged a core government function and can justify current funding levels.”

The alliance said that if sequestration of FDA funding occurs:

- drug and device approvals will be slower, conflicting with promises made to consumers and companies;
- problems with imports and globalization will become more numerous; and
- new laws involving food safety, drug and device safety, and biosimilars will be slowed in their implementation, and many programs to modernize FDA processes will be halted.

Additionally, the alliance said the president will be releasing his FY 2014 budget proposal in February. The FY 2013 continuing resolution also will expire on March 31, and the Alliance said it “will want to see that replaced by an omnibus appropriations bill that might be more FDA-friendly.”

PhRMA’s Priorities. Pharmaceutical Research and Manufacturers of America (PhRMA) Senior Vice President Matthew Bennett said in a statement that “PhRMA’s 2013 priorities continue to focus on improving the quality of patients’ lives, increasing the availability of life-saving and life-enhancing medical treatments and supporting the discovery of new treatments and cures by biopharmaceutical research companies.”

“Medicines are a critical source of better health outcomes and savings to the U.S. health care system and PhRMA will continue to advocate for policies that ensure patients of all ages continue to have access to these medicines, allow biopharmaceutical [research and development] to thrive, and support science-based regulatory systems,” Bennett said.

BY DANA A. ELFIN AND BRONWYN MIXTER