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Medical Devices Law & Industry Report™



*Outlook*

## FDA's Performance, Medicare Coverage, Pressure From Excise Tax on 2014 Agenda

For medical device makers, the key issues for the new year will include many of the same issues from 2013, such as the Food and Drug Administration's review of device applications, how the agency has been implementing its user fees law, Medicare coverage actions and repealing a medical device excise tax.

The other key topics the industry will be watching in 2014 include potential new policies for the regulation of health information technology and the use of social media by FDA-regulated companies, enforcement of fraud laws and the implementation of the ''sunshine'' requirements of the health-care reform law that will open company-physician financial relationships to greater scrutiny.

The industry will continue to try to convince Congress to repeal an excise tax on medical device sales imposed by the 2010 health-care reform law. Other Affordable Care Act provisions also will continue to catch the attention of the devices industry, like bundled payments, and accountable care organizations. Manufacturers and stakeholders told Bloomberg BNA they also expect the role of comparative effectiveness research (CER) to grow in 2014.

The FDA will continue finalizing its reforms to the 510(k) premarket notification process, and will continue working to meet the goals agreed to as part of the 2012 FDA user fees law. The agency and industry also will start implementing the first phase of the unique device identification (UDI) final rule. That UDI final rule was released in September 2013, and while implementation starts in 2014 for highest-risk devices, it will span several years.

Getting Congress to repeal the 2.3 percent excise tax on devices is once again the device industry's main priority, industry representatives told Bloomberg BNA. The tax took effect in 2013 as part of the ACA. Bipartisan bills were introduced in both the House and the Senate in 2013, and industry representatives said they were optimistic Congress would vote on the bills in 2014.

The tax will continue to be problematic for small device companies that sell most of their products domestically, attorney Sonali Gunawardhana, of Wiley Rein LLP in Washington, told Bloomberg BNA.

**FDA Performance.** According to the FDA's Center for Devices and Radiological Health, 2014 will be a year of implementing many changes associated with the new user fees reauthorization program in the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012. As part of the Medical Device User Fee Amendments (MDUFA III) in FDASIA, the FDA agreed to meet performance metrics, including expedited review times.

Under the user fees law, device companies are expected to pay $595 million over five years (fiscal years 2013 through 2017). Additional reviewers, enhanced training, and other resources provided by the agreement are intended to give the FDA what it needs to improve performance. The FDA also will hire 208 full-time employees.

According to the Advanced Medical Technology Association (AdvaMed), the performance of the FDA's device review program has declined sharply in recent years, and has only recently started to turn a corner. From 2007 to 2012, the average review time for 510(k) premarket notification submissions increased 45 percent, while the average review time for premarket approval (PMA) applications increased 75 percent. Consistency in the review process—as measured by metrics such as the average number of times the agency sends an application back to a company to ask additional questions and the number of times reviewers change during the course of a review—had similarly declined, AdvaMed has said.

**Industry says the future of FDA's device reviews looks brighter due to the performance targets set in the 2012 FDA Safety and Innovation Act.**

David Nexon, senior executive vice president at AdvaMed, told Bloomberg BNA that the future of device reviews looks brighter because of the FDASIA performance metrics.

''We feel we have a good working arrangement'' with the agency, Nexon said. ''Now the issue is their performance improving. We are cautiously optimistic, but things have deteriorated badly.''

Mark Leahey, president and chief executive officer of the Medical Device Manufacturers Association (MDMA), expressed similar feelings of cautious optimism.

''It's still early'' to judge how much progress the FDA has made on its FDASIA goals, Leahey told Bloomberg BNA. ''Our members feel FDA is responding [to new submissions] in a timely manner. We expect greater

predictability,'' Leahey said. ''They're trending in the right direction.''

During a congressional hearing in November 2013, CDRH Director Jeffrey Shuren said approval time for new devices is decreasing. He also said preliminary data suggest that the FDA has the potential to meet all of its fiscal year 2013 user fee commitment goals under the user fee amendments included in FDASIA.

For example, Shuren said the agency expects to see a 25 percent decrease in the backlog of 510(k) submissions. In addition, he said the FDA expects to see a decrease in average total time for review of 510(k) submissions and PMA applications.

Shuren said the agency considers FDASIA implementation to be a top priority. In the past, Shuren had indicated that insufficient funding was a major contributor to many of the problems associated with the agency's premarket approval program for devices.

Attorney Stephanie Philbin, with Goodwin Procter LLP in Washington, said, ''Hopefully, any turnover at CDRH this coming year will create less of a challenge for both the government and industry than it has in the past. Adequate training of new reviewers is critical to ensuring a robust and fair regulatory environment.''

Sequestration was a concern for industry and the agency, until a bipartisan budget deal passed in late December 2013 and signed by President Barack Obama Dec. 26 made user fees in FY 2014 and FY 2015 exempt from the sequestration cuts. Prior to the budget deal, AdvaMed said, the FDA's devices center had lost $2.9 million in industry user fees in 2013.

Ralph Hall, an adviser at FaegreBD Consulting in Minneapolis, told Bloomberg BNA there is still a lot of budgetary uncertainty. ''We started the [fiscal] year with a shutdown,'' he said, and the sequestration fix in the budget deal isn't permanent.

The key for the FDA is to move its goals forward despite the uncertainty. Many of the MDUFA goals begin in FY 2014—the current fiscal year—Hall said, making it a ''pivotal year'' for the current cycle of funding.

**Agency Actions.** Many of the FDA's actions for 2014 fall under FDASIA requirements. For instance, the agency will continue the reclassification of preamendment devices, which are devices on the market prior to May 1976, when the Medical Device Amendments were enacted.

According to Hall, 2014 will be a year for the FDA to finalize initiatives that were begun years ago. For example, the FDA in 2011 released a draft guidance on evaluating the substantial equivalence of a 510(k) premarket notification submission (6 MELR 9, 1/11/12).

The guidance provided recommendations about the content of 510(k) submissions and the decision-making process for determining substantial equivalence of devices reviewed under the 510(k) program. When finalized, the FDA said, the draft guidance will supersede the existing guidelines, which were written in 1986 and amended in 1998.

In early 2013, the Minnesota Medical Device Alliance (MMDA) filed a citizen petition with the agency, urging it to delay finalizing the guidance until it addresses a lengthy list of regulatory concerns. AdvaMed and other groups also submitted comments in 2012 urging the FDA not to make such radical changes to the substantial review paradigm.

Hall said the FDA also will once again start working on a draft guidance on when to submit a new 510(k) for a device modification. The agency originally issued a draft guidance on when to submit a new 510(k) for a modification in July 2011, but after massive industry pushback, the guidance was pulled as part of FDASIA.

FDA regulations state when a 510(k) must be submitted, but the agency has said the language used in this regulation sometimes leads to varying interpretations of when a 510(k) is required for a modification. To address this issue, the FDA issued a guidance document in 1997. The 2011 draft guidance was meant to update and replace the 1997 one, but the agency has been using the 1997 guidance since the 2011 guidance was pulled.

''For a couple of decades, companies felt like they understood reasonably what was expected of them in the way of new premarket notifications for modifications of existing devices,'' attorney Bradley Merrill Thompson, of Epstein Becker & Green in Washington, told Bloomberg BNA. ''Then FDA came out with its new guidance, and controversy ensued. Now we have no guidance, and manufacturers are left largely to grope in the dark.''

While he said that the FDA is likely to come out with new device modification guidance in 2014, he added, ''we have little way of knowing whether it will be an improvement.''

According to Wiley Rein's Gunawardhana, while the FDA is likely to act on the withdrawn 510(k) reforms guidance in 2014, it may not come out with a guidance.

The FDASIA law requires the FDA to submit a report to Congress in January. Congress will review the report, but the legislation also requires that no regulation or guidance be issued before one year after the report is submitted.

''This report is likely to provide insight into how FDA will address the negative responses it received to the draft guidance it issued on this subject in 2011,'' attorney Gregory H. Levine, of Ropes & Gray LLP in Washington, said.

And Thompson told Bloomberg BNA, ''I believe the Administration is committed to producing the FDASIA report as early in 2014 as possible, taking into account the government shutdown this fall. FDA will obey the Congressional directive not just because it is a Congressional directive, but also because of the mounting political pressure for Congress to step in and change the statute. I think the Administration will want to get its ideas out there in the public discussion just as soon as possible.''

**Health IT.** Also under FDASIA Section 618, the agency is required to issue in January a report on a strategy for regulating health information technology and mobile medical applications. This report is expected to come out in February or March.

**Industry is watching for an FDA report in early 2014 on a strategy for regulating information technology.**

The goal of the report is to promote safety and innovation and reduce regulatory duplication, attorney

   ISSN 1935-7230

Keith Barritt, of Fish & Richardson P.C. in Washington, told Bloomberg BNA. ''While streamlining regulatory approvals is certainly desirable, time will tell if there are really any synergies that can be found to minimize the burden on manufacturers from obtaining marketing authorization considering the different functions of the FDA and the FCC [Federal Communications Commission] in particular,'' he said.

And Barritt said, ''A related issue is Congressional efforts to limit FDA regulation of mobile medical applications and other software. The FDA has long held that software can fall within the statutory definition of a 'medical device,' and it would likely take a change in definition to change the FDA's position.''

''Excluding software from the FDA's regulatory jurisdiction could have dramatically dangerous consequences, considering that more and more functionality is software-based rather than hardware-based,'' he added.

Thompson predicted that 2014 will bring a lot of activity in the regulation of health information technology. The use of software is growing exponentially with the Stage 3 meaningful use program and the growing amount of health-care data, he said. Further, pharmaceutical companies are really ready to make use of such apps to guide the appropriate use of drugs.

He also mentioned the introduction of a bill, Sensible Oversight for Technology which Advances Regulatory Efficiency (SOFTWARE) Act (H.R. 3303), introduced in October 2013 by Rep. Marsha Blackburn (R-Tenn.). This legislation would create three categories of software for health-care products, giving the FDA jurisdiction over only the category called ''medical software,'' defined in the bill as products that change the structure or function of the body or that are marketed for use by consumers and make recommendations for clinical actions. The other two categories under the bill are clinical software and health software (7 MELR 668, 10/30/13). Thompson is general counsel for the mHealth Regulatory Coalition, which wants lawmakers to take a ''wait and see'' approach for new legislation on health information technology (8 MELR 5, 1/8/14).

In November 2013, FDA released a list of device guidance documents that it expects to complete in fiscal year 2014, which began Oct. 1. Higher-priority guidances on the agency's ''A-list'' for fiscal 2014 include questions and answers about the CDRH's appeals process, the de novo classification process (used for 510(k) devices that lack a substantially equivalent ''predicate'' device already on the market), in vitro diagnostics and how to protect devices from cybersecurity threats.

With regard to the de novo classification process, Gunawardhana said she expects there will be ''more clearances/approvals through the de novo process and overall collaboration between the FDA and industry in areas where there is a medical need for innovative device solutions.''

**Laboratory Tests, Social Media Guidances?** Some attorneys told Bloomberg BNA that the FDA is likely to issue guidances on in vitro diagnostics, laboratory tests and social media.

According to Levine, the FDA's issuance of final guidance on ''Research Use Only'' tests in late 2013 (7 MELR 728, 11/27/13), its inclusion of DTC (direct-to-consumer) genetic testing draft guidance on its 2014 priorities (7 MELR 695, 11/13/13), and the recent warning letter to genetic testing company 23andMe (7 MELR 763, 12/11/13) ''all suggest that FDA may be increasing its regulation of promotional claims for certain types of in vitro diagnostic tests.''

''Companies that provide such tests will be struggling with how they can market and promote their products and services,'' he said.

Thompson said 2014 may bring the FDA's release of guidance on lab-developed tests as well as a guidance document on companion diagnostics. ''Overall, the diagnostics industry will get a lot of attention in 2014,'' he said.

**The FDA is expected to scrutinize the diagnostics industry in 2014.**

''The recent warning letter to 23andMe highlights the issue of the use of genetic information generally to improve our lives versus the use of information to diagnose or treat disease,'' Thompson said. ''The FDA had already announced that it was developing a guidance on wellness in 2014. That guidance can't be released soon enough.''

And Thompson said the FDA's recently released final guidance on ''Research Use Only'' tests ''may suggest that the agency is gearing up for enforcement.'' Indeed, he said, ''The warning letter to 23andMe might be the first example of that.''

Levine also predicted that the FDA is likely to take initial steps toward a strategy for regulating laboratory-developed tests. But, he said, because ''the agency is aware that efforts to regulate such tests are likely to be controversial,'' it is likely to ''tread lightly at first.''

Thompson said he expects the guidance will be issued, followed by ''fireworks.''

''The battle lines are drawn, and the publication of the guidance will cause war. But it's a war that needs to be fought. And, in doing so, we all must keep an eye on what is best for the patient.''

Gunawardhana also said the FDA is likely to issue guidance on laboratory-developed tests in 2014. But she said that whether the FDA issued guidance in this area is likely to depend on if the issue becomes a more dominant public health concern.

In addition, by July 2014, two years after FDASIA's enactment, the FDA must issue guidance on Internet promotion of FDA-regulated products, including the use of social media.

Most likely, there will be a draft guidance in the social media area that is device-specific, Wiley Rein's Gunawardhana said.

''Scientists, just as everyone else on the planet, are flocking to social media,'' Thompson said. ''In their case, they're using social media for scientific exchange. But when you throw a manufacturer into the pot, the risk of FDA enforcement regarding off-label promotion can chill the discussion. The FDA needs to figure out where exactly they would draw the line.''

But, he said, ''[W]hat we see [in the social media area] might very well be anti-climactic.''

''The agency has already been actively enforcing in this area, so we already know a fair number of FDA positions from reading warning letters. That said, there's

likely to be some nuggets in there that will surprise everyone, and almost certainly there will be controversy. Too much is at stake, and the FDA and industry are on very different pages.''

''Guidance on clinical decision support tools and general wellness software are the key missing pieces in the agency's regulatory approach to regulation of software,'' Levine said. But, he said, the FDA will likely move forward with at least draft guidance on this issue in 2014. ''In the meantime,'' he said, ''companies will continue to struggle to understand FDA regulatory requirements for such software.''

Thompson said the FDA's release of guidance on mobile medical apps in September 2013 (7 MELR 607, 10/2/13) ''was much ado about nothing.''

''There was really nothing remarkable in the guidance, and it really doesn't change anything the FDA is doing except perhaps to clarify the rules for those who are new to the process and expand the agency's use of enforcement discretion. That expansion of enforcement discretion will help entrepreneurs avoid FDA review for low-risk apps.''

**Old Guidance.** ''One thing that is guaranteed for 2014,'' Philbin said, is that the FDA ''will continue to rely on draft guidances as final.''

Thompson agreed. ''Of course, we will continue to see the FDA rely on draft guidances as finals.''

''By my calculation, there are over 300 draft guidances, the oldest of which is 22 years old. Indeed, almost a third of those are over five years old. I promise you FDA is not ignoring those guidances. They may not be specifically citing them, but you can bet they are being guided by them,'' he said. ''This is why it's so important that someone, for example Congress, hold the FDA accountable to moving these guidances from proposed to final.''

The FDA in 2014 will also work toward implementing a set of ''high priority'' recommendations from Booz Allen Hamilton, which conducted an independent review of the agency's device approval process. Among the problems the consulting firm found were inconsistent decisions by device regulators and a lack of staff training on new information systems. The review was required under the MDUFA commitments.

The assessment will occur in two phases. The first phase involves an examination of the device submission review process the FDA uses as a result of the MDUFA III negotiations with industry, including the refuse to accept (RTA), substantive interaction (SI), interactive review (IR) and missed MDUFA decision (MMD) communication. The first phase also includes an assessment of the agency's IT infrastructure, training and retention policies and practices.

The FDA said it will publish an implementation plan within six months, or June 2014. Booz Allen will publish its final comprehensive findings and recommendations at the same time, the agency said.

The second phase will evaluate the FDA's implementation of selected recommendations from the first phase, the agency said. The contractor for the second phase will evaluate the implementation and publish a written assessment no later than Feb. 1, 2016, the agency said.

**Medicare Coverage.** The devices industry in 2014 also will be dealing with a new regulatory landscape concerning Medicare reimbursement and coverage decisions.

Jenny Gaffney, director in the reimbursement and product commercialization services practice at consulting firm Avalere Health LLC, told Bloomberg BNA that because of increasing coordination between the FDA and the Centers for Medicare & Medicaid Services, device manufacturers need to have two sets of evidence right from the start. Just because a device is cleared by the FDA doesn't necessarily mean Medicare will cover it for reimbursement.

''Companies are getting a wakeup call that the evidence bar is much higher out of the gate,'' Gaffney said. ''Manufacturers will need a higher quality of evidence.''

For example, the CMS in November 2013 opened a national coverage analysis (NCA) to determine if coverage of a transcatheter mitral valve repair (TMVR) device is reasonable and necessary. Gaffney said one such device, which has already been approved by the FDA, hasn't had nearly as much lead time to generate evidence in clinical trials as other devices, ''but the gates are being set up a lot faster that companies have to hurdle over.''

**Device manufacturers will need to start preparing for a 2015 change in how devices cleared under the investigational device exemption category will be reimbursed.**

Device manufacturers in 2014 also will need to start preparing for a 2015 change in how devices cleared under the investigational device exemption (IDE) category will be reimbursed under the Medicare physician fee schedule. The new policy states that the IDE Medicare coverage decision will be made centrally by the CMS. Currently, manufacturers or study sponsors can go to individual Medicare contractors to request coverage for IDE clinical trials, Gaffney said. But the new policy means that the CMS's decision to cover a device under Medicare will be universally effective across jurisdictions.

''Manufacturers like not having to go contractor to contractor,'' Gaffney said. It may lessen the burden of evidence needed to get a coverage determination and improve the predictability of the process. But under the current system, each decision is localized. ''It's not an all or nothing decision,'' Gaffney said.

The new policy leaves all kinds of questions for manufacturers in 2014 about what the transition process will look like, Gaffney said.

Gaffney said manufacturers also are waiting for the CMS to finalize its guidance on coverage with evidence development (CED). An increasing number of devices are being covered through the CED process, and Gaffney said there is little doubt about how the process will be used going forward. In two specific examples, devices or procedures that had ''robust bodies of evidence'' were covered only by using CED, Gaffney said.

  MELR ISSN 1935-7230

In October 2013, the CMS said it will only cover one positron emission tomography (PET) scan per beneficiary under CED to rule out Alzheimer's disease in narrowly defined diagnoses. And in 2012, the CMS used FDA-approved post-approval trial data to cover transcatheter aortic valve replacement (TAVR).

CED is used in instances when there is some evidence of medical benefit but more data are needed before a coverage decision can be made. The agency published a draft guidance in November 2012 that broadened the potential use of CED, and also introduced potential interactions between the CMS and the FDA in support of CED.

To help ease the collaboration between the CMS and the FDA, the agencies launched a parallel review pilot program in October 2011 as a voluntary way for companies to reduce the time between FDA market approval and CMS national coverage determinations (NCDs) for medical products. In late December 2013, the agencies extended the pilot for an additional two years.

Yet the program hasn't been widely used, and Gaffney, as well as AdvaMed's Nexon, said that isn't likely to change. Only two companies have announced that they are participating in the parallel review pilot program; Exact Sciences, which is seeking approval of a colorectal cancer screening test, and Medtronic, which is seeking approval of the Simplicity renal denervation system for treating hypertension.

''People have kept their distance from parallel review,'' Gaffney said. ''There's no proof that it's a beneficial process.''

''Parallel review is a promising step, but there's lots of kinks to work out,'' Nexon said.

According to Gaffney, the agencies are going to be collaborating more regardless of participation in the pilot. Also, there is ''only a small section of [devices] where the process will be useful. Unless you have a national non-coverage decision,'' parallel review won't really help, Gaffney said. ''It is the shiny object of coordination.''

Hall of FaegreBD said he expects to see more efforts from the CMS to link coverage decisions with approval and postmarket data. Historically, Medicare has used that kind of data to see if a device causes harm. In the future, postmarket and approval data should be used for covering expanded use of a device.

Hall said there also is a concern that the CMS may base its coverage decisions on cost effectiveness instead of clinical effectiveness. ''CMS will continue to focus on cost, but FDA should not. Whether it sinks into industry decisions—that will be important,'' Hall said.

Attorney Bethany J. Hills, of Epstein Becker & Green in New York, told Bloomberg BNA that there will be ''a continued emphasis on superiority for reimbursement coverage determinations and the need for comparative effectiveness results will shape how device companies deal with the convergence of payer, regulatory and provider pressures.'' Indeed, Hills said, ''companies will likely need to demonstrate superiority in clinical trials. This is a different standard than is often required in the FDA process.''

Device companies may even consider conducting defensive clinical studies to frame any competitor's studies, she added. The FDA's proposed rule in February 2013, titled ''Human Subject Protection; Acceptance of Data From Clinical Studies for Medical Devices,'' is another piece of evidence that the CDRH is continuing to focus on this issue, she said.

**Care Coordination.** The Affordable Care Act emphasizes quality of care and evidence-based medicine. So as providers deal with the new focus by integrating and forming accountable care organizations (ACOs), there will be implications for device makers.

One of the ACA's major developments was its intent to transform the health-care delivery system through the formation of ACOs, which are intended to allow integrated networks of providers to share in the risks and financial rewards of keeping a select group of patients healthy. An ACO may receive payments for shared savings if it meets certain quality performance standards and cost savings requirements.

ACOs aim to improve the quality and lower the cost of health care through several mechanisms, such as disease management programs, care coordination, and aligning financial incentives for hospitals and physicians. Many are focused on Medicare beneficiaries, but there are a growing number of similar arrangements in the private sector, as well. ACOs are generally a collaboration between hospitals and physicians, or are exclusively physician-run or hospital-run.

There have been about 250 Medicare ACOs established under the (Medicare Shared Savings Program) MSSP, and about half are physician-run. The initial terms of the ACO contracts were required to be at least three years, and Blair Childs, vice president of public affairs at the Premier health-care alliance, said he expects new regulations from the CMS in 2014 in advance of the second round of MSSP contracts in 2015.

Aside from ACOs, there are various delivery and payment reform demonstration projects being tested by the CMS's Center for Medicare and Medicaid Innovation (CMMI). One of the larger demonstrations that providers are looking to in 2014 is the Bundled Payments for Care Improvement (BPCI) initiative.

Medicare makes separate payments to providers for the services they furnish to beneficiaries for a single illness or course of treatment, leading to fragmented care with minimal coordination across providers and health care settings. Payment is based on how much a provider does, not how well the provider does in treating the patient. The BPCI initiative is aimed at providing more coordinated care and reducing costs by paying providers a lump sum for a patient's entire episode of care, according to the CMS.

**Changing Dynamics.** These new provider relationships represent a ''new and challenging payer environment'' that device manufacturers will have to navigate, AdvaMed's Nexon said. ''The ACA put in payment methods to assume risk—we think it's a positive trend. But we have concerns that a new emphasis on cost control could stint on care'' and patients wouldn't be able to get access to important technology.

The worry is that providers may be concerned about containing costs more than the value of the technology, Leahey of MDMA said. He said manufacturers have a ''great opportunity to educate [providers and lawmakers] on the value of medical technology.''

Nexon said if cost is a concern, the provider needs to look at the lifespan of the device. It may not represent a higher cost down the road, just at the particular point of measurement. But the cost reporting periods for providers participating in initiatives like ACOs don't necessar-

ily take that into account, he said. Manufacturers ''are coming to grips with these changes.''

According to Gaffney, ''the customer base is shifting for devices. [Manufacturers] can't play to physician preference anymore.''

Gaffney agreed that as a result of provider integration, ''the way companies are framing the value proposition of products is changing. They have to look at effectiveness across a broader timeframe. Providers are not looking at the immediate impact,'' she said, adding that they want to know ''What is the evidence over time? Will the patient be able to be discharged faster? Timeframe questions weren't being asked before, but now that you have bundles pushing the timeframe, manufacturers have to look 30, 60, 90 days down.'' This ''creates a need for field teams to be much more sophisticated'' in how they demonstrate and market the devices, she said.

In addition to changing the quality and type of evidence, the delivery system reforms are also forcing manufacturers to change how they approach research and development, Gaffney said. Device companies have to ''think beyond their products,'' she said.

For example, Gaffney pointed to Medtronic Inc.'s August 2013 acquisition of Cardiocom, a remote patient monitoring and disease management company.

''Ten years ago, cardiac monitoring was viewed as something with limited reimbursement,'' Gaffney said. ''But the reality with bundled payment is hospitals are financially accountable on new measures like care transitions and preventable readmissions.'' Device companies are recognizing their products need better analytics to help hospitals in the new environment, Gaffney said.

Price transparency is a big issue, Hills said. ''As providers are pressured to make their costs transparent (even when those costs do not accurately reflect amounts paid by any payer), every expenditure is scrutinized. Device companies need to justify the value of their products beyond competitive comparisons to demonstrate improved outcomes and non-monetary value.''

''The medical device tax and the Sunshine Act are direct results of the ACA that have an immediate reimbursement impact,'' she said.

''Device sales and marketing staff are often pressured to provide reimbursement solutions to purchasers,'' Hills said. ''When the pressure to provide reimbursement advice and solutions is high, there is an increased risk that suggested solutions will push the bounds of FDA approvals or proper reimbursement channels.''

And Mike Bell, of consulting firm R-Squared Services & Solutions Inc. in Princeton, N.J., told Bloomberg BNA that the ACA brings both challenges and opportunities for device manufacturers. ''Millions of previously uninsured Americans will have insurance and access to care, and consequently medical devices,'' he said. ''The challenge and opportunity for device manufacturers will be how best to reach and compete for this new population.'' Because the Department of Health and Human Services has clarified that the new health-care exchanges aren't federal health-care programs as that term is defined in fraud and abuse laws, he said, ''patient co-pay and financial support programs are freed from the complexities of the anti-inducement [civil monetary penalties] law and the kickback statute, and will be subject only to the rules (many nonexistent) of the sponsoring plan.''

**Enforcement Trends.** With regard to enforcement trends affecting device makers, Levine said 2014 may bring one or more court decisions addressing the validity of the False Claims Act theories underlying whistleblower lawsuits and government investigations. ''There are numerous qui tam lawsuits under investigation or in litigation alleging violations of the FDA's device regulations, such as failure to file Medical Device Reports (adverse event reports), failure to submit Correction and Removal Reports, failure to seek 510(k) clearance for product modifications, and failure to adhere to the Quality System Regulation,'' he said.

Attorney Kathleen McDermott, of Morgan, Lewis & Bockius LLP in Washington, predicted an increase in investigations related to quality issues, including manufacturing, clinical compliance and other FDA regulatory compliance issues.

And attorney Mark Langdon, of Sidley Austin LLP in Washington, said 2014 ''likely will see an increase in False Claims Act and similar state cases brought against device companies, predicated on kickback violations, quality of care issues, and off-label promotion, among other areas.''

**An attorney expects an increase in false claims cases against device companies, predicated on violations including quality of care and kickbacks.**

''Off-label promotion will continue to be a major issue, both because the legal consequences are so significant, but because the need to communicate with physicians is growing as well,'' Thompson said. ''The tension here makes for very high stakes as companies try to figure out how to legitimately promote their products and legitimately collaborate with physicians to identify innovative new uses for products, while avoiding legal violations.''

McDermott predicted 2014 would bring ''[i]ncreased litigation of whether regulatory violations may comprise a false claim and, if so, what is the parameter of such a theory.''

Moreover, she said, ''The conventional approach of express and implied certification related to conditions of payment or participation is wearing thin as a predictable judicial benchmark under False Claims Act jurisprudence. Generally, the judicial decisions appear to be concerned whether the alleged violation is material to payment.''

And she said, the *United States ex rel. Nathan v. Takeda Pharm. N. Am.* case, U.S., No. 12-1349, *petition filed* 5/10/13, which is awaiting a decision on certiorari from the Supreme Court, involves a Federal Circuit court split concerning the level of specificity about false claims that must be alleged in an FCA complaint. Not only is the case of interest for its articulation of the Federal Rule of Civil Procedure 9(b) standard, she said, but also it is a case that challenges to what extent a regulatory violation may be pled as a false claim and, if so, what must constitute sufficiency for pleading.

  MELR ISSN 1935-7230

McDermott also predicted that other False Claims Act litigation will focus on interpreting amendments related to the scope and definition of claims. And, she said, whistle-blower ''litigation will explode, providing opportunities to litigate the duration of seals, public disclosure and other important process issues.''

Langdon said the government may also focus enforcement energies on companies' so-called value-added programs. ''I think we will see a heightened interest and governmental scrutiny of 'value added' and other similar programs offered by manufacturers, as companies are not competing as much on price anymore, and are trying to drive home the value proposition to customers in other ways,'' he said. ''Such programs, if properly structured, can be defensible, but we have seen the government become aggressive in targeting types of these programs in the pharmaceutical arena.''

Epstein Becker & Green's Hills said ''one area that could be the next target for False Claims Act expansion is the area of device modifications that have not been submitted to the FDA for a new 510(k).''

Discounting, rebating, bundling, and similar practices ''could be subject to increasing attack by aggressive enforcement officials in the coming years, if developments in the pharmaceutical arena are any indication,'' Langdon said.

And Hills said that state attorneys general ''should be on the radar of every medical device company.''

''They are increasingly using the False Claims Act (and parallel state statutes) to pursue Medicaid dollars. I think that once the Sunshine Act detail is available publicly, these databases will become the basis for state attorney general investigations.'' She predicted that the current AG focus on drug and food labeling will ultimately shift to device labeling. ''Labeling and advertising is a natural fit for their existing areas of expertise, although often in different industries,'' she said. ''State AGs appear to be using experience in linking Medicaid payment to only approved uses of drugs to making a similar link [in the device arena]—arguing that Medicaid payments for medical devices are conditional upon the scope of the FDA approval.''

And Bell also said reporting by companies of their payments to physicians under the federal Physician Payments Sunshine Act will be a compliance focal point for device companies in 2014. ''Device manufacturers will be reporting for the first time ever data to CMS under the federal Sunshine Act,'' he said. ''Consequently, manufacturers must ensure that their processes and systems are in order, including means to resolve disputed spend items with their customers.''

''Sunshine Act and state reporting laws, and compliance with these laws, will be a critical area of focus for companies as well,'' Langdon said.

**The Sunshine Act's reporting requirements in 2014 will be a critical focus for device companies.**

And attorney Peter Kazon, with Alston & Bird LLP in Washington, agreed. Physician sunshine regulations ''will impose a significant reporting and tracking obligation on all providers,'' he said.

With regard to the implementation of the Sunshine Act, Philbin said ''[i]t is possible the government may show some leniency during this first year of reporting if companies fall short in their compliance efforts,'' but added that ''no one should count on that.''

Bell also noted that, in addition to the Sunshine Act's requirements, device manufacturers have evolving transparency reporting requirements in other countries such as France and Japan.

Other attorneys predicted increased enforcement of the Foreign Corrupt Practices Act.

''With increased enforcement of the FCPA, the enactment recently of anti-corruption and transparency laws in other countries, heavy reliance in third parties ex-U.S., the steep costs of an investigation, the costs of a government settlements and piggy-back shareholder derivative suits, and the disruption of post-settlement integrity obligations, device manufactures appropriately are focusing on establishing and improving upon global fraud compliance,'' Bell said.

Another emerging enforcement issue relates to 3D-printed medical devices, Jake M. Holdreith, of Robins, Kaplan, Miller & Ciresi LLP in Minneapolis, said. The FDA is investigating these devices, he said. The ease of copying 3D printing where you can simply take images of a product and print direct physical copies of it raises counterfeiting, quality, toxicity and other concerns, he said.

**Office of Compliance Reorganization.** Some attorneys predicted that in 2014, there could be more emphasis on promotional issues with CDRH's Office of Compliance's reorganization, including more warning or untitled (notice of violation) letters from the FDA.

''We may see a surge in compliance activities including warning letters'' in the area of television and print advertising and promotion of medical devices as a result of the reorganization, Wiley Rein's Gunawardhana said.

The FDA's reorganization of the Office of Compliance ''to include an advertising and labeling focused division is a key indicator of the FDA's focus in this area,'' Hills told Bloomberg BNA.

''Any reorganization has an impact on industry,'' Hills said. ''We are already seeing this impact on clients, particularly those with open action items or ongoing discussions with the FDA.'' Unfortunately, she said it sometimes ''becomes unclear where decisions are being made and who is taking responsibility.''

So far, she said, ''the FDA staff involved have been good about communicating with device companies.'' But, she said, ''delays in decisions are occurring.''

**Case Developments to Watch.** And attorneys told Bloomberg BNA that the device industry should be on the lookout for developments in key cases in a variety of areas, including advertising and patents.

Off-label promotion/First Amendment decisions ''are always highly anticipated, particularly since this is an unsettled area of the law,'' Bell said.

Kazon said the industry should be on the lookout for developments regarding the patentability of genes. In *Association for Molecular Pathology v. Myriad Genetics, Inc.*, decided by the Supreme Court in June 2013, the high court ruled that isolated DNA isn't eligible for patenting but that genetic materials created ''synthetically'' are patent-eligible.

More generally in the patent area, Holdreith said to watch for the *Medtronic, Inc. v. Boston Scientific Corp.* case now before the Supreme Court (7 MELR 712, 11/13/13). ''The issue is who bears the burden of proof when a manufacturer under a patent license introduces new products and the parties dispute whether they practice or avoid the patents and therefore bear a royalty under the license.''

Also, he said, *CLS Bank Int'l v. Alice Corp. Pty. Ltd.*, U.S., No. 13-298, *review granted,* 12/6/13, another case pending in the Supreme Court, concerns whether and when an invention embodied in software is patentable. Although the technology in that case isn't medical, Holdreith said, ''the issue could affect computerized methods used in the medical industry including records systems, diagnostic algorithms, and embedded software in devices.''

Holdreith also said the U.S. Court of Appeals for the Federal Circuit's decision in *Commil USA, LLC v. Cisco Sys., Inc.,* No. 2012-1042, *en banc hearing denied* 10/25/13, is likely to affect the assertion of induced patent infringement claims against surgical methods. In *Commil*, a divided appeals court panel held that invalidity assertions could negate the intent element of induced infringement. ''Because doctors enjoy a defense to liability for infringement under 35 USC Sec. 287(c), it can be important to holders of patents on methods of using medical devices to charge a competing manufacturer with inducement to infringe such a method,'' he said. ''The *Commil* decision has created a new defense in such a situation, making it harder to enforce the patent against the competing manufacturer.''

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  MELR ISSN 1935-7230