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Legal Outlook

Changes in FDA Processes, Enforcement Will Be Hot Topics in New Year, Experts Say

According to some members of the advisory board of *BNA's Medical Devices Law & Industry Report*, 2011 could see big changes in the way devices are developed, approved, and paid for, as well as a continued uptick in Food and Drug Administration enforcement actions.

Bethany J. Hills, of Hodgson Russ LLP in Albany, N.Y., for example, said the country is ''on the path for potentially drastic changes to the device system.'' She said that, if even half of the proposals made by FDA in 2010 regarding premarket clearance of devices are adopted, ''the impact on the device industry as we know it will be significant.''

But Stephanie Philbin, of Goodwin Procter LLP, Washington, said that numerous concerns and criticisms of these FDA proposals have been raised, especially on Capitol Hill. ''The agency appears to be taking a close look at these issues,'' she said, and is more likely to implement ''the less controversial proposals and, hopefully, rethink the proposals that are unproductive.'' Philbin added that a proposal to increase training of FDA reviewers ''is a step in the right direction.''

Section 510(k) Proposals. Among the proposals made in 2010 was a long-awaited plan to improve the Section 510(k) clearance process. The most common review path for lower-risk devices, the 510(k) procedure is used for devices that are substantially equivalent to other legally marketed devices.

Hills noted that a major guidance on modifications to devices is forthcoming that contains fundamental changes to the way devices are evaluated to assess whether there is a need to file a new 510(k) based on a modification. (According to FDA documents, the draft guidance will be released June 15.) She predicted that implementing this new guidance ''is going to be very difficult for companies in the upcoming year.''

Greg Levine, of Ropes & Gray LLP in Washington, agreed that Section 510(k) changes will be an issue to watch in 2011, while Michael Gaba, of Holland & Knight in Washington, expressed concern that the changes may get caught in a political tug-of-war.

''In a Washington where both houses of Congress and the White House are controlled by Democrats, one would expect the FDA to continue to develop and implement plans to refine the 510(k) process, creating subclassifications that require clinical data—in essence a more rigorous review process. But that world, which existed during the first two years of the Obama administration, exists no longer. With a Republican-controlled House, determined to conduct more oversight of the FDA, we can expect at best of tug-of-war on this issue. The new House leadership already has expressed concern over 510(k) modifications that would slow innovation and [lengthen the amount of time it takes to bring] products to market,'' Gaba said.

Bradley Merrill Thompson, of Epstein Becker & Green PC, Washington, and James R. Ravitz, of Arent Fox LLP, Washington, both expressed concern about particular proposed modifications to the 510(k) process. Thompson cited the proposal to clarify when a device no longer should be available for use as a predicate device, and Ravitz referred to the proposal to create a class IIb for devices for which more information (such as clinical information) or post-market evaluation would be needed to support a substantial equivalence determination.

In a Jan. 19 announcement regarding key changes to the 510(k) process it plans to implement in 2011, FDA said action on those two proposals would be deferred pending the completion of an Institutes of Medicine report.

Hills said the ''more intriguing'' changes to FDA procedures are those being made as a matter of policy, rather than as official guidance. For example, some of the industry's chief complaints have concerned a lack of

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transparency during FDA's 510(k) review and the inability to predict what the agency will do. This could only get worse, since, in light of official reaction to its proposals, it now ''seems plausible that the FDA will approach the changes by making internal policy changes in how products are reviewed without changing the statute, regulations, or guidance,'' she said.

Ravitz said there has been no improvement in resolving problems observed by *MELR*'s advisory board members last year concerning delays in obtaining clearances and requests for more information from regulators.

Parallel Review. According to Gaba, another change to the FDA review procedure that ''should be monitored throughout 2011'' is the new parallel review process by which medical products will be reviewed by both the Food and Drug Administration and Centers for Medicare & Medicaid Services (CMS).

The agencies have stated that the intent of parallel review is to reduce the time between FDA market approval and CMS national coverage determinations (NCDs) of a medical product. Under the proposed pilot program, which the two agencies announced in a September 2010 *Federal Register* notice, medical products such as drugs and devices would be reviewed concurrently by both agencies (75 Fed. Reg. 57045).

But Gaba said that, ''although the roots of better coordination and data sharing among the [health services] agencies date back to former Health and Human Services Secretary Tommy Thompson and his vision for 'One HHS,' one should expect publication of the [notice] and the ultimate implementation of the same, to be slowed considerably by the new Republican majority in the House.'' Gaba added that senior House staffers already have told FDA that lawmakers ''are concerned that a parallel review may unnecessarily inject CMS into FDA's jurisdiction.''

Hills also sees the FDA/CMS joint review process as ''significant.'' She said device companies ''should not only be aware of it as an option, but also as a ''potential change to the fundamental way products reach the market.''

Hills noted that limiting reimbursement for devices (and drugs) may be the ''most politically acceptable way'' of changing the health care reimbursement system. ''Ultimately, the squeeze on front-end reimbursement, combined with increased enforcement using unique and questionable False Claims Act theories and expanded FDA criminal and civil tools, will fundamentally change the way devices are conceived, delivered, and reimbursed in the United States,'' she said.

Enforcement Issues. The major issue in 2010 was FDA's announcement that it was going to step up its enforcement game and even begin bringing criminal charges against device companies and their individual officers and directors. Board members predicted more of the same for 2011, but they warned that differences between the device and drug industries, where such enforcement actions have been more prominent, may have an effect on the success of FDA's efforts.

In addition, most board members said device companies have learned from their drug industry brethren. Kathleen McDermott, at Morgan Lewis & Bockius LLP in Washington, said ''there has been a sea change in compliance in the device industry.'' While ''there is still some distance to travel, industry compliance efforts are very different today than they were five years ago in a positive way,'' she said.

McDermott also warned that ''off-label issues'' in the device industry differ from those in the pharmaceuticals industry ''because of the significant distinctions in product development, approval and clearances, and use.'' Still, ''it is an area for compliance advancement,'' she said.

Philbin agreed that device companies have taken steps to avoid enforcement issues. ''Among other things, device companies have adopted corporate compliance initiatives and undertaken training programs,'' she said. Philbin added that a ''healthy company is one that has strong groups or departments that are fully functional and in the mix, e.g., a regulatory group that is reviewing manufacturing changes, a legal department that is reviewing product claims, etc. Importantly, company management needs to ensure all parts are functioning well.''

Ravitz said he thinks ''device companies have heeded the warning signs and have improved their compliance-related activities.'' He pointed to sales training as a ''key component in compliance.''

Ravitz noted, however, that drug companies ''still seem to be the primary focus'' of FDA's enforcement initiative. ''The drug industry is just a larger and 'richer' target,'' he said.

But Hills said differences in the legal and regulatory structures also may make it easier for FDA to go after drug companies. ''Particularly for 510(k) cleared devices, where the concept of 'off-label' has evolved entirely through FDA policy—and no official guidance—the law and regulations have remained quite vague and have historically provided a fairly broad interpretation of cleared intended uses, as opposed to indications for use.''

Still, while the ''device system is not a mirror of the drug system, both FDA and outside enforcement agencies are more regularly applying drug-type standards to devices,'' Hills said. ''It may not be a fair interpretation of the current legal structure, but device companies can no longer ignore that they, too, have become a target.''

Thompson disagreed that device companies are doing enough to avoid FDA scrutiny. He said, ''Of course some medical device companies have'' stepped up compliance efforts,'' but said he ''fear[ed] the vast majority of them have not taken any material steps to really try to reduce the risk.'' Thompson noted that ''there are pockets of companies that have already been the subject of some enforcement actions that are taking it more seriously.'' And, he said, ''developing comprehensive and well-reasoned good promotional practices, then training personnel in those practices, remains the best way for companies to manage their compliance risk.''

Criminal Indictments Likely? In 2010, FDA officials threatened to start bringing criminal charges against executives of noncompliant companies and, in fact, filed an indictment against a former drug company in-house counsel. Thompson said this could happen in the device area as well, but doubted it would be soon or on a very large scale.

''FDA made so much noise about this that they would be frankly embarrassed if they did nothing,'' he said. Thompson added that he could ''see the government making an example out of a couple of people, but not pursuing it on any large scale.'' The same was true of

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exclusions, he said. ''The legal authorities are different, and the business practices are different'' between the drug and device industries, he said, adding that he ''hasn't seen any movement in that direction.''

Hills said that while ''it's less likely and very case specific . . . the potential [for exclusions] is there.'' She explained that the amount of money involved in device cases is lower, and the legal standards are different, making it harder to exclude device company executives. But an exclusion could be included in a settlement, she said.

''The opportunity for HHS Office of Inspector General or FDA exclusion is a prominent threat in any civil or criminal investigation,'' McDermott said, adding that ''the new emphasis on individual exclusions will alter how investigations are defended and resolved.''

McDermott predicted, however, that ''the practice of seeking exclusion against individuals completely uninvolved in the suspect conduct will eventually be a discredited exercise of enforcement discretion and will be less used by the Department of Justice where there is a level playing field with impartial federal judges.''

''Frequent use of the *Park* doctrine,'' under which misdemeanor criminal charges may be brought against any person in a company who has any responsibility over the suspect conduct, whether they knew of it or not, ''will not promote effective compliance in the health industry,'' McDermott said. She pointed out that the *Park* doctrine, named after a decision of the U.S. Supreme Court, *United States v. Park*, 421 U.S. 658 (1975), is ''intended for rare use.''

Still, Ravitz said, the *Park* doctrine ''could certainly be a powerful tool to incentivize for compliance.'' As for exclusions, he said FDA already has levied exclusions against a couple of executives of a Switzerland-based orthopedic device company based on off-label marketing. Ravitz predicted ''more use of exclusion in enforcement actions because a threat to one's livelihood is a great way to motivate the executives and corporate decision-makers.''

Philbin, while agreeing that the threat of criminal prosecution or exclusion ''should compel more compliance,'' cautioned against making generalizations. ''Each case has its own facts and nuances,'' she said, ''so one cannot necessarily draw parallels between different cases.'' Philbin said ''we will just have to wait and see'' whether the government will bring criminal cases against device company executives.

False Claims Act. ''Resolving and avoiding government enforcement actions initiated by whistleblower complaints'' will be a big issue in 2011, according to Levine and others.

One trend observers are watching is that of basing False Claims Act (FCA) complaints on deviations from FDA's quality standards regulations. ''The trend to look at regulatory deviations as quality of care issues will be a major enforcement theme in the health industry overall, including the device industry,'' McDermott said. ''Violating regulations designed to insure safety and quality has potent potential for enforcement and health policy, and the device industry will be impacted in hospital practices, as well as in manufacturing practices,'' she said.

Hills added that this trend already has been tested, and rejected, in the traditional health care provider environment. However, she said, ''there is a fundamental difference'' between device companies and health care providers: the providers do not face national exposure and national competition.

''Given the significant impact an FCA investigation can have on a company's sales and stock prices (a factor often ignored by enforcers arriving at a final settlement amount), it is often more attractive for device (and drug) companies to settle with an enforcement agency rather than push the issue to a court decision,'' she said. ''This is an unfortunate position,'' Hills added, ''because device companies could potentially be successful based upon existing precedent if these claims actually go to court.''

Another FCA-related issue is the Department of Justice's use of FCA investigations to flag suspected Medicare abuses—as seen in recent settlements by hospitals that were accused of overcharging the federal government for kyphoplasty procedures.

Hills said the success of the kyphoplasty initiative ''has emboldened'' federal prosecutors to use the FCA in this fashion, but that the impact on hospitals is more severe than the impact on device companies, simply because hospitals are subject to more government audits than device makers. Still, she said, ''additional DOJ-based audits can be confusing when evaluated in light of other audit initiatives and are frustrating because negotiations start from an FCA-treble damages perspective.''

McDermott suggested that, in light of amendments made to the FCA in 2009 and 2010, ''DOJ should update its FCA guidance and undertake training and monitoring efforts to assure the principled use of the statute.'' The government ''should not repeat the 1990s mistake of national cookie cutter initiatives and industry enforcement initiatives that diminish the principled exercise of individual enforcement discretion,'' she said. ''Each case should be judged solely on the evidence actually developed.''

McDermott added that ''DOJ should also avoid issuing high rhetoric press releases, especially for civil fraud settlements that it knows are in genuine dispute.''

Intellectual Property. Two advisory board members, Andrew E. Rawlins of Foley & Lardner LLP in Washington, and Keith Barritt, of Fish & Richardson PC in Washington, raised intellectual property-related issues device company attorneys should be watching in the coming year.

Barritt, who practices trademark law as well as medical device law, noted that ''2010 saw a flurry of lawsuits alleging false advertising of various products regulated by FDA,'' including medical devices. For example, he said, there was *Photomedex v. Irwin*, 601 F.3d 919 (9th Cir. 2010), in which a competitor in the market for eye laser surgery devices accused the device maker of falsely stating that its product was ''FDA approved'' or ''FDA authorized,'' when FDA had not officially cleared or approved the modified device.

''The Ninth Circuit affirmed a summary judgment for the device maker after finding that the claim came within FDA's exclusive jurisdiction,'' Barritt explained. However, the court also said a Lanham Act false advertising claim could have been pursued if the company had falsely claimed that FDA authorization had been obtained for the device, when no such authorization had been issued for any version, and FDA had taken no

enforcement action to stop the marketing of the modified device, he said.

More recently, the U.S. Court of Appeals for the Federal Circuit held that the color blue, used in a surgical device, was not entitled to trademark protection, *ERBE Elektromedizin GmbH v. Canady Technology LLC*, Fed. Cir., No. 2008-1425, 12/9/10. The maker of the device was unable to overcome a showing that the color was functional, as the color was used to allow surgeons to distinguish the device from body tissue.

''The interest of plaintiffs seeking to restrain competitors by alleging violations of the Federal Food, Drug and Cosmetic Act will likely continue, despite the hurdles such claims face,'' Barritt said.

Rawlins, a patent attorney, pointed out two cases device companies should be monitoring. In the first, *Microsoft v. i4i LP*, U.S., No. 10-290, the U.S. Supreme Court granted a petition for a writ of review Nov. 29, 2010, on the question of whether the standard for patent validity should shift from clear and convincing evidence to a preponderance of evidence when a defense of invalidity rests on prior-art evidence that was not considered by the Patent and Trademark Office.

The second case, Rawlins said, ''has a particular slant toward the medical sector.'' In *Prometheus Laboratories Inc. v. Mayo Collaborative Services*, Fed. Cir., No. 2008-1403, the U.S. Court of Appeals for the Federal Circuit held in December that claimed methods for calibrating the proper dosage of a drug for treating autoimmune diseases are patentable subject matter under Section 101 of the Patent Act.

Rawlins said a petition for review by the Supreme Court is expected in the *Prometheus* case on the issue of what subject matter is eligible for patent protection.

Mobile Devices, Other Issues. Both Barritt and Levine said FDA regulation of medical-related software, particularly mobile devices, is expected in 2011. Barritt said ''FDA anticipates releasing a final guidance document in 2011,'' and that the draft guidance, released in 2007, ''contains a reference to a myriad of issues that manufacturers are supposed to consider that are so numerous as to be nearly overwhelming.''

''In order to encourage manufacturers to embrace wireless technologies, with all of the potential for efficiency and improved care that they offer, the FDA will need to provide more comprehensible, actionable guidance,'' Barritt said. A memorandum of understanding FDA reached with the Federal Communications Commission might help streamline the regulatory process for wireless medical devices, he said. But, in the meantime, ''some manufacturers are moving forward with wireless devices, including devices that are clearly exempt from the 510(k) program,'' he said.

Hills and Levine said the ramifications of the Physician Payment Sunshine Act will be felt in 2011. The adoption of the federal law and complementary state laws ''is a major trend that will begin to impact device companies this year,'' Hills said. ''The internal effort needed to address this from a practical standpoint are enormous and require a significant amount of compliance oversight and effort,'' she said.

Thompson said he does not think the impact of the Patient Protection and Affordable Care Act on medical device companies ''will be terribly great.'' The law is ''much more significant for the drug industry,'' he said.

But Hills said the ''device tax included in the health reform bill cannot be underestimated.'' Hills predicted changes in medical device pricing in 2011 and 2012 to address the anticipated tax. ''At the very least,'' device companies should make ''a concentrated effort . . . to evaluate the impact of the tax and determine how it will affect research and development and other 'funded' lines within the company,'' she said.

Hills added that the movement to adopt uniform device identification systems also will gain ground in 2011. ''It too will take a significant effort to implement and, with substantive FDA guidance lacking, will require high-level regulatory decision making to ensure it is implemented effectively,'' she said.

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