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## Legal Outlook

### **Medical Device Law Experts Predict Issues Expected to Gain Momentum in Coming Year**

**M**embers of the advisory board for BNA's *Medical Devices Law & Industry Report* recently shared their views on issues sure to be on the minds of the medical device industry players this year.

The issues range from the future of the Food and Drug Administration, now solidly under the leadership of new Commissioner Margaret A. Hamburg, to new devices and improvements likely to be introduced in 2010, such as wireless devices.

Health reform, naturally, is on everyone's mind, though the medical device industry is narrowly focused on certain provisions within the pending legislation, such as those concerning comparative effectiveness. As of this writing, the health reform bill had not been finalized, and its prospects were cast in doubt by the Jan. 19 special Senate election in Massachusetts that caused the Democrats to lose their 60-seat supermajority.

By far, however, the most pressing concern is how the FDA will exercise its regulatory and enforcement authority in the coming year.

**FDA Enforcement Activity.** A number of board members said they expect FDA enforcement activity to grow across the board. For example, Bradley Merrill Thompson, of Epstein Becker & Green PC in Washington, predicted that FDA enforcement activity will increase in 2010. "For years, [FDA] talked about it, but it appears that this year they're likely to take it up by two or three notches," he said.

Michael M. Gaba, of Holland & Knight LLP in Washington, said that "with new leadership at the FDA, we can expect greater enforcement activities." He added that the "agency is under immense pressure from Congress to ensure the industry is producing safe and effective technologies."

Judith K. Meritz, at Baker Donelson in Washington, cited the increases "in inspection staff at the FDA field offices" and in compliance staff at the agency's headquarters as supporting her belief "that FDA enforcement will increase." She said that "the directives and the attitudes that we have heard from both Commissioner Hamburg and [Principal Deputy Commissioner Joshua] Sharfstein" have led her to expect a rise in inspections and warning letters.

"This is not a bad thing," she added, "as it works to put all companies on guard to beef up their quality and compliance activities and review their policies and procedures to ensure that the products that are manufactured and distributed are the best that they can be. It is important that companies understand that the FDA will work with them in these tough economic times; however, the challenge will be to understand the FDA's concerns and develop ways to address these."

One specific area likely to see more enforcement activity this year is off-label advertising and marketing. While the agency has stepped up efforts to rein in off-label promotions in recent years, prohibited advertising practices are "becoming more and more of an issue," according to Bethany J. Hills, of Hodgson Russ LLP in Buffalo. FDA's "interaction with the Department of Justice" may result more and more in the "dovetailing" of off-label cases with False Claims Act prosecutions, she said.

Hills added that "recent trends in off-label cases for drugs signal that the direct link to the anti-kickback law and the FCA for off-label promotions may be weak, but the legal theory is very much in play." Hills said the device industry must take its cue from the drug industry in developing ways to avoid off-label enforcement actions because "FDA guidance in this area for device companies is weak."

Meritz agreed that off-label promotions will be a focus of FDA enforcement activities this year. But she noted that "FDA has an opportunity to figure out how it can work with companies to move forward and perhaps develop innovative methods where patient health can

be improved with the ability to promote the additional uses of certain products.”

**Social Media.** Gerard J. Prud’homme and Michael Heyl, of Hogan & Hartson LLP in Washington, see a trend that could complicate FDA’s efforts to rein in off-label promotions: advertising in social media. “In the era of Facebook and Twitter, many companies are advertising and promoting their medical devices on social media websites, blogs, and other formats,” they said. “Although FDA held a public meeting at which it sought public comment, it is unclear how FDA will monitor such advertising and promotion and, when applicable, utilize its enforcement authority for such activities.”

But Gaba noted that FDA’s off-label promotions enforcement activities could run into a roadblock this year. He pointed out that Botox maker Allergan Inc. has filed an action in federal district court seeking a declaration that FDA’s prohibitions on truthful, nonmisleading, and accurate speech about off-label uses of drugs and devices are unconstitutional (*Allergan Inc. v. United States*, D.D.C., No. 09-1879, filed 10/1/09).

Gaba said, “we can expect this area to be a hot one to follow in 2010,” referring to the First Amendment challenge to the off-label rules. “I expect this case to eventually make its way to the Supreme Court,” he said. “Clearly an opportunity for the industry.”

Thompson, like the others, sees FDA focusing on off-label promotions. But he also believes the agency will begin more rigorously enforcing its requirements for clinical trials. “With the growing number of clinical trials required by FDA clearance rules, more and more manufacturers will have to ensure compliance with good clinical practices,” he said.

Michael D. Bell, of Mintz Levin in Washington, agreed that clinical trial fraud is an upcoming area for enforcement activity. “Issues ranging from failure to disclose conflicts to inappropriate/excessive payments will begin to surface, as organizations shift focus from pure marketing to ‘clinical marketing,’” he said. “In situations short of a required clinical trial (e.g., registries, case series, etc.), lack of a bona fide need and/or payment of fair market value for services will be at the heart of the allegations,” Bell predicted.

Prud’homme and Heyl said they also expect FDA to step up enforcement of the purchasing control provisions in the quality standards regulation, 21 C.F.R. § 820.50. “There has been an increase of FDA concern regarding a manufacturer’s level of control over its suppliers of components and contract manufacturers,” they said. “Several recent high profile safety and health issues have been the result of a manufacturer’s failure to control its suppliers. There also has seemingly been an uptick” in notices and warning letters citing purchasing control deficiencies, they said.

Some board members predicted that FDA enforcers will look beyond companies this year. Laura F. Laemmle-Weidenfeld, for example, said that increased enforcement will focus on health care providers who use medical devices in their practices. She said, “We will continue to see an increase in interest by the enforcement community in reimbursement and other aspects related to how health care providers and institutions use and bill for medical devices. This, in turn, will carry ramifications for how device manufacturers market their products to their customers, including what reimbursement advice they may provide to those custom-

ers.” Laemmle-Weidenfeld is with Patton Boggs LLP in Washington.

Gregory H. Levine, of Ropes & Gray LLP in Washington, included FDA enforcement generally on his list of top issues for the coming year, as did Stephanie Philbin, of Goodwin Procter LLP in Washington, and Anna L. Spencer, of Sidley Austin LLP in Washington. Philbin, however, questioned “whether this increased activity will result in a better public health outcome.”

**FDA Regulatory Activity.** Again given the new administration, board members opined that FDA regulatory activity will become more focused in 2010. Several members commented on what they perceive as the agency’s insistence that companies provide more rigorous support for clearance and approval applications.

Prud’homme and Heyl, for example, said, with respect to agency review of pre-market approval (PMA) applications, “FDA appears to be questioning the appropriateness of clinical study designs at times after pivotal studies have been completed, and even when study endpoints described in approved [investigational device exemptions (IDEs)] have been met. It will be important to see how frequently FDA will revisit what kind of data and studies they believe are needed to support PMA approval after IDE approved studies have been completed.”

Many board members are expecting changes in the agency’s review of applications for product clearances under the Section 510(k) process. Gaba, for instance, said he sees “this as an area of significant FDA activity in 2010. . . . The expectation of updating what is perceived as an antiquated system is likely to lead to additional data requirements to be met by industry.”

Gaba added that changes to the 510(k) process could have an effect on the PMA process as well. “If the FDA is able to modernize the 510(k) clearance process, industry will need to consider the ripple effect on the PMA process,” he said. “Will PMAs require even more data at some point or do the more complex 510(k)s transition to PMA-like data requirements? I see this as a challenge for industry, more so than a threat per se,” he said.

Hills also said that “changes to the 510(k) process are forefront on medical device companies’ minds.” She noted that the “uncertainty is painful and makes it very difficult for clients to project new developments and to anticipate timing for clearances/approvals. . . . Clients with class II devices subject to the 510(k) process are struggling with the uncertainty once submissions are under review.” Hills said that “FDA reviewers seem to be imposing new and more burdensome standards” for products seeking clearance.

“Modernization of the 510(k) process is looming,” Hills concluded.

Meritz said that “with regard to 510(k)’s there is no question that FDA has been moving to require ‘efficacy’-type data, over and above what was requested in the past when it was primarily concerned with substantial equivalence evaluations.” She predicted that “this will prove difficult for the medical device industry and especially for small to mid-sized companies.” She added that she is “concerned that smaller medical device companies will not be able to respond to the increasing requests by FDA reviewers for this type of additional efficacy data.”

Levine also said changing standards for 510(k) review are likely to surface this year, but Philbin disagreed. She said she does “not think we will see large scale changes to the 510(k) program this year,” though she acknowledged that “individual submissions may continue to hit stumbling blocks, such as requests for information that go beyond what is needed in order to make a substantial equivalence determination.”

Thompson, however, said that he expects “to see more demanding premarket standards as the 510(k) process is examined, and particularly of the process for evaluating when a change to a device might trigger the need for a new premarket submission.”

Thompson said, “FDA apparently wants to see manufacturers submit more pre-market notifications for changes in devices, perhaps to give FDA another look at the technology. The agency also seems to be backing off of the concept of predicate devices and precedent, suggesting that they will be more demanding in their reviews.”

**Post-Approval Obligations.** FDA also is expected to increase its post-approval activities, according to the BNA advisory board members.

For example, Prud’homme and Heyl said they expect FDA to increase its requirements for post-approval studies (PAS). “Such studies are becoming larger and more onerous than preapproval studies designed to demonstrate the safety and effectiveness of a device,” they said. “It will be important to see what FDA” will do in this area, they said.

Prud’homme and Heyl also are expecting more FDA scrutiny of device failures and patient-related events involving medical devices. “FDA is increasingly questioning [medical device reporting (MDR) standard] reportability determinations, as well as product recall determinations and classifications,” they said. “Utilizing what appears to be a zero risk approach when it comes to device safety, FDA is expecting companies to initiate product recalls even when the rate of occurrence of the subject event is extremely low,” they warned.

Gaba also foresees increased FDA post-approval activity, particularly with respect to post-market surveillance. The devices industry may be facing a “challenge . . . to refine its post-market practices, which may include handling additional FDA requirements to collect post-market data and report the same,” he said.

A development that Philbin will be watching for in 2010 is the incorporation of new science into the Center for Devices and Radiological Health’s regulatory decisionmaking. Philbin said FDA announced a public meeting and request for comments on the initiative in late 2009. The meeting is set for Feb. 9.

**Transparency: Two Sides.** While FDA enforcement and regulatory activities are expected to increase, there is some debate over whether the medical devices industry, and the public in general, will be able to review the agency’s actions.

Thompson told BNA he hopes “we will see growing transparency of FDA with regard to guidance development,” but he noted that “policymaking may not always be in the direction industry wants.”

Philbin noted that FDA undertook a “transparency initiative” in 2009 when it established a “Transparency Task Force, held two public meetings, and received a huge number of comments on specific questions the

agency posed.” It “will be interesting to see what 2010 brings” for this project, she said.

The other side of the transparency coin is focused on the industry, according to board members.

Levine noted that so-called sunshine laws on doctor-company interactions are gaining momentum as an element of health reform. Gaba added that “industry should expect more activity in this area, even if health reform legislation does not become law.”

“States aggressively set standards to require more disclosure of physician-company financial dealings,” he said. “And the federal provisions to be codified through health reform legislation set a floor, not a ceiling, for state regulation.”

Gaba said that “while a reasonable level of disclosure should be required, the extent to which it is occurring may very well stifle innovation and drive jobs from those states (like Massachusetts) setting high disclosure standards.”

Hills suggested that one approach to the proliferation of state transparency laws that will affect the ways medical device companies do business would be to “avoid doing business in those states with these requirements.” But, she acknowledged, “that is not a sustainable position (as many states are likely to pass similar laws in 2010).”

Hills said that “with independent sales contractors and the need for many medical device companies to have a hands-on approach to demonstrate and educate about the product,” which is very different from how drugs are marketed, device companies “are having to grapple with the issue of compliance—tracking what is done, by whom and where.” She said, “Establishing workable reporting policies is near impossible because each state has different forms, different monetary limits, and different triggers for reporting.”

Not only are these new state policies presenting administrative burdens, Hills said, “there is little evidence that transparency itself will reduce health care costs. Rather, it seems a perfect way to populate a government database from which state [attorneys general and Medicaid inspectors general] and federal DOJ can conduct data mining and analysis as a jumping point for False Claims Act actions or fraud and abuse claims.”

Bell agreed, noting that “federal and state enforcers will have access to a tremendous amount of previously undisclosed data that can be used in numerous collateral circumstances (e.g., Anti-kickback prosecution; investigator conflicts reporting; state licensing violations, etc.)” He said compliance with these new state laws will “present numerous legal, operational, and compliance challenges” for device companies.

**Health Reform-Related Issues.** Some board members, like Meritz, cited health reform generally as raising issues for the medical device industry in the coming year. Others, like Hills, focused on specific issues raised in the health reform debate that they think will have the most impact on the industry.

Hills, for example, cited comparative effectiveness provisions in the latest health reform bills. The “FDA’s role in or ability to incorporate comparative effectiveness research results into labeling and product approval/clearance processes is extremely unclear,” she said.

Gaba said of comparative effectiveness: “this to-be-developed framework to support evidence-based medi-

cine is here to stay with or without health reform legislation.”

“How these studies are to be designed and their results utilized will be both a challenge and an opportunity for the industry. [Comparative effectiveness is] only a threat if industry sits back and doesn’t participate in the process,” he said.

Spencer also cited comparative effectiveness as one of her top issues for the coming year.

Another proposal raised in the health reform debate was the integration of health care providers and services. Bell said this focus on alternative health care delivery models could have an impact on the medical devices industry.

**New Opportunities, Challenges.** “Accountable care organizations, the medical home models, gainsharing arrangements, device formularies, physician-owned buying organizations, and other new purchasing/delivery mechanisms will create both opportunities and significant challenges for the industry,” Bell said. But Bell also warned that “these new structures each present new fraud and abuse risk areas, requiring careful consideration of Anti-kickback/Stark (and state law analogs) and False Claims Act compliance.”

Bell added that the reform movement has created opportunities for device companies. “Millions of newly insured patients should present significant sales and growth opportunities for those device manufacturers that navigate the contracting pitfalls successfully,” he said.

Other board members, with their focus on medical devices, said that the development of products to aid seamless integration of health care providers will be an issue in the coming year.

Thompson, for example, said: “Over the last couple years, as we have been striving for greater efficiency and quality in healthcare, there has been a growing effort to network the health care system. That means connecting what have been previously fragmented institutions, but also ensuring that we stop rowing the steamship.”

“We have had technology on the shelf for years that would allow all of the various electric medical devices, both diagnostic and therapeutic, to talk with each other and deposit their data in electronic health records,” he said. “Obstacles have included FDA regulatory disincentives to interconnection, a lack of reimbursement to reward for installing the needed infrastructure, and the general resistance among the healthcare community to connections.”

“All of this is starting to fade away as the drive toward efficiency and quality builds steam,” Thompson observed. “In 2010, we will see much effort at clearing the obstacles to such technology. We will see remote monitoring technologies that allow for better managing the care for those with chronic diseases in their homes, and mobile healthcare that makes the cell phone a centerpiece of the care equation. We will also see hospitals and other institutions more fully wired so that the plethora of medical devices in the operating room as well as at the patient’s bedside can talk to each other and more automatically populate the electronic medical record.”

Keith A. Barritt, of Fish & Richardson PC in Washington, echoed Thompson’s remarks, saying that the growth in the development of wireless medical device

technology will help improve quality and costs of health care.

“The wireless age is changing the nature of health care delivery and has the potential to dramatically improve care and lower cost,” he said. “Patients who need monitoring no longer need to be tethered to one spot by a tangle of cables. Wireless monitoring permits patients to thrive outside health care institutions, reducing health care costs and enabling physicians to obtain vital information on a real time basis without the need for office visits or hospitalization. For an aging population, wireless technology offers an important solution for preventive and managed care.”

Looking to the future, Barritt said that as “microprocessors become smaller and more powerful, the development of an even wider array of wireless medical devices is inevitable, and presents an exciting opportunity for device manufacturers to develop new products that can be a large part of driving down the cost of health care. However, in order to bring wireless medical devices to market, manufacturers must understand the regulations of both the FDA and the Federal Communications Commission, which governs the use of the wireless spectrum. Thus, these devices face two regulatory hurdles, once from the FDA and the other from the FCC to be certain the device is compliant with the relevant technical standards.”

**Fraud and Abuse.** In 2009, the federal government seemed intent on using fraud and abuse enforcement mechanisms to recover some of the costs of federal health care programs. That trend promises to continue through 2010 and beyond, according to advisory board members.

According to Laemmle-Weidenfeld, the DOJ “has indicated that health care fraud enforcement not only remains a priority, but in fact the priority level is increasing.” She said this “prioritization is fueled in part, but not exclusively, by the increased scrutiny health care reform efforts place on federal funding of health care and by the 2009 amendments to the False Claims Act (FCA).”

“In addition to more civil enforcement activity, I expect to see more criminal cases and more matters brought directly by the Health and Human Services Office of the Inspector General,” Laemmle-Weidenfeld said.

Spencer added that bundling of products could attract the attention of anti-kickback statute enforcers this year.

Kathleen McDermott, of Morgan Lewis & Bockius LLP in Washington, warned that many of the enforcement issues pending before FDA “have compliance implications even if certain practices are not actually a violation of the False Claims Act.” She advised that companies “ensure that they are providing sufficient resources and emphasis to compliance programs and effectively assess business practices both domestically and for international operations.”

Compliance with international guidelines is important, as Laemmle-Weidenfeld pointed out, because the government also is taking a more active interest in enforcing the Foreign Corrupt Practices Act (FCPA). “Companies need to think about different compliance issues in connection with the FCPA and other fraud and abuse statutes,” she said. “Expect to see heightened enforcement of the FCPA with respect not only to pharma-

ceutical manufacturers but also with respect to device manufacturers.”

Bell also warned that device companies should be on the lookout for issues arising from international activities, such as outsourcing. “The reliance on third parties for the performance of key manufacturer functions, and consequently diminished oversight over such functions, will present contracting, compliance oversight, and liability challenges,” he said.

Whistleblower activity also is expected to increase, according to McDermott. These suits, brought by private individuals, and sometimes joined by the government, to obtain recompense for FCA violations, “will continue to drive the DOJ enforcement compliance agenda and resources,” she said. “There will be a greater interest in defending these allegations and having courts independently review some of the theories of liability.”

**Combo Products, HIPAA.** Board members suggested a few other issues that might grow in importance over the coming year.

With respect to FDA, Thompson said that “after a few years of relative quiet, the Office of Combination Products seems to be revving up for a new round of policy development. They’ve already published two new proposed rules on good manufacturing practices and adverse event reporting, as well as a guidance on contrast imaging. Several other policy initiatives seem to be teed up for proposals, including cross labeling,” he said.

Levine joined Thompson in predicting that there will be more activity with respect to regulation of in vitro diagnostic devices.

Thompson expressed “hope that FDA will make progress in harmonizing what would have been two very disparate systems: in vitro diagnostic test regulation and laboratory developed test regulation.” He added that, “while it’s too early to say what the final approach might look like, it seems more likely under the

current administration that FDA oversight of laboratory developed tests would be increased, rather than reducing the regulation of in vitro tests.”

McDermott and Spencer both added another issue: the importance of complying with device industry codes of ethics. McDermott predicted that similar codes will be adopted by the health care industry, saying: “Hospital and health systems codes of ethics will start to catch up with industry and professional codes of ethics, impacting and changing relationships with industry for everything from research and education funding to technical support in labs and operating rooms,” she said. “This trend should be embraced by industry and incorporated into existing practices.”

Bringing up a topic that has caught the attention of health care attorneys generally, Hills suggested that the new business associate provisions of the Health Insurance Portability and Accountability Act (HIPAA) will apply to medical devices companies.

“Medical device companies are often business associates of health care providers,” she said. Therefore, they will “have obligations under those business agreements with regard to protected patient information.”

“Under changes that take effect in February, business associates will have direct liability and responsibility under HIPAA to ensure data privacy and security,” she said. “Many device companies are not aware of this added liability or are finding it difficult to put into place the appropriate administrative and technical protections needed to comply.”

“Data privacy and security in general is a growing area of concern (there are layers and layers of legal requirements [including international requirements]) and the more regularly clinical data are required, the more important the proper handling of that data will be,” she said.

BY MARY ANNE PAZANOWSKI