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Enforcement

Attorneys, Device Company Officials Outline 2013 Liability Landscape for Device Makers

Medical device companies should make sure that they have robust compliance programs as they face increasing governmental enforcement action and new potential areas of liability, experts said at a conference March 4.

Discussing the liability landscape for device manufacturers in 2013 at the Food and Drug Law Institute's Medical Device Compliance, Regulation and Litigation conference in Washington, attorneys and device company officials said the government is increasingly focusing enforcement efforts on device companies.

''In the last ten years, the stakes have gotten a lot higher because the government has gotten more aggressive about enforcement actions,'' David J. Bloch, Washington-based principal legal counsel for Minneapolis-based Medtronic Inc., said. Moreover, he said, in the last four or five years, the government has started to hone in on the device industry.

Off-Label Promotion. One potential trouble spot concerns the promotion of devices for off-label uses—uses for which the Food and Drug Administration has not specifically cleared the device.

''We can only promote for on-label use, but there's often a disconnect,'' Bloch said.

''It's an ongoing challenge for industry to manage because there are a lot of ways off-label can pop up, and some of them are subtle,'' he said.

For example, he said, a device may be approved for certain age groups and not for others, but doctors may use it for unapproved age groups.

''There's an ongoing difficulty to communicate with your customers,'' he said. ''There are no clear guidelines.''

While decisions by the U.S. Supreme Court in 2011 and the U.S. Court of Appeals for the Second Circuit in 2012 addressed some of the First Amendment issues implicated in off-label cases, Bloch said FDA is not likely to shy away from the off-label enforcement area.

In 2011, the high court in *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2672 (2011), declared unconstitutional a Vermont statute that prohibits pharmacies from selling or disclosing prescriber-identifying information for marketing purposes and that precludes pharmaceutical manufacturers from using such information to market their products (5 MELR 628, 10/5/11). The high court found the ban an impermissible restriction on free speech.

Later, in December 2012, the U.S. Court of Appeals for the Second Circuit found that the criminalization of truthful, nonmisleading promotion of FDA-approved pharmaceuticals violates the First Amendment. The case involved Alfred Caronia, a former drug company sales representative (6 MELR 763, 12/12/12). The appeals court also reversed the conviction of Caronia for promoting an unapproved use of a drug.

Bloch said that since the *Sorrell* and *Caronia* cases, FDA has said it is not going to pull back from this enforcement area. ''They'll look for clear evidence of intent to misbrand and false statements and [a company] trying to increase market share by promoting off-label use,'' he said.

''The enforcement efforts [in the off-label area] continue and the large settlements continue to come in,'' he said.

Nonetheless, he predicted, in the wake of *Sorrell* and *Caronia*, industry likely will begin asserting its First Amendment rights more aggressively.

''The off-label field continues to be one of high interest to all of us who practice,'' he said. ''There are some new issues coming up and it'll be interesting to see how it all plays out.''

False Claims Act: Emerging Areas. In addition to off-label enforcement, Greg Levine of Ropes & Gray LLP in Washington said another emerging area of potential liability is the use of the False Claims Act in connection with federal food and drug law violations.

Liability under the FCA can be daunting because not only does the statute impose treble damages, but it also it links up with exclusions provisions under Medicare/Medicaid law under which a product could be excluded from reimbursement, Levine said.

He also noted that several pending suits against device manufacturers seek to expand the use of the FCA to more broadly enforce compliance with QSR (the Quality System Regulation) and current Good Manufacturing Practices (cGMPs)d.

For example, in a case pending in the U.S. District Court for the Central District of California, *United States ex rel. Ruhe v. Masimo Corp.*, the court refused to dismiss an FCA case alleging that the labeling of certain devices falsely claimed that the devices could measure hemoglobin to a certain level of accuracy. The court construed the FCA broadly and found it applies to all fraudulent undertakings that cause the government to pay money. In addition, it found that requesting reimbursement for defective or lesser quality goods also can constitute an FCA claim.

Other recent cases allege FCA liability based on companies' failure to fulfill device reporting and notification requirements, including medical device reporting and

correction and removal reporting. Investigations in this area are ongoing and some cases are being actively litigated, Levine said.

Another emerging area of potential liability is false or misleading claims about approved product indications, he said. In these types of cases, whistleblowers are alleging that a company's promotional messages about on-label uses violate federal food and drug law. The theory is that misleading on-label messages can lead to the government reimbursing products that are not medically reasonable and necessary. Examples of such promotional statements include false comparative claims, misrepresenting clinical trial data, or lack of fair balance, he said.

While there are not yet any reported cases in the device arena regarding on-label messaging, Levine said that ''this is one [area] that companies should have some concerns about.''

''The risks are increasing. I think these are real and new areas of risk and I think companies need to keep their eyes on them,'' he said.

FDA Warning Letters. On the FDA enforcement front, conference speakers said FDA is issuing an increasing number of warning letters to device makers over violations of FDA's Quality System Regulation and its cGMP requirements.

''The FDA is actually enforcing QSR [the Quality System Regulation for medical devices] quite vigorously these days,'' Levine noted, with the number of FDA warning letters alleging QSR violations trending upward.

And while ''FDA does not look at warning letters as punitive action ... if you've received one, they feel punitive,'' Sonali P. Gunawardhana of Wiley Rein LLP in Washington said.

Moreover, warning letters put your company in a holding pattern pending corrective action, she said. ''You can't export product until you take corrective action, and it can be tough for a device company, especially if they just have one product,'' she said.

FDA's main areas of concern with regard to cGMP violations are lack of written Medical Device Reporting (MDR) procedures, problems with how companies handle complaints, inadequate corrective action and preventive action procedures, inadequate process and design changes, and failure to maintain device history records (DHR), she said. Insufficient MDR procedures are a ''huge'' area of concern, she said.

Most FDA inspections are for violations of good manufacturing practices, she said. ''It is an area of vulnerability if you're not following the regulations.''

Because agency inspectors are going to look for documentation, Gunawardhana advised companies to make copies of anything the field inspector copies. Doing so, she said, will help a company respond to the agency later.

Also, she said, because FDA will hold manufacturers responsible for supplier errors, companies must have agreements in place with suppliers and revisit those agreements. Suppliers must have third party certification and companies must understand the road map for the supply chain for each of their products, she said.

''Revisiting often, training often, and understanding you're only as good as your employees'' is critical for device companies, Gunawardhana said.

''You have to make sure your quality procedures are in place and that you're following them,'' she said.

In addition to civil liability, cGMP violations can also lead down the criminal road, she said. Corporate officers can be held strictly and criminally liable for cGMP violations, she said.

''When FDA inspectors come out, they're looking for who the responsible person is,'' she said. Accordingly, Gunawardhana said, ''you also have to be careful about what statements you make to FDA inspectors.''

Consent decrees and criminal prosecutions generally name individuals as well as the corporation itself. ''If they can tie it back to you, you're going to be individually named,'' she said.

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