BUFFALO NIAGARA ENTERPRISE

Focus on FDA
Bethany J. Hills, J.D./M.P.H.
Hodgson Russ LLP

Hodgson Russ LLP ATTORNEYS

"Medical Devices: Caught in the Crosshairs of Change"

Anyone involved with the medical device industry is, by now, aware of the impending sea change in regulatory approval and safety processes threatened by the Food and Drug Administration (FDA) and others. These changes stemming from the FDA are over-arching, structural changes — like the intense review of the current 510(k) clearance process. Yet, although these FDA changes are significant, they are only one piece of the puzzle. Medical device companies are facing significant changes both domestically and internationally. The health care reform legislation passed in March 2010 creates at least two new burdens on the medical device industry — the medical device excise tax intended to raise $20 billion to pay for the insurance reforms and the new disclosure rules for payments from medical device companies to health care providers. Finally, although not addressed in depth here, international changes such as new European Union requirements for a clinical evaluation of every medical device and, more broadly, the maturation of device regulation internationally, add to the complexity for medical device companies.

Over the years, but particularly in light of the recent change in administration, the FDA has been working to evaluate the existing methods for clearing or approving products to be marketed in the United States. In early 2009, a long-awaited Government Accountability Office (GAO) report fell short of the widespread change many in the medical device industry expected. In response, the FDA itself hosted a full-day public meeting on February 18, 2010, to discuss ways to strengthen the 510(k) review process. Jeffrey Schren, director of the Center for Devices and Radiological Health (CDRH), has indicated that medical device companies should expect at least some initial administrative changes this fall. The FDA also commissioned a $1.2 million study by the Institute of Medicine (IOM) on the adequacy of the 510(k) review program. Changes may come quickly. The FDA's internal working group on this issue is expected to issue a report on May 31 with an opportunity for public comments during the month of June. Medical device companies manufacturing mid-level risk devices (Class II and some Class III) should seriously consider submitting comments in June, as the FDA internal working group expects to implement its recommendations in September. The IOM study is scheduled to be complete in early 2011. And the reauthorization of the

Medical Device User Fee Act, historically an opportunity for large legislative changes, approaches in 2012. The scope of the changes could range from as small as the FDA adopting additional special controls for some medical devices (such as post-market surveillance), as specific as the FDA issuing consistent clinical trial requirements for certain classes of devices, or as far-reaching as a total restructure of the predicate system and standard of "substantial equivalence" that the majority of medical devices on the market today rely upon as market authorization.

The U.S. health care reform legislation introduced a new excise tax on medical devices sold in the United States starting January 1, 2010. The tax is 2.3 percent of the price of the medical device and applies to all medical devices, regardless of risk, cost, or complexity. The legislation specifically exempts contact lenses and certain hearing devices, but it leaves all other Class I, low-risk medical devices subject to the tax. Combined with the FDA's request in the 2011 budget for an average 8.5 percent increase in medical device user fees, this excise tax will create additional financial burdens on the medical device industry.

Financial burdens are not the limit of the changes in the U.S. health care reform legislation that will impact the medical device industry. The Patient Protection and Affordable Care Act (H.R. 3590), part of the health care reform legislation, requires drug and device manufacturers to report electronically "any payment or other transfer of value" to health care providers. The reporting obligation begins on January 1, 2012, and guidance is expected before October 1, 2011. All payments made to doctors (like consulting fees, gifts, entertainment, license fees, grants, etc.) will be made public on a website. Some exclusions at this point are payments that do not exceed $100 per year, provision of product samples, and educational materials. Payments relating to research will still be reportable, but will not be made public until the FDA approves or clears the device or four years have passed. Failure to report these payments will result in strict penalties of not less than $1,000 and not more than $10,000 for each payment not reported. Monetary penalties increase if the failure to report was knowing. This new federal requirement will not preempt existing state requirements, like those in Minnesota, Massachusetts, Vermont, and proposed in New York. Therefore, the medical device industry can anticipate increased regulatory and reporting obligations in this area over the new few years.

These domestic changes may impact medical device companies in a more direct way, but they are not free of international layers of complication. Recent changes in the EU regarding clinical evaluation files for every medical device sold in the EU may ultimately impact the approach the FDA takes on device regulation here in the United States. And, as global harmonization continues in the medical device space, regulatory requirements (and the associated challenges) are maturing around the world, particularly in areas such as Asia, Australia/New Zealand, and Latin America.

On all fronts, the medical device industry truly is caught in the crosshairs of change.

Further information on these and other medical device regulatory topics can be found at www.hodgsonruss.com or by contacting Bethany directly at (716) 848-1554 or bhills@hodgsonruss.com.

1-800-916-9073 • fax (716) 842-1724 • info@buffaloniagara.org