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Recent Congressional Activity Presents Opportunity for Medical Device Industry

Focusing on burdensome regulatory issues and the imposition of a new medical device tax under the health care reform law, Congress has begun to examine specific changes to medical device regulations in the United States. As this debate unfolds, there is a clear opportunity for medical device manufacturers to engage actively in the legislative modifications that may emerge from this congressional oversight.

Recent Committee Activity

On Thursday, February 17, 2011, the Subcommittee on Health (the Subcommittee) of the House Committee on Energy and Commerce (the Committee) met to examine the impact of medical device regulations on jobs and patients. Members heard testimony from Jeffrey E. Shuren, M.D., J.D., Director of the Center for Devices and Radiological Health of the Food and Drug Administration (FDA), as well as several representatives from academia and the private sector.

As anticipated, in their opening statements and during their questioning of the witnesses, Republicans and Democrats on the Subcommittee expressed disparate points of view on the effect of regulations on the medical device industry. Republicans on the Subcommittee criticized the handling by the FDA of medical device approvals, stating that the slow and unreliable process in the United States has encouraged device manufacturers to shift their marketing focus overseas, thereby hurting American jobs.

While some Democrats conceded that the process could be improved, they were much less critical of the FDA, with certain members using the hearing as an opportunity to criticize House Republicans for proposing to cut FDA funding.

In his comments, Dr. Shuren did not break much new ground regarding the direction the FDA plans to pursue to reform the 510(k) process and modify "regulatory burdens." Shuren tried to counter the assertion that the European system is far more favorable to the medical device industry, but did acknowledge that the FDA could provide manufacturers with clearer guidance.

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Several key members appeared to present opening remarks:

Subcommittee Chairman Joe Pitts (R-PA) stated that the shorter, more predictable and more transparent approval process in Europe has led many device companies to seek a market for their products in Europe before submitting them for approval to the FDA. He expressed concern that this trend hurts the US economy and American patients. Chairman Pitts cited studies which have concluded that medical devices marketed through European Union (EU) processes are statistically as safe as FDA-approved devices and have comparable patient outcomes.

Committee Chairman Fred Upton (R-MI) reiterated Chairman Pitts' concerns that problems at the FDA are stifling American innovation, costing American jobs and hurting American patients. He indicated that the full Committee would work toward a reauthorization of the Medical Device User Fee Act (MDUFA) but that, in doing so, would also demand that the FDA remedy many of its problems.

While Committee Ranking Member Henry Waxman (D-CA) agreed that it takes much longer for devices to reach the market in the United States as compared to the EU, he also pointed out that if patients were to lose faith in the FDA, they would also lose confidence in the industry.

The hearing included the following key discussion points:

Subcommittee Ranking Member Rep. Frank Pallone (D-NJ) asked Dr. Shuren about the effect a proposal to cut FDA funding by ten percent would have on the medical device approval process. Not surprisingly, Dr. Shuren responded that a funding cut would result in further delays and lost jobs.

Representative John Shimkus (R-IL) stated that the way to create jobs without spending money would be to ease regulatory burdens. He rejected the idea that federal agencies such as the FDA need increased funding.

Rep. John Dingell (D-MI) presented several questions to Dr. Shuren regarding whether funding cuts would negatively impact the FDA, particularly in terms of staffing needs. Dr. Shuren affirmed that cuts would further impair the FDA and also responded in the affirmative to a question by Rep. Dingell regarding whether increased user fees would be necessary to sustain the 510(k) approval system.

Rep. Brett Guthrie (R-KY) inquired of several of those testifying about the effect of the new tax imposed on medical devices in the health care reform law. Dr. Josh Makower, Consulting Professor of Medicine at Stanford University, Chief Executive Officer of ExploraMed Development LLC and Venture Partner of New Enterprise Associates, responded that it is imperative to examine modifications to the tax. He indicated that under current law, companies would be paying merely for the privilege of doing business in the United States. Mark Deem, Managing Partner and Chief Technology Partner of The Foundry LLC, added that the tax would slow growth and cost jobs. Rep. Guthrie further commented that the medical device industry is being treated differently than other industries.

Rep. Leonard Lance (R-NJ) expressed concern that the new tax would be extremely burdensome, particularly in his district where, he argued, more individuals are employed in the medical device industry than anywhere else in the United States.

Rep. Marsha Blackburn (R-TN), commenting that her district is as well home to many device manufacturers, reiterated concerns that the FDA's approval process serves as an impediment to innovation and is costing her constituents' jobs.

Dr. Shuren, as part of his defense of the FDA's approval process, stated that when the FDA approves a device, other countries take notice and there is a resultant uptick in other countries' use of those devices. He proffered that the industry can often be a contributing factor in approval delays due to, at times, companies' poor performance of clinical studies. Mr. Deem countered that the FDA at times makes impossible demands for data from companies.

Other Legislative Activity

Several members of both the House and Senate have introduced legislation that would repeal the medical device tax enacted in the Health Care and Education Reconciliation Act of 2010. A version introduced by Senator Orrin Hatch (R-UT) (S. 17, Medical Device Access and Innovation Protection Act) is currently the primary legislative vehicle for this repeal.

Conclusion

As the 112th Congress addresses key issues in the health care area, the regulation and taxation of medical devices has become a significant concern. Medical device manufacturers of all sizes should closely monitor the oversight of the FDA in the upcoming months and consider how they may become involved in the MDUFA reauthorization process. MDUFA will likely not be a "clean" reauthorization, as a variety of policy proposals may find their way into the legislation extending the user fee system.