On May 12, 2009 the Subcommittee on Health, of the Committee on Energy and Commerce, House of Representatives, held a hearing on H.R. 1346, the "Medical Device Safety Act of 2009". If passed, it would overturn the Supreme Court decision, *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999 (2008), which held that under the express preemption clause of the Medical Devices Amendment of 1976 (MDA), the federal requirements created by the premarket approval process for Class III devices preempted state law tort claims that added or differed from the federal requirements. This hearing comes at the heels of public and media scrutiny of this decision, including last year's House Committee on Oversight and Government Reform preemption hearing held May 14, 2008 and the Senate Judiciary Committee's preemption hearing held June 11, 2008.

Before the invited panel of witnesses spoke, numerous members of the subcommittee provided opening remarks, which reflected the division among those who argued that the Supreme Court's analysis in *Riegel* departed from the legislative intent of the MDA, and those who agreed that the pending legislation would prevent innovation and access to medical devices that are life-saving. Arguments against the bill also noted that moving against preemption would otherwise place safety concerns in the hands of juries across the country, instead of on the FDA's safety and efficacy evaluations. Some focus was also placed on the FDA's effectiveness in policing the manufacturers, with several congress members such as Representative John Dingell, MI and Henry Waxman, CA arguing that the FDA has not been able to identify and take action on defective products, therefore calling into question their effectiveness in ensuring safety, while other congress members such as Representatives Steve Buyer, IN and Michael Burgess, TX argued that if the FDA is underfunded and without resources, the Committee should focus on the FDA, not on tort reform.

Most of the invited witnesses were repeat appearances from last year's hearing. David Vladeck, J.D., Professor of Law, Georgetown University Law Center presented his case in support of the bill, and repeated his concerns about the *Riegel* court's alleged deviation from congressional intent as reflected in legislative history. He also argued that manufacturers brought the express preemption defense to fore and that it was a more recent phenomena since the mid 1990s, after the *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517, 112 S.Ct. 2608, 2618 (1992) decision.

William H. Maisel, M.D., M.P.H., Director, Medical Device Safety Institute, Department of Medicine, Beth Israel Deaconess Medical Center, Boston also testified, as both a practicing cardiologist and as a consultant and advisory committee member for the FDA. He provided anecdotal background with what he represented as an example of a man who was implanted with a St. Jude pacemaker that allegedly was subjected to a recall and resulted in additional surgical procedures. In making this example, Dr. Maisel argued that the self-interest of companies are at odds with the congressional goal of ensuring public safety. Gregory Curfman, M.D., Executive Editor, New
England Journal of Medicine also echoed similar sentiments, and discounted the arguments made about innovation and safety for consumers being mutually exclusive.

Richard Cooper of the law firm Williams & Connolly LLP provided a big-picture review of what it would mean to have 50 state juries take the place of the FDA and seasoned clinicians when determining what constitutes a "defect" meriting liability. Mr. Cooper also emphasized that innovation would be hampered should preemption be denied to medical device companies, noting how many smaller companies that are focused on under-served areas of practice would be litigated out of their market share.

Bridget Robb of Pennsylvania and Michael Kinsley of Washington both presented anecdotal history with medical devices. Ms. Robb testified about her experience with a cardiac lead that she claimed unnecessarily shocked her and caused grievous subsequent emotional and physical injury, while Mr. Kinsley presented his story of how deep brain stimulation and other implanted medical devices has allowed him to lead a productive life despite a Parkinson's Disease diagnosis. Both presented different takes on the limits of how much risk a patient should face when balanced with the potential benefits offered by their medical devices.

Prior to the hearing, the Energy & Commerce Committee also published a letter asking the FDA to reexamine its decision to approve a medical device called the "collagen scaffold" that is used to reinforce and repair the meniscus, which is a natural cushion in the knee. This letter, as addressed to the FDA Principal Deputy Commissioner, seeks reexamination of the approval decision that the authors argue was made over the objection of FDA scientists.

For more information, please see the previous post "Will The May 12 Hearing On The "Medical Device Safety Act of 2009" Recognize The Costs Of Eliminating Preemption?"

Tags: Food and Drug Administration (FDA), H.R. 1346, Legislative Developments, Medical Device Safety Act of 2009, Medical Devices, Preemption, Riegel v. Medtronic