Medical device companies and their counsel should keep a wary eye on pending legislation aimed at reversing a U.S. Supreme Court decision that immunizes medical device companies from lawsuits brought by patients injured by certain devices. H.R. 1346, known as The Medical Device Safety Act of 2009 (“MDSA”), would nullify the Court’s February 2008 ruling in *Riegel v. Medtronic, Inc.*, 552 U.S. 2 (2008) that medical device manufacturers cannot be sued in state court by patients allegedly harmed by a device that had received marketing approval by the Food & Drug Administration (“FDA”). The *Riegel* court, relying on the language of the Medical Device Amendments of 1976 (“MDA”) to the Food, Drug & Cosmetics Act (“FDCA”), held that such claims are pre-empted and, therefore, barred. Since *Riegel*, thousands of lawsuits against medical device manufacturers have been dismissed.

The MDSA was introduced on March 5, 2009, by Congressman Henry Waxman (D-CA), Chair of the House Committee on Energy & Commerce, and Frank Pallone (D-NJ), Chair of the Health Subcommittee. Aimed at eliminating what Rep. Pallone has called the “blanket immunity that medical device companies . . . enjoy thanks to [the] unfortunate Supreme Court decision” in *Riegel*, the MDSA would amend the MDA by adding language that explicitly states that the MDA does not “nullify or otherwise affect any action for damages or the liability of any person under the law of any State.” To date, the proposed legislation has been co-sponsored by 86 other congressmen, the majority of whom are Democrats. A companion bill has been introduced in the U.S. Senate by Senator Edward Kennedy (D-MA), Chairman of the Senate Health, Education, Labor & Pensions Committee, and Senator Patrick Lahey (D-VT), Chairman of the Senate Judiciary Committee.

Hearings on the MDSA were held before the Health Subcommittee on May 11, 2009. The bill, which awaits referral to the full Committee on Energy and Commerce, has been endorsed by, among others, the New England Journal of Medicine, the American Bar Association, AARP, and the National Research Center for Women & Families. Critics have classified the MDSA as a “true trial lawyer earmark” that will expand liability and invite economically-crippling consumer lawsuits, but do nothing to improve the safety of medical devices. Hyperbole aside, passage of the MDSA would undoubtedly open courthouse doors to a stampede of lawsuits. Furthermore, coming on the heels of the Supreme Court’s recent decision in *Wyeth v. Levine*, in which the Court ruled that FDA approval of drug labels does not pre-empt failure-to-warn lawsuits against drug manufacturers, the MDSA would spell the end of federal pre-emption of failure-to-warn and design defect lawsuits for both medical devices and drugs. In short, given the surge in litigation that passage of the MDSA would unleash, medical device companies are wise to prepare for a pre-emption free future typified by a dramatic spike in consumer lawsuits.

Should you desire a full text of the Medical Device Safety Act of 2009, the Supreme Court’s opinion in *Riegel v. Medtronic, Inc.*, or have any questions regarding the issues of pharmaceutical or medical device liability, please contact one of our Pharmaceutical and Medical Device Liability Practice Group members.