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**Medical Device Safety Needs a Common Law Backup to FDA's Limited Regulation, CPR Member Scholar Tells Senate Committee**  
*Courts Can and Should Supplement FDA to Protect Public Safety*

(Washington) -- Current FDA regulation of medical devices is inadequate to protect public health and safety, and Congress should institute a fix to ensure that individuals injured by faulty medical devices have the right to claim damages in state civil courts, Professor Thomas McGarity told a senate committee Tuesday. McGarity, a Member Scholar of the Center for Progressive Reform, and professor of law at the University of Texas School of Law, testified before the Senate Committee on the Health, Education, Labor and Pensions.

"The implicit assumption in preempting medical device injury claims in state courts is that the FDA can and is performing its job perfectly, but that's just not the case," said Professor McGarity. "Common law still has an important role to play in providing justice to victims of defective products, and the public deserves that protection."

The Senate is currently considering a bill that would exempt state common law claims from the express preemption clause in the Medical Device Amendments to the Food, Drug and Cosmetics Act. Currently, individuals injured by a faulty medical device generally cannot sue the device manufacturer in state courts if that device was fully approved by the FDA, even if the manufacturer was aware of new research showing faults in the product.

McGarity's testimony argues:

- **The FDA's capabilities to protect public safety are limited.** FDA is almost entirely dependent on information submitted by medical device manufacturers at the initial approval stage, information that is easily manipulated by unscrupulous companies and their consultants. Because the device approval process is cloaked in secrecy, agency reviewers do not have the benefit of skeptical outsiders from public interest and patient advocacy groups. FDA also lacks subpoena power to obtain internal company documents that can tell a very different story than the one the agency reviewers hear in their meetings with company officials.
- **Courts have several institutional advantages over federal agencies in protecting the public.** Common law litigation can force information from company files and tease it out of company employees in depositions. Courts are also better adapted than agencies to respond rapidly to developments in the real world as new information on the hazards of products and activities becomes available. Courts are also far less subject to "capture," manipulation, and political pressure than federal agencies.

- **Tort law provides positive incentives for manufacturers to work to improve product safety.** It provides incentives for regulatees to take protective action when evolving practices and technologies create unanticipated gaps in the coverage of regulations and permit requirements that are difficult for agencies to fill on a short-term basis. It also provides a disincentive to engage in artful schemes to avoid the reach of regulatory requirements.
- **The deterrence function of state tort law is especially relevant to medical devices.** The device manufacturers that conduct the clinical trials and continually receive reports on their products will generally have access to more information on the risks posed by their products than doctors, patients or even FDA. Also, device manufacturers are in a far better position than doctors, patients or FDA to improve the safety of their products both before and after they enter the marketplace.
- **Frequent argument against jury trials is not matched by facts.** The available empirical evidence suggests that juries are capable of comprehending complex scientific and technical issues quite objectively with the help of judge-screened experts.
- **Common law litigation can assist agency enforcers in their compliance assurance efforts.** Evasion of regulation is currently too easy in many cases.

Professor McGarity recently published *The Preemption War: When Federal Bureaucracies Trump Local Juries*.

*The Center for Progressive Reform (www.progressivereform.org) is a nonprofit research and educational organization dedicated to protecting health, safety, and the environment through analysis and commentary. Visit CPR on the web at www.progressivereform.org and read CPRBlog at www.progressivereform.org/cprblog.cfm.*

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