

HEALTH CARE

NEWS AND INFORMATION

Volume 15 Number 7

February 22, 2008

Health Care: News and Information is a service of the Healthcare Leadership Council (HLC) to help our readers stay fully informed about the latest health care issues as we work to advance a high-quality health care system.

Jim Edwards, Editor

www.hlc.org

Supreme Court Issues Common-Sense Ruling In Device Case

The U.S. Supreme Court has come down on the side of common sense for FDA-approved medical devices.

- In a case involving a medical device that the Food and Drug Administration had approved, the court determined that such approval pre-empts state liability lawsuits.
- Federal “premarket approval” of a device precludes tort lawsuits brought in state court. The court overwhelmingly came to this conclusion, 8-1.
- This kind of liability limitation could go a long way toward separating the right to sue for injury stemming from a faulty product and using the legal system against a manufacturer whose product has gained regulatory approval.

Finally, the court has injected balance and judiciousness in liability law.

- Manufacturers of medical devices must meet high standards in order to get a new product approved by the FDA.
- In this case, a patient died after a coronary catheter burst following an angioplasty. But the FDA had approved the catheter before it was marketed. The court ruled that such approval bars liability lawsuits under state law.
- While everybody empathizes with the patient’s survivors, the fact is every state liability suit against an approved device’s maker takes resources from research, development and cost savings. Such state laws effectively add extra layers to standards manufacturers must meet.
- The court accepted the Bush administration’s argument that FDA-approved medical devices can’t be challenged in personal injury cases under state law. Injured parties may sue over whether a specific device had flaws, but can’t rely on state laws that add extra requirements beyond the FDA’s.

-- MORE --

- The majority ruled that state juries imposing liability on makers of approved devices “disrupts the federal scheme.” These cases lack balance: The FDA weighs risks and benefits in the

approval process, while juries are “not concerned with its benefits . . . [and] the patients who reaped those benefits are not represented in court.”

The vast majority of American people will benefit from the court’s determination favoring federal pre-emption for FDA-approved medical devices. This little toehold of liability limitation equals more resources available for R&D, and new breakthroughs that save lives and improve health. That’s a good thing for society. Legitimate cases may still be brought, but the FDA’s rigorous approval process gets the respect it deserves — and device makers get the protection that meeting FDA standards should afford.

The Healthcare Leadership Council, representing the innovators in each sector of the health care industry, is committed to advancing a market-based health care system that values innovation and provides affordable, high-quality care.

HLC field directors:

Darren Katz (404) 885-9351
(AL, AR, FL, GA, LA, MS, SC)

Paul Pearson (405) 488-0541
AZ, CO, KS, MN, NE, ND, NM, OK, SD, TX, UT)

Brad Crone (919) 834-8431
(DE, KY, NC, MD, MO, TN, VA, WV)

Larry Krutchik (818) 728-3355
(AK, CA, HI, ID, MT, NV, OR, WA, WY)

Brian Feldman (404) 885-1723
(IA, IL, IN, OH, MA, MI, RI, WI)

Tom Maher (603) 431-2340
(CT, ME, NH, NJ, NY, PA, VT)

If this fax arrives at an incorrect fax machine, if additional individuals in your company would like to receive a copy, if a recipient would like to be removed from the distribution list, or if a name or fax number needs to be changed in our system, please fax this information to Erin Mackay at 202-296-9561 or e-mail her at emackay@hlc.org.

**Healthcare Leadership Council
1001 Pennsylvania Avenue, Suite 550 South
Washington, DC 20004
(202) 452-8700
www.hlc.org**