

495 S. HIGH STREET
SUITE 450
COLUMBUS, OHIO 43215
TELEPHONE: 614.220.9200
FAX: 614.220.7900
www.randblp.com

MICHAEL J. ROURKE
KENNETH S. BLUMENTHAL
ROBERT P. MILLER
TIMOTHY M. MAHLER

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Senator Sherrod Brown
200 N. High Street, Room 614
Columbus, Ohio 43215

Re: Preemption of Medical Device and Medication Claims

Dear Senator Brown:

As we discussed previously, I am very concerned by recent decisions by the U.S. Supreme Court which have been backed by the Bush administration involving preemption of State product liability claims for devices that have received FDA approval. In Riegel vs. Medtronic, Inc., the U.S. Supreme Court ruled that victims of defective balloon catheters manufactured by Medtronic, Inc. are barred from seeking compensation for injuries and death against Medtronic because Medtronic had previously received FDA approval of the device. This sweeping ruling makes it impossible for the victims of defective medical products to seek compensation from the manufacturer. Further, this decision eliminates what is one of the most effective methods of policing the medical device industry to help ensure that the manufacturers do their utmost to design and manufacture safe devices which help patients rather than harm them.

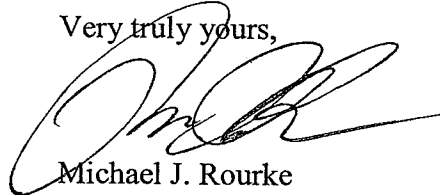
Currently, there are cases pending in the U.S. Supreme Court which could provide the same blanket immunity to manufacturers of drugs and medications that has been provided to the manufacturers of medical devices. If, as anticipated, the U.S. Supreme Court grants preemption to drug manufacturers, victims of drugs such as Thalidomide will have no recourse and drug manufacturers can avoid the consequences of manufacturing a defective drug or a drug without adequate warnings with impunity. For example, I recently met with the family of a woman who died of metastatic lung cancer who questioned whether the drug Aranesp contributed to their mother's death. Aranesp is prescribed for persons suffering from anemia, including persons suffering from anemia as a result of chemotherapy. Unfortunately, it has recently been revealed that Aranesp causes rapid growth of cancerous tumors which can result in curable cancers becoming metastatic killers. Although it is believed that the drug manufacturer knew about the adverse effects of Aranesp for several years, it was not until March of 2007 that the FDA ordered a "black box" warning for this drug warning physicians and patients of the potentially deadly effects of Aranesp. Unfortunately, this warning was much too late for my client's mother as she passed away from her cancer within two weeks of the issuance of this warning after having

received treatment with Aranesp for two years while she was also fighting her cancer. Unfortunately, I had to advise the family that it is very likely that the U.S. Supreme Court will make it impossible for them to seek justice in this case.

I believe that the only way to avoid the consequences of the Court's decision in Riegel vs. Medtronic, Inc., as well as other upcoming preemption cases involving products and drugs overseen by the FDA is legislation. I realize that such legislation would be subject to a presidential veto at this time, but I am certainly hopeful that you and others are doing whatever can be done to see to it that appropriate legislation is drafted and ultimately passed that returns the very important right to citizens to seek redress for harms caused by defective products and drugs.

Thank you for your attention to this matter.

Very truly yours,

A handwritten signature in black ink, appearing to read "Michael J. Rourke", written over a horizontal line.

Michael J. Rourke

MJR/mkb

cc: Jeffrey D. Boyd, Esq.
John Lancione, Esq.
Timothy M. Mahler, Esq. ✓