

[Your name address and phone number]

The Honorable _____ U.S. House of Representatives [or U.S. Senate]

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Washington, DC 20515

Re: Against Federal preemption of Medical Device or Drug Claims

Dear Congressman [or Congresswoman] _____:

On May 14, 2008, the House of Representatives Committee on Oversight and Government Reform convened a hearing to explore the legal doctrine of federal preemption in the context of product liability lawsuits involving FDA-approved drugs and medical devices.

On May 14th, Dr. Gregory Curfman, editor of the 200 year old *New England Journal of Medicine*, testified:

[P]reemption of common-law tort actions against drug and medical device companies is ill advised and will result in less safe medical products for the American people. ...

2. Serious adverse drug effects may not become apparent until *after* drugs are granted FDA approval, sometimes *long after* approval.
3. FDA approval by no means guarantees the safety of drugs.
4. The Congress's FDA reform efforts in 2007 made it clear that approval is usually based on short-term efficacy studies, not long-term safety studies.
5. Manufacturers may not immediately make public information indicating safety problems with their drugs.
6. Despite the usually admirable work of the FDA, the agency is hampered by lack of resources in addressing drug safety concerns and may be slow in resolving them.

If drug and medical device companies are shielded against common-law tort actions by preemption, what will be the effect on the safety of our drugs and devices? The answer is intuitively obvious. We recently wrote in an editorial in the *New England Journal of Medicine* that the safety of drugs and devices in our country will almost certainly be diminished. If drug and device companies are immunized against product-liability suits, companies will surely focus less attention on the safety of their products.

Also on May 14th Former Commissioner of the U.S. FDA, Dr. David Kessler, who served under two Presidents testified:

In 1996, Margret Jane Porter, a career public servant [and the FDA's Chief Counsel] summed up the Agency's position at a Food and Drug Law Institute Conference:

“FDA's view is that FDA product approval and state tort liability usually operate independently, each providing a significant yet distinct layer of consumer protection. FDA regulation of a device cannot anticipate and protect against all safety risks to individual consumers. Even the most thorough regulation of a product such as a critical medical device may fail to identify potential problems presented by the product. Preemption of all such claims would result in the loss of a significant layer of consumer protection leaving consumers without a remedy caused by defective medical devices.”

So, in general, I believe, as did my general counsel, that the two systems should operate in a complementary but independent manner.

... I believe it is wrong to focus on the moment of approval as determinative of the preemption question. The relevant timeframe is *post*-approval ... Once the drug enters the marketplace, risks that are not overly common, that manifest themselves only after an extended period of time, or that affect vulnerable subpopulations begin to emerge. These are often risks not foreseen by the drug's manufacturer or the FDA and, for that reason, are not addressed on the label. ***The FDA's statutory and regulatory tools for gathering post-approval information are relatively crude and often ineffective...*** The expectation that even an enhanced FDA post-market surveillance program will detect all emerging safety problems with drugs or devices is not realistic.

The fact is that companies will always have better, and more timely information about their own products than FDA will ever have at its disposal. Moreover, there are real limits on FDA: There are limits on FDA authority that prevent it from acting quickly in some settings, e.g., lack of drug recall authority and, as implemented by FDA, very slow device recall authority. In the drug advertising arena, FDA is never able to monitor what the thousands of drug representatives are saying to doctors that may be encouraging unsafe uses. Moreover, FDA usually gets the raw adverse reaction data, and does not have the benefit of all the analyses, review, thinking, and back and forth communication that occurred within the companies.

And, most importantly, there are real limits imposed by the limited resources the Agency has available. The case for preemption must be examined in light of a clear-eyed appraisal of the FDA's ability to assure the safety of the drugs being marketed in the United States. As we all know, the reality departs from what we would all wish could be the resources allocated to the Agency. The Institute of Medicine (IOM) reported in 2006 that the FDA “lacks the resources needed to

accomplish its large and complex mission today, let alone position itself for an increasingly challenging future.” FDA doctors and scientists share this view -- many believe that the FDA lacks sufficient resources to protect the public health, and many worry that the FDA is not adequately monitoring the safety of drugs once they are on the market. The FDA has long been hamstrung by resource limitations. Even if FDA’s funding were doubled or tripled, its resources and ability to detect emerging risks on the thousands of marketed drugs and devices would still be dwarfed by those of the drug and device companies who manufacture those products.

For that reason, the tort system has historically provided a critical incentive to drug and device companies to disclose important information to physicians, patients, and the FDA about newly emerging risks.

My greatest concern with preemption is that it would, I believe, dramatically reduce the incentives for manufacturers to act quickly and responsibly to detect, analyze, investigate, and take action on potentially serious and life threatening adverse reactions once a drug is on the market. ...

Doing away with the incentives to act responsibly and expeditiously to correct potential risks, incentives that are the result of state liability cases, would, I believe, jeopardize the public’s health.

I urge that you support legislation which will not strip American’s for the first time since the creation of the FDA in 1930’s of the rights of States to create and enforce laws which hold medical device and drug manufacturers to a higher standard than that required by the FDA. See, FDA Science and Mission at Risk, Prepared for the FDA Science Board, November, 2007.¹

The 2008 *Riegel v. Medtronic* decision does not rely on a Congressional mandate to preempt State Law claims, rather it is a strained interpretation of Congressional intent. The majority opinion does not address the purpose of the Medical Device Act, let alone suggest that preemption is right as a policy matter. Instead, the majority relied on the word “requirement,” which, the Court held, is a term of art that may, and in the MDA does, encompass state liability actions. The majority reasoned that because state liability actions seek to impose requirements” on device manufacturers “different from, or in addition to,” those imposed by FDA, they are preempted under a literal reading of the MDA. In the majority’s view, Congress’ selection of the word “requirement” demonstrates that Congress made the choice to preempt state law.

¹ **Dr. Gail Cassell an Eli Lilly VP**, former Advisory Committee member to the CDC and NIH and Chair of the Subcommittee which authored this work **testified before the U.S. Congress in January, 2008, that:** “It became readily apparent that the FDA suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities. It is agency wide, i.e. not limited to a single program or Center. Since every regulatory decision must be based on the best available scientific evidence in order to protect the public’s health, we concluded that American lives are at risk and that there is an urgent need to address the deficiencies. ... ***FDA cannot adequately monitor development of new medical products and adequately evaluate the safety of existing products because it is unable to keep up with scientific advances. ... The FDA cannot fulfill its mission because its scientific workforce does not have sufficient capacity or capability.***” (emphasis added)

Riegel deals a body blow to injured consumers and their families. However, the Court's opinion in *Riegel* makes it clear that the decision about preemption is one for Congress. The ball is squarely in Congress's court.

Here's the bottom line: If accepted by the courts and not overturned by Congress, FDA's pro-preemption position gives consumers the worst of both worlds. On one hand, despite FDA's claims otherwise, FDA cannot single-handedly accomplish the Herculean job of assuring the safety of the 11,000 drugs and thousands of medical devices on the market. Thus, consumers cannot depend on FDA regulation alone to protect them from unsafe or defective drugs and medical devices. That is why, until recently, FDA saw the discipline the liability system places on the market as an essential complement to its work.

Despite FDA's inability to safeguard the marketplace by itself, FDA claims that consumers injured by unsafe drugs or defective medical devices should be denied the ability to seek compensation for injuries they sustained through no fault of their own. That is a right that the liability system has guaranteed to the American people since the founding of the Republic. Let's be clear about this: Under FDA's view, consumers are forced to assume the risks of unsafe drugs and medical devices. At the same time, manufacturers of drugs and medical devices who fail to take reasonable steps to assure their drug or device is safe are immunized from liability, and, these days, essentially immune from FDA enforcement. This result is not only unfair, it is bad policy. Removing economic incentives for drug and device manufacturers to act responsibly serves no legitimate end, but instead jeopardizes the health and well-being of the public.

I urge you and your colleagues to pass legislation that will unambiguously eliminate the possibility of preemption of common-law tort actions for drugs and medical devices. Removing this patient right would not only be unjust, but will also result in less safe drugs and medical devices for the American people.

Respectfully yours,