



Thomas McGarity: Safeguard lawsuits that potentially save lives

05:09 PM CDT on Friday, May 9, 2008

A report recently published in the Journal of the American Medical Association should be deeply troubling to the millions of Americans who have taken the blockbuster painkiller Vioxx. The article demonstrated that many of the published scientific studies used to establish the drug's safety and efficacy had been "ghostwritten" by the manufacturer.

In addition to shaking their confidence in the pharmaceutical industry's science, the report should alert them to the even greater threat to public health posed by the Bush administration's recent attempts to terminate the litigation that uncovered the secret documents upon which it relied.

Much of the science that federal agencies like the Food and Drug Administration rely on to assess the safety of consumer products is sponsored by the regulated companies. And it should come as no surprise to learn the one who pays the piper usually calls the tune. Now we discover that the same person also writes the music.

This and many similar accounts of companies "bending" science to their advantage contain three additional messages for American consumers.

First, the regulators who are supposed to be protecting us are often asleep at the switch. The FDA officials who reviewed the studies in connection with their decision to approve Vioxx apparently did not discover the fact that the purported authors had little to do with the studies themselves.

The "regulatory reformers" in think tanks, the White House and Congress have chipped away at bedrock protective institutions like the FDA for so long we now face a situation in which our "hollow government" is incapable of overseeing the powerful industries that market potentially deadly products.

Second, we now know so much about the provenance of the Vioxx studies because the authors of the JAMA article had access to internal company documents that were uncovered in lawsuits filed by the alleged victims of Vioxx. But these are precisely the kind of lawsuits that corporate lobbyists are trying to make impossible or at least harder to pursue. It's worth remembering in the context of the "tort reform" debate that such lawsuits serve the useful purpose of revealing just such corporate misdeeds.

Third, these lawsuits would not have been filed if the Bush administration's efforts to shield the pharmaceutical industry from liability had been in place at the time they were filed.

Last February, the Supreme Court agreed with the administration that product liability claims aimed at medical devices that have received full FDA approval are pre-empted by federal law. Later this year, the Supreme Court will decide whether similar claims regarding FDA-approved drugs are pre-empted by administrative fiat. The Bush administration has taken exactly that position in the FDA's recent drug labeling regulations.

The FDA is only one of several agencies claiming that state lawsuits are pre-empted by federal regulation.

If they succeed, companies subject to the limited oversight of a hollow federal government will no doubt flourish, but the rest of us will not learn the truth about the safety of products that we purchase from them. Worse, consumers who are injured by those products will no longer have a day in court.

With the help of a new administration, Congress can overrule the Bush administration's past efforts and send a message to the Supreme Court that it should not be in the business of pre-empting state tort law. That is one more reason for voters to pay careful attention to the candidates in this election season. Our lives may depend on it.

Tom McGarity teaches at The University of Texas School of Law and is a board member of the Center for Progressive Reform. His book "Bending Science" (with co-author Wendy Wagner) was published this month, and his book "The Preemption War" will be published this fall. His e-mail address is TMcGarity@mail.utexas.edu.