

Trust in medications is matter for justice

By JACK LANDSKRONER

Safe and effective medications are critical to the health of many Americans. By contrast, medicines with undisclosed side effects can incur dire and life-threatening consequences.

As a matter of course, one would expect that pharmaceutical companies would fully disclose the known effects of the products they manufacture and distribute in order to keep both physicians and consumers fully informed of not only the benefits but the risk of taking their drugs. Unfortunately, left to the hands of the pharmaceutical companies, we often don't learn of known risks until long after hundreds of thousands, if not millions, of people are put in harm's way. In short, profits reign over safety when it comes to the pharmaceutical industry, and we are all well advised to keep this in mind when taking prescription medications.

The level of required disclosure and the extent of accountability of the pharmaceutical industry is now front and center before the U.S. Supreme Court. In *Wyeth vs. Levine*, a Vermont musician, Diane Levine, lost her arm after being given an injection of Phenergan, a nausea-reducing drug. She brought her claims against Wyeth, alleging that the company failed to provide her warning of the drug's risk and that its warning label was defective.

The pharmaceutical companies have come to the defense of Wyeth and have taken the position that they should be immune from accountability in any claim against a manufacturer, regardless of their knowledge or failure to disclose all risks of taking their drug. The pharmaceutical industry contends that no drug company should be held responsible for harm caused by their product, because warnings used on products are approved by the Food and Drug Administration, thus they contend that claims of those injured by their products are pre-empted.

The Wyeth case will address this issue and will also encompass arguments related to case studies of three other drugs, including Pondimin-Redux, Vioxx and Traysol. The manufacturers of these drugs withheld key

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information from the FDA while at the same time lobbying against stricter label warnings and marketing their unsafe drugs to an unsuspecting public.

Considering that these companies failed to provide the regulatory agencies of the government with the necessary information to determine if the warning labels were adequate and safe, common sense would certainly dictate that the pharmaceutical companies should not be granted complete immunity to operate under the protection of the federal government.

The position taken by the drug industry poses a serious threat to public health and safety; so much so that doctors and lawyers alike have come together to challenge the drug industry's position and to combat what could result in a dangerous outcome for consumers.

Ten current and former editors and contributing authors to the *New England Journal of Medicine* have joined with Public Justice, America's public-interest law firm, in pointing out that the resource-strapped FDA is already forced to rely upon the drug industry itself for information about the risks and benefits of prescription drugs. Thus, it cannot provide any reasonable or independent foundation to set standards that protect the drug manufacturers in claims that a specific drug fails to safely disclose its risks to consumers.

So the U.S. Supreme Court's review of the Wyeth case will once again test our system at its highest level. It will be interesting to know whether the interests of those least able to protect themselves will be circumvented by protections granted to those special interests with power, access and wealth or whether the voices of those injured will be heard over the rumblings of the profit-making machines of the pharmaceutical industry.

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