

Keeping the window into drug firms' practices open

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Author: Alison Bass

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IN NOVEMBER, the Supreme Court will hear a case that could make it much more difficult for public officials to expose drug industry practices that put profits ahead of patients. The court could conceivably strip state courts of the right to hear cases challenging the safety and effectiveness of drugs that have been approved by the US Food and Drug Administration. Such state lawsuits have been instrumental in forcing the industry to open its books and reveal embarrassing information.

Recently, for instance, researchers relied on trial documents to shed light on a dubious marketing practice employed by some drug companies: running studies purportedly meant to examine drug safety that in reality are designed to encourage the widespread adoption of a new drug. Such studies are called "seeding trials," and while they are thought to be relatively common, the Aug. 18 report in the *Annals of Internal Medicine* was the first to investigate these stealth marketing tactics in-depth and raise questions about the ethics of deceiving doctors and patients about the true purpose of these studies.

The report's researchers were able to expose the machinations behind a particular seeding trial - a 1999 study of the painkiller Vioxx by Merck - only because they got their hands on internal Merck documents subpoenaed by plaintiff attorneys. They had sued the firm after Vioxx was withdrawn from the market amid growing evidence that it increased the risk of heart attacks and strokes.

This is not the first time that litigation has provided the public with a glimpse of the lengths to which some drug companies will go to create blockbuster drugs. In 2004, the New York State attorney general's office relied on GlaxoSmithKline's own internal documents to sue the drug company for deceiving physicians and consumers about the safety and effectiveness of its best-selling antidepressant, Paxil. Similar to the Merck case, GlaxoSmithKline's internal documents revealed a rich vein of duplicity among company officials intent on suppressing negative findings about Paxil in treating depression among children and adolescents.

The Supreme Court case that could close this valuable window into drug company operations is an appeal of a lawsuit brought by a Vermont woman who sued Wyeth after being injected with a drug made by the company (her right arm was amputated as a result of complications from treatment). A Vermont jury awarded the woman compensatory damages, a decision affirmed by the Vermont Supreme Court. Wyeth appealed the verdict to the US Supreme Court, arguing that the FDA's approval of the drug in question essentially preempted state lawsuits. The Vermont Supreme Court found that Wyeth's argument held no water and was in fact contradicted by 70 years of coexistence between state law and FDA's regulations.

Tellingly, a US District Court judge in New York also dismissed a preliminary preemption argument brought by GlaxoSmithKline's attorneys trying to defend the company against the New York attorney general's Paxil lawsuit. GlaxoSmithKline settled that case, agreeing to post the results of all its clinical trials, negative as well as positive, on a public website.

Earlier this year, however, the Supreme Court ruled 8-1 in favor of preemption in a similar case about medical devices, and some observers say the court is leaning in favor of the drug industry in the Wyeth appeal. That assumption, whether correct or not, prompted the state of Alaska in March to prematurely settle its lawsuit against Eli Lilly for playing down the health risks of Zyprexa, a drug used to treat schizophrenia and bipolar disorder.

Consumer advocates are worried that a sweeping Supreme Court decision in favor of Wyeth would not only make it difficult for those harmed by new drugs to seek redress, but would shutter an important porthole into the less than savory tactics some drug companies use to market their wares. Let's hope the Supreme Court does not go down that road.

Alison Bass is the author of "Side Effects: A Prosecutor, A Whistleblower and a Bestselling Antidepressant on Trial" and a senior lecturer in journalism at Mount Holyoke College.

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Abstract (Document Summary)

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