Don't Kill the Pharmaceutical Golden Goose: Tort Litigation Against Merck Can Destroy New Drugs — and Lives

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What a Fall it's been - in every sense of the word - for drug giant Merck: late September saw its withdrawal of the blockbuster anti-arthritis and pain-relieving drug Vioxx. Then, last week, a new report revealed that a Merck vaccine against the virus that causes almost all cervical cancer was completely effective in a 4-year trial among over two-thousand patients.

But will this cancer vaccine - or other lifesaving drugs in the Merck pipeline - ever see the light of day? Not if "Trial Lawyers, Inc." has its way. Tort lawyers seasoned in the asbestos and silicone breast implant wars are filling the airwaves with solicitations for poor folks injured by Vioxx to come in (or just phone!) for a Free Consultation to Protect Your Rights. Those hoping to win the big-bucks lottery for a piece of Merck would get to share their multi-billion dollar damages with their attorney - sometimes 50-50, after expenses - while Merck goes bottom-up. Plaintiffs' lawyers just held a big conference in Las Vegas to organize most efficiently for the kill, and possibly to divvy up the spoils, just like they did with litigation against the tobacco industry.

The rest of the pharmaceutical industry, already burdened with the highest regulatory standards in the world, most likely will soon to have to hurdle an even higher bar at the FDA. The FDA has heard the howling of the wolves at their door, trying to place blame for not foreseeing the unforeseeable until it was too late. Now both the pharmaceutical industry and the FDA will become even more risk-averse - and how many patients will suffer needlessly due to a lack of innovative drugs never developed, or if developed, never approved?

Yet, the case can be made that both Merck and the FDA acted responsibly throughout this episode. Early on, the trials and initial post-marketing studies did not show significant data of increased risk from Vioxx. Also, Vioxx was one of only two COX-2 inhibitors available for those who needed the extra gastro-intestinal (GI) protection. The premise for the development of the COX-2 inhibitors was to protect patients with chronic arthritis from the ravages of GI damage from the toxic, older anti-arthritis drugs, called NSAIDs. And there is substantial data showing that Vioxx (and a drug with a similar mechanism of action, Pfizer's Celebrex) did indeed provide such protection. Only within the past two months did the evidence of increased cardiovascular risk become indisputable - and when it did Merck promptly withdrew the drug. The fact that there is another COX-2 option for patients was one factor in the withdrawal.

Given the investigations now ongoing, how long the COX-2 class of drugs will stay around is problematical. Yet doctors - and even lawyers - know that any drug can have side effects and adverse reactions. Will thousands of lawsuits seeking compensation for adverse cardiac effects,
allegedly resulting from taking Vioxx, bankrupt this once-vibrant company? It's far from impossible: the mere fear of lawsuits, based on much shakier scientific grounds, is largely responsible for the current dearth of lifesaving flu vaccine, as all but two of the previously numerous U.S. vaccine-makers fled the market.

Like every other drug, Vioxx had its risks and its benefits. For patients with severe arthritis and a history of ulcers or internal bleeding, it filled an important void in alleviating unremitting arthritis pain, with relative safety for most. With Celebrex also on the market, doctors could switch if they had concerns about Vioxx. The careful practitioner, aware of the risks and benefits, might still prescribe Vioxx to those at high risk of stomach problems, and avoid it in those with elevated risk of heart disease.

But not any more. While some patients undoubtedly were harmed by the drug's adverse reactions, many more were helped by it, and some lives were saved from the potentially lethal GI complications caused by alternative arthritis drugs.

Now Vioxx is gone - will the whole company soon follow?

Once in court, plaintiffs' attorneys will attack not only Merck, but the FDA for not using the oldest medical instrument, the only one guaranteed to be always right: the 20/20 retrospectroscope.

It's easy for Monday-morning quarterbacks to place blame after the facts are finally sorted out, but quite another matter to evaluate clinical data coming from small early phase trials. If Trial Lawyers, Inc. eviscerates the FDA in the court of public opinion, the agency will become excessively cautious, avoiding any potential side effects, causing needless deaths and suffering as a result of drugs that never reach market or are delayed years longer before they do.

The FDA has the nearly-impossible job of sorting through reams of research and clinical trial data prior to drug approval and marketing. The process is already unduly arduous and expensive, and the prospect of making it more so due to fear of grandstanding attacks from Congress and tort lawyers will serve no public health interest.

Merck is not Enron or R.J. Reynolds, plaintiffs' bar rhetoric to the contrary. In addition to its new foray into cancer prevention, Merck is the only pharmaceutical company still making vaccines for the national children's vaccine stockpile - all the other makers of kids' vaccines have abandoned this vital market due to burdensome regulations and economic disincentives.

For those millions of children, and millions more who might be helped in the future by life-saving drugs coming out of Merck's research labs, Trial Lawyers, Inc. says: Tough luck. We're here for our payday.

Everyone interested in public health should hope that those plotting to carve up Merck like a Thanksgiving turkey will not be successful, and that the promise of its fledgling cancer vaccine - and other drugs for AIDS, osteoporosis, and heart disease, to name just a few - will not be obliterated in Vioxx's wake.
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