

THE MOVE TO REVERSE MICHIGAN'S MODEL REFORMS Why Wolverine Staters Should Just Say No to the Trial Bar's War on Drugs

In state after state, Trial Lawyers, Inc.'s high-octane government-relations machine keeps businesses and consumers on the run. The latest race is on in Michigan, where the litigation industry is seeking to reverse part of a highly successful tort-reform package enacted by the legislature a decade ago.

The lawyers' legislative assault could not come at a worse time for the Wolverine State. Michigan has lost nearly one-third of its manufacturing jobs—its employment mainstay—since 1999, and has hemorrhaged 20,000 jobs since March of last year alone.¹ Anticipating just such an employment exodus from the besieged automobile sector, Michigan's legislators in 1996 passed an "FDA defense" law that has allowed another sector of Michigan's economy—medical research and development—to thrive. Should the plaintiffs' bar succeed in repealing this rule, Michigan's 12,000 pharmaceutical-industry jobs—with a direct and indirect economic impact of over \$4 billion—would be in jeopardy. Many manufacturers in other sectors, as well, would certainly view the legislature's retreat as an ominous portent for the state's litigation climate. Repeal would, for example, forestall any hoped-for growth in Michigan biotech that industry leaders have projected.

Michigan's Principled, Pragmatic Stand

In 1996, the Michigan legislature passed its historic "FDA defense" law, under which a drug's approval by the Food and Drug Administration (FDA) automatically sets limits on the suits that can be filed against its maker. Because Vioxx was approved by the FDA, for example, plaintiffs' ability to recover for alleged Vioxx-related injuries in Michigan courts is sharply curtailed.

Does the ten-year-old Michigan reform make sense? We think so. As we noted in our *Trial Lawyers, Inc.: Health Care* report:

Trial Lawyers, Inc.'s assault on the drug industry has undermined the democratic authority of Congress itself, which vests the Food and Drug Administration with responsibility for pharmaceutical regulation. . . . Though the FDA is far from perfect and needs reform, its onerous approval processes are specifically designed to test drugs' safety and efficacy with an eye toward the big picture: they determine whether the costs of allowing a drug into the marketplace are higher or lower than the benefits that the drug is expected to bring. In contrast, juries that decide lawsuits over drug side effects can consider only the case at hand, not the broader cost/benefit analysis.²

Common sense—and a commitment to democratic and federalist principles—dictates that local juries should not be able to trump the considered decisions of a federal regulatory agency. Runaway juries discourage vital innovation and harm the public health.

Given Michigan's current economic woes, though, it's important to realize that Michigan's lawmakers in 1996 weren't merely interested in federalist principles or the state of overall drug innovation in the United States. The FDA preemption law was specifically intended to give Michigan a comparative advantage over other states and attract high-technology pharmaceutical jobs. Notes Dick Posthumus, who as Senate majority leader led the 1996 reform efforts in the legislature:

One of the things we foresaw at the time was the need to diversify Michigan's economy. We saw coming what eventually happened, that is the globalization of the auto industry, which meant Michigan wouldn't be as dominant and we

would have to provide jobs in other industries. One of the industries we looked at as a state back then, and I think rightly so, was the life sciences industry. We had Pfizer in Ann Arbor and Upjohn in Kalamazoo. We had Dow in Midland and the University Research Center in Ann Arbor. . . . We had all of these pieces, so one of the things we wanted to do was encourage the expansion of the life sciences industry. There were a whole lot of pieces to that, but one of the pieces was to ensure that a pharmaceutical company working on a life-saving drug wouldn't have to worry about frivolous lawsuits.³

Just how well has the state legislature's plan worked? Life-sciences companies have invested \$355 million on research and development in Michigan since the preemption law's passage in 1996, and the pharmaceutical industry's 12,000 jobs in the state have a healthy average yearly wage of over \$60,000.⁴ And this in a state with a 6.6 percent unemployment rate, at a time when unemployment hovers under 5 percent nationally.

VIOXX SUITS: A Pain in the Neck

The context behind the legislative fight in Michigan is the battle royal being fought nationwide between the plaintiffs' bar and Merck & Co., the maker of the once-popular anti-inflammatory drug Vioxx. As we detailed in *Trial Lawyers, Inc.: Health Care*—and as anyone following the news is well aware—Merck has faced a barrage of lawsuits since health concerns prompted the company to voluntarily pull Vioxx from the market in 2005.⁵

Many of these lawsuits have rested and will continue to rest on the flimsiest of scientific evidence. For example, in the widely publicized Texas case of *Ernst v. Merck*, the jury awarded widow Carol Ernst \$250 million for her husband's death, though such damages will fortunately be reduced dramatically before all is said and done. Key to the Ernst case was the testimony of Dr. Maria Araneta, who initially determined that Robert Ernst's death was due to irregular heartbeat, but later changed her mind and claimed in a videotaped deposition that he had actually died of a Vioxx-caused blood clot. Never mind that Merck's clinical trial showed that it takes 18 months of Vioxx usage before the risk of cardiovascular events increases, and that Ernst had been taking the drug only for eight.⁶ Even more astonishing is the new Texas Vioxx verdict, in which a court awarded \$7 million in compensatory damages to the family of Leonel Garza, a 71-year-old smoker with a history of heart trouble. Garza used Vioxx for only a month before his heart attack—at least according to his family's lawyers. They were only able to produce concrete evidence, however, that Garza took it for one week.⁷

What has already become evident in the Vioxx cases—as has been the case in so many mass torts in the past—is that naive or misled juries will be unable or unwilling to assess scientific evidence and reach a dispassionate judgment in the face of tragedy, regardless of the facts or the law. Little wonder that Trial Lawyers, Inc. has thus far filed more than 11,500 lawsuits in Texas, New Jersey, California, and elsewhere.⁸

Trial Lawyers, Inc. against the “Little Guy”

Trial Lawyers, Inc., however, is not worried about Michigan’s unemployment. Despite its oft-voiced concern for workers, consumers, and the economy, the trial bar’s principal interest is expanding its opportunities for collecting multimillion-dollar verdicts and settlements. Since Michigan’s preemption law has made it a safe haven from predatory drug lawsuits, the state has become ground zero for the plaintiffs’ bar’s latest attack on the public interest.

Working in concert with Michigan House members Dianne Byrum and Ed Gaffney, the lawyers have launched a frontal assault on Michigan’s FDA preemption law. A bill that would overturn the law, HB 5527, is scheduled to come before the state legislature later this spring or early summer.⁹ Byrum, the bill’s chief advocate, repeats the tired refrain that drug companies put “profits before people and secrecy before safety.” Taking a page out of the Trial Lawyers, Inc. public-relations playbook, Byrum claims to be standing up “for the ‘little guy.’”¹⁰ But it’s precisely the “little guy”—the average medical consumer and citizen—who will be seriously hurt if Byrum and Trial Lawyers, Inc. succeed.

To understand how drug litigation affects medical consumers, consider the case of Iris Linder, a Michigan attorney who suffers from lupus.¹¹ Linder, once dependent on Vioxx to ease her chronic joint inflammation, now lacks an effective replacement. But for the specter of drug litigation, it’s highly unlikely that Merck would have pulled Vioxx completely from the market, given that its health risks are for identifiable populations taking the medicine for identifiable periods and doses. Now, Linder and the hosts of other “little guys” who once used Vioxx to ease their pain and improve their lives will simply have to suffer. Because of unfounded drug litigation such as the winning Vioxx suits filed by Carol Ernst and Leonel Garza, a variety of life-saving and life-enhancing medications—those now in development and others yet to be imagined—may never make it to the little guy’s medicine chest.



AP PHOTO/AL GOLDIN

Representative Dianne Byrum

Byrum, the Democratic Leader in the Michigan House, is leading the assault on the state’s FDA preemption law.

While Michigan’s laws can have only a marginal impact on the national problem of drug litigation, Michigan workers and taxpayers are certain to feel the bite should federal preemption be overturned. Not only will jobs leave the state as life-sciences industries decamp, but pharmaceutical companies will also pass the cost of lawsuits on to consumers in the form of higher prices. As Dr. David Janda, an orthopedic surgeon and health-care cost-containment expert, put it: “Repeal of preemption will raise the cost of health care for every family and every business in Michigan.”¹²

Finally, it’s important to recognize that the trial lawyers will not stop at FDA preemption reform. If Trial Lawyers, Inc. disposes of federal preemption in Michigan, it will set its sights on Michigan’s healthy battery of other tort reforms, including a two-tiered damage-cap system in medical suits (\$280,000 for “ordinary occurrences” and \$500,000 for brain/reproductive-organ damage), a similar system in product liability lawsuits, and a law limiting contingency fees to 33 percent of the amount recovered. Businesses will assume, quite

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Governor Jennifer Granholm

The governor needs to protect Michigan's emergent life-sciences industries from Trial Lawyers, Inc.

reasonably, that such reforms are much more likely to be repealed if the plaintiffs' bar succeeds in reversing the FDA defense. Given that 50 percent of business leaders say that their investment and relocation decisions are affected by states' litigation climates, a worsening legal climate is a risk that job-starved Michigan can ill afford.

Trial Lawyers, Inc. and its public advocates talk as though absolutely no protection for medical consumers exists in Michigan. This is simply not the case. Michigan's law has a provision allowing suits to proceed if it is determined that the drug company willfully withheld

or misrepresented information during the approval process.¹³ Such a safeguard is a necessary precaution: if the drug company lies to the FDA, the FDA's judgment is based on faulty information. The Michigan law strikes an appropriate balance, permitting the FDA to do its job but punishing companies that withhold valuable information and interfere with the FDA's good-faith cost/benefit analysis.

Michigan's FDA preemption law, as long as it stands, will limit the economic and social costs that the litigation industry imposes on the state. With luck, Michigan Chamber of Commerce president and CEO James Barrett and others interested in this issue will be able to stem the tide of opposition. Otherwise, an important line of defense in the struggle for tort reform will be lost. The Michigan law should serve as a model for other states and the federal government. Michigan's economic outlook is not so rosy that it can easily spare another 12,000 jobs, especially the high-paying kind that medical investment brings in. Michigan governor Jennifer Granholm has been aggressively pursuing nontraditional industries for the state—even traveling to Japan to lure biotech jobs to Michigan (pictured left)—but her leadership in protecting FDA preemption has been lacking to date. It would be a huge economic mistake if Michigan allowed Trial Lawyers, Inc. to gut the state's model reform—a mistake with real consequences for the health of Michigan's consumers and the wealth of its workers.

¹ Josee Valcourt and Louis Aguilar, *Detroit News*, 4/20/06

² (<http://www.triallawyersinc.com/TLI-HealthCare.pdf>)

³ John Reurink, *Michigan Forward*, March/April 2006

⁴ Milken Institute, *Biopharmaceutical report*, 10/04

⁵ (<http://www.triallawyersinc.com/TLI-HealthCare.pdf>)

⁶ Alex Berenson, *New York Times*, 8/20/06

⁷ Jennifer Won Tesoriero, *Wall Street Journal*, 4/22/06

⁸ Amanda Bronstad, *National Law Journal*, 3/27/06, Alex Berenson,

New York Times, 4/22/06

⁹ MIRS, 2/7/06

¹⁰ MIRS, 3/29/06

¹¹ Iris Linder, *Detroit News*, 1/25/06

¹² Phone interview, 5/2/06

¹³ Iris Linder, *Detroit News*, 1/25/06