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A TRAGIC BLUNDER MICHIGAN'S DRUG INDUSTRY IMMUNITY LAW By Amanda Melpolder

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In 1995, under the leadership of then Governor John Engler, the Michigan legislature passed an unprecedented law that prevents its residents from gaining access to the civil justice system if they were harmed by dangerous drugs approved by the Food and Drug Administration (FDA), with the limited exception that the drugmaker did not withhold information from the FDA. Michigan is the only state in the nation that has a drug industry immunity law which allows drug companies to escape accountability in this manner.

Over the last 15 years or more, as drug companies have had an increasing amount of influence over FDA decision-making and policy, the FDA has fallen down on its job of protecting the public. The result has been perilous for all Americans, with the news now replete with reports of drug industry marketing unsafe drugs to the public with the FDA's knowledge - Rezulin, Vioxx, and Trasyolol, recently featured on *60 Minutes*, to name just a few.¹ Yet unlike the residents of any other state, Michiganders have no legal recourse should they be hurt by these or other dangerous drugs that the FDA failed to keep off the market.

What Michigan lawmakers accomplished with this law is exactly what the pharmaceutical industry has been trying to accomplish unsuccessfully for the last three decades in Congress and state legislatures around the country – eliminating their liability for marketing unsafe drugs, and shielding them from responsibility when their harmful products hurt or kill.

With the problematic nature of the FDA, it is clear that Michigan needs the protection of its civil justice system. This law undermines public safety, is devastating to many people in Michigan and needs to be repealed.

¹ "One Thousand Lives A Month" *60 Minutes* aired February 17, 2008, available on-line at <http://www.cbsnews.com/stories/2008/02/14/60minutes/main3831900.shtml>; Berenson, Alex and Harris, Gardiner and Meier, Barry and Pollack, Andrew, "Despite Warnings, Drug Giant Took Long Path to Vioxx Recall," *New York Times*, November 14, 2004; Willman, David, "The Rise and Fall of the Killer Drug Rezulin," *Los Angeles Times*, June 4, 2000. Just recently, the FDA admitted it violated its own policies in failing to inspect a Chinese factory that supplies a key ingredient for the blood thinner drug Heparin. Within the same week, Baxter International, the maker of Heparin, announced it was suspending sales of the drug after four people died and hundreds of others suffered complications. Walt Bogdanich, Jake Hooker, "China Didn't Check Drug Supplier, Files Show," *New York Times*, February 16, 2008.

PRODUCT LIABILITY AND CIVIL JUSTICE

The National Conference of State Legislatures (NCSL) has said, “State tort laws and civil justice systems serve as an important check on federal standards. Our civil justice system establishes a duty of care that protects citizens when the federal government is too slow to act or when federal standards are insufficient. States have the ability to achieve greater protections for their citizens through successful product liability lawsuits.”²

Lawsuits against drug manufacturers are sometimes brought by people who have suffered harm or by the families of those who have died from unsafe drugs, holding the manufacturers of these drugs directly accountable for causing and often forcing changes in the sale of these drugs. Product liability is the specific area of law under which such cases are brought. These lawsuits often help uncover important information about dangerous drugs, and can create widespread publicity about them through the mass media and other means, alerting an unsuspecting public to drug dangers. In addition, they can spark medical research into areas that were previously ignored.³

History shows that women have been particularly helped by such litigation as many unsafe drugs that have caused some of the most serious injuries and death have been marketed specifically for women.⁴ For example, from 1939 until the FDA banned it in 1971, a synthetic estrogen called DES (diethylstilbestrol) that was thought to prevent miscarriages and promote healthy pregnancies was prescribed to nearly five million pregnant women. Not only did DES not work, it increased the risk for cancer, infertility and other serious health problems for the women who took it, and the children they carried. “Until women started bringing and winning lawsuits, many DES exposed women did not know about the risks they faced.”⁵ Moreover, “[u]ntil the first wave of successful lawsuits, little follow up research had been done to learn about the health effects of DES exposure. As such research has been done, more and more adverse health effects have come to light.”⁶

² National Conference of State Legislatures, <http://www.ncsl.org/statefed/health/RegAct.htm#drglble> (NCSL’s comments of concern regarding controversial language preempting state product liability that the FDA inserted into the preamble to its final rule on prescription drug labeling; see, “Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products,” 71 Fed. Reg. 3922-97 [Jan. 24, 2006]).

³ Finley, Lucinda M., “Female Trouble: The Implications Of Tort Reform For Women,” 64 *Tenn. L. Rev.* 847, Spring 1997. See also, Koenig, Thomas & Michael Rustad, “His And Her Tort Reform: Gender Injustice in Disguise,” 70 *Wash. L. Rev.* 1, 51 January 1995.

⁴ *Ibid.* In her study of injury cases, Professor Lucinda Finley, the Frank Raichle Professor of Law at the State University of New York at Buffalo Law School, noted, “some types of injuries happen primarily to women - impaired fertility or sexual functioning, miscarriage, incontinence, trauma associated with sexual relationships, scarring or disfigurement in personally sensitive intimate areas of the body.” See also, Koenig, Thomas & Michael Rustad, “His And Her Tort Reform: Gender Injustice in Disguise,” 70 *Wash. L. Rev.* 1, 51 (January 1995)

⁵ Finley, Lucinda M., “Female Trouble: The Implications Of Tort Reform For Women,” 64 *Tenn. L. Rev.* 847, 878, Spring 1997 In another example, a 20-year-old woman underwent an unnecessary hysterectomy and had part of her lung removed after a pregnancy test produced false positives for cancer. After the case, the manufacturer sent out warning letters to doctors and laboratories about the test’s propensity to give false-positives. (*Rufer v. Abbott Laboratories*, No. 99-2-27090-8 (King County Super. Ct., Wash., verdict June 29, 2001). See also, Fisk, Alan, “Warning sent after \$16M verdict; Hormone test could give false positives for cancer, company tells doctors,” *National Law Journal*, December 3, 2001; “Abbott letter cautions on test for pregnancy,” *Chicago Tribune*, November 14, 2001; Ostrom, Carol M., “Firm that lost big suit sends warning on diagnostic test; Abbott had blamed error on doctor,” *Seattle Times*, November 13, 2001.)

⁶ *Ibid.*

Since the DES situation, product liability lawsuits have only grown in importance, as corporate lobbyists and their political allies began making tremendous strides weakening regulations and safety standards for prevention of harm to Americans. Federal agencies like the FDA were created to conduct regulatory oversight and ensure public safety. However, as corporate lobbying has increasingly influenced the FDA, the regulatory agency has become less and less likely to step in, investigate safety problems with drugs and pull them from the market.⁷

Indeed, the public has become more and more familiar with the drug industry's extremely problematic safety record. Countless times in recent years, the FDA has failed to exercise proper oversight in order to save lives. As David C. Vladeck, Professor of Law at Georgetown University put it, "Congress is, of course, acutely aware of the shortcomings in the FDA's ability to police the marketplace on drug safety, which have been driven home by the recent public health failures involving widely-prescribed drugs like Vioxx, Bextra, Celebrex, Avandia, Rezulin and Baycol."⁸ The burden then rests with the public, through the use of the justice system, to correct drug industry wrongdoing.

FDA Defense in State Legislatures

By the 1980's, many state legislatures (with rare exceptions, injury, or "tort" laws are state laws, not federal laws) had considered some sort of product liability legislation. Some contained language typically referred to as "FDA defense."⁹ The idea behind the "FDA defense" was to establish, by legislation, the theory that courts (specifically, juries) should not be allowed to second-guess the agency by hearing injured consumers' tort claims or by awarding them punitive damages for injuries and deaths caused by drugs the FDA approved.

When a court requires a wrongdoer to pay punitive damages, it calls upon the wrongdoer to pay more than the amount required to compensate a person for the impact of a specific injury. Punitive damages are designed to be a deterrent against future serious misconduct. In other words, legislating the "FDA defense" idea could make it impossible for a consumer to ask a court to require a drug manufacturer to pay punitive damages even if the manufacturer had information that the drug was harmful, and even if the FDA knew the drug was harmful and refused to act.

In 1987, New Jersey and Oregon passed "FDA defense" legislation that limited punitive damages for FDA approved drugs. Oregon's law shielded drug companies from paying punitive damages even if the drug they manufactured had been found to cause harm.¹⁰ New Jersey's law stated that anything (food, drugs etc) regulated by the FDA was not subject to punitive damages

⁷ See, e.g., Gottlieb, Emily, "Corporate Empowerment And The Decline Of Public Safety," Center for Justice & Democracy 2007

⁸ David C. Vladeck, Professor of Law, Georgetown University Law Center, and Scholar, Center for Progressive Reform, "The Emerging Threat of Regulatory Preemption." American Constitution Society Issue Paper, January 2008.

⁹ "10 States Have Enacted or Are Now Considering Punitive Damages Legislation." *PR Newswire*, May 19, 1989.

¹⁰ Oregon Revised Statutes (2005 Edition) Chapter 30 — Actions and Suits in Particular Cases PRODUCT LIABILITY ACTIONS 30.927 Sec. 1 through 4

unless material information was withheld or misrepresented.¹¹ Until Michigan's law, however, which granted drug companies complete immunity, bills at the both the federal and state levels contained "FDA defense" language limiting punitive damages but did not completely eliminate accountability for harm.

Attempts at Federal Legislation

In the 1980's, federal legislation to "preempt" or override state product-liability statutes began appearing in Congress.¹² Typically these bills severely limited punitive damages, restricted the liability for sellers of defective products, and cut off manufacturers' liability for marketing unsafe drugs. Often when "FDA defense" language was included in these bills, the language limited the award of punitive damages in cases involving FDA approved drugs and/or medical devices. Such product liability legislation was vehemently opposed by national consumer advocacy organizations.¹³

By 1995, the United States had been introduced to newly chosen House Speaker Newt Gingrich's "Contract with America." Among other priorities of this new pro-business majority was a product liability bill¹⁴ that included protection from punitive damages for companies making FDA approved drugs and medical devices.¹⁵ For the first time ever, this type of legislation passed Congress. However, President Bill Clinton vetoed it in May 1996, because as he stated, it "tilt[ed] the playing field against consumers."¹⁶

Over the years, Congress continued to debate product liability issues and the legislation that was proposed often included language that would have shielded drug manufacturers from responsibility when harmful products hurt or kill.¹⁷ In 2003, the U.S. House of Representatives passed legislation, backed by the Bush administration that dealt primarily with medical malpractice cases but also contained language to limit punitive damages for FDA-approved drugs and devices in medical malpractice cases.¹⁸ The legislation failed to pass the Senate.¹⁹

¹¹ New Jersey Permanent Statutes Title 2A ADMINISTRATION OF CIVIL AND CRIMINAL JUSTICE 2A:58C-5. and "New Jersey Moves to Center Stage in Liability," *Chemical Week*, July 22, 1987

¹² Mayer, Caroline E., "Changes Urged in Product Liability Law; Product Liability Laws Overhaul Being Sought." *Washington Post*, March 10, 1982 ; Lewin, Tamar, "Business and the Law; If a Product is Defective," *New York Times*, April 20, 1982 ; "Product Liability Bill Opposed," *New York Times*, February 10, 1983 ; deCourcy Hinds, Michael, "A Move to Stem Liability Cases," *New York Times*, October 2, 1983 ; Mintz, Morton, "Sides Skirmish Over Product Liability Bill; Provision Limiting Suits Hotly Contested in Senate," *Washington Post*, March 25 1984.

¹³ Of the legislation, Pamela Gilbert of U.S. Public Interest Research Group (U.S. PIRG) wrote in a June 1988 *New York Times* Letter to the Editor, "a Congressional committee passed a bill to exempt manufacturers of drug or medical devices that comply with FDA regulations from paying punitive damages, no matter how egregious their behavior nor how severe the harm they cause. The bill would provide an absolute shield from punitive liability for Hoffmann-La Roche, Accutane's maker, as long as the company followed FDA rules, however inadequate." Ward, Ken Jr. "Rockefeller Liable to Keep Pushing for Product Bill," *Charleston Gazette*, June 21, 1994, Pg. P1B ; "Legal and Extralegal Barriers to Federal Product Liability Reform." *American Business Law Journal*, May 1995, Vol. 32 ; No. 4 ; Pg. 541.

¹⁴ Kellman, Laurie, "Next 100 days' of Hill action belong to Senate," *Washington Times*, April 24, 1995.

¹⁵ Labaton, Stephen, "G.O.P. Preparing Bill To Overhaul Negligence Law," *New York Times*, February 19, 1995.

¹⁶ Lewis, Neil A., "President Vetoes Limits on Liability," *New York Times*, May 3, 1996.

¹⁷ VandeHei, Jim, "Malpractice Bill Shields Drugmakers," *Washington Post*, January 5, 2005.

¹⁸ Stolberg, Sheryl Gay, "House Backs Limit on Malpractice Awards," *New York Times*, March 14, 2003.

¹⁹ Stolberg, Sheryl Gay, "Short of Votes, Senate G.O.P. Still Pushes Malpractice Issue," *New York Times*, July 6, 2003.

Following the 2003 defeat and continuing through 2006, Bush and Senate Majority Leader Bill Frist (R-Tenn.), with a close relationship to both to HCA hospitals and pharmaceutical giant Eli Lilly,²⁰ continued to try revive medical malpractice legislation containing a “FDA-defense” provision for punitive damages.²¹ The legislation was met with sharp criticism²² and like all the other legislation introduced before it, the bill failed to pass the Senate.

²⁰ See, e.g., Ireland, Doug, “The Bad Doctor; Bill Frist’s Long Record of Corporate Vices,” *LA. Weekly*, January 9, 2003; Stolberg, Sheryl Gay, “A Capitol Hill Mystery: Who Aided Drug Maker?,” *New York Times*, November 29, 2002.

²¹ See, e.g., Pear, Robert, “Bush Begins Drive to Limit Malpractice Suit Awards,” *New York Times*, January 6, 2005. See also, Doroshov, Joanne, “Legislative Malpractice,” May 8, 2006, *TomPaine.com*, available at http://www.tompaine.com/articles/2006/05/08/legislative_malpractice.php.

²² Henderson, Diedtra, “Limits Sought For Suits Over OK’d Drugs,” *Boston Globe* December 17, 2004 ; Herbert, Bob, “A Gift for Drug Makers,” *New York Times*, January 14, 2005; Reich, Robert B., “A Suitable Remedy; When the FDA Is Weak,” *Washington Post*, January 9, 2005.

MICHIGAN'S POLITICS AND THE DRUG IMMUNITY LAW

In 1995, the Michigan legislature passed product liability legislation that contained the most extreme “FDA defense” language ever signed into law.²³ The product liability package, which went into effect in 1996, prohibits all product liability lawsuits against the drugmakers for marketing unsafe drugs (provided the company did not fraudulently withhold information from the FDA) – leaving Michigan residents without any real legal remedy if they were harmed or killed by dangerous drugs.²⁴ Although there was little media discussion of the FDA defense language in the bill at the time the bill passed, it has since been opined by the editorial board of the *Detroit Free Press*, “the [drug] immunity law is easily one of the worst legacies of former Gov. John Engler.”²⁵

Before becoming Governor, John Engler served in Michigan’s State legislature for 20 years, including seven years as State Senate Majority Leader.²⁶ While in office, Engler was a supporter of restrictions on the rights of consumers to hold corporations accountable for harmful misconduct and seemed determined to get a radical version of this legislation passed in Michigan. In 1987, while Engler was the Senate Majority Leader, the Senate proposed a bill that “include[d] a legal presumption that all products [were] safe if they [met] existing government and industry standards at the time they [were] designed, manufactured and sold.”²⁷ In March 1988, the Mackinac Center, a conservative think tank co-founded by Engler²⁸ published an article entitled “Product-Liability Reform: Better Late Than Never” that supported some version of a law limiting the rights of injured consumers.²⁹

²³ State legislatures continued to consider some types of product liability legislation – some which included “FDA defense” language. In 1995, the Missouri legislature defeated a bill that would have shielded drug manufacturers from punitive damages if the company had followed FDA guidelines, yet North Carolina and Illinois both passed new legislation making it more difficult to sue if a product was approved by an applicable federal agency. Brizzolara, Margaret and Wencl, Annette, “The State of The Union; Tort Law Reform,” *Trial Magazine* 1 Nov. 1995.

²⁴ O’Steen, Jonathan O. and O’Steen, Van. “The FDA Defense: Vioxx® and the Argument Against Federal Preemption of State Claims for Injuries Resulting From Defective Drugs,”⁴⁸ *Arizona Law Review* 67, 91 (2006).

²⁵ “A Poison Legal Pill: Michigan Must Repeal Law That Leaves Victims Of Vioxx And Other Bad Drugs Shut Out Of Court,” *Detroit Free Press*, November 18, 2007, Editorial Pg. 1

²⁶ As State Senator, Engler befriended a constituent named Russell Kirk, one of the leading conservatives at the time, who became his mentor. (Miller, John J. “Citizen Engler.” *National Review*, January 2, 2003) After having served three terms as Governor, John Engler became President of the National Association of Manufacturers (NAM) in 2004, and an active leader in the so-called “tort reform” movement. See American Justice Partnership, “John Engler Biography,” available at http://www.legalreforminthenews.com/leaders/Engler/Engler_bio.html.

²⁷ Legislative Records for Senate Bill 338 (1987) and Engler, John. “What Did the Legislature Do For Michigan Business in 1987? Workers’ Comp, Unemployment Rates, Liability and Insurance Topped Agenda,” *Michigan Business* Jan. 1988, Vol. 4; No 10; Sec 1; Pg 30.

²⁸ According to a series of investigative reports published in 1996 by the *Metro Times*, Engler partnered with lobbyist Richard McLellan and insurance company executive D. Joseph Olson (whom Governor Engler later appointed to head the Michigan Insurance Bureau) to create the Mackinac Center for Public Policy, a “conservative free-market think tank” reportedly funded by corporations, particularly in the insurance industry. Available online at <http://www.metrotimes.com/johnengler/default.html>. In November 2006, the *New York Times* reported that when the Mackinac Center was started, Engler helped recruit his friend Lawrence W. Reed to run the think tank. DeParle, Jason, “Right-of-Center Guru Goes Wide With the Gospel of Small Government,” *New York Times*, November 17, 2006. In October 2007, the Lansing newspaper *City Pulse* called Engler “one of the original founders of the conservative, free-market Mackinac Center for Public Policy.” Canstanier, Bill, “Engler’s Legacy,” *City Pulse*, October 31, 2007.

²⁹ Mackinac Center, “Product-Liability Reform: Better Late Than Never” (1988).

Yet Engler was not the only Michigan politician at the time that supported limits on the legal rights of consumers injured by products. In October 1986, State Senator Richard Posthumus (who later became Engler's Lieutenant Governor) drafted a broad-sweeping product liability bill that immunized manufacturers if the "product [was] made in accordance with industry standards...[and] made in accordance with state and federal law."³⁰ During the 1988 Michigan state legislative session, Governor James Blanchard also supported product liability legislation.³¹

After Engler was elected Governor in 1990, one of the top priorities for "Engler loyalist" House Speaker Paul Hillegonds was working on "laws to curb product liability lawsuits."³² During the 1994 legislative session, a bill was introduced by State Representative Michael Nye and lobbied heavily by the state's business groups,³³ however the legislation "died by filibuster" that year.³⁴

During the 1995 legislative session, the Senate introduced broad sweeping product liability legislation.³⁵ The drug immunity language that was included in the final bill did not appear to be a public priority³⁶ and was scarcely mentioned in the press. The Senate passed its version of the bill in May,³⁷ but the House delayed its vote until the fall.³⁸ In a heated floor debate in October 1995, Representative Lynne Martinez stated:

This [product liability] bill is anti-consumer in the extreme. I cannot in good conscience allow corporations to avoid responsibility when one of my constituents is injured by one of their products. This bill will relieve manufacturers from the responsibility for making safe products. My constituents' right to be compensated from an at-fault party or manufacturer would be excessively and unfairly limited. This bill allows corporations to avoid responsibility when someone is injured by one of their products. There is no evidence of a product liability crisis in Michigan. This bill is creating the crisis – the small person's protection from unsafe products.³⁹

The House then voted the bill out by a slim margin of 59-48, and the legislation was returned to the Senate.⁴⁰

³⁰ Whisenhunt, Eric, "The Bucks Stop Where?" *Michigan Business*, December 1986, Vol. 3; No 9; Sec 1; Pg 32.

³¹ Casler, Kristin, "Michigan Prepares '88 Offensive State Lawmakers to Concentrate on Tax, Education Reforms," *Chicago Tribune*, January 29, 1988, Pg. 3.

³² Christoff, Chris, "A Nice Republican, A Tough Job Next State House Speaker Wins Praise, But Faces Perilous Path," *Detroit Free Press*, November 19, 1994.

³³ Blake, Laura, "Product Liability Breaks Sought," *Grand Rapids Business Journal*, July 5, 1994, Vol 12; No 27; Sec 1; pg 1.

³⁴ Blake, Laura, "Liability Breaks Put in Motion," *Grand Rapids Business Journal*, October 24, 1994, Vol 12; No 43; Sec B; pg 3.

³⁵ Michigan Legislative History for SB 344 (1995).

³⁶ Lane, Amy, "Biz Aims For Product Tort Reform," *Crain's Detroit Business*, February 2, 1995.

³⁷ Lane, Amy, "House Ready to Take Up Product-Liability Bill," *Crain's Detroit Business*, May 15, 1995.

³⁸ Lane, Amy, "Long-Sought Product-Liability Bill Nears Passage," *Crain's Detroit Business*, October 23, 1995.

³⁹ Journal of the House of Representatives of the State of Michigan 1995 Regular Session 88th Legislature, October 18, 1995, Pg. 2,425-6.

⁴⁰ Johnson, Malcolm, "House OKs Cutting Liability Measure Would Put Limits on Lawsuits Over Consumer Products," *Detroit Free Press*, October 19, 1995 ; Lane, Amy, "Long-Sought Product-Liability Bill Nears Passage," *Crain's Detroit Business*, October 23, 1995.

By late November 1995, the bill continued to be debated and amended several times which sent the bill back and forth between the House and the Senate.⁴¹ According to debates in the Senate, it was clear that the legislative intent was to provide immunity for drug manufacturers.⁴² In early December 1995, the product liability bill had passed the Senate and was again waiting for approval by the House, which it barely did by a vote of 57-52.⁴³ In late December 1995, Governor Engler⁴⁴ signed Senate Bill 344 into law.⁴⁵

Weak Justification for Legislation

The Michigan Manufacturers Association, a strong pro-business lobbying group, has stated that it supported the drug immunity law in order to “encourage companies – including pharmaceutical companies – to stay in Michigan.”⁴⁶ The high-paying pharmaceutical jobs, however, began trickling out of Michigan even as Governor Engler was signing the bill into law.

In 1995, the Kalamazoo-based pharmaceutical company Upjohn Co., the company the immunity law was meant to protect,⁴⁷ merged with the Swedish company Pharmacia Corp.⁴⁸ After the merger, the new company moved its headquarters and cut hundreds of jobs in Michigan.⁴⁹ In 2003, Pharmacia & Upjohn merged with Pfizer⁵⁰ and cut over a thousand additional jobs in Western Michigan.⁵¹

⁴¹ supra 35

⁴² Cilla, Dana, “Michigan Tort Reform: A Constitutional Haven for Pharmaceutical Companies and a Tough Pill to Swallow for Consumers,” *Thomas M. Cooley Law Review*, Vol. 19 (3): 331-360, 338 (2002)

⁴³ supra 35

⁴⁴ Around the same time Governor Engler was receiving national attention. In November 1995, he was elected Chairman of the Republican Governors Association (RGA). “Gov. Engler Elected Chairman of Republican Governors” Press Release November 21, 1995, available at <http://www.state.mi.us/migov/gov/PressReleases/199511/englerrrg.html>. There was speculation that he might run for Vice-President with Senator Bob Dole in 1996 (Lane, Amy, “Biz to Engler: Stay Put! Guvs Can Help More Than Veeps, They Say,” *Crain’s Detroit Business*, April 15, 1996, Pg. 3 ; “Dole Picks Jack Kemp As No.2; Former Rivals Join In White House Bid,” *St. Louis Post-Dispatch*, August 10, 1996, Pg. 1A) as well as run for President in 2000. Kraske, Steve, “Familiar faces set their sights on next round; Powell, Kemp remain party favorites for future, while other GOP stars seek new supporters,” *Kansas City Star*, August 19, 1996. He threw his support toward George W. Bush during the 2000 Presidential race. Mittelstadt, Michelle, “Possible Bush presidential candidacy draws support from governors,” *Associated Press State & Local Wire*, February 22, 1999. Engler remained Governor of Michigan through the end of his term in 2002. Upon leaving office, he took various jobs in the private sector working for pro-business organizations, including his current position of President of the National Association of Manufacturers (NAM).

⁴⁵ The Judicature Act 236 of 1961 Section 2946 product liability action; admissible evidence Section 2946 (5) (a) and (b) as amended in 1995, available at [http://www.legislature.mi.gov/\(S\(k4rsstbrcgwxvm45ezjlrwng\)\)/mileg.aspx?page=getObject&objectName=mcl-600-2946&highlight=product AND liability](http://www.legislature.mi.gov/(S(k4rsstbrcgwxvm45ezjlrwng))/mileg.aspx?page=getObject&objectName=mcl-600-2946&highlight=product AND liability).

⁴⁶ “Michigan’s Pharmaceutical Product Liability Laws Protect Consumers, Businesses and Employees,” *MiBiz*, September 19, 2005.

⁴⁷ O’Steen, Jonathan O. and O’Steen, Van. “The FDA Defense: Vioxx® and the Argument Against Federal Preemption of State Claims for Injuries Resulting From Defective Drugs.” 48 *Arizona Law Review* 67, 89 (2006).

⁴⁸ Uchitelle, Louis. “Aiming at H.M.O.’s, Upjohn Agrees to \$13 Billion Merger,” *New York Times*, August 21, 1995.

⁴⁹ Kosmetatos, Sofia, “How Kalamazoo survived Pfizer cuts; Ann Arbor looks to sister college town for lesson in keeping scientists, adding jobs,” *Detroit News*, March 15, 2007.

⁵⁰ Information can be found on Pfizer’s website at http://www.pfizer.com/about/history/pfizer_pharmacia.jsp

⁵¹ Kosmetatos, Sofia, “How Kalamazoo survived Pfizer cuts; Ann Arbor looks to sister college town for lesson in keeping scientists, adding jobs,” *Detroit News*, March 15, 2007.

In December 2006, responding to an effort to repeal the drug company immunity law, the *Detroit News* ran an editorial praising Pfizer for providing so many good jobs in the state.⁵² Less than a month later, Pfizer announced it was closing the Kalamazoo and Ann Arbor research and development facilities – a move that affected thousands of jobs in Michigan.⁵³ A year later, the Ann Arbor site was nearly abandoned and hundreds of Pfizer employees and their families had moved out of the state.⁵⁴

⁵² “Don't expose drug makers to business-killing lawsuits,” Editorial, *Detroit News*, December 18, 2006, Pg. 10A.

⁵³ “Pfizer closes Kalamazoo, Ann Arbor research sites,” *Kalamazoo Gazette*, January 22, 2007 ; “Pfizer to Shut Down 3 Michigan Facilities,” *ClickOn Detroit*, January 22, 2007. Michigan’s economic forecast for the next few years appears bleak. Leading scholars at the University of Michigan Institute of Labor and Industrial Relations conducted a study in February 2007, to look at the expected impact the Pfizer closings would have on the Michigan economy. The report predicted that 6,133 jobs would be lost by 2009 with an estimated 5,314 people leaving the state and \$629.5 million in personal income lost by 2012. Other executives in the pharmaceutical industry did not expect to be able to absorb the work force within the state with such a large job loss. “Shock waves loom from Pfizer exit. Researchers forecast grim effects on jobs,” *Ann Arbor News*, May 12, 2007.

⁵⁴ “One Year Later: Pfizer's Ann Arbor Site Nearly Deserted,” *Kalamazoo Gazette*, January 21, 2008.

LIMITATIONS FOR MICHIGAN RESIDENTS SEEKING LEGAL RELIEF

In March 1996, the drug immunity law went into effect and Michigan residents were essentially shut out of their local courts if they had been harmed by dangerous drugs approved by the FDA. However, exercising their constitutional right, a few Michigan residents have attempted to confront the manufacturers of those drugs in court. In fact, in December 2001, in a case brought by Michigan residents against the makers of the diet drugs Redux and Fen-Phen, the Michigan Court of Appeals ruled the 1995 immunity law to be unconstitutional because, “it improperly delegates state powers to a federal agency.”⁵⁵ But in March 2003, the Michigan Supreme Court⁵⁶ overturned the ruling asserting that the state legislature did have the authority to create an immunity law.⁵⁷ The following examples show the practical impact of the law on Michigan citizens.

Rezulin – Not Taken Off Market Soon Enough?

Rezulin, Warner-Lambert’s blockbuster diabetes drug, was the FDA’s first “fast-track” approved drug. Rather than the typical year or so it was taking to gain FDA approval in the mid 1990’s, Rezulin was approved in half of that time.⁵⁸ In the fall of 1996, during an FDA review,⁵⁹ a senior FDA medical officer became concerned about the potential for liver and heart damage and felt that the drug was unfit for approval. Under pressure from the drug’s manufacturer, however, that FDA official was removed from the Rezulin case and the drug was approved in March 1997. Then, in October 1997, senior Warner-Lambert officials contacted the FDA to inform them that some patients taking the drug were beginning to die of liver failure.⁶⁰

In December 1997, Rezulin was taken off the market in Britain over safety concerns of potential liver problems.⁶¹ But only in early 1999, after a *Los Angeles Times* investigative report raised significant concerns about correlations between the use of Rezulin and deaths due to liver failure,⁶² did the FDA begin to reevaluate the drug.⁶³ In March 1999, Dr. David Graham,⁶⁴ the FDA’s senior epidemiologist, told the FDA’s advisory committee, “Rezulin was one of the most

⁵⁵ *Taylor v. Gate Pharms.*, 639 NW2d 45 (Mich.Ct. App. 2001), rev’d, *Taylor v. Smithkline Beecham Corp.*, 658 NW2d 172 (Mich. 2003) ; Durbin, Dee-Ann, “Court: Law Limiting Drug Company Liability is Unconstitutional,” *Associated Press*, December 3, 2001.

⁵⁶ *Taylor v. Smithkline Beecham Corp.*, 658 NW2d 172 (Mich. 2003) At the time of the ruling, Governor Engler had appointed three out of the seven Supreme Court Justices. “Engler’s Legacy May Last Longest in The Judicial Branch,” *Associated Press State & Local Wire* December 17, 2002.

⁵⁷ Bailey, Amy F., “Supreme Court: Law Limiting Drug Companies Liability is Constitutional,” *Associated Press*, March 26, 2003.

⁵⁸ Willman, David, “The Rise and Fall of the Killer Drug Rezulin,” *Los Angeles Times*, June 4, 2000.

⁵⁹ While the FDA was studying Rezulin for approval, the drug became part of a \$150 million National Institute of Health (NIH) clinical trial. Dr. Richard C. Eastman, the top diabetes researcher for the NIH and the supervisor for the trial, was also employed by Warner-Lambert as a consultant at the time. Some questioned if that was a conflict of interest. Willman, David, “Drugmaker Hires NIH Researcher,” *Los Angeles Times*, December 7, 1998.

⁶⁰ *supra* 58

⁶¹ Wise, Jacqui. “Diabetes Drug Withdrawn After Reports of Hepatic Events” *BMJ* (British Medical Journal), December 13, 1997, 315: pp. 1559-64.

⁶² Willman, David, “Drugmaker Hires NIH Researcher,” *Los Angeles Times*, December 7, 1998.

⁶³ Noble, Holcomb B., “FDA Panel Recommends Continued Use Of Controversial Diabetes Drug,” *CNN*, March 26, 1999.

⁶⁴ Willman, David, “‘Fast Track’ drug to treat diabetes Tied to 33 Deaths,” *Los Angeles Times*, December 7, 1998.

dangerous prescription drugs on the market.”⁶⁵ Since its release, the FDA required the drug manufacturer to change Rezulin’s warning label repeatedly– yet it took until March 2000 for Rezulin to be taken off the U.S. market, after at least 63 patient deaths from liver toxicity were linked to the drug.⁶⁶

Less than a month after the drug was withdrawn, a Detroit law firm filed a federal class-action lawsuit led by Kimberly Kent on behalf of her deceased mother, Detroit resident Virginia Kent.⁶⁷ The lawsuit alleged, “the drug remained on the market too long” and that the manufacturer knew of problems with the drug. In its defense, Warner-Lambert replied, “it [had] strictly adhered to FDA regulations.”⁶⁸

Five years later, 187 Michigan residents or their families had taken part in the nation wide class-action suit against Pfizer, which had purchased Warner-Lambert in 2000. But in February 2005, a U.S. District Court federal judge threw out the Michigan cases because of the state drug immunity law.⁶⁹ The Second Circuit Court of Appeals disagreed and reversed that decision.⁷⁰ The case is now being heard by the U.S. Supreme Court.⁷¹

Accutane – Dangerous Drug Remains on Market

At the time of its approval by the FDA in 1983, the acne drug Accutane was already known to cause birth defects in animals and was suspected to cause birth defects in humans. By 1988, marketing experience had indicated that the drug caused birth defects in a significant number of infants who had been exposed in the womb. The FDA issued warnings against its use by pregnant women.⁷²

Over the years consumer advocacy organizations like the March of Dimes and Public Citizen demanded tougher restrictions and petitioned for stronger warnings to be placed on the drug.⁷³

⁶⁵ Willman, David, “Diabetes Drug Rezulin Pulled off the Market,” *Los Angeles Times*, March 22, 2000.

⁶⁶ “Removal of Diabetes Drug Meets With Mixed Feelings” *New York Times*, March 28, 2000 ; O’Connor, Eileen and Morris, Jim, “Diabetes Drug Rezulin Taken off Market: Pill Linked to 63 Liver-Poisoning Deaths,” *CNN*, March 23, 2000.

⁶⁷ Virginia Kent of Detroit died of liver failure in December 1997, at Henry Ford Hospital. According to J. Douglas Peters, the attorney who represented the 47 people from Michigan in the Rezulin case, Kent had been provided a free sample of Rezulin a month before her death and was brought to the hospital twice for liver problems over the next three weeks before her death. Anstett, Patricia and Norris, Kim. “Michigan Rezulin Lawsuits Tossed.” *Detroit Free Press*, February 25, 2005.

⁶⁸ “Detroit Lawyers Sue Maker of Diabetes Drug Pulled From Market,” *Associated Press*, April 17, 2000.

⁶⁹ “N.Y. Federal Judge Dismisses Michigan Residents’ Rezulin Claims,” *Associated Press*, February 25, 2005.

⁷⁰ *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2006), cert. granted sub. *Nom Warner-Lambert v. Kent*, 2007 WL 1420397 (September 27, 2007).

⁷¹ The case is *Warner-Lambert v. Kent*, No. 06-1498. “High Court Sets Date for Arguments in Second Preemption Case,” *FDA Week*, January 4, 2008; Rugaber, Christopher, “Supreme Court to Decide Extent of Pharmaceutical Companies’ Protection From State Lawsuits,” *Associated Press*, September 25 2007; “U.S. Supreme Court Agrees to Hear Pfizer Patent Case,” *Reuters*, September 25, 2007; “Michigan Resident, Kimberly Kent’s Drug Product Liability Case Will Be Argued in the United States Supreme Court on February 25, 2008,” *Fox Business*, February 19, 2008.

⁷² Willis, Judith. “New Warning About Accutane and Birth Defects,” *FDA Consumer*, October 1988.

⁷³ News Release, “Accutane Causing Miscarriages and Major Birth Defects, Tighter Controls Urgently Needed, March of Dimes Says,” March of Dimes, February 25, 2004 available at <http://www.marchofdimes.com/> and Testimony of Larry D. Sasich, Pharm.D., M.P.H, FASHP, Public Citizen’s Health Research Group before the FDA’s Dermatologic and Ophthalmic Drugs Advisory Committee meeting on isotretinoin (Accutane), September 18, 2000 available at <http://www.citizen.org/publications/release.cfm?ID=4899>.

Additional debate over the drug's link to suicide began after the heavily publicized suicides of B.J. Stupak, the teenage son of Congressman Bart Stupak, (D-Mich.) who shot himself in 2000, and Charles J. Bishop, the 15-year old who flew a plane into a Florida building in January 2002.⁷⁴ A congressional oversight committee's two-year investigation into the health effects and regulatory control of Accutane concluded in 2002 that the drug had frequently been associated with suicide.⁷⁵ Although increased warnings have been placed on the drug, it has never been removed from the market.⁷⁶

Michigan resident Robert Rowe used Accutane in 1997, after which he claimed he became depressed, attempted suicide and eventually sought psychiatric treatment. In March 2001, he sued Hoffmann-La Roche, the manufacturer of the drug. He filed his suit in New Jersey because the immunity law prevented him from bringing his suit in Michigan. The New Jersey trial court dismissed his complaint in 2006, saying that the Michigan law was applicable since he was a Michigan resident. Although New Jersey's Appellate Division reversed the trial court's ruling, the manufacturer appealed, and in April 2007, Rowe lost his appeal before the New Jersey Supreme Court, which determined that New Jersey's interest in the case was not strong enough to allow New Jersey law to be applied rather than Michigan law.⁷⁷

Vioxx – Luck of Settlement Only Relief for Michigan Residents

In September 2004, five years after it received a “fast-track” approval by the FDA, the multi-billion dollar blockbuster painkiller Vioxx was pulled off the market by its manufacturer Merck & Co.⁷⁸ The company had evidence that the drug increased the chance of heart attack and stroke in patients,⁷⁹ yet downplayed the findings over the years.⁸⁰ Despite concerns by the FDA's own analysts,⁸¹ the FDA never required Merck to withdraw the drug.⁸² In an interview on *National*

⁷⁴ Duenwald, Mary, “Debate on Acne Drug's Safety Persists Over Two Decades,” *New York Times*, January 22, 2002.

⁷⁵ Mitchell, Steve, “Congressional Committee Finds Accutane Causes Suicide.” *United Press International*, December 12, 2002.

⁷⁶ Meadows, Michelle, “The Power of Accutane: The Benefits and Risks of a Breakthrough Acne Drug,” *FDA Consumer*, Vol. 35 (March 2001).

⁷⁷ *Rowe v. Hoffman La Roche*, 917 A2d 767 (NJ 2007), reversing *Rowe v. Hoffman-La Roche*, 892 A2d 694 (NJSuperCtAppDiv 2006) ; Mazier, E.E. “Choice of Law; N.J.'s Interest in Michigan Residents Accutane Suit Outweighed by Michigan's Interest in Making Prescription Drugs Available,” *New Jersey Lawyer*, April 2, 2007, Vol. 16, No. 14, Pg. 15.

⁷⁸ Henderson, Diedtra and Rowland, Christopher, “Once ‘Too Slow,’ FDA Approvals Called ‘Too Fast’,” *Boston Globe*, April 10, 2005.

⁷⁹ Mathews, Anna Wilde and Martinez, Barbara, “Warning Signs: E-mails Suggest Merck Knew Vioxx's Dangers at Early Stage,” *Wall Street Journal*, Nov 1, 2004, p. 1 ; Berenson, Alex, “Evidence in Vioxx Suits Shows Intervention by Merck Officials,” *New York Times*, April 24, 2005; Mukherjee, Debabrata MD, Nissen, Steven E. MD, and Topol, Eric J. MD. “Risk of Cardiovascular Events Associated With Selective COX-2 Inhibitors.” *Journal of the American Medical Association*, August 22, 2001, Vol. 286, No 8 ; Colmenares, Clinton, “Vioxx linked to heart disease,” *The Reporter*, (Vanderbilt Medical Center) October 11, 2002 available at <http://www.mc.vanderbilt.edu/reporter/index.html?ID=2305>.

⁸⁰ Berenson, Alex, “At Midpoint of Vioxx Trial, Merck Looks Battered,” *New York Times*, August 6, 2005; Bradley, Ed, “Prescription For Trouble,” *60-Minutes* aired August 28, 2005 available at <http://www.cbsnews.com/stories/2004/11/14/60minutes/main655577.shtml>.

⁸¹ Stark, Lisa. “FDA Scientist Warned About Vioxx in August; Knew Vioxx Was Dangerous.” *ABC World News*, October 7, 2004 available at <http://abcnews.go.com/WNT/story?id=147101&page=1>; Harris, Gardiner, “FDA Failing in Drug Safety, Official Asserts,” *New York Times*, November 19, 2004.

⁸² “FDA says Merck misleading on Vioxx safety,” *Associated Press* September 25, 2001; Rubin, Rita, “FDA Sends A Warning Letter To Maker Of Vioxx Painkiller,” *USA Today*, September 25, 2001, p. 7D ; “FDA Issues Public Health Advisory on Vioxx as Manufacturer Voluntarily Withdraws Product,” *US Fed News*, September 30, 2004.

Public Radio the day that Merck bowed to public pressure and withdrew the drug from the market, Dr. Steven Galson, Acting Director, of the FDA's Center for Drug Evaluation and Research (CDER) said, "We have known for some years about an increased risk in cardiovascular events [like heart attacks] related to this drug."⁸³

Over the years as concerns over Vioxx's safety were made public, dozens of heart attack and stroke victims from around the country had started filing lawsuits against Merck.⁸⁴ After the announcement that Vioxx had been pulled from the market, many more victims filed suits against Merck. By August 2007, the *New York Times* reported that there were at least 45,000 lawsuits against Merck.⁸⁵ The Michigan Vioxx victims, however, were unlikely to have a judge or jury decide their case because of the drug immunity law.⁸⁶

In November 2007, Merck offered to pay \$4.85 billion to settle the tens of thousands of pending cases from people who were harmed by taking Vioxx.⁸⁷ Michigan residents initially thought that they would be left out of the settlement because of the immunity law,⁸⁸ fortuitously for these residents, the New Jersey judge overseeing the roughly 1,000 Michigan Vioxx claims had not yet thrown out the cases before Merck offered the settlement.⁸⁹ It seems clear that had Merck not offered a settlement, it would have been unlikely that the Michigan residents would have ever seen their cases in court.

⁸³ Knox, Robert, "Merck Pulls Arthritis Drug Vioxx From Market," *All Things Considered (NPR Radio)*, September 30, 2004 available at <http://www.npr.org/templates/story/story.php?storyId=4054991>

⁸⁴ Sowers, Carol, "Vioxx Users Sue Maker of Pain Pill," *Arizona Republic*, October 24, 2001 ; Huget, Jennifer, "Arthritis Cases: 21 Million," *Washington Post*, January 1, 2002.

⁸⁵ Berenson, Alex, "Plaintiffs Find Payday Elusive in Vioxx Cases," *New York Times*, August 21, 2007.

⁸⁶ "Rx Shield: Jury Verdict Reminds Michigan of Its Draconian Drug Law," *Lansing State Journal*, April 18, 2006 ; Hall, Sheri, "State Vioxx Users Line Up to Sue Over Heart Ailments; Michigan Law Protects Drugmakers," *Detroit News*, October 10, 2004.

⁸⁷ Press Release, "Merck Agreement to Resolve U.S. Vioxx Product Liability Lawsuits," Merck, November 9, 2007, available at http://www.merck.com/newsroom/press_releases/corporate/2007_1109.html and Longstreth Andrew ; "\$4.85 Billion Vioxx Settlement Validates Merck's Courthouse Strategy," *American Lawyer*, November 12, 2007.

⁸⁸ Aspiras, Jessica, "No Payout" *WILX News 10*, November 9, 2007 available at <http://www.wilx.com/medical/headlines/11157906.html?pollSubmit=y&submit=submit&oid=1&mr=1&cid=6500&pid=11156571#>.

⁸⁹ "Fight Over State Drug Law Intensifies: Despite Vioxx Settlement, Michigan Shields Pharmaceutical Makers," *Grand Rapid Press*, December 17, 2007.

PROBLEMS WITH THE FDA DEFENSE AND WHY LAWSUITS ARE CRITICAL

Every year there are over 2 million serious adverse drug reactions (ADRs). Of this total, an estimated 100,000 people die from ADRs, making it the fourth leading cause of death in the United States.⁹⁰ Recently approved drugs may be more likely to have unrecognized ADRs and, as one team of medical researchers concluded, “Many serious ADRs are discovered only after a drug has been on the market for years. Only half of newly discovered serious ADRs are detected and documented in the *Physicians' Desk Reference* within seven years after drug approval.”⁹¹

The FDA’s drug approval process works against the public in ensuring that serious ADR’s do not lead to major public health problems. Lawsuits are a critical supplement to the drug approval process in protecting the public health and safety. David C. Vladeck, Professor of Law at Georgetown University explained,

[The] FDA does not have the resources to perform the monumental task of monitoring the performance of every drug on the market. The FDA regulates products that amount to one-quarter of consumer spending in the United States, but it has only 9,000 employees nationwide.... [The] FDA’s Office of Drug Safety, the unit charged with monitoring adverse events associated with the 3,000 prescription drugs (and 11,000 drugs altogether) on the market, has about 100 professional employees. To be sure, Congress has recently enacted the Food and Drug Administration Amendments Act of 2007, which will add resources to the FDA and bolster its statutory authority. But as Senator Edward Kennedy, the Act’s principal Senate sponsor warned, even a beefed-up FDA will still face resource constraints and that “the resources of the drug industry to collect and analyze” safety data “vastly exceeds the resources of the FDA, and no matter what we do, they will always have vastly greater resources to monitor the safety of their products than the FDA does.

[Further], state damages litigation helps uncover and assess risks that are not apparent to the agency during a drug’s approval process, and this ‘feedback loop’ enables the agency to better do its job. FDA approval of drugs is based on clinical trials that involve, at most, a few thousand patients and last a year or so. These trials cannot detect risks that are relatively rare, affect vulnerable sub-populations, or have long latency periods. For this reason, most serious adverse effects do not become evident until a drug is used in larger population groups for periods in excess of one year.⁹²

Zyprexa is a good example of how lawsuits become a critical supplement to the FDA’s process. In 1996, the FDA approved Zyprexa and the drug quickly became the top seller for its maker, Eli

⁹⁰“Preventable Adverse Drug Reactions; A Focus on Drug Interactions,” FDA’s Center for Drug Evaluation and Research <http://www.fda.gov/cder/drug/drugReactions/default.htm>; and Public Citizen, “Adverse Drug Reactions,” http://www.worstpills.org/public/page.cfm?op_id=4.

⁹¹ Lasser, et al., “Timing of New Black Box Warnings and Withdrawals for Prescription Medications,” *Journal of the American Medical Association*, May 1, 2002. <http://jama.ama-assn.org/cgi/content/full/287/17/2215>.

⁹² David C. Vladeck, Professor of Law, Georgetown University Law Center, and Scholar, Center for Progressive Reform, “The Emerging Threat of Regulatory Preemption,” American Constitution Society Issue Paper, January 2008.

Lilly⁹³ until it was discovered that some patients taking the drug were also developing diabetes.⁹⁴ In 2003, the FDA announced that all of the drugs like Zyprexa needed warning labels stating that atypical antipsychotic drugs may cause weight gain and increase the chance for diabetes.⁹⁵

Over 30,000 people sued Eli Lilly and by January 2007, Eli Lilly had settled most of the cases for a total of \$1.2 billion.⁹⁶ Lawsuits uncovered disturbing information that Eli Lilly had evidence, even during the clinical trials, that some of the patients taking Zyprexa had experienced significant weight gain and high blood sugar – symptoms that frequently lead to diabetes. According to internal documents, Eli Lilly officials had instructed its sales representatives to downplay these possible side effects because it “might cause unwarranted fear among patients that will cause them to stop taking their medication.”⁹⁷ In spite of this problematic history, Zyprexa is currently under consideration again by the FDA – to approve its use by children.⁹⁸

Drug Approval Process Funded by Drug Companies

Another significant problem is bias in the drug approval process resulting from how the agency is funded. Over the last 15-years, drug companies and their lobbyists have had an increasing amount of influence over FDA decision-making and policy. In 1992, Congress passed the Prescription Drug User Fee Act (PDUFA) to speed up the FDA’s review and evaluation process for new drugs funded, in part, through user fees paid by the drug industry itself.

In 2006, the agency collected over \$300 million in these user fees. The user fees now constitute more than one-third of the entire budget for the Center for Drug Evaluation and Research, which is the FDA office that oversees drugs, thus making the FDA financially beholden to the pharmaceutical industry – a concern recently expressed by several scientists.⁹⁹

According to Dr. David Kessler, who was the head of the FDA at the time PDUFA was implemented, “The FDA became preoccupied with rapid drug reviews and less attention was paid to safety.”¹⁰⁰ Unfortunately, the emphasis appears to be on speed rather than accuracy. Arthur A. Levin, MPH, Center for Medical Consumers said in a meeting with the FDA on the reauthorization of PDUFA, “In 2004, most of the money for new drug reviews came from

⁹³ Herper, Matthew, “Lilly Ferociously Defends Its Top Seller,” *Forbes.com*, September 9, 2004, available at http://www.forbes.com/healthcare/2004/09/09/cx_mh_0909lly.html.

⁹⁴ Wheeler, Timothy B., “Studies Link Zyprexa to Diabetes Deaths,” *Baltimore Sun*, March 19, 2003.

⁹⁵ Burton, Thomas, “FDA to Require Diabetes Warning on Class of Schizophrenic Drugs,” *Wall Street Journal*, September 18, 2003.

⁹⁶ Berenson, Alex, “Lilly Settles With 18,000 Over Zyprexa,” *New York Times*, January 5, 2007.

⁹⁷ Berenson, Alex, “Eli Lilly Said to Play Down Risk of Top Pill,” *New York Times*, December 17, 2006.

⁹⁸ Farley, Robert, “A Risky Drug May Get Wider Market. The FDA May Approve Zyprexa for Kids, Despite Its Significant Side Effects in Adult Use,” *St. Petersburg Times*, December 16, 2007.

⁹⁹ Marcia Angell, M.D. *et al.*, Open Letter to Chairman Edward Kennedy *et al.*, dated March 14, 2007, available at <http://www.defending-science.org/newsroom/PDUFA-open-letter.cfm>.

¹⁰⁰ The FDA states that its mission is to ensure that drugs are safe and effective, but “when it comes to any drug, ‘safe’ means that the benefits of the drug outweigh the risks for the population the drug is intended to treat and for its intended use. Safe does not mean harmless.” Meadows Michelle, “Why Drugs Get Pulled off the Market,” *FDA Consumer Magazine*, (January/February 2002) http://www.fda.gov/fdac/features/2002/102_drug.html.

industry. Its growing role as the major source of funds for FDA reviews creates a potential conflict of interest that is likely to erode, if it hasn't already, the public's trust in both the FDA's independence and the safety of new drugs."¹⁰¹

In September 2007, when Congress extended PDUFA, it also passed the FDA Amendments Act of 2007 (FDAAA), a bi-partisan bill that strengthened the regulatory scope of the FDA. The FDAAA, however, also increased the "user fees" paid by the pharmaceutical industry for the drugs they want approved.¹⁰²

Although many politicians praised the new legislation, Dr. Sidney M. Wolfe, director of Public Citizen's Health Research Group expressed some concern, noting that, "The bill's improvements in FDA authority are important but inadequate. The bill would increase collaboration between the agency and the drug industry by increasing the agency's reliance on user fees to finance drug reviews."¹⁰³

¹⁰¹ Levin, Arthur, "Perils of Speedy Drug Approvals," available on the Center for Medical Consumers website <http://www.medicalconsumers.org/pages/PerilsofSpeedyDrugApproval.html>.

¹⁰² "Prescription Drug User Fee Rates for Fiscal Year 2008; Federal Register Extracts." *Food and Drug Administration Documents and Publications*, October 12, 2007.

¹⁰³ Pear, Robert, "Senate Approves Tighter Policing of Drug Makers," *New York Times*, May 10, 2007.

REPEAL MICHIGAN'S DRUG IMMUNITY LAW

Every legislative session since the 1995 drug immunity law was passed, Michigan legislators have introduced bills to repeal the law.¹⁰⁴ Twice, the House of Representatives passed this repeal. The first time was in 1997, just after the law was enacted, but the Senate killed it by failing to act.¹⁰⁵ The second time the House acted was in February 2007, the current legislative cycle. However, in the interim years there has been ongoing interest in repealing this law.

In 2003, after the Michigan Supreme Court threw out a case brought by the women who had taken the diet drugs Redux and Fen-Phen, State Representative Alan Cropsey, a long time supporter of legislation that limited lawsuits, changed his mind on the issue and said that he and others were fighting to repeal the immunity law calling the tort reform movement “misguided” in a 2003, *Washington Monthly* article.¹⁰⁶

Shortly after Vioxx was withdrawn from the market in 2004, attention increased over the issues surrounding immunity for drug companies. In April 2005, several bills to eliminate Michigan's drug immunity law were introduced in the House of Representatives.¹⁰⁷ “When it comes to protecting consumers from the drug industry, we're dead last,” said Representative Dianne Byrum who was one of the main sponsors of one of the 2005 bills. “It is shameful that Michigan residents who have been harmed by prescription drugs have no recourse simply because they live in our state.”¹⁰⁸

Michigan Residents Organize to Repeal Law

In 2005, a coalition of victims called Drug Industry Immunity Must End (D.I.I.M.E.) formed to advocate for the repeal of the law.¹⁰⁹ Michigan residents told their stories how they were unable to get their day in court even though they or their loved ones were hurt or injured by taking dangerous drugs approved by the FDA (many that were later removed from the market).

For example, Vicki Chamberlain from Lansing, a former General Motors worker who had a stroke while on Vioxx, said, “This law is so unfair. I thought at first it was bad luck. Then I found out there were people with the same physical problems as me. That's when I knew something was going on.”¹¹⁰

Another D.I.I.M.E. member, John Matznick of Owosso, whose two heart attacks and other health problems while on Vioxx caused him to leave his job at the Delphi Corp. Saginaw plant, said, “I

¹⁰⁴ Michigan Legislative History for HB 4165 of 1999 and Michigan Legislative History for HB 5895 of 2002 and Michigan Legislative History for HB 5392 of 2003.

¹⁰⁵ Eggert, David, “Questions Raised Over Michigan Law That Protects Drug Makers,” *Associated Press*, January 2, 2005.

¹⁰⁶ Mundy, Alicia, “Pillboxed In,” *Washington Monthly*, October 2003.

¹⁰⁷ Michigan Legislative History for HB 4773, HB 4811 HB 5071, HB 5139 and HB 5527 (all of 2005).

¹⁰⁸ Bailey, Amy F., “House Dems Want to Repeal Michigan Law That Protects Drug Makers,” *Associated Press*, April 9, 2005; “Dems: Drug Suit Law Not Working; Bills Aim to Repeal 1996 Legislation That Protects Pharmaceutical Firms,” *Grand Rapids Press*, April 10, 2005, Pg. B3.

¹⁰⁹ Martin, Tim, “Citizens Group Pushes For End to Drug Company Immunity,” *Associated Press*, May 9, 2005.

¹¹⁰ *Ibid.*

worked for General Motors and Delphi for 37 years and they have a guarantee on their cars. If something is wrong with it, you bring it back. If there's a problem, they do a recall. If I have to be responsible for everything I do in life, [drug companies] should be held accountable for what they do." Despite increased attention in the media¹¹¹ and the politicizing of the issue during the 2006 elections,¹¹² none of the bills made it out of the House that session.¹¹³

Legislative Support to Repeal Law

In January 2007, with new leadership in the House of Representatives, the fight to repeal the law was addressed again.¹¹⁴ "When a company sells a product that harms or kills, it must be held accountable," said Representative Mike Simpson who sponsored one of the bills.¹¹⁵ In February 2007, the House again voted to repeal the law, and the bill moved to the Senate.¹¹⁶ Yet the Senate, which had generally been unsupportive of the repeal, failed to take up the issue.¹¹⁷

Instead, in late January 2008, just hours before Governor Jennifer Granholm's State of the State address in which she expressed support for repeal,¹¹⁸ the Senate passed a non-binding resolution calling on the FDA to "establish stricter standards for the drug approval process."¹¹⁹ This was an obvious concession that the FDA was failing in its job, yet the Senate continued to support immunity for those harmed by the FDA's failures.¹²⁰ During the floor discussion, Senator John Gleason said,

"It is time to get this right. We have tried this for over a dozen years. Every single state has a right to remedy and they can do it in their own state. Michigan must travel half the continent across to present their difficulties; even in the most ill form, they must traverse halfway across this continent to see a judge—an impartial judge. That is all we are asking—give us that legal remedy that everybody else has."¹²¹

¹¹¹ Bailey, Amy, "House Moves Bills Allowing Drug Lawsuits; GOP Critical of Step," *Associated Press*, September 8, 2005; Putnam, Judy, "Drug Liability Issue Heats up in Michigan," *Muskegon Chronicle*, September 18, 2005; "Drug Liability Law Under Fire; Critics Want to Repeal Law in wake of Vioxx Lawsuits," *Grand Rapids Press*, September 20, 2005.

¹¹² Armentrout, Jill, "Drug Liability Law Under Fire," *Saginaw News*, October 26, 2006.

¹¹³ *supra* 107

¹¹⁴ Eggert, David, "Vote Could be Taken on Drug Liability Legislation," *Associated Press*, February 10, 2007.

¹¹⁵ Heinlein, Gary, "36 Bills Jump-Start Legislative Session," *Detroit News*, January 12, 2007.

¹¹⁶ Putnam, Judy, "House Targets Drug-Makers' Immunity," *Kalamazoo Gazette*, January 23, 2007.

¹¹⁷ "Bill To Overturn Preemption In Michigan Stalls Again In Statehouse," *FDA Week*, December 14, 2007, Vol. 13 No. 50.

¹¹⁸ Governor Jennifer Granholm, January 29, 2008, State of the State Address, State Capital, Lansing, Michigan, available at <http://www.michigan.gov/gov/0,1607,7-168--184537--00.html>.

¹¹⁹ Journal of the Senate 94th Legislature Regular Session of 2008; January 29, 2008; Pg 102.

¹²⁰ "[L]et me get this straight: Our drug immunity law is based on the FDA standard. The rationale behind that public policy is that the FDA standard is strict enough to protect our consumers, our citizens here in Michigan. Now instead of taking action like the other 49 states in the country have to protect our citizens, we are once again advocating and asking Congress to enact a stricter standard because we don't think their standard is strict enough, but that is our standard. So it leaves you to conclude that our law is not sufficient to protect Michigan citizens," said State Senator Gretchen Whitmer during a January 2008 debate on Senate Resolution 134 that requested the FDA establish stricter standards for the drug approval process rather than repeal the Michigan drug immunity law. Journal of the Senate 94th Legislature Regular Session of 2008; January 29, 2008; Pg. 102-103.

¹²¹ Journal of the Senate 94th Legislature Regular Session of 2008; January 29, 2008; Pg 103.

In February 2008, D.I.I.M.E. members and advocates again called for the Senate to take action on the bill.¹²² According to the *Jackson Citizen Patriot*, Leslie Richter of Lansing, whose husband, Richard, had two strokes and died in March 2003 after taking Vioxx, said, “[the State Senate] have to put the people of this state ahead of pharmaceutical companies.”¹²³

Conclusion – Repeal Michigan’s Drug Industry Immunity Law

As Michigan State Senator John Gleason said during the recent Senate floor debate:

“We not only need confidence in the medications that we take, but we need legal recourse when the medications go beyond the FDA and end up in the bodies of our Michigan citizens. . . . There were very horrendous efforts undertaken by those prior to us being here over a decade ago, but I have waited patiently for three years now to ask for a remedy.”¹²⁴

The 1995 drug industry immunity law harms rather than helps the people of Michigan. Since the implementation of the law, thousands of good paying jobs in the pharmaceutical industry have left the state, and hundreds or thousands of innocent people have been denied fair access to the civil justice system when dangerous drugs harmed or killed them. It is time to repeal this law.

¹²² “Victims of Prescription Drugs Speak Out at State Capitol,” *WLNS TV 6*, February 19, 2008; Barber, Barrie “Groups Upset With Kahn Over Drug Law” *Saginaw News*, February 19, 2008; “Lobby Overdose,” *MetroNews* February 20, 2008.

¹²³ Quisenberry, Danielle, “Woman Pleads for the Repeal of Immunity for Drug Industry,” *Jackson Citizen Patriot* February 19, 2008.

¹²⁴ Journal of the Senate 94th Legislature Regular Session of 2008; January 29, 2008; Pg 103.