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REPEATING A TRAGIC BLUNDER

Wisconsin's Drug and Device Immunity Bill

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"Fighting to protect the right to jury trial and an independent judiciary for all Americans."

INTRODUCTION

In 1995, Michigan enacted an unprecedented law that prevents its residents from gaining access to the civil justice system if they are harmed by dangerous drugs approved by the Food and Drug Administration (FDA).[1] Since that law passed, Michiganders – unlike anyone else living in the United States - have had no legal recourse against negligent drug companies, which market unsafe drugs to the public with the FDA's knowledge, drugs such as Rezulin, Vioxx, and Trasylol.[2] Now, Wisconsin legislation has been proposed that would not only limit Wisconsinites' rights in a similar fashion, but would also prevent actions against medical device companies.[3]

The Michigan law has been a failure at every level and the last thing any state should do right now is repeat this experience. Drug companies left Michigan almost as soon as it was enacted, after deceptively arguing that the law would save pharmaceutical jobs. Seriously injured victims have been left with no recourse, leaving state Medicaid to pick up the tab. Meanwhile, the drug and device industry is as dangerous as ever and the FDA's approval process continues to be incapable of ensuring that the public is protected from unsafe drugs and devices.

In February 2008, we published a study about Michigan law entitled *A Tragic Blunder: Michigan's Drug Industry Immunity Law*.[4] In light of several developments since that time, particularly the current threat to Wisconsin residents, we thought it time to revisit this issue.

BACKGROUND AND UPDATE: THE IMPORTANCE OF LITIGATION AGAINST DRUG COMPANIES

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 or medical devices. These lawsuits not only provide compensation for the injured, they also hold the manufacturers of these products directly accountable for causing these injuries, often forcing changes in the sale of these unsafe drugs. Lawsuits also often help uncover important information about dangerous drugs and devices, 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.[5]

We noted in *A Tragic Blunder* that one reason such lawsuits are critical is that the FDA is incapable or unwilling to exercise proper oversight over the pharmaceutical industry. 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.[6] 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."[7]

Zyprexa is a good example. In 1996, the FDA approved the antipsychotic drug Zyprexa and the drug quickly became the top seller for its maker, Eli Lilly[8] until it was discovered that some patients taking the drug were also developing diabetes.[9] 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.[10]

Over 30,000 people sued Eli Lilly and by January 2007, Eli Lilly had settled most of these cases for a total of $1.2 billion.[11] 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."[12]

We noted in A Tragic Blunder that the FDA's drug approval process works against the public in ensuring that serious ADR's do not lead to major public health problems. In that report, we quoted David C. Vladeck, Professor of Law at Georgetown University and currently Director of the Bureau of Consumer Protection of the Federal Trade Commission, who 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.[13]

Since we published A Tragic Blunder, the U.S. Supreme Court essentially confirmed Mr. Vladeck's analysis. In *Wyeth v Levine*,[14] the Court ruled that drug companies should not be immune from liability for injuring or killing patients with FDA-approved drugs. The Court stated, the "FDA has limited resources to monitor the 11,000 drugs on the market and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge," and the "FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation." In other words, the Court recognized that the FDA has limited resources when it comes to monitoring drugs and that state tort law serves an important purpose, adding a necessary layer of protection for consumers.

In recognizing this, the Court looked to congressional intent, stating, "Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs… Evidently, it determined that widely available state rights of action provided appropriate relief for injured consumers. It may also have recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings." Further, in terms of state tort law, the Court acknowledged that "State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly," and that such suits, "serve a distinct compensatory function that may motivate injured persons to come forward with information."

Aside from being undersourced, bias in the drug approval process resulting from how the FDA is funded is another important problem, suggesting that the FDA should not be the only arbiter as to whether a drug is safe when someone has been injured. Over the last

two decades, 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.[15]

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."[16] 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 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."[17]

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.[18]

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."[19]

WORKERS, TAXPAYERS AND VICTIMS HAVE ALL BEEN HURT BY MICHIGAN'S DRUG IMMUNITY LAW.

MICHIGAN LAW DID NOT SAVE JOBS

The Michigan Manufacturers Association, a strong pro-business lobbying group, stated that it supported the drug immunity law in order to "encourage companies – including pharmaceutical companies – to stay in Michigan."[20] The high-paying pharmaceutical jobs, however, began trickling out of Michigan even as the governor was signing the bill into law.

In 1995, the Kalamazoo-based pharmaceutical company Upjohn Co., the company the immunity law was meant to protect,[21] merged with the Swedish company Pharmeacia Corp.[22] After the merger, the new company moved its headquarters and cut hundreds of jobs in Michigan.[23] In 2003, Pharmeacia & Upjohn merged with Pfizer[24] and cut over a thousand additional jobs in Western Michigan.[25]

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.[26] 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.[27] A year later, the Ann Arbor site was nearly abandoned and hundreds of Pfizer employees and their families had moved out of the state.[28]

MICHIGAN TAXPAYERS ARE ON THE HOOK FOR DRUG COMPANIES MISTAKES

Over the years Michigan's drug immunity law has prevented relief for residents in a variety of cases. But a recent case illustrates just how far the courts are willing to go in interpreting how much immunity a law like this may provide the drug industry.

For a case to be considered a product liability action and thus subject to immunity under Michigan law, a key requirement is that the action must be brought for the death of a person, for injury to a person, or for damage to property.[29] When the Michigan Attorney General brought a case under Michigan's Medicaid False Claims Act seeking reimbursement for the $20 million the state paid for Vioxx prescriptions on behalf of Medicaid recipients, the state did not think they were bringing a product liability case. They alleged the defendant "knowingly made false and deceptive statements about the safety and efficacy of Vioxx in order to enhance its sales. They claimed that, in doing so, defendant duped the state into paying for those prescriptions."[30]

However, the Court of Appeals ruled that the case fell under product liability law – even though it did not - and therefore, the state could recover no money for its own taxpayers.[31] As Justice Marilyn Kelly stated in her dissent when the Michigan Supreme Court declined to hear the case, the Court of Appeals' decision "defies common sense."[32] By stretching the definition of product liability so far as to include a case brought by the state's Attorney General under the Medicaid False Claims Act, the court forced the taxpayers of Michigan to literally pay the price for the drug company's wrongdoing.

VICTIMS ARE UNABLE TO SEEK 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 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."[33] But in March 2003, the Michigan Supreme Court[34] overturned the ruling asserting that the state legislature did have the authority to create an immunity law.[35] 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.[36] In the fall of 1996, during an FDA review,[37] 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.[38]

In December 1997, Rezulin was taken off the market in Britain over safety concerns of potential liver problems.[39] 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,[40] did the FDA begin to reevaluate the drug.[41] In March 1999, Dr. David Graham,[42] the FDA's senior epidemiologist, told the FDA's advisory committee, "Rezulin was one of the most dangerous prescription drugs on the market."[43] 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.[44]

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.[45] 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."[46]

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.[47] The Second Circuit Court of Appeals disagreed and reversed that decision.[48] The case went to the U.S. Supreme Court[49] where the Second Circuit decision was affirmed in a 4-4 split. Chief Justice Roberts did not take part in the decision and no written opinion was issued.[50]

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.[51]

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.[52] Additional debate over the drug's link to suicide began after the heavily publicized suicides of B.J. Stupak, the teenage son of former 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.[53] 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.[54] Although increased warnings have been placed on the drug, it has never been removed from the market.[55]

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.[56]

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.[57] The company had evidence that the drug increased the chance of heart attack and stroke in patients,[58] yet downplayed the findings over the years.[59] Despite concerns by the FDA's own analysts,[60] the FDA never required Merck to withdraw the drug.[61] In an interview on *National 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."[62]

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.[63] 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.[64] The Michigan Vioxx victims, however, were unlikely to have a judge or jury decide their case because of the drug immunity law.[65]

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.[66] Michigan residents initially thought that they would be left out of the settlement because of the immunity law,[67] 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.[68] 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.

NOTES

[1] The law, which went into effect in 1996, prohibits all product liability lawsuits against drugmakers for marketing unsafe drugs (provided the company did not fraudulent withhold information from the FDA) – leaving Michigan residents without any real legal remedy if they were harmed or killed by dangerous drugs. MCL 600.2945 (5): In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller. However, this subsection does not apply to a drug that is sold in the United States after the effective date of an order of the United States food and drug administration to remove the drug from the market or to withdraw its approval. This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following: (a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act, chapter 675, 52 Stat. 1040, 21 U.S.C. 301 to 321, 331 to 343-2, 344 to 346a, 347, 348 to 353, 355 to 360, 360b to 376, and 378 to 395, and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted; (b) Makes an illegal payment to an official or employee of the United States food and drug administration for the purpose of securing or maintaining approval of the drug.

[2] "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. In addition, 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.

[3] Immunity would exist for both strict liability cases as well as failure to warn cases. However, while Michigan's law deals exclusively with drug sellers and manufacturers, the Wisconsin law would extend liability to manufacturers and sellers of medical devices as well. The Wisconsin proposal would exempt from this law devices approved pursuant to 510(k) of the Federal Food, Drug, and Cosmetic Act, 21 USC 360. These are devices approved by the FDA because they are "substantially equivalent" to a device already on the market that are not required to go through more rigorous FDA approval.

[4] [cite report]

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[6] "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.

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[9] Wheeler, Timothy B., "Studies Link Zyprexa to Diabetes Deaths," *Baltimore Sun*, March 19, 2003.

[10] Burton, Thomas, "FDA to Require Diabetes Warning on Class of Schizophrenic Drugs," *Wall Street Journal*, September 18, 2003.

[11] Berenson, Alex, "Lilly Settles With 18,000 Over Zyprexa," *New York Times*, January 5, 2007.

[12] Berenson, Alex, "Eli Lilly Said to Play Down Risk of Top Pill," *New York Times*, December 17, 2006.

[13] 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.

[14] *Wyeth v Levine*, 555 U.S. 555 (2009).

[15] Marcia Angell, M.D. *et al*., Open Letter to Chairman Edward Kennedy *et al*., dated March 14, 2007, available at http://www.defendingscience.org/newsroom/PDUFA-open-letter.cfm.
[16] 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.
[17] Levin, Arthur, "Perils of Speedy Drug Approvals," available on the Center for Medical Consumers website http://www.medicalconsumers.org/pages/PerilsofSpeedyDrugApproval.html.
[18] "Prescription Drug User Fee Rates for Fiscal Year 2008; Federal Register Extracts." *Food and Drug Administration Documents and Publications,* October 12, 2007.
[19] Pear, Robert, "Senate Approves Tighter Policing of Drug Makers," *New York Times*, May 10, 2007.
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[21] O'Steen, Jonathan O. and O'Steen, Van. "The FDA Defense: Vioxx® and the Argument Against Federal Preemption of Sate Claims for Injuries Resulting From Defective Drugs." 48 *Arizona Law Review* 67, 89 (2006).
[22] Uchitelle, Louis. "Aiming at H.M.O.'s, Upjohn Agrees to $13 Billion Merger," *New York Times,* August 21, 1995.
[23] 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.
[24] Information can be found on Pfizer's website at http://www.pfizer.com/about/history/pfizer_pharmacia.jsp
[25] 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.
[26] "Don't expose drug makers to business-killing lawsuits," Editorial, *Detroit News,* December 18, 2006, Pg. 10A.
[27] "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.
[28] "One Year Later: Pfizer's Ann Arbor Site Nearly Deserted," *Kalamazoo Gazette*, January 21, 2008.
[29] *Michigan v Merck*, 2011 WL 921669 (2011).
[30] *Michigan v Merck*, 2011 WL 4539641 (2011).
[31] *Michigan v Merck*, 2011 WL 921669 (2011).
[32] *Michigan v Merck*, 2011 WL 4539641 (2011).
[33] *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.
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[35] Bailey, Amy F., "Supreme Court: Law Limiting Drug Companies Liability is Constitutional," *Associated Press,* March 26, 2003.
[36] Willman, David, "The Rise and Fall of the Killer Drug Rezulin," *Los Angeles Times,* June 4, 2000.
[37] 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.
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