

A Prescription for Trouble: A Look at Why Michigan Can't Afford to Pierce the Pharmaceutical Veil

INTRODUCTION

Millions of people in the United States depend on prescription drugs daily in order to relieve themselves from the constant pain and suffering associated with their medical conditions. It is no secret that some drugs are unavoidably unsafe, but are placed on the market anyway because the benefits provided by the drug outweigh its potentially harmful, and sometimes fatal, side effects. Aside from strict liability, drug manufacturers have a duty of reasonable care to ensure their products are safe for public use and are accompanied by warning labels that thoroughly inform consumers of potential risks. In order to ensure that these drugs meet federally regulated safety standards, the Food and Drug Administration (“FDA”) requires that each drug undergo a pre-market approval process.¹

In recent years, however, the FDA’s approval process has been highly criticized. For example, Merck’s decision to withdraw its drug Vioxx from the market was viewed to be “a mere indicator of the substantial problems that cripple the effectiveness of FDA pharmaceutical regulatory approvals, particularly in regard to the management and use of clinical trials in the research and approval process.”² In light of these criticisms, the question remains: has the drug manufacturer met the reasonable standard of care when its drug has been approved by the FDA? This article looks at Michigan’s current laws which immunize drug manufacturers from liability as long as the drug was approved by the FDA. In addition, I will also explore several bills introduced into the Michigan Legislature that seek to rescind the provision which provides absolute immunity for drug companies, and I will also discuss various state approaches in regards to drug manufacturer liability. I will explain why this pending legislation is harmful to Michigan’s economic growth and may pose a threat to the research and development of life-altering drugs.

1. For an overview of the history of the Food and Drug Administration, see Sasha B. Rieders, *State Law Tort Claims and the FDA: Proposing A Consumer-Oriented Prescription in Medical Device Cases*, 25 CARDOZO L. REV. 1159, 1159-67 (2004).

2. Amanda J. Dohrman, Comment, *Rethinking and Restructuring the FDA Drug Approval Process in Light of the VIOXX Recall*, 31 J. CORP. L. 203, 204 (2005).

I. BACKGROUND

A. *The FDA Drug Approval Process*

The drug approval process involves three major steps. First, a drug sponsor, which is usually the manufacturer or scientific institution, is required to conduct preclinical research which evaluates the drug's toxic and pharmacological effects through animal testing.³ The data from these studies must prove to the FDA that the drug is reasonably safe for use in initial clinical trials.⁴ In order to make a smooth transition from animal testing to human subjects, the sponsor must determine how the drug may help to treat, prevent and cure diseases by looking at the basic functions of the human body.⁵ From there, the sponsor engages in test tube experiments by which hundreds of compounds are added one by one to enzymes and cell cultures.⁶ After the preclinical research is complete, the sponsor submits a request to the FDA to test the compound on human subjects.⁷

The second step in the process involves clinical trials on human subjects. Before a drug can be approved for marketing in the United States, there are three phases of clinical studies that must be successfully completed.⁸ Phase I trials are usually conducted in around twenty to eighty healthy volunteer subjects.⁹ The purpose of a Phase I trial is to determine the drug's basic safety and effectiveness.¹⁰ Phase II trials involve controlled studies of several hundred people who have the disease or condition in which the drug purports to treat.¹¹ These closely monitored trials help to determine the risks and side effects of the particular drug.¹² Phase III trials are expanded studies used to "evaluate the overall benefit-risk relationship of the drug" and involve several hundred to several thousand participants.¹³ During all clinical trial phases, the FDA's Center for Drug Evaluation and Research ("CDER") can "impose a clinical hold . .

3. THE CDER HANDBOOK, DEP'T OF HEALTH AND HUMAN SERV., FDA & CENTER FOR DRUG EVALUATION AND RESEARCH 5 (1998), *available at* <http://www.fda.gov/cder/handbook/handbook.pdf>.

4. *Id.*

5. *Id.*

6. *Id.*

7. *Id.* at 6.

8. *Id.* at 8-9. Phase IV involves post-marketing surveillance of approved drugs. *See infra* Part I.B.

9. *Id.* at 8. "[Institutional Review Boards] at hospitals and research institutions throughout the country make sure that participants are fully informed and have given their written consent before studies ever begin. IRBs are monitored by the FDA to protect and ensure the safety of participants in medical research." *Id.* at 6.

10. *Id.* at 8.

11. *Id.*

12. *Id.*

13. *Id.* at 8-9.

. for reasons of safety, or because of a sponsor's failure to accurately disclose the risk of study to investigators."¹⁴

Lastly, once a drug is deemed safe and efficient in the clinical stages, the sponsor then submits a New Drug Application ("NDA") to the FDA for review and approval for the public market.¹⁵ "[T]he NDA must provide all relevant data and information that a sponsor has collected during the product's research and development."¹⁶ Once the FDA reviews the application, it may take one of three actions: it may send a "not approvable letter," an "approval letter" or an "approvable letter" stating that the drug can be approved upon correction of minor deficiencies.¹⁷ The FDA estimates that this process can take approximately eight and a half years to study and test a new drug before it can be approved for the general public.¹⁸

At all stages of the drug approval process, the FDA and drug sponsor conduct meetings to ensure testing is done carefully and that the data from the clinical studies are formatted appropriately for submission with a NDA.¹⁹ The CDER may also use the advice and opinions obtained from outside expert advisors (advisory committees) when deciding drug issues in order to give the agency the benefit of national input.²⁰ Though the Committee recommendations are not binding on CDER, the agency will "consider[] them carefully when deciding drug issues."²¹

B. Post-Approval Drug Monitoring

The first three steps, detailed above, involve the process that the drug undergoes before it can be approved for public use. Phase IV involves monitoring a drug's ongoing safety after approval.²²

After the drug is approved and marketed, the FDA uses different mechanisms for assuring that firms adhere to the terms and conditions of approval described in the application and that the drug is manufactured in a consistent and controlled manner. This is done by periodic unannounced inspections of drug production and control facilities by FDA's field investigators and analysts.²³

14. *Id.* at 8.

15. *See id.* at 20-28.

16. *Id.* at 21. NDAs can consist of as many as 15 sections, including: index, summary, chemistry, manufacturing, samples, validation package, labeling, pharmacology, toxicology, clinical data, microbiology, safety update report, statistical data and patent information. *Id.*

17. *Id.* at 24.

18. *Id.* at 5.

19. *Id.* at 10-11.

20. *Id.* at 11.

21. *Id.*

22. *See id.* at 42.

23. *Id.* at 62.

In addition, the CDER reassesses drug risks based on new data learned after the drug has been marketed and then recommends ways to effectively manage those risks.²⁴ There are a few ways that the CDER goes about this. First, manufacturers are required by regulation to report new information about a drug to the CDER.²⁵ Also, the FDA initiated new programs that make it easier for hospitals, healthcare providers and lay persons to report problems.²⁶

C. *Vioxx Failure Becomes FDA Failure.*

On September 30, 2004, the pharmaceutical industry and the Food and Drug Administration came under fire when Merck decided to voluntarily withdraw its drug Vioxx from the market.²⁷ After three years of study, Merck discovered that the arthritis pain relieving drug increased risks of cardiovascular problems after a continuous period of use.²⁸ Merck's decision was "the largest and most expensive drug withdrawal in recent history; nearly 20 million Americans used Vioxx for arthritis and similar pain relief and were affected by Merck's decision."²⁹ Initially, Merck received praise for voluntarily withdrawing Vioxx, but that soon faded among allegations that Merck knew of the drug's potential cardiovascular risks and chose to ignore them.³⁰ Specifically, in 2001, Merck chose not to conduct a cardiovascular study on Vioxx, despite being urged to do so by various doctors.³¹ Due to concerns about Vioxx's safety, in 2001, the FDA wrote Merck, "accusing it of misleading the public about Vioxx's cardiovascular safety" and urged that a disclaimer accompany the product.³² Originally Merck refused, but later agreed by adding a mere warning in the precautions section.³³

24. *Id.* at 42.

25. *Id.* at 44.

26. *Id.* "The MEDWatch program makes it easy for healthcare professionals to report serious adverse events to FDA. It requires a single form that may be sent via postage-prepaid mail, fax or computer modem or uses a special call-in phone number to verbally report." *Id.* "[The] Spontaneous Reporting System (SRS) . . . contains the adverse drug reaction reports from hospitals, health care providers and lay persons that are sent either directly to the Agency (via MEDWatch) or first to the drug manufacturer, and then, by regulation, to the Agency by the manufacturer." *Id.* at 45.

27. See Press Release, Merck & Co., Inc., Merck Announces Voluntary Worldwide Withdrawal of VIOXX® (Sept. 30, 2004), available at http://www.merck.com/newsroom/vioxx/pdf/vioxx_press_release_final.pdf.

28. *Id.* "In this study, there was an increased relative risk for confirmed cardiovascular events, such as heart attack and stroke, beginning after 18 months of treatment in the patients taking VIOXX compared to those taking placebo." *Id.* at 1.

29. Dohrman, *supra* note 2, at 205.

30. *Id.*

31. *Id.* at 206.

32. *Id.* at 207 (citing Ron Winslow, *Researcher Raises Flag on Painkiller*, WALL ST. J., Nov. 11, 2004, at D6).

33. Dohrman, *supra* note 2, at 207.

Up until now, you are probably asking yourself: why is the FDA being blamed for this? The answer is that many believe that the FDA did not act in the best interest of the public during the time the drug was on the market.³⁴ Specifically, these people claim that “the FDA stood idly by or even suppressed vital information about health concerns related to Vioxx.”³⁵ Furthermore, “internal FDA documents and e-mails suggest that FDA examiners questioned the cardiovascular safety of Vioxx before Merck’s recall.”³⁶ In 2000, David Graham, a 20 year veteran of the FDA, decided to conduct a study measuring the incidence of cardiovascular effects associated with Vioxx.³⁷ However, Graham said that he was prohibited from presenting his findings when his supervisors at the FDA learned that his study concluded that in high doses, “Vioxx significantly increased the risk of heart attacks and sudden death and that the[se] high doses . . . should not be prescribed or used by patients.”³⁸ According to Graham, the FDA insisted that his conclusions should be changed because it was not contemplating warnings for the use of high-dose Vioxx.³⁹

Despite the arguments that the FDA system is broken and is a failure to the public, Michigan’s current product liability scheme protects drug manufacturers from tort liability if its drug was approved by the FDA. In fact, no other state contains an immunity as broad as this. The rest of this article will examine the history of drug liability in Michigan, discuss other state approaches, and assess the pros and cons of pending legislation seeking to change the weight FDA approval is given in determining whether a manufacturer acted reasonably.

II. THE HISTORY OF DRUG LIABILITY IN MICHIGAN

A. Michigan’s Absolute Immunity

In Michigan, prior to 1995, evidence of compliance with industry or government standards was admissible in determining whether the standard of reasonable care has been met in product liability actions.⁴⁰ However, courts have held that the statute allowing such evidence “[did] not provide that such standards are conclusive.”⁴¹ In 1995, Michigan passed legislation

34. Rita Rubin, *Scientist Says FDA System ‘Broken’*, USA TODAY, Nov. 19, 2004, at 1A, available at http://www.usatoday.com/money/industries/health/drugs/2004-11-18-vioxx_x.htm.

35. Dohrman, *supra* note 2, at 207.

36. *Id.*

37. *Id.* at 208.

38. *Id.*

39. *Id.*

40. See *Owens v. Allis-Chalmers Corp.*, 326 N.W.2d 372, 375 (Mich. 1982).

41. *Id.* at 375-76. “[C]ompliance with governmental and industrial standards [are] admissible as evidence but [are] not conclusive as to whether the defendant was negligent or the product was defective.” *Id.* at 376. See *Przeradski v. Rexnord, Inc.*, 356 N.W.2d 634,

reforming product liability laws. The amendment added section 2946(5) of the Michigan Compiled Laws, which states:

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.⁴²

MCL section 600.2946(5) grants drug manufacturers an affirmative defense in product liability actions when its drug was approved by the FDA: “[t]hus, the Legislature has determined that a drug manufacturer or seller that has properly obtained FDA approval of a drug product has acted sufficiently prudently so that no tort liability may lie.”⁴³ However, this does not mean that a manufacturer could never be sued if FDA approval was obtained. The statute further states that “[t]his subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:”⁴⁴

(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, . . . 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.⁴⁵

These exceptions seem to provide plaintiffs an opportunity to defeat the affirmative defense by presenting evidence that FDA approval was

636 (Mich. Ct. App. 1984); *Granger v. Fruehauf Corp.*, 383 N.W.2d 162, 167 (Mich. Ct. App. 1985), *rev'd on other grounds*, 412 N.W.2d 199 (Mich. 1987). “The customary usage and practice of the industry is relevant evidence to be used in determining whether or not [the] standard [of reasonable care] has been met. Such usage cannot, however, be determinative of the standard.” *Owens*, 326 N.W.2d at 375 (quoting *Marietta v. Cliffs Ridge, Inc.*, 189 N.W.2d 208, 209 (Mich. 1971)).

42. MICH. COMP. LAWS ANN. § 600.2946(5) (West 2000).

43. *Taylor v. Smithkline Beecham Corp.*, 658 N.W.2d 127, 131 (Mich. 2003).

44. § 600.2946(5).

45. *Id.*

obtained by fraud; yet, later in this article, I will explain how these exceptions only place plaintiffs on a collision course with the supremacy clause.⁴⁶ In the next sections, I will describe how section 2946(5) survived state and federal constitutional challenges.

B. Michigan's Law Survives State Constitutional Challenges

In *Taylor v. Smithkline Beecham Corp.*,⁴⁷ plaintiffs brought suit against prescription diet pill manufacturers seeking damages for injuries resulting from use of the drugs.⁴⁸ The plaintiffs did not seek to invoke the exceptions under the statute, but rather, “assert[ed] that the statute was an unconstitutional delegation of legislative power.”⁴⁹ The plaintiffs relied on the Michigan Constitution, which provides: “The powers of government are divided into three branches: legislative, executive and judicial. No person exercising powers of one branch shall exercise powers properly belonging to another branch except as expressly provided in this constitution.”⁵⁰ These principles are described as the nondelegation doctrine.⁵¹ “The nondelegation doctrine forbids the delegation of legislative powers, not only to the executive or judicial branches, but also to non-Michigan governmental agencies or to private individuals or associations.”⁵²

The Michigan Court of Appeals concluded that the statute was an unconstitutional delegation of legislative power because “it places the FDA in the position of final arbiter with respect to whether a particular drug may form the basis of a products liability action in Michigan.”⁵³ The Michigan Supreme Court reversed and held that the statute did not delegate authority to the FDA; “rather, it uses independently significant decisions of the FDA as a measuring device to set the standard of care for manufacturers and sellers of prescription drugs in Michigan.”⁵⁴ The court stated that the statute represented the legislature’s determination of when a manufacturer has acted reasonably, as a matter of law, for the purposes of product liability claims.⁵⁵

In her dissenting opinion, Justice Kelly stated that the majority lost sight of the fact that FDA standards change over time.⁵⁶ Justice Kelly reasoned:

-
46. *See infra* Part II.C.
 47. 658 N.W.2d 127 (Mich. 2003).
 48. *Id.* at 129.
 49. *Id.* at 130.
 50. MICH. CONST. art. III, § 2.
 51. *Taylor*, 658 N.W.2d at 131.
 52. *Id.* at 131 n.5.
 53. *Id.* at 130.
 54. *Id.* at 137.
 55. *Id.*
 56. *Id.* (Kelly, J., dissenting).

When the Legislature adopts the determinations of a foreign body, it implicitly determines that [its] choice is sufficiently reliable to be conclusive. When the foreign body alters the standards by which it makes its determinations, it undermines the stability of the Legislature's choice. The foreign body becomes the only authority that approves the changed standards as well as the one that applies them. At that point, it steps into the shoes of the Legislature, making a policy choice for the people of Michigan. Its decision no longer represents the Legislature's intent. A statute that enables a foreign body to make a policy determination not embraced by the Legislature perpetrates an unconstitutional delegation of the Legislature's power.⁵⁷

Justice Kelly, relying on previous court decisions, argued that "an unconstitutional delegation occurs when a statute references fact-finding that is based on standards that are not 'established and essentially unchanging.'"⁵⁸ According to her, it is very easy to see that FDA standards regarding drug safety are bound to change given the nature of science.⁵⁹ The majority, however, disagreed with the dissent and stated that FDA findings about a drug do not change for section 2946(5) purposes.⁶⁰ The court also overruled the decisions relied on by Justice Kelly, reasoning that they were misunderstood.⁶¹

Compared with the majority's holding, the Restatement of Torts seems to take a similar position in that regulatory compliance may allow a finding as a matter of law that the product was not defective. In relation to product liability claims, section 4(b) of the Restatement (Third) of Torts states:

[A] product's compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation, but such compliance does not preclude as a matter of law a finding of product defect.⁶²

The comment to section 4(b) explains that regulatory schemes and standards set forth in state statutes generally are minimal, leaving the question of whether higher standards should be applied.⁶³ Furthermore, "after reviewing relevant circumstances, a court may properly conclude that a particular product safety standard set by statute or regulation

57. *Id.*

58. *Id.* (quoting *Taylor v. Gate Pharm.*, 639 N.W.2d 45, 54 (Mich. Ct. App. 2001)).

59. *Id.* at 138.

60. *Id.* at 136-37 n.19 (majority opinion).

61. *Id.* at 136 n.18.

62. RESTATEMENT (THIRD) OF TORTS § 4(b) (1998).

63. *Id.* § 4 cmt. e.

adequately serves the objectives of tort law and therefore that the product that complies with the standard is not defective as a matter of law.”⁶⁴ This is consistent with the holding in *Taylor*; however, Justice Kelly’s argument that changing FDA standards undermine legislative intent, may also be supported by the comment to section 4(b), which further states: “[s]uch a conclusion may be appropriate when the safety statute or regulation was promulgated recently, thus supplying currency to the standard therein established.”⁶⁵ Nevertheless, section 2946(5) survived the challenges under the state constitution.

C. Michigan’s Law Survives Federal Constitutional Challenges

Shortly after the decision in *Taylor*, MCL section 600.2946(5) survived federal constitutional challenges in *Garcia v. Wyeth-Ayerst Laboratories*.⁶⁶ In *Garcia*, the plaintiff claimed that the statute violated the United States Constitution because “it has been impliedly preempted by the federal Food, Drug and Cosmetic Act . . . and therefore runs afoul of the Supremacy Clause.”⁶⁷ The plaintiff also claimed that “it interfere[d] with [her] fundamental right of access to the courts and her Seventh Amendment right to a jury trial.”⁶⁸ Lastly, plaintiff claimed it violated the Fourteenth Amendment Due Process Clause by “depriving her of the right to use a traditional common law tort remedy as a means of seeking redress for her injuries.”⁶⁹

Section 2946(5) provides immunity for FDA approved drugs; however, as mentioned earlier, there are exceptions which allow a person to file suit if they can prove that the manufacturer intentionally withheld or misrepresented information concerning the drug to the FDA.⁷⁰ This statutory exception is known as a “fraud-on-the-FDA” claim.⁷¹ The plaintiff in *Garcia* claimed that, by requiring proof of fraud on the FDA, “the state necessarily obligates the courts to oversee and second-guess the FDA’s regulatory decisions and impermissibly encroach on its authority, creating a conflict with federal law.”⁷² The plaintiff relied on the United States Supreme Court decision in *Buckman Co. v. Plaintiffs’ Legal Committee*,⁷³ in which the Court held that state common law fraud-on-the-FDA tort claims were impliedly preempted by the Food, Drug and Cosmetic Act (“FDCA”) as amended by the Medical Device

64. *Id.*

65. *Id.*

66. 265 F. Supp. 2d 825 (E.D. Mich. 2003), *aff’d*, 385 F.3d 961 (6th Cir. 2004).

67. *Id.* at 829.

68. *Id.*

69. *Id.*

70. See MICH. COMP. LAWS ANN. § 600.2946(5)(a) (West 2000).

71. See, e.g., *Buckman Co. v. Plaintiffs’ Legal Committee*, 531 U.S. 341, 347 (2001).

72. *Garcia*, 265 F. Supp. 2d at 830.

73. 531 U.S. 341 (2001).

Amendments.⁷⁴ The Supreme Court stated that “[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA’s responsibility to police fraud consistently with the Administration’s judgment and objectives.”⁷⁵ Despite preemption, Justice Stevens in his concurring opinion stated that some instances may allow for fraud-on-the-FDA state claims to proceed, i.e., “where the FDA *itself* determines that an applicant committed fraud and takes steps to remove the drug from the market.”⁷⁶ With the exception of this limited circumstance, plaintiffs are sent down a “dead-end road” because the immunity from the FDA defense “can be upset only by a statutory exception that federal law preempts.”⁷⁷

The *Garcia* court acknowledged that *Buckman*’s holding created a “Catch-22,”⁷⁸ but nevertheless held that section 2946(5) was not

74. *Id.* at 347-48.

The FDA is empowered to investigate suspected fraud[,] and citizens may report wrongdoing and petition the agency to take action. In addition to the general criminal proscription on making false statements to the Federal Government[,] the FDA may respond to fraud by seeking injunctive relief and civil penalties[,] seizing the device[,] and pursuing criminal prosecutions. The FDA thus has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud upon the Administration.

Id. at 349 (internal citations omitted). Section 396 of the FDCA expressly states: “Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.” 21 U.S.C.A. § 396 (West 1999). “Thus, the FDA is charged with the difficult task of regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals.” *Buckman*, 531 U.S. at 350.

75. *Buckman*, 531 U.S. at 350.

76. *Garcia*, 265 F. Supp. 2d at 831 (emphasis added) (citing *Buckman*, 531 U.S. at 354 (Stevens, J., concurring)).

77. *Id.* at 832. Not all courts have agreed that Michigan law implicated the same concerns generated in *Buckman*. See *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2nd Cir. 2006).

[C]ommon law liability cannot be easily displaced in our federal system. *Buckman* underscored this fact, finding implied preemption of a newly-fashioned state cause of action only where (1) no presumption against federal preemption obtained, and (2) the cause of action, by assigning liability *solely* on the basis of fraud against the FDA, imposed significant and distinctive burdens on the FDA and the entities it regulates. . . . In the presence of this presumption, because Michigan law does not in fact implicate the concerns that animated the Supreme Court’s decision in *Buckman*, and because Appellants’ lawsuits depend primarily on traditional and preexisting tort sources, not at all on a “fraud-on-the-FDA” cause of action created by state law, and only incidentally on evidence of such fraud, we conclude that the Michigan immunity exception is not prohibited through preemption.

Id. at 98.

78. Catch-22 is commonly known as a no-win situation, and is defined as “a frustrating situation in which one is trapped by contradictory regulations or conditions.” RANDOM HOUSE UNABRIDGED DICTIONARY (2006), <http://dictionary.reference.com/browse/catch%2022>.

unconstitutional.⁷⁹ The court said that state legislatures are free to create immunity defenses for certain causes of action and furthermore, “the invalidity of the statutory exceptions to that immunity does not vitiate the immunity itself.”⁸⁰ The court also cited section 8.5 of the Michigan Compiled Laws which states:

If any portion of an act or the application thereof to any person or circumstances shall be found to be invalid by a court, such invalidity shall not affect the remaining portions or applications of the act which can be given effect without the invalid portion or application, provided such remaining portions are not determined by the court to be inoperable, and to this end acts are declared to be severable.⁸¹

The *Garcia* court declared that states have a choice to withdraw remedial safeguards provided by the tort system if the state feels that the federal regulatory scheme is adequate in protecting its citizens against potential injury from new medication.⁸²

Next, the plaintiff argued that section 2946(5) limited her ability to recover damages from a defective product; therefore, her rights of access to the court and trial by jury were abridged.⁸³ The court acknowledged that such rights were fundamental under the Constitution and even noted that these claims “can be established when a person can prove that a state’s judicial process does not provide an adequate procedure to remedy an alleged wrong”; however, they were only recognized for civil suits where the evidence was spoiled or the filing of a lawsuit had been interfered with.⁸⁴ Accordingly, plaintiff’s argument that the statute required too much and that the immunity granted was too broad did not raise an issue of ability to access the courts.⁸⁵

Lastly, plaintiff argued that her Due Process rights were violated. In procedural due process cases, there are two steps to follow: “First, there must be a protected liberty or property interest with which the state interferes. Second, the [c]ourt must decide whether the state provided procedural safeguards [are] consistent with the nature of the right or interest at stake.”⁸⁶ The *Garcia* court, in finding that the plaintiff did not pass this test, cited a Supreme Court decision which held that “due process

79. *Garcia*, 265 F. Supp. 2d at 832.

80. *Id.* See also *Kobar v. Novartis Corp.*, 378 F. Supp. 2d 1166, 1177 (D. Ariz. 2005) (holding that the fraud-on-the-FDA provision was severable from the remaining portion of the statute which granted immunity to drug manufacturers from punitive damage awards).

81. MICH. COMP. LAWS ANN. § 8.5 (West 2004).

82. *Garcia*, 265 F. Supp. 2d at 833.

83. *Id.*

84. *Id.*

85. *Id.* at 834.

86. *Id.* (citing *Kentucky Dep’t of Corr. v. Thompson*, 490 U.S. 454, 460 (1989)).

does not prohibit the abolition of causes of action by a state legislature because ‘a person has no property, no vested interest, in any rule of the common law.’⁸⁷ Furthermore, the *Garcia* court, using a rational basis test, did not find a violation of substantive due process.⁸⁸

The decisions in *Taylor* and *Garcia* sent a powerful message to plaintiffs seeking damages in Michigan from drug manufacturers’ products, in that, unless they were able to prove a valid exception under the statute, the only way to get around the immunity is to remove subsection (5) from the statute. The next parts of this article will discuss the weight that FDA approval has been given in other states and various bills that have been proposed by the Michigan legislature that seek to remove the FDA approval defense. As you will see, these bills are not only helpful for future plaintiffs, but also for plaintiffs like *Taylor* and *Garcia* who have been previously affected by the defense.

III. PRODUCT LIABILITY LAWS THROUGHOUT THE UNITED STATES

Michigan is currently the only state in the nation to create a statute granting absolute immunity (with a few rare exceptions) to drug manufacturers whose products were approved by the FDA. Several other states have created similar statutes; however, none of these statutes grant immunity as broad as Michigan. For example, Arizona, New Jersey, Ohio, Oregon and Utah all have statutes which provide that punitive damages may not be awarded if the drug received pre-market approval from the FDA and was deemed safe by its regulations.⁸⁹ All of these statutes contain a “fraud-on-the-FDA” exception, yet only Arizona, like the *Garcia* case in Michigan, has ruled this exception to be unconstitutional.⁹⁰ This is because the issue has not yet been raised in the remaining states. Below is an individual look at how some state statutes and judicial decisions have treated FDA approval in product liability claims.⁹¹

87. *Id.* (quoting *Second Employers’ Liability Cases*, 223 U.S. 1, 50 (1912)).

88. *Id.* at 834-835. Rational basis only requires loose means to achieve a legitimate end.

89. See ARIZ. REV. STAT. ANN. § 12-701 (2003); N.J. STAT. ANN. § 2A:58C-5 (West 2000); OHIO REV. CODE ANN. § 2307.80(C) (LexisNexis 2005); OR. REV. STAT. § 30.927 (2005); UTAH CODE ANN. § 78-18-2 (2002).

90. See *Kobar v. Novartis Corp.*, 378 F. Supp. 2d 1166 (D. Ariz. 2005). “Subsection B is unconstitutional as applied to this case as its requirement that a plaintiff prove fraud on the FDA is impliedly preempted by federal law. However, because Subsection B is severable from the remaining sections of the statute, Defendant is immune from punitive damage liability . . .” *Id.* at 1177.

91. Not listed is North Carolina, which does not specifically grant immunity or a rebuttable presumption if the drug was FDA approved, but conforming to government standards may serve as a relevant factor in determining whether the manufacturer acted reasonably. See N.C. GEN. STAT. § 99B-6(b) (2005). For claims based on inadequate design or formulation, section 99B-6(b) states in part:

A. *Utah*

Although Utah's statute only applies the FDA defense for punitive damage claims, the Utah Supreme Court, in *Grundberg v. Upjohn Co.*,⁹² held that FDA approved drugs were unavoidably unsafe and thus, manufacturers were immune from strict liability claims based on design defects.⁹³ The court adopted the unavoidably unsafe exception listed in comment k of the Restatement (Second) of Torts § 402A which states in part:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . . *Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous.* . . . The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, *is not to be held to strict liability for unfortunate consequences attending their use*, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.⁹⁴

By its literal interpretation, comment k exempts only unavoidably unsafe drugs from strict liability, but the *Grundberg* court expanded comment k's interpretation by characterizing all FDA approved drugs as unavoidably unsafe and stated that "a drug approved by the [FDA], properly prepared, compounded, packaged, and distributed, cannot as a matter of law be 'defective' in the absence of proof of inaccurate, incomplete, misleading, or fraudulent information furnished by the manufacturer in connection with FDA approval."⁹⁵ The *Grundberg* court found its interpretation to be sound and in accordance with the Utah legislature's recognition of the value of the FDA approval process, as

(b) In determining whether the manufacturer acted unreasonably under subsection (a) of this section, the factors to be considered shall include, but are not limited to, the following:

. . . .

(4) The extent to which the labeling for a prescription or nonprescription drug approved by the United States Food and Drug Administration conformed to any applicable government or private standard that was in effect when the product left the control of its manufacturer.

Id. § 99B-6(b).

92. 813 P.2d 89 (Utah 1991).

93. *Id.* at 90.

94. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965) (emphasis added).

95. *Grundberg*, 813 P.2d at 90.

shown by its statute prohibiting punitive damages against federally approved drugs.⁹⁶

B. California

In *Brown v. Superior Court*,⁹⁷ the Supreme Court of California also adopted comment k in shielding manufacturers of prescription drugs from strict liability claims.⁹⁸ The court held that “because of the public interest in the development, availability, and reasonable price of drugs, the appropriate test for determining responsibility is the test stated in comment k.”⁹⁹ Furthermore, because of these policy decisions, the court overruled the decision in *Kearl v. Lederle Laboratories*,¹⁰⁰ which held that only “prescription drugs found to be ‘unavoidably dangerous’ should be measured by the comment k standard and that strict liability should apply to drugs that do not meet that description.”¹⁰¹

The *Brown* court noted that its decision—that comment k applies to all prescription drugs—was in accordance with almost all of the states that have considered the issue.¹⁰² In addition, the court stated that “the benefit of the negligence standard stated in the comment would be greatly diminished if all drugs were required to run the gauntlet of a risk/benefit analysis in order to qualify for application of the standard.”¹⁰³

C. Nebraska

Unlike Utah, which held that all FDA approved drugs were unavoidably unsafe, and California, which held that comment k should apply to all prescription drugs, the Supreme Court of Nebraska in *Freeman v. Hoffman-La Roche, Inc.*¹⁰⁴ stated that comment k’s immunity did not apply to all prescription drugs. The court concluded:

[C]omment k . . . should be applied on a case-by-case basis and as an affirmative defense in cases involving prescription drug products. Under this rule, an application of the comment does

96. *Id.* at 97.

97. 751 P.2d 470 (Cal. 1988).

98. “Our conclusion does not mean, of course, that drug manufacturers are free of all liability for defective drugs. They are subject to liability for manufacturing defects, as well as under general principles of negligence, and for failure to warn of known or reasonably knowable side effects.” *Id.* at 483 n.12.

99. *Id.* at 477. “[W]e hold that a manufacturer is not strictly liable for injuries caused by a prescription drug so long as the drug was properly prepared and accompanied by warnings of its dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution.” *Id.* at 482-83.

100. 218 Cal. Rptr. 453 (Cal. Ct. App. 1985).

101. *Brown*, 751 P.2d at 477 (citing *Kearl*, 218 Cal. Rptr. at 817).

102. *Id.* at 482 n.11.

103. *Id.*

104. 618 N.W.2d 827 (Neb. 2000).

not provide a blanket immunity from strict liability for prescription drugs. Rather, the plaintiff is required to plead the consumer expectations test, as he or she would be required to do in any products liability case. The defendant may then raise comment *k*. as an affirmative defense. The comment will apply to except the prescription drug product from strict liability when it is shown that (1) the product is properly manufactured and contains adequate warnings, (2) its benefits justify its risks, and (3) the product was at the time of manufacture and distribution incapable of being made more safe.¹⁰⁵

The Nebraska Supreme Court's test would require a risk/benefit analysis which was rejected by the *Brown* court in California. This test also requires a showing that the product is unavoidably unsafe within its literal meaning, which means that FDA approval will weigh in on a product's capability of being made safer.

D. Indiana and New Jersey

Indiana's product liability law does not specifically state that a product approved by the FDA is not defective.¹⁰⁶ The law provides a rebuttable presumption that the product is not defective, and therefore the manufacturer is not negligent, if the product complied with federal standards.¹⁰⁷

New Jersey's product liability law is similar to Indiana's in that it provides a rebuttable presumption; however, it only applies to the adequacy of warnings and instructions. Moreover, New Jersey's statute specifically refers to FDA approval. Section 2A:58C-4 includes in part:

[I]n the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician[, i]f the warning or instruction given in connection with a drug or device or food or food additive has been approved or prescribed by the federal Food and Drug

105. *Id.* at 840. *See also* Toner v. Lederle Labs, 732 P.2d 297 (Idaho 1987) "[T]he comment does not apply to *all* drugs. Rather, the comment applies 'when the situation calls for it,' which is when the product is unavoidably unsafe . . ." *Id.* at 308.

106. *See* IND. CODE ANN. § 34-20-5-1 (LexisNexis 1998).

107. *Id.* Section 34-20-5-1 states in relevant part:

In a product liability action, there is a rebuttable presumption that the product that caused the physical harm was not defective and that the manufacturer or seller of the product was not negligent if, before the sale by the manufacturer, the product:

....

(2) complied with applicable codes, standards, regulations, or specifications established, adopted, promulgated, or approved by the United States or by Indiana, or by an agency of the United States or Indiana.

Administration . . . a rebuttable presumption shall arise that the warning or instruction is adequate.¹⁰⁸

As explained further in the next section, when compared to Michigan's affirmative defense, it is clear that a rebuttable presumption is highly favorable to a plaintiff. Because of this, critics claim that the New Jersey courts' preference for New Jersey law in product liability claims lure out of state plaintiffs and result in mass litigation.¹⁰⁹ This is supported by the New Jersey Superior Court's decision in *Rowe v. Hoffmann-La Roche Inc.*¹¹⁰ In *Rowe*, the court favored New Jersey product liability law over Michigan's in a choice-of-law decision.¹¹¹ The defendant was a New Jersey company that manufactured the popular prescription acne drug Accutane.¹¹² The plaintiff claimed that as a result of using the drug, he became severely depressed and attempted suicide on several occasions.¹¹³ The plaintiff alleged that the defendant had acted negligently, carelessly and recklessly by failing to adequately warn him of the dangers of using the drug.¹¹⁴ The plaintiff was at all relevant times a Michigan resident, and all contacts relating to his treatment of Accutane occurred in Michigan.¹¹⁵ In light of this, the *Rowe* court was faced with a difficult conflict-of-law decision that would greatly impact the strength or weakness of the case. On one hand, if Michigan law was applied, the defendant would prevail because Accutane was an FDA approved drug, therefore, the manufacturer would be immune from suit. On the other hand, New Jersey law provided a rebuttable presumption that the warnings were adequate.

Despite all contacts occurring in Michigan, the court concluded that the defendant's conduct occurred entirely in New Jersey¹¹⁶ and that it would be "difficult to see how Michigan's interest in protecting Michigan drug manufacturers would be furthered by applying its immunity statute to this case. Likewise, it is difficult to see that Michigan has any interest in protecting out-of-state manufacturers like defendants here."¹¹⁷ "[A]lthough place of injury is a significant factor in many tort actions, it does not warrant undue weight in product liability cases."¹¹⁸ In concluding, the court held that "deterrence and compensation are interests more likely to be

108. N.J. STAT. ANN. § 2A:58C-4 (West 2000).

109. Beth S. Rose & Steven R. Rowland, *Choosing New Jersey: Preference for New Jersey Law in Products Liability Claims Draws Out-of-state Plaintiffs*, 184 N.J. L.J. 363 (2006).

110. 892 A.2d 694 (N.J. Super. Ct. App. Div. 2006).

111. *See id.* at 709.

112. *Id.* at 698.

113. *Id.*

114. *Id.* at 699.

115. *Id.* at 698.

116. *Id.* at 703.

117. *Id.* at 706.

118. *Id.* at 703.

served in this case by application of New Jersey law than Michigan law. New Jersey law therefore applies to plaintiff's products liability failure-to-warn claim."¹¹⁹ This was a big win for the plaintiff because the rebuttable presumption provided by New Jersey law is strong, but nevertheless, is not conclusive.¹²⁰ This presumption disappears if the plaintiff can present sufficient evidence which would allow a jury to find that the warning was inadequate.¹²¹

The dissent in *Rowe* disagreed with the majority's holding that New Jersey law should be applied.¹²² Moreover, the dissenting opinion is important because it draws attention to the numerous amounts of tort actions litigated within the state. The dissent stated in part:

New Jersey courts are, for whatever reason, the site of much mass-tort litigation. The Mass Tort Information Center in *NJCourtsonline.com*, for example, lists seven pending mass tort actions in New Jersey involving pharmaceuticals. New Jersey

119. *Id.* at 709.

120. *Id.* at 700.

121. Rose & Rowland, *supra* note 109.

[A]pplication of Michigan law would require the court to dismiss Rowe's claim as a matter of law. New Jersey law would regard the adequacy of Accutane's warning to be an issue of fact for the jury. Since the *Rowe* decision implies that the Accutane label contained no warning about depression or suicide, the heeding presumption found in New Jersey law would require the jury to find that Rowe would have heeded an adequate warning if one had been given. . . . Thus, assuming that Rowe can rebut the presumption that the FDA warning is adequate and that Hoffmann-La Roche did not warn about Accutane's alleged psychological effects, New Jersey law would appear to be highly favorable to Rowe.

Id. (internal citations omitted).

122. *Rowe*, 892 A.2d at 709-11 (Wefing, J., dissenting).

I do not share my colleagues' inference that the purpose of the Michigan Legislature in adopting this legislation was restricted to the protection of Michigan businesses, specifically Michigan drug manufacturers. Rather, as they note, this provision was but one part of a comprehensive tort reform bill passed by the Michigan Legislature that addressed a variety of topics, including joint and several liability, expert testimony, and limitations on damages for non-economic losses.

. . . .

In addition, I cannot conclude that applying Michigan law would frustrate New Jersey's interest in deterrence. Pharmaceutical manufacturers do not supply different labels in different states, depending upon the nature of that state's product liability law. A New Jersey pharmaceutical manufacturer cannot rest secure based upon its knowledge that its labeling and warnings have been approved by the FDA because our legislature has declined to afford the pharmaceutical industry a blanket immunity based upon such FDA approval. Whatever deterrence is created by *N.J.S.A. 2A:58C-4*'s rebuttable presumption remains and is unaffected by applying Michigan law to a Michigan claimant who was treated in Michigan.

Id. at 710-11.

should not become the asylum for claims asserted by citizens of another state whose legislature has made a policy choice to immunize a particular defendant from such litigation.¹²³

A closer look at New Jersey's mass tort litigation website confirms these assertions.¹²⁴ In regards to Vioxx litigation alone, the case list¹²⁵ as of February 28, 2007, is 350 pages long including "over 5000 cases pending before Judge Carol Higbee in Atlantic City—out of approximately 10,000 personal injury cases nationwide."¹²⁶ Thus, it is easy to see that out-of-state plaintiffs have an incentive to litigate their claims in New Jersey - a state which is willing to hear them.

IV. PENDING MICHIGAN LEGISLATION

A. Rescission of Subsection Five

Currently before the Michigan legislature, both the Senate and the House have introduced Bills which seek to rescind section 2946(5).¹²⁷ The amendment would remove the FDA approval defense but would leave sections 2946(1)-(4) intact. Even though drug manufacturers would lose the absolute defense previously granted to them, it still may be possible to use evidence of FDA compliance allowed by MCL section 600.2946(4), which provides:

In a product liability action brought against a manufacturer or seller for harm allegedly caused by a product, there is a *rebuttable presumption* that the manufacturer or seller *is not liable* if, at the time the specific unit of the product was sold or delivered to the initial purchaser or user, the aspect of the product that allegedly caused the harm was in *compliance with standards relevant to the event causing the death or injury set forth in a federal or state statute* or was approved by, or was in compliance with regulations or standards relevant to the event causing the

123. *Id.* at 711.

124. New Jersey's Mass Tort Information Center can be found at <http://www.judiciary.state.nj.us/mass-tort/index.htm> (last visited May 25, 2008).

125. New Jersey's Vioxx Mass Tort case list is available at http://www.judiciary.state.nj.us/mass-tort/vioxx/case_list.htm (last visited May 25, 2008).

126. Rose & Rowland, *supra* note 109.

127. See H.R. 4044, 94th Leg., Reg. Sess. (Mich. 2007); S. 43, 94th Leg., Reg. Sess. (Mich. 2007). In the past few years, the Michigan legislature has proposed the same or similar bills in regards to MCL section 2946(5). See H.R. 5392, 92nd Leg., Reg. Sess. (Mich. 2003); H.R. 4811, 93rd Leg., Reg. Sess. (Mich. 2005) (allowing liability suits brought against drug manufacturers for drugs that have been approved by federal food and drug administration). See also H.R. 4773, 93rd Leg., Reg. Sess. (Mich. 2005); S. 1242, 93rd Leg., Reg. Sess. (Mich. 2006) (rescinding subsection five). The Michigan House of Representatives also previously drafted a bill that sought to create a rebuttable presumption instead of absolute immunity. See H.R. 5527, 93rd Leg., Reg. Sess. (Mich. 2005).

death or injury promulgated by, a federal or state agency responsible for reviewing the safety of the product. Noncompliance with a standard relevant to the event causing the death or injury set forth in a federal or state statute or lack of approval by, or noncompliance with regulations or standards relevant to the event causing the death or injury promulgated by, a federal or state agency does not raise a presumption of negligence on the part of a manufacturer or seller.¹²⁸

In any case, as mentioned earlier in this article, rebuttable presumptions are not conclusive and can be overcome by showing sufficient evidence for the jury to find that the manufacturer or seller's actions were inadequate.

B. Revived Statute of Limitation Window

House Bill 4045 seeks to amend MCL section 600.5805 by extending the statute of limitations period three years after rescission of the FDA defense.¹²⁹ All causes of action previously barred by section 2946(5), that otherwise could have been brought from January 2, 1996 (the effective date of the FDA defense) until the effective date of House Bill 4045, are granted the three-year window.¹³⁰

Though extending the limitations period may seem unfair to drug manufacturers, the constitutionality of revival statutes in product liability actions has been upheld in *Hymowitz v. Eli Lilly & Co.*¹³¹ In *Hymowitz*, the defendants argued that "revival of [previously] barred DES¹³² claims was unconstitutional as a denial of both due process and equal protection."¹³³ The court stated that statutes of limitation "'represent a public policy about the privilege to litigate . . . the history of pleas of limitation shows them to be good only by legislative grace and to be subject to a relatively large degree of legislative control.'"¹³⁴ In regards to DES claims, the court concluded that "the revival statute has a rational basis, and the Legislature acted within its broad range of discretion in enacting the law."¹³⁵

128. MICH. COMP. LAWS ANN. § 600.2946(4) (West 2000) (emphasis added).

129. See H.R. 4045, 94th Leg., Reg. Sess. (Mich. 2007).

130. *Id.* In 2005, the Michigan House of Representatives sought similar legislation. See H.R. 5139, 93rd Leg., Reg. Sess. (Mich. 2005); H.R. 5527, 93rd Leg., Reg. Sess. (Mich. 2005).

131. 539 N.E.2d 1069 (N.Y. 1989).

132. Plaintiffs claim that the drug diethylstilbestrol (DES), which was ingested by their mothers during pregnancy, was the cause of their injuries. *Id.* at 1071.

133. *Id.* at 1079.

134. *Id.* (quoting *Chase Securities Corp. v. Donaldson*, 325 U.S. 304, 314 (1945)).

135. *Id.* at 1080.

C. Amendment to the Michigan Consumer Protection Act

The Michigan Consumer Protection Act contains a list of unlawful actions that are considered “[u]nfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce.”¹³⁶ House Bill 4046 seeks to add the following to that list: “Failure . . . to accurately represent the risks involved in the intended use of a prescription or over-the-counter drug or medication or an herbal product, dietary supplement, or botanical extract.”¹³⁷ In addition, the bill also would include “a legal pharmaceutical product” in the definition of a “good.”¹³⁸

V. EFFECTS OF PENDING LEGISLATION

A. The Case for Changing Michigan’s Current Scheme

The House Bills listed in the previous section demonstrate that their supporters are not happy with Michigan’s current product liability laws. But what exactly is fueling their criticisms?

First, the supporters feel that drug companies should be held liable for knowingly placing dangerous products on the market that can prove to be fatal. Critics argue that the current law only protects pharmaceutical companies and fails to protect the safety of its citizens. In addition, once manufacturers obtain FDA approval, they have many incentives to remain ignorant on the risk of their drugs. For example, “[a]ny new information the manufacturer produces by post-approval testing can lead to tort liability or withdrawal of FDA approval.”¹³⁹ These manufacturers know that damaging information may result from testing; however, they are in the best position to undertake the task because “patients who suspect they have been injured by a drug cannot afford an epidemiological study to determine conclusively the cause of their injury.”¹⁴⁰ Such studies can cost over \$100 million.¹⁴¹ In light of these concerns, critics believe that immunity should only be granted after manufacturers conduct post-approval testing.

Another concern is that the FDA system is flawed and is not equipped to protect the public from another major drug defect. In regards to post-approval testing, the “FDA can require pharmaceutical manufacturers to report available information on a drug, but cannot require that the

136. MICH. COMP. LAWS ANN. § 445.903(1) (West 2002).

137. H.R. 4046, 94th Leg., Reg. Sess. (Mich. 2007). Similar legislation was previously proposed in H.R. 5071, 93rd Leg., Reg. Sess. (Mich. 2005).

138. H.R. 4046, 94th Leg., Reg. Sess. (Mich. 2007).

139. David Rosenberg, *Post-Approval Testing By Pharmaceutical Manufacturers*, at ¶ 1, LEDA at Harvard Law School, Apr. 30, 2002, available at <http://leda.law.harvard.edu/leda/data/324/Cave2.html> (last visited May 25, 2008).

140. *Id.* at ¶ 6.

141. *Id.*

manufacturer conduct testing to produce new information.”¹⁴² “Even if FDA regulations did require post-approval testing, FDA would be unable to require efficient testing because it lacks the resources to monitor all the drugs that are on the market.”¹⁴³ Furthermore, the FDA only has fifty-five full time employees engaged in post-approval surveillance, as compared to over 1,700 workers engaged in the pre-approval stages of a new drug application.¹⁴⁴

Another reason that some legislators are trying to rescind the FDA defense is that it purports to allow plaintiffs to present findings that the manufacturers obtained approval by fraud in order to defeat the immunity; however, since this exception was deemed unconstitutional as being impliedly preempted by federal law,¹⁴⁵ plaintiffs have no avenue of relief against the wrongdoings of these drug companies.

B. Michigan’s Current Scheme Does Not Need Change

1. Allowing liability suits against manufacturers of FDA approved drugs will delay processing of new drugs and will cause a surge in health care costs

As previously mentioned, it is estimated that studying and testing a new drug can take eight and a half years.¹⁴⁶ The reason that it takes so long is that the current approach is not lackadaisical. Drug manufacturers and the FDA undergo a series of closely monitored studies before a drug will ever become marketed to the public. The argument that manufacturers should engage in post-approval testing may be sound, but the result of such testing will lead to increased health care costs for the consumer. Also, more litigation will cause pharmaceutical companies to invest more in defense lawyers than in new life saving drugs. Michigan Representative Jack Hoogendyk, in opposition to House Bill 4044, stated:

Let us be mindful that should this legislation pass our loved ones and future generations will be that much further from a cure for any number of diseases because the companies whose mission it is to find that cure had to divert precious research dollars to pay lawyers to defend a product which had already undergone years of research, development, testing and FDA approval.¹⁴⁷

142. *Id.* at ¶ 15.

143. *Id.* at ¶ 16.

144. *Id.*

145. *See Garcia v. Wyeth-Ayerst Labs.*, 265 F. Supp. 2d 825 (E.D. Mich. 2003), *aff’d*, 385 F.3d 961 (6th Cir. 2004).

146. *See supra* note 18.

147. House Journal No. 17, at 175, 94th Leg., Reg. Sess. (Mich. 2007) (statement of Rep. Hoogendyk).

Many people in this country wait patiently, hoping that one day these companies may develop a potentially life saving drug, but if companies are constantly being sued, there might not be any more research money to keep those hopes alive. The windfall of a few hundred plaintiffs may hurt our nation's access to necessary medicine.

2. *FDA standards are already strict*

It should be well noted that turnaround times for new drugs in the United States are longer than anywhere in the world. Michigan Representative Fulton Sheen mentioned this when he stated that:

The FDA approval process is by leaps and bounds the most stringent, costly, and time-consuming drug approval process in the world. It is one of the reasons prescription drugs cost more in the United States than anywhere else and why it generally takes 7 to 10 years and millions of dollars to get a new drug approved. Most of the drugs currently being reviewed in the U.S. are already available in other countries. People around the world are already benefiting from these new drugs and in some situations these drugs have saved their lives.¹⁴⁸

FDA guidelines are very strict and a manufacturer can only do so much in order to get life-saving drugs on the market. If manufacturers follow these regulations, the line must be drawn somewhere. In addition, “[t]he FDA’s scientific expertise and broad regulatory perspective make it the better institution to decide scientific issues on a society-wide basis.”¹⁴⁹

[The] FDA is better able to weigh the risks and benefits of a drug because it considers the drug in the context of the entire national population instead of focusing on a single victim. Juries make decisions case by case, in an isolated and uncoordinated fashion. . . . Juries are not institutionally equipped to decide whether the risks of a drug outweigh its benefits for the entire national population. This is a decision best made by FDA, which has both the expertise and the proper perspective to make it.¹⁵⁰

The FDA may have to revise some of its policies in order to avoid another Vioxx disaster, but the current system is better than allowing courts to be flooded with frivolous lawsuits that may cripple the pharmaceutical industry. The FDA knows how the industry should do its job.

3. *Michigan does not need mass litigation*

Change in Michigan’s current law would generate too many lawsuits in the state. Proponents for change may argue that, even if the FDA

148. *Id.* at 178 (statement of Rep. Sheen).

149. Rosenberg, *supra* note 139, at ¶ 43.

150. *Id.*

defense is rescinded, a rebuttable presumption that the manufacturer is not liable for conforming to government standards would remain, but since the presumption is not conclusive, the state would still be subject to mass litigation, as illustrated earlier by New Jersey's current scheme.¹⁵¹

In addition to allowing liability suits against drug manufacturers, House Bill 4045's attempt to revive previously barred claims will also flood the dockets. In the DES case, the *Hymowitz* court itself said that 800 DES cases would eventually be brought under the revival statute¹⁵² and that statute only revived claims for one year—compared to the three years proposed by House Bill 4045.¹⁵³

4. Michigan's struggling economy (literally) can not afford to impose more liability on pharmaceutical companies

It is no secret that Michigan's bread and butter is the auto industry; however, the recent struggles of the big three automakers taught Michigan that it should not be too dependant on the auto industry and should start to grow in other areas. In fact, Michigan did just that by expanding its involvement in the life sciences industry, but pending legislation threatens the jobs and companies within it. Legislators stress that these bills would be fatal to Michigan's frail economy. The following statement by Representative Hoogendyk reflects these concerns:

Let us not forget this is one of the key industries our governor has highlighted for growth, and rightly so. In my district alone, over 40 new life sciences companies have spun off or started up in the last ten years. These are not 'big pharma' companies, not greedy corporations who only care about profits, no, these companies are just trying to create jobs and new, life saving drugs. But passage of this bill will not encourage job growth. Currently, there are over 13,000 men and women in Michigan who earn their livelihood from the pharmaceutical and life science industry, 4000 in my district alone. I shudder to think what message this legislation will send to those individuals and the companies who employ them.¹⁵⁴

The economic reasons given in opposition to these bills reflect the same view legislators had when they first enacted the "FDA defense." Dick Posthumus, the Senate majority leader who led the 1996 reform efforts, stated that:

One of the things we foresaw at the time was the need to diversify Michigan's economy. We saw coming what eventually

151. See *supra* Part III.D.

152. *Hymowitz v. Eli Lilly & Co.*, 539 N.E.2d 1069, 1073 (N.Y. 1989).

153. See H.R. 4045, 94th Leg., Reg. Sess. (Mich. 2007).

154. House Journal No. 17, at 175, 94th Leg., Reg. Sess. (Mich. 2007) (statement of Rep. Hoogendyk).

happened, that is the globalization of the auto industry, which meant Michigan wouldn't be as dominant and we would have to provide jobs in other industries. One of the industries we looked at as a state back then, and I think rightly so, was the life sciences industry. We had Pfizer in Ann Arbor and Upjohn in Kalamazoo. We had Dow in Midland and the University Research Center in Ann Arbor. . . . We had all of these pieces, so one of the things we wanted to do was encourage the expansion of the life sciences industry. There were a whole lot of pieces to that, but one of the pieces was to ensure that a pharmaceutical company working on a life-saving drug wouldn't have to worry about frivolous lawsuits.¹⁵⁵

Since 1996, life sciences companies have invested \$355 million on research and development in Michigan and the pharmaceutical industry has over 12,000 jobs in the state with an average yearly salary of over \$60,000.¹⁵⁶ A loss of which has "a direct and indirect economic impact of over \$4 billion."¹⁵⁷

CONCLUSION

The bills that are currently before the Michigan legislature do not lack good intention. They were formulated with the notion that some drug companies commit wrongdoing and as a result many people may become injured or even die. Since Michigan provides immunity to these companies, some fear that we are not looking after the "little guy." However, even though these bills seek relief for those wrongly injured, we cannot compromise life saving research and development and the thousands of jobs that come with it. Michigan's economy is like that heavyweight boxer who's seeing double and is one shot away from being knocked out. House Bills 4044-46 stand to deliver another blow. How much more can Michigan take?

ZIYAD I. HERMIZ*

155. *The Move to Reverse Michigan's Model Reforms: Why Wolverine Staters Should Just Say No to the Trial Bar's War on Drugs*, TRIAL LAWYERS INC., No. 2, June 2006, at 2.

156. *Id.*

157. *Id.* at 1.

* The author would like to thank Professor Andrew Moore for his help and assistance in preparing this article. The author would also like to thank his family, friends and loved ones for their continued support, encouragement and patience over the last three years.