

MICHIGAN’S DRUG IMMUNITY: NOT A MODEL TO FOLLOW

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INTRODUCTION

Elections bring a variety of issues to the forefront of the citizenry’s thoughts. Some issues are boring and hardly catch anyone’s attention; while others are highly emotional. During the highly publicized mid term elections of November 2006, Michiganders showed sensitivity to one issue regarding the election of the state Congressman. This was drug manufacturer liability. During a commercial impeaching the character of Leslie Moritmer, the voice over disparaged her for being on the side of big drug makers and supporting the current Michigan statutory immunity for all consumer claims against drug manufacturers.

This statutory immunity was created in 1996 with the passage of Michigan statute 600.2946(5).<sup>1</sup> This statute makes it impossible for any individual to bring suit against a drug

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<sup>1</sup> MICH. COMP. LAWS ANN. § 600.2946(5) (West 2000).

manufacturer for injury cause by a United States Food and Drug Administration (FDA) approved drug.<sup>2</sup> This leaves Michigan consumers in the unique position of being completely without redress in product liability against a drug manufacturer.<sup>3</sup> Those who ingest deadly drugs such as Vioxx, Fen-Phen, Rezulin, or Baycol have no opportunity to hold the drug manufacturers accountable for the damage done.<sup>4</sup>

Drug manufacturers and their allies in tort reform encourage other states to adopt a statute like the one utilized in Michigan.<sup>5</sup> This paper will show why the “Michigan model” should not be followed, and in fact, should be repealed. FDA approval of a drug should not form the basis of state statutory preclusions of tort liability for all injury to consumers because FDA regulations inadequately protect consumers; statutory preclusions of tort liability ignore the prudence of a dual regulatory system, and are possibly unconstitutional.

Part I of this of this paper will show the history of product liability in general, and product liability in Michigan before 1996. Part II will examine the Michigan law in its current form and the case law that flows from it. Part III of this paper will then analyze the reasons why the statute should be repealed. This section will explain why the FDA approval process should not serve as a defense to all product liability claims because it does not adequately protect consumers. Further, this section will provide reasons why a system of dual regulation is preferable. Lastly, this section will explain why the Michigan statute may even be unconstitutional.

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<sup>2</sup> *Id.*

<sup>3</sup> Michigan is the only state in the nation to provide a broad drug immunity. Jonathan V. O’Steen & Van O’Steen, *The FDA Defense: Vioxx(R) and the Argument Against Federal Preemption of State Claims for Injuries Resulting From Defective Drugs*, 48 ARIZ. L. REV. 67, 91 (2006).

<sup>4</sup> So long as the drug is approved by the FDA and complies with the labeling instructions, a drug manufacturer is immune from any product liability claim. MICH. COMP. LAWS ANN. § 600.2946(5) (West 2000).

<sup>5</sup> O’Steen & O’Steen, *supra* note 3, at 91.

## I. HISTORY OF PRODUCT LIABILITY

This section of the paper will give background on the common law theories of product liability. It will then show how product liability actions were brought against drug manufactures in Michigan before the 1996 law was enacted. Next, this section will go through the 1996 amendment to the product liability law of Michigan, and examine the cases that have challenged this law.

### A. Product Liability in General

Product liability is a form of common law tort liability that encompasses negligence, express or implied warranty, and strict liability.<sup>6</sup> These theories allow plaintiffs to recover damages when they are injured by defective goods.<sup>7</sup> A negligence claim is the oldest form of liability and continues to be a popular means of recovery.<sup>8</sup> A negligence claim allows the plaintiff to present all evidence of manufacturer wrong doing to the jury, and is therefore a more effective way to play to the juror's sensibilities.<sup>9</sup>

A warranty claim is different than a claim in negligence because it is not based solely on tort theory, but is instead a hybrid between tort and contract.<sup>10</sup> Express warranties allow a plaintiff to recover when she has been explicitly guaranteed qualities in a product and these qualities are absent.<sup>11</sup> Implied warranties of merchantability and implied warranties of fitness for a particular purpose provide a consumer with implied warranties under which he may sue if the product does not perform as it should.<sup>12</sup>

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<sup>6</sup> VICTOR E. SCHWARTZ ET AL., PROSSER, WADE AND SCHWARTZ'S TORTS 712 (10th ed. 2000).

<sup>7</sup> *Id.* at 712.

<sup>8</sup> *Id.* at 716 (stating that nearly every action for product liability contains a negligence count).

<sup>9</sup> *Id.* at 717.

<sup>10</sup> *Id.* at 717.

<sup>11</sup> *Baxter v. Ford Motor Co.*, 12 P.2d 409, 412 (Wash. 1932).

<sup>12</sup> *Henningsen v. Bloomfield Motors, Inc.*, 161 A.2d 69, 76 (N.J. 1960).

Lastly, strict liability in tort allows a plaintiff to sue a manufacturer without proving negligence or breach of warranty. A manufacturer is strictly liable in tort when it places an item on the market, knowing that it will not be inspected before use, and this item proves to be defective and causes injury.<sup>13</sup> In order to establish liability under this theory of recovery, a plaintiff need only prove injury caused by the item while used for its intended.<sup>14</sup>

According to the Third Restatement of Torts “[o]ne engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect.”<sup>15</sup> The Third Restatements of Torts has a section specially designated to product liability stemming from a prescription drug.<sup>16</sup> This section recognizes that there is a product liability cause of action when a drug is defective.<sup>17</sup> A drug is considered defective if it “contains a manufacturing defect; or is not reasonably safe due to defective design as defined in subsection (c); or is not reasonably safe due to inadequate instructions or warnings as defined in subsection (d).”<sup>18</sup>

#### B. Product Liability in Michigan

Michigan’s product liability causes of action are codified in the Michigan statute 600.2946.<sup>19</sup> Another statute defines product liability by stating that “[p]roduct liability action’ means an action based on a legal or equitable theory of liability brought for the death of a person or for injury to a person or damage to property caused by or resulting from the production of a product.”<sup>20</sup> Prior to 1996, this statute extended to product liability actions against drug

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<sup>13</sup> Greenman v. Yuba Power Products, Inc., 377 P.2d 897, 900 (Cal. 1963).

<sup>14</sup> *Id.*

<sup>15</sup> RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 1 (1998).

<sup>16</sup> RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 (1998).

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> MICH. COMP. LAWS ANN. § 600.2946 (West 2000).

<sup>20</sup> MICH. COMP. LAWS ANN. § 600.2945 (West 2000).

manufacturers.<sup>21</sup> This statute allowed evidence to show compliance with governmental or industry standards, but did not hold this evidence as dispositive.<sup>22</sup>

Michigan recognized two theories of recovery in the area of product liability: negligence and breach of implied warranty.<sup>23</sup> The burden of proof was different depending on which theory the plaintiff chose to pursue.<sup>24</sup> Under a negligence theory, the plaintiff had to prove the traditional common law elements of duty, breach, causation and damage.<sup>25</sup> However, if the plaintiff chose to establish a breach of implied warranty, he had to show that the defect in the product, which was attributable to the manufacturer, caused his injuries.<sup>26</sup> If the plaintiff proved each of these elements, the drug manufacturer was liable to the plaintiff for the damage caused by the defective drug.

In the case of *Smith v. E.R. Squibb & Sons, Inc.*, the plaintiffs brought an action against a drug manufacturer under both products liability theories, negligence and implied warranty.<sup>27</sup> The plaintiff claimed that Squibb failed to warn the medical profession effectively as to the dangers of a drug, and that this failure constituted a defect in the drug and was the proximate cause of death.<sup>28</sup> The court found that a drug manufacturer can be liable to a consumer due to a defective warning.<sup>29</sup> It also recognized that implied warranty and negligence are “separate and

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<sup>21</sup> See *Abel v. Eli Lilly & Company*, 289 N.W.2d 20 (Mich. Ct. App. 1980) (alleging cancerous conditions as a result of consumption of prescription drugs by their mothers while plaintiffs were in utero); *Moll v. Abbott Laboratories*, 506 N.W.2d 816 (Mich. 1993) (examining pharmaceutical product liability cases of action filed by two plaintiffs alleging that exposure to diethylstilbestrol caused genital abnormalities and infertility).

<sup>22</sup> MICH. COMP. LAWS ANN. § 600.2946(5) (West. 2000).

<sup>23</sup> *Abel*, 289 N.W.2d at 20 (Mich. Ct. App. 1980).

<sup>24</sup> *Id.*

<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

<sup>27</sup> *Smith v. E.R. Squibb & Sons, Inc.*, 245 N.W.2d 52 (Mich. Ct. App. 1976).

<sup>28</sup> *Id.* at 55.

<sup>29</sup> *Id.*

distinct” theories of recovery under which a plaintiff may prove a product liability cause of action.<sup>30</sup>

Similarly, in *Moll v. Abbott Laboratories*, plaintiffs brought a product liability action against a pharmaceutical company.<sup>31</sup> The plaintiffs here claimed that exposure to a drug called diethylstilbestrol (DES), a synthetic estrogen ingested by mothers to prevent miscarriages, caused genital abnormalities and infertility in female offspring.<sup>32</sup> The court in this case recognized the plaintiffs’ cause of action and stated that the discovery rule applied to product liability cases and their statute of limitations.<sup>33</sup>

A product liability cause of action regarding the drug diethylstilbestrol was also recognized in the case of *Abel v. Eli Lilly & Company*.<sup>34</sup> The plaintiffs sued several drug manufacturer defendants alleging negligence, breach of express and implied warranties, fraud and conspiracy.<sup>35</sup> The court held that this action was sustainable even though the plaintiffs couldn’t pinpoint which of the defendants distributed the drug to each individual.<sup>36</sup> The trend of drug manufacturer liability, however, came to an end in the mid 1990’s.

## II. THE CREATION OF MICHIGAN’S DRUG IMMUNITY

In 1996 Michigan statute 600.2946(5) was amended to give broad protections to manufacturers of prescription drugs.<sup>37</sup> The statute states in pertinent part:

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

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<sup>30</sup> *Id.*

<sup>31</sup> *Moll v. Abbott Laboratories*, 506 N.W.2d 816 (Mich. 1993).

<sup>32</sup> *Id.*

<sup>33</sup> *Id.* at 11.

<sup>34</sup> *Abel v. Eli Lilly & Company*, 289 N.W.2d 20 (Mich. Ct. App. 1980).

<sup>35</sup> *Id.*

<sup>36</sup> *Id.* at 25.

<sup>37</sup> MICH. COMP. LAWS. ANN. 600.2946(5) (West 2000); *see also* O’Steen & O’Steen, *supra* note 3, at 89.

compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller.<sup>38</sup>

This statute affords much more protection for the pharmaceutical companies than did the previous statute, "which merely allowed a drug manufacturer to enter into evidence any compliance with federal laws, rules or regulations."<sup>39</sup> Instead, the amended statute provides the manufacturer or seller with an absolute defense to a product liability claim, absent fraud or bribery.<sup>40</sup>

In particular, the new statute aimed to protect drug manufacturer Upjohn Company, a Michigan based pharmaceutical manufacturer.<sup>41</sup> The Michigan legislature intended to free this manufacturer, and other potential Michigan based drug companies, from liability because they thought that if the product was deemed safe by the FDA, lay jurors or judges should not be able to "second-guess" the standards and decisions set by government experts.<sup>42</sup>

The Michigan legislature intended this bill to act as an absolute immunity to product liability actions against drug companies.<sup>43</sup> It purposely limited the ability of consumers to seek

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<sup>38</sup> § 600.2946(5).

<sup>39</sup> Dana Cilla, *Michigan Tort Reform: A Constitutional Haven for Pharmaceutical Companies and a Tough Pill to Swallow for Consumers*, 19 T.M. COOLEY L. REV. 331, 334 (2002).

<sup>40</sup> *Taylor v. SmithKline Beecham Corp.*, 658 N.W.2d 127 (Mich. 2003). The Michigan statute has two exceptions in which the general immunity will not apply. "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 . . . , and the drug would have not been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted." There is also an exception for illegal payment to an official for the purpose of securing or maintaining approval of the drug. MICH. COMP. LAWS ANN. § 600.2946(5) (a)-(b) (West 2000). These exceptions have been found preempted for plaintiffs suits based on state court findings of fraud on the FDA. Therefore the only hypothetical way a plaintiff could bring an action against the FDA would be on the FDA finding of fraud. This, however, hasn't been tested. *Garcia v. Wyeth-Ayerst Lab.*, 385 F.3d 961 (6th Cir. 2004). The court then severed the exceptions leaving the rest of the statute valid and providing a blanket immunity to drug manufacturers.

<sup>41</sup> O'Steen & O'Steen, *supra*, note 3 (Upjohn was later purchased by Pfizer Inc. and still employs thousands of Michigan residents).

<sup>42</sup> Cilla, *supra* note 39, at 335.

<sup>43</sup> *Id.* at 336-37.

redress in the court system.<sup>44</sup> The bill stripped the common law right of product liability actions from the citizens of Michigan and “put[] them at the mercy of some of the largest corporations and their attorneys.”<sup>45</sup>

After this bill was passed, cases arose challenging the validity of the law and its mechanics.<sup>46</sup> The first constitutional challenge to the statute came in 2002 in the case of *Taylor v. SmithKline Beecham Corporation*.<sup>47</sup> In this case two plaintiffs brought suit against Gate Pharmaceuticals and other manufacturers, seeking damages for injuries resulting from the use of a diet drug (Fen-Phen).<sup>48</sup> The plaintiffs challenged the statute as an unconstitutional delegation of legislative power.<sup>49</sup> The court disagreed and found that the Michigan statute did not delegate anything to the FDA, and therefore was valid.<sup>50</sup>

Instead of finding a delegation of power to the FDA, the court found that the statute acted as a measuring device to set the standard of care for the drug companies in Michigan.<sup>51</sup> The court found that the statute determined that a finding by the FDA of safety and efficacy is held to satisfy the duty of reasonable care owed to the consumer by the drug company.<sup>52</sup> The court explained that the FDA did not decide who may bring a product liability action or what the

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<sup>44</sup> *Id.* at 337. “The true nature and the reason for this particular legislation is . . . not to reform product liability; it’s to limit the ability of citizens of this country and this state to . . . go to court and get redress.” 1995 Journal of the S. No. 40, at 868 (statement of Sen. V. Smith) (May 10, 1995).

<sup>45</sup> Cilla, *supra* note 39, at 337.

<sup>46</sup> *Taylor v. Smithkline Beecham Corp.*, 658 N.W.2d 127 (Mich. 2003) (stating that the Michigan Statute is no unconstitutional); *Garcia v. Wyeth Lab.*, 385 F.3d 961 (6th Cir. 2004) (finding that the Michigan statute is not unconstitutional); *Michal v. PDK Labs*, No. 234943, 2003 WL 22160438 (Mich. App. 2003); *Duronio v. Merck & Co.*, No. 267003, 2006 WL 1628516 at \*6-7 (Mich. App. 2006) (holding that a consumer protection cause of action is the same as a product liability suit and is therefore barred by the Michigan statute).

<sup>47</sup> *Taylor*, 658 N.W.2d at 127 (this case is a consolidation of two cases involving plaintiffs Tamara Taylor and Lee Anne Rintz against Gate Pharmaceuticals and other manufacturers).

<sup>48</sup> *Id.* at 129.

<sup>49</sup> *Id.* at 130 (the case defines the doctrine with a statement found in *Field v. Clark*, 143 U.S. 649, 692 (1892), stating that “‘the integrity and maintenance of the system of government ordained by the Constitution’ precludes Congress from delegating its legislative power to either the executive branch or the judicial branch.”).

<sup>50</sup> *Taylor*, 658 N.W.2d at 137.

<sup>51</sup> *Id.*

<sup>52</sup> *Id.* at 134.

outcome must be, but instead the Michigan legislature determined the consequences of a finding of safety and efficacy by the FDA.<sup>53</sup>

The Michigan statute was next challenged in the Sixth Circuit case of *Garcia v. Wyeth-Ayerst Laboratories*.<sup>54</sup> In this case the plaintiff, Julia Garcia, brought a product liability suit against Wyeth-Ayerst Laboratories for injuries she sustained from taking Duract (a non-steroidal, anti-inflammatory prescription drug made by the defendant).<sup>55</sup> The plaintiff claimed that the Michigan statute was unconstitutional because it was impliedly preempted by the Food, Drug and Cosmetic Act, interfered with her right of access to the courts, and violated the due process clause by depriving her of traditional common law tort causes of action.<sup>56</sup>

The federal appellate court found that the plaintiff could not sustain her claim in federal court.<sup>57</sup> The court held that the statute was not an unconstitutional invasion of the rights of consumers and did not deny a plaintiff access to the courts.<sup>58</sup> Further, the court held that this statute did not violate plaintiff's substantive due process rights.<sup>59</sup>

In the summer of 2006 Michigan also recognized an exemption to the Michigan Consumer Protection Act that protects drug companies from claims brought under the Act.<sup>60</sup> In this case the plaintiff filed suit against Merck seeking a refund of the purchase cost of the drug Vioxx, and costs related to his medical expenses.<sup>61</sup> Plaintiff sought this recovery on theories of common law fraud and the Michigan Consumer Protection Act.<sup>62</sup>

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<sup>53</sup> *Id.* at 134.

<sup>54</sup> *Garcia v. Wyeth-Ayerst Lab.*, 385 F.3d 961 (6th Cir. 2004).

<sup>55</sup> *Id.* at 963.

<sup>56</sup> *Id.*

<sup>57</sup> *Id.* at 968.

<sup>58</sup> *Id.* at 968 (stating that “[t]he argument that a state statute stiffens the standard of proof of a common law claim does not implicate this right.”).

<sup>59</sup> *Id.*

<sup>60</sup> *Duronio v. Merck & Co.*, No. 267003, 2006 WL 1628516 (Mich. Ct. App. 2006).

<sup>61</sup> *Id.* at \*1.

<sup>62</sup> *Id.*

The court in this case did not provide a way for consumers to hold drug companies responsible for their actions; but instead held that both product liability and consumer protection causes of action are barred.<sup>63</sup> The Michigan Court of Appeals found that because the plaintiff brought suit for damages to property caused by Vioxx, plaintiff's common law fraud claim was actually, in substance, a product liability action.<sup>64</sup> Therefore, this claim was subject to the absolute defense provided by Michigan statute 600.2946(5).<sup>65</sup>

Next the court found that the consumer protection claim was not valid.<sup>66</sup> In analyzing the Michigan Consumer Protection Act, the court determined that since the Act does not apply to "a transaction or conduct specifically authorized under laws administered by a regulatory board or officer . . .," a plaintiff may not bring a consumer protection action regarding a drug regulated by the FDA.<sup>67</sup>

These cases show that Michigan statute 600.2946(5) successfully precludes any product liability action a consumer may want to bring against a drug manufacturer in the state of Michigan.

### III. MICHIGAN'S IMMUNITY FOR DRUG COMPANIES IS NOT A MODEL STATUTE

"Michigan legislators placed their state in the dubious position of being the only state in the nation to prohibit lawsuits against manufacturers of defective drugs."<sup>68</sup> Drug manufacturers urge Congress and the legislatures of many states to adopt the model that Michigan currently employs.<sup>69</sup> This section will show that this is unwise because FDA regulations are not sufficient to protect citizens from harm. This section will also explain why a system of dual regulation is

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<sup>63</sup> *Id.*

<sup>64</sup> *Id.* at \*5.

<sup>65</sup> *Id.*

<sup>66</sup> *Id.* at \*7.

<sup>67</sup> *Id.*

<sup>68</sup> O'Steen & O'Steen, *supra* note 3, at 91.

<sup>69</sup> *Id.* (stating that the Michigan statute is viewed as a model by drug companies lobbying for similar laws in other states).

preferable. Lastly, this section will analyze the possible unconstitutionality of the Michigan drug immunity statute.

A. Michigan's Tort Immunity Model Inadequately Protects Consumers Because FDA Approval Does Not Provide Sufficient Protection

Those who urge legislatures to adopt a statute similar to the one used in Michigan, argue that the FDA is superior to lay judges and juries and therefore, it is rational to defer to the FDA regulations in determining if a drug is safe and effective.<sup>70</sup> This argument, however, ignores the reality that the Food Drug and Cosmetic Act's (and its interpreting regulations in the Code of Federal Regulations) approval process is inadequate to protect consumers.

1. *A Brief Overview of the FDA Approval Process*

A pharmaceutical manufacturer who wishes to introduce a new drug into the market must first get approval from the FDA.<sup>71</sup> The manufacturer must apply for approval through the New Drug Application process.<sup>72</sup> "The New Drug application is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S."<sup>73</sup> The drug manufacturer will first submit an "investigational new drug" application, in which they try to convince the FDA that their drug is safe.<sup>74</sup>

Included in the investigational new drug application is information regarding the results of the sponsors preclinical testing done on animals.<sup>75</sup> They also include what their plans are for

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<sup>70</sup> Teresa Moran Schwartz, *Regulatory Standards and Products Liability: Striking the Right Balance Between the Two*, 30 U. MICH. J.L. REFORM 431, 439 (1997).

<sup>71</sup> 21 U.S.C. § 355 (2006); *see also* 21 C.F.R. § 314.105 (2005). This paper recognizes that there is also an abbreviated new drug application but does not cover it in detail. *See* 21 U.S.C. § 355(j) (2006).

<sup>72</sup> 21 C.F.R. § 314.50 (2005); *see also* 21 U.S.C. § 355 (2006).

<sup>73</sup> New Drug Application Process, <http://www.fda.gov/cder/regulatory/applications/NDA.htm> (last visited Nov. 30, 2006).

<sup>74</sup> 21 C.F.R. § 312.23 (2005).

<sup>75</sup> The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective, <http://www.fda.gov/fdac/special/testtubetopatient/drugreview.html> (last visited Nov. 30, 2006).

testing on humans.<sup>76</sup> It is at this stage that the FDA decides whether or not it is safe for the company to move forward with testing the drug in humans.<sup>77</sup> After permission from the FDA, human testing may begin.<sup>78</sup> The human testing takes place in three or four stages, and at the end of these stages the New Drug Application is filed.<sup>79</sup> The New Drug Application is the formal step in which the sponsor company asks the FDA to approve the drug.<sup>80</sup> The FDA then has to decide whether to file the request for review or refuse to file the application.<sup>81</sup>

If the drug is accepted for review, a team is assembled to evaluate the studies submitted by the sponsor company to show that their drug is safe and effective.<sup>82</sup> The review team then determines whether or not the benefits of the drug outweigh the risks associated with its side effects.<sup>83</sup> For the drug to be approved, the FDA must determine “that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling . . . .”<sup>84</sup>

There is also an accelerated approval process.<sup>85</sup> Accelerated approval is used to expedite approval for drugs that are used to treat serious or life-threatening illnesses.<sup>86</sup> This process allows new drug applications to be approved before information about the drugs effectiveness is available.<sup>87</sup> The most recent drugs approved through this process are Vectibix (a treatment for

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<sup>76</sup> *Id.*

<sup>77</sup> *Id.*

<sup>78</sup> *Id.*

<sup>79</sup> *Id.*

<sup>80</sup> *Id.*

<sup>81</sup> *Id.*

<sup>82</sup> New Drug Application Process, *supra* note 73.

<sup>83</sup> *Id.*; *see also* 21 C.F.R. § 314.105(c) (2005).

<sup>84</sup> 21 C.F.R. § 314.105(c) (2005); *see also* Victor E. Schwartz & Phil Goldberg, *A Prescription for Drug Liability and Regulation*, 58 OKLA. L. REV. 135, 142 (2005).

<sup>85</sup> 21 U.S.C. § 356 (2006); *see also* The FDA’s Drug Review Process: Ensuring Drugs Are Safe and Effective, *supra* note 75.

<sup>86</sup> Neal D. Fortin, *Food & Drug Regulation: Law, Science, Policy, and Practice IX-52* (2006) (electronic casebook, on file with the author and the Institute for Food Laws and Regulations, Michigan State University).

<sup>87</sup> The FDA’s Drug Review Process: Ensuring Drugs Are Safe and Effective, *supra* note 75.

metastatic carcinoma of the colon or rectum), Elaprase (an enzyme replacement therapy for patients with Hunter syndrome), and Atripla (a drug for the treatment of HIV).<sup>88</sup>

2. *The FDA New Drug Approval Process Does Not Create a Suitable Product Liability Defense*

Approval gained by the above mentioned FDA approval process is deemed sufficient to protect drug manufacturers from all product liability claims in Michigan.<sup>89</sup> This is, however, undesirable because, while the FDA approval process does attempt to maintain safety in the drug industry, it alone does not adequately protect consumers from those who produce harmful drugs.

As diligent as the FDA is, drugs such as Vioxx, Rezulin and Bextra still make it on to the market and cause harm to thousands of consumers. Even with FDA approval, these drugs caused the death of at least one Michigan resident, Mr. Richard Richter.<sup>90</sup> After 62 year old Richter died of a heart attack caused by taking Vioxx prescribed for arthritis, his widow was barred from seeking redress against the manufacturer of Vioxx, Merck & Co., because she lives in Michigan.<sup>91</sup> The danger that this drug has caused demonstrates why FDA approval is inadequate to protect consumers. FDA approval is inadequate for many reasons inherent in the FDA approval process.

The first problem with the FDA approval process is that it is not complete.<sup>92</sup> Although it is true that the FDA has numerous regulations<sup>93</sup>, the approval process is not fool proof and oftentimes significant adverse side effects are not discovered during the approval process.<sup>94</sup> It is

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<sup>88</sup> CDER Fast Track Products Approved Since 1998 through 9/30/06, <http://www.fda.gov/cder/rdmt/internetftap.htm> (last visited Nov. 30, 2006).

<sup>89</sup> MICH. COMP. LAWS § 600.2946(5) (West 2000).

<sup>90</sup> Audio Tape: HouseDems Report: Ending Drug Industry Immunity (Oct. 10, 2005) <http://www.housedems.com/?p=156> (last visited Dec. 1, 2006).

<sup>91</sup> *Id.*

<sup>92</sup> Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J.L. REFORM 461, 496 (1997) (stating that the IND process is inadequate to identify all of the risks of a drug).

<sup>93</sup> See 21 U.S.C. §§ 355- 360ee (2006).

<sup>94</sup> Green, *supra* note 92, at 496.

undeniable that hazards of new drugs will emerge as they are disseminated and used by the general public.<sup>95</sup> Experts say that studies mandated by the FDA can miss serious problems with drugs before approval.<sup>96</sup> Further the FDA has been criticized for having a failing system for drug regulation and approval.<sup>97</sup>

Proof that the drug approval process is inadequate is seen on the FDA's own website.<sup>98</sup>

The FDA issues public health advisories to warn the public of dangers that have become apparent after a drug has been approved, disseminated and used by the public.<sup>99</sup> These advisories come out quite frequently and as recently as November 27, 2006 a new advisory was put up for the use of methadone to control pain.<sup>100</sup> The advisory states that the use of methadone may result in death or life threatening changes in breathing or heartbeat.<sup>101</sup>

Similarly, the testing process for approval does not reveal dangerous interactions with other drugs.<sup>102</sup> A public health advisory was issued for the combined use of 5-Hydroxytryptamine Receptor Agonists (Triptans), Selective Serotonin Reuptake Inhibitors (SSRIs) or Selective Serotonin/Nor epinephrine Reuptake Inhibitors (SNRIs).<sup>103</sup> The FDA

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<sup>95</sup> *Id.* at 497.

<sup>96</sup> Christopher Lee, *Reports Faults FDA on Drug Safety* (Oct. 10, 2006), available at <http://www.washingtonpost.com/wp-dyn/content/article/2006/10/09/AR2006100901029.html>.

<sup>97</sup> *Id.* (stating that finding made by the congressionally chartered Institute of Medicine, "which found that the system for approving and regulating drugs is in serious disrepair).

<sup>98</sup> Public Health Advisories, <http://www.fda.gov/cder/news/pubpress.htm> (last visited Dec. 1, 2006).

<sup>99</sup> *Id.*

<sup>100</sup> *Id.*

<sup>101</sup> *Id.* Other drugs that have been put on the public health advisory page include Epoetin alfa (marketed as Procrit, Epogen) which was found to heighten the chance of combination death, heart attack, heart failure or stroke when used in patients with chronic kidney disease who are not on dialysis, and Aprotinin Injection (marketed as Trasylol) which was found to increase the chance of kidney failure, heart attack and stroke in patients treated with Trasylol compared to those treated with similar drugs).

<sup>102</sup> Green, *supra* note 92, at 497.

<sup>103</sup> FDA Public Health Advisory: Combined Use of 5-Hydroxytryptamine Receptor Agonists (Triptans), Selective Serotonin Reuptake Inhibitors (SSRIs) or Selective/Nor epinephrine Reuptake Inhibitors (SNRIs) May Result in Life-threatening Serotonin Syndrome, [http://www.fda.gov/cder/drug/advisory/SSRI\\_SS200607.htm](http://www.fda.gov/cder/drug/advisory/SSRI_SS200607.htm) (last visited Dec. 1, 2006).

found that the use of these drugs in combination can lead to a life-threatening condition called serotonin syndrome.<sup>104</sup>

Furthermore, the “fast track” process allows drugs to get on the market faster and without as many tests.<sup>105</sup> Drugs that are put through the accelerated approval process are often evaluated by the FDA for only six months before approval.<sup>106</sup> This short term approval process is inadequate to discover the dangerous character of the drugs up for approval.<sup>107</sup> This is apparent in the approval of at least 3 drugs which have caused great harm and were pushed through using the fast track process.<sup>108</sup>

The first drug that grabbed public attention was Rezulin. This drug was used to treat type two diabetes, and was associated with liver failure and death in patients who ingested it.<sup>109</sup> These deaths came after the FDA dismissed warnings of danger while it was being pushed through the fast track process.<sup>110</sup> The second “fast track” drug pulled from the shelves over safety concerns was Lotronex.<sup>111</sup> This drug was approved for treating irritable bowel syndrome in women.<sup>112</sup> It, however, caused constipation and ischemic colitis, which can be potentially fatal.<sup>113</sup> Lastly, the harmful drug Vioxx was also fast tracked by the FDA.<sup>114</sup>

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<sup>104</sup> *Id.*

<sup>105</sup> The FDA’s Drug Review Process: Ensuring Drugs are Safe and Effective, *supra* note 75.

<sup>106</sup> O’Steen & O’Steen, *supra* note 3, at 86.

<sup>107</sup> *Id.*

<sup>108</sup> Neal D. Fortin, Food & Drug Regulation: Law, Science, Policy, and Practice IX-60, 64 (2006) (electronic casebook, on file with the author and the Institute for Food Laws and Regulations, Michigan State University) (stating the Rezulin and Lotronex were fast tracked); *see also* O’Steen & O’Steen, *supra* note 3, at 86 (stating that Vioxx was fast tracked).

<sup>109</sup> Fortin, *supra* note 108, at 60.

<sup>110</sup> *Id.*

<sup>111</sup> *Id.* at 64.

<sup>112</sup> *Id.*

<sup>113</sup> *Id.*

<sup>114</sup> O’Steen & O’Steen, *supra* note 3, at 86.

The FDA process is further incomplete because of the inadequacy of the post approval monitoring process.<sup>115</sup> The FDA requires manufacturers to “report to FDA adverse drug experience information.”<sup>116</sup> However, this reporting process is often ignored by manufacturers.<sup>117</sup> In the case of *Benedi*, the court found that the drug company McNeil withheld forty adverse drug experience reports from the FDA.<sup>118</sup>

Avoidance of the post approval reporting process often goes unnoticed because of the limited resources that are available to the FDA.<sup>119</sup> If post approval monitoring was substantial, there might be an argument in favor of a compliance defense. However, because inadequate resources are given to the FDA to carry out all of their duties, post approval regulation is often overlooked.<sup>120</sup>

Some proponents of the Michigan drug shield, point to the Application Integrity Policy and its “citizen’s petition” as an opportunity for citizens to hold drug companies liable for wrongdoing during the application process.<sup>121</sup> They argue that an injured citizen in Michigan can file a petition with the FDA, and this in turn could lead to the FDA finding criminal fraud, and thus cause the withdrawal of the drugs approval.<sup>122</sup> This then would fall under the exception in the Michigan law for litigation.<sup>123</sup>

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<sup>115</sup> Green, *supra* note 92, at 499 (stating that the reporting requirement imposed by the FDA is not effective).

<sup>116</sup> 21 C.F.R. § 314.80(c) (2005). The statute defines adverse drug experience as “any adverse event associated with the use of a drug in human, whether or not considered drug related, including the following: An adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action.” 21 C.F.R. § 314.80(a) (2005).

<sup>117</sup> See *Benedi v. McNeil P.P.C., Inc.*, 66 F.3d 1378 (4th Cir. 1995); see also Green, *supra* note 92, at 498-500 (stating that “reporting by manufacturers to the FDA, despite the legal requirement, has been less than perfect”)

<sup>118</sup> *Id.* at 1387.

<sup>119</sup> Schwartz, *supra* note 70, at 445-46.

<sup>120</sup> Green, *supra* note 92, at 499.

<sup>121</sup> D.I.I.M.E. (Drug Industry Immunity Must End) Greenspan: Mich. residents can’t rely on FDA fro drug checks, <http://www.rxvictims.com/greenspanjune2006.html> (last visited Dec. 1, 2006).

<sup>122</sup> *Id.*

<sup>123</sup> MICH. COMP. LAWS § 600.2946(5)(a)-(b) (West 2000). Although subsections (a) and (b) have been severed in most circumstances, it is theoretically possible for a citizen to bring an action against a drug manufacturer after a

This, however, is not an option. The Application Integrity Policy (AIP) was not initiated to protect consumers, but instead to ensure propriety in the drug application process.<sup>124</sup> The FDA was concerned with bribes, fraud, and illegal gratuities in the application process, and therefore to ensure that data relayed by these reviewers is reliable, David Kessler brought these procedures to the FDA in 1991.<sup>125</sup> AIP mandates employees to report and investigate any suspected wrongful act that raises significant questions of data integrity or reliability.<sup>126</sup> Because the suspected wrongful acts arise out of the application, only those who read the applications have any idea of what is suspicious. Therefore an average citizen would have no way to use this process to complain of fraud or bring any other action against the drug manufacturer.<sup>127</sup>

Another inherent problem with the FDA approval process is the drug industry's participation. The FDA approval process depends entirely on data supplied to them by the drug companies themselves.<sup>128</sup> All of the information the FDA uses to determine the safety and efficacy of a drug is information that the drug company chooses to provide.<sup>129</sup> The FDA does not conduct any of the tests to ensure the safety of a drug, and bases their approval solely on the

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finding of fraud by the FDA. This, however, has never happened and is therefore an untested hypothetical. *See* Garcia v. Wyeth-Ayerst Lab., 385 F.3d 961 (6th Cir. 2004).

<sup>124</sup> U.S. Food and Drug Administration: AIP Procedures, [http://www.fda.gov/ora/compliance\\_ref/aip\\_procedures/aip\\_policy.html#background](http://www.fda.gov/ora/compliance_ref/aip_procedures/aip_policy.html#background) (last visited Dec. 1, 2006).

<sup>125</sup> *Id.*; *see also* D.I.I.M.E. (Drug Industry Immunity Must End) Greenspan: Mich. residents can't rely on FDA for drug checks, *supra* note 121.

<sup>126</sup> AIP Procedures, 1-1-5(1)(c); U.S. Food and Drug Administration: AIP Procedures [http://www.fda.gov/ora/compliance\\_ref/aip\\_procedures/resp.html](http://www.fda.gov/ora/compliance_ref/aip_procedures/resp.html) (last visited Dec. 1, 2006).

<sup>127</sup> D.I.I.M.E. (Drug Industry Immunity Must End) Greenspan: Mich. residents can't rely on FDA for drug checks, *supra* note 121 (stating "how would an "average citizen know there was something unkosher in a new drug application? By overhearing it on a bus? A barroom confession?").

<sup>128</sup> 21 C.F.R. § 314.50 (2005) (stating that the "application is required to contain reports of all investigations of the drug product sponsored by the applicant, and all other information about the drug pertinent to an evaluation of the application that is received or otherwise obtained by the applicant from any source"); 21 U.S.C. § 355(b) (2006); *see also* Green, *supra* note 92, at 481.

<sup>129</sup> 21 C.F.R. § 314.50 (2005).

test results given to them in the application.<sup>130</sup> “In short, the FDA has essentially entrusted the fox with the responsibility of guarding the proverbial henhouse.”<sup>131</sup>

An immunity for drug manufacturers based on the studies and information provided by drug industry researchers seems to be circular. Self interest of the drug companies makes an approval and compliance defense even more inadequate. Without the threat of tort liability, drug companies will have less incentive to make their drugs safe because they only have to pass FDA approval, and that process is dependant on the information given to the FDA by the company itself.<sup>132</sup>

Furthermore, it is well recognized that drug companies have great amounts of influence over state legislatures and the FDA.<sup>133</sup> According to the Michigan House Democrats, the drug industry has spent more than \$800 million dollars in political lobbying since 1998.<sup>134</sup> These efforts are in an attempt to continue the Michigan drug immunity and convince the legislatures of other states to adopt the “Michigan Model”.<sup>135</sup> It is dangerous to allow any industry, especially and industry that can be potentially deadly, to make their own law.

Not only does the drug industry have incredible influence over the regulatory process, but once FDA approval is given, the FDA has inadequate resources to make sure that they comply with the FDA regulations.<sup>136</sup> The drug industry has more technology and information than the

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<sup>130</sup> *Id.* (stating all of the tests and information required of the drug sponsor).

<sup>131</sup> Michael E. Petrella, *License to Maim: Federal Pre-Emption and the Medical Device Amendments of 1976*, 6 HEALTH MATRIX 349, 362 (1996).

<sup>132</sup> *See id.* (stating “is it beyond the realm of possibility that some applicants might exploit this situation by ‘simplifying’ testing, recording, and reporting procedures?”).

<sup>133</sup> *See* Lars Noah, *Symposium: Regulatory Compliance as a Defense to Products Liability*, 88 GEO. L.J. 2147, 2154-55 (stating that the drug industry has “tremendous resources” that they can use to influence the legislative processes and regulatory processes); *see also* Schwartz, *supra* note 70, at 445 (stating that because of the resources that the industry has at its disposal, the drug manufactures can exert an enormous influence on the regulatory outcome).

<sup>134</sup> Michigan House Democrats: GOP Dismisses Drug Immunity Repeal as ‘Frivolous, Absurd’, <http://www.housedems.com/?p=193> (last visited Dec. 1, 2006).

<sup>135</sup> O’Steen & O’Steen, *supra* note 3, at 91.

<sup>136</sup> Green, *supra* note 92, at 482 (stating that the “FDA does not have the resources to monitor and ensure universal compliance”).

FDA, and therefore, the FDA is at their mercy when trying to control compliance.<sup>137</sup> Even if the FDA was provided with enormous resources, it is likely that the FDA would still be dependant on the drug companies to find dangers in the drugs and to report them.<sup>138</sup>

Because the FDA approval process is incomplete and the drug industry has great influence over this process, drug approval should not form the basis of tort immunity in Michigan or any other state in the nation.

B. Dual Regulation Should be Reinstated in Michigan and Should Continue to be Utilized in Other States

As shown in the previous section, FDA approval should not form a tort shield for drug companies because FDA approval procedures are insufficient to protect consumers. This section will show that dual regulation (tort liability and FDA regulation) is the preferable way to protect consumers and provide safe and effective drugs to everyone.

1. *Michigan's Attempt to Reinstate Dual Regulation*

After ten years of drug immunity, Michigan consumers and legislators are fighting back against the oppressive regime. Discontent with the Michigan drug immunity drove Michigan legislators to propose a series of bills that would replace and repeal the current law.<sup>139</sup> These bills recognize that Michigan consumers can not blindly trust the FDA and must have some recourse in the courts.

The first bill would replace the drug immunity provision with a *rebuttable presumption* of non-liability if the drug was in compliance with FDA regulations.<sup>140</sup> This bill would also

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<sup>137</sup> *Id.*

<sup>138</sup> Justice in Michigan: Why We Must Rescind Michigan's Drug Shield Law, <http://www.justiceinmichigan.org/whywemust.html> (last visited Dec. 1, 2006).

<sup>139</sup> H.B. 5527, 93rd Leg., (Mich. 2005) (providing for a rebuttable presumption rather than absolute defense); H.B. 4811, 93rd Leg., (Mich. 2005) (allowing liability suits for drugs that have been approved by the federal food and drug administration); H.B. 4773, 93rd Leg., (Mich. 2005) (rescinding the immunity for drugs that have been approved by the federal food and drug administration).

<sup>140</sup> H.B. 5527, 93rd Leg., (Mich. 2005).

make the immunity repeal retroactive, so that consumers can obtain redress for injuries that occurred after 1996.<sup>141</sup> The other bills would completely rescind the absolute defense, and allow the filing of product liability actions against all drug companies.<sup>142</sup> Under these bills, if a plaintiff can overcome this presumption and establish negligence or breach of a warranty, then a finding of liability would be appropriate.<sup>143</sup>

Consumers who have felt the effect of the immunity have come forward to support its repeal and offer their own heart wrenching stories of losing loved ones due to defective prescription drugs.<sup>144</sup> The Michigan consumers truly affected by the bill's immunity support the new legislation and are frustrated by the current drug shield.<sup>145</sup> These consumers don't understand why Michigan does not hold the drug industry accountable, when it holds "auto-makers, toy-makers and everyone else accountable for their products."<sup>146</sup>

This outcry against the Michigan drug immunity shows that this model is not a viable option in other states. The failure of other states to adopt the Michigan model shows the lack of confidence that other states have in blanket tort immunity for drug companies.<sup>147</sup> Therefore,

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<sup>141</sup> H.B. 5527, 93<sup>rd</sup> Leg., (Mich. 2005); *see also* Michigan House Democrats: GOP Dismisses Drug Immunity Repeal as 'Frivolous, Absurd,' *supra* note 134 (stating that Dianne Byrum spearheaded legislation that would repeal the 1996 total immunity law and be retroactive to give victims the right to hold drug companies accountable).

<sup>142</sup> H.B. 4811, 93<sup>rd</sup> Leg., (Mich. 2005) (allowing liability suits for drugs that have been approved by the federal food and drug administration); H.B. 4773, 93<sup>rd</sup> Leg., (Mich. 2005) (rescinding the immunity for drugs that have been approved by the federal food and drug administration).

<sup>143</sup> These bills in essence will return the liability law to what it was before 1996. *See* Section I.B. for this structure of liability.

<sup>144</sup> A news investigation uncovered the tragedies of both Leslie Richter and Dr. David Cox. These individuals were shut out of the courts by the Michigan drug immunity after experiencing adverse effects of the drug Vioxx. Leslie Richter's husband died after taking the medication for his arthritis and Dr. David Cox suffered a stroke because after ingesting Vioxx. Ray Sayah, *Michigan Law Protects Drug Companies* (April 27, 2006), *available at* [http://www.wxyz.com/wxyz/ys\\_investigations/article/0,2132,WXYZ\\_15949\\_4655319,00.html](http://www.wxyz.com/wxyz/ys_investigations/article/0,2132,WXYZ_15949_4655319,00.html).

<sup>145</sup> Leslie Richter speaks out in a House Dems report against the Michigan tort immunity. Larry Shoemaker also spoke out against the drug immunity because of his experience with the drug Vioxx. These Michigan citizens want the current bill repealed. Audio Tape: HouseDems Report: Ending Drug Industry Immunity, *supra* note 90.

<sup>146</sup> *Id.*

<sup>147</sup> While some states have limited tort liability for drug companies no state has gone as far as Michigan. *See* Ark. Code Ann. § 16-116-105(a) (Michie 1987) (allowing compliance with regulatory standards as evidence that a product is not unreasonably dangerous); Ariz. Rev. Stat. Ann. § 12-701(A)(2002), N.J. Stat. Ann. § 2A:58C-4, 5(c)

dual regulation that allows consumers to bring actions for injury caused by harmful drugs, and also recognizes compliance with the FDA regulations as *only evidence* of drug safety, is the proper structure of liability for drug manufacturers.

2. *Dual Regulation Provides Adequate Protection for Consumers*

The Michigan legislators that support repealing the immunity law know that dual regulation is the best way to protect Michigan residents and consumers all around the nation. Dual regulation provides safety and efficiency incentives that a pure FDA approval defense can't, and is therefore the proper structure for drug liability. While the FDA does the best it can when regulating the safety and efficacy of prescription drugs, tort liability is essential to hold drug companies liable when things go wrong.

After showing that FDA regulation alone is insufficient in section III. A, this section will provide additional reasons why dual regulation is necessary. Why have tort liability in conjunction with FDA regulation? Simply put, "federal regulation and legal liability mutually reinforce drug safety."<sup>148</sup>

First, tort liability is necessary for drug companies because the FDA standards are only minimum standards of safety.<sup>149</sup> These standards are not meant to be preclusive of tort liability,<sup>150</sup> but rather useful as a floor from which the tort system then ensures that drugs are designed as safely as possible.<sup>151</sup> The FDA does not have enough resources or information to

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(West 1985 & Supp. 2005), Ohio Rev. Code Ann. § 2307.80 (LexisNexis 2004) (all of these statutes provide a rebuttable presumption that a product is not defective). Schwartz & Goldberg, *supra* note 84, at 135, 176, n.262.

<sup>148</sup> Justice in Michigan: Why We Must Rescind Michigan's Drug Shield Law, *supra* note 138 (stating that at a meeting last June Alan Goldhammer (associate vice president of the Pharmaceutical Research and Manufacturers Association) spoke of the dual purpose of FDA regulation and tort liability).

<sup>149</sup> Elissa Levy, *The Health Act's FDA Defense to Punitive Damages: A Gift to the Drug Makers or to the Public?*, 74 *FORDHAM L. REV.* 2425, 2453 (2006).

<sup>150</sup> Schwartz, *supra* note 70, at 443-44.

<sup>151</sup> Levy, *supra* note 149, at 2453.

ensure that drugs are made to the highest quality, and therefore tort liability is needed to provide an extra layer of protection to the consumer.<sup>152</sup>

Examples of tort liability prompting drug makers to make their drugs safer are seen in the manufacturer's treatment of Tylenol, arthritis pain relief drugs, and Vioxx. Suits over Tylenol's toxic quality when mixed with alcohol, spurred Johnson & Johnson to put warnings on its' product.<sup>153</sup> Eli Lilly removed their arthritis drug from the market after being slapped with civil damage awards upwards of seven million dollars.<sup>154</sup> Lastly, Merck voluntarily recalled Vioxx after studies that found an increase in the risk of heart attacks in those who used the drug.<sup>155</sup> Even after the FDA was aware of studies that showed the risks of Vioxx, the FDA did not recall the drug.<sup>156</sup>

Second, tort liability is necessary to hold drug manufacturers liable for behavior that is unconscionable. Henry Greenspan, founding board member of Justice in Michigan, testified to the state legislature that there are several kinds of misconduct for which there is no liability under Michigan's drug immunity.<sup>157</sup> This includes "[a] company may submit raw data to the FDA, but the company's own interpretation of that data, and its potentially ominous significance,

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<sup>152</sup> Green, *supra* note 92, at 482 (stating that "Sometimes it is the tort system that uncovers instances of noncompliance with FDA regulatory standards, rather than the FDA itself."); *see also* Robert B. Reich, *A Suitable Remedy When the FDA is Weak* (Jan. 9, 2005), available at <http://www.washingtonpost.com/wp-dyn/articles/A58316-2005Jan8.html> (stating that the FDA lacks the authority to suspend sales of drug except under extraordinary circumstances and that the tort system is important because it is the threat of tort suits that convinced manufactures like Merck to take deadly drug Vioxx off the market).

<sup>153</sup> Neal D. Fortin, *Food & Drug Regulation: Law, Science, Policy, and Practice XIX-6* (2006) (electronic casebook, on file with the author and the Institute for Food Laws and Regulations, Michigan State University) (citing *Benedi v. McNeil P.P.C., Inc.*, 66 F.3d 1378 (4th Cir. 1995)).

<sup>154</sup> *Id.* (citing *Borom v. Eli Lilly & Co.*, No. 83-38-COL (M.D. Ga., Nov. 21, 1983)).

<sup>155</sup> O'Steen & O'Steen, *supra* note 3, at 87-88.

<sup>156</sup> *Id.* at 88; *see also* Barnaby J. Feder, *Lawyers Organizing for Mass Suits Over Vioxx* (Nov. 5, 2004), available at <http://www.nytimes.com/2004/11/05/business/05suits.html?ei=5090&en=615b4ae0cb164e03&ex=1257310800&partner=rssuserland&pagewanted=print&position> (stating that "The Lancet, a respected British medical journal, published an analysis of all the clinical trials of Vioxx completed by 2001, and concluded that Merck and the F.D.A. should have known enough about the drug's hazards to withdraw it years ago).

<sup>157</sup> Tort Victim Tragedies: Third Edition – "Tort Reformers" Argue that Cheaper is Better than Safer, [http://agonist.org/cyrus\\_dugger/20060811/tort\\_victim\\_tragedies\\_third\\_edition\\_tort\\_reformers\\_argue\\_that\\_cheaper\\_is\\_better\\_than\\_safer](http://agonist.org/cyrus_dugger/20060811/tort_victim_tragedies_third_edition_tort_reformers_argue_that_cheaper_is_better_than_safer) (last visited Dec. 1, 2006).

is left out. Or that company later acknowledges that an interpretation of data was false or incomplete.”<sup>158</sup> Therefore, tort liability is necessary to hold drug companies liable for these actions.

Third, although some commentators say that tort liability is dangerous because it could jeopardize access to new prescription drugs and open the flood gate to lawsuits<sup>159</sup>, manufacturers have been developing new drugs long before (and after) blanket immunity was introduced in only one state. Furthermore, fear over liability should not deter drug making or improving upon a drug, but instead provide incentives to make drugs safer. One commentator has voiced his concern that because of drug liability, manufacturers won't voluntarily withdraw products, and therefore dangerous drugs will stay on the shelf instead of being improved upon.<sup>160</sup> This problem, however, also exists when there is only federal regulation. This is because of the lack of authority and ability the FDA has to regulate drugs post approval.<sup>161</sup> Without the threat of tort liability, dangerous drugs could sit on the shelves forever without any risk of liability at all.

Fourth, a state tort system is important to keep drugs safe and consumers compensated. Those who disfavor product liability cite it as the reason for increased costs in prescription drugs to consumers.<sup>162</sup> Critics of product liability suggest a no-fault system for compensation to consumers.<sup>163</sup> A no-fault system, however, would still be costly to the consumer and would not provide the benefits of product liability. Under a no-fault system, a fund would be created to

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<sup>158</sup> *Id.*

<sup>159</sup> MichBio Press: MichBio Joins Opposition to State Tort Reform, <http://www.michbio.org/Press/MichbioPress.aspx?pr=michbio/062106tortreform> (last visited Dec. 1, 2006).

<sup>160</sup> Omri Ben-Shahar, *The (Legal) Pains of Vioxx: Why Product Liability Can Make Products More Dangerous*, THE ECONOMISTS' VOICE: Vol. 3: No. 6, Article 6 (2006).

<sup>161</sup> Reich, *supra* note 152 (stating that the FDA doesn't have any systematic way to monitor the safety of drugs once they have been approved, other than relying on the manufactures report about adverse drug reactions.)

<sup>162</sup> Gregory C. Jackson, *Pharmaceutical Product Liability May Be Hazardous to your Health: A No-Fault Alternative to Concurrent Regulation*, 42 AM. U. L. REV. 199, 229 (1992).

<sup>163</sup> *Id.* at 235.

compensate those injured by defective drugs.<sup>164</sup> This fund would be paid into by the drug industry in the form of a tax sold on medications.<sup>165</sup> Because of this tax on the industry, they would then raise the prices of their drugs so that they would make the same profit. Further, because the drug company's liability is built into the system, there is no incentive to keep their drugs safe.

Furthermore, oversight by lay judges and juries is important, and this importance can not be overcome by the argument that they should not be able to second guess the expertise of the FDA.<sup>166</sup> Judges and jurors are not second guessing the approval of the drug, but rather holding companies accountable for wrong doing during drug making and marketing. Many times civil tort suits uncover violations of FDA regulations that the FDA would have found if they had the resources to uncover them.<sup>167</sup> Further, dual regulation does not upset federalist principles because the decision of the FDA to approve a drug does not have any preemptive effect on state tort liability.<sup>168</sup>

Lastly, protection of industry and economy in the states in which the industry has immunity does not justify abrogating product liability. Those who advocate for the continuation of the drug immunity in Michigan, argue that this law was an attempt by Governor Engler to bring jobs to Michigan in the face of the states declining economy.<sup>169</sup> Further, Michigan's

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<sup>164</sup> *Id.*

<sup>165</sup> *Id.* (stating that this no-fault system would be modeled after the National Childhood Vaccine Injury Act and the Swedish Pharmaceutical Insurance program).

<sup>166</sup> Schwartz & Goldberg, *supra* note 84, at 164 (stating that "prescription drug litigation requires judges and jurors to consider complicated legal, moral, and scientific topics in an emotionally charged courtroom without the time or training to wrestle with the issues").

<sup>167</sup> Green, *supra* note 92, at 482 (stating that "Sometimes it is the tort system that uncovers instances of noncompliance with FDA regulatory standards, rather than the FDA itself.")

<sup>168</sup> Neal D. Fortin, Food & Drug Regulation: Law, Science, Policy, and Practice XX-8 (2006) (electronic casebook, on file with the author and the Institute for Food Laws and Regulations, Michigan State University) (stating that the FDCA generally has no explicit pre-emption of the states. There are, however, specific pre-emptive provisions for: special categories of medical devices, vaccines, infant formula, and nutritional labeling of food).

<sup>169</sup> Trial Lawyers Inc.com: The Move to Reverse Michigan's Model Reforms Why Wolverine Staters Should Just Say No to the Trial Bar's War on Drugs, [http://www.triallawyersinc.com/updates/tli\\_update\\_michigan\\_0606.html](http://www.triallawyersinc.com/updates/tli_update_michigan_0606.html)

chamber of commerce wants to keep the restrictions on drug liability lawsuits because it helps the “state’s business climate by protecting against unwarranted or frivolous litigation.”<sup>170</sup>

Opponents of repealing this statute claim that allowing these lawsuits will only put money in the pockets of attorneys and scare drug companies away from doing business in Michigan.<sup>171</sup>

These arguments fail for two reasons. First and most importantly, the lives of every consumer and the safety of drugs are more important than having a money making sector of the economy. Furthermore, this sector of the economy can still thrive under a dual regulation system by ensuring that their drugs are safe, and by being truthful in their studies to both the FDA and the public.<sup>172</sup> Providing a liability-free shelter for drug companies in order to attract and protect them, promotes the wrong priorities in Michigan. By putting “profits before people and secrecy before safety,”<sup>173</sup> Michigan is creating a dangerous environment for its own citizens.

Secondly, the 1996 law has not helped the economy in Michigan. Michigan’s unemployment rate as of October 2006 was 6.9%.<sup>174</sup> The unemployment rate in Michigan has only increased since 1996.<sup>175</sup> The economy in Michigan has not been saved by the drug

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(last visited Dec. 1, 2006) (stating that Michigan legislators anticipated the withdrawal of the automobile sector and passed the drug immunity law to allow the medical research and development sector to thrive).

<sup>170</sup> The Michigan Daily: Tension rises over limits on drug liability lawsuits (March 8, 2006), <http://www.michigandaily.com/media/storage/paper851/news/2006/03/08/News/Tension.Rises.Over.Limits.On.Drug.Liability.Lawsuits-1659075.shtml> (last visited Dec. 1, 2006).

<sup>171</sup> Sayah, *supra* note 144.

<sup>172</sup> In Michigan, the democrats are creating a plan to force drug companies to make public all drug safety results, “including those that show negative and harmful side effects. Currently, drug companies are not required to disclose this important information that can save lives.” Michigan House Democrats: Dems: Rx Companies Must Reveal All Drug Safety Results (March 20, 2006), <http://www.housedems.com/?p=182> (last visited Dec. 1, 2006).

<sup>173</sup> *Id.*

<sup>174</sup> Department of Labor and Economic Growth: Labor Market Information, <http://www.milmi.org/> (last visited Dec. 1, 2006).

<sup>175</sup> According to the statistics prepared by the Michigan Department of Labor and Economic Growth the number of people unemployed in 1996 was 4,677,000. The number of people unemployed every year since 1996 has been above the 1996 level and as of October 2006 the number of unemployed is 4,759,000. Department of Labor and Economic Growth: Unemployment Statistics, <http://www.milmi.org/cgi/dataanalysis/labForceReport.asp?menuchoice=LABFORCE> (last visited Dec. 1, 2006).

immunity law and therefore, those who argue for its usefulness as an economic stimulant are misguided.

Because of all of the aforementioned reasons, dual regulation is preferable. Michigan needs to reinstate a dual regulation system to protect its citizens, and the rest of the nation need not implement statutes similar to that of Michigan's in their own states.

C. FDA Approval and Compliance is Not an Adequate Replacement for Tort Liability; Is it also Unconstitutional?

In the case of *Garcia v. Wyeth-Ayerst Laboratories*, the plaintiff claimed that the Michigan statute immunizing drug manufacturers from tort liability violated her fundamental right of access to the courts.<sup>176</sup> Although the Sixth Circuit found that the law did not violate the plaintiff's access to court, the statute does in fact make it impossible for a plaintiff to pursue their statutory right to redress for a product liability claim in the courts.

A person has a fundamental right of access to the court.<sup>177</sup> This right can be implicated when the judicial process does not provide an adequate procedure to remedy an alleged wrong.<sup>178</sup> As stated in *Garcia*, "such claims are generally recognized for civil litigants only in the context of spoliation of evidence or interference with filing a lawsuit."<sup>179</sup> It can be argued, however, that the Michigan tort immunity in combination with its exemption from the Michigan Consumer Protection Act violates a person's right of access to the courts.

Michigan tort law gives plaintiffs the statutory right to bring product liability actions under MCL 600.2946.<sup>180</sup> The *Garcia* court stated that the Michigan drug immunity statute only stiffens the standard of proof necessary for a common law claim of product liability and

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<sup>176</sup> *Garcia v. Wyeth-Ayerst Lab.*, 385 F.3d 961, 967 (6th Cir. 2004).

<sup>177</sup> *Id.* at 967-68.

<sup>178</sup> *Id.* at 967.

<sup>179</sup> *Id.* at 968.

<sup>180</sup> MICH. COMP. LAWS ANN. §600.2945 (West 2000); MICH. COMP. LAWS ANN. § 600.2946 (West 2000).

therefore, does not act as a denial of access to the courts.<sup>181</sup> However, because the exceptions for fraud and bribery to the Michigan statute have been severed from the rest of the statute there is no avenue of redress for plaintiffs injured by a defective drug. Furthermore, the only other suit that can be maintained by a plaintiff in Michigan is for injury caused by a drug that has not been approved or approval has been withdrawn.<sup>182</sup> This, however, does not give plaintiffs a remedy because the majority of the drugs out on the market with the potential to injure consumers are those that have been approved.<sup>183</sup> Therefore, plaintiffs in Michigan are denied an adequate remedy for a statutory right.<sup>184</sup>

Not only are consumers blocked from the courts through the tort immunity, but drug companies are also exempt from the Michigan Consumer Protection Act (MCPA).<sup>185</sup> The MCPA “protects Michigan’s consumers by prohibiting various methods, acts and practices in trades or commerce.”<sup>186</sup> This Act is supposed to give the citizens of Michigan an enlarged remedy for consumers injured by deceptive business practices.<sup>187</sup>

The court in *Duronio*, however, limited the scope of the MCPA to prohibit consumers from using it for actions against drug manufacturers.<sup>188</sup> The court held that the MCPA not apply to a “transaction or conduct specifically authorized under laws administered by a regulatory board or officer acting under statutory authority of this state or the United States.”<sup>189</sup> Therefore,

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<sup>181</sup> *Garcia*, 385 F.3d at 968.

<sup>182</sup> MICH. COMP. LAWS ANN. § 600.2946(5) (West 2000).

<sup>183</sup> *See* 21 U.S.C. § 355(a) (2006) (stating that “no person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed . . . is effective with respect to such drug).

<sup>184</sup> *Jung v. Ass’n of Am. Med. Coll.*, 339 F.Supp.2d 26 (D.D.C. 2004) (stating that “the very point of recognizing any access claim is to provide some effective vindication for a separate and distinct right to seek judicial relief for some wrong”).

<sup>185</sup> *Duronio v. Merck & Co*, No. 267003, 2006 WL 1628516 (Mich. Ct. App. 2006). *See* Section II. for a complete discussion of this case.

<sup>186</sup> *Id.* at \*6.

<sup>187</sup> *Id.*

<sup>188</sup> *Id.*

<sup>189</sup> *Id.*

the court held that because the drug industry is sufficiently regulated by the Food, Drug and Cosmetic Act, the plaintiff could not bring an action under the MPCA.<sup>190</sup>

This bar to relief under the MPCA acts as a supplementary bar to access to the courts for actions against drug manufacturers. Because these statutes have sufficiently eliminated any remedy for consumer protection or tort causes of action they violate a plaintiff's fundamental right of access to the courts.

A state legislature may limit the ability to recover under a statute but may not totally eliminate a remedy.<sup>191</sup> These Michigan statutes, however, act as a total block to any remedy for injury to Michigan consumers caused by a defective drug. If similar statutes are adopted in other states, there would be a complete lack of redress for the consumers, therefore violating the federal constitution and the constitutions of many states.<sup>192</sup>

#### CONCLUSION

In conclusion, Michigan's product liability statute<sup>193</sup> and the immunity it provides, is not desirable in this state, nor should it be followed in any other state. The "Michigan model" is dangerous for consumers, and therefore dual regulation should be implemented in this state and should be continued in every other state in the nation.

The Michigan model is dangerous because the FDA approval process alone is inadequate to protect consumers from dangerous drugs. The FDA approval process is inadequate because it is not complete and inherently flawed. Further, the FDA approval process is strongly influenced by the very industry it attempts to regulate.

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<sup>190</sup> *Id.*

<sup>191</sup> *Gutierrez v. Lee*, 812 S.W.2d 388, 393 (Tex. App. 1991) (stating that a statute violates the right of access to courts if it makes it impossible for the plaintiff to enforce his rights).

<sup>192</sup> States such as Colorado and Texas have open court provisions in their constitutions.

<sup>193</sup> MICH. COMP. LAWS ANN. § 600.2946(5) (West 2000).

Because FDA approval alone is insufficient to protect consumers, a dual system of tort liability and FDA regulation is preferable. Michigan consumers and legislators recognize that tort liability is needed to protect consumers. Tort liability provides important incentives to the drug industry to make their drugs safe and effective. Further tort liability appropriately holds drug manufactures accountable when things go wrong. Therefore, dual regulation is preferable.

This dual system of regulation is preferable and possibly mandated by the constitution. A drug immunity statute, such the one employed in Michigan, may violate a plaintiff's constitutional right of access to the courts. The drug immunity statute eliminates any remedy a plaintiff may seek for violation of the common law right of product liability, and therefore cuts off any access to the courts. Therefore, drug immunity should not be utilized in Michigan or any other state.

