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Michigan's Regulatory Compliance Defense: Ill-Founded Immunity For Pharmaceutical Manufacturers

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**MICHIGAN’S REGULATORY COMPLIANCE DEFENSE: ILL-FOUNDED IMMUNITY
FOR PHARMACEUTICAL MANUFACTURERS**

*Aaron L. Vorce**

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INTRODUCTION

When Michigan passed its tort reform laws in 1996 a provision was adopted – codified at M.C.L. § 600.2946(5) – that established a virtual immunity from products liability for drug manufacturers. Under this provision, immunity is offered to drug manufacturers as long as the drug has been approved by the FDA – what is commonly referred to as a “regulatory compliance defense.” When Michigan’s immunity provision was adopted, the FDA’s regulatory process was a complex, comprehensive, and quite stringent system that erred on the side on caution. At that time, the culture of the FDA centered on ensuring the safety of drugs at the expense of rapid approval rates. However, following the most progressive federal legislation targeted at drastically decreasing the approval times for promising pharmaceutical products – the FDA

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Modernization Act of 1997 – the FDA’s culture shifted. Now, the FDA is more focused on rapid approval rates, seemingly at the expense of the public health and safety. Many factors have contributed to this culture shift; however, a recurrent criticism is that the FDA is increasingly beholden to the pharmaceutical industry.

In any event, for a variety of significant reasons in addition to the shift in the FDA’s culture, a regulatory compliance defense that provides a virtual immunity from tort liability based on FDA approval is ill-founded. The failure of other jurisdictions to follow Michigan’s lead by adopting similar provisions in the several years following the codification of M.C.L. § 600.2946(5) lends credibility to this position. Now, since M.C.L. § 600.2946(5) has survived attacks on its constitutionality, for the sound reasoning offered in the proceeding sections of this article, the Michigan legislature should consider repealing or modifying this section of its tort reform legislation and do away with the regulatory compliance defense.

This article will first review the history of Michigan’s tort reform with respect to M.C.L. § 600.2946(5). Next, the general arguments for and against a strong regulatory compliance defense will be examined. The article will then analyze the history of the FDA drug approval process and discuss the FDA’s current regulatory climate. Finally, the article will conclude with a brief look at some additional specific concerns with a regulatory compliance defense premised on FDA approval.

I. MICHIGAN’S PHARMACEUTICAL PRODUCTS LIABILITY STATUTE.

In 1996 Michigan became the first state to provide pharmaceutical manufacturers and distributors virtual, if not actual, immunity from product liability suits.¹ Despite the passage of nearly a decade from the adoption of M.C.L. § 600.2946(5) (“Michigan’s Pharmaceutical

¹ P.A.1995, No. 249, § 1, Eff. March 28, 1996 (codifying MICH.COMP.LAWS § 600.2946(5) (2004) that allows for an unprecedented level of immunity for pharmaceutical manufacturers and distributors).

Products Liability Statute”), today, Michigan still stands alone in offering pharmaceutical companies an unprecedented level of statutory protection from product liability. The operative section of Michigan’s Pharmaceutical Products Liability Statute 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.²

This provision, in its essence, statutorily defines reasonable conduct that would shield drug manufacturers from liability – creating a “regulatory compliance defense.”

Looking to regulatory agencies for guidance in establishing what constitutes due care is not a novel concept. Courts, under the common law, have traditionally borrowed legislative and regulatory standards to define the duty of care under the tort system and have uniformly held that violations of those standards create negligence per se, while compliance with those standards merely amounts to additional but not conclusive evidence of due care.³ In *Grand Trunk Railway Co. of Canada v. Ives*,⁴ the United States Supreme Court rendered the first authoritative statement on a regulatory compliance defense. In that case, the plaintiff was ultimately harmed because of obstructions along the side of a road at a railway crossing. The defendant argued that it had complied with all of the applicable regulatory requirements, and as a result, the plaintiff should have been precluded from prevailing in its claim because regulatory compliance was dispositive of the defendant’s due care. There, the Supreme Court rejected the regulatory compliance defense stating:

² MICH.COMP.LAWS § 600.2946(5) (2004).

³ Theresa Moran Schwartz, *Regulatory Standards and Products Liability: Striking the Right Balance Between the Two*, 30 U. MICH. J. L. REFORM 431, 431 (1997).

⁴ 144 U.S. 408 (1892).

The underlying principle in all cases of this kind ... is that neither the legislature nor railroad commissioners can arbitrarily determine in advance what shall constitute ordinary care or reasonable prudence in a railroad company at a crossing, in every particular case which may afterwards arise; ... each case must stand upon its own merits, and be decided upon its own facts and circumstances, and these are the features which make the question of negligence primarily one for the jury to determine, under proper instructions from the court.⁵

Michigan has generally followed this tradition when relying on various legislation and administrative agency standards when developing the standard of care to utilize in particular instances.⁶ Thus, at least on a conceptual level, M.C.L. § 600.2946(5) may be seen as not a complete deviance from the traditional concept of borrowing a standard of care from an administrative agency. However, M.C.L. § 600.2946(5) is entirely unique because it transcends the boundaries of these historical practices by creating a virtual immunity from liability for pharmaceutical companies.

Prior to 1996, the Michigan statute afforded much less protection for pharmaceutical companies. The earlier law merely allowed a pharmaceutical company to enter into evidence its compliance with federal laws or regulations in order to bolster its defense.⁷ In other words, it did not provide immunity from liability for compliance with laws or regulations and it allowed the jury to decide if a pharmaceutical company acted reasonably in products liability claims. The 1996 changes to law took away the jury's ability to determine reasonableness and drastically increased drug companies' protections against product liability suits by incorporating the virtually impenetrable regulatory compliance defense.

⁵ See *id.* at 427.

⁶ 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, 333 (2002) (citing *State Conservation Dep't v. Seaman*, 240 N.W.2d 206 (Mich. 1976); *City of Pleasant Ridge v. Romney*, 169 N.W.2d 625 (Mich. 1969); *Argo Oil Corp. v. Atwood*, 264 N.W. 285 (Mich. 1935); *People v. Soule*, 213 N.W. 195 (Mich. 1927); *People v. Urban*, 206 N.W.2d 511 (Mich. Ct. App. 1973)).

⁷ M.C.L. § 600.2946(2) (1978).

The policy considerations by those proponents of this immunity provision have been well articulated. Essentially, “[t]he 1995 changes to the law are deeply reflective of the legislative intent to rectify the trend toward runaway jury verdicts and seemingly frivolous lawsuits with the hope of stabilizing corporate liability.”⁸ The House Legislative Analysis clearly articulated the policy reasons for the proposed changes in product liability law as it specifically pertained to drug companies:

[Drug] companies whose products receive FDA approval for safety or effectiveness are not liable unless the company deceived the government in the approval process. Drug companies spend large sums of money and expend enormous energy getting approval for their products. Many valuable products never reach the market or are withdrawn because of successful lawsuits (or the threat of future lawsuits) even though there is no medical evidence that they are harmful.⁹

In addition, the Senate Fiscal Agency Bill Analysis explained the need to provide heightened protection for a manufacturer that has complied with legitimately applicable governmental standards:

It is unfair to deem a product defective when it conforms to applicable governmental standards. These standards are promulgated after intense public scrutiny, expert evaluation, and thorough product evaluation. Lay jurors should not be permitted to second-guess a standard that has been developed by government experts.¹⁰

The most recent restatement on torts further supports such a regulatory compliance defense offering virtual immunity. The Restatement (Third) of Torts: Products Liability (Restatement (Third)) provides a basic source for the reasoning behind a regulatory compliance defense in the products liability arena.¹¹ The Restatement (Third), in § 4b, states:

A product's compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective

⁸ Cilla, *supra* note 6, at 334.

⁹ H. Leg. Analysis 1995 S.B. 344, at 12 (June 8, 1995).

¹⁰ Senate Fiscal Agency Bill Analysis, S.B. 344, at 13 (Jan. 11, 1996).

¹¹ Restatement (Third) of Torts: Products Liability (1997) [hereinafter, Restatement (Third)].

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.¹²

This section on its face instructs that the drafters did not intend for a regulatory compliance defense in products liability. However, the commentary to the Restatement establishes that this basic premise – no regulatory compliance defense – is founded on the notion that product safety statutes and regulations are, as a general matter, minimum standards.¹³ The commentary states:

Subsection (b) reflects the traditional view that the standards set by most product safety statutes or regulations generally are only minimum standards. Thus, most product safety statutes or regulations establish a floor of safety below which product sellers fall only at their peril, but they leave open the question of whether a higher standard of product safety should be applied. This is the general rule, applicable in most cases.¹⁴

Following this logic, the drafters of the Restatement (Third) explained that a regulatory compliance defense may be justified if the statute or regulation:

[W]as promulgated recently, thus supplying currency to the standard therein established; when the specific standard addresses the very issue of product design or warning presented in the case before the court; and when the court is confident that the deliberative process by which the safety standard was established was full, fair, and thorough and reflected substantial expertise.¹⁵

Furthermore, just prior to the Restatement (Third), an ALI report entitled, *Enterprise Responsibility for Personal Injury*, supported a regulatory compliance defense under similar circumstances requiring “that the regulation be promulgated by a specialized agency with domain-specific authority over the risk-creating conduct at the core of the tort claim.”¹⁶ Thus, the Michigan legislature does not stand alone in at least the acknowledgment of the potential validity of a regulatory compliance defense such as that codified in M.C.L. § 600.2946(5).

¹² *See id.* at § 4b.

¹³ Restatement (Third), *supra* note 11, § 4 cmt. e.

¹⁴ *See id.*

¹⁵ *See id.*

¹⁶ Robert L. Rabin, *Keynote Paper: Reassessing Regulatory Compliance*, 88 Geo. L.J. 2049, 2051 (2000) (citing American Law Institute, 2 Reporters’ Study on Enterprise Responsibility for Personal Injury 83-110 (1991)).

Despite these justifications for the defense, M.C.L. § 600.2946(5) has been repeatedly attacked on a variety of grounds. Recently, Michigan’s Pharmaceutical Products Liability Statute was attacked on the grounds that it was an unconstitutional delegation of state legislative power to a federal agency.¹⁷ In *Taylor v. Smithkline Beecham Corporation*,¹⁸ the Michigan Supreme Court reversed the Court of Appeals decision that found M.C.L. § 600.2946(5) unconstitutional and held that the statute did not unconstitutionally delegate legislative power.¹⁹ Since it appears as though Michigan’s regulatory compliance defense is constitutional, it is necessary to rely on other reasoning for why the justifications for M.C.L. § 600.2946(5) and its efficacy should be reconsidered. The remainder of this article will explore these issues.

II. ARGUMENTS SUPPORTING A REGULATORY COMPLIANCE DEFENSE.

Numerous persons argue for a stronger regulatory compliance defense; the vast majority of whom are members of a larger group that criticizes the product liability system more generally.²⁰ The many wide-ranging attacks on the product liability system include claims that it is “too costly and erratic,”²¹ reduces the affordability and availability of insurance,²² drastically increases the prices of some products,²³ deters innovation (especially in the pharmaceutical industry),²⁴ slows the development and marketing of products,²⁵ unduly burdens interstate

¹⁷ *Taylor v. Gate Pharmaceuticals*, 248 Mich.App. 472; 639 N.W.2d 45 (2001).

¹⁸ 468 Mich. 1; 658 N.W.2d 127 (2003).

¹⁹ *Id.*

²⁰ Schwartz, *supra* note 3, at 436-37.

²¹ *See id.* (citing Newt Gingrich et al., *Contract with America* 143 (Ed Gillespie & Bob Schellhas eds., 1994); American Law Inst., *Reporters' Study: Enterprise Responsibility for Personal Injury* Vol. 2, at 50 (1991); President's Council on Competitiveness, *Agenda for Civil Justice Reform in America* 1-6 (1991); Tort Policy Working Group, U.S. Attorney Gen., *Report on the Causes, Extent and Policy Implications of the Current Crisis in Insurance Availability and Affordability* 30-52, 60-75 (1986)).

²² *See id.* (citing Tort Policy Working Group, *supra* note 23, at 45-52).

²³ *See id.* (citing *Brown v. Superior Ct.*, 751 P.2d 470, 479 (Cal. 1988)).

²⁴ *See id.* (citing Peter W. Huber, *Liability: The Legal Revolution and Its Consequences* 155-61 (1988)).

²⁵ Schwartz, *supra* note 3, at 436-37 (citing Common Sense Product Liability Legal Reform Act of 1996, H.R. 956, 104th Cong. s 2(a)(4) (1996) (vetoed); *Brown*, 751 P.2d at 479).

commerce,²⁶ and reduces the United States' competitiveness in the global marketplace.²⁷ By effectively spinning these various arguments against the product liability system, these critics have been quite successful in pushing for product liability reforms that generously benefit the manufacturing industry while “generously” harming the victims of defective products.

Over the last decade or more, proposed and enacted reforms have included various measures that make bringing or winning claims more difficult and typically institute caps on recoverable damages for the few persons who are able to successfully overcome those reforms' other impediments.²⁸ Some tort reform proposals have been exceedingly harsh, asking for extreme damage caps on non-economic losses and provisions to require the losing party to pay all attorney fees.²⁹ Moreover, numerous tort reform proposals have allowed for a strengthened regulatory compliance defense though not generally proposing a virtual immunity to tort liability as is the case in Michigan tort reform. However, unlike the Michigan tort reform law, most proposals to strengthen the regulatory compliance defense have been based on more solid policy grounds and have not been as harsh as other provisions in the proposals.³⁰

The basic thrust of the arguments supporting a strong regulatory compliance defense is that regulatory agencies, such as the FDA, have greater expertise than do judges and juries for determining reasonable product safety.³¹ Moreover, such agencies are also superior to courts in making the necessary technical and policy decisions involved with products; especially products

²⁶ See *id.* (citing H.R. 956, s 2(a)(3)).

²⁷ See *id.* (citing Alfred W. Cortese, Jr. & Kathleen L. Blaner, *The Anti-Competitive Impact of U.S. Product Liability Laws: Are Foreign Businesses Beating Us at Our Own Game?*, 9 J.L. & Com. 167, 169 (1989)).

²⁸ See Martha Middleton, *A Changing Landscape*, A.B.A. J., Aug. 1995, at 56, 59 (offering a summary of the various state tort law reform over approximately the last decade.).

²⁹ Schwartz, *supra* note 3, at 439.

³⁰ See *id.* (citing Product Liability Fairness Act, S. 640, 102d Cong. s 303(c) (1991)).

³¹ See, e.g., W. Kip Viscusi & Michael J. Moore, *Rationalizing the Relationship Between Product Liability and Innovation in Tort Law and the Public Interest* 125 (Peter H. Schuck ed., 1991).

with a high level of technical complexity such as pharmaceuticals.³² Plus, agencies like the FDA should have greater access to all of the relevant information through their rulemaking procedures.³³ Simply put, “these proponents contend that government standards, crafted by experts and developed through a quasi-legislative process, are more likely to be sound and consistent measures of reasonable safety than those set on a case-by-case basis by judges and juries.”³⁴

More specifically on point with this article, numerous commentators have argued that the FDA is a model example of an agency that warrants the application of a strong regulatory compliance defense to pharmaceutical products.³⁵ Various assertions are proffered to support this position. For one, such proponents claim that the regulatory system for pharmaceuticals is more comprehensive than systems for other products, requiring lengthy, scientific examination before these products are offered to the public – thus, arguably providing product safety standards above the minimum requirements and potentially approaching optimal requirements.³⁶ Additionally, pharmaceuticals are such a valuable product to society that a heightened regulatory compliance defense is necessary to limit the scope of liability and encourage the more expedient production of innovative, effective, and potentially life saving drugs.³⁷ Moreover, a regulatory compliance defense based on FDA approval will necessarily provide consistent and predictable

³² See, e.g., *Grundberg v. Upjohn Co.*, 813 P.2d 89, 98-99 (Utah 1991).

³³ See Clarence Morris, *The Role of Criminal Statutes in Negligence Actions*, 49 Colum. L. Rev. 21, 47 (1949); see also *Ramirez v. Plough, Inc.*, 863 P.2d 167, 176 (Cal. 1993).

³⁴ Schwartz, *supra* note 3, at 439 (citing Paul Dueffert, Note, *The Role of Regulatory Compliance in Tort Actions*, 26 HARV. J. ON LEGIS. 175, 208 (1989); Lars Noah, *Reconceptualizing Federal Preemption of Tort Claims As the Government Standards Defense*, 37 WM. & MARY L. REV. 903, 965 (1996)).

³⁵ See, e.g., William G. Childs, *The Implementation of FDA Determinations in Litigation: Why Do We Defer to the PTO but Not to the FDA?*, 5 Minn. Intell. Prop. Rev. 155 (2004); Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 Geo. L.J. 2147 (2000).

³⁶ See Peter W. Huber & Robert E. Litan, *Overview*, in *The Liability Maze: The Impact of Liability Law on Safety and Innovation* 1, 13 (Peter W. Huber & Robert E. Litan eds., 1991).

³⁷ See Lars Noah, *Triage in the Nation's Medicine Cabinet: The Puzzling Scarcity of Vaccines and Other Drugs*, 54 S.C. L. Rev. 741 (2002).

standards that proponents argue are currently unnecessarily confusing and unpredictable.³⁸ All of this, it is argued, makes FDA approval the optimum foundation for a strong regulatory compliance defense.

III. ARGUMENTS AGAINST A REGULATORY COMPLIANCE DEFENSE.

Despite the arguments for a stronger regulatory compliance defense, this author's position is that such a defense in general and specifically premised on FDA decisions is neither suited nor adequate to the necessary purposes of the products liability tort system. A variety of important propositions and concerns support this position. For one, the legislature and the agencies on which the regulatory compliance defense is premised are unduly influenced by the respective industries – namely the pharmaceutical industry in this case. Additionally, political influences weigh heavily on regulatory decision-making causing a state of flux that is incompatible with product liability law. Also, more simply, regulatory standards are not a good match with the tort system and were not designed to be so. Related to this is the fact that regardless of the state of tort law in Michigan at this time, one purpose of product liability law should be to ensure compensation to its citizens in accidental harm situations and promote broad risk-spreading on the part of product manufacturers. A regulatory compliance defense is simply not consistent with this purpose. Plus, a regulatory compliance defense does not serve the tort system's purpose of eliciting information about risk and aberrant conduct. Moreover, we should not put faith during this highly technological era in regulatory agencies, such as the FDA, to keep pace with frantic technological advancements. More likely than not, the pharmaceutical industry at times will outpace the FDA's regulations, and as a result, regulatory compliance will not provide adequate safety standards for tort liability purposes.

³⁸ Schwartz, *supra* note 3, at 441-42.

Fundamentally, a legitimate regulatory compliance defense must necessarily be grounded in objective regulatory standards. Thus, if the regulatory agency charged with approving products, such as pharmaceuticals, is heavily influenced by the industry being regulated or another interested industry, then the respective regulatory compliance defense is ill-founded. In general, government agencies must extensively rely on the industries that they are regulating because the industries know more about the details, data, cost and benefits, and risks of their own products.³⁹ The pharmaceutical industry is not an exception to this rule. Pharmaceutical companies clearly have greater technological expertise with respect to their products, as successful pharmaceutical companies only employ the best and the brightest persons to develop marketable and profitable drugs. Moreover, nothing can refute the fact that pharmaceutical companies have greater knowledge of the details of their products than the FDA could ever have despite the FDA's extensive disclosure requirements. Because of this, the FDA must rely heavily on the pharmaceutical industry's candidness and cooperation, and as a result, the industry exerts incredible influence on the agency and its regulatory determinations. Plus, what will be subsequently discussed in more detail, is the fact that the "user fee" provision adopted in the FDA Modernization Act creates even greater FDA reliance on the industry and increases industry influence. These facts seriously undermine the credibility of a regulatory compliance defense premised on FDA approval.

Moreover, politics permeates any regulatory process. Of course, the degree to which politics plays a role in a particular regulatory agency varies, but nevertheless, politics still has its effect. For instance, during the Reagan era, deregulation was a prominent political platform in

³⁹ *See id.* (citing Joan Claybrook, *Retreat from Safety: Reagan's Attack on America's Health* xxiv-xxv (1984) for the proposition that "the government has far less information than the regulated industry with which to make key regulatory decisions").

an effort to provide regulatory relief for businesses.⁴⁰ Specifically, the FDA was hard hit during this era, suffering serious resource cutbacks. As a result, the number of FDA enforcement actions was drastically reduced⁴¹ and proposed regulatory actions were stymied.⁴² This culminated in a stream of scandals at the FDA.⁴³ As one commentator succinctly put it: “Whatever the impact, and however deep and long lasting, one thing is clear: the regulatory environment shifts with the political environment. Such shifts should raise serious concerns for the judiciary about relying on the regulatory system to set the safety standards for the tort system.”⁴⁴

In a more general sense, regulatory standards are simply not suited for establishing standards for products liability cases. When courts determine what standards fit a particular case they necessarily analyze whether the standard promotes the purpose of the statute in question and whether the standard addresses the type of injury in question.⁴⁵ In Michigan, the legislature has made these determinations without fully exploring whether the FDA standards address the types of injuries in question. Specifically, the legislature has not established that the FDA, when making its decisions, contemplates the ramifications its decisions have on legitimate products liability claims and the potential limiting effect on an injured person’s compensation for his or her injuries. Perhaps, if the FDA was aware of the fact that its decisions were being used for such purposes, the FDA’s decision-making process may substantially differ from its current practices.

⁴⁰ See Teresa Moran Schwartz, *A Product Safety Agenda for the 1990s*, 45 WASH. & LEE L. REV. 1355, 1362-66 (1988).

⁴¹ See Julie Kosterlitz, *Reagan is Leaving His Mark on the Food and Drug Administration*, 17 NAT’L J. 1568, 1569-71 (1985)

⁴² Schwartz, *supra* note 3, at 447.

⁴³ See *id.* at n. 80 (listing several scandals including: “One major fraud on the FDA in the 1980s--when the FDA, in effect, had ‘stopped being a regulatory agency’-- involved the bribery of FDA staff by generic drug industry members;” “a manufacturer of heart catheters who lied to the FDA about the experimental use of its devices, sold devices without FDA approval, and covered up its actions. The FDA ordered a recall of the products by 1990 and then pursued criminal charges. . . . The criminal prosecution resulted in a \$61 million fine--the largest fine ever imposed in an FDA enforcement case;” and “[s]till another instance of wrongdoing in the 1980s involved Eli Lilly’s failure to reveal serious adverse reactions experienced by English users of its drug Oralflex. . . . The drug was approved, promoted heavily, and caused an estimated 50 deaths before it was withdrawn from the U.S. market.”

⁴⁴ Schwartz, *supra* note 3, at 448.

⁴⁵ See *id.* (explaining that “[f]urthering the safety aims of the statute has become the principal rationale for borrowing standards in tort cases.”).

Moreover, there are a variety of justifications for a strict products liability system that equally apply as criticisms of the regulatory compliance defense. For example, the “enterprise liability” doctrine suggests that manufacturers such as pharmaceutical companies are in a position to more easily distribute the costs of injuries from defective products by raising prices or purchasing insurance.⁴⁶ Drug companies implicitly represent that their products are safe and in fact, FDA approval strengthens this presumption with respect to consumers creating, in essence, an explicit representation of the product’s safety.⁴⁷ As such, consumers are justified in relying on these representations and should not be punished by being barred from securing their just compensation for injuries from defective products. What follows is that drug companies should be if not strictly liable for injuries statistically associated with the manufacturing enterprise, at least legally responsible for injuries resulting from their negligence in manufacturing the drugs. Such liability is merely “a cost of doing business that should be born by someone other than injured individuals.”⁴⁸

More simply, the regulatory compliance defense is generally unfair. Drug companies enjoy vast benefits by putting their products into the stream of commerce and they should also accept the few disadvantages such as the costs of injuries resulting from their negligence.⁴⁹ Also, the regulatory compliance defense is undermined by the theory of “nonreciprocal risks” – the theory that “the manufacturer imposes risks on the consumer that are quite different from any risks the consumer imposes on the manufacturer.”⁵⁰ In the context of pharmaceutical companies, the consumer is faced with grave risks of being seriously injured or killed by defective drugs for

⁴⁶ DAN B. DOBBS & PAUL T. HAYDEN, TORTS AND COMPENSATION 626 (4th ed. 2001).

⁴⁷ *See id.* (explaining that “[m]anufacturers implicitly represent that the products they make are safe and healthy, and consumers are justified in relying [on] that implicit representation”).

⁴⁸ *See id.* at 627.

⁴⁹ *See id.* (explaining that “because the manufacturer enjoys the advantages of sending its products into commerce, it should also take the disadvantages in the form of injury costs when the risks of such activity come to fruition”).

⁵⁰ *See id.*

the sake of society's need for innovative and effective products; however, the consumer does not impose a comparable risk on the drug company. Fundamentally, no injured person should be required to sacrifice his or her legitimate claim against a defendant manufacturer for the benefit of the common good.

Still another attack on the regulatory compliance defense is that the tort system provides a valuable mechanism for "educating the public about unscrupulous and socially dangerous business practices detrimental to the public health."⁵¹ At the very least, the products liability system serves a positive function by revealing the concealment of risk information from the FDA.⁵² But, this valuable function is eviscerated by the regulatory compliance defense since it leaves this fraud-finding function in the hands of the regulatory agency. Of course, proponents of the regulatory compliance defense will point out that the Michigan statute does not provide the regulatory compliance defense to a pharmaceutical company that commits a fraud such as withholding risk information from the FDA. Generally, those proposing such statutes do include a fraud exception to the defense. The Michigan statute specifically states that the regulatory compliance defense does not apply to a company that "[i]ntentionally 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."⁵³

Thus, on the surface it appears that the Michigan statute does not undermine the tort system's valuable function of revealing the concealment of risk information from the FDA.

⁵¹ Rabin, *supra* note 16, at 2068.

⁵² *See id.* at 2069 (citing Teresa Moran Schwartz, *Punitive Damages and Regulated Products*, 42 AM. U. L. REV. 1335, 1348-52 (1993) for examples of the concealment problem arising in FDA licensing cases).

⁵³ M.C.L. § 2946(5)(a) (2005).

However, it is first important to note that “it often takes more broadly applicable theories than fraud to uncover fraud.”⁵⁴ As a result, the fraud exception to the defense may not be enough to allow the tort system to fully realize its fraud revealing function. But more importantly, the most recent case considering the fraud exception issue with respect to Michigan’s product liability statute, *Garcia v. Wyeth-Ayerst Laboratories*,⁵⁵ confirms that despite this fraud exception in the statute, the tort system’s function of revealing fraud is entirely undermined.

The *Garcia* court explained that state-law fraud-on-the-FDA claims seriously conflict with the FDA’s requirement to police fraud in a way that is consistent with the FDA’s judgment and objectives.⁵⁶ The court then noted that the specific exception for fraud on the FDA to the general immunity provided by Michigan’s regulatory compliance defense is distinguishable from a general state-law fraud-on-the-FDA claim.⁵⁷ Nevertheless, it concluded that the difference was immaterial and that “remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims.”⁵⁸ Thus, the court held that the only findings of fraud that may be utilized to establish the fraud exception under Michigan’s Pharmaceutical Products Liability Statute are findings made by the FDA itself.⁵⁹ Because of federal preemption, the state court is not allowed to humor findings of fraud other than federal findings. Clearly, this entirely undermines the tort system’s function of uncovering such fraud since, according to *Garcia*, this function is wholly in the Agency’s hands. Plus, evidence indicates that the tort

⁵⁴ Rabin, *supra* note 16, at 2068 (explaining that “[f]raud is in fact a narrowly defined claim. For example, traditionally one must establish scienter and offer ‘clear and convincing’ evidence to prevail.”).

⁵⁵ 385 F.3d 961 (6th Cir. 2004).

⁵⁶ *Garcia v. Wyeth-Ayerst Laboratories*, 385 F.3d 961, 965 (6th Cir. 2004) (citing *Buckman Co. v. Pls.’ Legal Comm.*, 531 U.S. 341, 350 (2001)).

⁵⁷ *See id.* at 965-66.

⁵⁸ *See id.*

⁵⁹ *See id.* at 966 (explaining that “[i]n the final analysis, the exemptions are invalid as applied in some settings (e.g., when a plaintiff asks the state court to find bribery or fraud on the FDA) but not in others (e.g., claims based on federal findings of bribery or fraud on the FDA).”).

system does play this fraud-revealing role with some regularity.⁶⁰ Ultimately, “if the tort system’s role in educating the public about serious health risks and profit-driven efforts to conceal those risks is regarded as socially important, unconstrained tort action is very arguably called for.”⁶¹

Another serious problem arises when regulatory standards cannot keep pace with technological change.⁶² The administrative rulemaking procedures often cause severe lags in time between the necessary change in standards and the conditions that necessitated such changes.⁶³ “As a consequence, government standards frequently become outdated, and are therefore poor measures of safety for the tort system.”⁶⁴ Thus, the applicable FDA approval standards might not have been suitable at the time injury occurred to warrant a regulatory compliance defense. In fact, this “regulatory lag” problem has been previously evidenced with respect to the FDA. For example, the rule that classified breast implants as a “high risk device” took six years to complete and another three years to finalize.⁶⁵ Also, it took the FDA approximately two decades to complete its massive review of prescription drugs that led to the recall of over a thousand different drugs that were on the market.⁶⁶ The FDA acknowledges this problem and only expects it to grow.⁶⁷

Related to the problem of technology outpacing regulatory standards is the problem of limited government resources. The government functions on a supply of limited resources, and

⁶⁰ See Rabin, *supra* note 16, at 2070 (pointing to asbestos and tobacco litigation as prime examples).

⁶¹ See *id.*

⁶² Schwartz, *supra* note 3, at 444-45.

⁶³ See *id.* at 445.

⁶⁴ See *id.* at 444-45 (noting that “risks became known in 1970 that were not available when FDA’s regulation of oral contraceptives was issued in 1968” and that in *Feldman v. Lederle Lab.*, 479 A.2d 374, 379 (N.J. 1984), “the manufacturer and the FDA had knowledge of risks, but that the FDA failed to act before plaintiff’s injury”).

⁶⁵ Schwartz, *supra* note 3, at 444 n. 62.

⁶⁶ See *id.* at 445, n. 61.

⁶⁷ See generally Advisory Comm. on the Food and Drug Admin., U.S. Dep’t of Health and Human Servs., Final Report (1991).

as a result, it is often the case that an agency such as the FDA lacks the necessary resources to properly review the data submitted to it by the industry.⁶⁸ This is especially the case with an agency such as the FDA that has the most comprehensive regulatory responsibilities.⁶⁹ This lack-of-funding problem is compounded when either an agency's jurisdiction is expanded or the number and prevalence of products under its purview dramatically increases and there is no corresponding increase in funding.⁷⁰ Historically, this phenomenon has negatively impacted the effectiveness of the FDA. The FDA has noted, for example, that between 1980 and 1990 its jurisdiction was greatly expanded and the number and complexity of products under its purview drastically increased but it did not receive the necessary increase in funding or staffing to adequately monitor or regulate the drug industry.⁷¹ It will be explained later that the problem has been somewhat alleviated by the "user fee" provision in the FDA Modernization Act of 1997; however, there is no guarantee that this problem will not occur again in the future. All of the aforementioned issues weigh heavily against the regulatory compliance defense, especially one like Michigan's that provides a virtual immunity from tort liability.

IV. THE FDA'S DRUG APPROVAL HISTORY AND CURRENT REGULATORY CLIMATE.

Today, "[t]he [FDA] is caught in pincers between two intense political pressures: demands from the industry and the political right to move faster and faster in approving drugs, and rising insistence from consumer groups and the left to show more caution."⁷² Within the last couple of decades, the public and the scientific community have criticized the FDA for its protracted approval process. Congress has responded to these concerns by enacting legislation

⁶⁸ Schwartz, *supra* note 3, at 446.

⁶⁹ *See id.*

⁷⁰ *See id.*

⁷¹ Advisory Comm. on the Food and Drug Admin., U.S. Dep't of Health and Human Servs., Final Report at 15-17, app. C at 2-3; 9-10 (1991).

⁷² Alison R. McCabe, *A Precarious Balancing Act – The Role of the FDA as Protector of Public Health and Industry Wealth*, 36 SUFFOLK U.L. REV. 787, 787 (2003) (quoting Rochelle Sharpe, FDA Tries to Find Right Balance on Drug Approvals, WALL ST. J., Apr. 20, 1999, at A24).

that requires the pharmaceutical industry to fund the FDA's approval process in return for expedited approval times.⁷³

Now, however, people are questioning whether the FDA has become a "servant to the industry" rather than the protector of the public health.⁷⁴ Many think that the legislation Congress enacted with the intent to expedite approval rates was successful in that aim but only at the expense of drug safety.⁷⁵ In fact, the recent upsurge in drug recalls and drug related injuries and deaths are considered by many to be the result of hasty drug approvals.⁷⁶ Arguably, as a result of this legislation, the FDA has become more dependent on industry funding and is allowing the pharmaceutical industry to seize control of public health from the Agency.

Currently, the primary mission of the FDA is to enforce the Federal Food, Drug and Cosmetics Act of 1938 (FFDCA) – thus, regulating food, drugs, labeling, cosmetics, and medical devices. In 1962, the Kefauver-Harris Amendments ("Drug Amendments")⁷⁷ were the beginning of a trend of reforms that culminated in the rigorous pre-market approval standard that in some circumstances is still applied today. This pre-market approval process begins with a pharmaceutical company's submission of an investigational new drug application ("INDA").⁷⁸ However, before the INDA is filed, the pharmaceutical company, to evaluate the preliminary safety, must conduct approximately 3 ½ years of laboratory and animal testing on the drug.⁷⁹ After receiving this application, the FDA will either approve or reject the INDA. If the INDA is approved, the pharmaceutical company then may begin the necessary three phases of human

⁷³ *Id.* at 788.

⁷⁴ *See id.*

⁷⁵ *See id.*

⁷⁶ *See id.*

⁷⁷ Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780.

⁷⁸ *See* Elizabeth M. Rutherford, *The FDA and Privatization--The Drug Approval Process*, 50 FOOD DRUG L.J. 203, 212-13 (1995) (summarizing the FDA's approval process).

⁷⁹ *See id.*

clinical studies.⁸⁰ Phase I is devoted to evaluating safety and lasts approximately one year.⁸¹ Phase II focuses on efficacy, side effects, and dosing and lasts approximately two years.⁸² Finally, Phase III lasts approximately three years, which is used to gather additional data on the safety and efficacy of the drug.⁸³ Once all of the Phases of testing are complete, the pharmaceutical company files a new drug application (“NDA”) with the FDA containing all of the clinical data – this complete application may be as long as 100,000 pages or more.⁸⁴ Due to the enormity of the application, it typically takes the FDA thirty months to review the NDA. In order to expedite this lengthy process, the Drug Amendments did allow a generic drug manufacturer to submit an abbreviated new drug application if it could establish that its proposed drug was essentially a “bioequivalent” of a drug that had already been approved.⁸⁵

By the 1980’s, the public was becoming impatient with this complex and lengthy drug approval process because the FDA was impeding the approval of several promising life-saving drugs.⁸⁶ The scientific community was generally in agreement on this issue and also pressed for a more modernized and streamlined new drug investigation and approval process.⁸⁷ As a result, in 1992, the Prescription Drug User Fee Act (“PDUFA”)⁸⁸ was enacted. This act somewhat loosened the drug approval standard and it also required pharmaceutical companies to pay “user fees” when promoting new drugs.⁸⁹ These fees are used to fund the FDA’s drug approval process

⁸⁰ *See id.*

⁸¹ *See id.*

⁸² *See id.*

⁸³ Rutherford, *supra* note 78, at 212-13 (summarizing the FDA’s approval process).

⁸⁴ *See id.*

⁸⁵ McCabe, *supra* note 72, at 791.

⁸⁶ *See id.* (pointing to potential Alzheimer’s drugs as a prime example of those being impeded by the FDA approval process).

⁸⁷ *See id.* at 792; *see also* Jennifer Kulynych, *Will FDA Relinquish the "Gold Standard" for New Drug Approval? Redefining "Substantial Evidence" in the FDA Modernization Act of 1997*, 54 *FOOD DRUG L.J.* 127, 141 (1999).

⁸⁸ Pub. L. No. 102-571, Title I, § 102, 105 Stat. 4491 (codified at 21 U.S.C. § § 379g, 379h).

⁸⁹ McCabe, *supra* note 72, at 792.

in order to help expedite the approval of life saving and other important drugs.⁹⁰ Ultimately, the purpose of the PDUFA was to reduce the review time for new drug applications by about fifty-percent, which is intended to benefit the public by expediting the approval of beneficial and life saving drugs, but also to benefit the pharmaceutical companies by making the industry more profitable.⁹¹

The PDUFA was extremely effective in reducing FDA drug approval times, and it was subsequently reauthorized in the FDA Modernization Act (“FDAMA”).⁹² However, the FDA’s utilization of user fees to fund its staff among other things most definitely raises the specter of greater industry influence because of the FDA’s increased reliance on industry funding. Moreover, the FDAMA raises other concerns over whether a regulatory compliance defense to products liability can appropriately be founded on FDA approval. Following FDAMA’s enactment, the FDA has set aggressive performance goals, management goals, and procedural goals intended to drastically reduce the review and approval time for new drug applications.⁹³ Arguably these aggressive approval time reductions are not proportionate with the supposed increased effectiveness that the FDA expects to achieve through the user fees. Also, FDAMA codifies and expands the FDA’s current regulations regarding pharmaceutical products that are eligible for accelerated drug approval.⁹⁴ In fact, the scope of drugs that are now eligible for “fast track” approval is severely broadened as a result of FDAMA.⁹⁵

⁹⁰ *See id.*

⁹¹ *See id.* (explaining that the pharmaceutical companies gain tremendous economic benefits from expedited approval times because the effective patent life of the drug is not reduced by the more time consuming procedures).

⁹² Food and Drug Administration Modernization Act of 1997, 21 U.S.C. § 301 (1997).

⁹³ Parver, *supra* note 93, at 1259-1260 (explaining that “[i]n return for the increased resources provided by user fees, the FDA, through the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER), set forth ambitious and promising performance goals;” and “ The FDA established various management goals that will facilitate the interaction between the FDA and drug manufacturers”).

⁹⁴ *See id.* (citing H.R. Rep. No. 105-310, at 54).

⁹⁵ *See id.*

The fast track program under FDAMA allows a pharmaceutical company to request fast track approval at any time during the approval process on a rolling review basis.⁹⁶ This means that an application can be reviewed even if it is incomplete if the drug company can show signs of efficacy.⁹⁷ The typical method by which a drug meets the necessary safety and efficacy standards is by demonstrating its “effect on a clinical endpoint, such as morbidity or mortality, or on a validated surrogate endpoint, such as cholesterol levels or blood pressure.”⁹⁸ However, FDAMA allows a drug to be “fast tracked” if it is demonstrated that the drug has an effect on a “surrogate endpoint that is reasonably likely to predict a clinical benefit.”⁹⁹ In other words, the clinical benefits are merely suggested but not proven.¹⁰⁰ Because of the expedited nature of these fast track approvals under uncertain conditions, the FDA requires subsequent post-approval requirements and retains the ability to expeditiously withdraw a drug after only an informal hearing.¹⁰¹ All of this suggests that such approvals are not an appropriate foundation for a regulatory compliance defense, especially in light of the numerous recent withdrawals of such drugs from the market by the FDA.

Essentially, the FDA is confronted with conflicts arising within its ambit of protecting the public’s health and safety. On one hand, the FDA should not hastily approve a drug that will subsequently be found to be unsafe after being thrust into the marketplace because it is “reasonably likely to predict a clinical benefit.”¹⁰² On the other hand, the FDA should not unnecessarily delay the approval of an ultimately safe and highly beneficial drug that may

⁹⁶ *See id.* at 1261.

⁹⁷ *See id.* (citing H.R. Rep. No. 105-310, at 56).

⁹⁸ *See id.* (citing H.R. Rep. No. 105-310, at 54).

⁹⁹ FDA Modernization Act § 112(b)(1).

¹⁰⁰ Parver, *supra* note 93, at 1262 (citing H.R. Rep. No. 105-310, at 54).

¹⁰¹ *See id.*

¹⁰² *See* Rutherford, *supra* note 78, at 214 (“The drug reviewer’s job highlights the problem of few or misplaced incentives. He or she can make two types of errors. The first error would be to approve a drug that later proves to have serious adverse events -- another thalidomide. The second error would be to reject, or even delay, approval of a beneficial drug.”).

positively effect or even save lives.¹⁰³ With respect to these conflicts, prior to FDAMA's enactment, the FDA erred on the side of caution, favoring unnecessary delay over the potential hasty approval of a promising but unsafe drug.¹⁰⁴ This was due to a variety of factors including: "political pressure for safe drugs, rather than fast review times; a complex regulatory framework; and a highly deferential judiciary."¹⁰⁵ Politically, the FDA reviewers were subject to intense congressional examination, professional criticism, and were likely lose their jobs if a bad judgment was made.¹⁰⁶ The complex regulatory framework, which was self evident, caused substantial delay in approval times and was fostered by the political climate prior the enactment of FDAMA.¹⁰⁷ Lastly, the deference that the FDA received from the judiciary prior to FDAMA discouraged the FDA from functioning more effectively and efficiently.¹⁰⁸ Ultimately, the FDA's mindset was to delay approval rather than suffer another Thalidomide debacle.¹⁰⁹

However, after FDAMA's enactment, the FDA is seemingly more focused on approving drugs as hurriedly as it can with diminished respect for its duty to protect the public's health.¹¹⁰ Now, rather than the FDA reviewer's performance being linked to the safety of the drugs approved, his or her performance is now directly linked to the number of drugs approved as a result of FDAMA's ambitious performance goals.¹¹¹ Moreover, pharmaceutical manufacturers,

¹⁰³ *See id.*

¹⁰⁴ *See id.* (explaining the FDA's inclinations at a time prior to FDAMA's enactment stating: "The system has few, if any, incentives to encourage drug approval. In fact, strong disincentives are built into the drug approval process.")

¹⁰⁵ *See id.*

¹⁰⁶ *See id.* (explaining that this was the case because "The specter of thalidomide still looms large in Congress, the media, and the FDA, which provides a constant reminder that extreme conservatism in reviewing drugs is paramount.")

¹⁰⁷ *See id.* at 215 (explaining [prior to the enactment of FDAMA] that "Congress, until very recently, has been controlled by Democrats, who typically have helped foster the complex regulatory scheme.")

¹⁰⁸ Rutherford, *supra* note 78, at 215 ("[T]he judiciary provides the FDA no incentive to work quicker or more efficiently, due to its highly deferential standard of review. This deference allows the FDA to extend its power base, including the review process, virtually unchecked.")

¹⁰⁹ *See id.* at 214 ("The specter of thalidomide still looms large in Congress, the media, and the FDA, which provides a constant reminder that extreme conservatism in reviewing drugs is paramount.")

¹¹⁰ Parver, *supra* note 93, at 1264.

¹¹¹ *See id.* at 1265.

physicians, and Wall Street exert tremendous pressure on the FDA for rapid approval rates.¹¹² Even more alarming is the fact that since FDAMA the FDA is working more closely with the drug manufacturer during the approval process – raising the specter of industry influence and undermining the FDA’s necessary objectivity. As a result of all of this, following FDAMA, record numbers of approved drugs have been recalled by the FDA because the drugs later proved to be harmful.¹¹³ Arguably, “[t]he current system of testing new drugs may be too brief to detect harmful reactions that could surface after repeated use.”¹¹⁴

The public’s response to this precarious situation following FDAMA “has recurrently been one of doubt, distrust, and fear.”¹¹⁵ Many critics believe that the FDA simply caters to the drug companies that fund it and are altogether indifferent to the needs for public safety and its review process.¹¹⁶ In fact, many FDA drug reviewers admit that they are pressured to approve questionable drugs by the powers that be – i.e. the pharmaceutical industry, Congress, and even FDA senior officials.¹¹⁷ Now, some previous advocates of expedited approval rates find themselves reversing their opinion after observing the market being flooded with “poorly tested drugs of unknown efficacy.”¹¹⁸ Evidence suggests that such rapidly approved drugs later found to be harmful are often the result of FDA oversight, the drug company’s reliance on outdated or insufficient data, or insufficient long-term testing.¹¹⁹

¹¹² See *id.* (citing Stephen Fried, *The Will of the Pill; Inside the FDA, Pressure to Approve New Drugs Can Clash With Safety*, Wash. Post, May 31, 1998, at C1).

¹¹³ See *Id.*; And for more recent examples, consider the Fen-Phen, Redux, and Vioxx concerns.

¹¹⁴ See *id.* at 1265-66 (citing John Schwartz, *Is FDA Too Quick to Clear Drugs?*, Wash. Post, Mar. 23, 1999, at A1).

¹¹⁵ McCabe, *supra* note 72, at 787 (citing Arthur A. Levin, *RxNews: FDA Finds Safety of New Drugs Not Compromised*, HEALTHFACTS, June 1, 1999).

¹¹⁶ See *id.* (citing FDA Hearing Considers the Future of User Fees, CHAIN DRUG REV., Oct. 23, 2000).

¹¹⁷ See *id.* (explaining the findings of a study conducted by the Public Citizen Health Research Group that surveyed FDA drug reviewers).

¹¹⁸ See *id.* (quoting Louis K. Perrin, Note, *The Catch-22 for Persons with AIDS: To Have or Not to Have Easy Access to Experimental Therapies and Early Approval For New Drugs*, 69 S. CAL. L. REV. 105, 112-13 (1995)).

¹¹⁹ See *id.* at 800.

These facts drastically undermine the appropriateness of a regulatory compliance defense founded on FDA approvals. One author states: “Because it is fundamentally infeasible to identify all of a drug’s attendant risks and side effects, the FDA endeavors to regulate and enforce the proper use of drugs during the post-approval period.”¹²⁰ This means that currently in Michigan because of the blanket immunity provided by the regulatory compliance defense, unwarrantedly injured persons have no redress for those injuries caused by unsafe drugs between the time the drug is hastily approved and the time it takes the FDA to properly investigate and withdraw the drug during the post-approval period. Simply put, the FDA’s current regulatory process is not commensurate with what is necessary for the proper foundation of a regulatory compliance defense, if such a foundation even exists.

V. SOME ADDITIONAL CONSIDERATIONS WITH RESPECT TO FDA APPROVAL AND MICHIGAN’S REGULATORY COMPLIANCE DEFENSE.

As previously mentioned, the FDA approval process is considered by many to be the strongest case for a regulatory compliance defense. According to such regulatory compliance proponents, the FDA drug approval process is a comprehensive regulatory scheme founded on scientific expertise, and the product being approved is extremely important for public health.¹²¹ As such, these proponents argue that the manufacturers of important drugs approved under the rigorous FDA approval process deserve relief from burdensome tort litigation.¹²² They consider the tort system an over-deterrence for imposing liability on manufacturers when they were in compliance with these comprehensive and rigorous standards; and also a substantial deterrence even when there is ultimately no liability because of the substantial litigation costs of defending

¹²⁰ *See id.*

¹²¹ Rabin, *supra* note 16, at 2074 (citing Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J.L. REFORM 461 (1997); Schwartz, *supra* note 3, at 440).

¹²² *See id.*

such claims.¹²³ In fact, critics of the tort system’s effect on the pharmaceutical industry have pointed to the FDA’s approval process stating that it “so stringent as to have created a drug lag that prevents American consumers from gaining access to new pharmaceuticals on a timely basis.”¹²⁴ This fact, it is argued, coupled with the tort system’s effects, creates a sort of double-deterrence that is detrimental to the effective manufacture and marketing of important and potentially life-saving drugs and is ultimately detrimental to the public health – thus, the need for a regulatory compliance defense.

Of course, you will find few if any authorities who propose that a regulatory compliance defense, such as Michigan’s, is warranted when the governing regulatory body merely sets minimum safety standards.¹²⁵ This is, no doubt, one reason why the Michigan legislature has chosen only to apply the regulatory compliance defense to FDA decisions. Although many critics of the FDA proclaim that FDA standards are minimum standards, the more realistic view is that this is not the case.¹²⁶ This does not mean that FDA standards are optimal, however, for all of the reasons previously discussed throughout this article – especially with respect to those drugs approved through the “fast track” process. However, even if we assume that, in the least, the FDA approval process is optimally rigorous, it is still not the case that the tort system would have this double-deterrent effect.

If, for example, the majority of states do not adopt a regulatory compliance defense then there will be only a negligible lessening of deterrence since drug companies will still be faced with substantial liability in the majority of jurisdictions. Thus, a potential justification for

¹²³ See *id.* at 2075.

¹²⁴ W. Kip Viscusi et al., *Deterring Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 SETON HALL L. REV. 1437, 1454 (1994).

¹²⁵ Rabin, *supra* note 16, at 2074 (explaining that “it should be observed that no serious commentator would argue for a regulatory compliance defense in circumstances where the agency regulations are regarded as minimum safety standards rather than optimal standards.”).

¹²⁶ See *id.* (citing *Edwards v. Basel Pharm.*, 933 P.2d 298, 302-03 (Okla. 1997) as an “example of ‘minimum standards’ analysis of FDA regulation.”).

Michigan’s regulatory compliance defense is moot. But, on the other hand, if the vast majority of jurisdictions do eventually adopt a regulatory compliance defense similar to Michigan’s, then a “compensation void” will result.¹²⁷ The ultimate effect of this would be an increase in political pressure to minimize injuries from products because of the unavailability of compensation for severely injured persons.¹²⁸ In effect, the overdeterrence argument for a regulatory compliance defense is reliant on the fact that “the agency would continue to operate free of any internal or external bureaucratic/political demands to ratchet up the stringency of its approval process in a world where tort remedies for drug-related injuries were nonexistent.”¹²⁹ In reality, this is simply not the case.

There are still other reasons why the regulatory compliance defense based on FDA approval is ill-founded. For one, the post-approval period, especially for “fast tracked” drugs, is quite unpredictable. The regulatory compliance defense based on FDA approval is in part premised on the notion that pharmaceutical products by their very nature are dynamic and unpredictable and that is why we must consider the FDA’s expert opinion to be the best indication of product safety.¹³⁰ For example, “prescription drugs have side-effects that occur in such a narrow sub-sample of the population that they do not show up in the NDA process, which of necessity is limited to a relatively small sample of the universe of eventual users.”¹³¹ Also, many side effects are not exposed until substantial lag in time – often longer than the new drug application process. Proponents of the defense say that this is precisely why the FDA’s expert opinion is superior to litigation – the FDA is in the best situation to minimize ill-effects – and as

¹²⁷ See *id.* at 2076 (discussing the effects of a national, blanket FDA regulatory compliance defense).

¹²⁸ See *id.* (“With a compensation void created by a regulatory compliance defense, the political pressure to minimize injuries from products passing through the regulatory screen might be substantially enhanced.”).

¹²⁹ Rabin, *supra* note 16, at 2076.

¹³⁰ See *id.* at 2077.

¹³¹ See *id.*

such, “a manufacturer’s compliance with the FDA optimal deterrence protocol should be taken as conclusively presumptive of reasonable design and warning.”¹³²

There are definite problems with this assumption. First, the FDA’s regulatory process is telling in that it admits the expectation of regular post-approval problems for precisely these reasons. The process provides for strict monitoring of post-approval drugs that recently has resulted in numerous post-approval recalls or revisions. This is especially true for “fast tracked” drugs, which have an even stricter post-approval regime. Impliedly, this admits the fact that the pre-approval process is less than optimal, severely undermining the regulatory compliance defense. Second, as was briefly mentioned before, at the least, the regulatory compliance defense is inapt for the period of time between FDA approval and FDA post-approval recall or revision. For example, consider the situation where an injury is caused by an inadequate warning label prior to a subsequent revision in the post-approval monitoring period. In this situation a regulatory compliance defense should not be applicable. More than likely, in this scenario, either the “drug company did not report incoming adverse consequences data to the agency . . . the physician-hospital monitoring system – on which both the manufacturer and the agency rely – was deficient, or that the agency itself acts less than ‘optimally’ at this relatively informal, postlicensing compliance review stage of its process.”¹³³ These are simply not cases in which a regulatory compliance defense should apply.

Another problem with an FDA regulatory compliance defense is the wide spread practice of off-label use. In fact, it has been estimated that forty to sixty percent of all drugs prescribed are for off-label uses.¹³⁴ One might ask: What is the relevance of this with respect to FDA approval, drug manufacturer liability, and the regulatory compliance defense when it is the

¹³² *See id.*

¹³³ Rabin, *supra* note 16, at 2076.

¹³⁴ *See* Fran Kritz, FDA Seeks to Add Drugs' New Uses to Labels, WASH. POST, Mar. 29, 1994, at Z11

physicians who are prescribing drugs for these off-label uses? The answer is it is extremely relevant. The fact is the FDA endorses off label use and considers such uses critical to adequate health care.¹³⁵ Clearly, pharmaceutical manufacturers are aware of the wide-spread off-label use of their drugs and the FDA's endorsement of those uses. Thus, the relevant question is "whether the company should have supplied additional information to prescribing physicians on the risks associated with the supplemental use, irrespective of its obligation to seek supplemental certification from the FDA."¹³⁶ Under Michigan's compliance defense, this question is irrelevant since the manufacturer is immune from liability irrespective of the answer. This is yet another scenario in which the regulatory compliance defense is wholly inapt.

Still another aspect of potential pharmaceutical manufacturer liability that should raise concerns over Michigan's regulatory compliance defense is the ever-increasing controversial drug company advertising campaigns. One problem here is the potential for a drug company's aggressive drug advertising campaign to "create[] an atmosphere in which the consumer [is] led to disregard the prescribed warning" associated with a particular drug.¹³⁷ Prior to FDAMA, pharmaceutical companies refrained from massive ad campaigns because they were required to explicitly state in the media the risks associated with the advertised drug.¹³⁸ Following FDAMA, restrictions on advertising were relaxed and drug companies were merely required to provide

¹³⁵ Rabin, *supra* note 16, at 2078-79 (explaining that "the substantial lag time between filing a supplemental NDA and receiving approval--estimated until recently to run more than two years --as well as the financial burden of revisiting the application process, make off-label use a cornerstone of innovative medical treatment. Thus, drugs end up being prescribed for a range of diseases in addition to those for which they were certified, or they are used on different patient populations, in different dosages, or most notoriously of late (in the case of fen-phen), in combination with other drugs.").

¹³⁶ *See id.* at 2079.

¹³⁷ *See id.* (citing John R. Gashin, Ads May Cause Adverse Reaction, 100 BEST'S REV.--PROP.-CASUALTY INS. EDITION 101 (1999); Edward S. Kornreich & Herschel Godfield, Guidance Regulates Off-Label Drug Use, NAT'L L.J., Mar. 15, 1999, at B7).

¹³⁸ Edward S. Kornreich & Herschel Godfield, *Guidance Regulates Off-Label Drug Use*, NAT'L L.J., Mar. 15, 1999, at B7.

collateral sources of risk information.¹³⁹ The result has been a dramatic increase in the number and controversial nature of drug advertisements.¹⁴⁰

A regulatory compliance defense should not apply in this context because “the contention is that an independent basis exists for holding the product supplier responsible that shows no disregard for the expertise brought to bear in framing the label or to the virtues of uniformity – a contention asserting in effect that the . . . company has consciously fostered inattention to the warnings on the package.”¹⁴¹ *Stevens v. Parke, Davis & Co.*¹⁴² provides an illustration of such a claim where the court held:

Although the manufacturer or supplier of a prescription drug has a duty to adequately warn the medical profession of its dangerous properties or of facts which make it likely to be dangerous, an adequate warning to the profession may be eroded or even nullified by overpromotion of the drug through a vigorous sales program which may have the effect of persuading the prescribing doctor to disregard the warnings given.¹⁴³

This scenario is simply not within the purview of the regulatory compliance defense. All of these additional issues further buttress the position that as written, M.C.L. § 600.2946(5) is not well-founded.

CONCLUSION

In the end, it is telling that other jurisdictions have not followed Michigan’s lead in providing a virtual immunity from products liability for pharmaceutical manufacturers via the

¹³⁹ Rabin, *supra* note 16, at 2080 (explaining that “drug companies were provided the option of satisfying agency requirements by providing a toll-free number through which the information was available, by making reference to availability from a health professional, by providing internet access to information, or by providing the information through secondary availability of printed materials”).

¹⁴⁰ *See id.* (“In the new advertising climate, prominent figures from the world of sports, entertainment, and politics extol the benefits of products such as Viagra and Propecia that promise a lifestyle makeover. Promotional ads likewise offer promises to alleviate the miseries of individuals suffering from maladies ranging from allergies to rheumatism. Correspondingly, pharmaceutical company budgets for print and TV advertising aimed at potential consumers have risen steadily from \$595 million in 1996 to \$1.3 billion in 1998.”).

¹⁴¹ *See id.* at 2081.

¹⁴² 507 P.2d 653 (Cal. 1973)

¹⁴³ *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 661 (Cal. 1973).

regulatory compliance defense. Numerous policy considerations weigh heavily against such a defense and FDA approval is simply not an adequate foundation for providing immunity to pharmaceutical companies. Put simply, despite the arguments in favor of Michigan’s regulatory compliance defense, such a defense is “seriously compromised by real-world considerations. . . . [and] [p]rescription drug injury claims frequently arise under circumstances that fall outside the scope of the ‘comprehensive’ regulatory scheme.”¹⁴⁴ Consequently, the Michigan legislature should take appropriate actions by either repealing or modifying M.C.L. § 600.2946(5) and do away with its current regulatory compliance defense.

¹⁴⁴ Rabin, *supra* note 16, at 2082.