IN THE SUPREME COURT

(ON APPEAL FROM THE MICHIGAN COURT OF APPEALS)
(Collins, P.J. (not participating), and Murphy and Jansen, JJ.)

TAMARA TAYLOR, LEE ANNE RINTZ,
Plaintiffs-Appellees,

v S.C. Nos. 120637-120641

GATE PHARMACEUTICALS,
Defendant-Appellant,

and

ABANA PHARMACEUTICALS, INC., RICHWOOD PHARMACEUTICAL COMPANY, INC., ION LABORABORIES, INC., SMITHKLINE BEECHAM CORPORATION, ZENITH GOLDLINE PHARMACEUTICALS, INC., INTERNEURON PHARMACEUTICALS, INC., CAMALL COMPANY, LABORTORIES SERVIER, MEDEVA PHARMACEUTICALS, INC., A.H. ROBINS COMPANY, INC., WYETH-AYERST LABORATORIES COMPANY, AMERICAN HOME PRODUCTS CORPORATION, and ALL MICHIGAN PHYSICIANS WHO PRESCRIBED OR GAVE FEN-PHEN AND/OR REDUX TO MICHIGAN PATIENTS,
Defendants.
_____/

DEFENDANT-APPELLANT GATE PHARMACEUTICAL, INC.'S BRIEF ON APPEAL IN DOCKET NOS. 120624-54 (TAYLOR) AND 120646 (ROBARDS)

***** ORAL ARGUMENT REQUESTED *****

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AUG 27 2002
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JUDITH H. ROBARDS and KENNETH W. ROBARDS,
Plaintiffs-Appellees,

v

S.C. Nos. 120641

GATE PHARMACEUTICALS,
Defendant-Appellant,

and

JOYCE E. KAFERLE, M.D., EVELYN ECCLES, M.D., SMITHKLINE BEECHAM CORPORATION, ZENITH GOLDLINE PHARMACEUTICALS, INC., ABANA PHARMACEUTICALS, INC., RICHWOOD PHARMACEUTICAL COMPANY, ION LABORATORIES, INC., MEDEVA PHARMACEUTICALS, INC., A. H. ROBINS COMPANY, INC., AMERICAN HOME PRODUCTS CORPORATION, WYETH-AYERST LABORATORIES, INC., PARMED PHARMACEUTICALS, INC., EON LABS MANUFACTURING, INC., and LABORATORIES SERVIER,
Defendants.
_____/

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I. BASIS OF JURISDICTION OF THE MICHIGAN SUPREME COURT/DATE AND NATURE OF ORDER APPEALED FROM

The Michigan Supreme Court has jurisdiction in this matter pursuant to MCR 7.301(A)(2) and MCR 7.302(B)(1), 7.302(B)(3) and 7.302(B)(5). This Court granted leave to appeal to Defendant-Appellant Gate Pharmaceuticals ("Gate"), Division of Teva Pharmaceuticals USA, Inc. in connection with the Court of Appeals published decision which was issued on November 30, 2001 and reported at 248 Mich App 472; 639 NW2d 45 (2001).

This appeal involves a substantial question as to the *validity of a legislative act*, namely the constitutionality of MCL §600.2946(5). Secondly, this appeal involves *legal principles of major significance* to the State's jurisprudence. Thirdly, the Court of Appeals' Opinion as published is *clearly erroneous* and will *cause material injustice* by allowing drug product liability litigation over a product such as Phentermine, which has been determined to be effective and reasonably safe.

The Court of Appeals published an Opinion based upon a decision rendered by two of the three Court of Appeals Judges who heard oral argument. The Presiding Judge at the time of oral argument, Judge Jeffrey G. Collins, did not participate in the decision, presumably as a result of his appointment as U.S. Attorney for the Eastern District of Michigan. Judge William Murphy authored the Opinion which was joined by Judge Kathleen Jansen. The Court of Appeals issued its Opinion in response to consolidated appeals arising out of separate Trial Court Orders in Wayne Circuit Court and Washtenaw County Circuit Court. In one instance, the Court of Appeals Opinion *affirms* the Wayne County Circuit Court Opinion of Judge Marianne Battani denying

Motions for Summary Disposition filed by Defendant pharmaceutical manufacturers. The Court of Appeals Opinion *reverses* the Order of Summary Disposition *in favor* of the Defendants-Appellants as entered by Washtenaw County Circuit Court Judge David Swartz.

II. STATEMENT OF QUESTION PRESENTED

WHETHER THE MICHIGAN LEGISLATURE'S ADOPTION OF MCL 600.2946(5); MSA 27A.2946(5), AS PART OF TORT REFORM LEGISLATION, PROVIDES AN AFFIRMATIVE DEFENSE TO CIVIL LIABILITY FOR MANUFACTURERS AND SELLERS OF DRUGS WHICH ARE PROPERLY APPROVED FOR SAFETY AND EFFICACY BY THE FDA WITHOUT ANY IMPERMISSIBLE DELEGATION OF LEGISLATIVE AUTHORITY UNDER THE MICHIGAN CONSTITUTION?

Defendant-Appellant Gate Pharmaceutical says "yes".

Plaintiffs-Appellees say "no".

The Wayne County Trial Court in *Taylor* says "no".

The Washtenaw County Trial Court in Robards says "yes".

The Michigan Court of Appeals says "no".

III. STATEMENT OF FACTS

Two separate, but nearly identically plead lawsuit Complaints involving drug product liability claims were filed by Plaintiffs Taylor/Rintz in Wayne County Circuit Court and Plaintiff Robards in the Washtenaw County Circuit Court. In both the Trial Court and on appeal the Plaintiffs have referred to the several Defendant Manufacturers' products as "Fen-Phen", a phrase which does not describe any one drug product manufactured by Gate Pharmaceutical or any of the other numerous drug manufacturers sued by the Plaintiffs. Gate Pharmaceutical and a number of other drug companies manufactured and/or distributed a product generically known as "Phentermine Hydrochloride". Other pharmaceutical companies manufactured and/or distributed the drugs "fenfluramine" and/or "dexfenfluramine" which are very different from phentermine hydrochloride. The Plaintiffs maintain in the underlying cases that they were injured as result of their ingestion of either fenfluramine or dexfenfluramine alone or alternatively, *in combination with* a phentermine product as a treatment for obesity. The latter combination gave rise to the **Fen-Phen** label.

Gate Pharmaceutical distributed its "phentermine hydrochloride" product under the brand name "Adipex-P" which has been approved for safety and efficacy by the Federal Food and Drug Administration ("FDA") for decades prior to the Michigan legislature's adoption of the subject tort reform legislation, including MCL 600.2946(5). Phentermine hydrochloride continues to remain on the market under various brand names as an FDA approved drug.

Gate Pharmaceutical and other Defendant drug manufacturers sought dismissal of Plaintiffs-Appellees' lawsuit Complaint in separate Wayne and Washtenaw Circuit

Court actions based upon the affirmative defense that their products had been approved for safety and efficacy by the FDA, consistent with MCL §600.2946(5); MSA §27A.2946)(5). The subject statute provides inter alia that, *subject to certain exceptions*, a manufacturer or seller of a drug is not liable in a product liability action if the drug was approved for safety and efficacy by the FDA **and** the drug and its labeling were in compliance with the FDA's approval at the time the drug left the control of the manufacturer and seller. At no time in these proceedings have plaintiffs alleged that any of the exceptions to the statutory defenses contained in MCL §600.2946(5) apply to Gate or any other Defendant. Thus, if constitutional, the statute itself sets forth a limitation on the cause of action against Defendants-Appellants that Plaintiffs otherwise attempt to maintain. In both of the cases pending in Wayne County Circuit Court and Washtenaw County Circuit Court, all of the parties agreed, with the Trial Court's approval, to the Court's consideration of the Plaintiff's constitutional challenges to the statute itself. In each case, one or more Defendant manufacturers filed Motions for Summary Disposition with timely and permissible joinders filed by other manufacturers in such dispositive motions. Plaintiffs in each case opposed the Defendant manufacturers' Motion for Summary Disposition on several grounds allegedly based upon the Michigan Constitution.

A. Trial Court Rulings.

In the Wayne County Circuit Court action, following briefing and hearing (Transcript of the September 11, 1998 Hearing, Apx 185a), Circuit Court Judge Marianne Battani issued her November 24, 1998 Opinion (Apx 115a) denying *all of the plaintiffs' challenges* to MCL §600.2946(5), and to the underlying Tort Reform Act,

except one. In the latter regard, Judge Battani wrote in her opinion that, "in summary, the court finds that Section 2946(5) is unconstitutional *because it improperly delegates to the FDA the legislative function of determining what is a cause of action*." (Apx 115a at p. 16). Based upon this finding, the Trial Court entered its Order, dated January 8, 1999 (Apx 131a) denying Defendants' Motion For Summary Disposition.

In the Washtenaw County action, Co-Defendant American Home Products Corporation (Wyeth) filed a Motion for Summary Disposition on December 14, 1999. The remaining Defendant manufacturers, including Gate, joined in that Motion through formal concurrence and joinders. On February 23, 2000, Plaintiff answered the Motion for Summary Disposition, and *conceded that §2946(5) applies and that none of the exceptions listed in the statute applied to Plaintiff's case*. On March 15, 2000, the Trial Court entertained oral argument on the Motion for Summary Disposition and thereafter ruled that MCL §2946(5) *is constitutional*. A conforming Order was entered on April 12, 2000 (Apx 135a).

B. <u>Court of Appeals Ruling</u>.

The November 30, 2001 Opinion of the Michigan Court of Appeals, signed by two of its members, states that the Court of Appeals was "presented *a close question*: is MCL 600.2946(5) constitutionally infirm under Constitution 1963, Article IV, § 1, as an unlawful delegation of legislative authority?" (Opinion, p. 6, Apx 115a). The Court of Appeals Opinion *affirms* the summary disposition ruling of the Wayne Circuit Court and *reverses* the summary disposition Order of the Washtenaw Circuit Court. The Opinion also explicitly states an attempt to "briefly address Defendants' most detailed and *seemingly compelling argument* in favor of finding MCL 600.2946(5) constitutional."

C. Content of MCL 600.2946(5); MSA 278.2946(5) – Legislative History

Gate and other Defendant manufacturers sought dismissal of Plaintiffs' complaints based on MCL §600.2946(5). This 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 **Food and Drug Administration**, *and the drug and its labeling were in compliance with* the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller. However, this subsection does not apply to a drug that is sold in the United States after the effective date of an order of the United States food and drug administration to remove the drug from the market or to withdraw its approval. This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following: (a) intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act, chapter 675, 52 Stat. 1040, 21 U.S.C. 301 to 321, 331 to 343-2, 344 to 346a, 347, 348 to 353, 355-360, 360b to 376, and 378 to 395, and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted. (b) makes an illegal payment to an official or employee of the United States food and drug administration for the purpose of securing or maintaining approval of the drug.

The statute provides that, subject to certain exceptions, a manufacturer or seller of a drug is not liable in a product liability action if the drug was approved for safety and efficacy by the FDA and the drug and its labeling were in compliance with the FDA's approval at the time the drug left the control of the manufacturer and seller. Plaintiffs admitted in each of the consolidated cases that: (1) the drugs at issue were labeled in compliance with FDA requirements; and (2) Plaintiffs-Appellees have not pled any of the statutory exceptions to non-liability resulting from the statutory defense.

MCL 600.2946(5); MSA 27A.2946(5) is but *one part of one section* of the Michigan Legislation *governing products liability actions.* Prior to the Michigan Legislature's adoption of Public Act 1995, No. 161, effective March 28, 1996, product liability actions were legislatively defined in Section 2945 of the Michigan Compiled Laws (MCL §§ 600.2945; MSA 27A.2945). *The former statute* contained several sections, including MCL 600. 2945 -2949.

The former MCL 600. 2945 specifically defined "products liability action" as meaning:

> "An action based on *any legal or equitable theory of liability*" brought for or on account of death or injury to personal property caused by or resulting from the manufacture, construction, design, formula, development of standards, preparation, processing, assembly, inspection, testing, listing, certifying, warning, instructing, marketing, advertising, packaging, or labeling of a product or a component of a product." (Emphasis added)

Former Section 2946 set forth the Michigan Legislature's determination that certain evidence would be admissible in products liability actions and provided in MCL 600.2946(2); MSA 27A.2946(2) as follows:

> "(2) It shall be admissible as evidence in any products liability action that the manufacture, construction, design, formula, development of standards, preparation, processing, assembly, inspection, testing, listing, certifying, warning, instructing, marketing, advertising, packaging, or labeling was done ***pursuant to the federal and state law, rules, or regulations in effect*** at the time the product was sold or delivered by the defendant to the initial purchaser or user."

The aforesaid reference by the Michigan Legislature to the "**federal** and state law, rules, or regulations", was never found by this Court to be an unconstitutional delegation of *legislative* authority to any other state or federal agency. Furthermore, former Section

2946(1) legislatively provided that it was permissible to submit in a products liability action evidence of compliance with "generally recognized and prevailing non-governmental standards". (MCL 600.2946(1); MSA 27A.2946(1)). This Court has never determined that such reference to "non-governmental standards" constituted any kind of improper or unconstitutional delegation of *legislative* authority by the Michigan Legislature.

In 1995, the Michigan Legislature took up a review of the product liability statute as part of an overall tort reform analysis. Legislators in both the Michigan House of Representatives and Michigan Senate undertook to study and debate the then current tort law provisions governing product liability litigation. The Legislature reviewed criticisms of the product liability law and tort law system in general as they related to the stifling of product innovation, the restriction on the availability of goods and services, and the reduced competitiveness of Michigan businesses acting as manufacturers or sellers of products. The legislative history of MCL 600.2946(5) includes the Michigan Legislature's review of a number of broad policy considerations as part of the Legislature's mandate. A House Analysis Report states:

> . . . Critics [of the tort system] claim that defendants are sometimes victims of "junk science" – theories of causation propagated by professional expert witnesses outside the scientific mainstream but convincing to juries of ordinary citizens . . . The uncertainty and fear that surround the arena of product liability inhibits the development and introduction of new products, critics say, including products with great utility in the prevention of illness and disease.

House Legislative Analysis Section Report on Senate Bill 344 (H6) first analysis dated 6/8/95 at 1. (Emphasis added).

The Report further states with regard to MCL 600.2946(5):

> . . . The [House Substitute Bill] does contain the *absolute defense language* for a manufacturer or seller of drugs that are FDA approved. . . . The Bill says, moreover, that drug companies whose products receive FDA approval for safety and effectiveness are not liable unless the product deceived the government in the approval process. Drug companies spend large sums of money and expend enormous energy getting approval of 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 . . . (Id. at p. 8-10).

A Senate Fiscal Agency Bill Analysis on Senate Bill 344, Date Completed 8/28/95, states at 9-10:

> It is unfair to deem a product defective when it conforms to *all government standards*, especially if the product has been *tested under the oversight of a Federal or state agency*. These *standards are promulgated after intense public scrutiny, expert evaluation*, and thorough product evaluation. Lay jurors should not be allowed to second-guess a standard that has been developed by government experts. . .

The Michigan Legislature carried out its legislative duties by conducting public debate and review of product liability issues and then formulating statutory definitions and guidelines by which product liability actions are to be governed. The Michigan Legislature properly and constitutionally adopted a series of amendments to the product liability statute which became effective March 28, 1996. Section 2945(h) now defines "product liability action" as meaning:

> 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. MCL 600.2945(h).

The Michigan Legislature ***did not*** through the amendments to the product liability statutes eliminate the right to maintain a product liability cause of action.

It is important for purposes of this review that the content of MCL 600.2946(5) be clear in terms of what *it does* and *does not provide for*. It does ***not***:

(1) Establish the requisite elements of a drug product liability action in general; or

(2) Prohibit a claimant from maintaining a products liability lawsuit which satisfies all of the elements of a common law products liability action where a product has not been properly approved by the Federal food and drug administration; or

(3) Prohibit a cause of action from being maintained and litigated where non-compliant drug product labeling exists; or

(4) Preclude the litigation of a product liability drug claim when either one of the two proscribed activities on the part of a drug manufacturer exists as referenced in MCL 2946(5)(a) or (b).

What the content of MCL 600.2946(5) ***does*** do is provide an *affirmative defense barring liability where:*

> A drug manufacturer/seller has complied with ***both*** FDA drug approval procedures and labeling requirements prior to the sale of the subject drug.

Not unlike the bar of a statute of limitations, or a statute of repose, MCL 600.2945(5) provides a bar to civil liability in circumstances where the legislature has determined it to be appropriate to provide affirmative relief to litigation defendants.

IV. ARGUMENT

MCL §600.2946(5) IS CONSTITUTIONAL AND DOES NOT CONSTITUTE AN IMPROPER DELEGATION OF LEGISLATIVE AUTHORITY.

A. Standard of Review.

The issue decided erroneously by the Michigan Court of Appeals is one of first impression in Michigan. It is extremely important to the jurisprudence of the State to have the highest Court determine the constitutionality of a statute which significantly impacts commerce within the State as well as litigation involving drug products.

This Court reviews the constitutionality of a statute de novo. See McDougall v Schanz, 461 Mich 15; 597 NW2d 148 (1999) and Wickens v Oakwood Health Care System, 465 Mich 53, 59; 631 NW2d 686 (2001). Under Michigan law, the Court must uphold a statute unless it plainly appears to be in violation of constitutional principles. Thayer v Michigan Dept of Agriculture, 323 Mich 403; 35 NW2d 360 (1949). In passing on the constitutionality of a statute, the court should not consider whether it is in harmony with the common law because the legislature may alter or repeal the common law. Bowerman v Sheehan, 242 Mich 95; 219 NW 69 (1928). The validity of the statute must be sustained unless it is prohibited by the express language of the Constitution or by necessary implication, and a statute should not be declared unconstitutional unless the conflict between the Constitution and the statute is palpable and free of doubt. Evans Products Co v Fry, 307 Mich 506; 12 NW2d 448 (1943). Accordingly, the court should not decide against the validity of a statute unless it is clearly convinced that it conflicts with the constitution. Fifield v Close, 15 Mich 505 (1867). Every reasonable doubt is to be resolved

in favor of the constitutionality of a legislative enactment. Dation v Ford Motor Co, 314 Mich 152; 22 NW2d 252 (1946).

B. The Michigan Legislature Itself Determined Who Can Maintain A Cause Of Action and Properly Provided for An Affirmative Defense to Such Cause of Action.

The Court of Appeals Opinion is erroneous in affirming the Wayne County Trial Court's decision to deny Defendant-Appellant's Motion for Summary Disposition, and is based upon a flawed analysis of what the Plaintiffs maintained was an impermissible delegation of legislative authority. MCL 600.2946(5) resulted from an appropriate and constitutional exercise of the Michigan Legislature's authority to enact the laws of this State as provided for in the Michigan Constitution 1963, Article IV, Section 1. It is the State Legislature's responsibility to decide the wisdom of what statutory schemes shall best govern conduct in this State. Manistee Bank and Trust Co v McGowan, 394 Mich 655, 666; 232 NW2d 636 (1975). Common law rights may be modified or abolished by the Michigan Legislature. In re Midland Publishing Co Inc., 420 Mich 148, 362 NW2d 580 (1984). Furthermore, the power to abrogate a common law cause of action is within the province of the Legislature. Anderson v City of Detroit, 54 Mich App 496; 221 NW2d 168 (1974); lv app den; Shavers v Kelly, 402 Mich 554; 267 NW2d 72 (1997). "Legislative power" has been defined in Michigan as the authority to make, alter, amend and repeal laws. *See* Harsha v City of Detroit, 261 Mich 586, 590; 246 NW2d 849 (1933).

The Michigan courts have repeatedly held that the delineation of substantive rights, and in particular, the scope of any alleged duties of pharmaceutical manufacturers, is properly within the authority of the Michigan Legislature. In re

Certified Questions, 419 Mich 686, 691-692; 358 NW2d 873 (1984). MCLA 600.2946(5) is a clear expression of the Legislature's own determination of what constitutes an appropriate statutory framework for product liability actions which can be brought against pharmaceutical manufacturers and sellers and what conduct on the part of such manufacturers and sellers will give rise to defenses to such causes of action.

As the Michigan Supreme Court has recognized, the Michigan Legislature is uniquely well equipped to reach informed decisions about the need to legislatively balance broad public policy considerations and to weigh alternative statutory approaches in performing their law-making responsibilities accorded them by the Michigan Constitution. The Michigan Supreme Court held in Glancy v City of Roseville, 457 Mich 580, 589; 577 NW2d 897, 902 (1998) that:

> . . . The Legislature, with its ability to consider the testimony from a variety of sources and make compromise decisions, is much better positioned than the judiciary to consider such policy arguments and make policy choices. 'The responsibility for drawing lines in a society as complex as ours – of identifying priorities, weighing the relevant considerations and choosing between competing considerations is the Legislature's not the judiciary's. [citation omitted].

Pharmaceutical products provide a unique solution in many circumstances to significant health problems or medical conditions of state citizens justifying the passage by the Michigan State Legislature of laws such as MCL 600.2946(5). Pharmaceutical products with public health benefits depend heavily upon innovation. As a matter of federal law, the FDA predominantly controls a manufacturer's obligation to warn of the potential adverse effects of a product through regulation of product labeling. Extensive controls promulgated under the Federal Food, Drug and Cosmetic Act, 21 USC §301 et seq. (1988), form a complete regulatory framework for the labeling of prescription drugs.

The comprehensive federal regulatory regime carefully balances therapeutic risk and benefit in approving products on a case-by-case basis. There are pervasive reporting requirements, a comprehensive and detailed regime of regulatory controls, and strong market incentives to generate safer products. The activity in question – the production of products intended to improve the quality of life – contemplates the manufacture and sale of a uniform, nationally-marketed product under a regulatory scheme with its ultimate origin in the United States Constitution.

The Legislature's adoption of MCL 600.2946(5) was clearly an exercise of a legislative prerogative to make changes in Michigan product liability law. In setting substantive standards for conduct which may give rise to an affirmative defense to a cause of action against pharmaceutical manufacturers and sellers, the Legislature properly considered the effect of product liability legislation on drug product innovation, research funding, product costs and competitiveness. The Legislature properly enacted legislation which it determined would promote the development of products that may reduce disease and enhance the quality of life. Such Legislative endeavors are completely consistent with the Legislature's powers granted by the Michigan Constitution.

Defendants-Appellants are unaware of any constitutional provision which would have precluded the Michigan Legislature from adopting an entirely new product liability statute and statutorily establishing the elements necessary for a *prima facie* product liability cause of action. Consistent with the Legislature's prerogative to modify or abolish common law rights, such a statutory scheme would have been entirely appropriate and constitutional. The Plaintiffs-Appellees misdirected the lower court's

analysis in this matter by referring to the subject statute as *establishing a cause of action* and by arguing that the statutory scheme impermissibly delegates to the FDA the requisites for proceeding with such a cause of action. Such analysis misstates what in fact MCLA 600.2946(5) accomplishes.

It is instructive to review what was stated by a Federal District Court Judge for the Eastern District of Michigan, Northern Division, in reviewing the Michigan product liability statute in connection with the Federal Court's consideration of a summary judgment motion filed by a defendant drug manufacturer in 1998. Attached is a copy of United States District Court Judge Robert H. Cleland's March 23, 1998 Order Granting Defendants' Motion for Summary Judgment. In analyzing the Michigan product liability law, Judge Cleland states at p. 5-6 of his Opinion:

> Prior to March 28, 1996, Michigan law provided:
>
> **[a] 'products liability action' means an action based on any legal or equitable theory** of liability brought for or on account of death or injury to person or property caused by or resulting from the . . . warnings, instructing, marketing, advertising, packaging, or labeling of a product or a component of product . . .
>
> **This statute did not create a cause of action, but rather expressly presupposed the existence of a "theory of liability".** Lewin v McCreight, 655 F.Supp 282, 283 (E.D. Mich. 1987). As a result, liability under the statute was analyzed in the same manner as a common law products liability claim. Fisher v Kawasaki Heavy Industries, Ltd, 854 F. Supp 467, 475 N. 8 (E.D. Mich. 1994).
>
> **In 1995, however, this statute was rewritten and now provides definitions for:** alteration, drug, economic loss, gross negligence, misuse, non-economic loss, product, product liability action, and sophisticated user. P.A. 1995, No. 161, § 1;P.A. 1995,

> No. 249, § 1. "Product liability action" is presently defined as "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 a production of a product. "MCLA 600. 2945(h) . .
>
> The 1995 amendment also rewrote Sections 600.2946 and 600. 2947. Section 600.2946(5) provides:
>
> In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller. However, this subsection does not apply to a drug that is sold in the United States after the effective date of an order of the United States food and drug administration to remove the drug from the market or to withdraw its approval. This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following: (a) intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act, chapter 675, 52 Stat. 1040, 21 U.S.C. 301 to 321, 331 to 343-2, 344 to 346a, 347, 348 to 353, 355-360, 360b to 376, and 378 to 395, and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted. (b) makes an illegal payment to an official or employee of the United States food and drug administration for the purpose of securing or maintaining approval of the drug.

Judge Cleland's review of the amended product liability statute includes the following analysis at p. 8 of his Opinion:

> The current versions of both Sections 600.2945 and 600. 2946 confirm that ***no cause of action is created by the statutes***. As such, Michigan common law governing products liability is a theory of liability which Plaintiff must prove in this case. (Emphasis added).

Defendant-Appellant respectfully submits that Judge Cleland's logical analysis of the pertinent product liability sections provide an appropriate judicial view that MCL 600.2945-600.2946 does not even establish the requisite elements of a product liability cause of action. Instead, the current statutory scheme recognizes and accepts the existence of product liability actions which by common law are based upon a negligence or warranty theory. *See* generally the Michigan Standard Jury Instructions governing product liability actions, including SJI 25.01-25.45. Product liability claimants may continue to maintain their causes of action against product manufacturers and sellers, subject to all of the affirmative defenses that are made available under common law or by statute. The Michigan Supreme Court Committee on Standard Jury Instructions states in its product liability "Introductory Directions to the Court" as follows:

> The following are products liability instructions for cases involving express and implied warranties and negligent designs and/or manufacture. These instructions should be preceded by the applicable general instructions in Section 1 and the applicable instructions in Chapters
> 10-17 in Section 2 . . .
>
> Where the Plaintiff is pursuing several theories, which may include a basic negligence claim, the Court should indicate that there are alternative or concurrent theories. Greater clarity may be achieved by discussing the several theories in the space provided in SJI2d 7.01 Issues for The Jury and Theories of the Parties . . .

> Two public acts passed in late 1995 affect the products liability area, 1995 PA 161 and 249. 1995 PA affects tort actions generally, while 1995 PA 249 focuses on products liability actions specifically. Some of the provisions of 1995 PA codify existing principles of law and others represent a significant departure. Several provisions limit liability and damages in cases involving drugs or other products that comply with federal or state standards or that have received approval of certain federal or state agencies. Issues may arise that are not covered by the instructions in this chapter. In such cases, it may be appropriate for the trial judge to give additional instructions.

MCL 600.2946(5) simply outlines as one such affirmative defense the approval of a drug for safety and efficacy by the United States Food and Drug Administration. This statutory defense also requires a drug to have product labeling fully approved by the U.S. Food and Drug Administrations at the time that the drug left the control of the manufacturer or seller. If a drug manufacturer has not obtained such FDA product approval, the affirmative defense will not apply. Even if such FDA approval was obtained but the drug manufacturer or seller did not supply FDA approved labeling with the drug, no affirmative defense under the subject statute will avoid liability for the defendant manufacturer or seller of the drug. Additionally, the FDA approval/compliance affirmative defense is not available to manufacturers or sellers who fall within the statutory exceptions as set forth in MCL 600. 2946(a) or (b).

In contrast, and contrary to the Court of Appeals Opinion in the Taylor and Robards cases, the FDA exercises no legislative power. Under MCL §600.2946(5), the FDA is not empowered to, nor does it, make, alter, amend, or repeal Michigan law. The FDA is not empowered to, nor does it, engage in the competing policy analysis, and policy choice, that the Michigan Legislature undertook when it evaluated the state of

product liability claims in Michigan. The FDA is not empowered to, nor does it, determine the substantive standards for Michigan causes of action against drug manufacturers and sellers. Under MCL §600.2946(5), the FDA does not control who can or cannot bring a lawsuit. The Legislature made that substantive decision as its own prerogative to make, alter or repeal laws, or to make basic policy. The Michigan Legislature constitutionally exercised those legislative powers when it adopted MCL §600.2946(5).

C. MCL §600.2946(5) Permissibly Incorporates By Reference FDA Approval of Drug Products in Determining a Statutory Defense to Product Liability.

In MCL §600.2946(5), the Michigan Legislature properly incorporated by reference FDA approval of the efficacy and safety of drugs, to be used in implementing the statute. As a longstanding principle of Michigan law, such incorporation by reference is not an unconstitutional delegation of legislative authority. See e.g. City of Pleasant Ridge v Governor, 382 Mich 225, 244-46; 169 NW2d 625 (1969). (Statute incorporating Federal Highway Standards was held constitutional).

By adopting MCL §600.2946(5), the Michigan Legislature determined that the FDA's decision concerning approval of drugs, under a federal statutory scheme ultimately unrelated to any decision concerning who can or cannot sue, was an appropriate threshold for the Legislature's **own** determination of who could maintain a cause of action, and under what circumstances. The FDA's approval of a drug for safety and efficacy deals with a different subject and purpose than MCL §600.2946(5), and the FDA determinations are exclusively within the federal sphere, such that they cannot be affected by Michigan law. In addition, the FDA is an independent agency guided by

objectives unrelated to the Michigan statute, and the FDA's drug approval decisions have significance independent of the operation of MCL §600.2946(5). Accordingly, the reference to an independent determination by the FDA does not delegate any of the Michigan Legislature's power to make, amend, alter or repeal the basic policy decision of the Legislature itself. The Legislature's incorporation by reference of such laws, process, and outcome was and is fully appropriate and constitutional. City of Pleasant Ridge, *supra*, 382 Mich at 244.

MCL §600.2946(5) also contains procedural safeguards such that the FDA will not in any way dictate Michigan policy. It is also true that the Legislature may confer fact-finding and status-finding duties to another entity without offending the Michigan Constitution. As the Court stated in City of Livonia v Department of Social Services, 423 Mich 466, 502; 378 NW2d 402 (1985):

> The legislature cannot delegate its power to make a law; but it can make a law to delegate a power to determine some fact or state of things upon which the law makes, or intends to make, its own action depend. To deny this would be to stop the wheels of government...[Id., quoting Locke's Appeal, 72 Pa 491, 498-499 (1873).]

As set forth above, in enacting MCL §600.2946(5), among other policy choices, the Legislature intended to enhance the development and marketing of new and innovative medications and treatments. Use of FDA drug approval as a threshold is rationally related to the Legislature's goal that manufacturers and sellers of FDA-approved, innovative medicines should be encouraged to make the treatments more readily available.

The Legislature must be allowed to set standards that are "flexible and practicable enough so that those standards can be adapted to conditions that involve

details with which the Legislature cannot deal with practically on an individual basis." Petrus v Dickinson County Board of Commissioners, 184 Mich App 282, 294-295; 457 NW2d 359 (1990). The trend has been toward allowing legislatures to adopt the standards of others and to delegate "fact-finding" or "status determinations." See, e.g., City of Detroit v Detroit Police Officers Association, 408 Mich 410, 435 n 3; 294 NW2d 68, 72 (1980). Consequently, the Michigan Constitution allows the Legislature to set standards that are "flexible and practicable" enough to be "adapted to conditions that involve details with which the Legislature cannot deal practically on an individual basis." Petrus, *supra*, 184 Mich App at 294-295.

Finally, because MCL §600.2946(5) does not delegate the power to the FDA to decide or alter policies of statewide concern, it should not be construed as delegating **legislative** authority. At most, the statute's reference to FDA drug approval is a permissible incorporation of standards of conduct by reference to federal law, as well as an adoption of a determination as to the "state of things upon which the law makes, or intends to make, its own action depend." See, Department of Natural Resources v Seaman, 396 Mich 294, 308; 240 NW2d 206, 210 (1976). Accordingly, MCL §600.2946(5) does not constitute an improper delegation of legislative authority in violation of the Michigan Constitution.

1. Appellees' Reliance Upon Coffman and Colony Town Club Decisions.

The Plaintiffs-Appellees' position in the Trial Courts and before the Court of Appeals has been based upon an inappropriate interpretation of the Michigan Supreme Court decisions in Coffman v State Board of Examiners and Optometry, 331 Mich 582; 50 NW2d 322 (1951) and the Michigan Supreme Court's earlier decision in Colony Town Club v Michigan Unemployment Compensation Comm, 301 Mich 107; 3 NW2d 28 (1942), a decision referenced in the Coffman case. The Court of Appeals' Opinion in the present appeal refers to each of these opinions in its analysis that results in the stated conclusion that legislative delegation to governmental agencies established under Michigan law are allowable while delegations to foreign agencies are not. Taylor, *supra* at p. 482.

In Coffman, supra, the Michigan Supreme Court reviewed a *writ of mandamus* to compel a state board of examiners in optometry to permit the claimant to take a licensing examination. The claimant graduated from an Illinois College which did not meet the rating requirements of the "international association of boards of examiners in optometry" as provided by MCL § 338.253. Another related statute MCL 338.251; MSA 14.641 also specifically provided that the state board of examiners in optometry, a state board which was different from the international association of boards of examiners, was "authorized to make rules and regulations governing the practice of optometry and such other rules as may be necessary to carry out the provisions of the act." Coffman, at p. 586. The Court observed that the state optometry board adopted a rule which raised the statutory minimum educational requirement from two years of course work to at least four years at a university, school or college approved by the state board. The Court, in dicta, observed that the Michigan Attorney General had approved the rule

adopted by the state optometry board in 1944. In 1951, the Attorney General issued an Opinion stating that the provision of MCL 338.253 which required a licensing applicant to be a graduate of a college rated by the international association of board of examiners in optometry was void as an attempted delegation of legislative power. Both the Plaintiff and Defendants in Coffman accepted the ruling of the Attorney General, including the Attorney General's Opinion that the removal of that portion of MCL 388.253 said to constitute an *ultra vires* act would not effect the remaining validity of the statute. The Michigan Supreme Court then held that the subject statute, MCL 338.253, would be interpreted (and restated) to provide for an educational prerequisite consistent with the express language of the statute. (See p.588 of the Coffman Opinion, setting forth the restatement of the subject statute).

Important to the present analysis, is the understanding that in Coffman, the Court was concerned about the adoption of rules and regulations by a board which *was inconsistent* with the very statute which provided for the establishment of requisite educational requirements as part of a professional licensing scheme. The Court in Coffman was clearly concerned about a board exercising authority given to it by the legislature which conflicted with the provisions set forth in the enabling statute. However, consistent with the position of the Defendants-Appellants in the instant case, the Supreme Court in Coffman recognized the right of the legislature to rely upon an administrative agency to adopt rules and regulations "to effectuate the purposes" of legislation. The Coffman Opinion states at pp. 588-589:

> There is no question but that the legislature, acting under its police power, has the power and authority to prescribe minimum requirements for those who seek to become optometrists. . .

> The right to allow an administrative agency to adopt rules and regulations to effectuate the purposes of the legislation is well recognized. See, United States v Grimaud, 220 U.S. 506 (31 SCt. 480, 55 L Ed 563); People v Soule, 238 Mich 130; Sherlock v Stuart, 96 Mich 193 (21 LRA 580).

The Coffman Opinion also refers to a number of additional case opinions and legal treatises, including Am Jur, in support of the accepted legal principle that it is perfectly permissible for the Michigan State Legislature to confer upon an administrative agency the right to adopt reasonable rules and regulations as long as the same do not exceed the powers given to the agency through the enabling statute which constitutes the source of its empowerment. At p. 590 of its Opinion, the Coffman Court refers to the Michigan Supreme Court's earlier decision in Argo Oil Corporation v Atwood, 274 Mich 47; 264 NW 285 (1935), wherein it was stated:

> "'It is too well settled to need the citation of supporting authorities that the legislature, within limits defined in the law, may confer authority on an administrative officer or board to make rules as to details, to find facts, and to exercise some discretion, in the administration of a statute'".

The Coffman Court goes on to conclude at p. 591: "It does not follow that the board cannot, within reason, adopt higher standards than the minimum set up in the legislation. We have examined the rule adopted by the board and conclude that it has a proper relationship to the legislative act. The rule does not deprive plaintiff of any personal property rights." The Coffman Court *rejected* the plaintiff's request for *writ of mandamus* and stated that the plaintiff's right to practice optometry was a privilege granted by the state and was subject to the statutory law and the reasonable and proper rules of the board.

The Court of Appeals in the present appeal also relied upon language contained in Colony Town Club v Michigan Unemployment Compensation Comm, 301 Mich 107; 3 NW2d 28 (1942), as a basis for concluding that case law has been established to make a distinction between delegations to governmental agencies established under Michigan law and delegations to foreign agencies or private entities. The Court of Appeals in Taylor states at p. 482 of its Opinion:

> While the former are allowable, the latter run afoul of the constitutional prohibition against delegation of legislative power because the Michigan legislature retains no oversight function and is unable to guide the exercise of its delegated power via the establishment of standards.

The Supreme Court in Colony reviewed the plaintiff's contention that the decision of the Internal Revenue Commissioner was binding upon a referee of the Michigan Unemployment Compensation Commission in connection with an employee's claim for unemployment benefits. The plaintiff relied upon an amendment of the state unemployment compensation statute which provided that the term "employment" shall exclude any service not included as "employment" under title 9 of the federal Social Security Act. The Plaintiff argued that an IRS determination that Plaintiff was exempt from social security and federal income taxes also required Michigan to provide an exemption from the payment of state unemployment compensation. The dictum in Colony Town Club relied upon by Plaintiffs-Appellees and Court of Appeals stated that P.A. 324, § 42, of Public Acts 1939 was unconstitutional *if* the statutory provision was given the construction claimed by the plaintiff for the reason that it attempted to delegate to a federal agency the final decision regarding the "interpretation and construction to be placed upon a state statute". The Plaintiff's interpretation and

construction of the state statute was rejected by the Supreme Court which states at p. 114:

> It is doubtful if the 1939 legislature intended to delegate such authority. This conclusion is justified by the fact that this amendment was changed by the 1941 legislature and the statute now in effect does not apply to the case at bar.

The lower court's reliance upon the dictum in Colony Town Club was inappropriate since statements in an opinion which are not necessary or essential to a determination lack the force of an adjudication. Hett v Duffy, 346 Mich 456, 461; 78 NW2d 284 (1956). The Court's statement of a hypothetical construction of a statute, together with a corresponding comment on the constitutionality of such construction, was gratuitous as the *sole issue* on appeal before the Court in Colony Club was stated at p. 110 of its Opinion:

> The issue thus raised, and **the only issue** now before us in this appeal, is concisely stated by counsel for the appellant ... "Is the Colony Town Club a corporation organized and operated exclusively for literary or educational purposes ... and therefore, in accordance with the provisions of section 47(7)(h) of the Michigan Unemployment Compensation Act exempt from the taxes imposed by said Act?" [Emphasis supplied.]

The Court in Colony Club was not presented by the parties before it with a constitutional analysis of a statute. The use of dicta from such an opinion as a justification for reaching a determination as to the constitutionality of MCL 600.2946(5) is contrary to a well reasoned legal analysis required for as important a matter as the validity of a legislative act.

Furthermore, the statutory scheme embodied by MCL 600.2946(5) does not delegate to a federal agency the final decision regarding the interpretation and construction to be placed upon a state statute as was argued by the Plaintiff in Colony Town Club. Instead MCL 2946(5) is a result of a deliberate decision by the Michigan Legislature to use FDA approval of a pharmaceutical drug as a benchmark for an affirmative defense *which does not conflict with the Legislature's own statutory scheme.*

2. Court of Appeals Reliance Upon Radecki Opinion.

The Court of Appeals' November 30, 2001 Opinion relies upon a 1994 Court of Appeals decision, Radecki v Workers Comp Director, 208 Mich App 19 (1994) which was not cited or argued by the Plaintiffs in either the Trial Court or the Court of Appeals. The Court of Appeals discusses near the end of its Opinion what the Court saw as a problem if standards incorporated by legislation are perceived to be established or changeable *in the future*. In reaching that analysis the Court of Appeals agrees with language from Radecki, supra, which states at p. 23:

> Statutes that incorporate existing *federal* statutes by reference *are valid and constitutional*. Pleasant Ridge v Governor, 382 Mich 225, 243-248; 169 NW2d 625 (1969); People v Urban, 45 Mich App 255, 262-263; 206 NW2d 511 (1973). However, it is an unlawful delegation of legislative power to adopt by reference *future legislation enacted by another sovereign entity*. Urban, supra.
>
> Thus, when a Michigan statute adopts by reference *a federal law that is subsequently amended*, but the Michigan statute remains unchanged, the Courts are *constitutionally required to construe the statute as continuing to refer to the original federal enactment before amendment.*

The Michigan Court of Appeals' analysis of Radecki, in terms of the language cited by the Court, does not in any way support a finding that the subject statute, MCL 600.2946(5) is anything but constitutional. Quoting directly from the Court of Appeals own Opinion in the instant case, it is clear that the Michigan legislature properly relied upon and incorporated by reference standards of conduct that were established to constitute affirmative defenses. The Court of Appeals states at p. 483 of its Opinion:

> Radecki thus acknowledges the propriety of so-called reference statutes, but firmly defines the limits of their acceptability: in enacting a new statute the Michigan Legislature *may rely on and incorporate by reference standards established by its sister states and the federal government*, but, as applicable to Michigan, those standards may only evolve by action of the Michigan Legislature.

The Court of Appeals concludes its Opinion by responding to the Defendant manufacturers assertion that the FDA determinations have legal consequences with independent, nationwide significance. The Court of Appeals states at pp. 484-485 of its Opinion:

> The short and simple response to this *almost convincing argument* is found on a test previously discussed in connection with the reference statutes. (citing Radecki).

The Court of Appeals Opinion continues:

> "Assimilation of standards adopted for a purpose separate from the incorporating legislation, and having independent significance, presents no problem if the standards are established and essentially unchanging."

The Court of Appeals analysis fails to discern that at most the Radecki decision constitutes a review of legislation and *a determination of the intent* of the legislature in failing to amend certain provisions of the Workers Disability Compensation Act. The

Radecki Court of Appeals panel was not in fact considering a constitutional challenge to the Workers Disability Compensation Act. The Radecki Court instead states at p. 23 of its Opinion:

> "Thus, when a Michigan statute adopts by reference a federal law that is subsequently amended, but the Michigan statute remains unchanged, the Courts are constitutionally required to construe the statute as continuing to refer to the original federal enactment before amendment. By failing to amend these Michigan statutes, the legislature is presumed to have intended to freeze the federal law as it was at the time of the original state statute....
>
> We conclude that, by failing to amend the Workers Disability Compensation Act to incorporate the 1986 federal tax reforms, the legislature intended the Act to continue to refer to the pre-1986 Internal Revenue Code...."

In the present case, Defendant Gate, and other Defendant manufacturers, had Phentermine products which had been approved by the FDA for decades *prior to the time* that the subject legislation was amended in 1996. There simply was no "changing standard" on the part of the FDA that could conceivably provide any basis for concern that the Michigan Legislature was abdicating its legislative authority to changing "future" federal legislation. Moreover, Radecki should not be read as containing a holding that suggests that *independent findings of the FDA in the future*, as they may relate to future products, constitutes "future legislation enacted by another sovereign entity". The obviously flawed analysis set forth in the Court of Appeals Opinion as arguably based upon Radecki, should be corrected by this Court. Defendants such as Gate that had FDA approved products at the time the 1996 legislation was enacted will otherwise

suffer an injustice which will otherwise result if the constitutionality of MCL 600.2946(5) is not upheld.

V. CONCLUSION AND RELIEF REQUESTED

MCL §600.2946(5) is constitutionally sound and does not constitute an improper delegation of legislative authority. The Plaintiffs-Appellees cannot overcome the presumption of constitutionality of the statute. Moreover, the legislative history of the subject product liability statute makes it clear that the Michigan Legislature appropriately devised a legislative scheme to support its broad social policy decision to provide an affirmative defense to product manufacturers who comply with FDA drug product approval and labeling requirements. The Michigan Legislature has adopted a statute as a constitutional exercise of its law-making authority. The Michigan Supreme Court upheld the constitutionality of another section of the tort reform legislation in McDougall v Schanz, 416 Mich 15; 597 NW2d 148 (1999). The majority in McDougall recognized the limits which are properly placed on the judiciary by the Michigan Constitution in reviewing the authority of the Legislature to adopt substantive law. The Supreme Court again recognized that the Legislature is authorized to change a common-law cause of action or abolish it altogether. This Court should also avoid any strained interpretation of MCL 600.2946(5) and recognize that the subject statute is the product of an appropriate Legislative initiative.

Appellant Gate therefore respectfully requests this Honorable Court to reverse the decision of the Court of Appeals, affirm the Washtenaw County Circuit Court Order Granting Summary Disposition to Defendants, and reverse the Wayne County Circuit Court's Order Denying Summary Disposition.

Respectfully submitted,

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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
NORTHERN DIVISION

FILED
MAR 23 3 45 PM '98

MILT LONDON and SYBIL LONDON,

Plaintiffs,

Case No: 97-CV-10099-BC

v.

SMITHKLINE BEECHAM
PHARMACEUTICALS,

Defendant.

_____/

ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

I. Introduction

This matter is before the court on defendant's motion for summary judgment. The issues have been fully briefed by both parties and oral argument was heard on February 25, 1998. The court finds that the case is ripe for disposition.

II. Background[1]

Plaintiff saw his family doctor, Dr. Letson,[2] on June 21, 1994, for a sinus infection. Dr. Letson diagnosed plaintiff as

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[1] The following facts serve as background to defendant's motion. Wherever "facts" are stated they are either not disputed by the parties or presented in the light most favorable to plaintiffs, as the nonmoving party.

[2] Dr. Letson is an ear, nose, and throat physician who has treated plaintiff since May, 1979. Dr. Letson and plaintiff are also social friends. (Letson Dep. at 30.)

having bacterial sinusitis and provided him with a twenty day supply of Augmentin[3] from the drug samples defendant's drug representative had provided. (Letson Dep, at 39, 44, 45, 52.) Dr. Letson also gave plaintiff a twenty day supply of Humibid.

On July 13, 1994, plaintiff phoned Dr. Letson to indicate that his sinus infection was still present. (*Id.* at 57.) Dr. Letson provided plaintiff with an additional ten day supply of Augmentin drug samples and Humibid. (*Id.*) Plaintiff's last day on Augmentin was July 23, 1994. (*Id.* at 60.) Plaintiff called Dr. Letson on August 3, 1994, to report that he had been jaundiced for four or five days and wondered about the side effects of the medications Dr. Letson had given him. (*Id.* at 61.)

Plaintiff was admitted to Saginaw General Hospital on August 4, 1994, for painless jaundice and reddish urine. (Pl. Ex. A.) Plaintiff was subsequently transferred to the University of Michigan Hospitals on August 18, 1994, and discharged September 28, 1994. (Pl. Ex. E.) Plaintiff experienced jaundice, cholestatic hepatitis, anemia, thrombocytopenia, liver disease, and renal

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[3] "Augmentin," a registered trademark of defendant SmithKline Beecham, is an oral antibacterial medication.

(kidney) failure. (*Id.*) Upon discharge from the University of Michigan, Dr. Howell wrote: "To the best of our understanding, this was most likely drug induced insult, and we recommended that [plaintiff] would not use Augmentin again." (*Id.*)

III. Standard

Under Rule 56 of the Federal Rules of Civil Procedure, summary judgment is proper when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. "Where the moving party has carried its burden of showing that the pleadings, depositions, answers to interrogatories, admissions and affidavits in the record construed favorably to the non-moving party, do not raise a genuine issue of material fact for trial, entry of summary judgment is appropriate." *Gutierrez v. Lynch*, 826 F.2d 1534, 1536 (6th Cir. 1987) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 91 L.Ed.2d 265, 106 S. Ct. 2548 (1986)). Summary judgment is not appropriate when "the evidence presents a sufficient disagreement to require submission to a jury." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251-52, 91 L.Ed.2d 202, 106 S. Ct. 2505 (1986). The existence of some factual dispute does not defeat a properly supported motion for summary judgment; the disputed factual issue must be material.

The burden placed upon the movant for summary judgment is to show that the non-moving party has failed to establish an essential element of its case upon which the non-moving party would bear the ultimate burden of proof at trial. *Celotex Corp.*, 477 U.S. at 322. But the moving party need not support its motion with affidavits or other similar materials "negating" the opponent's claim. *Id.* at 323. Once the moving party meets this burden, the burden passes to the non-moving party to establish, after an adequate opportunity for discovery, the existence of a disputed factual element necessary to its case with respect to which it bears the burden of proof. *Id.* at 323. The non-moving party must show that there is sufficient evidence for a jury to return a verdict in its favor, *Street v. J.C. Bradford & Co.*, 886 F.2d 1472 (6th Cir. 1989), *i.e.*, that there is doubt as to the material facts and that the record, taken as a whole, does not lead to a judgment for the movant. *Id.* at 1476. The non-moving party must present affirmative evidence on critical issues. *Id.* at 1477.

IV. Discussion

Plaintiff claims that defendant is liable for his injuries because it failed to adequately warn Dr. Letson about Augmentin's recently discovered dangers, specifically the risk of hepatic

dysfunction related to the liver. (Pl. Br. at 6.) Plaintiff argues that summary judgment is inappropriate because there is a factual and legal basis for his claim.

Defendant asserts that summary judgment is appropriate because Michigan law provides both a presumption and preemption theory negating liability. In addition, defendant claims that no proximate cause can be established because Dr. Letson testified that he would have prescribed Augmentin anyway. Furthermore, defendants argue that Michigan law regarding sophisticated users and the common law theory of learned intermediary precludes liability in this case since plaintiff received the Augmentin from his treating physician.

A. Michigan Law

Prior to March 28, 1996, Michigan law provided:

> [a] 'products liability action' means an action based on any legal or equitable theory of liability brought for or on account of death or injury to person or property caused by or resulting from the . . . warnings, instructing, marketing, advertising, packaging, or labeling of a product or a component of a product.

M.C.L.A. § 600.2945. This statute did not create a cause of action, but rather expressly presupposed the existence of a "theory of liability." *Lewin v. McCreight*, 655 F. Supp. 282, 283 (E.D.

Mich. 1987). As a result, liability under this statute was analyzed in the same manner as a common law products liability claim. *Fisher v. Kawasaki Heavy Industries, Ltd.*, 854 F. Supp. 467, 475 n.8 (E.D. Mich. 1994).

In 1995, however, this statute was rewritten and now provides definitions for: alteration, drug, economic loss, gross negligence, misuse, noneconomic loss, product, product liability action, product, and sophisticated user. P.A. 1995, No. 161, § 1; P.A. 1995, No. 249, § 1. "Product liability action" is presently defined as "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." M.C.L.A. § 600.2945(h). The 1995 amendments apply in the instant case since it was filed after March 28, 1996, the date the amendments became effective. P.A. 1995, No. 249, § 3.

The 1995 amendment also rewrote sections 600.2946 and 600.2947. Section 600.2946(5) provides:

> 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. . . . 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 not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.

(b) Makes an illegal payment to an official or employee of the United States food and drug administration for the purpose of securing or maintaining approval of the drug.

M.C.L.A. § 600.2946(5)(emphasis added). In addition, section 600.2947(4) states:

> Except to the extent a state or federal statute or regulation requires a manufacturer to warn, a **manufacturer** or seller is **not liable** in a product liability action **for failure to provide an adequate warning** if the product is provided for use by a **sophisticated user.**[4]

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[4] A "sophisticated user" is defined as "a person or entity that, by virtue or training, experience, a profession, or legal obligations, is or is generally expected to be knowledgeable about a product's properties, including a potential hazard or adverse effect." M.C.L.A. § 600.2945(j).

M.C.L.A. § 600.2947(2) and (4). The current versions of both sections 600.2945 and 600.2946 confirm that no cause of action is created by the statutes. As such, Michigan common law governing products liability is the theory of liability which plaintiff must prove in this case.

Under the common law in Michigan, a failure to warn claim requires plaintiff to show that defendant had a duty to make the warning, breached that duty, and that the breach of its duty to warn was the proximate cause of plaintiff's injury. *Fisher*, 854 F. Supp. at 472. Defendant can succeed on a summary judgment motion if it can establish that the duty was not breached or that the alleged breach of the duty to warn was not the proximate cause of the injuries alleged. Where causation is lacking, the question of duty to warn need not be addressed. *Id.*

A manufacturer of a prescription drug has a legal duty to warn the medical profession of any risks inherent in the use of the drug which the manufacturer knows or should know to exist. *Smith v. E.R. Squibb & Sons*, 405 Mich. 79, 88 (1979); *see also In re Certified Questions*, 419 Mich. 686, 692 & n.3 (1984) (stating that the manufacturer's duty to warn is not questioned); *Nichols v. Clare Comm. Hosp.*, 190 Mich. App. 679, 682 (1991). The

manufacturer is held to the knowledge of an expert and is presumed to know of scientific studies and articles concerning the safety of its products. *May v. Parke, Davis & Co.*, 142 Mich. App. 404, 412 (1985). "Determination of whether this duty has been breached in the context of a negligence claim necessitates that the warnings given be examined as to their reasonableness under the circumstances." *Smith*, 405 Mich. at 88-89, 91. Reasonableness is a question of fact. To establish causation, plaintiff must show that an adequate warning would have prevented the alleged injury by altering the doctor's conduct or that the physician might have heeded an adequate warning. *May*, 142 Mich. App. at 418.

The learned intermediary rule provides that a manufacturer has a duty to warn the medical profession about necessary information or warnings involving "therapeutic, diagnostic or curative drugs;" because it is unreasonable to expect the average citizen to understand the information, its implications, or applications. *Brown v. Drake-Willock Int'l*, 209 Mich. App. 136, 148-49 (1995). Where a drug is provided by prescription through a physician, the learned intermediary rule applies and can prevent liability of the manufacturer to the patient. *Id.* at 149; *Mowery v. Crittenton Hosp.*, 155 Mich. App. 711, 718-20 (1986).

B. Application of Michigan Law

Michigan law provides that when a manufacturer's drug has been approved by the FDA for safety and efficacy and the labeling is in compliance with FDA approval at the time the drug leaves its control, no liability can be established. M.C.L.A. § 600.2946(5) The statute provides two exceptions: (1) if information about the drug is intentionally withheld or misrepresented to the FDA, or (2) an illegal payment is made to the FDA for the purpose of approval. M.C.L.A. § 600.2946(5)(a-b).

In this case, Augmentin was approved for safety and efficacy by the FDA in 1984. (Shapowal Aff. at 1.) The labeling for Augmentin was in compliance with all FDA requirements from 1984 through 1994. (*Id.* at 2.) Defendant provides that it has not intentionally withheld or misrepresented any information about Augmentin to the FDA (*Id.*) At oral argument, plaintiff stated that he was not alleging that defendant intentionally withheld information about Augmentin. Moreover, there is no evidence to suggest, nor does plaintiff allege, that any illegal payments were made by defendants to the FDA. Therefore, the court finds that the prerequisites of section 600.2946(b) have been met and neither of the exceptions are present in this case. As a result, Augmentin is

not defective nor unreasonably dangerous, and defendant is not liable under Michigan law. *See* M.C.L.A. § 600.2946(5).

C. Proximate Cause

Defendant can also avoid liability upon showing that plaintiff has failed to establish that defendant's alleged failure to warn was the proximate cause of plaintiff's alleged injuries. Plaintiff conceded at oral argument that Dr. Letson would have prescribed Augmentin to plaintiff even knowing the risk of liver disease for older patients. Dr. Letson stated as following:

> **Q:** So let's say that as of June 20, 1994, you knew all the things that you knew when you did the literature search in August of 1994, you knew that there was a potential for hepatic injury for patients who had been on Augmentin, Understanding that the risk was extremely low at that point in time, would you still have gone ahead and given the Augmentin to Mr. London?
>
> **A:** With the knowledge I had at that time, having never encountered a problem of hepatic disease--and there are many medications that list as possible adverse side effects some hepatic changes. Based on that at that point in time, and never experiencing it, I prob--I would find no reason why I would not have went ahead with Augmentin therapy.

(Letson Dep. at 69.) In addition, Dr. Letson testified that with the low risk, because so many other medications listed some form of hepatic problems, reading that the risks were reversible, having never encountered a problem, and having no literature to alert him,

he would "go ahead and probably prescribe it" even today. (*Id.* at 83-84.)

Where Dr. Letson would have prescribed Augmentin despite the warning plaintiff claims defendant should have issued, defendant's alleged failure to warn could not have altered Dr. Letson's decision to prescribe Augmentin to plaintiff. As a result, there are no facts to support plaintiff's claim that defendant's alleged breach of the duty to warn was the proximate cause of his injuries. Without a showing of causation, defendant cannot be liable for plaintiff's alleged injuries. See *Fisher*, 854 F. Supp. at 472.

D. Adequacy of the Warning

Defendant had a duty to warn the medical profession of the risks inherent in the use of Augmentin. *In re Cert. Question*, 419 Mich. at n.3; *Smith*, 405 Mich. at 88. The evidence in the record establishes that defendant fulfilled its duty to warn prescribing physicians such as Dr. Letson. Michigan law provides that a manufacturer which provides a drug to a sophisticated user is not liable for failure to provide an adequate warning. M.C.L.A. § 600.2947(4). This is essentially the learned intermediary rule recognized at common law.

Plaintiff argues that Dr. Letson, while familiar with Augmentin, was not informed of the "new risk" in prescribing the drug, namely that males of advanced age on long-term therapy of Augmentin were at risk of liver failure and cholestatic injury. (Pl. Br. 1) Plaintiff argues that defendant had a duty to warn prescribing physicians directly of this change in the prescribing information. The prescribing information included in the packaging of Augmentin as well as the Physician's Desk Reference (PDR) stated the following in 1992:

> "PRECAUTIONS"
> *General*: While Augmentin possesses the characteristic low toxicity of the penicillin group of antibiotics, periodic assessment of organ system functions, including renal, hepatic and hematopoietic function, is advisable during prolonged therapy.
>
> "ADVERSE REACTIONS"
> *Liver*: A moderate rise in SGOT, SGPT, AST and/or ALT has been noticed in patients treated with ampicillin class antibiotics including Augmentin. The significance of these findings is unknown. As with some other penicillins and some cephalosporins, hepatic dysfunction has been reported rarely, with the predominant effects being cholestatic, hepatocellular, or mixed cholestatic-hepatocellular. Signs/symptoms may appear during or after therapy and they resolve completely over time.
>
> *Hemic and Lymphatic Systems*: Anemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia and agranulocytosis have been reported during therapy with penicillins. Theses reactions are usually reversible on discontinuation of therapy and are believed to be

> hypersensitivity phenomena. A slight thrombocytosis was noticed in less than 1% of the patients treated with Augmentin.

(Pl. Ex. D.)

After plaintiff was admitted to the hospital, Dr. Letson wrote to defendant inquiring whether elderly individuals should have a liver profile prior to the institution of long-term, high-dose penicillin therapy. (Pl. Ex. B.) In a letter dated September 15, 1994, defendant stated that in 15 cases of Augmentin hepatotoxicity, men were more frequently affected than women and that age may be another important factor since 9 of the 15 patients evaluated were 60 years of age or more. (Pl. Ex. C.) Defendant also reported that one case of Augmentin-induced jaundice resulted in a fatality where the 81-year-old patient was being treated with prostatic malignancy. (*Id.*) Even after plaintiff was hospitalized and Dr. Letson conducted a search on Augmentin and jaundice, Dr. Letson discovered that the risk/incidence of hepatic injury was very low; he learned that in the 10 years since Augmentin has been prescribed, only 23 patients had hepatic injury. (Letson Dep. at 35-38, 64, 68-69.)

Moreover, the information Dr. Letson found and which defendant relayed in its letter to Dr. Letson does not establish a high

degree of risk. Dr. Letson's statement that he was unaware of the relationship between Augmentin and hepatic injury or jaundice does not establish that defendant failed to provide that information to the medical community. (*Id.* at 64.) A prescribing physician's failure to heed the warning provided by the manufacturer does not establish that the warning was unreasonable. *See Nicholas*, 190 Mich. App. at 683.

The court finds that the evidence in the record does not establish that a "new risk" arose related to the use of Augmentin. In fact, the 1990 prescribing information contained the same general warning on organ systems functions, and a specific warning about the liver and hemic and lymphatic systems, as the 1992 prescribing information. (*Cf.* Pl. Ex. D & F.) Dr. Letson has prescribed Augmentin since its inception in the mid-1980s; he describes Augmentin as "the most effective oral antibiotic when you are dealing with resistance. And it is the gold standard by which I think the other pharmaceuticals compare themselves with today, how effective is their product as compared to that." (Letson Dep. at 14.) Dr. Letson writes approximately 250 prescriptions per year for Augmentin. (*Id.* at 84.) In the late 1980s or early 1990s, Dr. Letson gave two presentations on Augmentin to his colleagues in

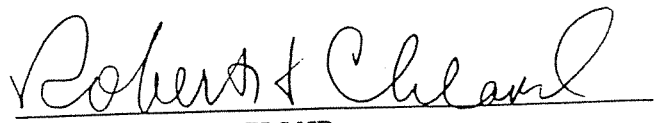
which he presented and discussed the side effects of the drug. (*Id.* at 12-21.) Dr. Letson also testified that he had participated in interactive audio conferences on the use of Augmentin, had seen advertisements for Augmentin, and received information on the drug from defendant. (*Id.* at 87-90.) There is thus no dispute in the evidence about Dr. Letson's status as a "sophisticated user" and a "learned intermediary;" this acts as a complete bar to plaintiff's claim of liability. M.C.L.A. § 600.2947(4); *Brown*, 209 Mich. App. at 148-49. Defendant's warnings contained in the prescribing information, the PDR, promotional materials, and specifically Dr. Letson's presentations on Augmentin for defendant are sufficient to establish that the warnings provided were reasonable under the circumstances. *See Smith*, 405 Mich. at 88-89, 91.

Given the facts of this case, the court finds that both M.C.L.A. §§ 600.2946(5), 600.2947(4) apply in this case to establish that defendant is not liable to plaintiff in this products liability action. In addition, the court finds that defendant's alleged failure to warn was not the proximate cause of plaintiff's injuries. Defendant has succeeded in proving that plaintiff is unable to establish essential elements of a failure to warn claim. As a result, summary judgment is appropriate.

V. Conclusion

Accordingly, IT IS ORDERED that defendant's motion for summary judgment is GRANTED.

Robert H. Cleland



ROBERT H. CLELAND
UNITED STATES DISTRICT JUDGE

March 23, 1998

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Karen S Richards

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PROOF OF SERVICE

STATE OF MICHIGAN)
) ss.
COUNTY OF OAKLAND)

DENISE S. EDWARDS, being first duly sworn, deposes and says that on August 27, 2002, she served by first-class mail a copy of DEFENDANT-APPELLANT GATEPHARMACEUTICAL, INC.'S BRIEF ON APPEAL IN DOCKET NOS. 120624-54 (TAYLOR) AND 120646 (ROBARDS) upon all parties listed on the attached addendum, via First Class mail, by placing same in a sealed envelope with postage thereon fully prepaid and by depositing same in a U.S. mail box.

I DECLARE THAT THE ABOVE STATEMENTS ARE TRUE TO THE BEST OF MY KNOWLEDGE, INFORMATION AND BELIEF.

DENISE S. EDWARDS

Subscribed and sworn to before me this 27th day of August 2002

Connie Coughlin, Notary Public
Oakland County, Michigan
My Commission Expires: 4/24/03

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