

STATE OF MICHIGAN
COURT OF APPEALS

TAMARA TAYLOR and LEE ANN RINTZ,

Plaintiffs-Appellees/Cross-
Appellants,

v

GATE PHARMACEUTICALS, ABANA
PHARMACEUTICALS, INC., RICHWOOD
PHARMACEUTICAL COMPANY, ION
LABORATORIES, INC., SMITHKLINE
BEECHAM CORPORATION, ZENITH
GOLDLINE PHARMACEUTICALS, INC.,
INTERNEURON PHARMACEUTICALS, INC.,
CAMALL COMPANY, LABORATORIES
SERVIER, and MEDEVA
PHARMACEUTICALS, INC.,

Defendants-Cross-Appellees,

and

A. H. ROBINS COMPANY, INC., WYETH-
AYERST LABORATORIES COMPANY,
AMERICAN HOME PRODUCTS
CORPORATION,

Defendants-Appellants/Cross-
Appellees,

and

ALL MICHIGAN PHYSICIANS WHO
PRESCRIBED OR GAVE FEN-PHEN AND/OR
REDUX TO MICHIGAN PATIENTS,

Defendants.

FOR PUBLICATION
November 30, 2001
9:05 a.m.

No. 217269
Wayne Circuit Court
LC No. 97-731636-NP

TAMARA TAYLOR and LEE ANNE RINTZ,

Plaintiffs-Appellees/Cross-
Appellants,

v

No. 217279
Wayne Circuit Court
LC No. 97-731636-NP

GATE PHARMACEUTICALS, SMITHKLINE
BEECHAM CORPORATION, ZENITH
GOLDLINE PHARMACEUTICALS, INC.,
ABANA PHARMACEUTICALS, INC.,
RICHWOOD PHARMACEUTICAL COMPANY,
ION LABORATORIES, INC., A.H. ROBINS
COMPANY, INC., WYETH-AYERST
LABORATORIES COMPANY, AMERICAN
HOME PRODUCTS CORPORATION,
INTERNEURON PHARMACEUTICALS, INC.,
CAMALL COMPANY, and LABORATORIES
SERVIER,

Defendants-Cross-Appellees,

and

MEDEVA PHARMACEUTICALS, INC.,

Defendant-Appellant/Cross-
Appellee,

and

ALL MICHIGAN PHYSICIANS WHO
PRESCRIBED OR GAVE FEN-PHEN AND/OR
REDUX TO MICHIGAN PATIENTS,

Defendants.

TAMARA TAYLOR and LEE ANNE RINTZ,

Plaintiffs-Appellees/Cross-
Appellants,

v

No. 217290
Wayne Circuit Court
LC No. 99-005373-NM

GATE PHARMACEUTICALS, ZENITH
GOLDLINE PHARMACEUTICALS, INC.,
ABANA PHARMACEUTICALS, INC.,
RICHWOOD PHARMACEUTICAL COMPANY,
ION LABORATORIES, INC., MEDEVA
PHARMACEUTICALS, INC., A. H. ROBINS
COMPANY, INC., WYETH-AYERST
LABORATORIES COMPANY, AMERICAN
HOME PRODUCTS CORPORATION,
INTERNEURON PHARMACEUTICALS, INC.,
CAMALL COMPANY, and LABORATORIES
SERVIER,

Defendants-Cross-Appellees,

and

SMITHKLINE BEECHAM CORPORATION,

Defendant-Appellant/Cross-
Appellee,

and

ALL MICHIGAN PHYSICIANS WHO
PRESCRIBED OR GAVE FEN-PHEN AND/OR
REDUX TO MICHIGAN PATIENTS,

Defendants.

TAMARA TAYLOR and LEE ANNE RINTZ,

Plaintiffs-Appellees/Cross-
Appellants,

v

No. 217328
Wayne Circuit Court
LC No. 97-731636-NP

SMITHKLINE BEECHAM CORPORATION,
ZENITH GOLDLINE PHARMACEUTICALS,
INC., ABANA PHARMACEUTICALS, INC.,
RICHWOOD PHARMACEUTICAL COMPANY,
ION LABORATORIES, INC., MEDEVA
PHARMACEUTICALS, INC., A. H. ROBINS
COMPANY, INC., WYETH-AYERST
LABORATORIES COMPANY, AMERICAN
HOME PRODUCTS CORPORATION,
INTERNEURON PHARMACEUTICALS, INC.,
CAMALL COMPANY, and LABORATORIES
SERVIER,

Defendants-Cross-Appellees,

and

GATE PHARMACEUTICALS,

Defendant-Appellant/Cross-
Appellee,

and

ALL MICHIGAN PHYSICIANS WHO
PRESCRIBED OR GAVE FEN-PHEN AND/OR
REDUX TO MICHIGAN PATIENTS,

Defendants.

JUDITH H. ROBARDS and KENNETH W.
ROBARDS,

Plaintiffs-Appellants,

v

No. 227700
Washtenaw Circuit Court
LC No. 97-731636-NP

JOYCE E. KAERLE, M.D., and EVELYN
ECCLES, M.D.,

Defendants,

and

GATE PHARMACEUTICALS, SMITHKLINE
BEECHAM CORPORATION, ZENITH
GOLDLINE PHARMACEUTICALS, INC.,
ABANA PHARMACEUTICALS, INC.,
RICHWOOD PHARMACEUTICAL COMPANY,
ION LABORATORIES, INC., MEDEVA
PHARMACEUTICALS, INC., A. H. ROBBINS
COMPANY, AMERICAN HOME PRODUCTS
CORPORATION, WYETH LABORATORIES,
INC., PARMED PHARMACEUTICALS, INC.,
EON LABS MANUFACTURING, INC., and LES
LABORATORIES SERVIER,

Updated Copy
February 1, 2002

Defendants-Appellees.

Before: Collins, P.J., and Murphy and Jansen, JJ.

MURPHY, J.

At issue in these consolidated products liability appeals is the constitutionality of MCL 600.2946(5), which limits the liability of drug manufacturers and sellers. In Docket Nos. 217269, 217279, 217290, and 217328, defendants American Home Products Corporation,¹

¹ Defendants-appellants in Docket No. 217269 represent that A.H. Robins Company, Inc., merged with American Home Products Corporation and ceased to exist as an entity. Accordingly, American Home Products Corporation now responds to allegations directed at A.H. Robins. Defendants-appellants also represented that American Home Products Corporation and Wyeth-Ayerst Laboratories Company will be collectively referred to as "American Home Products." This opinion uses the same collective reference.

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Medeva Pharmaceuticals, Inc., SmithKline Beecham Corporation, and Gate Pharmaceuticals appeal by leave granted an order of the Wayne Circuit Court that denied their motion for summary disposition predicated on MCL 600.2946(5). The court ruled that MCL 600.2946(5) was unconstitutional because it improperly delegated to the United States Food and Drug Administration (FDA) the legislative function of determining a cause of action.² In Docket No. 227700, plaintiffs Judith and Kenneth Robards appeal by leave granted an order of the Washtenaw Circuit Court granting summary disposition in favor of the manufacturing defendants on the basis of MCL 600.2946(5). That court found MCL 600.2946(5) to provide an affirmative defense to liability and held that the provision was not constitutionally infirm.³ Our review of the statutory provision at issue leads us to the conclusion that it works an unconstitutional delegation of legislative authority. Accordingly, we affirm the decision of the Wayne Circuit Court, reverse the decision of the Washtenaw Circuit Court, and remand.

Plaintiffs in these separate cases are suing the drug manufacturers and distributors of certain diet drugs. The primary drugs at issue are dexfenfluramine (commonly known as Redux) and fenfluramine and phentermine (in combination, commonly known as fen-phen). Defendants moved for summary disposition citing MCL 600.2946(5), which tort reform statute limits the liability of drug manufacturers and sellers in products liability actions if the drug at issue was approved for safety by the FDA and labeled in compliance with FDA standards.⁴ Plaintiffs did not contest the applicability of MCL 600.2946(5), nor did they argue that they had pleaded their complaints to avoid its application. Rather, plaintiffs contended that the statute was unconstitutional on various grounds.

This Court reviews de novo a trial court's ruling on a motion for summary disposition. *Spiek v Dep't of Transportation*, 456 Mich 331, 337; 572 NW2d 201 (1998). The constitutionality of a statute is also reviewed de novo as a question of law. *Stevenson v Reese*, 239 Mich App 513, 516; 609 NW2d 195 (2000). Here, we are presented a close question: Is MCL 600.2946(5) constitutionally infirm under Const 1963, art 4, § 1 as an unlawful delegation of legislative authority?⁵

The general standards applicable to claims that a statute is facially unconstitutional are well established:

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² In granting summary disposition in favor of plaintiffs, the Wayne Circuit Court considered materials outside the pleadings and thus treated defendants' motion as if based on MCR 2.116(C)(10).

³ In granting summary disposition in favor of defendants, the Washtenaw Circuit Court considered only the pleadings and treated the motion as presented pursuant to MCR 2.116(C)(8).

⁴ The statute contains a few exceptions, none of which are herein relevant.

⁵ Both circuit courts reached the conclusions that the statute does not violate the constitutional right of access to the courts and does not violate rights of equal protection or substantive due process. In view of our holding, we need not address the parties' appellate claims respecting those issues.

Statutes are presumed to be constitutional, and courts have a duty to construe a statute as constitutional unless its unconstitutionality is clearly apparent. *Caterpillar, Inc v Dep't of Treasury*, 440 Mich 400, 413; 488 NW2d 182 (1992); *Mahaffey v Attorney General*, 222 Mich App 325, 344; 564 NW2d 104 (1997). The party asserting the constitutional challenge has the burden of proving the law's invalidity. *In re Hamlet (After Remand)*, 225 Mich App 505, 521-522; 571 NW2d 750 (1997). A party challenging the facial constitutionality of a statute must establish that no circumstances exist under which it would be valid. *Council of Organizations & Others For Ed About Parochiaid, Inc v Governor*, 455 Mich 557, 568; 566 NW2d 208 (1997). [*Stevenson, supra* at 517.]

The parties dispute whether MCL 600.2946(5) violates Const 1963, art 4, § 1, which states: "The legislative power of the State of Michigan is vested in a senate and a house of representatives." Legislative power, in general, refers to the authority to make, alter, amend, and repeal laws. *Harsha v Detroit*, 261 Mich 586, 590; 246 NW 849 (1933). Although Michigan's Constitution does not explicitly provide that legislative power cannot be delegated, a nondelegation doctrine has been applied through judicial interpretation. *Miller v Dep't of Treasury*, 385 Mich 296, 313; 188 NW2d 795 (1971) (Brennan, J., dissenting).

Challenges premised on the theory of improper delegation are common. Thus, the framework and standards by which courts address this specific constitutional challenge are equally well established:

Challenges of unconstitutional delegation of legislative power are generally framed in terms of the adequacy of the standards fashioned by the Legislature to channel the agency's or individual's exercise of the delegated power. See, e.g., *Osius v St Clair Shores*, 344 Mich 693, 698; 75 NW2d 25 (1956). Although for many years this and other courts evaluated delegation challenges in terms of whether a legislative (policymaking) or administrative (factfinding) function was the subject of the delegation, this analysis was replaced by the "standards" test as it became apparent that the essential purpose of the delegation doctrine was to protect the public from misuses of the delegated power. The Court reasoned that if sufficient standards and safeguards directed and checked the exercise of delegated power, the Legislature could safely avail itself of the resources and expertise of agencies and individuals to assist the formulation and execution of legislative policy.

The criteria this Court has utilized in evaluating legislative standards are set forth in *Dep't of Natural Resources v Seaman*, 396 Mich 299, 309; 240 NW2d 206 (1976): 1) the act must be read as a whole; 2) the act carries a presumption of constitutionality; and 3) the standards must be as reasonably precise as the subject matter requires or permits. The preciseness required of the standards will depend on the complexity of the subject. *Argo Oil Corp v Atwood*, 274 Mich 47, 53; 264 NW 285 (1935). Additionally, due process requirements must be satisfied for the statute to pass constitutional muster. *State Highway Comm v Vanderkloot*, 392 Mich 159, 174; 220 NW2d 416 (1974). [*Blue Cross & Blue Shield of Michigan v Governor*, 422 Mich 1, 51-52; 367 NW2d 1 (1985).]

MCL 600.2946(5), as amended by 1995 PA 249, effective March 28, 1996, 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 USC 301 to 321, 331 to 343-2, 344 to 346a, 347, 348 to 353, 355 to 360, 360b to 376, and 378 to 395, and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.

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

It is the plaintiffs' position that the statute is unconstitutional because it improperly delegates to the FDA, without establishing standards for oversight, the authority to determine which drugs may be subject to a products liability lawsuit, and thus the power to define what constitutes a cause of action under Michigan law. Defendants, meanwhile, contend that the Legislature in fact exercised its constitutional power to make Michigan law by determining that FDA approval of prescription drugs was an appropriate external standard for defining limits on products liability. The Wayne Circuit Court essentially agreed with plaintiffs' position. The court issued a lengthy written opinion addressing each constitutional argument raised by plaintiffs. With respect to this particular issue, the court found that the statute unlawfully delegated legislative power by making the FDA decision regarding the safety and fitness of a particular drug binding on Michigan courts. Relying on the Michigan Supreme Court decisions of *Coffman v State Bd of Examiners in Optometry*, 331 Mich 582; 50 NW2d 322 (1951), and *Colony Town Club v Michigan Unemployment Compensation Comm*, 301 Mich 107; 3 NW2d 28 (1942), the court found that the legislative function of determining a cause of action was unlawfully delegated.⁶

⁶ The Washtenaw Circuit Court made its ruling on the record at the conclusion of a hearing on the defendants' motion for summary disposition. The court ruled in favor of defendants after noting that the issue of the constitutionality of the statute was presently before this Court (defendants' appeal of the Wayne Circuit Court decision), that tort reform provisions had
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In *Coffman, supra*, our Supreme Court considered a statute that addressed requirements for taking an examination in optometry after May 1, 1925. In striking down the part of the statute providing for an applicant to have graduated from an optometry school rated at a particular level by an "international association of boards of examiners in optometry," because that international association was not a Michigan agency, the Court agreed with a state Attorney General opinion, which stated that the "legislature is prohibited by the Constitution from delegating legislative powers to non-Michigan governmental agencies . . . or to private individuals or associations" *Id.* at 587-588. The Court, however, upheld that part of the statute that provided the state board of examiners in optometry the authority to adopt rules and regulations, including rules regarding the standards of schooling required of applicants. *Id.* at 589-591.

Colony Town Club, supra, was one of two cases cited in the state Attorney General opinion in *Coffman* for the principle that delegation of legislative powers cannot be made to non-Michigan governmental agencies. See *Coffman, supra* at 587-588. At issue in *Colony Town Club* was a 1939 amendment of the Michigan Unemployment Compensation Act that defined "employment" as not to include "[a]ny service not included as 'employment' under title 9 of the social security act." *Colony Town Club, supra* at 113. The appellant argued that this amendment made a decision already rendered by the Commissioner of Internal Revenue, a federal official, final and binding with respect to what constituted employment under the Michigan act. Our Supreme Court rejected the appellant's claim. *Id.* at 115. Before doing so, it remarked:

This amendment, if given the construction claimed for it by appellant, is unconstitutional in that it attempts to delegate to a Federal agency the final decision regarding the interpretation and construction to be placed upon a State statute. It would make the decision of the commissioner of internal revenue as to who is entitled to exemption from paying the Michigan tax conclusive and binding upon the Michigan unemployment compensation commission, the appeal board, and the State courts. [*Id.* at 113.]

Thus is established by case law a distinction between delegations to governmental agencies established under Michigan law and delegations to foreign agencies or private entities. 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 by the establishment of standards.

Yet a further distinction is suggested by case law, this between reference to existing and potential future legislation or agency standards. For example, in *Dearborn Independent, Inc v Dearborn*, 331 Mich 447; 49 NW2d 370 (1951), the Court considered a statute enacted by the Legislature that prescribed qualifications for a newspaper to publish legal notices. One qualification was that the newspaper "shall have been admitted by the United States post-office department for transmission as mail matter of the second class" *Id.* at 454. The Court found an unlawful delegation because this requirement would "make the validity of the

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consistently been held constitutional, and that plaintiffs had failed to cite any specific precedent compelling a finding of unconstitutionality with respect to the instant statute.

publication of legal notices depend upon the future as well as present regulations of the United States post-office department." *Id.* In the context of future legislation, the issue has been addressed more recently by this Court. In *Radecki v Director of Bureau of Worker's Disability Compensation*, 208 Mich App 19, 23; 526 NW2d 611 (1994), it was stated:

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.

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.

Given these distinctions and parameters, we conclude that MCL 600.2946(5) operates as an unconstitutional delegation of legislative authority. It places the FDA in the position of final arbiter with respect to whether a particular drug may form the basis of a products liability action in Michigan. Regardless of the expertise the FDA possesses in the area of drug evaluation, specifically regarding safety and fitness determinations, this is unacceptable. Michigan retains no oversight of this federal agency, it cannot check the exercise of its delegated power with standards of any precision and, because of the nature of science and the FDA's processes of approval and withdrawal of the same, an ever-evolving list of drugs will be excluded as bases of liability actions.

For these reasons we are affirming the summary disposition order of the Wayne Circuit Court and reversing the opposite order of the Washtenaw Circuit Court. Before we close this opinion, however, we must briefly address defendants' most detailed and seemingly compelling argument in favor of finding MCL 600.2946(5) constitutional. Defendants contend that pursuant to the doctrine of "independent significance," courts routinely uphold against similar constitutional challenges the assimilation into statutory law of standards and determinations of public and private organizations. Defendants argue that the controlling factor determining constitutionality is whether the assimilated standards were adopted specifically for the purpose of the legislation at issue; if not, no delegation occurred. Defendants assert that the FDA determinations have legal consequences with independent, nationwide significance. They maintain that by adopting these external standards as its own, in the exercise of its lawmaking power, the Legislature has merely established the manner in which these legal consequences are to pertain to Michigan products liability law.

The short and simple response to this almost convincing argument is found in the test previously discussed in connection with reference statutes. See *Dearborn, supra*; *Radecki*,

supra. 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.⁷ Where, however, as here with the FDA efficacy determinations, it is known at the outset that the relevant feature will be in constant flux, a fatal problem does present itself under the constitutional nondelegation doctrine as developed and applied in Michigan.⁸

Affirmed in part, reversed in part, and remanded. We do not retain jurisdiction.

/s/ William B. Murphy

/s/ Kathleen Jansen

Collins, P.J., did not participate.

⁷ To the extent that any of the foreign jurisdiction cases defendants cite in support of this argument do not fall within this acceptable boundary, we say only that in light of Michigan's development and application of the nondelegation doctrine, we could not consider such cases controlling precedent. We find the single Michigan case cited, meanwhile, to involve a statute and incorporated standard falling within the boundary. In *Michigan Baptist Homes & Development Co v Ann Arbor*, 55 Mich App 725; 223 NW2d 324 (1974), this Court opined that in establishing a federal official's determination as the trigger for operation of a Michigan statute, the Legislature had intended and provided for the creation of a "special category of low-income housing for the elderly which is to be granted tax-exempt status." *Id.* at 738. While we acknowledge that varying determinations could be made over time by that federal official, it is clear that to the extent those determinations would trigger the operation of the Michigan statute, the variations would all exist within that intended special category. Thus, the high limit of the special category was established at the time the Legislature acted and the Legislature could be confident that such limit would remain unchanged regardless of the federal official's decision making.

⁸ Related to this principle defense argument, defendant American Home Products also strongly contended:

Declaring [MCL 600.2946(5)] unconstitutional would destroy the well-accepted legislative practice of assimilating nationwide standards and findings, jeopardizing the constitutionality of a wide range of similar Michigan statutes.

Defendant American Home Products details a number of these statutes asserted to be at risk, noting that the proffered listing is not exhaustive. To the extent any of these statutes become subject to similar constitutional challenge by an aggrieved party, an eventuality we find unlikely given that none of these statutes operate like the instant provision to entirely foreclose a right of action otherwise available to an individual, we likewise believe that it would be appropriate to subject those statutes to analysis under the framework applicable to reference statutes. See *Dearborn, supra*; *Radecki, supra*. It appears that under this framework a majority of the listed statutes involve the acceptable adoption of static standards, and those that do not could at minimum be satisfactorily interpreted under the principle that courts should apply the standard in existence at the time of enactment of the Michigan statute. Accordingly, we do not share defendants' concern that our result in the instant case places a multitude of Michigan statutes in constitutional jeopardy.