Michigan Supreme Court
Lansing, Michigan 48909

Opinion

FILED MARCH 26, 2003

TAMARA TAYLOR and LEE ANNE RINTZ,

Plaintiffs-Appellees,

v **No. 120624**

SMITHKLINE BEECHAM CORPORATION,

Defendant-Appellant.

TAMARA TAYLOR and LEE ANNE RINTZ,

Plaintiffs-Appellees,

v **Nos. 120637-120640**

GATE PHARMACEUTICALS,

Defendant-Appellant.

JUDITH H. ROBARDS and KENNETH W. ROBARDS,

Plaintiffs-Appellees,

v **No. 120641**

GATE PHARMACEUTICALS,

Defendant-Appellant.

TAMARA TAYLOR and LEE ANNE RINTZ,

Plaintiffs-Appellees,

v **Nos. 120642-120645**

MEDEVA PHARMACEUTICALS, INC.,

Defendant-Appellant.

JUDITH H. ROBARDS and KENNETH W. ROBARDS,

Plaintiffs-Appellees,

v **No. 120646**

MEDEVA PHARMACEUTICALS, INC.,

Defendant-Appellant.

TAMARA TAYLOR and LEE ANNE RINTZ,

Plaintiffs-Appellees,

v **No. 120653**

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

Defendants-Appellants,

JUDITH H. ROBARDS and KENNETH W. ROBARDS,

Plaintiffs-Appellees,

v **No. 120654**

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

Defendants-Appellants.

BEFORE THE ENTIRE BENCH

TAYLOR, J.

We granted leave to appeal in these consolidated products liability cases to consider the Court of Appeals holding that MCL 600.2946(5) is unconstitutional because it constitutes an improper delegation of legislative authority. As will be explained, we reverse the judgment of the Court of Appeals because, correctly understood, the statute is a legitimate exercise of legislative authority. A delegation of legislative power does not occur when a statute merely provides that specific legal consequences under Michigan law will result from an act or determination by a federal agency of a fact that has independent significance.

I

Tamara Taylor and Lee Anne Rintz filed a products liability lawsuit in the Wayne Circuit Court against Gate Pharmaceuticals and other manufacturers and distributors of certain prescription diet drugs,[1] seeking damages for injuries resulting from use of the drugs. A similar lawsuit was filed in the Washtenaw Circuit Court by Judith and Kenneth Robards. In each lawsuit, the defendants filed a motion arguing that they were entitled to summary disposition on the basis of MCL

[1]**The primary drugs at issue are dexfenfluramine (commonly known as Redux) and fenfluramine and phentermine (commonly referred to as fen-phen when taken together).**

600.2946(5), which limits the liability of drug manufacturers and sellers where the drug at issue was approved for safety and efficacy by the United States Food and Drug Administration and labeled in compliance with FDA standards.[2]

The respective plaintiffs opposed the motions for summary disposition, asserting that the statute was an unconstitutional delegation of legislative power. The Wayne Circuit Court entered an order denying defendants' motion for summary disposition, ruling that the statute was an unconstitutional delegation of legislative power. In contrast, the Washtenaw Circuit Court entered an order granting defendants' summary disposition motion, rejecting the claim that the statute was unconstitutional.

The Court of Appeals granted an application for leave to appeal in each lawsuit and consolidated the appeals. The Court concluded that MCL 600.2946(5) operates as an unconstitutional delegation of legislative authority because it places the FDA in the position of final arbiter with respect to whether a particular drug may form the basis of a products liability action in Michigan.[3] We subsequently granted leave to appeal to defendants.[4]

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[2]**It is uncontested that the FDA approved the challenged drugs and their labeling before the drugs left the control of any defendant.**

[3]**248 Mich App 472; 639 NW2d 45 (2001).**

[4]**466 Mich 889 (2002).**

II

This Court reviews de novo a trial court's ruling on a motion for summary disposition. *Veenstra v Washtenaw Country Club*, 466 Mich 155, 159; 645 NW2d 643 (2002). The constitutionality of a statute is also reviewed de novo as a question of law. *McDougall v Schanz*, 461 Mich 15, 23; 597 NW2d 148 (1999). Statutes are presumed to be constitutional, and courts have a duty to construe a statute as constitutional unless its unconstitutionality is clearly apparent. *Id*. at 24. Further, when considering a claim that a statute is unconstitutional, the Court does not inquire into the wisdom of the legislation. *Council of Organizations & Others for Ed About Parochiaid, Inc v Governor*, 455 Mich 557, 570; 566 NW2d 208 (1997).

III

Before it was amended in 1995, MCL 600.2946(5) provided that evidence showing compliance with governmental or industry standards was admissible in a products liability action in determining if the standard of care had been met. *Owens v Allis-Chalmers Corp*, 414 Mich 413, 422; 326 NW2d 372 (1982). The 1995 amendment of the statute went one step further and provided that compliance with federal governmental standards (established by the FDA) is conclusive on the issue of due care for drugs.

MCL 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 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.**

Pursuant to this statute, unless the fraud exception in subsection a or the bribery exception contained in subsection b applies (plaintiffs make no such claim here), a manufacturer or seller of a drug that has been approved by the FDA has an absolute defense to a products liability claim if the drug and its labeling were in compliance with the FDA's approval at the

time the drug left the control of the manufacturer or seller. Thus, the Legislature has determined that a drug manufacturer or seller that has properly obtained FDA approval of a drug product has acted sufficiently prudently so that no tort liability may lie.

IV

The United States Constitution provides that "[a]ll legislative powers herein granted shall be vested in a Congress of the United States . . . ." US Const, art I, § 1. Similarly, the Michigan Constitution provides that "[t]he legislative power of the State of Michigan is vested in a senate and a house of representatives." Const 1963, art 4, § 1. The Michigan Constitution also provides: "The powers of government are divided into three branches: legislative, executive and judicial. No person exercising powers of one branch shall exercise powers properly belonging to another branch except as expressly provided in this constitution." Const 1963, art 3, § 2.

These constitutional provisions have led to the constitutional discipline that is described as the nondelegation doctrine. A simple statement of this doctrine is found in *Field v Clark*, 143 US 649, 692; 12 S Ct 495; 36 L Ed 294 (1892), in which the United States Supreme Court explained that "the integrity and maintenance of the system of

government ordained by the Constitution" precludes Congress from delegating its legislative power to either the executive branch or the judicial branch.[5] This concept has its roots in the separation of powers principle underlying our tripartite system of government.[6] Yet, the United States Supreme Court, as well as this Court, has also recognized "that the separation of powers principle, and the nondelegation doctrine in particular, do not prevent Congress [or our Legislature] from obtaining the assistance of the coordinate Branches." *Mistretta v United States*, 488 US 361, 371; 109 S Ct 647; 102 L Ed 2d 714 (1989).[7]

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[5]**The nondelegation doctrine forbids the delegation of legislative powers, not only to the executive or judicial branches, but also to non-Michigan governmental agencies or to private individuals or associations. *Coffman v State Bd of Examiners in Optometry*, 331 Mich 582, 587-588; 50 NW2d 322 (1951).**

[6]**As we stated in *People v Turmon*, 417 Mich 638, 649; 340 NW2d 620 (1983): "As a threshold matter, we recognize that some legislative powers are simply not delegable. Though not specifically mandated by any constitutional provision, this prohibition arises from the basic structure of the government."**

[7]**See *Detroit v Detroit Police Officers Ass'n*, 408 Mich 410, 458, n 29; 294 NW2d 68 (1980) (Opinion by Williams, J.):**

> **Perhaps the most concise description of the delegation doctrine was enunciated in the seminal case of *Locke's Appeal*, 72 Pa 491, 498-499 (1873):**
>
> **"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**

(continued...)

The first category of nondelegation case law involves an assertion that the Congress or a state legislature improperly delegated its legislative power to a federal agency or state agency, respectively.

In the federal courts these improper delegation challenges to the power of federal regulatory agencies have been uniformly unsuccessful since the advent of large regulatory agencies in the 1930s.[8] A recent case, which is representative of the manner in which the federal judiciary has handled these challenges, is *Whitman v American Trucking Ass'ns*, 531 US 457, 465; 121 S Ct 903; 149 L Ed 2d 1 (2001), in which the United States Supreme Court considered a statute that directed the Environmental Protection Agency to set primary air quality standards "which are requisite to protect the public health" with "an adequate margin of safety." It was argued that this delegation was too vague. It was held, however, that this direction to the EPA was not an improper delegation of legislative authority to the agency because there was within the delegation "intelligible principle."

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[7](...continued)
the wheels of government."

[8]**The United States Supreme Court has not used the nondelegation doctrine to invalidate a federal statute since the New Deal period. See *ALA Schechter Poultry Corp* v *United States*, 295 US 495, 537-542; 55 S Ct 837; 79 L Ed 1570 (1935); *Panama Refining Co v Ryan*, 293 US 388, 420-430; 55 S Ct 241; 79 L Ed 446 (1935).**

In Michigan, this Court has considered similar claims regarding statutes where the claims included an allegation of improperly delegating the Legislature's power to a Michigan agency, and we have rejected the claims on a basis similar to the federally developed rationale.[9]

The second category of cases in which there are challenges concerning the delegation of legislative authority involves situations where the Congress, or the Legislature, enacts a statute that might be described as a referral statute,[10] in which, depending on a factual development that is outside the control of the legislative body, certain consequences will ensue.

An example of a permissible federal referral statute was the 1810 United States statute in which Congress authorized the President to bar trade with France or Great Britain if one of those countries had revoked its decree authorizing the

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[9]**In *Turmon*, *supra* at 641-642, the Court considered a challenge to a statute that authorized the Board of Pharmacy to classify controlled substances within legislatively established schedules. This Court, on the basis that the statute provided the agency with "sufficient standards" and safeguards, rejected the claim that an improper delegation of authority had occurred. However, the delegation must have standards or principles. If there are none, the delegation is improper because the Legislature's powers have been improperly given to the agency. *Blue Cross & Blue Shield of Michigan v Governor*, 422 Mich 1, 53-55; 367 NW2d 1 (1985).**

[10]**What we describe as a referral statute should not be confused with a reference statute, which is a statute that incorporates by reference a separate statute. *Pleasant Ridge v Governor*, 382 Mich 225, 246-247; 165 NW2d 625 (1969).**

seizure of American ships and the other country did not follow suit within three months. When the statute was challenged as an improper delegation of legislative power, the United States Supreme Court held that this was not a delegation of legislative power because the statute only called on the President to determine if a fact, revocation of the decree, had taken place. If so, the President was authorized by the Congress to act. *Cargo of the Brig Aurora v United States*, 11 US (7 Cranch) 382, 388-389; 3 L Ed 378 (1813).

Michigan's referral statutes are apparently so uncontroversial as to be rarely challenged. This is not surprising when one considers that, for example, any statutory reference to time, weight, age, gender, birth, death, or even print size for legal documents[11] is an exercise of the Legislature referring to findings made by someone other than itself. As is apparent in the case of time[12] this would be

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[11]**For example, pursuant to MCL 168.544c(1), nominating petitions must be "8-½ inches by 14 inches in size" and the words "nominating petition" must be printed in 24-point boldface type. "We, the undersigned" must be printed in 8 point type. "Warning" and the language in the warning must be printed in 12-point boldface type.**

See also MCL 445.953(1)(m), which requires that certain rental purchase agreements contain a notice in type not smaller than 12-point type or in legible print with letters not smaller than 1/8 inch.

[12]**Representative of this type of statute are MCL 168.720 and 168.721, which provide that the polls shall be open on election day from 7:00 a.m. until 8:00 p.m. Eastern Standard Time.**

the Naval Observatory and when it comes to weights, it would be the National Bureau of Standards.[13] Regarding birth and death, it would be the governmental agencies collecting vital statistics; and, in the case of print size, standards established by consensus in the printing industry. The Legislature can, of course, do such things without fear of running afoul of the nondelegation doctrine because these public or private agency fact findings are considered to be findings of independent significance. That is, there is no improper delegation where the agency or outside body making the finding (such as when it is, say, 7:00 a.m., or when a person was born, or what weight equals a pound, and so forth) is doing it for purposes independent of the particular statute to which it makes reference.

The independently significant standard was described well recently by the New Mexico Supreme Court in *Madrid v St Joseph Hosp*, 122 NM 524, 531; 928 P2d 250 (1996), in which that court stated:

> **[W]here a private organization's standards have significance independent of a legislative enactment, they may be incorporated into a statutory scheme without violating constitutional restrictions on delegation of legislative powers. A private entity's standards cannot be construed as a deliberate law-making act when their development of**

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[13]**MCL 290.603 provides that basic units of weight and measure "as published by the national bureau of standards" govern transactions in Michigan.**

the standards is guided by objectives unrelated to the statute in which they function.

This concept was also recognized in *Lucas v Maine Comm of Pharmacy*, 472 A2d 904, 911 (1984), in which the Maine Supreme Court held that legislative incorporation of a decision by a private entity does not violate the nondelegation doctrine where the decision has aspects of significance beyond the legislature's reliance on it.

The independently significant standard has also been discussed by administrative law scholars. Professor Kenneth C. Davis in 1 Administrative Law (2d ed), § 3.12, p 196, has explained it as follows: "statutes whose operation depends upon private action which is taken for purposes which are independent of the statute." Here in Michigan, Thomas M. Cooley Law School Dean Don LeDuc, in his treatise on Michigan Administrative Law, § 2.25, p 71, has succinctly warned of its limitations and described its operation as follows: "Care must be exercised in distinguishing between statutes which delegate the authority to make the standards to private parties and those which refer to outside standards as the measuring device."

We deal here with the latter type of statute. MCL 600.2946(5) is a statute that refers to factual conclusions of independent significance, i.e., the FDA conclusion regarding the safety and efficacy of a drug, that once made causes, at

the Michigan Legislature's direction, Michigan courts to find as a matter of law that the manufacturer or seller acted with due care. The FDA decision is, in Dean LeDuc's formulation, simply a "measuring device."

V

The Court of Appeals in its handling of this matter concluded that MCL 600.2946(5) is an unconstitutional delegation of legislative power because it believed the statute placed "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." 248 Mich App 483. Yet, this statute only establishes that a determination of independent significance, here the FDA finding that a drug is safe and effective, will be the measure in Michigan of whether the duty of reasonable care has been met by a drug manufacturer or seller in a tort case. While the Court of Appeals recognized that the Legislature can alter the common-law duty of reasonable care in a drug products liability tort case, the panel and the dissent in this Court contend that MCL 600.2946(5) went beyond this and gave the FDA the authority to "make, alter, amend, and repeal laws." 248 Mich App 478. This is incorrect. The FDA does not decide who may bring a products liability action in Michigan; rather, the FDA, for its own reasons that are independent of Michigan tort law, simply makes a factual finding regarding the safety and

efficacy of drugs. It is the Michigan Legislature that has determined the legal consequences that flow from that finding. The Legislature's action in doing so is no different from the Legislature's referring to weights and measures or even dates and times, which are, as discussed above, all findings of independent significance by bodies deemed by the Legislature to be expert. By using such independent determinations as a referent, the Legislature is not delegating how that fact will be used, just as the Congress in 1810 was not delegating the making of rules to France or Great Britain in *Cargo of the Brig Aurora, supra*.

The Court of Appeals acknowledged the independently significant standard, but placed an unjustified limitation on it. The panel correctly stated that, "[a]ssimilation of standards adopted for a purpose separate from the incorporating legislation, and having independent significance, presents no problem," but added a condition, which was *"if* the standards are established and essentially unchanging." 248 Mich App 485 (emphasis added). There is no sound legal basis for this limitation.[14] Whether the Legislature's adoption of the actions of an external body as a cause for statutory legal consequences is a delegation of

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[14] **In the words of *Locke's Appeal*, *supra*, the Legislature can make a law delegating its "power to determine some fact or state of things upon which the law makes, or intends to make, its own action depend."**

legislative authority cannot rationally depend on a court's perception of the relative permanence of the actions adopted.[15]

The Court of Appeals, in buttressing its holding, relied on language in *Coffman v State Bd of Examiners in Optometry*, 331 Mich 582; 50 NW2d 322 (1951), to the effect that the Legislature could not require an applicant for a license to practice optometry to have graduated from an optometry school or college that received a certain rating by the international association of boards of examiners in optometry. This language was dicta because the actual holding in *Coffman* was that the applicant was not entitled to mandamus. As dicta, it is in no sense binding authority.

The Court of Appeals also cited *Colony Town Club v Michigan Unemployment Compensation Comm*, 301 Mich 107; 3 NW2d 28 (1942). This case merely rejected a party's *argument* that a decision by the federal government interpreting a federal statute was binding on a substantially similar Michigan

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[15]**Moreover, any change issue is irrelevant here because under MCL 600.2946(5) the bar the statute establishes applies only to drugs approved by the FDA at the time the drug leaves the control of the manufacturer or seller. The bar does not apply to a drug sold after the effective date of an order from the FDA to remove the drug from the market or to withdraw its approval. Thus, the FDA's conclusion in effect when a manufacturer or seller distributes a drug is unchanging with regard to that batch of drugs. The Court of Appeals incorrectly concluded that the FDA determinations were not constant. The dissent's assertion that FDA decisions are not "essentially unchanging", *post* at 7, is incorrect.**

statute. In contrast with the argument rejected in *Colony Town Club*, the statute at issue here, MCL 600.2946(5), neither purports to give the FDA the final say in the interpretation of a state statute nor provides that a Michigan court in applying Michigan law is bound by an interpretation made by a federal agency in interpreting a substantially similar provision of federal law. *Colony Town Club* is thus inapposite.

The Court of Appeals also cited *Dearborn Independent, Inc v Dearborn*, 331 Mich 447; 49 NW2d 370 (1951). In *Dearborn*, the Court considered a statute that provided that a newspaper was qualified to publish legal notices if it was admitted by the United States Post Office for transmission of second-class mail. The Court held the statute in violation of the nondelegation doctrine because it "unlawfully attempts to delegate to the United States post-office department the determination of the qualifications of a newspaper to publish legal notices." *Id*. at 454. The Court was concerned that the statute made the validity of publication of legal notices dependent on the future as well as present regulations of the United States Post Office. *Id*. To the extent that the post office's decision whether to approve a newspaper for second-class mail is an act of independent significance, which it appears to us to be, *Dearborn Independent* is inconsistent with the independently significant standard. It was, thus,

incorrectly decided in light of the law's subsequent development in this area and is overruled.[16]

The Court of Appeals also cited *Radecki v Director of Worker's Disability Compensation*, 208 Mich App 19; 526 NW2d 611 (1994). In *Radecki*, the Court considered a state statute that incorporated by reference a federal statute. The Court said that state statutes may incorporate existing federal statutes, but not future legislation. *Id*. at 23. Utilizing its "no change" argument, the Court of Appeals characterized MCL 600.2946(5) as an impermissible "reference statute" that incorporates future standards promulgated by the FDA. 248 Mich App 483. We disagree. First, MCL 600.2946(5) is not a "reference statute" as that phrase is used, which is to mean incorporation into Michigan law of a standard from a different jurisdiction as a rule of law to be applied in Michigan courts. Rather, it provides that certain legal consequences flow from factual determinations made by the FDA and is not a delegation. Accordingly, *Radecki,* whatever its merits as law, is not relevant to a consideration of whether MCL 600.2946(5) is an improper delegation of legislative

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[16]We also note that in this case there is no concern regarding future regulations issued by a federal governmental agency. As noted above, the determination whether a particular drug had been approved by the FDA when the drug left the manufacturer or seller is constant with regard to that batch of the drug. Although there certainly will be new drugs approved by the FDA in the future, the key question pursuant to MCL 600.2946(5) is whether the drug was approved when sold.

power.

Finally, to deal with the last of the Michigan cases on which the Court of Appeals relied, our analysis is consistent with *Michigan Baptist Homes & Dev Co v Ann Arbor*, 55 Mich App 725; 223 NW2d 324 (1974).[17] In *Baptist Homes*, a state statute granted a property tax exemption to nonprofit corporations that had obtained financing under § 202 of the National Housing Act (12 USC 1701q). The plaintiff argued that the Legislature had made the state tax exemption dependent upon action by the Secretary of Housing and Urban Development and that limiting the state statute in this manner was invalid because it was an unconstitutional delegation of power to a federal official to decide who gets the exemption. The Court of Appeals correctly rejected this argument, explaining that the federal official does not make a determination of who shall receive the state exemption. This is because the federal official merely determines which nonprofit corporations are eligible to receive federal financing pursuant to the federal act. This is to be understood, in Dean LeDuc's useful characterization, as an example of the "measuring stick." In our case, also, because the FDA decision is only the measure, i.e., the enabling fact, MCL 600.2946(5) is not an unlawful delegation of legislative authority.

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[17]**Aff'd 396 Mich 660; 242 NW2d 749 (1976).**

VI

The dissent misunderstands the independently significant standard.[18] What is central to grasping this doctrine is that if the fact or finding to which the Legislature refers has significance independent of a legislative enactment, because the agency or outside body making the finding is doing it for purposes independent from the particular statute that refers to it, then there is no delegation. Whether the fact or finding of independent significance changes thereafter is irrelevant to the question whether there has been an improper delegation.[19]

VII

In sum, MCL 600.2946(5) delegates nothing to the FDA; rather, it uses independently significant decisions of the FDA as a measuring device to set the standard of care for manufacturers and sellers of prescription drugs in Michigan. It represents a legislative determination as a matter of law

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[18]**The only basis for the dissent's position is *Dearborn Independent* where the doctrine was misunderstood also and accordingly has today been overruled.**

[19]**Although, in response to the arguments advanced by the Court of Appeals and the dissent, we have established in this opinion that FDA findings regarding a drug do *not* in fact change as far as MCL 600.2946(5) is concerned, we emphasize that we are not required to do so in determining whether a legislative act has made a delegation of legislative authority in violation of the Constitution. Stability of a fact or finding is not an element of the independently significant standard analysis.**

of when a manufacturer or seller of a prescription drug has acted sufficiently reasonably, solely for the purpose of defining the limits of a cognizable products liability claim under Michigan law. Accordingly, we reverse the judgment of the Court of Appeals that the statute constitutes an improper delegation of legislative power.

Clifford W. Taylor
Maura D. Corrigan
Michael F. Cavanagh
Robert P. Young, Jr.
Stephen J. Markman

WEAVER, J.

I concur in the result only.

Elizabeth A. Weaver

S T A T E O F M I C H I G A N

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KELLY, J. (*dissenting*).

I agree with the rulings of the Wayne Circuit Court[1] and the Court of Appeals[2] holding that MCL 600.2946(5) represents an unconstitutional delegation of the Legislature's power. The majority reverses these rulings by adopting, with little discussion, the "independently significant standard" doctrine, while restricting the limitation that our lower courts and our precedent have placed on legislative delegations. In keeping with the wisdom of our lower courts' rulings and our precedent, I would affirm the decisions by holding MCL 600.2946(5) unconstitutional.

I

The majority focuses on the independence of the Food and Drug Administration (FDA). In so doing, it loses sight of the significant fact that the standards used by the FDA change from time to time.

When the Legislature adopts the determinations of a foreign body, it implicitly determines that the body's choice

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[1]**Judge Marianne O. Battani.**

[2]**Judges William B. Murphy and Kathleen Jansen, Judge Jeffrey G. Collins not participating, 248 Mich App 472; 639 NW2d 45 (2001).**

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

The analysis I have set forth is the basis for the Court of Appeals holding: an unconstitutional delegation occurs when a statute references fact-finding that is based on standards that are not "established and essentially unchanging." 248 Mich App 472, 485; 639 NW2d 45 (2001). Contrary to the assertion of the majority, the Court of Appeals did not invent this limitation. Rather, it drew it directly from this Court's holding in *Dearborn Independent, Inc v Dearborn*, 331 Mich 447; 49 NW2d 370 (1951).

In *Dearborn*, we examined a statute that prescribed qualifications a newspaper must satisfy in order 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 held that this reference to post office determinations depended on "future as well as present regulations . . . ." *Id*. Because the postal authority could and might at any time revise the standards for second-class mail, the statute allowed the authority to step into the shoes of the Legislature. Thus, it constituted an unlawful delegation of legislative power.[3]

Conversely, if the qualifications for second-class mail had been unchanging, the law would have been constitutional. The standard would have had independent significance and its content would have been known to the legislators who adopted it. The Court of Appeals properly interpreted the *Dearborn* holding as requiring both "established and essentially unchanging" standards. 248 Mich 485.

The present situation closely parallels that in *Dearborn*.

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[3]In the analogous context of reference statutes, the Court of Appeals has held that "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 v Director of Bureau of Worker's Disability Compensation*, 208 Mich App 19, 23; 526 NW2d 611 (1994).

Here, the statute refers to the findings of the FDA, which are based on changing standards. As a consequence, MCL 600.2946(5) must be held unconstitutional under the logic employed by the *Dearborn* Court. Because it is empowered to change the standards by which it approves drugs, the FDA, not the Legislature, determines whether an action for the injuries drugs cause may be sustained in Michigan. That constitutes an exercise of the Legislature's power to act as the lawmaker in Michigan.

II

No previous Michigan case has adopted the "independently significant standard" doctrine. In embracing it, the majority eradicates the precedent that would limit it, overruling *Dearborn* as "incorrectly decided in light of the law's subsequent development in this area . . . ."[4] *Ante* at 19-20.

I disagree with this approach and prefer to square the "independently significant standard" doctrine with our precedent by limiting the doctrine as *Dearborn* would have

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[4]The majority also holds that any change in FDA standards is irrelevant because the Legislature restricted the statute's application to the time the drug leaves the manufacturer's hands. The date the drug was manufactured is not relevant to whether the statute is unconstitutional. The pertinent question is, when the FDA evaluates a drug in the future, does it use the standards that the Legislature knew of and relied on when the act was passed?

limited it. That is, we should hold it constitutionally acceptable to adopt by reference independent decisions of a foreign body as long as the foreign body's standards are "established and essentially unchanging."

The present statute fails the test. The natures of both science and the drug approval process are of the sort that the FDA's standards must evolve over time. Accordingly, FDA determinations are not "essentially unchanging" and a statute that incorporates them perpetrates an unlawful delegation.

The majority rejects this analysis, saying that the determination of a statute's constitutionality "cannot rationally depend on a court's perception of the relative permanence of the actions adopted." *Ante* at 17. To the contrary, I believe that courts are able to make that assessment with great accuracy. Courts can distinguish between static standards and evolving standards. For example, the standard by which the Naval Observatory calculates the passage of time reasonably can be expected not to change. Contrast that with the manner in which the FDA determines the safety and efficacy of a drug, an evolving standard.

Distrust of the judiciary's ability to distinguish standards is an inappropriate basis for upholding an unconstitutional statute and discarding the precedents of this

Court.

III

Some characterize MCL 600.2946(5) as a tort-reform statute that adopts a foreign body's standards while maintaining the consumer's ability to bring suit in the event of fraud or bribery. It is of interest that, after MCL 600.2946(5) was enacted, the United States Supreme Court decided the case of *Buckman Co v Plaintiff's Legal Committee*, 531 US 341; 121 S Ct 1012; 148 L Ed 2d 854 (2001). Under *Buckman* and its progeny, a plaintiff's allegations of fraud or bribery are preempted by federal law. Only the FDA may determine whether it was defrauded or bribed when it approved a drug.

MCL 600.2946(5) precludes a person who claims to have been injured by an FDA-approved drug from suing the manufacturer in a Michigan court. When read in conjunction with the *Buckman* decision, this simple tort-reform statute becomes elevated to a "tort-elimination" statute.

IV

In sum, I would affirm the judgments of the Wayne Circuit Court and the Court of Appeals holding MCL 600.2946(5) unconstitutional. The majority misconstrues my position. The conclusiveness of the FDA's decisions does not undermine the

statutes's constitutionality. What undermines it is the fact that the FDA's decisions are founded on shifting standards. It is only when the standards are "established and essentially unchanging" that a statutory reference to the products of the standards should be ruled a constitutional delegation of the legislative power. The holding I advocate would accord with logic and this Court's precedent, while adopting with appropriate restriction the "independently significant standard" doctrine.

Marilyn Kelly