

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
NORTHERN DIVISION

JULIA GARCIA,

Plaintiff,

v.

Case Number 01-10002-BC
Honorable David M. Lawson

WYETH-AYERST LABORATORIES,

Defendant.

**ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT
AND DENYING PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT**

Before the Court are cross-motions for summary judgment by the parties in this drug products liability case, together with the magistrate judge's Report and Recommendation and the parties' objections to it. For reasons explained in detail below, the Court will reject the magistrate judge's Report and Recommendation, grant the defendant's motion for summary judgment, and dismiss the case.

I.

Julia Garcia, the plaintiff, was thirty-nine years old in September 1997 when she was treating with Dr. Alexander Iwanow for persistent pain in her neck and shoulders. To alleviate her pain, Dr. Iwanow gave her a prescription for Duract, a non-steroidal, anti-inflammatory medication manufactured by the defendant, Wyeth-Ayerst Laboratories, which had been approved for use earlier that year by the United States Food and Drug Administration (FDA). The drug destroyed Julia Garcia's liver; she was required to undergo a liver transplant in 1998 to save her life. Ms. Garcia has sued Wyeth for making and selling an unsafe drug, and she seeks compensation for her injury, including past and future medical expenses,

which likely will involve another liver transplant. Wyeth has since voluntarily withdrawn the drug from the market.

Michigan law governs this diversity action. Michigan has a drug products liability statute that immunizes drug manufacturers from liability for damages in suits contending that their drug was defective or unreasonably dangerous “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 manufacturer or seller.” Mich. Comp. Laws § 600.2946(5). However, the immunity does not attach if the manufacturer intentionally withholds from or misrepresents material information to the FDA, or bribes an FDA official or employee in order to secure approval of the drug. *See id.*, § 600.2946(5)(a) & (b). Likewise, the immunity statute does not apply if the offending drug was sold after the FDA withdrew approval or ordered the drug removed from the market. *See id.*, § 600.2946(5).

The Michigan Court of Appeals held that this statute was repugnant to the Michigan constitution in the case of *Taylor v. Gate Pharmaceuticals*, 248 Mich. App. 472, 639 N.W.2d 45 (2001), because the statute impermissibly delegated legislative authority to the FDA as the final arbiter of drug safety in Michigan. However, the state supreme court overturned that ruling and held that the statute’s linking of dangerousness to the FDA’s complex and detailed approval process is nothing more than an incorporation of common standards, such as weights and measures or the time of day, which are also determined by federal agencies. *See Taylor v. Smithkline Beecham Corp.*, ___ Mich. ___, ___, 658 N.W.2d 127, 134 (2003).

In this case, Wyeth has moved for summary judgment, claiming the protection of the statute's immunity provision. The plaintiff has moved for partial summary judgment seeking a declaration that the statute is unconstitutional. The state supreme court's determination upholding the statute's constitutionality was made solely on the basis of Michigan's constitution. Since diversity jurisdiction is the source of this Court's authority to adjudicate the dispute, under the rule of *Erie R.R. v. Tompkins*, 304 U.S. 64, 78 (1938), state law, as determined by the state's highest court, furnishes the substantive rules for decision. *See also Garden City Osteopathic Hosp. v. HBE Corp.*, 55 F.3d 1126, 1130 (6th Cir. 1995); *Angelotta v. American Broad. Corp.*, 820 F.2d 806, 807 (6th Cir. 1987). However, the plaintiff claims that the statute violates the *federal* constitution, a determination that is not influenced by the state court holdings. *See Barden Detroit Casino, L.L.C. v. City of Detroit*, 230 F.3d 848 (6th Cir. 2000) (affirming dismissal of a challenge to a Michigan statute on federal constitutional grounds).

The Court has twice referred the motions to the magistrate judge for a Report and Recommendation on the plaintiff's motion challenging the constitutionality of the statute on federal constitutional grounds. Both times, the magistrate judge made reports and recommendations based on Michigan state law and failed to address the plaintiff's issues under federal law. The magistrate judge initially recommended that the plaintiff's motion be held in abeyance and the case be stayed pending the certification of a question to the Michigan Supreme Court on the constitutionality of the statute under the state constitution. This Court rejected the Report and Recommendation and instructed the magistrate judge to promptly proceed to decide the federal issues, and to notify the Michigan Attorney General in accordance with 28 U.S.C. § 2403(b) that the state statute was challenged under the United States Constitution. On July 2, 2002, the magistrate judge issued a second report on the plaintiff's motion

recommending the motion be granted based on the premise that the Michigan Court of Appeals had held the statute unconstitutional, once again under state law. Both recommendations were made without the benefit of the state supreme court's latest decision upholding the statute under state constitutional law in *Taylor*, and neither report addressed the federal issues. The second report, premised upon the state intermediate appellate court decision, will be rejected.

The Court proceeds now to a *de novo* review of the motions for summary judgment, focusing on the issues raised by the parties, particularly the plaintiff's contention that the statute violates the Constitution and laws of the United States.

II.

The plaintiff argues that Mich. Comp. Laws § 600.2946(5) is unconstitutional because it has been impliedly preempted by the federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301, *et seq.*, and therefore runs afoul of the Supremacy Clause; it interferes with the plaintiff's fundamental right of access to the courts and her Seventh Amendment right to a jury trial; and it violates the Due Process Clause by depriving her of the right to use a traditional common law tort remedy as a means of seeking redress for her injuries.

A.

As an initial matter, the Court turns to a claim in the complaint that the statute is inapplicable to the defendant. The plaintiff alleged in her complaint that Wyeth intentionally misrepresented material information and made illegal payments to the FDA during the drug approval process. Compl. ¶¶ 14-17. If that is true, the defendant cannot claim protection from the statute's immunity from liability according to

the statute's own terms. However, the defendant contends that the plaintiff has not come forward with any evidence supporting these allegations.

A motion for summary judgment under Federal Rule Civil Procedure 56 presumes the absence of a genuine issue of material fact for trial. The Court must view the evidence and draw all reasonable inferences in favor of the non-moving party, and determine "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251-52 (1986). When the "record taken as a whole could not lead a rational trier of fact to find for the nonmoving party," there is no genuine issue of material fact. *Simmons-Harris v. Zelman*, 234 F.3d 945, 951 (6th Cir. 2000).

The party bringing the summary judgment motion has the initial burden of informing the district court of the basis for its motion and identifying portions of the record which demonstrate the absence of a genuine dispute over material facts. *Mt. Lebanon Pers. Care Home, Inc. v. Hoover Universal, Inc.*, 276 F.3d 845, 848 (6th Cir. 2002). The party opposing the motion then may not "rely on the hope that the trier of fact will disbelieve the movant's denial of a disputed fact" but must make an affirmative showing with proper evidence in order to defeat the motion. *Street v. J.C. Bradford & Co.*, 886 F.2d 1472, 1479 (6th Cir. 1989). A party opposing a motion for summary judgment must designate specific facts in affidavits, depositions, or other factual material showing "evidence on which the jury could reasonably find for the plaintiff." *Anderson*, 477 U.S. at 252. If the non-moving party, after sufficient opportunity for discovery, is unable to meet his or her burden of proof, summary judgment is clearly proper. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986).

The party who bears the burden of proof must present a jury question as to each element of the claim. *Davis v. McCourt*, 226 F.3d 506, 511 (6th Cir. 2000). Failure to prove an essential element of a claim renders all other facts immaterial for summary judgment purposes. *Elvis Presley Enters., Inc. v. Elvisly Yours, Inc.*, 936 F.2d 889, 895 (6th Cir. 1991).

The plaintiff has not offered any evidence supporting its claims of bribery and misrepresentation. In fact, it appears that those claims have been abandoned. Although Duract was withdrawn from the market, the plaintiff has not offered any evidence that this action was precipitated by the FDA or based on any provable misconduct by Wyeth. Moreover, there is no factual dispute that Duract was approved by the FDA before it was prescribed to Julia Garcia. Consequently, if Section 600.2946(5) is constitutional, the defendant is immune from liability and the plaintiff's case cannot proceed.

B.

The plaintiff insists that Section 600.2946(5) conflicts with and is impliedly preempted by federal law because the statute requires a plaintiff to prove fraud on the FDA as part of her cause of action against a drug manufacturer. By importing these elements into Michigan's product liability tort claims, the plaintiff contends, the state necessarily obligates the courts to oversee and second-guess the FDA's regulatory decisions and impermissibly encroach on its authority, creating a conflict with federal law. In support of this argument, the plaintiff relies heavily on *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), in which the Supreme Court found that state law claims of fraud-on-the-FDA were impliedly preempted by federal law. The plaintiff also cites *Lewis v. Brunswick Corp.*, 107 F.3d 1494, 1505 (11th Cir. 1997), *abrogated by Sprietsma v. Mercury Marine*, 123 S. Ct. 518, 522, 530 (2002), holding that a claim of fraud on the United States Coast Guard was barred by reason of implied conflict preemption,

and *Welchert v. American Cyanamid, Inc.*, 59 F.3d 69, 73 (8th Cir. 1995), holding that claims attacking the underpinnings of federal agency action concerning a herbicide were subject to preemption.

“The Constitution and the Laws of the United States which shall be made in Pursuance thereof. . . shall be the supreme Law of the Land.” U.S. Const. art VI, cl. 2. Federal law preempts state law where “(1) a federal statute expressly preempts state law, (2) a federal law impliedly preempts state law, or (3) federal law and state law actually conflict.” *Gibson v. Am. Bankers Ins. Co.*, 289 F.3d 943, 948-49 (6th Cir. 2002). “Implied preemption occurs if a scheme of federal regulation is so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it, if the Act of Congress . . . touches a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject, or if the goals sought to be obtained and the obligations imposed reveal a purpose to preclude state authority.” *Id.* at 949 (quoting *Wis. Pub. Intervenor v. Mortier*, 501 U.S. 597, 605 (1991)). In analyzing implied preemption, a court must begin with the assumption that a state law is valid, *see New York State Dep’t of Social Servs. v. Dublino*, 413 U.S. 405, 413 (1973), and should be reluctant to resort to the Supremacy Clause. *See Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1176 (5th Cir. 1988) (citing *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 714 (1985)).

In *Buckman*, however, the Court found that “no presumption against pre-emption obtains” in a case where the plaintiff brought a common-law fraud-on-the-FDA claim against the manufacturer of a bone screw, alleging that the manufacturer’s misrepresentations to the FDA permitted the medical devices to reach the market, where they injured the plaintiffs when they were used in orthopedic surgeries. 531 U.S. at 348. The Court held that a state common law fraud-on-the-FDA tort claim was impliedly preempted

by the Food, Drug and Cosmetic Act and the Medical Device Act (MDA), 21 U.S.C. §§ 360e(b)(1)(A, B). “State-law fraud-on-the-FDA claims inevitably conflict with the FDA’s responsibility to police fraud consistently with the Agency’s judgment and objectives. As a practical matter, complying with the FDA’s detailed regulatory regime in the shadow of 50 States’ tort regimes will dramatically increase the burdens facing potential applicants – burdens not contemplated by Congress in enacting the FDCA and the MDA.” *Id.* at 350.

In this case, Wyeth argues that the plaintiff’s claim is different than the one advanced in *Buckman*, since the plaintiff must show that Duract was unreasonably dangerous when Wyeth released it into the market. However, to get to that point, the plaintiff must prove that Wyeth committed fraud on the FDA or bribed one of its employees. Section 600.2946(5) effectively mandates a plaintiff to offer evidence of fraud on the FDA as an element of its product liability claim against a drug manufacturer.

There may be some instances in which a fraud-on-the-FDA claim may proceed, as in the circumstance described by Justice Stevens in his concurring opinion in *Buckman*, where the FDA itself determines that an applicant committed fraud and takes steps to remove the drug from the market. *See id.* at 354 (Stevens, J., concurring). However, where, as here, the FDA has not so acted, or such action is forestalled by the voluntary withdrawal of the drug from the market, *Buckman* teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims. Section 600.2946(5), therefore, sends plaintiffs down a dead-end road, inasmuch as it creates immunity for drug manufacturers that can be upset only by a statutory exception that federal law preempts, except, perhaps, in the limited circumstance mentioned by Justice Stevens.

This statutory “Catch-22” does not render Section 600.2946(5) unconstitutional, however. The Michigan legislature may choose to provide remedies to damage claimants that are largely illusory, even when the only path around Section 600.2946(5)’s immunity for drug manufacturers puts a putative plaintiff on a collision course with the Supremacy Clause. A state legislature has authority to create, abolish, or modify common law causes of action. *Ferri v. Ackerman*, 444 U.S. 193, 198 (1979) (“[W]hen state law creates a cause of action, the State is free to define the defenses to that claim, including the defense of immunity”). Where the state legislature has created immunity from liability for a certain group of potential tortfeasors, the invalidity of the statutory exceptions to that immunity does not vitiate the immunity itself. *See Mich. Comp. Laws § 8.5* (“If any portion of an act or the application thereof . . . shall be found to be invalid by a court, such invalidity shall not affect the remaining portions or applications of the act which can be given effect without the invalid portion or application.”); *Mich. Bell Tel. Co. v. Engler*, 257 F.3d 587, 591-92 (6th Cir. 2001) (applying Mich. Comp. Laws § 8.5 and finding that a provision in Michigan’s Telecommunications Act was severable from the remaining portions of the statute); *Eubanks v. Wilkinson*, 937 F.2d 1118, 1121-22 (6th Cir. 1991) (holding that portions of a Kentucky abortion statute which was held unconstitutional should have been severed from the constitutional portions, thereby preserving the statute from being declared unconstitutional in its entirety). It has been credibly argued that common law products liability and tort law has played a major role in promoting and improving consumer product safety over the years. *See Donald P. Judges, Of Rocks and Hard Places: The Value of Risk Choice*, 42 *Emory L.J.* 1, 83-84, n.277 (1993) (concluding that while many commentators have challenged the assumption that products liability law has a demonstrably positive effect on product safety, the general concern about tort litigation and liability affects manufacturers’ decisions regarding the safety of their products); James T.

O'Reilly, *Dialogue with the Designers: Comparative Influences on Products Design Norms Imposed by Regulators and by the Third Restatement of Products Liability*, 26 N. Ky. L. Rev. 655 (1999) (finding that products liability, tort law, and the Restatement of Products Liability influence and encourage the design and implementation of safer products); Vincent R. Johnson, *Liberating Progress and the Free Market from the Specter of Tort Liability*, 83 Nw. U. L. Rev. 1026, 1037 n.69 (1989) (discussing a possible link between the products liability system and improved design and manufacturing practices). However, if the Michigan legislature chooses to strip this measure of protection from its citizenry, the United States Constitution will not present an obstacle to such a prospective change in state law.

The Supremacy Clause does not prevent the state from using federal agency standards as a common denominator of acceptable behavior. See *Schweiker v. Chilicky*, 487 U.S. 412, 424 (1988) (observing that a state agency may use federal standards and criteria when determining a claimant's eligibility for disability benefits); *F.E.R.C. v. Mississippi*, 456 U.S. 742, 761-64 (1982) (holding that a state utility commission may be required to use standards promulgated by the Federal Energy Regulatory Commission). The federal government attempts to monitor the safety and effectiveness of new medications and medical devices through the regulations administered by the FDA; if the state decides that the federal regulatory scheme furnishes its citizens protection enough against potential injury from the unanticipated effects of a new medication, the state has the prerogative to withdraw the compensatory and remedial safeguards that the tort reparations system might otherwise provide.

C.

The plaintiff contends, however, that the limits imposed by Section 600.2946(5) on her ability to recover damages caused by drug manufacturers' products are so severe that her rights of access to the courts and to a jury trial are abridged. "It is beyond dispute that the right of access to the courts is a fundamental right protected by the Constitution." *Graham v. Nat'l Collegiate Athletic Ass'n*, 804 F.2d 953, 959 (6th Cir. 1986). The Sixth Circuit has observed that this right finds its origins in several constitutional provisions, including the Fourteenth Amendment's Due Process and Equal Protection Clauses, the right to petition government for redress of grievances contained in the First Amendment, and the Privileges and Immunities Clause in Article IV. *See Swekel v. City of River Rouge*, 119 F.3d 1259, 1261-62 (6th Cir. 1997) (collecting cases). The right of access protects not only a person's ability to physically enter a court facility, but guarantees access that is "adequate, effective, and meaningful." *Bounds v. Smith*, 430 U.S. 817, 822 (1977).

Thus, violations of this right have been found where inmates have been denied the means to file appeals because no trial transcript was available, *see Griffin v. Illinois*, 351 U.S. 12, 18-19 (1956), or because of regulations forbidding the assistance of other inmates in preparing court papers, *see Johnson v. Avery*, 393 U.S. 483, 490 (1969); *Wolff v. McDonnell*, 418 U.S. 539, 577-80 (1974), or where prison law libraries were inadequate. *See Bounds*, 430 U.S. at 828. Likewise, a state violates a citizen's right of access to the courts when its functionary destroys or conceals evidence that is necessary to the presentation of a case. *See Swekel*, 119 F.3d at 1262 (holding that the right of access is destroyed when "the courtroom door [is] hermetically sealed by a functionary who destroys the evidence crucial to [a party's] case").

Although a right-of-access case can be established when a person can prove that a state's judicial process does not provide an adequate procedure to remedy an alleged wrong, *see Glover v. Johnson*, 75 F.3d 264, 268 (6th Cir. 1996) (“Access to the courts . . . encompasses all the means a defendant . . . might require to get a fair hearing from the judiciary on all charges brought against him or grievances alleged by him”) (citing *Gilmore v. Lynch*, 319 F. Supp. 105, 110 (N.D. Cal. 1970), *aff'd sub nom. Younger v. Gilmore*, 404 U.S. 15 (1971)), such claims are generally recognized for civil litigants only in the context of spoliation of evidence or interference with filing a lawsuit. *See Swekel*, 119 F.3d at 1263-64. A cognizable claim can be made out “only by showing that the defendants’ actions foreclosed [a potential litigant] from filing suit in state court or rendered ineffective any state court remedy [the litigant] previously may have had.” *Ibid*. The argument that a state statute stiffens the standard of proof of a common law claim does not implicate this right.

In this case, the plaintiff does not allege that she was unable to gain access to court to litigate her claim. Rather, she contends in essence that Section 600.2946(5) requires too much, and that the immunity it grants to drug manufacturers is too broad. These allegations do not constitute a claim of denial of access to the courts.

D.

Finally, the plaintiff argues that because Section 600.2946(5) effectively forecloses an injured party's right to recover damages from manufacturers of defective drugs, the statute violates her rights under the Due Process Clause. Section 1 of the Fourteenth Amendment states: “No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law.” Courts examine claims of

denial of procedural due process in two steps. First, there must be a protected liberty or property interest with which the state interferes. Second, the Court must decide whether the state provided procedural safeguards consistent with the nature of the right or interest at stake. *Kentucky Dep't of Corr. v. Thompson*, 490 U.S. 454, 460 (1989)); *Tony L. v. Childers*, 71 F.3d 1182, 1185 (6th Cir.1995).

In this case, the plaintiff is not able to meet the first element of the test. “A litigant has no vested property right in a cause of action until it accrues.” *Hartford Fire Ins., Co. v. Lawrence, Dykes, Goodenberger, Bower & Clancy*, 740 F.2d 1362, 1367 (6th Cir. 1984). Furthermore, the Supreme Court has held that due process does not prohibit the abolition of causes of action by a state legislature because “a person has no property, no vested interest, in any rule of the common law.” *Ibid* (quoting *Second Employers' Liability Cases*, 223 U.S. 1, 50 (1912)). Section 600.2946(5) was amended to include its present language in 1995. The plaintiff's injury occurred in 1997 through 1998, when she started taking Duract and later was diagnosed with liver failure. Therefore, the plaintiff's cause of action accrued after the statute was amended; the immunity which the state granted to drug sellers and manufacturers was already in place with the 1995 amendment to Section 600.2946(5).

Nor can the plaintiff fare any better asserting a claim based on substantive due process. “[S]tate legislatures are presumed by federal courts to have acted constitutionally in making laws.” *Hartford Fire*, 740 F.2d at 1366. The Supreme Court has analyzed legislation which limits tort claimants rights of recovery under the rational basis test. *See Duke Power Co. v. Carolina Env'tl. Study Group, Inc.* 438 U.S. 59, 83-84 (1978). Thus, “legislative Acts adjusting the burdens and benefits of economic life come to the Court with a presumption of constitutionality, and . . . the burden is on one complaining of a due

process violation to establish that the legislature has acted in an arbitrary and irrational way.” *Usery v. Turner Elkhorn Mining Co.*, 428 U.S. 1, 15 (1976).

Here, it is not difficult to divine a rationale which may have been the basis of the state’s preference of drug manufacturers over tort claimants that would comfortably fall within the wide boundaries of the rational basis test. The Court finds that the Michigan legislature acted within its authority when it granted immunity from liability to drug sellers and manufacturers who market their products after obtaining approval from the FDA.

III.

Section 600.2946(5) bars a person injured by the ingestion of a drug which was marketed by a putative defendant after FDA approval was obtained. There is no factual dispute that Duract, although since withdrawal from the market, had the FDA’s imprimatur when it was prescribed to Julia Garcia. The Court can find no basis on which to declare the statute invalid. The plaintiff’s lawsuit, therefore, may not proceed.

Accordingly, it is **ORDERED** that the Report and Recommendation of the magistrate judge dated July 2, 2002 [dkt # 104] is **REJECTED**.

It is further **ORDERED** that the defendant’s motion for summary judgment [dkt # 39] is **GRANTED** and the case is **DISMISSED**.

It is further **ORDERED** that the plaintiff’s motion for partial summary judgment [dkt # 21] is **DENIED**.

It is further **ORDERED** that the plaintiff’s motions in limine [dkts # 74, 77] are **DENIED** as moot.

It is further **ORDERED** that the defendant's motion in limine [dkt # 81] is **DENIED** as moot.

It is further **ORDERED** that the defendant's motion to modify order rejecting the magistrate judge's Report and Recommendation [dkt # 94] is **DENIED** as moot.

_____/s/_____
DAVID M. LAWSON
United States District Judge

Dated: May 19, 2003

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Magistrate Judge Charles E. Binder