Legislative Watch

Protections for Manufacturers and Sellers

By John G. Mitchell

A review of recent statutory developments.

The intent of this article is to note recent reform proposals at the federal level. It will then examine some existing statutes at the state level. Derivative from the specific state statutes, the article then examines constitutional challenges to such reforms. Finally, there will be a brief discussion on practical implications for manufacturers and sellers of drugs and medical devices of tort reform and efforts to defeat such reforms.

Recent Federal Tort Reform Proposals

The Help Efficient, Accessible, Low-Cost, Timely Health Care (HEALTH) Act of 2005, HR5, was introduced into the House of Representatives on July 21, 2005. The bill, which passed the House on July 28, 2005, was described as "a bill to improve patient access to health care services and provide improved medical care by reducing the excessive burden the liability system places on the healthcare delivery system."

Although sounding like a measure addressing medical malpractice claims, Section 7 of the proposed bill prohibits a punitive damage award in a product liability suit against a manufacturer, distributor, or supplier of a medical product that has been approved by the Food and Drug Administration (FDA) or that is generally recognized among qualified experts as safe and effective pursuant to the conditions established by the FDA. As an exception to this prohibition, punitive damages would still be available if the finder of fact determines by clear and convincing evidence that: 1) the product is "substantially out of compliance with applicable labeling or packaging regulations"; 2) the product is one where there has knowingly been "misrepresented or withheld from the FDA required information that is material and causally related to the harm suffered by the claimant"; or 3) "an illegal payment is made to an FDA official to secure approval." The bill also prohibits product liability suits against a medical care provider who prescribes or dispenses such a medical product approved by the FDA.

The scope of the prohibition of punitive damages is as against "a manufacturer, distributor or supplier of a medical product." The proposed provision reads as follows:

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(c) No Punitive Damages for Products That Comply With FDA Standards.

(1) In General—

(A) No punitive damages may be awarded against the manufacturer or distributor of a medical product, or a supplier of any component or raw material of such medical product, based on a claim that such product caused the claimant's harm where—

(i) (I) such medical product was subject to premarket approval, clearance, or licensure by the Food and Drug Administration with respect to the safety of the formulation or performance of the aspect of such medical product which caused the claimant's harm or the adequacy of the packaging or labeling of such medical product; and

(II) such medical product was so approved, cleared, or licensed; or

(ii) such medical product is generally recognized among qualified experts as safe and effective pursuant to conditions established by the Food and Drug Administration and applicable Food and Drug Administration regulations, including without limitation those related to packaging and labeling, unless the Food and Drug Administration has determined that such medical product was not manufactured or distributed in substantial compliance with applicable Food and Drug Administration statutes and regulations.

The bill has been referred to the Senate Committee on the Judiciary, as of July 29, 2005. No action has yet been taken.

This follows the February 10, 2005, introduction of the Senate version of the HEALTH Act of 2005. Although defining its purpose, in language similar to that of the House version, as being "to improve patient access to health care services and provide improved medical care by reducing the excessive burden the liability system places on the health care delivery system," the Senate version of the bill does not provide for protection against punitive damages for "the manufacturer or distributor of a medical product." The protection from punitive damage awards only pertains to "a health care provider" who prescribes or dispenses a drug or device approved by the FDA. This bill provides further protections to health care providers by noting that they "shall not be named as a party to product liability lawsuit invoking such drug or device," and "shall not be liable to a claimant in a class action lawsuit against the manufacturer, distributor, or product seller of such drug and device." This bill uses the terms "drug" and "device" as having the meanings given such terms in Sections 201(g)(1) and 201(h) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 321). However, the Senate version of the bill, currently in the Judiciary Committee, does not extend the protection against punitive damages to the manufacturers and distributors of such products.

From a completely different perspective is a Bill, HR3970, which was introduced in the House on October 6, 2005, to provide liability protections for certain pandemics and countermeasures. The Bioterror and Pandemic Preparedness Protection Act was introduced "to amend the federal judicial code to establish an exclusive federal cause of action for all claims related to a qualified pandemic or epidemic product or a security countermeasure." The bill would restrict all causes of action for such claims against a manufacturer, distributor, or health care provider, limiting the sole and exclusive action as one against the United States. Section 4101 of Chapter 181 creates an "exclusive federal cause of action for all claims for lost property, personal injury, bodily injury, including mental anguish, or death arising out of, or related to, or resulting from the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, administration, or use of a qualified pandemic or epidemic product..." The exception to this immunity would be if, as to a manufacturer, distributor, administrator, or health care provider, the Attorney General makes a determination, and finds by clear and convincing evidence, that such intended party "intentionally or with willful disregard" violated a provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) or the Public Health Service Act. The party wishing to prosecute such an action may petition the Attorney General for such an investigation, but the decision to investigate is within the exclusive discretion of the Attorney General and shall not be subject to judicial review.

The statutory scheme is designed to encourage the resolution of claims.

HR 3970 has been referred to the House Committees on the Judiciary and Energy and Commerce.

Similar to the HEALTH Act 2005, the Patients First Act of 2005 was introduced in the Senate on July 27, 2005. This bill is predicated upon Congress' finding that "our current civil justice system is adversely affecting patient access to health care sources, better patient care, and cost-efficient health care, in that the current health care liability system is a costly and ineffective mechanism for resolving claims of health care liability and compensating injured patients, and is a deterrent to the sharing of information among health care professionals which impedes efforts to improve patient safety and quality of care." The statutory scheme is designed to encourage the resolution of claims. It also provides in any health care lawsuit the "amount of noneconomic damages recovered may be as much as $250,000, regardless of the number of parties against whom the action is brought or the number of separate claims or actions brought with respect to the same occurrence."

While the language of the proposed statute would suggest that it is only designed to address medical malpractice claims, pursuant to Section 109 (D)(7), the term "health care lawsuit" means "any health care liability claim concerning the provision of health care goods or services affecting interstate commerce, or any health care liability action concerning the provision of health care goods or services affecting

interstate commerce, brought in a State or Federal court or pursuant to an alternative dispute resolution system, against a health care provider, a health care organization, *or the manufacturer, distributor, supplier, marketer, promoter, or seller of a medical product, regardless of the theory of liability on which the claim is based....*" (Emphasis added.) For the purposes of this statute, a "medical product" means a drug or device intended for humans, and the terms "drug" and "device" have the "meanings given such terms in sections 201(g)(1) and 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321), respectively, including any component or raw material used therein...."

There are laws that provide benefit, but not absolute immunity, for compliance with FDA regulations.

For the purposes of this proposed statute, which has been referred to the Committe on Finance, the terms "health care lawsuit," "health care liability action," and "health care liability claim" are all treated the same, and include claims, civil actions, or demands brought against "the manufacturer, distributor, supplier, marketer, promoter or seller of a medical product."

A similar, but narrower, bill, Healthy Mothers and Healthy Babies Access to Care Act of 2005, was introduced into the Senate on February 10, 2005. This bill was intended "to improve women's access to health care services and provide improved medical care by reducing the excessive burden the liability system places on the delivery of obstetrical and gynecological services." Using definitions that are the same, and in fact employ the same sections, as those from the Patients First Act of 2005, section 6 of this bill provides that punitive damages are only available in a "health care lawsuit" if "it is proven by clear and convincing evidence that a person acted with malicious intent to injure the claimant or that such person deliberately failed to avoid unnecessary injury as such person knew the claimant was substantially certain to suffer." In attempting to seek punitive damages, "no demand for punitive damages shall be included in a health care lawsuit as initially filed." A pleading, by way of an amended pleading, may seek punitive damages "only upon a motion by the claimant and after a finding by the court, upon review of supporting and opposing affidavits or after a hearing, after weighing the evidence, that the claimant has established by a substantial probability that the claimant will prevail on the claim for punitive damages." Section 6, subsection (1) and (2).

This bill also provides that a health care provider who prescribes or dispenses, pursuant to a prescription, a drug or device approved by the FDA shall not be named as a party to a product liability lawsuit invoking such drug or device and shall not be liable to a claim in a class action lawsuit against a manufacturer, distributor, or product seller of such drug or device. The bill has been referred to the Senate Judiciary Committee.

Similarly, the Pregnancy and Trauma Care Access Protection Act of 2005, introduced in the Senate on February 10, 2005, and currently in the Judiciary Committee, caps non-economic damages, eliminates joint and several liability, and restricts punitive damages in claims involving pregnancy and trauma care. Its purpose is "to improve access to health care services, and the access of all individuals to emergency and trauma care services, by reducing the excessive burden the liability system places on the delivery of such services." The proposed statute uses the same definitions as previously discussed and precludes a health care provider from being part of a product liability action, a class action, or similar proceedings. Further, this statute considers a "health care lawsuit," a "health care liability action," and a "health care liability claim" to include claims against manufacturers, distributors, suppliers, marketers, promoters, or sellers of medical products (which, again, by definition are drugs and devices as defined by the FDA).

State Statutory Action

State legislation, specifically applicable to drug and device litigation, can be categorized in three ways. First, there is the statute that, for all practical purposes, creates absolute immunity for manufacturers' and sellers' prescription medications, which is seen in Michigan. Second, there are laws that provide benefit, but not absolute immunity, for compliance with FDA regulations. Finally, there are statutes that present a benefit if there is compliance with state or federal regulations, in general, but not specifically referencing the Food, Drug and Cosmetic Act (FDCA) or action by the FDA.

The most clearly defined tort reform provision affording functional immunity to the manufacturers and sellers of drugs, but not medical devices, is that established by Michigan in MCL §600.2946(5). This provision provides:

> (5) 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 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.

Although Section 2946(5) does not pertain to medical devices, MCL 600.2946(1) and (4) provide protection, although not as clearly drawn. The statutory scheme, as is the case with statutory schemes in some other jurisdictions, affords presumptive protection, but not immunity, when products, which by extension should include medical devices, are in compliance within existing governmental regulations and/or then existing industry standards.

After Michigan's statute, New Jersey's statute may be considered the strictest with regard to drug and device product liability. It creates a rebuttable presumption of non-negligence for pharmaceutical companies when they comply with FDA standards. N.J. Stat. Ann §2a:58C-4 (1987), states in pertinent part:

> In any product liability action the manufacturer or seller shall not be liable for harm caused by a failure to warn if the product contains an adequate warning or instruction or, in the case of dangers a manufacturer or seller discovers or reasonably should discover after the product leaves its control, if the manufacturer or seller provides an adequate warning or instruction.... If the warning or instruction given in connection with a drug or device or food or food additive has been approved or prescribed by the federal Food and Drug Administration under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. §301 et seq., or the "Public Health Service Act," 58 Stat. 682, 42 U.S.C. §201 et seq., a rebuttable presumption shall arise that the warning or instruction is adequate. For purposes of this section, the terms "drug," "device," "food," and "food additive" have the meanings defined in the "Federal Food, Drug, and Cosmetic Act." (Emphasis added.)

While New Jersey's statute gives drug and device manufacturers and sellers a fair amount of protection from liability as long as the FDA approved the warning or instruction on the drug, it stops short of the protection that the Michigan law grants drug and device products for governmental compliance. New Jersey still allows parties injured by a drug or device to bring suit against the manufacturer or seller for failure to warn even though the warning or instruction was approved by the FDA. However, compliance with governmental standards creates a rebuttable presumption that the drug or device company is not liable for the harm caused by the drug or device.

New Jersey's statute is similar to the Michigan statute. The New Jersey Supreme Court held that the rebuttable presumption of non-negligence standard required intentional action on the part of the drug or device manufacturer or seller. *Perez v. Wyeth Labs, Inc.*, 161 N.J. 1, 734 A.2d 1245 (N.J. 1999). The court held that "absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive of such claims." *Id.* at 1259.

Ohio's statute, as it applies to drug and device cases, bars punitive damages against a manufacturer of a drug or device and labeled in compliance with FDA requirements. O.R.C. Ann. §2307.80(C), as effective April 7, 2005. The statute states in pertinent part:

(1) [I]f a claimant alleges in a product liability claim that a drug or device caused harm to the claimant, the manufacturer of the drug or device shall not be liable for punitive or exemplary damages in connection with that product liability claim if the drug or device that allegedly caused the harm satisfies either of the following:
   (a) It was manufactured and labeled in relevant and material aspects in accordance with the terms of an approval or license issued by the federal food and drug administration under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C. 301-392, as amended or the "Public Health Service Act," 58 Stat. 682 (1944), 42 U.S.C. 201-300cc-15, as amended...
(2) Division (C)(1) of this section does not apply if the claimant establishes, by a preponderance of the evidence, that the manufacturer fraudulently and in violation of applicable regulations of the food and drug administration withheld from the food and drug administration information known to be material and relevant to the harm that the claimant allegedly suffered or misrepresented to the food and drug administration information of that type.
(3) For purposes of divisions (c) and (d) of this section,
   (a) "Drug" has the meaning given to that term in the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 1041 (1938), 21 U.S.C. 321(g)(1), as amended.
   (b) "Device" has the meaning given to that term in the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 1041 (1938), 21 U.S.C. 321(h), as amended.

Rather than completely shielding drug and device companies from liability as does the Michigan law, the Ohio statute provides assistance to the drug and device manufacturers and sellers by limiting the amount of recoverable damages. As long as the drug or device has been approved by the FDA, an injured party cannot recover punitive or exemplary damages from the manufacturer or seller.

Oregon's product liability statute also bars punitive damages in a case in which a drug, but not a device, has labeling as approved by the FDA, provided that material information was not withheld or misrepresented. O.R.S. §30.927 (1987). The statute states:

(1) Where a drug allegedly caused the plaintiff harm, the manufacturer of the drug shall not be liable for punitive damages if the drug product alleged to have caused the harm:
   (a) Was manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the federal Food and Drug Administration under the Federal Food, Drug and Cosmetic Act or the Public Health Service Act; or
   (b) Is generally recognized as safe and effective pursuant to conditions established by the federal Food and Drug Administra-

tion and applicable regulations, including packaging and labeling regulations.

(2) Subsection (1) of this section does not apply if the plaintiff proves, in accordance with the standard of proof set forth in ORS 30.925(1), that the defendant, either before or after making the drug available for public use, knowing in violation of applicable federal Food and Drug Administration regulations withheld from or misrepresented to the agency or prescribing physician information known to be material and relevant to the harm which the plaintiff allegedly suffered.

(3) Nothing contained in this section bars an award of punitive damages where a manufacturer of a drug intentionally fails to conduct a recall required by a valid order of a federal or state agency authorized by statute to require such a recall.

(4) For the purposes of this section, the term "drug" has the meaning given to the term in section 1201(g)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 321(g)(1).

As in Ohio, Oregon's legislature squarely addressed the issue of numerous and overly excessive damage awards in favor of injured parties and against drug manufacturers and sellers. Rather than creating a law that completely barred plaintiffs from all types of recovery against drug companies, the Oregon legislators limited the type of damages the plaintiffs could recover, excluding punitive damages if the drug had been approved by the FDA. An important feature of this statute is an exception where information is withheld that is material to the harm allegedly caused. Oregon's statute lays out the exception, explicitly including fraud before and after FDA approval, as grounds for being excluded from the ban on punitive damages. This statute allows consumers to bring suit against a drug manufacturer or seller for harm caused by a drug even though the drug was approved by the FDA.

Utah's pharmaceutical product liability statute is similar to Ohio's and Oregon's in that it prohibits the award of punitive damages if a drug, but not a device, causing harm was premarket-approved by the FDA or otherwise approved by the FDA. Utah Code Ann. §78-18-2 (1989) reads:

(1) Punitive damages may not be awarded if a drug causing the claimant's harm:

(a) received premarket approval or licensure by the Federal Food and Drug Administration under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Section 301 *et seq.* or the Public Health Act, 42 U.S.C. Section 201 *et seq.*;

(b) is generally recognized as safe and effective under conditions established by the Federal Food and Drug Administration and applicable regulations, including packaging and labeling regulations.

(2) This limitation on liability for punitive damages does not apply if it is shown by clear and convincing evidence that the drug manufacturer knowingly withheld or misrepresented information required to be submitted to the Federal Food and Drug Administration under its regulations, which information was material and relevant to the claimant's harm.

Utah's legislature, like Ohio's and Oregon's, did not extend the protection it provides drug manufacturers and sellers beyond eliminating punitive damages. By limiting a plaintiff's ability to recover huge settlements from drug companies, the legislature was assisting in the stabilization of corporate liability and helping businesses in Utah avoid economic harm as a result of runaway jury verdicts and frivolous lawsuits.

Finally, there are a number of statutes that provide beneficial presumptions when a product is subject to regulatory compliance, without specific reference to the FDA or the FDCA. *See* Table I.

Constitutional Challenges

The constitutionality of Michigan's immunity statute has been established. Originally, MCL 600.2946(5) was challenged at the trial court level as violating the Michigan Constitution by improperly delegating legislative and/or judicial powers, violating due process, violating equal protection, and denying access to the courts. Eventually, the appellate focus was narrowed to the single issue of delegation of powers. The Michigan Supreme Court has affirmed that there is no improper delegation, and that

Table I: Compliance with Federal or State Regulations

State	Statute	Effect
Arkansas	Ark. Code Ann. §16-116-105(a)	Must be considered as evidence that the product is not in an unreasonably dangerous condition in regard to matters covered by these standards
Colorado	Colo. Rev. Stat. §13-21-403(1)(b)	Rebuttable Presumption that a product is not defective or unreasonably dangerous
Georgia	Ga. Code Ann. §51-1-11(b)	Compliance with government standards may be a factor for the jury to consider
Kansas	Kan. Stat. Ann. §60-3304(a)	Shall be deemed not defective by reason of design or performance; not a conclusive presumption
Michigan	Mich. Comp. Laws Ann. §600.2946(4)	Admissible but not conclusive
North Dakota	N.D. Cent. Code §28-01.3-09	Rebuttable Presumption that a product is not defective or unreasonably dangerous
Tennessee	Tenn. Code Ann. §29-28-104	Rebuttable Presumption that a product is not defective or unreasonably dangerous
Utah	Utah Code §78-15-6(3)	Rebuttable Presumption that a product is free from any defect

Section 600.2946(5) is constitutional. *Taylor v. Smith Kline Beecham*, 468 Mich. 1, 658 N.W.2d 127 (Mich. 2003).

A second challenge to MCL 2946(5) claimed violation of the United States Constitution, under Article VI, the Supremacy Clause, access to courts, the Seventh Amendment, and due process. As to each challenge, the Sixth Circuit Court of Appeals has held that there is no violation of the U.S. Constitution and that Section 600.2946(5) is a constitutional exercise of legislative authority. *Garcia v Wyeth Ayerst Laboratories*, 385 F.3d 961 (6th Cir. 2004).

Generally, the challenges to MCL 600.2946(5) constitute traditional mechanisms by which constitutional challenges are presented. The nature and scope of all challenges is more extensive than is permitted in this particular discussion. For reference, and as applies to exemplar statutes of potential significance to drug and device manufacturers and sellers, Table II presents an analysis of statutory schemes, cases, constitutional challenges, and the results of such challenges to various tort reform provisions. The statutory schemes set forth herein are not necessarily specific to drugs and medical devices, nor product liability. Instead, what is presented is a survey of some of the challenges and the results of such challenges, to reforms, generally.

Throughout 2005, there were and continue to be constitutional challenges presented. These challenges have resulted in determinations that statutes, not surprisingly, both have and have not violated constitutional protections.

For example, *Reust v. Alaska Petroleum Contrs., Inc.*, 127 P.3d 807 (Alaska 2005), involved a constitutional challenge to Alaska's restriction on punitive damages. The reform statute placed caps on actions against employers to recover for unlawful employment practices and required those receiving a punitive damage award to deposit 50 percent of that award into the general fund of the state. Alaska Stat. §09.17.020(j) and (h). The court held that subsection (j) does not violate substantive due process because it was rational for the legislature to expect that fewer punitive damage claims would be filed and that more would be settled if the potential payoff is capped or reduced by allocating half of any punitive damage awards to the state. Furthermore, subsection (j) does not constitute an unconstitutional taking because punitive damages are not a protected property right. The court held that subsection (h) does not violate equal protection because the plaintiff's interests in unlimited damages are merely economic, and therefore, the state's objec-

Table II: Constitutional Challenges to Select Tort Reform Statutes

State	Statute	Case	Constitutional Challenge	Upheld
Alabama	Ala. Code 1975 §6-5-549 (standard of proof is substantial evidence in medical liability action)	*Cackowski v. Wal-Mart Stores, Inc.*, 767 So.2d 319 (Ala. 2000)	Equal Protection (Ala. and U.S. Const.)	Yes
Arizona	A.R.S. §§12-2501 to 12-2509, the Uniform Contribution Among Tortfeasors Act (UCATA)	*Jimenez v. Sears, Roebuck and Co.*, 183 Ariz. 399, 904 P.2d 861 (Ariz. 1995)	Ariz. Const. Art. 2 §31 (prohibits laws limiting damages)	Yes
Illinois	Public Act 89-7 (non economic damage caps, abolishment of joint and several liability)	*Best v. Taylor Mach. Works*, 179 Ill.2d 367, 228 Ill. Dec. 636 (Ill. 1997)	Separation of Powers, Prohibition against "special legislation"	No No
Michigan	MCL §600.2946a (damage caps in products liability)	*Kenkel v. Stanley Works*, 256 Mich. App. 548, 665 N.W.2d 490 (Mich. 2003)	Due Process, Equal Protection Mich. Const. Art. 4 §29 (prohibition against class legislation), Separation of Powers	Yes Yes Yes
Michigan	MCL §600.2946(4) (rebuttable presumption of no liability when comply with Fed or state safety standards)	*Mutual Ins. Co. of America v. Royal Appliance Mfg. Co.*, 112 Fed. Appx. 386 (6th Cir. 2004)	Delegation of powers (Mich. Const.)	Yes
Ohio	Am.Sub.H.B. No. 350 (general tort reform legislation passed in 1996 amending over 100 statutes)	*State ex rel. Ohio Academy of Trial Lawyers v. Sheward*, 86 Ohio St.3d 451, 715 N.E.2d 1062 (Ohio 1999)	Separation of powers (Ohio Const.), One subject provision (Ohio Const.)	No No
Texas	Tex. Civ. Prac. & Rem. Code §82.004 (inherently unsafe product defense)	*Burleson v. Liggett Group, Inc.*, 111 F. Supp. 2d 825 (N.D. Tex. 2000)	Equal Protection (Tex. and U.S. Const.)	Yes
Texas	Tex. Civ. Prac. & Rem. Code §82.004 (inherently unsafe product defense)	*Hughes v. Tobacco Institute, Inc.*, 278 F.3d 417 (5th Cir. 2001)	Open Courts guarantee (Tex. Const.), Due Process (U.S. and Tex. Const.)	Yes Yes
Texas	Tex. Civ. Prac. & Rem. Code §82.004 (inherently unsafe product defense)	*Perez v. Brown & Williamson Tobacco Corp.*, 967 F. Supp. 920 (S.D. Tex. 1997)	Retroactive law or open courts provisions of Tex. Const.	Yes

tives need only be "legitimate"—not "compelling"—to justify the state's action. The court held that the legislature's stated goals underlying the damages caps were "plainly legitimate."

In contrast, in *Ferdon v. Wis. Patients Comp. Fund*, 2005 WI 125 (Wis. 2005) the plaintiff challenged the constitutionality of Wisc. Stat. §§655.017 and 893.55(4)(d) as violative of the equal protection guarantees of the Wisconsin Constitution. In holding the statutes unconstitutional, the court applied a rational basis level of scrutiny and found that the legislature's goals of adequately compensating malpractice victims, limiting malpractice premiums, and keeping the defendant's assessment level at a low rate were not rationally related to the cap, as the cap punished the most severely injured victims, and the facts did not support the assumption that a cap on non-economic damages achieved any of the other stated goals. The *Ferdon* holding was followed in *Kaul v. St. Mary's Hosp.-Ozaukee*, 704 N.W.2d 423 (Wis. Ct. App. 2005) later that year.

The court held that the legislature's stated goals underlying the damages caps were "plainly legitimate."

Practical Implications

Nothing may be more practically significant to statutory reforms than action to repeal the protections currently afforded manufacturers and sellers of drugs and devices. Currently, there are at least four separate bills pending before the Michigan Legislature seeking, at the very least, to repeal or modify MCL 600.2946(5). Introduced in the Michigan House of Representatives over the past few months were House Bill 4773, House Bill 4811, House Bill 5071, and House Bill 5139.

In Oregon, there is a similar effort currently pending in the form of House Bill No. 2743, introduced March 2, 2005, with the proposed intent of repealing O.R.S. 30.927. Replacing the prior limitations on punitive damages would be provisions that provide protection to health practitioners and pharmacists with respect to the prescription and sale of FDA approved drugs.

It is difficult to come by "hard" data regarding the effect of tort reform on exposure to litigation in particular. Although one could credit reduced filings to an adverse environment for a claimant to prosecute an action, this phenomenon may mean nothing more than the absence of any viable claims. Thus, to evaluate the impact of tort reform, one needs to look at patterns rather than cases filed. There is no doubt that the number of cases involving diet drugs and Vioxx filed within the State of Michigan, subsequent to the passage of MCL 600.2946(5), was but a fraction of those filed in states of comparable population. However, tort reform did not necessarily stop claimants from bringing cases. Tort reform statutes, often, merely changed the venue in which an action was filed.

Tort reform did not stop the active solicitation of possible plaintiffs. Radio, newspaper, Internet, and television ads were still run. Lawyers found clients and clients found lawyers. The difference is that the actions were prosecuted in state courts with favorable joinder rules, such as Georgia, or in state courts of the domicile of the target defendant. Cases that could have been filed in Michigan, were filed elsewhere as a result of forum shopping, application of aggressive use of joinder rules, and favorable diversity determinations.

Many statutes, as we have discussed, do not directly impact the prosecution of claims against drug and device manufacturers and distributors. Such provisions, however, may preclude the naming of a non-diverse medical care provider as a party and interfere with any plan to name such a party solely for the purpose of defeating federal diversity jurisdiction for product liability claims that would otherwise be removable to the appropriate federal district court.

Conclusion

Tort reform continues to be of great interest to drug and device manufacturers and sellers. Historic efforts have been inconsistent regarding a manufacturer's or seller's ability to obtain statutory relief from potential claims.

Currently, two primary efforts are underway. First, there are renewed efforts at the federal level to create statutory reform with, at least, partial protection afforded drug and device companies. Such efforts, however, are often unique and specific to individualized types of claims. Second, and more broadly, state statutes are in place in certain jurisdictions. Such reforms may apply to the entire range of claims against a manufacturer or seller of drugs or devices, or may simply affect the extent to which there is exposure to non-economic damages and/or punitive damages. FTD