

Update Materials

Franklin, Rabin & Green, "Tort Law and Alternatives" (8th ed. 2006)

Chapter I

Page 28 after note 3 (new note). Some courts, however, do not require reliance on the physician's being an employee, but instead demand only that the patient rely on the hospital to provide competent medical care. See *York v. Rush-Presbyterian-St. Luke's Medical Center*, 854 N.E.2d 635 (Ill. 2006). For a discussion of the range of approaches employed by courts on the issue of apparent agency of hospital physicians and whether reliance is required, see John D. Ingram, *Vicarious Liability of the Employer of an Apparent Servant*, 41 *Tort Trial & Ins. Prac. L.J.* 1 (2005).

Chapter II

Page 100 note 8. A case, the first so far as we know, recognizing a cause of action against a third party for negligent spoliation is *Killings v. Enterprise Leasing Co., Inc.*, ___ So.2d ___, 2008 WL 4967412 (Ala. 2008). Plaintiff was driving a car rented from defendant when the wheel came off. Driver sued manufacturer and others who had maintained the car. Plaintiff's lawyer called the car rental company and requested that the car, which had been totaled, be preserved and that he be notified before it was scrapped or otherwise disposed of. Despite agreeing, the rental company (and defendant here) disposed of the wreck, and plaintiff's expert testified that he couldn't determine the cause of the wheel coming off the car without testing the car. The court recognizes a third-party negligent spoliation claim, conditioned on:

- actual knowledge of "pending or potential litigation" on the part of the spoliator;
- a voluntary undertaking, agreement, or specific request establishing a duty; and
- evidence that the missing evidence was vital to the underlying claim.

Page 115 after note 1 (new note). Confronting head on an issue that lurks unresolved in the *Sheely* case is *Arpin v. U.S.*, 521 F.3d 769 (7th Cir. 2008). Plaintiff fell and, after experiencing terrible pain, presented at a family clinic where he was seen by a second-year resident. Suit against her was based on failing to conduct certain medical tests that would have revealed a very rare muscle infection that ultimately led to his death but which could have been

treated with antibiotics if diagnosed. The court says: "[T]he majority rule, which in default of any Illinois case we'll assume is the rule in Illinois as well, holds residents to the same standard of care as physicians who have completed their residency in the same field of medicine." For a thorough assessment of the range of views on this question reflected in the case law—from using a standard specific to residents of that amount of training to the standard of care for specialists—see Joseph H. King, *The Standard of Care for Residents and Other Medical School Graduates in Training*, 55 Am. U.L. Rev. 683 (2006)

Chapter III

Section B. Affirmative Obligations to Act.

Page 144 after note 2 (new note). Recognizing an arguably new special relationship is *Bjerke v. Johnson*, 742 N.W.2d 660 (Minn. 2007). Defendant owned a stable and had minor-plaintiff reside there for significant periods of time with approval of her parents. Defendant told the parents she would look after their child. The minor, during a period when she was 14-18 years old, had a sexual relationship with the defendant's live-in boyfriend and sues defendant claiming she had a duty to protect her. The court finds a special relationship based on the surrogate parent/custodial role that defendant undertook when she invited plaintiff to live with her. (This is the same court that decided *Harper*.)

Page 145 note 7. A variation on the pre-employment physical occurred in *Draper v. Westerfield*, 181 S.W.3d 283 (Tenn. 2005). The defendant-radiologist was hired by the state department of social services to review scans taken of the infant child because of suspected child abuse. The child was subsequently killed by her father. The doctor did not report that the tests revealed strong evidence of abuse, likely by the parents. The physician claimed that he had no duty to the decedent with whom he did not have a doctor-patient relationship. The court concluded otherwise, finding the basis for a duty in the physician's undertaking to review the medical records and report the results to state investigators.

Page 165 note 3. The *Tenuto* case produced a \$22.5 million award in March 2009. *Father Blamed Vaccine for Giving him Polio*, Nat'l L.J., March 20, 2009, at 15.

Page 172 note 3. Courts seem regularly to confuse negligence per se, in which a statutory provision provides a more specific standard for what constitutes negligence, with whether a statute can provide the basis for a cause of action or affirmative duty that otherwise has not been recognized by tort law. To be sure, once a court concludes that a statutory standard—such as a statute requiring a hospital to report suspected child abuse to state authorities—provides a cause of

action or imposes a duty, the statutory standard also provides what is required for breach of the newly-recognized duty. For a recent example of a court confusing negligence per se and whether a statute provides a new tort duty, see *T & M Jewelry, Inc. v. Hicks*, 189 S.W.3d 526 (Ky. 2006). In *Hicks*, the court rejected the plaintiff's claim that violation of a federal statute barring the sale of guns to a minor constituted negligence per se on the ground that the statute could not be read as implicitly providing a private right of action. Yet, in part based on the statute, the court concluded that defendant was subject to a common law duty of care in selling handguns to minors.

Page 182 note 9. *Olivo v. Owens-Ill., Inc.*, 895 A.2d 1143 (N.J. 2006). By contrast with the New York Court of Appeals in *New York City Asbestos Litigation*, the New Jersey Supreme Court had little difficulty finding that a refinery owed a duty to the spouse of a welder who was exposed to asbestos at the defendant's refinery and brought home clothes laden with asbestos. The spouse's exposure when cleaning the clothes caused her to contract mesothelioma. Relying on the foreseeability of harm to the spouse of a worker, the court brushed aside the "limitless liability" concern that weighed heavily with the New York court. Courts continue to confront and resolve this issue. The latest are *Satterfield v. Breeding Insulation Co.*, 266 S.W.3d 347 (Tenn. 2008) (discussing whether case involved misfeasance or nonfeasance and concluding that it was a misfeasance case for which the ordinary duty of reasonable care existed based on the foreseeability of harm) and *Riedel v. ICI Americas Inc.*, ___ A.2d ___, 2009 WL 536540 (Del. 2009) (treating case as one involving nonfeasance and finding no basis for a duty because of the lack of a special relationship between plaintiff-spouse and defendant-employer).

Page 187 after note 5 (new note). Does a person who agrees to act as a designated driver have a duty to third persons? Yes, qualifiedly, says the court in *White v. Sabatino*, 415 F. Supp. 2d 1163 (D. Haw. 2006). The qualification is that a duty arising from the undertaking exists only if performance begins. Thus, a broken promise to serve as a designated driver cannot be the basis for a duty. (The issue of whether a bare promise, without any further action, is sufficient for an undertaking has long been a matter of controversy, although it appears the modern view is that it can be. See Restatement (Third) of Torts: Liability for Physical Harm § 42; Comment e (Proposed Final Draft No. 1, 2005).)

Page 187 note 6, last ¶. The judgment in the Giants Stadium case was overturned on appeal. *Verni v. Harry M. Stevens, Inc.*, 903 A.2d 475 (N.J. Super. Ct. App. Div. 2006). The court explained:

[The beer vendors] argue that the trial judge erred in admitting evidence of a "culture of intoxication" at the stadium. They urge that such evidence is

irrelevant to the central issue in a claim against a licensed beverage server and that admission of such evidence caused undue prejudice to [the vendors]. We agree . . . and thus, a new trial is required.

The court observed that under the dram shop act the issue is whether the driver was visibly intoxicated when he was served. Whether others were similarly served, or a generally rowdy culture existed, or violations of defendant's own service policies occurred, were irrelevant to the central question in the case.

After remand, the case was settled for \$25 million. Mark Mueller, *Paralyzed Girl and Mom Received \$25m Settlement from Beer Vendor*, The Star-Ledger (Newark, N.J.), Dec. 4, 2008, at 13.

Page 195 or Page 218 new section entitled "A Reprise on Duty." Instructors may want to include the following case either at the conclusion of Section C, Policy Bases for Invoking No Duty or at the conclusion of Section D, The Duties of Landowners and Occupiers. We envision using this case to play off many of the themes in the prior sections, including the ordinary duty of reasonable care, the use of factors to decide if a duty exists and especially the role of foreseeability in that inquiry, whether statutes can be the source of (affirmative) duties in tort, the relationship between an implied private right of action and a statute providing a basis for an affirmative tort duty, and the role of relationships as a basis for the ordinary duty of care as well as affirmative duties. This case would be fine at the conclusion of Section C, but since it does refer to duties imposed on landowners, suggesting that they are a remaining bastion in which duty arises from a relationship (rather than landowner duties being partial dispensations from the ordinary duty of reasonable care), and because the case is a good foil for *Posecai*, some instructors may want to defer coverage until after completing Section D.

Gipson v. Kasey
Supreme Court of Arizona, 2007
214 Ariz. 141, 150 P.3d 228.

BALES, JUSTICE.

The issue presented is whether persons who are prescribed drugs owe a duty of care, making them potentially liable for negligence, when they improperly give their drugs to others. We conclude that such a duty is owed.

FACTS AND PROCEDURAL BACKGROUND

...

Kasey attended an employee holiday party hosted by the restaurant where he worked. Also present were his co-worker, Nathan Followill, and Followill's girlfriend, Sandy Watters. The restaurant provided beer for the guests. Kasey brought whiskey to the party and he gave shots to others present, including Followill, who was twenty-one years old. Kasey also brought pain pills containing oxycodone, a narcotic drug, which he had been prescribed for back pain. On prior occasions, Kasey had given pain pills to other co-workers for their recreational use.

During the party, Watters asked Kasey for one of his pain pills. Kasey gave Watters eight pills, noting that they were of two different strengths, but not identifying them by name. Although Kasey knew that combining the pills with alcohol or taking more than the prescribed dosage could have dangerous side effects, including death, he did not tell Watters this information.

When Kasey gave the pills to Watters, he knew that she was dating Followill. Kasey also knew that Followill was interested in taking prescription drugs for recreational purposes because Followill had on prior occasions asked Kasey for some of his pills, but Kasey had refused because he thought Followill was "too stupid and immature to take drugs like that."

Shortly after she obtained the pills from Kasey, Watters told Followill she had them, and Followill took the pills from her. As the night progressed, Followill became increasingly intoxicated. Around 1:00 a.m., Watters and Followill left the party. The next morning, Watters awoke to find that Followill had died in his sleep. The cause of death was the combined toxicity of alcohol and oxycodone.

Gipson, Followill's mother, filed a wrongful death action against Kasey. The superior court granted summary judgment for Kasey, finding that he owed Followill no duty of care

The court of appeals reversed, holding that Kasey did owe Followill a duty of care

DISCUSSION

To establish a claim for negligence, a plaintiff must prove four elements: (1) a duty requiring the defendant to conform to a certain standard of care; (2) a breach by the defendant of that standard; (3) a causal connection between the defendant's conduct and the resulting injury; and (4) actual damages. [] The first element, whether a duty exists, is a matter of law for the court to decide. [] The other elements, including breach and causation, are factual issues usually decided by the jury. []

The existence of a duty of care is a distinct issue from whether the standard of care has been met in a particular case. As a legal matter, the issue of duty involves generalizations about categories of cases. Duty is defined as an "obligation, recognized by law, which requires the defendant to conform to a particular standard of conduct in order to protect others against unreasonable risks of harm." . . . Whether the defendant has met the standard of care--that is, whether there has been a breach of duty--is an issue of fact that turns on the specifics of the individual case.

Whether the defendant owes the plaintiff a duty of care is a threshold issue; absent some duty, an action for negligence cannot be maintained. [] Thus, a conclusion that no duty exists is equivalent to a rule that, for certain categories of cases, defendants may not be held accountable for damages they carelessly cause, no matter how unreasonable their conduct. []

In this case, the court of appeals held that Kasey owed Followill a duty of care, based on the totality of the circumstances as reflected in the following factors: (1) the relationship that existed between Kasey and Followill, (2) the foreseeability of harm to a foreseeable victim as a result of Kasey giving eight pills to Watters, and (3) the presence of statutes making it unlawful to furnish one's prescription drugs to another person not covered by the prescription.

Kasey argues that none of these factors support a finding that he owed a duty of care to Followill. Although we disagree with aspects of the analysis of the court of appeals, that court correctly concluded that Kasey owed a duty of care.

A. Foreseeability

Kasey argues that the court of appeals erred by relying on foreseeability of harm because this Court held in *Martinez v. Woodmar IV Condominiums Homeowners Ass'n, Inc.* that foreseeability should no longer be a factor in determining whether a duty exists. 189 Ariz. 206, 211, 941 P.2d 218, 223 (1997). Gipson, on the other hand, argues that our prior cases have relied on

foreseeability in determining whether a duty is owed. See, e.g., *Donnelly Constr. Co. v. Oberg/Hunt/Gilleland*, 139 Ariz. 184, 187, 677 P.2d 1292, 1295 (1984) ("Duty and liability are only imposed where both the plaintiff and the risk are foreseeable to a reasonable person.").

We acknowledge that our case law has created "some confusion and lack of clarity . . . as to what extent, if any, foreseeability issues bear on the initial legal determination of duty." [] To clarify, we now expressly hold that foreseeability is not a factor to be considered by courts when making determinations of duty, and we reject any contrary suggestion in prior opinions.

Whether an injury to a particular plaintiff was foreseeable by a particular defendant necessarily involves an inquiry into the specific facts of an individual case. See W. Jonathan Cardi, *Purging Foreseeability: The New Version of Duty and Judicial Power in the Proposed Restatement (Third) of Torts*, 58 Vand. L. Rev. 739, 801 (2005). Moreover, foreseeability often determines whether a defendant acted reasonably under the circumstances or proximately caused injury to a particular plaintiff. Such factual inquiries are reserved for the jury. The jury's fact-finding role could be undermined if courts assess foreseeability in determining the existence of duty as a threshold legal issue. [] Reliance by courts on notions of "foreseeability" also may obscure the factors that actually guide courts in recognizing duties for purposes of negligence liability. []

Foreseeability, as this Court noted in *Martinez*, is more properly applied to the factual determinations of breach and causation than to the legal determination of duty. 189 Ariz. at 211, 941 P.2d at 223 ("[F]oreseeable danger [does] not dictate the existence of duty but only the nature and extent of the conduct necessary to fulfill the duty."); []. We believe that such an approach desirably recognizes the jury's role as factfinder and requires courts to articulate clearly the reasons, other than foreseeability, that might support duty or no-duty determinations. See Restatement (Third) of Torts: Liability for Physical Harm § 7 cmt. j (Proposed Final Draft No. 1, 2005) ("Third Restatement") (rejecting foreseeability as a factor in determining duty).

B. Relationship Between the Parties

Kasey also argues that he did not owe Followill a duty of care because they had no "direct" or "special" relationship. Duties of care may arise from special relationships based on contract, family relations, or conduct undertaken by the defendant. [] A special or direct relationship, however, is not essential in order for there to be a duty of care.³

³ That particular "relationships" may provide the basis for a duty of care reflects the historical evolution of the common law, which before the nineteenth century recognized fault-

Under Arizona common law, various categorical relationships can give rise to a duty. These include, but are not limited to, the landowner-invitee relationship, [], the tavern owner-patron relationship, [], and those "special relationships" recognized by § 315 of the Restatement (Second) of Torts (1965) that create a duty to control the actions of another, []. None of these relationships existed between Followill and Kasey.

Although a duty of care may result from the nature of the relationship between the parties, we decline to recognize such a duty here based on the particular facts (some of which are disputed) of the relationship between Kasey and Followill. In identifying this relationship as a factor supporting a finding of duty, the court of appeals noted that "[t]hey were co-workers and friends; they had socialized previously; [and] Followill had asked Kasey for pills in the past." []

A fact-specific analysis of the relationship between the parties is a problematic basis for determining if a duty of care exists. The issue of duty is not a factual matter; it is a legal matter to be determined *before* the case-specific facts are considered. []; see 1 Dan B. Dobbs, *The Law of Torts* § 226, at 577 (2001) ("The most coherent way of using the term duty states a rule of law rather than an analysis of the facts of particular cases."). Accordingly, this Court has cautioned against narrowly defining duties of care in terms of the parties' actions in particular cases. "[A]n attempt to equate the concept of 'duty' with such specific details of conduct is unwise," because a fact-specific discussion of duty conflates the issue with the concepts of breach and causation. . . .

A finding of duty, however, does not necessarily depend on a preexisting or direct relationship between the parties. As we explained in *Stanley*, "[t]he requirement of a formalized relationship between the parties has been quietly eroding . . . and, when public policy has supported the existence of a legal obligation, courts have imposed duties for the protection of persons with whom no preexisting 'relationship' existed." 208 Ariz. at 221-22 ¶ 8, 92 P.3d at 851-52 (internal citations omitted).

based liability in "actions on the Case" between parties having relationships to each other by contract or status. 1 Dan B. Dobbs, *The Law of Torts* § 111, at 259-63 (2001). As the common law evolved during the nineteenth century, courts extended the scope of negligence actions by recognizing a more general duty of care applicable to suits among strangers, like those involved in railway crossing accidents. *Id.* § 112, at 265-66. Relationships, however, have continued to provide a basis for identifying and defining duties of care. *Id.* § 113, at 266.

C. Public Policy

Having rejected foreseeability as a factor in the duty analysis and declining to recognize a duty based on the particular relationship between the parties, we turn to public policy considerations. Public policy may support the recognition of a duty of care. []

Kasey argues that recognizing a duty here would imply that all people owe a duty of care to all others at all times, a proposition he contends was rejected in *Wertheim v. Pima County*, 211 Ariz. 422, 426 ¶ 17, 122 P.3d 1, 5 (App.2005) ("We do not understand the law to be that one owes a duty of reasonable care at all times to all people under all circumstances." []). It is not necessary, however, to frame the issue this broadly to recognize a duty on the part of Kasey. Instead, in this case, Arizona statutes themselves provide a sufficient basis for a duty of care.⁴

It is well settled that "[t]he existence of a statute criminalizing conduct is one aspect of Arizona law supporting the recognition of [a] duty." [] Not all criminal statutes, however, create duties in tort. A criminal statute will "establish a tort duty [only] if the statute is 'designed to protect the class of persons, in which the plaintiff is included, against the risk of the type of harm which has in fact occurred as a result of its violation. . . .'" []

Several Arizona statutes prohibit the distribution of prescription drugs to persons lacking a valid prescription. [] As the court of appeals recognized, "[t]hese statutes are designed to avoid injury or death to people who have not been prescribed prescription drugs, who may have no medical need for them and may in fact be endangered by them, and who have not been properly instructed on their usage, potency, and possible dangers." [] Because Followill is within the class of persons to be protected by the statute and the harm that occurred here is the risk that the statute sought to protect against, these statutes create a tort duty.

Kasey argues that because the legislature did not create a civil duty for a violation of these criminal statutes, a duty does not exist. But this notion was

⁴ This Court has, however, previously noted that "every person is under a duty to avoid creating situations which pose an unreasonable risk of harm to others." [] Similarly, § 7 of the proposed Third Restatement recognizes that "[a]n actor ordinarily has a duty to exercise reasonable care when the actor's conduct creates a risk of physical harm." Based on such statements, one could conclude that people generally "owe a duty to exercise reasonable care to avoid causing physical harm" to others, subject to exceptions that eliminate or modify this duty for reasons of policy, such as the social host rule. See *id.* § 7 & cmt. a; accord *Dobbs*, *supra*, § 227, at 578. Because we find a duty based on Arizona statutes, we need not decide if a duty would exist independently as a matter of common law. . . .

rejected in *Ontiveros*: “[A] duty of care and the attendant standard of conduct may be found in a statute silent on the issue of civil liability.” 136 Ariz. at 510, 667 P.2d at 210 (internal citations omitted).

...

Alternatively, Kasey argues that this Court should adopt a no-duty rule precluding recovery on the grounds that a person who voluntarily becomes intoxicated and thereby sustains an injury should not be able to recover from the person supplying the intoxicants. We reject this reasoning. Followill’s own actions may reduce recovery under comparative fault principles or preclude recovery if deemed a superseding cause of the harm, but those are determinations to be made by the factfinder. For the reasons stated, neither our case law nor considerations of policy justify a blanket no-duty rule that would insulate persons who improperly distribute prescription drugs from tort liability.

CONCLUSION

We hold that Kasey did owe a duty of care based on Arizona’s statutes prohibiting the distribution of prescription drugs to persons not covered by the prescription. Accordingly, we vacate the part of the opinion of the court of appeals that addresses the issue of duty and remand to the superior court for further proceedings consistent with this opinion.

HURWITZ, JUSTICE, concurring.

[While agreeing with the majority on the current state of Arizona law, Justice Hurwitz, following up on the suggestion in footnote 4, ruminated on whether the court should adopt a framework recognizing a duty of reasonable care as a default, as proposed by the Third Restatement. Then, in exceptional cases, the court might rule that public policy requires an exemption from liability, which would be accomplished by developing a no-duty rule broad enough to cover cases falling within the policy thought to require exemption. Thus, rather than looking for a criminal statute in this case, since the defendant’s actions were implicated in causing the harm (i.e., this was not a case in which the basis for an affirmative duty was required), the court should only have considered whether the defendant provided some good ground why the ordinary duty of reasonable care should be negated. This might “simplify our analytical task in future cases and remove some understandable confusion among the bar and lower courts on the duty issue.” Nevertheless, such a change had not been proposed by the parties or briefed, counseling deference to another case and day.]

Page 208 new note (after note 8). Chapter 9 of the Restatement (Third) of Torts: Liability for Physical and Emotional Harm addresses landowner duties. The Restatement provides a current tally on state laws, explaining that “states are split right down the middle on whether to retain the status-based duties or move to a unitary standard.” Although half the states have reformed their laws to provide a duty of reasonable care to invitees and licensees, only approximately ten have extended that duty to trespassers. The new Restatement provides for a unitary duty of reasonable care to invitees, licensees, and most trespassers. Trespassers are divided into two classes: “flagrant” trespassers and ordinary trespassers. Ordinary trespassers are also owed a duty of reasonable care. Flagrant trespassers are those whose trespass on the land is particularly violative of the landowner’s rights—a burglar, for example, would be a flagrant trespasser. A landowner is only liable for wantonly, willfully, or intentionally harming flagrant trespassers. This Chapter, contained in Tentative Draft No. 6, was approved at the ALI meeting in May 2009.

Section F. Governmental Entities.

Page 234 new note (before note 1). In 2007, a DVD version of *Crazy Love*, a documentary about the relationship between Burton Pugach and Linda Riss, was released. The movie covers their courtship and the lye incident, as well as their subsequent marriage after he was released from jail and Riss’s support for her husband when he was criminally charged in the 1990s with harassing another woman.

Pages 235-37 notes 2.c. and 4. In contrast to *Cuffy and Muthukumarana* is *Reis v. Delaware River Port Authority*, 2008 WL 425522 (N.J. Super. Ct. App. Div. 2008). The court draws a different line for determining when a duty is owed to those who place a 911 call. Plaintiff’s decedent was abducted, and a witness called 911. The 911 dispatcher “inadvertently” failed to enter the information, and consequently no officers were dispatched to the location. The court interprets the government immunity statute to distinguish between discretionary and ministerial functions, with only the latter immunized. The dispatchers’ duty here was ministerial, and defendants are liable for negligence in carrying out such tasks.

Page 260 note 3. *Hinsley v. Standing Rock Child Protective Servs.*, 516 F.3d 668 (8th Cir. 2008), brings home the point of this note. A Bureau of Indian Affairs (“BIA”) agent placed a male teen in a foster home but did not tell the foster parent of his history of child sexual abuse. The foster parent, who was also the half sister of the BIA agent, left the teen with her three children, and he sexually abused the three-year old daughter. The foster parent sued for negligence in failing to notify her of the teen’s history. Defendant asserted the discretionary

function exception. The court finds no legal mandate requiring notification when a known child abuser is placed in a foster home. Since the federal agent *could* have decided based on privacy that notice should not be provided, the discretionary function exception applies. The court is quite explicit that it makes no difference whether the BIA agent actually made such a judgment, so long as she could have made such a judgment the exception applies. "In cases alleging negligent failure to warn '[i]t is also irrelevant whether the alleged failure to warn was a matter of 'deliberate choice,' or a mere oversight.'" (quoting *Allen v. United States*, 816 F.2d 1417, 1422 n. 5 (10th Cir.1987)).

Chapter IV

Section A. Emotional Harm.

Page 264 after initial ¶. In May 2007, Chapter 8 of the Restatement (Third) of Torts: Liability for Physical and Emotional Harm was approved by the American Law Institute. Expanded from its original scope that covered only physical-harm torts, the Restatement contains three Sections that prescribe the limited circumstances in which stand-alone emotional harm can be recovered. These provisions can be found in the Westlaw "rest-tort" database and in the Lexis "Restatement 3d, Torts – Drafts" database.

The first Section in the Chapter largely follows the intentional infliction of emotional distress contained in the Second Restatement and covered in Section A.4 of Chapter XII at page 908. The second Section reflects cases like *Falzone* and *Gammon*, involving emotional harm caused directly to the victim. One Subsection provides for liability when the plaintiff is in the zone of danger, while a second states that certain categories in which the risk of emotional harm is especially high may be recognized by courts as appropriate for permitting recovery of emotional harm. Mishandling of the dead, contaminated foodstuffs, and prenatal injuries are categories envisioned by this Subsection, which provides examples but does not attempt to prescribe which ones qualify. Finally, the Chapter includes a rule-based bystander Section that reflects California's move from the relatively unconstrained "foreseeability" approach of *Dillon v. Legg* to the three-requirement test in *Thing v. La Chusa* (see note 4, p. 291 *infra*) designed to stem the early experience with *Dillon* of "ever widening circles of liability."

Page 299 note 6. *Jarrett v. Jones*, 258 S.W.3d 442 (Mo. 2008). Plaintiff suffered minor physical injuries in an automobile accident resulting from defendant's negligence. Plaintiff went to check on the occupants of defendant's car, where he found defendant's two-year-old dead. Plaintiff seeks to recover for his physical injury, consequential emotional harm, and emotional harm from observing the

child. The court categorizes plaintiff as a direct victim and, as such, the restrictive rules on bystander recovery do not apply. The court relies on the fact that direct victims are a limited class, so concerns about floodgates are relieved and on the administrative difficulty of sorting out distress consequential to his own harm and distress from observing the child.

Pages 303-05 loss of consortium. Charron v. Amaral, 889 N.E.2d 946 (Mass. 2008). Same-sex partner sought consortium in a medical malpractice case. Plaintiff was legally barred from marriage at the time and married partner as soon as the Massachusetts Supreme Judicial Court overturned the bar on such marriages. The court holds that lost consortium is not available, relying largely on prior decisions that had denied consortium to couples living in a stable relationship but who had not married. Accord Bashaway v. Cheney Bros., Inc., 987 So. 2d 93 (Fla. Dist. Ct. App. 2008).

Section C. Wrongful Birth and Wrongful Life.

Page 333 note 4. Schirmer v. Mt. Auburn Obstetrics & Gynecologic Ass'n., Inc., 844 N.E.2d 1160 (Ohio 2006) (parents of child born with profound mental and physical defects asserting claim of negligent genetic testing could recover only for costs incurred in pregnancy and child birth, and could not recover any damages for providing extraordinary care required by handicapped child).

Page 335 new note (after note 8). For a thought-provoking article on the legal and ethical challenges created by new technology that permits prenatal genetic testing for a variety of diseases and birth defects, set in the context of a story about a family that had a child with a non-hereditary genetic defect that resulted in severe mental retardation and their malpractice suit against their obstetrician, see Elizabeth Weil, *A Wrongful Birth?*, N.Y. Times, March 12, 2006, at § 6, p.1.

Page 345 note 6. Paz v. Brush Engineered Materials, Inc., 555 F.3d 383 (5th Cir. 2009). Plaintiffs claimed they suffered from chronic beryllium disease ("CBD"), but based on evidentiary rulings their claims for that injury were dismissed and they were left only with a claim for beryllium sensitization ("BeS"), an injury defendant claimed was non-compensable under applicable state (Mississippi) law. BeS involves a physical change in the immune system but no impairment. The court concludes that BeS is not a compensable injury under state law. Plaintiffs also cannot recover for the risk of contracting CBD in the future absent proof that there is a reasonable probability of contracting it. (The court neglects to address whether suit can be brought for a probable future harm in the absence of some current compensable injury.) Nor can plaintiffs recover for their fear of contracting CBD in the future.

Chapter V

Section A. Cause in Fact

Page 356 new note (after note 1). Recall the use of expert testimony to prove the standard of care in medical malpractice cases, at p. 111. Does *Daubert* apply to an expert testifying to the standard of care? Not ordinarily, says the court in *Palandjian v. Foster*, 842 N.E.2d 916 (Mass. 2006), because the issue is one of fact: How do other physicians practice in like circumstances? But, says the court, when an expert's testimony on standard of care is interwoven with scientific knowledge (whether a family history of gastric cancer was relevant to whether the defendant should have tested decedent for such disease), *Daubert* is applicable.

Page 358 note 7. In *Williams v. Utica College of Syracuse University*, 453 F.3d 112 (2d Cir. 2006), plaintiff, a college student, was sexually assaulted in her dorm room. She sued the college, alleging it should have had better security to keep intruders from entering the building. The issue is whether better security would have prevented the attack. The difficulty is that the individual who committed the assault could have been either an outsider or someone who lived within the dormitory. Thus, the question becomes whether the lack of security is a factual cause of the plaintiff's harm. One might have thought that the "increasing the risk" language of *Zuchowicz* would save the day for the plaintiff who had no evidence about the assaulter. But that's not the case, the court, per Calabresi, J., holds. Summary judgment was properly granted against the plaintiff based on her inability to prove causation. The court retreats from the burden shifting in *Zuchowicz* and distinguishes this case from *Martin v. Herzog* and *Zuchowicz*. Three factors bear on whether a plaintiff can satisfy the burden of proof on causation based only on the negligent act and inference: 1) circumstantial evidence; 2) the relative ability of the parties to obtain evidence about what happened; and 3) whether the case is one in which there is reason to have different concerns about errors favoring plaintiffs as opposed to defendants. This case seems to drive a significant wedge in the presumption rule adopted in *Zuchowicz*.

Page 369 new note (after note 7). *Medved v. Glenn*, 125 P.3d 913 (Utah 2005) provides an occasion to rehearse the single judgment rule, statutes of limitation, the need to determine damages for future anticipated harm and lost chance. In *Medved*, defendant was negligent in diagnosing the plaintiff's cancer, requiring plaintiff to undergo more extensive treatment. That constituted physical injury and the basis for recovery of damages. But, pursuant to the single judgment rule, plaintiff can—indeed must—recover for anticipated future harm—her likelihood of having a recurrence due to the delay. (The court does not confront whether a

less than 50% chance of recurrence can be recovered.) For statute of limitations purposes, the court distinguishes another line of cases in which it held that a risk of future harm alone is inadequate to start the statute running, so that plaintiff here must recover for the risk of future harm in conjunction with the suit for injury from the delayed diagnosis, thereby tying together the statute of limitations, single judgment rule, and a lost chance to avoid future harm.

Page 372 in connection with the changes to joint and several liability. Among states that have legislatively modified joint and several liability, some of those statutes do not address whether the doctrine is retained when multiple tortfeasors engage in concerted action. The Iowa Supreme Court confronted this situation in *Reilly v. Anderson*, 727 N.W.2d 102 (Iowa 2006)—the Iowa comparative fault act has no explicit provision for joint and several liability of concerted actors. Nevertheless, the court held that a driver and his front-seat passenger who caused an accident when the passenger attempted to steer the automobile while the driver took a hit from a marijuana bong were jointly and severally liable to the plaintiff.

Page 378 note 7. Presenting a different question from *Loui* and *Gross* is the situation in which some of the plaintiff's injury was caused non-tortiously but, as in those cases, causal apportionment is difficult. In *Rowe v. Munye*, 702 N.W.2d 729 (Minn. 2005), the plaintiff's pre-existing condition was not tortiously caused. Thus, the court concluded that the burden-shifting employed by some courts and the Second Restatement when two defendants each cause an indeterminate amount of damage is inapplicable. As a consequence, plaintiff bears the burden of proof in demonstrating the harm caused by the defendant above and beyond the pre-existing condition.

Page 387 notes and questions. Instructors who are interested in the story behind Vioxx--the New Drug Application process, Merck's marketing and aspirations for the drug, the VIGOR study and the concerns it raised internal to Merck, Merck's spin on the heart effects found in that study, and the difficulties of the FDA in effectively regulating drugs in the post-approval period--may want to take a look at *McDarby v. Merck & Co., Inc.*, 949 A.2d 223 (N.J. Super. Ct. App. Div. 2008). The court, in the course of affirming a compensatory damages award on behalf of plaintiff, tells the story in considerable detail. For an assessment of the Vioxx litigation, including the global settlement between Merck and claimants, see Frank M. McLellan, *The Vioxx Litigation: A Critical Look at Trial Tactics, the Tort System, and the Roles of Lawyers in Mass Tort Litigation*, 57 DePaul L. Rev. 509 (2008). An audio program, organized by the American Enterprise Institute, of several experts discussing the settlement can be found at <http://aci.org/event/1626>.

Page 391 note 9. Some instructors may want to use this case in connection with Chapter VI for more extensive consideration of statutes of limitations. In *Grisham v. Philip Morris USA, Inc.*, 151 P.3d 1151 (Cal. 2007), the court provided guidance on when and how a plaintiff could invoke the discovery rule for a claim that would otherwise be time-barred. Plaintiffs brought suit alleging that their addiction to smoking caused them economic loss--the cost of buying cigarettes--as well as for physical injuries suffered later. Rejecting defendant's claim that by 1988 everyone knew that cigarettes were addictive and therefore the statute had to begin running no later than that date, the court held that plaintiffs invoking the discovery rule must plead when and how they discovered the factual basis for their claim and why it was reasonable for them not to have been aware earlier of those facts. Moreover, the statute of limitations for the economic loss claim did not affect claims for later-occurring diseases nor did the single-judgment rule require that claims for economic loss and for physical injury be pursued in the same suit.

Page 395 note 2. In *Engle v. Liggett Group, Inc.*, 945 So. 2d 1246 (Fla. 2006), the lower court had certified a class of smokers and tried the case with the jury awarding \$145 billion in punitive damages and compensatory damages to three named plaintiffs. The court affirmed two of the compensatory awards but decertified the class, holding that favorable determinations on common issues could be used by members of the class in future proceedings, in which they would have to prove only issues that were not common, such as that their injury was caused by smoking. In a splintered decision, the court also struck down the punitive damages award because a predicate for such an award--proof of liability on all issues--was not established for the class.

Page 398 note 4. A trend away from recognizing medical monitoring claims has emerged. In *Lowe v. Philip Morris USA, Inc.*, 183 P.3d 181 (Or. 2008), the court held that plaintiff-smoker's claim that defendant's negligence created a significantly increased risk of developing lung cancer in the future would not support a medical monitoring claim. Two other State Supreme courts in the past two years have ruled similarly, both on the grounds that plaintiffs had not suffered a cognizable injury. See *Sinclair v. Merck & Co., Inc.*, 948 A.2d 587 (N.J. 2008); *Paz v. Brush Engineered Materials, Inc.*, 949 So. 2d 1 (Miss. 2007).

Section B. Proximate Cause

Page 403 note 1. *Rowe v. Munye*, 702 N.W.2d 729 (Minn. 2005), discussed previously in these Update Materials in connection with the burden of proof on the extent of injury, p. 378. The plaintiff had a pre-existing condition that was aggravated in some indeterminate amount by defendant. The dissent claimed that the eggshell plaintiff rule would permit plaintiff to recover for all of his harm,

not just the enhanced harm. The court explained why the rule is inapplicable--the eggshell plaintiff rule is not about the amount of harm *caused* by the defendant but whether the harm that is caused is recoverable--when a plaintiff has a predisposition that results in greater than anticipated harm. Indeed, the court explains that the need for proof of enhancement and the eggshell rule may co-exist in a case.

Page 424 note 7. *Soto v. New York City Transit Auth.*, 846 N.E.2d 1211 (N.Y. 2006). Plaintiff, a teenager who had consumed alcohol, was on a catwalk that ran parallel to an elevated track in an effort to get to the next station to catch a train. He was struck by a train and sued claiming that the train operator was negligent in keeping a lookout and failing to stop the train in time to avoid the accident. Over the defendant's claim that plaintiff's reckless conduct was a superseding cause of his injuries, the court held that although plaintiff was reckless and his conduct substantially contributed to the accident, that conduct should reduce his recovery based on comparative fault and not absolve the defendant from liability.

Chapter VI

Section A. The Plaintiff's Fault.

Page 441 insert new ¶ (just before *Statutes* ¶). Another lack of symmetry occurred in *Dodson v. South Dakota Dept. of Human Services*, 703 N.W.2d 353 (S.D. 2005). Plaintiff's decedent, who was being treated for bipolar disorder, committed suicide after being discharged by defendant physicians. The court held that the decedent's conduct should be evaluated by using a subjective standard that reflected her mental capacity rather than employing the traditional objective standard used for defendants with mental deficiencies.

Page 452 note 4, end of 1st ¶. *Nash v. Port Authority of New York & New Jersey*, 856 N.Y.S.2d 583 (App. Div. 2008), reflects a contrasting approach (the court never confronts the evident tension between its decision and that of the Court of Appeals in *Chianese*). This case arises out of the first World Trade Center terrorist attack in 1993 when terrorists exploded a bomb in the parking garage. The case tells a chilling tale of how the WTC was recognized as a target for a terrorist attack as early as the 1980s by the Port Authority. The jury assigned defendant 68% of the comparative fault, more than it assigned to the terrorists. The court declines to upset that ruling, even though it means that under New York law the defendant will be subject to joint and several liability. The court relies on the "jury's exercise of its unique capacity to arrive at a more nuanced understanding of the nature and quality of the culpable conduct and its role in causing the plaintiff's harm" to justify this result. "[A]s this case so vividly illustrates, the blameworthiness of negligence may actually be increased by the

heinousness of the wrongdoing it directly and foreseeably facilitates." The impetus for such relative assignments of comparative fault to negligent and intentional tortfeasors, which has occurred in other cases in which the negligent tortfeasor was at fault because of a failure to protect the plaintiff from the intentional tortfeasor, is reflected in Restatement (Third) of Torts: Apportionment of Liability § 14. That section makes such a negligent tortfeasor liable for both its fault and any fault assigned to the intentional tortfeasor, regardless of the status of joint and several liability generally under the jurisdiction's rules.

Page 453 new note (after note 4). *Plaintiff no-duty rules.* In the same way that courts adopted no-duty rules to exempt defendants from liability as reflected in Chapter III, might there be no-duty rules (however awkward it is to speak to of a plaintiff's duty to him or herself) for plaintiffs? In other words, are there certain arenas in which a plaintiff's conduct, even if negligent, will not be considered in a tort suit? The issue arises in cases involving minors having (arguably consensual) sex with adults. In *Christensen v. Royal School Dist. No. 160*, 124 P.3d 283 (Wash. 2005), a 13-year-old student sued the school and principal as a result of a sexual relationship the student had with a teacher. Defendants claimed that her voluntary participation constituted contributory negligence. The court held that her consent could not constitute contributory fault. It cited two policy reasons: the same concerns for protection of minors that mandate statutory rape as a crime, regardless of consent, and the "solemn duty" of a school district to protect its minor students.

Page 454 note 8. *J & J Timber Co. v. Broome*, 932 So. 2d 1 (Miss. 2006), constitutes a modern trap for the unwary that harks back to the days when a settlement with a jointly-liable tortfeasor released the plaintiff's claims against all tortfeasors. In this narrower context, in which one party is vicariously liable for the other's negligence, the court holds that a settlement with an employee releases the employer from its vicarious liability, regardless of what the settlement agreement provides. There are several reasons for this, the most significant being that releasing the employee and maintaining a claim against the employer creates conflicts with the employer's right to seek indemnification from the employee. The Third Restatement provides for similar treatment of partial settlements with vicariously liable parties. See Restatement (Third) of Torts: Apportionment of Liability § 16, Comment d.

Page 454 note 9. *In re Eighth Judicial Dist. Asbestos Litigation*, 872 N.E.2d 232 (N.Y. 2007), reveals the variations that can occur in settlements but a common principle: when a settlement may affect a settling defendant's incentives and the defendant remains in the case, the agreement must be disclosed. In this multi-defendant case, one entered into a high-low agreement with the plaintiff that was based on the jury's award against that defendant. The court orders a new trial

because the agreement was not disclosed to the non-settling defendants. The principle here is the same as exists in jurisdictions requiring disclosure of Mary Carter agreements.

Section B. Assumption of Risk.

Page 472, new note (after note 7). In a trilogy of decisions, the Connecticut Supreme Court imposed substantial restrictions on the use of contractual waivers of liability. The first, *Hanks v. Powder Ridge Restaurant Corp.*, 885 A.2d 734 (Conn. 2005), addressed a waiver required of snowtubers. In a 4-3 decision with a vigorous dissent, the court paid homage to the *Tunkl* factors, while largely ignoring them in holding the waiver violated public policy. The court focused on the facility's control of the risks involved in snowtubing and that the waiver was an adhesion contract. The dissent argued that the majority was out of step with contemporary decisions (if not *Dalury*), especially in its reliance on the waivers being adhesion contracts. *Hanks* was followed by *Reardon v. Windswept Farm, LLC*, 905 A.2d 1156 (Conn. 2006), which extended the public policy proscription to a waiver obtained by a horseback riding stable. The final case, *Brown v. Soh*, 909 A.2d 43 (Conn. 2006), involved a professional car racer employed as an instructor at a car racing school. The instructor was injured when a student driver, while engaging in an instructional exercise, struck him. The instructor had signed a waiver that released the school and others. (The court does not explain why workers' compensation is inapplicable here, although subsequently all claims against the school were dismissed, so the issue is the effectiveness of the waiver against a student and others but not the employer.) In one sense this is a less compelling case for striking the waiver, as the employee was well aware of the risks he was confronting. Nevertheless, based on disparities in bargaining power and the waiver being a contract of adhesion, the court strikes it, ruling broadly: "When we apply the factors that guide us, we conclude that exculpatory agreements in the employment context violate Connecticut public policy."

In contrast to Connecticut (and *Dalury*) is *McGrath v. SNH Dev., Inc.*, 2009 WL 928858 (N.H. 2009). The court held that a waiver signed by a season ticket holder barred a claim for negligence by a snowboarder arising out of a collision with a snowmobile operated by an employee of the ski area. Among other reasons, the court asserted that recreational activities are not of special public concern nor do they involve essential services. Curiously, the court also claimed that there was no disparity in bargaining power because, although the waiver was presented on a take it or leave it basis, plaintiff "was under no physical or economic compulsion" to sign. . See also *Pearce v. Utah Athletic Foundation*, 179 P.3d 760 (Utah 2008) ("as a general rule . . . recreational activities do not constitute a public interest and . . . therefore, preinjury releases for recreational activities cannot be invalidated under the public interest exception").

Page 480 note 6. Instructors who want to employ a contrasting hypothetical might find the situation with maple baseball bats useful. Those bats splinter at a considerably higher rate than bats made of other woods. The maple bat problem is explored in Bruce Jenkins, *Maple Bats Are Risky Business*, S. F. Chron., June 9, 2008, at C1, which details a case in which a fan in Dodger stadium had her jaw broken by a broken bat. Query who the target defendants might be, the theories against them, and the extent to which they would be protected by primary assumption of risk.

Section C. Pre-emption.

Page 497. Two particularly important pre-emption cases have been decided since *Geier*. Last year, we included an edited version of *Riegel v. Medtronic, Inc.*, which is retained in this year's Update. We have added *Wyeth v. Levine*, decided this year. Some instructors may want to use *Riegel* because it addresses express pre-emption and the statutory interpretation issue is a good vehicle for engaging students in the methodology of reading and interpreting statutes. Other instructors may prefer *Wyeth*, because it addresses implied pre-emption and the especially important context of prescription drugs. If time permits, some instructors may want to cover both in order comprehensively to cover all aspects of federal pre-emption. By including both, we leave this decision to individual instructors.

Riegel v. Medtronic, Inc.
Supreme Court of the United States, 2008.
___ U.S. ___, 128 S. Ct. 999, 169 L. Ed. 2d 892.

JUSTICE SCALIA delivered the opinion of the Court.

We consider whether the pre-emption clause enacted in the Medical Device Amendments of 1976, 21 U.S.C. § 360k, bars common-law claims challenging the safety and effectiveness of a medical device given premarket approval by the Food and Drug Administration (FDA).

The Federal Food, Drug, and Cosmetic Act (FDCA), 52 Stat. 1040, as amended, 21 U.S.C. § 301 *et seq.*, has long required FDA approval for the introduction of new drugs into the market. Until the statutory enactment at issue here, however, the introduction of new medical devices was left largely for the States to supervise as they saw fit. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475-476, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996).

The regulatory landscape changed in the 1960's and 1970's, as complex devices proliferated and some failed. Most notably, the Dalkon Shield intrauterine device, introduced in 1970, was linked to serious infections and several deaths, not to mention a large number of pregnancies. Thousands of tort claims followed. R. Bacigal, *The Limits of Litigation: The Dalkon Shield Controversy* 3 (1990). In the view of many, the Dalkon Shield failure and its aftermath demonstrated the inability of the common-law tort system to manage the risks associated with dangerous devices. See, e.g., S. Foote, *Managing the Medical Arms Race* 151-152 (1992). Several States adopted regulatory measures, including California, which in 1970 enacted a law requiring premarket approval of medical devices. []; see also Leflar & Adler, *The Preemption Pentad: Federal Preemption of Products Liability Claims After Medtronic*, 64 Tenn. L. Rev. 691, 703, n. 66 (1997) (identifying 13 state statutes governing medical devices as of 1976).

Congress stepped in with passage of the Medical Device Amendments of 1976(MDA), 21 U.S.C. § 360c *et seq.*, which swept back some state obligations and imposed a regime of detailed federal oversight. The MDA includes an express pre-emption provision that states:

"Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement-

"(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

"(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." § 360k(a).

The exception contained in subsection (b) permits the FDA to exempt some state and local requirements from pre-emption.

The new regulatory regime established various levels of oversight for medical devices, depending on the risks they present. Class I, which includes such devices as elastic bandages and examination gloves, is subject to the lowest level of oversight: "general controls," such as labeling requirements. [] Class II, which includes such devices as powered wheelchairs and surgical drapes, *ibid.*, is subject in addition to "special controls" such as performance standards and postmarket surveillance measures, [].

The devices receiving the most federal oversight are those in Class III, which include replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators, []. In general, a device is assigned to Class III if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and the device is "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or "presents a potential unreasonable risk of illness or injury. [].

Although the MDA established a rigorous regime of premarket approval for new Class III devices, it grandfathered many that were already on the market. Devices sold before the MDA's effective date may remain on the market until the FDA promulgates, after notice and comment, a regulation requiring premarket approval. [] A related provision seeks to limit the competitive advantage grandfathered devices receive. A new device need not undergo premarket approval if the FDA finds it is "substantially equivalent" to another device exempt from premarket approval. [] The agency's review of devices for substantial equivalence is known as the § 510(k) process, named after the section of the MDA describing the review. Most new Class III devices enter the market through § 510(k). In 2005, for example, the FDA authorized the marketing of 3,148 devices under § 510(k) and granted premarket approval to just 32 devices. []

Premarket approval is a "rigorous" process. [] A manufacturer must submit what is typically a multivolume application. [] It includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a "full statement" of the device's "components, ingredients, and properties and of the principle or principles of operation"; "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device"; samples or device components required by the FDA; and a specimen of the proposed labeling. [] Before deciding whether to approve the application, the agency may refer it to a panel of outside experts, [], and may request additional data from the manufacturer, [].

The FDA spends an average of 1,200 hours reviewing each application, *Lohr, supra*, at 477, 116 S.Ct. 2240, and grants premarket approval only if it finds there is a "reasonable assurance" of the device's "safety and effectiveness," [] The agency must "weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." [] It may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives. It approved, for example, under its Humanitarian Device Exemption procedures, a ventricular assist device for children with failing hearts, even though the survival rate of children using the device was less than 50 percent. []

The premarket approval process includes review of the device's proposed labeling. The FDA evaluates safety and effectiveness under the conditions of use set forth on the label, [], and must determine that the proposed labeling is neither false nor misleading, [].

After completing its review, the FDA may grant or deny premarket approval. [] It may also condition approval on adherence to performance standards, 21 CFR § 861.1(b)(3), restrictions upon sale or distribution, or compliance with other requirements, § 814.82. The agency is also free to impose device-specific restrictions by regulation. []

If the FDA is unable to approve a new device in its proposed form, it may send an "approvable letter" indicating that the device could be approved if the applicant submitted specified information or agreed to certain conditions or restrictions. [] Alternatively, the agency may send a "not approvable" letter, listing the grounds that justify denial and, where practical, measures that the applicant could undertake to make the device approvable. []

Once a device has received premarket approval, the FDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness. [] If the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application. []

After premarket approval, the devices are subject to reporting requirements. [] These include the obligation to inform the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of, [], and to report incidents in which the device may have caused or contributed to death or serious injury, or

malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred, []. The FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling. [] (recall authority).

B

Except as otherwise indicated, the facts set forth in this section appear in the opinion of the Court of Appeals. The device at issue is an Evergreen Balloon Catheter marketed by defendant-respondent Medtronic, Inc. It is a Class III device that received premarket approval from the FDA in 1994; changes to its label received supplemental approvals in 1995 and 1996.

Charles Riegel underwent coronary angioplasty in 1996, shortly after suffering a myocardial infarction. [] His right coronary artery was diffusely diseased and heavily calcified. Riegel's doctor inserted the Evergreen Balloon Catheter into his patient's coronary artery in an attempt to dilate the artery, although the device's labeling stated that use was contraindicated for patients with diffuse or calcified stenoses. The label also warned that the catheter should not be inflated beyond its rated burst pressure of eight atmospheres. Riegel's doctor inflated the catheter five times, to a pressure of 10 atmospheres; on its fifth inflation, the catheter ruptured. [] Riegel developed a heart block, was placed on life support, and underwent emergency coronary bypass surgery.

Riegel and his wife Donna brought this lawsuit in April 1999, in the United States District Court for the Northern District of New York. Their complaint alleged that Medtronic's catheter was designed, labeled, and manufactured in a manner that violated New York common law, and that these defects caused Riegel to suffer severe and permanent injuries. The complaint raised a number of common-law claims. The District Court held that the MDA pre-empted Riegel's claims of strict liability; breach of implied warranty; and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the catheter. [] It also held that the MDA pre-empted a negligent manufacturing claim insofar as it was not premised on the theory that Medtronic violated federal law. [] Finally, the court concluded that the MDA pre-empted Donna Riegel's claim for loss of consortium to the extent it was derivative of the pre-empted claims. []

The United States Court of Appeals for the Second Circuit affirmed these dismissals. [] The court concluded that Medtronic was "clearly subject to the federal, device-specific requirement of adhering to the standards contained in its individual, federally approved" premarket approval application. [] The Riegels' claims were pre-empted because they "would, if successful, impose state

requirements that differed from, or added to" the device-specific federal requirements. [] We granted certiorari. []

II

Since the MDA expressly pre-empts only state requirements "different from, or in addition to, any requirement applicable . . . to the device" under federal law, § 360k(a)(1), we must determine whether the Federal Government has established requirements applicable to Medtronic's catheter. If so, we must then determine whether the Riegels' common-law claims are based upon New York requirements with respect to the device that are "different from, or in addition to" the federal ones, and that relate to safety and effectiveness []

We turn to the first question. In *Lohr*, a majority of this Court interpreted the MDA's pre-emption provision in a manner "substantially informed" by the FDA regulation set forth at []. That regulation says that state requirements are pre-empted "only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device. . . ." [] Informed by the regulation, we concluded that federal manufacturing and labeling requirements applicable across the board to almost all medical devices did not pre-empt the common-law claims of negligence and strict liability at issue in *Lohr*. The federal requirements, we said, were not requirements specific to the device in question—they reflected "entirely generic concerns about device regulation generally." [] While we disclaimed a conclusion that general federal requirements could never pre-empt, or general state duties never be pre-empted, we held that no pre-emption occurred in the case at hand based on a careful comparison between the state and federal duties at issue. []

Even though substantial-equivalence review under § 510(k) is device specific, *Lohr* also rejected the manufacturer's contention that § 510(k) approval imposed device-specific "requirements." We regarded the fact that products entering the market through § 510(k) may be marketed only so long as they remain substantial equivalents of the relevant pre-1976 devices as a qualification for an exemption rather than a requirement. []

Premarket approval, in contrast, imposes "requirements" under the MDA as we interpreted it in *Lohr*. Unlike general labeling duties, premarket approval is specific to individual devices. And it is in no sense an exemption from federal safety review—it *is* federal safety review. Thus, the attributes that *Lohr* found lacking in § 510(k) review are present here. While § 510(k) is "focused on equivalence, not safety," [], premarket approval is focused on safety, not equivalence. While devices that enter the market through § 510(k) have "never been formally reviewed under the MDA for safety or efficacy," *ibid.*, the FDA may

grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness, []. And while the FDA does not "require" that a device allowed to enter the market as a substantial equivalent "take any particular form for any particular reason," [], the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness.

III

We turn, then, to the second question: whether the Riegels' common-law claims rely upon "any requirement" of New York law applicable to the catheter that is "different from, or in addition to" federal requirements and that "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device." § 360k(a). Safety and effectiveness are the very subjects of the Riegels' common-law claims, so the critical issue is whether New York's tort duties constitute "requirements" under the MDA.

A

In *Lohr*, five Justices concluded that common-law causes of action for negligence and strict liability do impose "requirement[s]" and would be pre-empted by federal requirements specific to a medical device. See 518 U.S., at 512, 116 S.Ct. 2240 (opinion of O'Connor, J., joined by Rehnquist, C. J., and SCALIA and THOMAS, JJ.); *id.*, at 503-505, 116 S.Ct. 2240 (opinion of BREYER, J.). We adhere to that view. In interpreting two other statutes we have likewise held that a provision pre-empting state "requirements" pre-empted common-law duties. *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 125 S.Ct. 1788, 161 L.Ed.2d 687 (2005), found common-law actions to be pre-empted by a provision of the Federal Insecticide, Fungicide, and Rodenticide Act that said certain States "shall not impose or continue in effect *any requirements* for labeling or packaging in addition to or different from those required under this subchapter." *Id.*, at 443, 125 S.Ct. 1788 (discussing 7 U.S.C. § 136v(b); emphasis added). *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992), held common-law actions pre-empted by a provision of the Public Health Cigarette Smoking Act of 1969, 15 U.S.C. § 1334(b), which said that "[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes" whose packages were labeled in accordance with federal law. See 505 U.S., at 523, 112 S.Ct. 2608 (plurality opinion); *id.*, at 548-549, 112 S.Ct. 2608 (SCALIA, J., concurring in judgment in part and dissenting in part).

Congress is entitled to know what meaning this Court will assign to terms regularly used in its enactments. Absent other indication, reference to a State's "requirements" includes its common-law duties. As the plurality opinion said in *Cipollone*, common-law liability is "premised on the existence of a legal duty," and a tort judgment therefore establishes that the defendant has violated a state-law obligation. [] And while the common-law remedy is limited to damages, a liability award "can be, indeed is designed to be, a potent method of governing conduct and controlling policy." []

In the present case, there is nothing to contradict this normal meaning. To the contrary, in the context of this legislation excluding common-law duties from the scope of pre-emption would make little sense. State tort law that requires a manufacturer's catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect. Indeed, one would think that tort law, applied by juries under a negligence or strict-liability standard, is less deserving of preservation. A state statute, or a regulation adopted by a state agency, could at least be expected to apply cost-benefit analysis similar to that applied by the experts at the FDA: How many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm? A jury, on the other hand, sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court. As Justice BREYER explained in *Lohr*, it is implausible that the MDA was meant to "grant greater power (to set state standards 'different from, or in addition to' federal standards) to a single state jury than to state officials acting through state administrative or legislative lawmaking processes." 518 U.S., at 504, 116 S.Ct. 2240. That perverse distinction is not required or even suggested by the broad language Congress chose in the MDA, and we will not turn somersaults to create it.

For the foregoing reasons, the judgment of the Court of Appeals is

Affirmed.

JUSTICE GINSBURG, dissenting.

The Medical Device Amendments of 1976 (MDA or Act), 90 Stat. 539, as construed by the Court, cut deeply into a domain historically occupied by state law. The MDA's preemption clause, 21 U.S.C. § 360k(a), the Court holds, spares medical device manufacturers from personal injury claims alleging flaws in a design or label once the application for the design or label has gained premarket

approval from the Food and Drug Administration (FDA); a state damages remedy, the Court instructs, persists only for claims "premised on a violation of FDA regulations." *Ante*, at 1011.¹ I dissent from today's constriction of state authority. Congress, in my view, did not intend § 360k(a) to effect a radical curtailment of state common-law suits seeking compensation for injuries caused by defectively designed or labeled medical devices.

Congress' reason for enacting § 360k(a) is evident. Until 1976, the Federal Government did not engage in premarket regulation of medical devices. Some States acted to fill the void by adopting their own regulatory systems for medical devices. Section 360k(a) responded to that state regulation, and particularly to California's system of premarket approval for medical devices, by preempting State initiatives absent FDA permission. See § 360k(b).

I

The "purpose of Congress is the ultimate touchstone of pre-emption analysis." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992) (internal quotation marks omitted). Courts have "long presumed that Congress does not cavalierly pre-empt state-law causes of action." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996). Preemption analysis starts with the assumption that "the historic police powers of the States [a]re not to be superseded . . . unless that was the clear and manifest purpose of Congress." [] "This assumption provides assurance that 'the federal-state balance' will not be disturbed unintentionally by Congress or unnecessarily by the courts." []

The presumption against preemption is heightened "where federal law is said to bar state action in fields of traditional state regulation." [] Given the traditional "primacy of state regulation of matters of health and safety," *Lohr*, 518 U.S., at 485, 116 S.Ct. 2240, courts assume "that state and local regulation related to [those] matters . . . can normally coexist with federal regulations," [].

Federal laws containing a preemption clause do not automatically escape the presumption against preemption. See *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449, 125 S.Ct. 1788, 161 L.Ed.2d 687 (2005); *Lohr*, 518 U.S., at 485, 116 S.Ct. 2240. A preemption clause tells us that Congress intended to supersede or modify state law to some extent. In the absence of legislative precision, however, courts may face the task of determining the substance and scope of Congress' displacement of state law. Where the text of a preemption

¹ The Court's holding does not reach an important issue outside the bounds of this case: the preemptive effect of § 360k(a) where evidence of a medical device's defect comes to light only after the device receives premarket approval.

clause is open to more than one plausible reading, courts ordinarily "accept the reading that disfavors pre-emption." *Bates*, 544 U.S., at 449, 125 S.Ct. 1788.

II

...

"Absent other indication," the Court states, "reference to a State's 'requirements' includes its common-law duties." [] Regarding the MDA, however, "other indication" is not "[a]bsent." Contextual examination of the Act convinces me that § 360k(a)'s inclusion of the term "requirement" should not prompt a sweeping preemption of mine-run claims for relief under state tort law.³

A

Congress enacted the MDA "to provide for the safety and effectiveness of medical devices intended for human use." []⁴ A series of high-profile medical device failures that caused extensive injuries and loss of life propelled adoption of the MDA. Conspicuous among these failures was the Dalkon Shield intrauterine device, used by approximately 2.2 million women in the United States between 1970 and 1974. [] Aggressively promoted as a safe and effective form of birth control, the Dalkon Shield had been linked to 16 deaths and 25 miscarriages by the middle of 1975. [] By early 1976, "more than 500 lawsuits seeking compensatory and punitive damages totaling more than \$400 million" had been filed. [] Given the publicity attending the Dalkon Shield litigation and Congress' awareness of the suits at the time the MDA was under consideration, I find informative the absence of any sign of a legislative design to preempt state common-law tort actions.⁷

³ The very next provision, § 360k(b), allows States and their political subdivisions to apply for exemption from the requirements for medical devices set by the FDA when their own requirements are "more stringent" than federal standards or are necessitated by "compelling local conditions." This prescription indicates solicitude for state concerns, as embodied in legislation or regulation. But no more than § 360k(a) itself does § 360k(b) show that Congress homed in on state common-law suits and meant to deny injured parties recourse to them.

⁴ Introducing the bill in the Senate, its sponsor explained: "The legislation is written so that the benefit of the doubt is always given to the consumer. After all it is the consumer who pays with his health and his life for medical device malfunctions." 121 Cong. Rec. 10688 (1975) (remarks of Sen. Kennedy).

⁷ "[N]othing in the hearings, the Committee Reports, or the debates," the *Lohr* plurality noted, "suggest[ed] that any proponent of the legislation intended a sweeping pre-emption of traditional common-law remedies against manufacturers and distributors of defective devices. If Congress intended such a result, its failure even to hint at it is spectacularly odd, particularly since Members of both Houses were acutely aware of ongoing product liability litigation." []

The Court recognizes that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations." [] That remedy, although important, does not help consumers injured by devices that receive FDA approval but nevertheless prove unsafe. The MDA's failure to create any federal compensatory remedy for such consumers further suggests that Congress did not intend broadly to preempt state common-law suits grounded on allegations independent of FDA requirements. It is "difficult to believe that Congress would, without comment, remove all means of judicial recourse" for large numbers of consumers injured by defective medical devices. []

... The Court's construction of § 360k(a) has the "perverse effect" of granting broad immunity "to an entire industry that, in the judgment of Congress, needed more stringent regulation," *Lohr*, 518 U.S., at 487, 116 S.Ct. 2240 (plurality opinion), not exemption from liability in tort litigation.

The MDA does grant the FDA authority to order certain remedial action if, *inter alia*, it concludes that a device "presents an unreasonable risk of substantial harm to the public health" and that notice of the defect "would not by itself be sufficient to eliminate the unreasonable risk." [] Thus the FDA may order the manufacturer to repair the device, replace it, refund the purchase price, cease distribution, or recall the device. [] The prospect of ameliorative action by the FDA, however, lends no support to the conclusion that Congress intended largely to preempt state common-law suits. Quite the opposite: Section 360h(d) states that "[c]ompliance with an order issued under this section shall not relieve any person from liability under Federal or State law." That provision anticipates "[court-awarded] damages for economic loss" from which the value of any FDA-ordered remedy would be subtracted. []

B

Congress enacted the MDA after decades of regulating drugs and food and color additives under the Federal Food, Drug, and Cosmetic Act (FDCA), 52 Stat. 1040, as amended, 21 U.S.C. § 301 *et seq.* The FDCA contains no preemption clause, and thus the Court's interpretation of § 360k(a) has no bearing on tort suits involving drugs and additives. But § 360k(a)'s confinement to medical devices hardly renders irrelevant to the proper construction of the MDA's preemption provision the long history of federal and state controls over drugs and additives in the interest of public health and welfare. Congress' experience regulating drugs and additives informed, and in part provided the model for, its

regulation of medical devices. I therefore turn to an examination of that experience.

[Justice Ginsburg related the history of the Food, Drug and Cosmetic Act from 1938 when the first premarketing approval process was mandated. Other amendments to the Act from that time until the MDA in 1976 mandated premarketing approval, but none contained an express preemption clause. That was true, even though when they were enacted, there was a background of tort suits about the newly regulated products, including medical devices at the time of the MDA. The reason for the express preemption clause in the MDA was that states had already been regulating medical devices, and it was this state regulation that was the target of § 360k(a) and (b), which were "to empower the FDA to exercise control over state premarket approval systems installed at a time when there was no preclearance at the federal level."]

In sum, state premarket regulation of medical devices, not any design to suppress tort suits, accounts for Congress' inclusion of a preemption clause in the MDA; no such clause figures in earlier federal laws regulating drugs and additives, for States had not installed comparable control regimes in those areas.

C

Congress' experience regulating drugs also casts doubt on Medtronic's policy arguments for reading § 360k(a) to preempt state tort claims. Section 360k(a) must preempt state common-law suits, Medtronic contends, because Congress would not have wanted state juries to second-guess the FDA's finding that a medical device is safe and effective when used as directed. [] The Court is similarly minded. []

But the process for approving new drugs is at least as rigorous as the premarket approval process for medical devices. Courts that have considered the question have overwhelmingly held that FDA approval of a new drug application does not preempt state tort suits. Decades of drug regulation thus indicate, contrary to Medtronic's argument, that Congress did not regard FDA regulation and state tort claims as mutually exclusive.

III

Refusing to read § 360k(a) as an automatic bar to state common-law tort claims would hardly render the FDA's premarket approval of Medtronic's medical device application irrelevant to the instant suit. First, a "pre-emption provision, by itself, does not foreclose (through negative implication) any possibility of implied conflict preemption." [] Accordingly, a medical device manufacturer may have a

dispositive defense if it can identify an actual conflict between the plaintiff's theory of the case and the FDA's premarket approval of the device in question. As currently postured, this case presents no occasion to take up this issue for Medtronic relies exclusively on § 360k(a) and does not argue conflict preemption.

Second, a medical device manufacturer may be entitled to interpose a regulatory compliance defense based on the FDA's approval of the premarket application. Most States do not treat regulatory compliance as dispositive, but regard it as one factor to be taken into account by the jury. [] In those States, a manufacturer could present the FDA's approval of its medical device as evidence that it used due care in the design and labeling of the product.

The Court's broad reading of § 360k(a) saves the manufacturer from any need to urge these defenses. Instead, regardless of the strength of a plaintiff's case, suits will be barred *ab initio*. The constriction of state authority ordered today was not mandated by Congress and is at odds with the MDA's central purpose: to protect consumer safety.

...

For the reasons stated, I would hold that § 360k(a) does not preempt Riegel's suit. I would therefore reverse the judgment of the Court of Appeals in relevant part.

Wyeth v. Levine
Supreme Court of the United States, 2009.
___ U.S. ___, 129 S. Ct. 1187.

Justice STEVENS delivered the opinion of the Court.

Directly injecting the drug Phenergan into a patient's vein creates a significant risk of catastrophic consequences. A Vermont jury found that petitioner Wyeth, the manufacturer of the drug, had failed to provide an adequate warning of that risk and awarded damages to respondent Diana Levine to compensate her for the amputation of her arm. The warnings on Phenergan's label had been deemed sufficient by the federal Food and Drug Administration (FDA) when it approved Wyeth's new drug application in 1955 and when it later approved changes in the drug's labeling. The question we must decide is whether the FDA's approvals provide Wyeth with a complete defense to Levine's tort claims. We conclude that they do not.

I

Phenergan is Wyeth's brand name for promethazine hydrochloride, an antihistamine used to treat nausea. The injectable form of Phenergan can be administered intramuscularly or intravenously, and it can be administered intravenously through either the "IV-push" method, whereby the drug is injected directly into a patient's vein, or the "IV-drip" method, whereby the drug is introduced into a saline solution in a hanging intravenous bag and slowly descends through a catheter inserted in a patient's vein. The drug is corrosive and causes irreversible gangrene if it enters a patient's artery.

Levine's injury resulted from an IV-push injection of Phenergan. On April 7, 2000, as on previous visits to her local clinic for treatment of a migraine headache, she received an intramuscular injection of Demerol for her headache and Phenergan for her nausea. Because the combination did not provide relief, she returned later that day and received a second injection of both drugs. This time, the physician assistant administered the drugs by the IV-push method, and Phenergan entered Levine's artery, either because the needle penetrated an artery directly or because the drug escaped from the vein into surrounding tissue (a phenomenon called "perivascular extravasation") where it came in contact with arterial blood. As a result, Levine developed gangrene, and doctors amputated first her right hand and then her entire forearm. In addition to her pain and suffering, Levine incurred substantial medical expenses and the loss of her livelihood as a professional musician.

After settling claims against the health center and clinician, Levine brought an action for damages against Wyeth, relying on common-law negligence and strict-liability theories. Although Phenergan's labeling warned of the danger of gangrene and amputation following inadvertent intra-arterial injection,¹ Levine

¹ The warning for "Inadvertent Intra-arterial Injection" stated: "Due to the close proximity of arteries and veins in the areas most commonly used for intravenous injection, extreme care should be exercised to avoid perivascular extravasation or inadvertent intra-arterial injection. Reports compatible with inadvertent intra-arterial injection of Phenergan Injection, usually in conjunction with other drugs intended for intravenous use, suggest that pain, severe chemical irritation, severe spasm of distal vessels, and resultant gangrene requiring amputation are likely under such circumstances. Intravenous injection was intended in all the cases reported but perivascular extravasation or arterial placement of the needle is now suspect. There is no proven successful management of this condition after it occurs. . . . Aspiration of dark blood does not preclude intra-arterial needle placement, because blood is discolored upon contact with Phenergan Injection. Use of syringes with rigid plungers or of small bore needles might obscure typical arterial backflow if this is relied upon alone. When used intravenously, Phenergan Injection should be given in a concentration no greater than 25 mg per mL and at a rate not to exceed 25 mg per minute. When administering any irritant drug intravenously, it is usually preferable to inject it through the tubing of an intravenous infusion set that is known to be functioning satisfactorily. In the event that a patient complains of pain during intended intravenous injection of Phenergan

alleged that the labeling was defective because it failed to instruct clinicians to use the IV-drip method of intravenous administration instead of the higher risk IV-push method. More broadly, she alleged that Phenergan is not reasonably safe for intravenous administration because the foreseeable risks of gangrene and loss of limb are great in relation to the drug's therapeutic benefits. []

Wyeth filed a motion for summary judgment, arguing that Levine's failure-to-warn claims were pre-empted by federal law. The court found no merit in either Wyeth's field pre-emption argument, which it has since abandoned, or its conflict pre-emption argument. With respect to the contention that there was an "actual conflict between a specific FDA order," [], and Levine's failure-to-warn action, the court reviewed the sparse correspondence between Wyeth and the FDA about Phenergan's labeling and found no evidence that Wyeth had "earnestly attempted" to strengthen the intra-arterial injection warning or that the FDA had "specifically disallowed" stronger language, []. The record, as then developed, "lack[ed] any evidence that the FDA set a ceiling on this matter." []

The evidence presented during the 5-day jury trial showed that the risk of intra-arterial injection or perivascular extravasation can be almost entirely eliminated through the use of IV-drip, rather than IV-push, administration. An IV drip is started with saline, which will not flow properly if the catheter is not in the vein and fluid is entering an artery or surrounding tissue. [] By contrast, even a careful and experienced clinician using the IV-push method will occasionally expose an artery to Phenergan. [] While Phenergan's labeling warned against intra-arterial injection and perivascular extravasation and advised that "[w]hen administering any irritant drug intravenously it is usually preferable to inject it through the tubing of an intravenous infusion set that is known to be functioning satisfactorily," [], the labeling did not contain a specific warning about the risks of IV-push administration.

The trial record also contains correspondence between Wyeth and the FDA discussing Phenergan's label. The FDA first approved injectable Phenergan in 1955. In 1973 and 1976, Wyeth submitted supplemental new drug applications, which the agency approved after proposing labeling changes. Wyeth submitted a third supplemental application in 1981 in response to a new FDA rule governing drug labels. Over the next 17 years, Wyeth and the FDA intermittently corresponded about Phenergan's label. The most notable activity occurred in 1987, when the FDA suggested different warnings about the risk of arterial exposure, and in 1988, when Wyeth submitted revised labeling incorporating the proposed changes. The FDA did not respond. Instead, in 1996, it requested from Wyeth the labeling then in use and, without addressing Wyeth's

Injection, the injection should be stopped immediately to provide for evaluation of possible arterial placement or perivascular extravasation." []

1988 submission, instructed it to "[r]etain verbiage in current label" regarding intra-arterial injection. [] After a few further changes to the labeling not related to intra-arterial injection, the FDA approved Wyeth's 1981 application in 1998, instructing that Phenergan's final printed label "must be identical" to the approved package insert. []

Based on this regulatory history, the trial judge instructed the jury that it could consider evidence of Wyeth's compliance with FDA requirements but that such compliance did not establish that the warnings were adequate. He also instructed, without objection from Wyeth, that FDA regulations "permit a drug manufacturer to change a product label to add or strengthen a warning about its product without prior FDA approval so long as it later submits the revised warning for review and approval." []

Answering questions on a special verdict form, the jury found that Wyeth was negligent, that Phenergan was a defective product as a result of inadequate warnings and instructions, It awarded total damages of \$7,400,000, which the court reduced to account for Levine's earlier settlement with the health center and clinician. []

On August 3, 2004, the trial court filed a comprehensive opinion denying Wyeth's motion for judgment as a matter of law. After making findings of fact based on the trial record (supplemented by one letter that Wyeth found after the trial), the court rejected Wyeth's pre-emption arguments. It determined that there was no direct conflict between FDA regulations and Levine's state-law claims because those regulations permit strengthened warnings without FDA approval on an interim basis and the record contained evidence of at least 20 reports of amputations similar to Levine's since the 1960's. The court also found that state tort liability in this case would not obstruct the FDA's work because the agency had paid no more than passing attention to the question whether to warn against IV-push administration of Phenergan. In addition, the court noted that state law serves a compensatory function distinct from federal regulation. []

The Vermont Supreme Court affirmed. It held that the jury's verdict "did not conflict with FDA's labeling requirements for Phenergan because [Wyeth] could have warned against IV-push administration without prior FDA approval, and because federal labeling requirements create a floor, not a ceiling, for state regulation." [] In dissent, Chief Justice Reiber argued that the jury's verdict conflicted with federal law because it was inconsistent with the FDA's conclusion that intravenous administration of Phenergan was safe and effective.

. . . The question presented by the petition [for certiorari] is whether the FDA's drug labeling judgments "preempt state law product liability claims

premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use." []

II

Wyeth makes two separate pre-emption arguments: first, that it would have been impossible for it to comply with the state-law duty to modify Phenergan's labeling without violating federal law, [], and second, that recognition of Levine's state tort action creates an unacceptable "obstacle to the accomplishment and execution of the full purposes and objectives of Congress," [], because it substitutes a lay jury's decision about drug labeling for the expert judgment of the FDA. As a preface to our evaluation of these arguments, we identify two factual propositions decided during the trial court proceedings, emphasize two legal principles that guide our analysis, and review the history of the controlling federal statute.

... That the inadequate label was both a but-for and proximate cause of Levine's injury is supported by the record and no longer challenged by Wyeth.²

The trial court proceedings further established that the critical defect in Phenergan's label was the lack of an adequate warning about the risks of IV-push administration. Levine also offered evidence that the IV-push method should be contraindicated and that Phenergan should never be administered intravenously, even by the IV-drip method. Perhaps for this reason, the dissent incorrectly assumes that the state-law duty at issue is the duty to contraindicate the IV-push method. [] But, as the Vermont Supreme Court explained, the jury verdict established only that Phenergan's warning was insufficient. It did not mandate a particular replacement warning, nor did it require contraindicating IV-push administration: "There may have been any number of ways for [Wyeth] to strengthen the Phenergan warning without completely eliminating IV-push administration." [] We therefore need not decide whether a state rule proscribing intravenous administration would be pre-empted. The narrower question presented is whether federal law pre-empts Levine's claim that Phenergan's label did not contain an adequate warning about using the IV-push method of administration.

Our answer to that question must be guided by two cornerstones of our

² The dissent nonetheless suggests that physician malpractice was the exclusive cause of Levine's injury. See, e.g., *post*, at 1217 (opinion of ALITO, J.) ("[I]t is unclear how a 'stronger' warning could have helped respondent"); *post*, at 1225 - 1227 (suggesting that the physician assistant's conduct was the sole cause of the injury). The dissent's frustration with the jury's verdict does not put the merits of Levine's tort claim before us, nor does it change the question we must decide-whether federal law pre-empts Levine's state-law claims.

pre-emption jurisprudence. First, "the purpose of Congress is the ultimate touchstone in every pre-emption case." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) (internal quotation marks omitted); []. Second, "[i]n all pre-emption cases, and particularly in those in which Congress has 'legislated . . . in a field which the States have traditionally occupied,' . . . we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" []³

In order to identify the "purpose of Congress," it is appropriate to briefly review the history of federal regulation of drugs and drug labeling. In 1906, Congress enacted its first significant public health law, the Federal Food and Drugs Act, ch. 3915, 34 Stat. 768. The Act, which prohibited the manufacture or interstate shipment of adulterated or misbranded drugs, supplemented the protection for consumers already provided by state regulation and common-law liability. In the 1930's, Congress became increasingly concerned about unsafe drugs and fraudulent marketing, and it enacted the Federal Food, Drug, and Cosmetic Act (FDCA), ch. 675, 52 Stat. 1040, as amended, 21 U.S.C. § 301 *et seq.* The Act's most substantial innovation was its provision for premarket approval of new drugs. It required every manufacturer to submit a new drug application, including reports of investigations and specimens of proposed labeling, to the FDA for review. Until its application became effective, a manufacturer was prohibited from distributing a drug. The FDA could reject an application if it determined that the drug was not safe for use as labeled, though if the agency failed to act, an application became effective 60 days after the filing. FDCA, § 505(c), 52 Stat. 1052.

In 1962, Congress amended the FDCA and shifted the burden of proof from the FDA to the manufacturer. Before 1962, the agency had to prove harm to keep a drug out of the market, but the amendments required the manufacturer to demonstrate that its drug was "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling" before it could distribute the drug. §§ 102(d), 104(b), 76 Stat. 781, 784. In addition, the amendments required the manufacturer to prove the drug's effectiveness by introducing "substantial evidence that the drug will have the effect it purports or is

³ Wyeth argues that the presumption against pre-emption should not apply to this case because the Federal Government has regulated drug labeling for more than a century. That argument misunderstands the principle: We rely on the presumption because respect for the States as "independent sovereigns in our federal system" leads us to assume that "Congress does not cavalierly pre-empt state-law causes of action." [] The presumption thus accounts for the historic presence of state law but does not rely on the absence of federal regulation.

represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling." § 102(d), *id.*, at 781.

As it enlarged the FDA's powers to "protect the public health" and "assure the safety, effectiveness, and reliability of drugs," *id.*, at 780, Congress took care to preserve state law. The 1962 amendments added a saving clause, indicating that a provision of state law would only be invalidated upon a "direct and positive conflict" with the FDCA. § 202, *id.*, at 793. Consistent with that provision, state common-law suits "continued unabated despite . . . FDA regulation."

...

In 2007, after Levine's injury and lawsuit, Congress again amended the FDCA. [] For the first time, it granted the FDA statutory authority to require a manufacturer to change its drug label based on safety information that becomes available after a drug's initial approval. [] In doing so, however, Congress did not enact a provision in the Senate bill that would have required the FDA to preapprove all changes to drug labels. Instead, it adopted a rule of construction to make it clear that manufacturers remain responsible for updating their labels. []

III

Wyeth first argues that Levine's state-law claims are pre-empted because it is impossible for it to comply with both the state-law duties underlying those claims and its federal labeling duties. [] The FDA's premarket approval of a new drug application includes the approval of the exact text in the proposed label. [] Generally speaking, a manufacturer may only change a drug label after the FDA approves a supplemental application. There is, however, an FDA regulation that permits a manufacturer to make certain changes to its label before receiving the agency's approval. Among other things, this "changes being effected" (CBE) regulation provides that if a manufacturer is changing a label to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product," it may make the labeling change upon filing its supplemental application with the FDA; it need not wait for FDA approval.

Wyeth argues that the CBE regulation is not implicated in this case because a 2008 amendment provides that a manufacturer may only change its label "to reflect newly acquired information." 73 Fed.Reg. 49609. Resting on this language (which Wyeth argues simply reaffirmed the interpretation of the regulation in effect when this case was tried), Wyeth contends that it could have

changed Phenergan's label only in response to new information that the FDA had not considered. And it maintains that Levine has not pointed to any such information concerning the risks of IV-push administration. Thus, Wyeth insists, it was impossible for it to discharge its state-law obligation to provide a stronger warning about IV-push administration without violating federal law. Wyeth's argument misapprehends both the federal drug regulatory scheme and its burden in establishing a pre-emption defense.

We need not decide whether the 2008 CBE regulation is consistent with the FDCA and the previous version of the regulation, as Wyeth and the United States urge, because Wyeth could have revised Phenergan's label even in accordance with the amended regulation. As the FDA explained in its notice of the final rule, "newly acquired information" is not limited to new data, but also encompasses "new analyses of previously submitted data." [] The rule accounts for the fact that risk information accumulates over time and that the same data may take on a different meaning in light of subsequent developments: "[I]f the sponsor submits adverse event information to FDA, and then later conducts a new analysis of data showing risks of a different type or of greater severity or frequency than did reports previously submitted to FDA, the sponsor meets the requirement for 'newly acquired information.'" []

...

Wyeth's cramped reading of the CBE regulation and its broad reading of the FDCA's misbranding and unauthorized distribution provisions are premised on a more fundamental misunderstanding. Wyeth suggests that the FDA, rather than the manufacturer, bears primary responsibility for drug labeling. Yet through many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market. See, e.g., 21 CFR § 201.80(e) (requiring a manufacturer to revise its label "to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug"); § 314.80(b) (placing responsibility for postmarketing surveillance on the manufacturer); 73 Fed.Reg. 49605 ("Manufacturers continue to have a responsibility under Federal law . . . to maintain their labeling and update the labeling with new safety information").

Indeed, prior to 2007, the FDA lacked the authority to order manufacturers to revise their labels. [] When Congress granted the FDA this authority, it reaffirmed the manufacturer's obligations and referred specifically to the CBE regulation, which both reflects the manufacturer's ultimate responsibility for its label and provides a mechanism for adding safety information to the label prior to

FDA approval. See *id.*, at 925-26 (stating that a manufacturer retains the responsibility "to maintain its label in accordance with existing requirements, including subpart B of part 201 and sections 314.70 and 601.12 of title 21, Code of Federal Regulations (or any successor regulations)" (emphasis added)). Thus, when the risk of gangrene from IV-push injection of Phenergan became apparent, Wyeth had a duty to provide a warning that adequately described that risk, and the CBE regulation permitted it to provide such a warning before receiving the FDA's approval.

Of course, the FDA retains authority to reject labeling changes made pursuant to the CBE regulation in its review of the manufacturer's supplemental application, just as it retains such authority in reviewing all supplemental applications. But absent clear evidence that the FDA would not have approved a change to Phenergan's label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements.

Wyeth has offered no such evidence. It does not argue that it attempted to give the kind of warning required by the Vermont jury but was prohibited from doing so by the FDA. [] And while it does suggest that the FDA intended to prohibit it from strengthening the warning about IV-push administration because the agency deemed such a warning inappropriate in reviewing Phenergan's drug applications, both the trial court and the Vermont Supreme Court rejected this account as a matter of fact. . . .

Impossibility pre-emption is a demanding defense. On the record before us, Wyeth has failed to demonstrate that it was impossible for it to comply with both federal and state requirements. The CBE regulation permitted Wyeth to unilaterally strengthen its warning, and the mere fact that the FDA approved Phenergan's label does not establish that it would have prohibited such a change.

IV

Wyeth also argues that requiring it to comply with a state-law duty to provide a stronger warning about IV-push administration would obstruct the purposes and objectives of federal drug labeling regulation. Levine's tort claims, it maintains, are pre-empted because they interfere with "Congress's purpose to entrust an expert agency to make drug labeling decisions that strike a balance between competing objectives." [] We find no merit in this argument, which relies on an untenable interpretation of congressional intent and an overbroad view of an agency's power to pre-empt state law.

Wyeth contends that the FDCA establishes both a floor and a ceiling for drug regulation: Once the FDA has approved a drug's label, a state-law verdict

may not deem the label inadequate, regardless of whether there is any evidence that the FDA has considered the stronger warning at issue. The most glaring problem with this argument is that all evidence of Congress' purposes is to the contrary. Building on its 1906 Act, Congress enacted the FDCA to bolster consumer protection against harmful products. [] Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs in the 1938 statute or in any subsequent amendment. Evidently, it determined that widely available state rights of action provided appropriate relief for injured consumers. It may also have recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings.

If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history. But despite its 1976 enactment of an express pre-emption provision for medical devices, [], Congress has not enacted such a provision for prescription drugs. [] It did not do so, but instead wrote a pre-emption clause that applies only to medical devices"). Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness. . . .

Despite this evidence that Congress did not regard state tort litigation as an obstacle to achieving its purposes, Wyeth nonetheless maintains that, because the FDCA requires the FDA to determine that a drug is safe and effective under the conditions set forth in its labeling, the agency must be presumed to have performed a precise balancing of risks and benefits and to have established a specific labeling standard that leaves no room for different state-law judgments. In advancing this argument, Wyeth relies not on any statement by Congress, but instead on the preamble to a 2006 FDA regulation governing the content and format of prescription drug labels. [] In that preamble, the FDA declared that the FDCA establishes "both a 'floor' and a 'ceiling,' " so that "FDA approval of labeling . . . preempts conflicting or contrary State law." [] It further stated that certain state-law actions, such as those involving failure-to-warn claims, "threaten FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs." []

This Court has recognized that an agency regulation with the force of law can pre-empt conflicting state requirements. [] In such cases, the Court has performed its own conflict determination, relying on the substance of state and federal law and not on agency proclamations of pre-emption. We are faced with no such regulation in this case, but rather with an agency's mere assertion that state law is an obstacle to achieving its statutory objectives. Because Congress has not authorized the FDA to pre-empt state law directly, cf. 21 U.S.C. § 360k

(authorizing the FDA to determine the scope of the Medical Devices Amendments' pre-emption clause), the question is what weight we should accord the FDA's opinion.

In prior cases, we have given "some weight" to an agency's views about the impact of tort law on federal objectives when "the subject matter is technical and the relevant history and background are complex and extensive." [] Even in such cases, however, we have not deferred to an agency's *conclusion* that state law is pre-empted. Rather, we have attended to an agency's explanation of how state law affects the regulatory scheme. While agencies have no special authority to pronounce on pre-emption absent delegation by Congress, they do have a unique understanding of the statutes they administer and an attendant ability to make informed determinations about how state requirements may pose an "obstacle to the accomplishment and execution of the full purposes and objectives of Congress." [] The weight we accord the agency's explanation of state law's impact on the federal scheme depends on its thoroughness, consistency, and persuasiveness. []

Under this standard, the FDA's 2006 preamble does not merit deference. When the FDA issued its notice of proposed rulemaking in December 2000, it explained that the rule would "not contain policies that have federalism implications or that preempt State law." 65 Fed.Reg. 81103; see also 71 *id.*, at 3969 (noting that the "proposed rule did not propose to preempt state law"). In 2006, the agency finalized the rule and, without offering States or other interested parties notice or opportunity for comment, articulated a sweeping position on the FDCA's pre-emptive effect in the regulatory preamble. The agency's views on state law are inherently suspect in light of this procedural failure.

Further, the preamble is at odds with what evidence we have of Congress' purposes, and it reverses the FDA's own longstanding position without providing a reasoned explanation, including any discussion of how state law has interfered with the FDA's regulation of drug labeling during decades of coexistence. The FDA's 2006 position plainly does not reflect the agency's own view at all times relevant to this litigation. . . .

In short, Wyeth has not persuaded us that failure-to-warn claims like Levine's obstruct the federal regulation of drug labeling. Congress has repeatedly declined to pre-empt state law, and the FDA's recently adopted position that state tort suits interfere with its statutory mandate is entitled to no weight. Although we recognize that some state-law claims might well frustrate the achievement of

congressional objectives, this is not such a case.

V

We conclude that it is not impossible for Wyeth to comply with its state and federal law obligations and that Levine's common-law claims do not stand as an obstacle to the accomplishment of Congress' purposes in the FDCA. Accordingly, the judgment of the Vermont Supreme Court is affirmed.

Justice BREYER, concurring.

I write separately to emphasize the Court's statement that "we have no occasion in this case to consider the pre-emptive effect of a specific agency regulation bearing the force of law." *Ante*, at 1203. State tort law will sometimes help the Food and Drug Administration (FDA) "uncover unknown drug hazards and [encourage] drug manufacturers to disclose safety risks." But it is also possible that state tort law will sometimes interfere with the FDA's desire to create a drug label containing a specific set of cautions and instructions. I also note that some have argued that state tort law can sometimes raise prices to the point where those who are sick are unable to obtain the drugs they need. [] The FDA may seek to determine whether and when state tort law acts as a help or a hindrance to achieving the safe drug-related medical care that Congress sought. [] It may seek to embody those determinations in lawful specific regulations describing, for example, when labeling requirements serve as a ceiling as well as a floor. And it is possible that such determinations would have pre-emptive effect. [] I agree with the Court, however, that such a regulation is not at issue in this case.

Justice THOMAS, concurring in the judgment.

I agree with the Court that the fact that the Food and Drug Administration (FDA) approved the label for petitioner Wyeth's drug Phenergan does not pre-empt the state-law judgment before the Court. . . .

...

I write separately, however, because I cannot join the majority's implicit endorsement of far-reaching implied pre-emption doctrines. In particular, I have become increasingly skeptical of this Court's "purposes and objectives" pre-emption jurisprudence. Under this approach, the Court routinely invalidates state laws based on perceived conflicts with broad federal policy objectives, legislative history, or generalized notions of congressional purposes that are not embodied within the text of federal law. Because implied pre-emption doctrines that wander

far from the statutory text are inconsistent with the Constitution, I concur only in the judgment.

I

...

B

In light of these constitutional principles, I have become "increasing[ly] reluctan[t] to expand federal statutes beyond their terms through doctrines of implied pre-emption." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 459, 125 S.Ct. 1788, 161 L.Ed.2d 687 (2005) (THOMAS, J., concurring in judgment in part and dissenting in part). My review of this Court's broad implied pre-emption precedents, particularly its "purposes and objectives" pre-emption jurisprudence, has increased my concerns that implied pre-emption doctrines have not always been constitutionally applied. Under the vague and "potentially boundless" doctrine of "purposes and objectives" pre-emption, *Geier v. American Honda Motor Co.*, 529 U.S. 861, 907, 120 S.Ct. 1913, 146 L.Ed.2d 914 (2000) (STEVENSON, J., dissenting), for example, the Court has pre-empted state law based on its interpretation of broad federal policy objectives, legislative history, or generalized notions of congressional purposes that are not contained within the text of federal law. See, e.g., *Pharmaceutical Research and Mfrs. of America v. Walsh*, 538 U.S. 644, 678, 123 S.Ct. 1855, 155 L.Ed.2d 889 (2003) (THOMAS, J., concurring in judgment) (referring to the "concomitant danger of invoking obstacle pre-emption based on the arbitrary selection of one purpose to the exclusion of others"); *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 388-391, 120 S.Ct. 2288, 147 L.Ed.2d 352 (2000) (SCALIA, J., concurring in judgment) (criticizing the majority's reliance on legislative history to discern statutory intent when that intent was "perfectly obvious on the face of th[e] statute"); *Geier, supra*, at 874-883, 120 S.Ct. 1913 (relying on regulatory history, agency comments, and the Government's litigating position to determine that federal law pre-empted state law).

Congressional and agency musings, however, do not satisfy the Art. I, § 7 requirements for enactment of federal law and, therefore, do not pre-empt state law under the Supremacy Clause. When analyzing the pre-emptive effect of federal statutes or regulations validly promulgated thereunder, "[e]vidence of pre-emptive purpose [must be] sought in the text and structure of the [provision] at issue" to comply with the Constitution. . . .

...

Justice ALITO, with whom THE CHIEF JUSTICE and Justice SCALIA join, dissenting.

This case illustrates that tragic facts make bad law. The Court holds that a state tort jury, rather than the Food and Drug Administration (FDA), is ultimately responsible for regulating warning labels for prescription drugs. That result cannot be reconciled with *Geier v. American Honda Motor Co.*, 529 U.S. 861, 120 S.Ct. 1913, 146 L.Ed.2d 914 (2000), or general principles of conflict pre-emption. I respectfully dissent.

I

The Court frames the question presented as a "narro[w]" one—namely, whether Wyeth has a duty to provide "an adequate warning about using the IV-push method" to administer Phenergan. *Ante*, at 1194. But that ignores the antecedent question of who—the FDA or a jury in Vermont—has the authority and responsibility for determining the "adequacy" of Phenergan's warnings. Moreover, it is unclear how a "stronger" warning could have helped respondent, see *ante*, at 1199; after all, the physician's assistant who treated her disregarded at least six separate warnings that are already on Phenergan's labeling, so respondent would be hard pressed to prove that a seventh would have made a difference.

More to the point, the question presented by this case is not a "narrow" one, and it does not concern whether Phenergan's label should bear a "stronger" warning. Rather, the real issue is whether a state tort jury can countermand the FDA's considered judgment that Phenergan's FDA-mandated warning label renders its intravenous (IV) use "safe." Indeed, respondent's amended complaint alleged that Phenergan is "not reasonably safe for intravenous administration," []; respondent's attorney told the jury that Phenergan's label should say, "Do not use this drug intravenously," []; respondent's expert told the jury, "I think the drug should be labeled 'Not for IV use,' []; and during his closing argument, respondent's attorney told the jury, "Thank God we don't rely on the FDA to . . . make the safe[ty] decision. You will make the decision. . . . The FDA doesn't make the decision, you do," [].

Federal law, however, *does* rely on the FDA to make safety determinations like the one it made here. The FDA has long known about the risks associated with IV push in general and its use to administer Phenergan in particular. Whether wisely or not, the FDA has concluded—over the course of extensive, 54-year-long regulatory proceedings—that the drug is "safe" and "effective" when used in accordance with its FDA-mandated labeling. The unfortunate fact that respondent's healthcare providers ignored Phenergan's labeling may make this an ideal medical-malpractice case. But turning a common-law tort suit into a "frontal assault" on the FDA's regulatory regime for

drug labeling upsets the well-settled meaning of the Supremacy Clause and our conflict pre-emption jurisprudence [].

II

A

To the extent that “[t]he purpose of Congress is the ultimate touchstone in every pre-emption case,” [], Congress made its “purpose” plain in authorizing the FDA-not state tort juries-to determine when and under what circumstances a drug is “safe.” “[T]he process for approving new drugs is at least as rigorous as the premarket approval process for medical devices,” [], and we held that the latter pre-empted a state-law tort suit that conflicted with the FDA’s determination that a medical device was “safe,” [].

Under the Federal Food, Drug, and Cosmetic Act (FDCA), a drug manufacturer may not market a new drug before first submitting a new drug application (NDA) to the FDA and receiving the agency’s approval. See 21 U.S.C. § 355(a). An NDA must contain, among other things, “the labeling proposed to be used for such drug,” § 355(b)(1)(F), “full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use,” § 355(b)(1)(A), and “a discussion of why the benefits exceed the risks [of the drug] under the conditions stated in the labeling,” 21 CFR § 314.50(d)(5)(viii) (2008). The FDA will approve an NDA only if the agency finds, among other things, that the drug is “safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof,” there is “substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof,” and the proposed labeling is not “false or misleading in any particular.” 21 U.S.C. § 355(d).

...

Thus, a drug’s warning label “serves as the standard under which the FDA determines whether a product is safe and effective.” 50 Fed.Reg. 7470 (1985). Labeling is “[t]he centerpiece of risk management,” as it “communicates to health care practitioners the agency’s formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively.” The FDA has underscored the importance it places on drug labels by promulgating comprehensive regulations-spanning an entire part of the Code of Federal Regulations, see 21 CFR pt. 201, with seven subparts and 70 separate sections-that set forth drug manufacturers’ labeling obligations. Under those regulations, the FDA must be satisfied that a drug’s warning label contains, among other things, “a summary of the essential scientific information needed for the safe and

effective use of the drug," § 201.56(1), including a description of "clinically significant adverse reactions," "other potential safety hazards," "limitations in use imposed by them, . . . and steps that should be taken if they occur," § 201.57(c)(6)(i). Neither the FDCA nor its implementing regulations suggest that juries may second-guess the FDA's labeling decisions.

B

1

Where the FDA determines, in accordance with its statutory mandate, that a drug is on balance "safe," our conflict pre-emption cases prohibit any State from countermanding that determination. []

...

III

In its attempt to evade *Geier*'s applicability to this case, the Court commits both factual and legal errors. First, as a factual matter, it is demonstrably untrue that the FDA failed to consider (and strike a "balance" between) the specific costs and benefits associated with IV push. . . .

A

Phenergan's warning label has been subject to the FDA's strict regulatory oversight since the 1950's. For at least the last 34 years, the FDA has focused specifically on whether IV-push administration of Phenergan is "safe" and "effective" when performed in accordance with Phenergan's label. The agency's ultimate decision-to retain IV push as one means for administering Phenergan, albeit subject to stringent warnings-is reflected in the plain text of Phenergan's label (sometimes in boldfaced font and all-capital letters). And the record contains ample evidence that the FDA specifically considered and reconsidered the strength of Phenergan's IV-push-related warnings in light of new scientific and medical data. The majority's factual assertions to the contrary are mistaken.

1

The FDA's focus on IV push as a means of administering Phenergan dates back at least to 1975. In August of that year, several representatives from both the FDA and Wyeth met to discuss Phenergan's warning label. At that meeting, the FDA specifically proposed "that Phenergan Injection should not be used in Tubex & reg;." [] "Tubex" is a syringe system used exclusively for IV push. See App. 43. An FDA official explained that the agency's concerns arose

from medical-malpractice lawsuits involving IV push of the drug, see 1975 Memo 586, and that the FDA was aware of "5 cases involving amputation where the drug had been administered by Tubex together with several additional cases involving necrosis," []. Rather than contraindicating Phenergan for IV push, however, the agency and Wyeth agreed "that there was a need for better instruction regarding the problems of intraarterial injection." []

The next year, the FDA convened an advisory committee to study, among other things, the risks associated with the Tubex system and IV push. App. 294. At the conclusion of its study, the committee recommended an additional IV-push-specific warning for Phenergan's label, see *ibid.*, but did not recommend eliminating IV push from the drug label altogether. In response to the committee's recommendations, the FDA instructed Wyeth to make several changes to strengthen Phenergan's label, including the addition of upper case warnings related to IV push. []

In 1987, the FDA directed Wyeth to amend its label to include the following text:

"[1] When used intravenously, [Phenergan] should be given in a concentration no greater than 25 mg/ml and at a rate not to exceed 25 mg/minute. [2] Injection through a properly running intravenous infusion may enhance the possibility of detecting arterial placement." []

The first of the two quoted sentences refers specifically to IV push; as respondent's medical expert testified at trial, the label's recommended rate of administration (not to exceed 25 mg per minute) refers to "IV push, as opposed to say being in a bag and dripped over a couple of hours." [] The second of the two quoted sentences refers to IV drip. See *id.*, at 15-16 (emphasizing that a "running IV" is the same thing as "IV drip").

In its 1987 labeling order, the FDA cited voluminous materials to "support[t]" its new and stronger warnings related to IV push and the preferability of IV drip. [] One of those articles specifically discussed the relative advantages and disadvantages of IV drip compared to IV push, as well as the costs and benefits of administering Phenergan via IV push. The FDA also cited published case reports from the 1960's of gangrene caused by the intra-arterial injection of Phenergan, and the FDA instructed Wyeth to amend Phenergan's label in accordance with the latest medical research. The FDA also studied drugs similar to Phenergan and cited numerous cautionary articles-one of which urged the agency to consider contraindicating such drugs for IV use altogether.

When respondent was injured in 2000, Phenergan's label specifically addressed IV push in several passages (sometimes in lieu of and sometimes in addition to those discussed above). For example, the label warned of the risks of intra-arterial injection associated with "aspiration," which is a technique used only in conjunction with IV push. The label also cautioned against the use of "syringes with rigid plungers," [], which are used only to administer the drug via IV push. As respondent's medical expert testified at trial, "by talking plungers and rigid needles, that's the way you do it, to push it with the plunger." [] Moreover, Phenergan's 2000 label devoted almost a full page to discussing the "Tubex system," [], which, as noted above, is used only to administer the drug via IV push.

While Phenergan's label very clearly authorized the use of IV push, it also made clear that IV push is the delivery method of last resort. The label specified that "[t]he preferred parenteral route of administration is by deep intramuscular injection." [] If an intramuscular injection is ineffective, then "it is usually preferable to inject [Phenergan] through the tubing of an intravenous infusion set that is known to be functioning satisfactorily." [(conceding that the best way to determine that an IV set is functioning satisfactorily is to use IV drip)]. Finally, if for whatever reason a medical professional chooses to use IV push, he or she is on notice that **"INADVERTENT INTRA-ARTERIAL INJECTION CAN RESULT IN GANGRENE OF THE AFFECTED EXTREMITY."** [(Under no circumstances should Phenergan Injection be given by intra-arterial injection due to the likelihood of severe arteriospasm and the possibility of resultant gangrene)].

Thus, it is demonstrably untrue that, as of 2000, Phenergan's "labeling did not contain a specific warning about the risks of IV-push administration." [] And whatever else might be said about the extensive medical authorities and case reports that the FDA cited in "support" of its approval of IV-push administration of Phenergan, it cannot be said that the FDA "paid no more than passing attention to" IV push, [], nor can it be said that the FDA failed to weigh its costs and benefits, Brief for Respondent 50. []

For her part, respondent does not dispute the FDA's conclusion that IV push has certain benefits. At trial, her medical practitioners testified that they

used IV push in order to help her "in a swift and timely way" when she showed up at the hospital for the second time in one day complaining of "intractable" migraines, "terrible pain," inability to "bear light or sound," sleeplessness, hours-long spasms of "retching" and "vomiting," and when "every possible" alternative treatment had "failed." []

Rather than disputing the benefits of IV push, respondent complains that the FDA and Wyeth underestimated its costs (and hence did not provide sufficient warnings regarding its risks). But when the FDA mandated that Phenergan's label read, **"INADVERTENT INTRA-ARTERIAL INJECTION CAN RESULT IN GANGRENE OF THE AFFECTED EXTREMITY,"***id.*, at 391, and when the FDA required Wyeth to warn that "[u]nder no circumstances should Phenergan Injection be given by intra-arterial injection," [], the agency could reasonably assume that medical professionals would take care not to inject Phenergan intra-arterially. [] Unfortunately, the physician's assistant who treated respondent in this case disregarded Phenergan's label and pushed the drug into the single spot on her arm that is *most* likely to cause an inadvertent intra-arterial injection.

As noted above, when the FDA approved Phenergan's label, it was textbook medical knowledge that the "antecubital fossa" creates a high risk of inadvertent intra-arterial injection, given the close proximity of veins and arteries. [] According to the physician's assistant who injured respondent, however, "[i]t never crossed my mind" that an antecubital injection of Phenergan could hit an artery. [] Oblivious to the risks emphasized in Phenergan's warnings, the physician's assistant pushed a double dose of the drug into an antecubital artery over the course of "[p]robably about three to four minutes," [], notwithstanding respondent's complaints of a " 'burn [ing]' " sensation that she subsequently described as " 'one of the most extreme pains that I've ever felt.' " [] And when asked why she ignored Phenergan's label and failed to stop pushing the drug after respondent complained of burning pains, the physician's assistant explained that it would have been "just crazy" to "worr[y] about an [intra-arterial] injection" under the circumstances, [].

The FDA, however, did not think that the risks associated with IV push—especially in the antecubital space—were "just crazy." That is why Phenergan's label so clearly warns against them.

...

C

By their very nature, juries are ill-equipped to perform the FDA's cost-benefit-balancing function. As we explained in *Riegel*, juries tend to focus on the

risk of a particular product's design or warning label that arguably contributed to a particular plaintiff's injury, not on the overall benefits of that design or label; "the patients who reaped those benefits are not represented in court." [] Indeed, patients like respondent are the only ones whom tort juries ever see, and for a patient like respondent—who has already suffered a tragic accident—Phenergan's risks are no longer a matter of probabilities and potentialities.

In contrast, the FDA has the benefit of the long view. Its drug-approval determinations consider the interests of all potential users of a drug, including "those who would suffer without new medical [products]" if juries in all 50 States were free to contradict the FDA's expert determinations. [] And the FDA conveys its warnings with one voice, rather than whipsawing the medical community with 50 (or more) potentially conflicting ones. After today's ruling, however, parochialism may prevail.

...

To be sure, state tort suits can peacefully coexist with the FDA's labeling regime, and they have done so for decades. [] But this case is far from peaceful coexistence. The FDA told Wyeth that Phenergan's label renders its use "safe." But the State of Vermont, through its tort law, said: "Not so."

Page 503 new note. *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233 (3d Cir. 2009). Even after *Levine*, preemption continues to develop. This case involved express preemption in the Childhood Vaccine Act, and the court finds an express provision exempting unavoidably unsafe vaccines from tort liability to preempt all design defect claims for vaccines. By contrast, reprising the controversy over the Second Restatement § 402A, Comment k and prescription drugs, the Georgia Supreme Court has held that whether vaccine design claims are preempted depends on a case-by-case assessment of the vaccine and the claim. *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236 (Ga. 2008). This issue, in the context of the Third Restatement's treatment of design defects for pharmaceuticals, is addressed in note 6 at p. 611 of the text.

Page 503 note 5, after first full ¶. Would a claim that promoting certain brands of cigarettes as "Light" is misleading and a violation of a state deceptive trade practices statute be preempted by *Cipollone*? No, said the Supreme Court, because these claims were most like a claim of fraudulent misrepresentation, which the plurality in *Cipollone* concluded would not be preempted by the language in the preemption section of the Cigarette Labeling and Advertising Act. *Altria Group, Inc. v. Good*, 129 S. Ct. 538 (2008).

Pages 504-05 note 8 (add at the end). For an assessment of the Supreme Court's preemption jurisprudence affecting state tort claims from *Cipollone* to *Wyeth*, see Robert L. Rabin, *Conflicting Conceptions of Tort Preemption: Territorial Claims in the Domain of Accidental Harm*, 74 Brooklyn L. Rev. ____ (2009).

Page 505 new note (after note 8). *Lundeen v. Canadian Pac. R. Co.*, 532 F.3d 682 (8th Cir. 2008), provides a harbinger of what may happen in the future: this case reflects Congress legislatively overturning preemption that had previously been held to apply to railroads and to the claims asserted by these plaintiffs. Plaintiffs were injured by a freight-train derailment, but their suit was dismissed based on a preemption provision contained in the Federal Railroad Safety Act. During appeal—and after considerable media attention—Congress repealed the preemption provision, and the court holds that the repeal is applicable to this suit.

Chapter VII

Page 528 new note (after note 7). *Birmingham Coal & Coke Co., Inc. v. Johnson*, ____ So.2d ____, 2008 WL 5105458 (Ala. 2008). Can a plaintiff recover for emotional distress in a strict liability claim that would not be recoverable in a negligence claim? No, concludes the Alabama Supreme Court. Defendant engaged in blasting and was subject to strict liability for it. Plaintiffs recovered for property damage to their home, but the court decided that plaintiffs could not recover for any emotional harm they suffered. Alabama requires physical injury or zone of danger in negligence and products liability claims, and the court analogizes this abnormally-dangerous strict liability claim to those claims. No emotional harm damages are available in pure property damages cases, and thus the award of damages for this harm is overturned.

Chapter VIII

Section A. Introduction

Page 563 note 6.b. In *Semenetz v. Sherling & Walden, Inc.*, 851 N.E.2d 1170 (N.Y. 2006), the court declined to adopt a product line exception to the traditional successor liability rules based on concern about the impact on small business owners:

Importantly, the “product line” exception threatens “economic annihilation” for small businesses []. Because small businesses have limited assets, they face potential financial destruction if saddled with liability for their predecessors' torts. This threat would deter the purchase of ongoing businesses that manufacture products and, instead, force potential sellers

to liquidate their companies. As the Florida Supreme Court has observed, 90% of the nation's manufacturing enterprises are small businesses, and "[i]f small manufacturing corporations liquidate rather than transfer ownership, the chances that the corporations will be replaced by other successful small corporations are decreased" [].

Section C. Design Defects

Page 594 note on Inferring the Existence of an Unidentified Defect. *Smoot v. Mazda Motors of America, Inc.*, 469 F.3d 675 (7th Cir. 2006). The airbag in the plaintiff's car deployed suddenly when it should not have, according to the plaintiff. But the car was repaired and sold before suit, so direct evidence of what happened was not available. The court considered whether plaintiff could make out a prima facie case of defect without further evidence and analyzed the issue employing *res ipsa loquitur* principles for inferring negligence, concluding with the observation:

Although we have been speaking so far of "negligence" because it is primarily in negligence cases that *res ipsa loquitur* is invoked, this is a products liability case and the issue is not whether the defendant was negligent but whether its product, namely the car in which Mrs. Smoot was injured, was defective. However, there need be no practical difference between a claim that a product was negligently manufactured and a claim that it has a defect rendering it unreasonably dangerous, see [], and so it is no surprise that, as we have seen, *res ipsa loquitur* is applied in products cases. It would make no difference, so far as application of the doctrine was concerned, if a car accelerated when the brake was depressed because the brake had been manufactured negligently or designed improperly.

The Products Liability Restatement also recognizes the connection between Section 3 and its negligence ancestry: "This Section traces its historical antecedents to the law of negligence, which has long recognized that an inference may be drawn in cases in which the defendant's negligence is the best explanation of the cause of an accident" Restatement (Third) of Torts: Products Liability § 3, comment a.

Section D. Safety Instructions and Warnings.

Page 610 new note (after note 3). In *State v. Karl*, 647 S.E.2d 899 (W. Va. 2007), the court refused to adopt the learned intermediary doctrine. Characterizing it as outdated and not in keeping with modern conditions in the pharmaceutical industry and health care delivery, the court discusses direct to

consumer advertising and the growth of the internet as the source of health care information and drug dispensing. Influenced by the West Virginia Supreme Court in *Karl, Rimbert v. Eli Lilly & Co.*, 577 F. Supp. 2d 1174 (D.N.M. 2008), predicts that the New Mexico Supreme Court would also decline to adopt the learned intermediary defense. Although *Karl* was limited to drugs with direct to consumer advertising, it is not clear--indeed it appears otherwise--that this case is so limited.

Section H. The Intersection of Tort and Contract.

Page 664 note 8. *Lloyd v. General Motors Corp.*, 916 A.2d 257 (Md. 2007). This case reveals a far larger role for the "asbestos exception" than one might have initially thought. Plaintiffs sued for the cost of repairing a defect in their automobiles that could result in the seatback collapsing in a rear-end collision, and the occupant being propelled backward with risks of spine compression injuries, including paraplegia. The court held that plaintiffs could maintain their tort actions, as an exception to the economic loss rule, relying in part on the asbestos exception. Referring to an earlier case, in which the court permitted a tort suit to proceed against the general contractor and others of a building that had inadequate fire protection, the court wrote:

[A] plaintiff should not "have to wait for a personal tragedy to occur in order to recover damages to remedy or repair defects[.] In the final analysis, the cost to the developer for a resulting tragedy could be far greater than the cost of remedying the condition." [] If, therefore, the conduct complained of creates a risk of death or personal injury, this Court continued, "the action will lie for recovery of the reasonable cost of correcting the dangerous condition in a tort action seeking purely economic loss." [] The Court [in *Whiting-Turner*, 517 A.2d at 345] explained:

"it is the serious nature of the risk that persuades us to recognize the cause of action in the absence of actual injury. Accordingly, conditions that present a risk to general health, wealth, or comfort but fall short of presenting a clear danger of death or personal injury will not suffice. A claim that defective design or construction has produced a drafty condition that may lead to a cold or pneumonia would not be sufficient."

The *Lloyd* court concluded that the allegations in the complaint met this standard. Further supporting the idea that the asbestos exception has more heft is *Colleton Preparatory Academy, Inc. v. Hoover Universal, Inc.*, 666 S.E.2d 247 (S.C. 2008). Plaintiff sued the manufacturer of fire retardant after determining that

wood roof trusses treated with the retardant were in danger of failing. Based on the risk of personal injury, inter alia, the court holds that the economic loss rule does not apply and plaintiff may maintain this claim in tort.

Page 666 note 11. Haglund v. Philip Morris, Inc., 847 N.E.2d 315 (Mass. 2006), addresses the question of what affirmative defenses are available in products liability action based on implied warranty (Massachusetts does not recognize a strict tort theory). In an earlier case, the court had decided that unreasonable assumption of risk (unreasonable use of product subjectively known to be defective and dangerous) constituted an affirmative defense barring recovery. However, unlike other products, cigarettes inherently entail danger and thus "there can be no nonunreasonable use of cigarettes." If the extant assumption of risk defense were available in cigarette cases, it would bar all such suits. Rejecting the traditional form of assumption of risk in cigarette cases, the court nevertheless declines to rule that no affirmative defense is available. If a plaintiff's use is, under the specific circumstances, "so overwhelmingly unreasonable in light of the consumer's knowledge about, for example, a specific medical condition from which he suffers," the claim could be barred.

Chapter IX

Section B. Nuisance.

Page 676 Public Nuisance. In re Lead Paint Litig., 924 A.2d 484 (N.J. 2007). The court decided (4-2) that plaintiffs, governmental entities, cannot maintain a public nuisance claim against paint manufacturers for lead abatement costs. In the course of its opinion, the court surveyed the emergence and development of public nuisance, including its evolving into a source for environmental claims. The court distilled these principles of public nuisance claims:

First, a public nuisance, by definition, is related to conduct, performed in a location within the actor's control, which has an adverse effect on a common right. Second, a private party who has suffered special injury may seek to recover damages to the extent of the special injury and, by extension, may also seek to abate. Third, a public entity which proceeds against the one in control of the nuisance may only seek to abate, at the expense of the one in control of the nuisance. These time-honored elements of the tort of public nuisance must be our guide in our consideration of whether these complaints have stated such a claim.

The dissent argues it's time to modernize this tort to keep up with contemporary problems.

Reaching the same result as *In re Lead Paint Litigation*, the Rhode Island Supreme Court unanimously overturns a judgment against three lead pigment manufacturers. *State v. Lead Indus., Ass'n, Inc.*, 951 A.2d 428 (R.I. 2008). The public nuisance claims founder on two elements: the defendants were not in control of the instrumentality causing the intrusion and there was no interference with any "public right;" this case involved only an aggregation of private rights.

Page 677 last full ¶. The constitutionality of the Protection of Lawful Commerce in Arms Act was upheld in *City of New York v. Beretta U.S.A. Corp.*, 524 F.3d 3847 (2d Cir. 2008). The court also reversed the lower court's holding that an exception in the Act for violations of state law "applicable to the sale or marketing of [firearms]" permitted this suit for injunctive and declaratory relief to go forward. The court of appeals concluded that this language applies to statutes specific to gun distributions and does not apply to New York's criminal public nuisance statute. In accord with *Beretta* is *Ileto v. Glock, Inc.*, ___ F.3d ___, 2009 WL 1272629 (9th Cir. 2009). The case arose out of the wounding of five victims at a Jewish Community Center summer camp. Plaintiffs' claim is overselling, knowing that the guns will get into the hands of criminals and others who will use them for illegal purposes. The court rejected the same argument attempting to invoke the exception in the Act that the Second Circuit rejected in *Beretta*. The court also affirmed the constitutionality of the Act, including its retroactive effect.

Chapter X

Section A. Damages.

Page 706 note 1. *Madeira v. Affordable Housing Foundation, Inc.*, 469 F.3d 219 (2d Cir. 2006), reveals yet another facet of the contemporary immigration debate. When an undocumented alien recovers lost wages in a tort suit, in which labor market should those lost wages be valued? Defendants relied on a Supreme Court case, *Hoffman Plastic*, 535 U.S. 137 (2002), that held that the Immigration Reform and Control Act of 1986 ("IRCA") barred the NLRB from awarding backpay to an illegal alien. Defendants claimed that IRCA preempted state tort law that would provide damages based on what the plaintiff would earn in the United States and that if any damages for lost wages were awarded it should be based on earnings capacity in the plaintiff's home country. The court rejected defendant's claim, relying heavily on an earlier New York Court of Appeals decision, *Balbuena v. IDR Realty LLC*, 845 N.E.2d 1246 (N.Y. 2006):

The Court specifically noted that, in *Balbuena*, as opposed to *Hoffman Plastic*, the undocumented aliens had not themselves violated federal immigration law in procuring employment. [] Further, the Court of Appeals

noted that New York law for compensating personal injury specifically sought to avoid any conflict with federal immigration law by instructing juries to consider the fact of a plaintiff's removability in determining what, if any, lost United States earnings should be compensated. []

Madeira also noted the varying results in about a half dozen other cases confronting the same issue.

Page 706 note 2, 2d full ¶. In *McMillan v. City of New York*, 253 F.R.D. 247 (E.D.N.Y. 2008), Judge Weinstein accepted the Chamallas argument and held that use of race-based actuarial tables was unconstitutional.

Page 714 note 9, 2d full ¶. Continuing the theme sounded in *Jutzi-Johnson*, Judge Posner in *Arpin v. U.S.*, 521 F.3d 769 (7th Cir. 2008), required the trial judge, as finder of fact, to explain the basis for a \$7 million award to a widow and adult children for loss of consortium. Even though Illinois law does not favor consideration of comparable awards, this is a procedural matter and therefore governed by federal law. The court also suggested that the consideration of similar cases might begin by determining the ratio of compensatory to consortium damages in other cases and then deciding whether an adjustment from that overall ratio is appropriate based on the facts of the instant case.

Page 714 note 9, 3d full ¶. In *Arpin*, *supra*, Judge Posner explained how tradeoffs of risk and safety as revealed in behavior could provide a basis for determining damages for intangible losses:

It used to be thought that noneconomic losses were arbitrary because incommensurable with any dollar valuation. That is not true. People are constantly trading off hazards to life and limb against money; consider combat pay and re-enlistment bonuses in the army. Even when the tradeoff is between two nonmonetary values, such as danger and convenience (as when one crosses a street against the lights because one is in a hurry, or drives in excess of the speed limit), it may be possible to express the tradeoff in monetary terms, for example by estimating, on the basis of hourly wage rates, the value of the time saving. And if we know both the probability of a fatal accident and the benefit that a person would demand to bear it we can estimate a value of life and use that value to calculate damages in wrongful death cases. See W. Kip Viscusi and Joseph E. Aldy, "The Value of a Statistical Life: A Critical Review of Market Estimates Throughout the World," 27 J. Risk & Uncertainty 5 (2003); Paul Lanoie, Carmen Pedro & Robert Latour, "The Value of a Statistical Life: A Comparison of Two Approaches," 10 J. Risk & Uncertainty 235 (1995); W. Kip Viscusi, "The Value of Risks to Life and

Health," 31 J. Econ. Lit. 1912 (1992). Suppose a person would demand \$7 to assume a one in one million chance of being killed. Then we would estimate the value of his life at \$7 million. Not that he would sell his life for that (or for any) amount of money, but that if the risk could be eliminated at any cost under \$7 he would be better off. Suppose it could be eliminated by the potential injurer at a cost of only \$5. Then we would want him to do so and the prospect of a \$7 million judgment if he failed to would give him the proper incentive.

Id. at 775-76.

Page 726 new note (after note 5). Professors Bagenstos and Schlanger apply research into "adaptive preferences" to the question of hedonic damages. They explain the adaptation that takes place among those who suffer disabling injuries—people learn to endure and adapt their preferences to their newly limited capacities—rather than being discontented and unhappy over the long term. This is a phenomenon that the non-disabled do not understand, which led the authors to conclude that monetary damages for loss of life's pleasures due to a disability ought not be awarded. Samuel R. Bagenstos & Margo Schlanger, Hedonic Damages, Hedonic Adaptation, and Disability, 60 Vand. L. Rev. 745 (2007).

Page 730, 2d full ¶. *Langan v. St. Vincent's Hosp. of New York*, 850 N.E.2d 672 (Table) (N.Y. 2006). An appeal of the Appellate Division's decision was dismissed on finality grounds. Whether and when this case will get to the Court of Appeals is uncertain because the merits of the underlying medical malpractice claim may moot an appeal of the statutory and constitutional issues discussed in the text.

Page 738 note 5. *Robinson v. Bates*, 857 N.E.2d 1195 (Ohio 2006) (citing cases on both sides). Contra to *Acuar*, this court stated that the collateral source rule is not implicated by the "write down" amount on the formal ground that the write down is not a benefit because it wasn't actually "paid." The court went on to say that the jury should decide the appropriate amount to award based on the standard of the reasonable value of medical services provided. Thus, the jury might award the amount billed, the amount paid, or something in between. The court concluded on this issue:

It may well be that the collateral-source rule itself is out of sync with today's economic realities of managed care and insurance reimbursement for medical expenses. However, whether plaintiffs should be allowed to seek recovery for medical expenses as they are originally billed or only for

the amount negotiated and paid by insurance is for the General Assembly to determine.

Additional cases continue to confront this issue. See *Butler v. Indiana Dept. of Ins.*, 904 N.E.2d 198 (Ind. 2009) (finding that, under wrongful death statute, recovery is limited to the amount paid). By contrast with *Butler*, in *Wills v. Foster*, 892 N.E.2d 1018 (Ill. 2008) (identifying different approaches and citing cases), the court adopts the "reasonable value," standard and holds defendant may not introduce evidence about the amount paid by Medicaid and Medicare, even with regard to the reasonableness of the charges for medical care.

Page 758 note 2. In its latest foray on punitive damages, *Philip Morris USA v. Williams*, 127 S. Ct. 1057 (2007), the Supreme Court confronted the question of the role of harm to other persons in determining the proper amount of punitive damages. On top of an \$820,000 compensatory damage award to a smoker, the jury awarded \$79.5 million in punitive damages. The state Supreme Court rejected the defendant's argument that the trial court erred by failing to give an instruction on this issue proposed by defendant. That instruction stated that defendant could not be punished for the harm it had done to others--such a proposition was put directly to the jury by plaintiff's counsel--and, based on the defendant's reprehensible conduct, left the punitive damage award untouched. The Supreme Court ruled that the due process clause barred consideration of harm to others in awarding punitive damages. Adjudicating the existence and number of others harmed, the seriousness of harm suffered, and the tortiousness of defendant's conduct toward others is nearly impossible. Without requiring such proof and affording defendant the opportunity to respond denies defendant fundamental procedural protection. Drawing a fine distinction that will be reflected in future jury instructions--query its impact on jury decisionmaking--the Court held that a jury may consider the harm inflicted on others in assessing the reprehensibility of the defendant and in deciding on the proper ratio between compensatory and punitive damages. At the same time, a jury may not punish a defendant for harm to others. Dissenting, Judge Stevens tartly commented, "This nuance eludes me." Three other Justices dissented in two additional dissenting opinions. On remand, the Oregon Supreme Court found other grounds, based on state law, why defendant's proffered instruction was improper and reaffirmed its earlier decision, thereby reinstating the punitive damage award. *Williams v. Philip Morris Inc.*, 176 P.3d 1255 (Or. 2008).

Notwithstanding the final outcome in *Williams*, the impact of *Campbell* and *Williams* on the potential for very large punitive damage awards is illustrated by *Bullock v. Philip Morris USA, Inc.*, 71 Cal. Rptr. 3d 775, 802-07 (Ct. App. 2008), in which the court overturned a \$28 million punitive damage award on the basis of a jury instruction inconsistent with the due process limitations established in

Williams. On the other hand, in *Boeken v. Philip Morris, Inc.*, 19 Cal. Rptr. 3d 101, 108 (Ct. App. 2004), the trial court reduced a \$3 billion jury award for punitive damages to \$100 million. *Id.* at 108. On appeal, the court further reduced this award to \$50 million. *Id.* at 148. Final judgment in this latter amount was entered upon the appellate court's reconsideration in light of *State Farm*. See *Boeken v. Philip Morris USA, Inc.*, 26 Cal. Rptr. 3d 638, 684-87 (Ct. App. 2005), cert. denied, 547 U.S. 1018 (2006).

Page 760 new note (after note 6). *Exxon Shipping Co. v. Baker* 128 S.Ct. 2605 (2008). Finally resolving this longstanding litigation over Exxon's liability arising out of the oil spill by the Exxon Valdez off of Alaska in 1989, the Court addressed appropriate punitive damage awards under maritime common law. Surveying the empirical literature on awards of punitive damages in the United States, the Court concluded that much of the criticism of them is unjustified and that overall they were awarded with "restraint." Nevertheless, the Court expressed concern about the variation in punitive damage awards and consequent unpredictability and concluded that the best solution for narrowing the variance was a limit on the ratio of punitive to compensatory awards. Based on studies of punitive damage awards, which revealed a median ratio of less than 1-1, the Court adopted a maximum limit of a 1-1 ratio for maritime law. While binding only in maritime cases, the influence of this decision on state courts in those states that have not already addressed the matter through reform legislation remains to be seen. On remand, the parties stipulated that Exxon was obliged to pay \$507.5 million, the amount of compensatory damages, in punitive damages. Interest on that amount from its initial award will also be added to the judgment. *Exxon Valdez v. Exxon Mobil Corp.*, ___ F.3d ___, 2009 WL 1652256 (9th Cir. 2009).

Page 760 new note (after note 6). Post-*Campbell*, the court in *Goddard v. Farmers Ins. Co. of Oregon*, 179 P.3d 645 (Or. 2008) held that when economic, rather than physical, harm is involved the limit on the ratio of punitive to compensatory damages that is constitutionally permissible is 4-1. The court found this in scattered bits of language in *Campbell*, *Haslip*, and *Gore*, as well as in civil penalty statutes that provide for double, treble, or quadruple damages.

Page 762 new note (after note 9). Adam Liptak, *Foreign Courts Wary of U.S. Punitive Damages*, N.Y. Times, March 26, 2008, at A1 reports on the negative attitude of the rest of the world about United States law on punitive damages. The occasion is the Italian Supreme Court's refusal to permit enforcement of a United States judgment because the idea of using damages in a civil case to punish is so antithetical to Italian notions of justice. Similarly, Helmut Koziol reports on the refusal of the German Supreme Court to enforce a United States

judgment for \$400,000 in punitive damages. Helmut Koziol, *Punitive Damages—A European Perspective*, 68 La. L. Rev. 741, 742 (2008).

Page 762 note 10. A fascinating case study of the 20-year *Campbell* litigation from initial traffic accident through Supreme Court decision, of the *Agent Orange on Trial* genre, designed for use in torts and insurance law classes is Jeffrey W. Stempel, *Litigation Road: The Story of Campbell v. State Farm* (2008).

Section B. Insurance

Page 762 1st ¶. For an analysis of the role that liability insurance has had on the growth of tort law and corresponding expansion of liability as well as the way in which tort law has affected insurance, see Kenneth S. Abraham, *The Liability Century* (2008).

Page 768 1st full ¶. Settlement of the 9/11 insurance coverage dispute occurred after almost six years of litigation. It resulted in the insurers paying a total of \$4.55 billion, between the \$3.5 billion limit per occurrence, which the insurers contended was due, and \$7 billion that the insureds claim on the theory that there were two occurrences. Charles V. Bagli, *Insurers in Deal to Pay Billions at Ground Zero*, N.Y. TIMES, May 24, 2007, at A1.

This settlement occurred after a decision by the Second Circuit, *SR Int'l Bus. Ins. Co., Ltd. v. World Trade Center Props., LLC*, 467 F.3d 107 (2d Cir. 2006). That case upheld the lower court, including the judgment based on the jury verdict reported in the Text on the ambiguous policy, and the jury's determination about which insurers were governed by the policy that, as a matter of law, limited the attacks to a single occurrence.

Page 777 new note (after note 5). What happens to a workers' compensation insurer's subrogation claim in a wrongful death action? *Gillette v. Wurst*, 937 A.2d 430 (Pa. 2007), provides an answer that protects the insurer. In *Gillette*, the insurer had only a right to the widow's share of recovery from the tortfeasor. Under the state's intestacy laws, the widow attempted to disclaim her share of the settlement, thereby having it go to her children, which would have avoided subrogation claim. The court held that she can't defeat the subrogation claim to the extent that she was entitled under the law to a portion of the proceeds of the wrongful death suit.

Page 792 note 3. *Twin City Fire Ins. Co. v. Ben Arnold-Sunbelt Beverage Co. of S.C.*, 433 F.3d 365 (4th Cir. 2005), contains an excellent explanation of the two obligations of a liability insurer and how those disputes are handled when questions arise over whether the policy includes coverage for the loss:

When a party with insurance coverage is sued, the insured notifies the insurance company of the suit. The insurance company, in turn, typically chooses, retains, and pays private counsel to represent the insured as to all claims. If the suit involves some claims that are covered under the insurance policy and some claims that are not covered, the insurance company typically will send a reservation of rights letter to the insured stating what claims the insurance company believes are covered and what claims it believes are not covered. In this case, we examine whether, under South Carolina law, such a reservation of rights letter automatically triggers a conflict of interest entitling the insured to reject counsel tendered by the insurance company and instead to choose and retain its own counsel and to have the insurance company pay for that counsel.

The court then considered whether a per se rule permitting the insured to hire private counsel should be employed (under South Carolina law) or, alternatively, a court must examine the situation to see if a conflict exists. There are conflicting decisions on this issue, which the court canvasses before addressing who gets to choose private counsel if a conflict is determined to exist. The court adopted the rule requiring judicial examination and concluded in this case that the reservation of rights by the insurer did not create a conflict permitting the insured to hire private counsel.

Chapter XI

Section A. Incremental Tort Reform

Page 814 1st full ¶. The Public Readiness and Emergency Preparedness Act, P.L. 109-148 was enacted as part of the appropriation bill for the Department of Defense for 2006. It includes immunity from lawsuits under state and federal law for manufacturers and distributors of pandemic and epidemic products (including vaccines), in the event that the Health and Human Services Department (HHS) secretary declares a public health emergency as a result of a disease or other health condition. The only exception to this immunity is for "willful misconduct."

The legislation also provides a process for establishing an emergency compensation fund to compensate individuals whose injuries or death are directly caused by the administration or use of a product covered by an emergency declaration. But it does not provide any specific funding for this eventuality. A description of the provisions in this legislation can be found at <http://www.cga.ct.gov/2006/rpt/2006-R-0060.htm> For an assessment of this legislation's ability to accomplish its goals while providing compensation to

victims, see Lincoln Mayer, Note, Immunity for Immunizations: Tort Liability, Biodefense, and Bioshield II, 59 Stan. L. Rev. 1753 (2007).

Page 815 ¶ on Constitutionality. *Ferdon v. Wis. Patients Compensation Fund*, 701 N.W.2d 440 (Wis. 2005). A Wisconsin statute placing a \$350,000 cap, adjusted for inflation, on noneconomic damages in medical malpractice actions was declared unconstitutional as violative of equal protection even under the rational basis test. The statute was not rationally related to the legislative objectives of compensating victims fairly, lowering medical malpractice insurance premiums, keeping the Wisconsin Patients Compensation Fund's annual assessments to health care providers at low rates and enabling the Fund, which provided excess liability coverage for health care providers, to operate on a sound financial basis, lowering overall health care costs for consumers of health care, and ensuring quality health care by creating an environment in which health care providers were likely to move into, or less likely to move out of, Wisconsin.

Section B. Occupational Injuries–Workers' Compensation.

Page 835 notes on New York statute (add at end). N. R. Kleinfield & Steven Greenhouse, *A World of Hurt: For Injured Workers, a Costly Legal Swamp*, N.Y. Times, March 31, 2009, at A1. This article (one in a series of articles on the New York workers' compensation system published between March 30 and April 2, 2009) paints a bleak picture of the workers' compensation system in New York. It explains the arbitrariness, delays, inconsistencies, patronage, inadequate benefits, and fraud that pervade the system. Videos of an examination by an "independent medical examiner" and of a victim wending her way through the claims process can be found at:

<http://video.nytimes.com/video/2009/03/31/nyregion/1194838956105/a-world-of-hurt-the-examination.html?scp=4&sq=world%20of%20hurt&st=cse>
and

<http://video.nytimes.com/video/2009/03/30/nyregion/1194838956544/a-world-of-hurt-anatomy-of-a-case.html?scp=2&sq=world%20of%20hurt&st=cse>.

Page 837 note 12.b. A trio of cases decided in the past year reveal the full spectrum of approaches to when an injured employee can bypass workers' compensation and proceed in tort. At the most restrictive end of that spectrum is *Franklin Corp. v. Tedford*, 2009 WL 1015170 (Miss. 2009). The employer permitted employees to be exposed to excessive glue vapors by failing to install ventilation equipment or to provide personal protective equipment. The Mississippi Supreme Court requires that there be a purpose (although it doesn't

use that word) to injure in order for the employee to make a tort claim outside workers' compensation. *Helf v. Chevron U.S.A., Inc.*, 203 P.3d 962 (Utah 2009), hews a more middle ground, requiring that the employer or supervisor have a purpose to harm or expect that harm will occur. The court makes an effort to distinguish the "substantially certain" standard, which it claims only involves a probability of injury in contrast with an expectation or knowledge that injury is "virtually certain" to occur. The court finds its test satisfied on the facts of the case. While the employer was not trying to harm the plaintiff, it put her in a situation cleaning toxic sludge with a different and cheaper method that the employer knew released toxic and noxious gases.

Reflecting the most lenient position is *Hannifan v. American National Bank of Cheyenne*, 185 P.3d 679 (Wyo. 2008). The court requires that the defendant's conduct be "wanton and willful" for the plaintiff to avoid the exclusive remedy bar to tort. The court explains that in the context of the workplace that means that "the co-employee had knowledge of the dangerous condition and demonstrated a disregard of the risks through intentional acts." The facts are complicated but the gist is that high walls in a coal mine created a risk of rocks coming loose and cascading down onto those working in the mine, which is what happened to plaintiff. These circumstances and the supervisors' knowledge of them was sufficient for the jury to find wanton or willful conduct.

Page 838 note on railroad and maritime workers. *Norfolk S. Ry. Co. v. Sorrell*, 127 S. Ct. 799 (U.S. 2007) (holding that, under FELA, the same standard of factual causation (which is a relaxed one) as is applicable to a defendant's negligence is applicable to a plaintiff's contributory negligence).

Section D. Focused No-Fault Schemes.

Page 870 note 4. Illustrating the complicated eligibility issue explained in this note is a trio of high profile Childhood Vaccine Act cases. *Snyder ex rel. Snyder v. Sec'y of Dept. of HHS.*, 2009 WL 332044 (Fed. Cl. 2009); *Cedillo v. Sec'y of Dept. of HHS*, 2009 WL 331968 (Fed. Cl. 2009); *Hazlehurst v. Sec'y of Dept. of HHS*, 2009 WL 332306 (Fed. Cl. 2009). For several years, claims that childhood vaccines, especially those containing mercury in the preservative thimerosal, cause autism have been accumulating. In three separate cases, three special masters (who serve as the equivalent of trial judges) wrote lengthy comprehensive opinions explaining why the plaintiff's evidence was insufficient to establish causation.

Page 871 note 6. *Caman v. Continental Airlines, Inc.*, 455 F.3d 1087 (9th Cir. 2006) holds that an airline passenger's suffering deep vein thrombosis on a flight

did not constitute an "accident" for purposes of the Act. Defendant claimed the airline was negligent for failing to warn of the danger. The court reasoned that the airline's failure to warn was an omission rather than an act of commission and therefore not an "event," as required by *Air France* for an accident to exist.

Chapter XII

Pages 898-902 ATCA. Interrogations at Guantanamo are the subject of Alien Tort Act claims and others that the court concludes are properly suits under the Federal Tort Claims Act, which provides plaintiffs their exclusive remedy. Defendants must be sued under the FTCA because they are federal employees acting within the scope of employment. *Rasul v. Myers*, 512 F.3d 644 (D.C. Cir. 2008). (Because plaintiffs failed to exhaust administrative remedies the court also determined that the FTCA claims have to be dismissed.)

In fact, as the district court correctly noted, "the complaint alleges torture and abuse tied exclusively to the plaintiffs' detention in a military prison and to the interrogations conducted therein." [] Under *Ballenger*, then, the underlying conduct—here, the detention and interrogation of suspected enemy combatants—is the type of conduct the defendants were employed to engage in. Just as the telephone conversation in *Ballenger*, the mattress delivery in *Lyon* and the removal of clothes from the washing machine in *Thompson* was each part of the employee's job description or assignment, the detention and interrogation of suspected enemy combatants is a central part of the defendants' duties as military officers charged with winning the war on terror. [] While the plaintiffs challenge the methods the defendants used to perform their duties, the plaintiffs do not allege that the defendants acted as rogue officials or employees who implemented a policy of torture for reasons unrelated to the gathering of intelligence. [] Therefore, the alleged tortious conduct was incidental to the defendants' legitimate employment duties.

Page 901 last full ¶. *Boim v. Holy Land Foundation for Relief and Develop.*, 549 F.3d 685 (7th Cir. 2008) (cert. petition filed May 1, 2009). This is a high profile case that decided a number of issues about the TVPA, per Judge Posner in an en banc opinion (the panel decision was covered in the 2008 Materials and the court's interlocutory review of the denial of a motion to dismiss for failure to state a claim is explained in the text) after a trial and plaintiff's verdict. Hamas terrorists murdered a U.S. (and Israeli) citizen in Israel. His parents sued three organizations and an individual who contributed to Hamas. The majority decides there is no implied secondary liability (e.g., aiding or abetting) under the TVPA, but that the statute does proscribe donations to terrorist organizations (what one

might think of otherwise as aiding and abetting). The scienter required is knowledge (or deliberate indifference to the fact) that the organization engages in terrorist acts. The most interesting aspect of this case is when it gets to causation. The court invokes the multiple sufficient causes paradigm (text page 359) with a vengeance. Thus, so long as the donation by a defendant would have been necessary even if some other contributions are ignored, defendant can be found to be a cause in fact. The majority also holds that donations to the humanitarian causes of Hamas are equally a cause because they permit the organization to shift money from charity to terrorism. Judge Rovner writes an agitated dissent criticizing that latter causation aspect as well as the conclusion that secondary liability does not exist in the statute and the failure to require intent to assist in terrorist activities. Judge Wood also dissents.

Page 902, first full ¶. In re Terrorist Attacks on September 11, 2001, was affirmed by the Second Circuit. In re Terrorist Attacks on September 11, 2001, 538 F.3d 71 (2d Cir. 2008).

Pages 937 and 942 notes and questions. Adam Liptak, *15 States Expand Right to Shoot in Self Defense*, N.Y. TIMES, Aug 7, 2006, at A1, details legislation providing expanded self-defense rights permitting individuals to “stand their ground” and not requiring that they retreat. Some also permit the use of deadly force in protection of home or vehicle and do not require fear for one’s safety as a condition for the use of such force.

Section B. Government Liability.

Page 962 note 1. *Pearson v. Callahan*, 129 S. Ct. 808 (2009) modifies the requirement set out in *Wilson* and mandated in *Saucier* that the two-step process of deciding constitutional violation and then immunity be followed. While it is often beneficial, the Court recognizes, after reciting a litany of evils that can occur by rigidly imposing the *Saucier* two step, that there are cases in which it is more sensible to proceed directly to the matter of qualified immunity and decide that matter first.

Pages 963-64 note 4. *Van De Kamp v. Goldstein*, 129 S. Ct. 855 (2009). Where on the spectrum of prosecutorial functions does failing properly to train lawyers in the office about their obligations to provide impeachment material to defense counsel, specifically information about concessions made to a jail-house informant for helpful information passed along to law enforcement officials, fall? A unanimous Court declares that it falls on the “lawyer function” side, even though it looks like an administrative/supervisory task. The court reasons that if the defendants had been accused of failing to provide impeachment material, they

would be entitled to absolute immunity. That they are alleged to have failed to provide adequate training for other lawyers should not change that outcome. Preparing training materials of this sort requires legal knowledge and much the same analysis as would be required of a prosecutor directly confronting this issue.

Pages 968-69, ¶ about *Chappel v. Wallace*. *Wilson v. Libby*, 535 F.3d 697 (D.C. 2008). Valerie Plame's suit against Vice-President Cheney, Scooter Libby, and others founders on this "alternative remedy" doctrine. Here, the Privacy Act is such a scheme, even though it does not apply to Cheney and two other defendants.

Pages 968-69, discussion of *Bivens* claims. *Ashcroft v. Iqbal*, ___ S.Ct. ___, 2009 WL 1361536 (U.S. 2009). Plaintiff sued claiming that defendants discriminated against Arab and Muslim prisoners based on their religion and ethnicity in the wake of the 9/11 attacks. This case is predominantly about the procedural question of pleading adequately a *Bivens* claim. But the Court splits 5-4 on whether supervisory liability exists, the majority holding not only that there is no vicarious liability, as with Section 1983 claims, but that a superior cannot be held liable even with knowledge and acquiescence in a subordinate's violation. Instead, a government official can only be held liable for his or her unconstitutional activity; here, that would require a purpose to discriminate rather than mere knowledge of a subordinate's purpose.

A Canadian citizen, suspected of being an Al Qaeda member, was detained by federal officials in New York and sent to Syria. He alleged that he was tortured by Syrian government officials after his extraordinary rendition and brought suit against several U.S. officials. In a 2-1 decision, the Second Circuit decided that plaintiff could not invoke *Bivens* in his action for damages. *Arar v. Ashcroft*, 532 F.3d 157 (2d Cir. 2008), en banc rehearing granted and pending. The majority relied on the existence of an alternative remedial scheme, the Foreign Affairs Reform and Restructuring Act, and judicial hesitation to intrude on matters of national security. Plaintiff also did not state a claim under the Torture Victim Protection Act (pp. 899-900), because there was no charge that the U.S. officials were acting under the authority of foreign law.

Chapter XIII

Section A.1. What is Defamatory.

Page 980 1st ¶. In *Tuite v. Corbitt*, 866 N.E.2d 114 (Ill. 2006), the court, despite an invitation from the plaintiff, declined to overturn the “innocent construction” rule.

Page 985 note 2. *Jews For Jesus, Inc. v. Rapp*, 997 So. 2d 1098 (Fla. 2008), provides a different context for determining the appropriate audience in whose eyes the plaintiff suffers reputational harm. “The gravamen of Rapp’s claim is that Jews for Jesus [based on an article her stepson, an employee of defendant, wrote] falsely and without her permission stated that she had “joined Jews for Jesus, and/or [become] a believer in the tenets, the actions, and the philosophy of Jews for Jesus.” The court adopts the standard in Restatement (Second) of Torts § 559 cmt. e, which requires only that the statement would prejudice the plaintiff with a “substantial and respectable minority.”

Section A.5. Defenses.

Page 1026 note 4. *Barrett v. Rosenthal*, 146 P.3d 510 (Cal. 2006). Defendant, an alternative health proponent critical of conventional medicine, posted to newsgroups on the Internet an e-mail message she had received from another person referring to one of the plaintiffs in vituperative terms:

Dr. Barrett is arrogant, bizarre, closed-minded; emotionally disturbed, professionally incompetent, intellectually dishonest, a dishonest journalist, sleazy, unethical, a quack, a thug, a bully, a Nazi, a hired gun for vested interests, the leader of a subversive organization, and engaged in criminal activity (conspiracy, extortion, filing a false police report, and other unspecified acts).

Barrett and another doctor brought suit against the alternative health proponent. The Court held that the section 230 (c) immunity applied to distributors of internet communications and that the defendants qualified as “users” within the meaning of the Act. Thus, the only person subject to liability for the defamatory communication was its originator.

Page 1027 after note 4 (new note). *Barnes v. Yahoo!, Inc.*, 2009 WL 1232367 (9th Cir. 2009). Plaintiff’s former boyfriend posted on a public Yahoo web site nude photographs of plaintiff taken without her knowledge and soliciting sexual intercourse. Plaintiff was inundated in her office with emails, phone calls, and

personal visits, all in the expectation of sex. Based on Yahoo policy, she applied multiple times to have the offending material removed, but Yahoo basically ignored her requests for months (until she filed suit), save for one occasion when a Yahoo employee contacted plaintiff, asked her to fax her prior communications, and promised to undertake removal. The employee didn't. The interesting point of this case is the language in §230(c)(1) of the CDA that providers not be treated "as the publisher or speaker of any information." Plaintiff's tort claim is negligent undertaking based on defendant's promise to remove the content. The court concludes that this undertaking claim involves precisely what publishers do and therefore cannot be pursued because of the CDA. But, the court holds that plaintiff's promissory estoppel claim—a derivative of contract law—is not barred by the CDA.

For spritely coverage of a suit by two female Yale law students against the notorious (at least in the law school world) AutoAdmit and Google raising similar issues about the CDA, see David Margolick, *Slimed Online*, Conde Nast Portfolio, March 2009, at 80.

B. Constitutional Limitations.

Page 1064 note 5. *Senna v. Florimont*, 958 A.2d 427 (N.J. 2008). Even for ordinary, non-public interest, non-public figure speech, negligence is required for liability. In this case, the court decides that the extended protection for matters of public interest previously adopted and reflected in note 5 is not applicable to the speech in this case: a competitor's employees broadcast bad-mouthing of another boardwalk game operator, calling him a crook and dishonest and stating that he didn't redeem coupons won at his games. Thus, defendant is subject to a negligence, rather than actual malice standard. This court clearly lays out the development of common law privileges as the backdrop for *Sullivan*, the progeny of *Sullivan*, and state court developments more protective than the First Amendment.

Pages 1115-18 note on Need for Reform. An explanation about the role that more liberal British law on defamation is playing in inhibiting American authors—London has become the so-called "libel capital" of the world—and reform efforts to stem those effects can be found in Eric Pfanner, *A Fight to Protect Americans From British Libel Law*, N.Y. Times, May 24, 2009, at B3.

Chapter XIV

Section C. Intrusion.

Page 1174 new note (after note 3). *Taus v. Loftus*, 151 P.3d 1185 (Cal. 2007). Plaintiff was the subject of an article on recovery of repressed memory of childhood sexual abuse. Defendants, two critics of repressed memory recovery theory, published an article criticizing the original article, in the course of which the family background of and personal details about the subject, but not her identity, were revealed. The court rejected plaintiff's claim of intrusion based on information about her that was gleaned from public records. However, based on allegations that one of the defendants made misrepresentations (hotly denied by defendant Elizabeth Loftus) about her working with the author of the first article (whom the family trusted) to family members of the subject in the course of interviewing them, the court held that such improper and deceitful conduct could support a claim for intrusion.

Page 1207 new note (after note 4). *Boehner v. McDermott*, 484 F.3d 573 (D.C. Cir. 2007), addresses an aspect of *Bartnicki*: the means by which the publisher obtains the illegally obtained communication, and perhaps more importantly, whether the context of the acquisition imposes limitations on the recipient's use of it. Defendant, a member of the House of Representatives, obtained a recording of an illegally intercepted telephone conversation among several Republican politicians, including Newt Gingrich, about how to handle an ethics violation. Defendant obtained the tape from the couple who had made it and who became concerned about their having violated the law. They brought it to Washington, and gave it to defendant, concerned about their potential liability, after being advised that they should turn it in to the House Ethics Committee, of which defendant was a member. After playing the tape, defendant turned it over to two journalists who then wrote articles about it. Unlike *Bartnicki*, defendant did not have a First Amendment right to disseminate the communication, because he breached House rules mandating confidentiality for evidence obtained by the Committee, in making public information that he received as an agent of the House Ethics Committee.