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Pharmaceuticals and Medical Devices: Products Liability Risk Management

Implementing Compliance Programs and Other Measures to Avoid FDA and State Law Violations and Minimize Tort Liability

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Preventive Law, Ethics and Legal Compliance

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Preventive Law

"A branch of law that endeavors to minimize the risk of litigation or to secure more certainty as to legal rights and duties."

Other definitions

- Systematic attention is given to minimizing the risk that the client's affairs will be disrupted or its aspirations not maximized because of some dispute or other legal problems arising in the future.

- Litigating lawyers are historians. Preventive lawyers must be prophets.

Other definitions

- It is more important to predict what people will do, than it is to predict what a court will do.
- Thinking preventively is to be able to anticipate when and where a person's perceptions of injury are likely to arise during the course of any particular transaction or business activity.
- Preventive law, in part, involves planning for litigation.

Legal Compliance

- Oversight and enforcement of specific legal requirements (regulatory and common law).
- Mitigate sanctions for violations of criminal law.
- Application of legal requirements to any corporate conduct.
- Moral minimum.

Ethics and Integrity

- Set of moral principles and values.
- Concerns what should be done, not what must be done.
- Beyond compliance.
- Rules for behavior.

Ethics and Integrity

- Business ethics refers to how a company integrates core values - such as **honesty, trust, respect, fairness** - into its policies, practices and decision-making throughout all levels of the company.
- Uncompromising honesty and integrity.

Corporate Responsibility

- Business decision-making linked to ethical values, compliance with legal requirements, and respect for people, communities and the environment

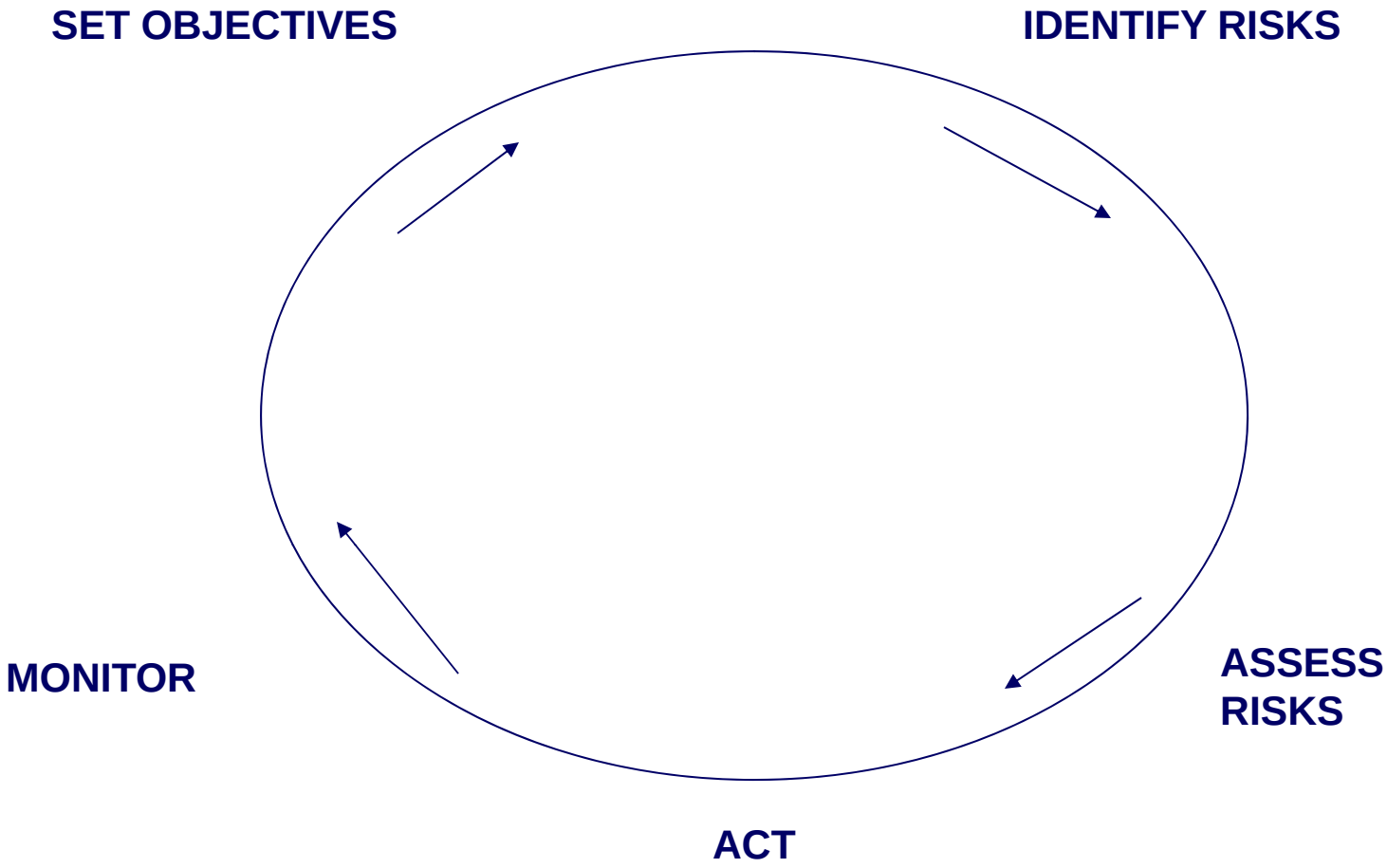
- Business meets or exceeds the ethical, legal, commercial and public expectations that society has of business.

Interrelationship of Concepts

Ethical/CR/Preventive Law

Legal Compliance

Illegal/non-compliant/unethical

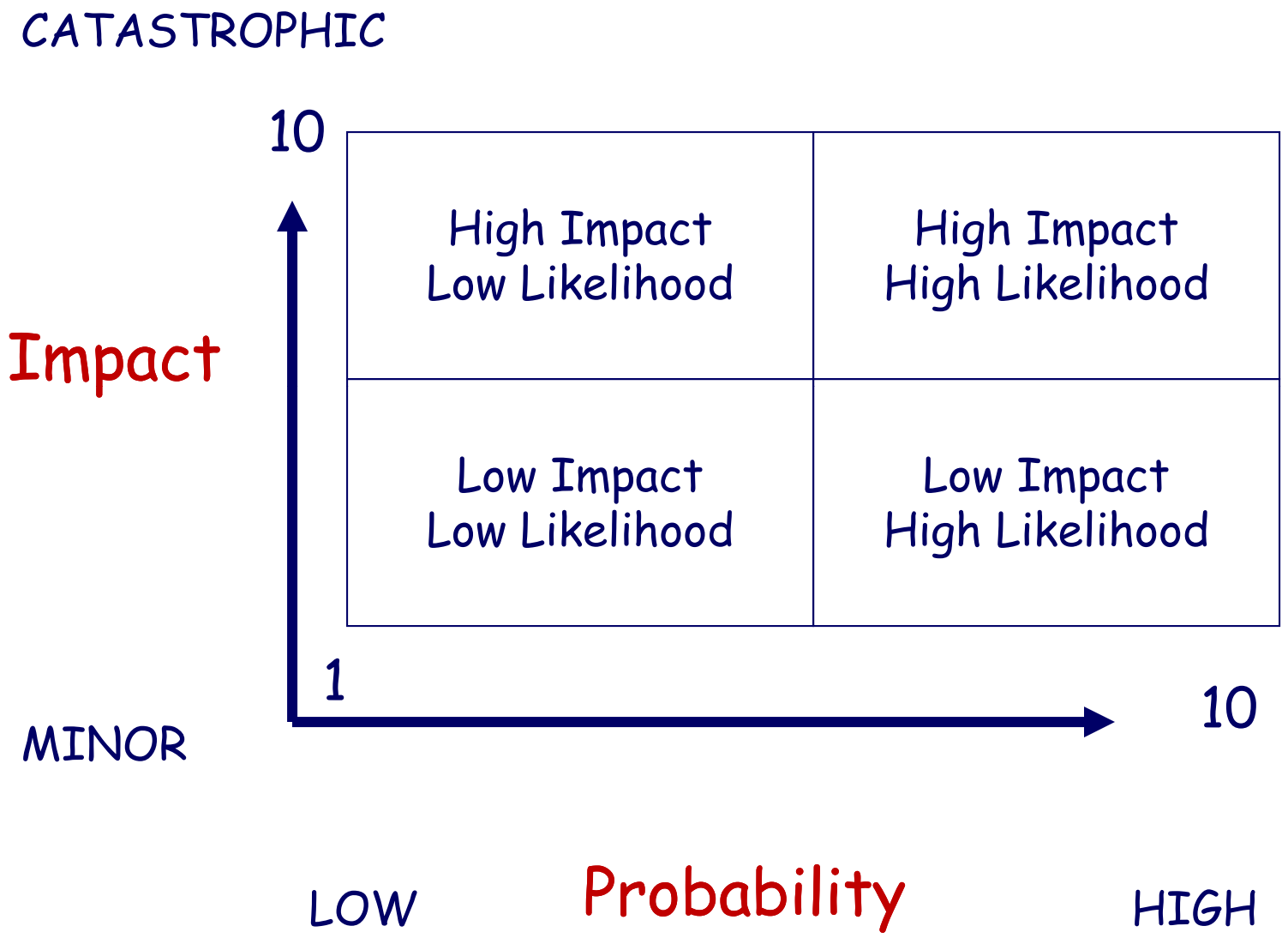


Business Risk Assessment Process

Legal Risk Assessment

- Identify legal risk - before or after it occurs.
- Quantify the probability it will happen in the future.
- Identify consequences if risk occurs.
- Identify techniques to minimize probability or severity of consequences.
- Decide on future actions and implement.

Assess Risks



Preventive Law, Compliance and Ethics Techniques

- Before problem arises:
  - Legal audit/risk assessment
  - Legal and regulatory compliance systems
  - Risk minimization programs
  - Codes of conduct and ethics programs
  - Incentive analysis
  - Client education

Preventive Law, Compliance and Ethics Techniques

- After problem arises:
  - Establish systems to learn about possible or real problems, conflicts, legal concerns.
  - Have personnel promptly analyze this information.
  - Take appropriate risk reduction or remedial actions.

Conclusion

- Regulatory compliance is bare minimum. Compliance may or may not be consistent with business ethics policy or code of conduct.
- Should exceed to minimize future business and legal risks.
- Need to anticipate and plan for defensibility of product and company.

- For more information on prevention and compliance techniques, see:

  www.productliabilityprevention.com

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Relationships That Drive Results

Products Liability Risk Management: Compliance Measures to Minimize Tort Liability

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Topics

- Tort Law: Policy Considerations
- Product Liability 101
- Pharma and Device Claims
- Preemption
- The Regulatory Compliance Defense
  - Variations
- Benefits of Compliance: The “Responsible Corporate Officer” (“RCO”) Doctrine
- Compliance and Juries
- Compliance as Prophylaxis

Tort Law: Policy Considerations

The Plaintiffs' Case for Products Claims

- Checks and balances against strength of the industry
  - Detailers' influence on prescribers
  - Pharma, device company lobbying
  - FDA "capture"
- Agencies generate minimal, not optimal levels of safety
  - Law stimulates regulatory agencies, such as FDA, to take stronger action to safeguard public health
- ↓ Inappropriate marketing and scientific fraud
  - Law fosters informing the public about risks
- ↑ Product research

Consequences of Products Claims

- (a) Unrecoverable defense costs
- (b) High money damages
  - New claims
  - Bankruptcy
- (c) Adverse publicity
  - Verdicts *against* a manufacturer are newsworthy
  - Verdicts *favoring* a manufacturer are not
- (d) Loss of new sales
- (e) Adverse governmental action
- (f) Potentially, derivative suits

The Distortions Products Claims Introduce

- Industry is heavily regulated
  - FDA refuses to approve unsafe drugs, devices
  - FDA calls its stamp of approval a ceiling, not a floor
  - FDA authorized to regulate and monitor drugs post-approval
    - FDA Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823
- Companies may fear to disclose information to regulators when it can be used against them in court
- Court's decision-making process is inferior to FDA's
  - Jurors lack FDA's technical competence in labeling
- Tort litigation → over-deterrence

Goals of Tort Law

- Plaintiff-specific compensation
- Regulatory compliance
- Efficient risk-spreading

Compliance: Asymmetry in the Tort System

- In most states, compliance with regulations is no defense to a tort claim
- But "failure to comply with a safety standard is a *per se* violation of the standard of care imposed by tort law."

Products 101

Products Liability 101

- Theories of Liability:
  - Negligence: duty, breach, causation, damages
  - **Strict liability**: Section 402A, Restatement of Torts, 2d
  - Breach of warranty
    - Express
    - Implied warranty of merchantability
    - Implied warranty of fitness for a particular purpose
  - Consumer Protection Statutes

Strict Liability: *Greenman v. Yuba Power Products,* 59 Cal. 2d 57, 377 P.2d 897 (1963)

- D legally responsible for damages even if D was not at fault or negligent
  - P may recover even if seller has exercised all possible care in the preparation and sale of the product
- P must prove that:
  - Product was defective;
  - Defect proximately caused the injury; and
  - Defect rendered the product unreasonably dangerous

Defects: Examples

- Whether a product design presents "excessive preventable danger" or
- Product's risks outweigh its benefits or
- Product fails to meet "consumer expectations" for safety or
- Product is "not reasonably safe"

Restatement (Third) Torts: Product Liability § 2(a), (b), and (c): Types of Claims

- Manufacturing defect
  - Product departs from intended design even though D exercised all possible care in the preparation and marketing of the product
- Design defect
  - D seller or a predecessor in the commercial chain of distribution could have reduced or avoided foreseeable risks of harm by adopting a reasonable alternative design, and the omission of the alternative design renders the product not reasonably safe.

Restatement (Third) Torts: Product Liability § 2(a), (b), and (c): Types of Claims, 2

- **Failure to warn**
  - Seller or a predecessor in chain of distribution could have reduced or avoided foreseeable risks of harm by providing reasonable instructions or warnings, and omission of instructions or warnings renders the product not reasonably safe
- Factors:
  - Extent of the risk
  - Likelihood that it will arise
  - User's likely understanding of the danger
  - Means available to convey a warning
  - Risk that too many warnings will decrease the effectiveness of each

Pharma and Device Claims

Pharma and Device Claims

- Manufacturing, design claims: rare
  - Manufacturing: contamination in the drug batch, e.g.
- Most claims challenge the sufficiency of warnings
  - Theory: If warnings inadequate, product is misbranded and defective
  - Yet FDA approves, and authors, most warnings
  - An “FDA compliance” defense may dispose of an entire case if product is labeled in accordance with FDA approval

Pharmaceutical Labeling Requirements: 21 CFR Part 201 (selected examples)

- § 201.5- Adequate directions for use
- § 201.6 - Misleading statements
- § 201.15-Prominence of required label statements
- § 201.23-Required pediatric studies
- § 201.50-Statement of identity
- § 201.55-Statement of dosage
- § 201.56-Requirements on content and format of labeling
- § 201.57-Specific requirements on content and format of labeling for human prescription drug and biological products described in 201.56(b)(1)

Protection from Strict Liability: Restatement of Torts, 2d, §402A, Comment k, Unavoidably unsafe products

- "There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs…The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use , merely because he has undertaken to supply to the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk."

Brown v. Superior Court, 44 Cal. 3d 1049, 751 P.2d 470, 245 Cal. Rptr. 412 (1988)

- Ps' claim: DES manufacturers made a drug that 'was unsafe for use in preventing miscarriage and resulted in severe injury' to each P *in utero* when her mother ingested it
- "A drug manufacturer's liability for a defectively designed drug should not be measured by the standards of strict liability."
- "Because of the public interest in the development, availability, and reasonable price of drugs, the appropriate test for determining responsibility is the test stated in comment k to section 402A of the Restatement (Second) of Torts."

Daniel v. Fisons Corp., 740 NE 2d 681, 683-4 (Ohio Ct. App. 2000)

- Though theophylline cannot be made completely safe for its intended use, it is not "unreasonably dangerous as a matter of law" if D provides the prescribing physician with adequate warnings and instructions
  - Physician is "learned intermediary"

Preemption

The Pre-Emption Defense: Supremacy Clause, US Constitution, Art. VI. Cl. 2

- Affirmative defense; D can waive
- Arises when federal regs conflict with state law claims
- Express: federal statute's language expressly preempts state regulation or legislation
- Implied
    - *Field* preemption: Either
        - Pervasive federal regulatory scheme already exists; or
        - Federal interest is so dominant that law assumes that enforcement of state laws on same issue is precluded
    - *Conflict* preemption: Either
        - Direct conflict between federal and state provisions, so compliance with both is impossible, or
        - A state obscures "the accomplishment and execution of the full purposes and objectives of Congress"

Medical Device Amendments of 1976, Pub L. No. 94-295, 90 Stat. 539 (codified as amended at 21 U.S.C. § 360 (2000)) (MDA)

- Requires screening of all medical devices seeking approval through a pre-market approval process (PMA)
- Provides express preemption for medical devices
  - Plaintiffs' claims that an arterial catheter was designed, labeled, and manufactured in a way that violated New York common law were preempted. *Riegel v. Medtronic, Inc., 552* U.S. 312 (2008).
- No such express preemption clause for Rx drugs

FDA Preamble

- "FDA approval of labeling under the act. . . preempts conflicting or contrary State law."
  - Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 21 C.F.R. § 201.56 (2007)

Dusek v. Pfizer, Inc., Civil Action No. H-02-3559 (S.D. Tex. 2/20/04)

- P alleged Zoloft label should have warned of suicidal ideation
- D moved for summary judgment: FDA had rejected such a warning for lack of causation and determined that such a label would be false and misleading
- Court granted motion: a cause of action based on P's proposed additional warning to the product label would conflict with FDA's decision against adding such a warning
  - No causal link had in fact been established
  - Warning would in effect be false and misleading in violation of federal law

Pre-empting "Fraud-on-the-FDA": *Buckman Co. v. Plaintiffs' Legal Committee,* 531 U.S. 341, 353 (2001)(off- label marketing of screws used in spinal surgery)

- State tort law claims based on fraud on a federal agency are preempted
  - Relationship between agency and industry is "inherently federal in character", as all aspects originate under and as a result of federal law
- Stand-alone state-law claims for fraud-on-the-FDA conflict with the FDA's authority to police such fraud

A Preemption Reversal: *Wyeth v. Levine,* 129 S. Ct. 1187, 1198 (2009)(Phenergan by IV push)

- "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."

Pharmaceutical Label Revisions

- NDA holders must revise product labeling "when new info becomes available that causes the labeling to become inaccurate, false, or misleading." 21 C.F.R. § 201.56(a)(2).
- Holder of approved NDA must notify FDA of, and usually seek approval of, any change in a condition established in the approved application. 21 C.F.R. § 314.70(a)(1)
- Categories of changes:
  - Major: require prior approval
  - Moderate: FDA must approve, but may be implemented before it renders its decision
  - Minor: must be reported annually. Id. § 314.70(b)-(d)

"Changes Being Effected" ("CBE"), 21 C.F.R. § 314.70(c)(6)(iii)

- Company may describe certain safety-related changes in a supplement submitted to FDA contemporaneously with, or sometimes 30 d before, new labeling is used
- CBE supplement OK only when
  - Changes reflect newly acquired information, 21 C.F.R. § 314.70(c)(6)(iii); *see also* id. § 314.3(b) and
  - There is sufficient evidence of causation. 73 Fed. Reg. 2,848, 2,848 (Jan. 16, 2008) (codified at 21 C.F.R. pts. 314, 601, and 814)

Warner-Lambert Co. v. Kent, 128 S. Ct. 1168, 1168 (2008)(liver injuries allegedly 2° Rezulin)

- Federal law prohibits fraudulent disclosures to a government agency
  - Under *Buckman*, FDA polices fraud against itself
- State law grants plaintiffs a cause of action to sue for injuries sustained from defective products that would not have reached the market absent fraud on the FDA
- Does the Federal law preempt the state?
  - 4-4 split; Roberts, C.J., abstaining
  - Left intact 2d Cir. decision answer: No. See, *Desiano v. Warner-Lambert*, 467 F.3d 85 (2d Cir. 2006).

The Regulatory Compliance Defense

Regulatory Compliance Defense: "State-Sponsored Pre-Emption." State Adopts Federal Reg as Standard of Care

- FDA-regulated products: uniquely need FDA approval
- FDA determines that:
  - Drug's benefits outweigh risks
  - Drug comes with appropriate warnings, and
  - Proposed mfg method yields a safe, consistent product
- FDA regs encompass nearly all areas of safety and potential risk reduction. *See, e.g.,*
  - INDs: 21 CFR 312.21
  - NDAs: 21 USC 355 (a), (e)
  - 21 CFR parts 210.56, 314, 355(b) and (d)
- FDA remains involved in evaluating labeling during the post-marketing phase

Michigan: Mich. Comp. Laws § 600.2946(5) (2000)

- "In a product liability action against a manufacturer or seller, a…drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the [FDA], and the drug and its labeling were in compliance with the [FDA's] approval at the time the drug left the control of the manufacturer or seller."
  - Applies to off-label uses. *White v. SmithKline Beecham Corp.*, 538 F. Supp. 2d 1023, 1030 (W.D. Mich. 2008)
  - Applies to common law fraud and Consumer Protection Act claims. *Duronio v. Merck & Co., Inc.*, 2006 WL 1628516, at *5 (Mich. Ct. App. 2006)

Michigan's Law is Constitutionally Sound

- Legislature "determined that a drug manufacturer or seller that has properly obtained FDA approval of a drug product has acted sufficiently prudently so that no tort liability may lie." *Taylor v. SmithKline Beecham Corp.*, 468 Mich. 1, 7, 19; 658 N.W.2d 127, 131, 137 (2003)(law passes state constitutional muster)
- Michigan "decide[d] that the federal regulatory scheme furnishes its citizens protection enough against potential injury from the unanticipated effects of a new medication." *Garcia v. Wyeth-Ayerst Labs*, 265 F. Supp. 2d 825, 833 (E.D. Mich. 2003)(law is also valid under U.S. Constitution)

Exceptions: 1) fraud on FDA, Mich. Comp. Laws § 600.2946(5)(a); 2) bribery, *Id.* § 600.2946(5)(b)

- Subsection does not apply if D (a) Intentionally withholds from or misrepresents to [FDA] information concerning the drug that is required to be submitted under [FFDCA] . . . and the drug would not have been approved, or the [FDA] would have withdrawn approval for the drug if the info were accurately submitted.
- Fraud exception does not cover non-fraud disclosure problems (unintentional or negligent failure to disclose)
- For state to prosecute fraud, FDA must 1st determine that fraud has occurred; otherwise *Buckman* would be violated. *Garcia v. Wyeth-Ayerst Laboratories,* 385 F.3d 961 (6th Cir. 2004).
- *But see*, *Desiano v. Warner-Lambert & Co*., 467 F.3d 85, 95 (2d Cir. 2006) (*Buckman* was not applicable because the Michigan statute did not create a new cause of action for fraud on FDA).

Modified Versions of the Regulatory Compliance Defense

- Bar punitive damages for drugs approved by the FDA (or for other products that otherwise meet government standards) or
- Create a rebuttable presumption of non-liability in light of FDA approval.

N.J. Stat. Ann. § 2A:58C-5(c) (West 2000): No punitives for warnings c/w FDA's requirements

- Creates rebuttable presumption that drug's warnings are adequate
- To overcome, P must show of knowledge of the withheld info
- Presumption "does not change the burden of proof" in failure-to-warn cases, and, though a court may instruct them otherwise, jurors remain "free to disregard evidence of [FDA] 'approval…'" *Feldman v. Lederle Labs,* 125 N.J. 117, 157; 592 A.2d 1176, 1197 (1991)
- "Failure-to-warn" claims under NJ's product liability law are not preempted; state law punitive damage provisions are preempted. *McDarby v. Merck & Co.,* 949 A.2d 223 (N.J. Super. Ct. App. Div. 2008)(Vioxx)

Punitives: Barred where mfr made and labeled Rx in compliance with FDA regulations

- Ariz. Rev. Stat. Ann. § 12-701(a)(1) (2003)
- Colo. Rev. Stat. § 13-64-302.5(5)(a) (2007)
- N.D. Cent. Code § 32-03.2-11(6) (2007)
- N.J.S.A. § 2A:58C- 5
- Ohio Rev. Code Ann. § 2307.80(c)(1) (West 2006)
- Or. Rev. Stat. § 30.927(1)(a) (2005)
- Utah Code Ann. § 78-18-2(1) (2002)

Rebuttable Presumption: Compliance with FDA Labeling Requirements Suffices to Warn

Texas: Tex. Civ. Prac. & Rem. Code Ann. § 82.007. Rebuttable presumption that FDA-approved warnings on pharmaceutical drugs are sufficient

- Can be rebutted if D withheld or misrepresented information
  - But can it? *Buckman* preempts the fraud-on the-FDA *exception* to non-liability, leaving only the *immunity* intact. *Ledbetter v. Merck & Co.,* No. 14-07-00551-CV, 2008 WL 2066580 (Tex. App. --Houston (14th Dist.) May 15, 2008)
- Exception for <u>unapproved</u> uses

Colorado Col. Rev. Stat. § 13-21- 403

- Creates a rebuttable presumption that a product was not defective if, at the time of sale, it complied with any applicable state or federal "code, standard, or regulation."
- Applies generally to compliance with government standards
  - Not specific to FDA compliance

Rebuttable Presumption that, in Failure-to-Warn Claims, FDA-Approved Warnings are Adequate

- Colo. Rev. Stat. § 13-21-403(1) (2007)
- Ind. Code Ann. § 34-20-5-1 (LexisNexis 1998)
- Kan. Stat. Ann. § 60-3304(a) (1994)
- Ky. Rev. Stat. Ann. § 411.310(2) (LexisNexis 2005)
- N.J. Stat. Ann. § 2A:58C-4
- Tenn. Code Ann. § 29-28-104 (2000)
- Tex. Civ. Prac. & Rem. Code Ann. § 82.007 (Vernon 2005)
- Utah Code Ann. § 78-15-6(3) (2002)

Arkansas: Ark. Code Ann. § 16-116-105

- Permits introduction of evidence of compliance with "any federal or state statute or administrative regulation existing at the time a product was manufactured and prescribing standards of design, inspection, testing, manufacture, labeling, warning, or instructions for use."
- Compliance is evidence of non-defectiveness

Benefits of Compliance: The “Responsible Corporate Officer” (“RCO”) Doctrine

United States v. Park, 421 U.S. 658 (1975): The "Responsible Corporate Officer" Doctrine

- To convict executive for allowing warehoused food to be exposed to rodent contamination, need but show executive was positioned to prevent that exposure
- RCO: put company executives in jail on the theory that they have not been enforcing company compliance plans

Penalties

- Penalties are varied and can be harsh:
  - Significant fines
  - Debarment preventing executives from providing services to a regulated company
  - Individual and corporate exclusion from participation in federal health care programs
  - Probation and prison time
- Due Process: career-ending punishment?
- If you have a plan, enforce it

"Responsible Corporate Officer" Doctrine: Recent Applications

- 3 former Purdue Pharma executives: 12-y exclusion
  - 2007: pled guilty to a misdemeanor for misbranding OxyContin
- 3 former Synthes executives: prison sentences of 5-10 m for their role in an illegal test of a bone-cement product
  - Alleged: Synthes tried to cover up its conduct after 3 patients treated with the product died during surgery.
  - Executives did not admit to knowingly violating the law
  - Under strict liability, prosecutors need not prove that executive knew of an alleged violation. Need but show executive was in a position to prevent offense.

Compliance and Juries

Jury Reasoning

- Jurors: who is the "good" guy or "better" guy among the "bad." Winner: the party the jurors decide is "good" or "better than" the opposition
- Factors:
  - Knowledge;
  - Power /ability; and
  - Intention/diligence
- Hiding:
  - Knowledge and an unwillingness to act upon it
  - Power and ability to act to avoid a problem

Compliance as Prophylaxis

Compliance as Prophylaxis (with thanks to Sid Kanazawa, Esq.)

- Be serious from top to bottom: do it or don’t
- Develop risk context material
- Set internal guidelines for "acceptable levels of risk“
- Evaluate the risks
- Propose warnings to eliminate excessive preventable danger
- Act quickly and decisively on information received
- Do not create the impression of hiding
- Respect employees
- Respect the media
- Organize to minimize internal political fights

Compliance as Prophylaxis, 2

- Check advertising and representations
- Teach employees how to write
- Create forms and systems to streamline communications
- Create workable document retention policy and management system
- Create crisis team
- Obtain sensible insurance

Product Liability Audits

- Can consist of a review of company's documentation, including documentation relating to its equipment, manufacturing and sales, correspondence with government agencies and policy manuals
- May also include ways to avoid product liability claims, ways to protect against defect injuries, public relations, document control and insurance considerations

Questions or Comments?

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