

The State Factor

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The Impact of Federal & State Safety Regulations on Liability

State Legislative Action has Greater Importance After U.S. Supreme Court Ruling

EXECUTIVE SUMMARY

The United States Supreme Court's recent ruling in *Wyeth v. Levine*¹ has given state legislators an increased role in protecting citizens from harm caused by certain products, such as prescription medicines, or services, where the products or services are heavily regulated by state and federal agencies. When a person is injured by a regulated product or service, and sues the product's manufacturer or the service provider, state law must determine the proper standard for assessing whether the product was defective or the conduct was tortious. Where a defect or tort caused the injury, the plaintiff may recover his or her damages. But if there is no defect or tortious conduct, there is no recovery because the defendant did not wrongfully cause the plaintiff's injury. In these limited situations, the harm is an accepted risk of using the product or service in question.

This article focuses on the responsibility of state legislatures in setting standards of care for judges and juries to use when determining whether liability should exist in these situations. The key question is: what happens when a manufacturer has complied completely with the government safety standards for the aspects of the product or service at issue in the case? For example, if a person experienced a side effect from a prescription drug, can the product's design or warnings be considered defective in the ensuing litigation if the design and warnings were specifically approved by the United States Food and Drug Administration (FDA)?

In *Wyeth v. Levine*, the U.S. Supreme Court concluded that for the facts in that case, there was no federal mandate preempting states from answering this question. The standard of care would be set by state legislators, the state judge hearing the claim, or the jury rendering the verdict. In some states, legislatures have decided that government safety standards are also the standards of care to be used to assess the defendant's conduct in tort

lawsuits. These liability regimes, also called "regulatory compliance defenses," have been powerful tools for creating proper incentives for businesses to meet government safety standards.

In other states, standards of care are set by judges and juries for each individual's lawsuit. The problem with this approach is that when court-based liability standards differ from agency regulations, the court standards end up trumping agency rulings. In these situations, the defendant, despite meeting the agency's safety standards, will likely change the product or service in question to avoid future liability. These courts do not have the scientific expertise of the agency regulators; they can only look at issues affecting the plaintiff alleging injury and the evidence presented by two lawyers arguing the case. While the court only sees one plaintiff who was injured by the product, the tens of thousands of people who have benefited from the product or service are not in the courtroom.

In light of these facts and to help implement sound

public policy, ALEC has created the Model Regulatory Compliance Congruity with Liability Act. The Act provides three options for legislatures in determining the appropriate deference their courts should give to government safety standards in determining liability.

This article shows the foundation for the Act's adoption. The article also discusses the Supreme Court's recent ruling in *Wyeth v. Levine* and clarifies myths about the decision being spread by those interested in generating litigation. It then explains why deference to government safety standards in certain litigation is the sound public policy. Finally, it explains the three options under ALEC's model act.

The Supreme Court's Ruling

Wyeth v. Levine involved a woman who sustained a serious side effect from a prescription medicine. The plaintiff, Diana Levine, went to a clinic for treatment of a migraine headache. The pain medicine used to treat migraines may produce severe nausea, and the drug Phenergan®, which has been available for many decades, counters that nausea. Ms. Levine was initially given Phenergan® by what is called the “drip” method. This method takes a long time to act. Ms. Levine returned later in the day when her symptoms failed to subside. This time, a clinician administered the medicine through direct IV injection or “push” method. The “push” injection is more aggressive and is known to have the potential for harmful side effects. The makers of the medicine warned about the side effects and provided specific directions as to how the drug was to be administered. The technician did not follow the directions, and the drug entered Ms. Levine's artery instead of her vein. Gangrene resulted, and Ms. Levine, a musician, had to have her forearm amputated.

After settling malpractice claims with the clinician and health care center, Ms. Levine sued Wyeth, the maker of Phenergan®, under Vermont state law claiming the company failed to provide an adequate warning of the push method's risks.² Even though evidence presented at trial indicated that Levine's injury was caused by the clinician's negligence in disregarding the drug's warning, the jury found that Ms. Levine's injury would not have occurred if the label had a stronger warning against the push method and required Wyeth to pay her substantial damages.

Wyeth challenged the verdict arguing that the warning could not be defective because it had been specifically approved by the Food and Drug Administration (FDA). During the several decades that Phenergan® had been on the market, Wyeth and the FDA repeatedly corresponded regarding the drug's warning label.³ The FDA instructed Wyeth to include on its label that the drip method was “preferable,” and specific warnings on the risks of direct injection.

The Supreme Court of the United States let the multi-million dollar jury verdict stand. The Court stated that FDA rulings on warnings do not come with an automatic federal mandate preempting (or voiding) warning defect claims brought under state tort law. The Court explained that the governing federal statute did not expressly preempt Ms. Levine's claims, as federal statutes do with some other products, and that it would not read such an implied preemption provision into federal law.

Instead, the Court found that preemption of state tort law may only occur in limited circumstances, such as where there is clear evidence that the FDA would not have approved a label change that was suggested in a state tort lawsuit. The Court found that it would be possible for the warning at issue to comply with both the FDA and the ruling in the tort suit. Assessing impossibility is a fact-intensive look at the interactions between the manufacturer and the FDA and others to see how the precise warnings were developed.

From a public health perspective, this ruling has major shortcomings. With Phenergan®, the ruling will negatively impact patients who might benefit from the push method. As the FDA understood, when properly administered, the push method helps patients obtain quick relief when they are in extreme discomfort. This method is to be used only when the person's condition did not improve after the drip method or if the person could not wait for the drip method to take effect. Because the jury found the warning defective in Ms. Levine's case, Wyeth will be forced to rewrite the warning and strongly caution against direct injection. As a result, doctors will be less likely to recommend, and patients will be less likely to request, the faster relief available through push administration of the drug.

The ramifications are not limited to Phenergan® alone. Within the prescription drug world, for example, already in litigation are claims alleging that anti-depres-

sant drugs should more strongly warn about the risk of suicide. Significant attention has been given to this issue. The FDA and independent public health experts have expressed an equal or greater concern that stronger warnings on anti-depressants against suicide would cause many people who need these drugs not to take them, causing greater hazard for these individuals, their families and their communities.⁴ Absent federal preemption of such claims, in states without regulatory compliance defenses, the FDA would not have the sole authority to set such policy through study of the best available medical science and cost-benefit analyses. Rather, prescription drug safety in these states would be dictated by individual lawsuits.

The Supreme Court's decision also is certain to affect other heavily regulated products and services. Absent action by the legislature, some state courts may be less likely to defer to government safety standards when they determine the standards of care for liability cases. The result could be liability-driven "regulation" that is not in the best interest of consumers. For example, there have been lawsuits claiming that closed-back design of forklift cabs would have prevented particular plaintiffs from being ejected from a forklift.⁵ But, occupational safety experts recommend the open design because the ability to exit quickly in the case of an emergency is more important to the operator's overall safety.⁶

How Does the U.S. Supreme Court's Decision in *Wyeth v. Levine* Impact ALEC's Model Act?

The distinction between *Wyeth v. Levine* and the ALEC model act is the difference between federally mandated preemption and state-based determinations about how much deference should be given to a safety regulation in a state tort suit. The Supreme Court's decision in *Wyeth v. Levine* was only about federal preemption; it did not interfere with the ability of states to decide how much deference should be given to a federal or state safety regulation in state tort suits.

Justice Clarence Thomas, in his concurring opinion in *Wyeth v. Levine*, suggests that these decisions are best made at the state level.⁷ Justice Thomas, an advocate of states' rights, stated that "states retain substantial sovereign authority,"⁸ which includes the ability to engage in careful policy deliberations as to how standards of care in tort law should be established.

Deference to Government Safety Standards is Sound Public Policy

Many states have enacted laws giving deference to government safety experts and, following the *Wyeth v. Levine* decision, more may consider doing so.

State legislatures and Congress have charged state and federal agencies, respectively, with studying and making risk-benefit balancing decisions for specific products and services. These products and services often have inherent risks, and the goal of regulation is to find the right balance so that the products and services

Federal Preemption

Federal preemption is a federal mandate. Under the Supremacy Clause of the United States Constitution,⁹ federal laws can displace state legislative, regulatory, or judicial decisions. One option is for Congress to expressly preempt state laws by saying so in a federal statute. Alternatively, a court can find that a federal law or regulatory regime preempts state law because there is a conflict between the federal and state law, or the state law would stand as an obstacle to achieving the purpose of the federal law. In these situations, federal law prevails, and state law or tort suits on the issue are barred. *Wyeth v. Levine* determined there was no federal preemption or mandate prohibiting state-based liability for the warnings at issue in Ms. Levine's lawsuits, which were approved by the FDA.

State-Based Regulatory Compliance Defense

By contrast, regulatory compliance laws are based on a state's individual public policy choices. Legislatures and courts exercise their own judgment and authority to use a federal or state regulation as the standard of care for measuring tort liability. State legislatures have the ability to enact laws that properly consider the role of state and federal government agencies when those agencies heavily regulate the products or services in question. The resulting liability rules distinguish the situations when a company has fully met government safety standards from when it has failed to do so.

It is sound public health and legal policy for state tort and product liability law to provide substantial deference to the FDA's expert decision-making when considering the safety of a product's design or adequacy of its warnings.

are safe for the public as a whole. Such regulations provide standards for designs and warnings related to automobiles, airplanes, construction equipment, bicycle helmets, swimming pools, lawn mowers, automatic garage doors, ladders and scaffolding, workplace protection, pacifiers and rattles and even matchbooks. Sometimes, the regulations set minimum standards. Other times, the agency specifically approves an aspect of a product or service.

Government safety standards balance both the risks and benefits of a product. Such decisions should be given due deference in litigation when the harm alleged is based on the aspect of the product or service that was regulated. Regulatory compliance defenses are powerful incentives for protecting patients and consumers. These defenses properly reward behavior that is in the public interest by encouraging companies to adhere to government safety standards. They also assure that complex decisions about product safety are based on broad consideration of the benefits and risks to the public, not a judgment confined to a highly specific lawsuit with a very sympathetic plaintiff.

Nevertheless, in many states, even the most closely regulated products and services are subject to lawsuits. These suits often advance theories of liability at odds with reasoned decisions of government regulators. Such claims impose liability, sometimes even punitive damages, on those who faithfully comply with the law. Liability also may conflict with remedies that agencies have for an industry (such as with ratemaking). Thus, the lawsuits create unpredictability and confusion among manufacturers and service providers as to one's legal obligations. Does one follow the standards set by government experts charged by legislatures to make these balancing decisions in protection of the public? Or, should one follow the jury's verdict and change a product or service to avoid liability?

Opponents of state regulatory compliance defenses assert that such defenses provide blanket immunity from lawsuits and shield bad behavior. That is not so. Regulatory compliance defenses provide a standard of care for design and warnings for a product. But, under existing state legislation a company will be subject to liability if it wrongfully withholds material information from an agency or makes false or misleading statements about the safety of its product. This means that companies, like people, will or should know when they engage in conduct that can give rise to liability.

The Specific Case of FDA Approval of Prescription Drugs

With respect to prescription drugs, regulatory compliance laws provide states with the means to have their litigation standards of care set by those who are in the best position to make those determinations: the FDA. The key question for state legislators is: should decisions about the health and safety of patients in the state rest with a single plaintiff's experience or the drug's benefits to society as a whole? Should health and safety decisions about a product's benefits and risks be made by FDA experts who take a societal point of view or should the decision rest on the outcome of hindsight determinations based on two attorneys arguing before a court and jury?

Prescription drugs present one of the strongest cases for state regulatory compliance defenses because they cannot be sold in the United States without FDA review and approval.¹⁰ All prescription drugs come with inherent risks. A drug may save lives, enhance well-being, and provide hope. But the same medicine that provides a cure or therapy for some may, for others, have very serious adverse side effects. Finding the right balance between benefits and side effects for medicines and warnings involves complicated medical and scientific issues. Some complain the FDA is too slow or cautious with approvals, particularly with medicines for HIV, cancer and heart disease. Others say just the opposite: it acts too quickly. The FDA is not a political body. It is experienced and able to balance all factors to set the correct level of warnings to encourage proper use by the particular set of patients most likely to benefit from the treatment.

To obtain FDA approval, a manufacturer ordinarily submits a New Drug Application (NDA),¹¹ which in-

cludes, among many other items: “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;”¹² “adequate tests ... to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling;”¹³ proposed labeling;¹⁴ and “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.”

The FDA reviews an NDA to identify potential safety risks with a drug before the FDA can approve it as “safe and effective” for a class of patients. During this process, the FDA works with the manufacturer on labeling for the drug to accurately inform doctors of the drug’s known risks and benefits. The labeling describes the drug’s indications, dosages, routes, methods, frequency and duration of administration, and any relevant hazards, contraindications, side effects, or precautions.¹⁵ The FDA avoids representations of unsubstantiated risks that may unnecessarily deter use of the drug and deprive patients of its beneficial treatment. The entire process takes about 10 years.

It is sound public health and legal policy for state tort and product liability law to provide substantial deference to the FDA’s expert decision-making when considering the safety of a product’s design or adequacy of its warnings. When these designs and warnings are judged on a case-by-case basis, the result will be a hodgepodge of hindsight jury verdicts – some determining the designs and warnings were appropriate, others finding them defective. The FDA approval process may have its flaws, but it is grounded in science and does not have the random or emotional factor that is inherently part of tort trials.

Further, when the FDA approves a medicine and its warnings as “safe and effective,” the approval comes after extensive testing, research, and communication with the manufacturer, and the FDA considers how to set the best health care policy for all potential patients. Individual tort suits focus on only one plaintiff at a time and are an ineffective means of challenging or second-guessing the FDA approval process. Failure to warn claims filed by individual plaintiffs challenging FDA warning labels do not present the total picture, even to the most well-meaning juries.

For example, juries are shown only the side effects experienced by the injured plaintiff, who may happen to be very sympathetic. Those patients cured or receiving important therapeutic benefits from a treatment are absent from the courtroom and, therefore, are equally absent from the jury’s decision-making. Also, courtroom experts, hired by the plaintiff or the defendant, are generally not the unbiased researchers and experts found at the FDA who make the decisions regarding the efficacy of a drug and the strength of the accompanying product warning label.

Accordingly, allowing the standard of care to be set judicially through individual trials may have negative side effects more drastic than any caused by the medication itself – preventing patients access to a proven treatment or method of administration. For example, manufacturers can be induced to over-warn against certain side effects to avoid liability, the price of medication may rise to incorporate litigation costs, doctors may not prescribe appropriate treatments for fear of personal liability, and patients may not take a prescribed treatment due to concerns created by publicized litigation or improper safety warnings that are not grounded in science.¹⁶

The key question for state legislators is: should decisions about the health and safety of patients in the state rest with a single plaintiff’s experience or the drug’s benefits to society as a whole?

Some medicines, such as Bendectin,TM which was the only safe and effective drug to prevent morning sickness, and certain vaccines have been taken off the market due to tort liability even though courtroom “experts” were later shown to have gotten the science wrong. Lawsuits challenging the FDA’s reasoned decision-making can also deter innovation of new medicines by undermining the certainty companies need when deciding whether to invest in developing a potentially promising drug. Only one of every 5,000 to 10,000 potential pharmaceuticals is ultimately approved by the FDA. As has been indicated, obtaining this approval takes on average 10 years. It costs more than \$800 million, with much of

the financial investment arising before the drug even begins the FDA approval process.

In sum, excessive tort litigation makes valuable medicines less available to patients who need them and a regulatory compliance defense can help protect your state's citizens from these "adverse reactions." With the FDA's experience and specialization in determining the content of warning labels should come the ability for its decisions to set the standard of care for litigation about the adequacy of those warnings.

Some medicines, such as Benedectin™ – which was the only safe and effective drug to prevent morning sickness – and certain vaccines have been taken off the market due to tort liability even though courtroom "experts" were later shown to have gotten the science wrong.

ALEC's Solution:

Three Options Under the Model Bill

ALEC's model Regulatory Compliance Congruity with Liability Act applies broadly to all regulated products and services. It can be tailored to apply only to prescription drugs or other products approved by the FDA, an approach taken by some states.

Legislation based on the model act provides consistency between the regulatory decisions and the state's civil justice system. It accomplishes this objective by providing three options for state legislatures. Each option offers an approach for courts for weighing a product's or service's compliance with regulatory standards or government approval in deciding civil causes of action, including negligence, product liability, and deceptive trade practice act claims. The options are drawn from existing state laws and find support in other state laws precluding lawsuits alleging deceptive trade practices for conduct regulated, permitted, or approved by a government agency.¹⁷

The model act does not give "immunity" or a free pass from liability. Rather, it embodies a policy judgment that a defendant is acting properly when it satisfies existing government standards and regulations. It does

not apply if the regulatory decision-making process was compromised by misconduct of the defendant, such as through a material misrepresentation or omission of required information. In such cases, claimants may pursue their claims. The model act focuses liability on those who do not follow the law, rather than those who do. Thus, it also provides incentives to comply with regulatory requirements.

By aligning government regulations and the liability system, the model act provides much needed clarity, stability and predictability in the law; treats manufacturers, product sellers, and service providers with fairness; and protects the public interest.

Option 1: No Liability

The first option provides for full congruence between regulatory compliance and liability. If a product or service is in compliance with regulatory standards or was approved by a government agency, then its manufacturer or provider would not be subject to liability for claims related to the aspect of the product or service that is in line with government regulations. There are several important exceptions.

One exception addresses claims based on manufacturing defects, where a product does not conform to the manufacturer's own specifications. Manufacturing defects may occur randomly or due to error in a small percentage of products, such as a foreign object inside a soda bottle or a missing bolt that would have secured parts of an airplane. In such cases, a product may become dangerous although its design is perfectly safe. Such claims would remain subject to strict liability. Another exception to the model act addresses circumstances in which the manufacturer or service provider has engaged in misconduct that affects the regulatory process. The liability limitation would not apply if the business intentionally misrepresented or omitted material information during the approval of the product or service, withholds information required by law to be reported after approval of the product or service (such as known reports of injuries), bribed an official to gain or maintain approval, or sold the product after the withdrawal of approval.

The policy objectives of this option are to encourage product manufacturers and service providers to comply with the law in all respects and for that compliance to

receive due deference in court. Compliance with regulatory standards and approvals may require considerable business expenditures. The liability protections place compliance with regulatory standards and approvals firmly in a business's self interest. Thus, it aims to promote compliance as a paramount business consideration, and one that businesses can ill-afford to disregard. Michigan follows this model with respect to prescription drugs approved by the FDA.¹⁸

Option 2: Rebuttable Presumption

The second option establishes a “rebuttable presumption” for those who comply with applicable government standards or approvals. There is a presumption in court that a product or service that complies with government regulations is not subject to liability unless a plaintiff provides sufficient proof to overcome that presumption. In addition to including Option 1's exceptions for misconduct, this alternative provides that a manufacturer or service provider may still be subject to liability if a plaintiff can show that the regulations at issue were wholly inadequate to protect the public from the harm at issue.

This option is sound public policy because it reduces unnecessary and cumbersome litigation in which a product or service that has already undergone governmental approval is then effectively subject to a similar, duplicative judicial process that can reach an inconsistent result. The overall effect encourages safety and lawful conduct, while allowing some claims to proceed in the legal system if there is strong evidence that the government's regulation of the product or service at issue was ineffective. Colorado,¹⁹ Kansas,²⁰ Kentucky,²¹ Michigan,²² Tennessee,²³ Texas²⁴ and Utah²⁵ have adopted a rebuttable presumption similar to that provided by the model act.

Option 3: No Punitive or Exemplary Damages When Compliant

The third option embraces what should be a universally accepted principle: one should not be “punished” when following the law. Unlike Options 1 and 2, this alternative does not affect liability for compensatory damages, such as medical expenses, lost wages, and pain and suffering. Option 3 only eliminates the potential for punitive damages, an award intended to punish a business, when the product or service at issue complied with gov-

ernment standards. In other words, a person can receive compensation for his or her injuries, but the product manufacturer or service provider is not subject to the potential for sometimes multiple punitive damages awards if they complied with government safety requirements. As with the other alternatives, Option 3 does not apply if a manufacturer or service provider engaged in misconduct during the regulatory process.

Several states, including Arizona,²⁶ New Jersey,²⁷ Ohio,²⁸ Oregon²⁹ and Utah,³⁰ have enacted laws providing that punitive damages are not appropriate when the product or service at issue was approved by the government. With the exception of the law in Ohio, these laws apply specifically to FDA-approved pharmaceuticals and medical devices.

Wyeth v. Levine leaves to state legislatures and courts the power to make sound public health and safety decisions for their citizens.

Conclusion

The *Wyeth v. Levine* decision limits **federally** mandated preemption of state tort claims regarding pharmaceutical products that are subject to federal agency regulation. It leaves to state legislatures and courts the power to make sound public health and safety decisions for their citizens. The decision presents state legislators with an opportunity to adopt laws that facilitate judicial consideration of compliance with government regulations on the very point at issue in the litigation. These determinations balance the benefits and risks of the product or service to the population as a whole, not on the dynamics of highly emotionally charged individual lawsuits.

ALEC's model Regulatory Compliance Congruity with Liability Act provides state legislators with three options reflecting varying levels of deference to a manufacturer's or service provider's compliance with safety standards in determining liability. It is a step forward in achieving this goal. ■

ENDNOTES

- 1 *Wyeth v. Levine*, 555 U.S. ___, 129 S. Ct. 1187 (2009).
- 2 *Wyeth*, 129 S. Ct. at 1191. “Although Phenergan’s® labeling warned of the danger of gangrene and amputation following inadvertent intra-arterial injection, Levine 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.” *Id.* at 1191-92.
- 3 *Wyeth* and the FDA corresponded repeatedly on the drug’s label and, even though *Wyeth* had submitted labeling regarding the risk at issue, FDA eventually instructed *Wyeth* to retain the current label and that the final label “must be identical” to the approved 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 1988 submission, instructed it to ‘[r]etain verbiage in current label’ regarding intra-arterial injection.” *Levine*, 129 S. Ct. at 1192.
- 4 See, e.g., *Colacicco v. Apotex, Inc.*, 521 F.3d 253, 261 (3d Cir. 2008) (dismissing claims that anti-depressant drugs were defective and resulted in suicides because they should have carried a stronger warning that they might cause suicidality in adults where it would be physically impossible for the manufacturer to alter its warnings as sought by the plaintiffs because the FDA required the manufacturer to use the precise labeling approved, and the FDA had repeatedly found insufficient scientific evidence to support the sought warning), vacated and remanded for further consideration in light of *Wyeth v. Levine*, -- S. Ct. -- (U.S. Mar. 9, 2009); *Dobbs v. Wyeth Pharmas.*, 530 F. Supp.2d 1275 (W.D. Okla. 2008) (same).
- 5 *Tuggle v. Raymond Corp.*, 868 S.W.2d 621, 624-25 (Tenn. 1992) (upholding a trial court’s refusal to instruct the jury that forklift complied with OSHA design standards).
- 6 See 29 C.F.R. § 1910.178 (adopting by reference the American National Standards Institute’s Powered Industrial Truck for design and construction of forklifts, which recommends against operator enclosures because “rapid and unobstructed ingress or egress for the operator is considered more desirable”).
- 7 U.S. Const. art. VI.
- 8 *Wyeth v. Levine*, 555 U.S. ___, 129 S. Ct. 1187, 1204 (2009) (Thomas, J., concurring in judgment only).
- 9 *Id.* at 1205. Justice Thomas further stated: “In accordance with the text and structure of the Constitution, ‘[t]he powers delegated by the proposed constitution to the federal government, are few and defined’ and ‘[t]hose which are to remain in the state governments, are numerous and indefinite.’” The Federalist No. 45, at 237-238. Indeed, in protecting our constitutional government, ‘the preservation of the States, and the maintenance of their governments, are as much within the design and care of the Constitution as the preservation of the Union and the maintenance of the National government.’” *Id.*
- 10 21 U.S.C. § 321(p).
- 11 21 U.S.C. §§ 355, 393(b)(2).
- 12 21 U.S.C. § 355(b)(1)(A).
- 13 21 U.S.C. § 355(d)(1).
- 14 21 U.S.C. § 355(b)(1)(F).
- 15 21 C.F.R. §§ 201.56(b) and (d); 201.57; 201.100(c)(1); 314.125(b)(6), (8).
- 16 In a January 2006 policy statement, FDA explained how state law tort claims could interfere with and frustrate FDA’s public health mission and regulation of prescription drug labeling:

State law actions also threaten FDA’s statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs. State actions are not characterized by centralized expert evaluation of drug regulatory issues. Instead, they encourage, and in fact require, lay judges and juries to second-guess the assessment of benefits versus risks of a specific drug to the general public the central role of FDA sometimes on behalf of a single individual or group of individuals. That individualized reevaluation of the benefits and risks of a product can result in relief including the threat of significant damage awards or penalties that creates pressure on manufacturers to attempt to add warnings that FDA had neither approved nor found to be scientifically required. This could encourage manufacturers to propose ‘defensive labeling’ to avoid State liability, which, if implemented, could result in scientifically unsubstantiated warnings and underutilization of beneficial treatments.

Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3, 935 (Jan. 24, 2006).
- 17 Approximately two-thirds of state consumer protection laws, which allow private lawsuits, exclude conduct in compliance with certain state or federal laws or regulations, or an agency order or rule. See Victor E. Schwartz & Cary Silverman, *Common Sense Construction of Consumer Protection Acts*, 54 Kan. L. Rev. 1 (2006).
- 18 Mich. Comp. Laws § 600.2946(5).
- 19 Colo. Rev. Stat. § 13-21-403(1)(b).
- 20 Kan. Stat. Ann. § 60-3304(a).
- 21 Ky. Rev. Stat. Ann. § 411.310(2).
- 22 Mich. Comp. Laws § 600.2946(4).
- 23 Tenn. Code Ann. § 29-28-104.
- 24 Tex. Civ. Prac. & Rem. Code § 82.008.
- 25 Utah Code Ann. § 78-15-6(3).
- 26 Ariz. Rev. Stat. § 12-701.
- 27 N.J. Stat. § 2A:58C-5.
- 28 The manufacturer or supplier is not liable for punitive damages if it fully complied with all applicable government safety and performance standards relative to the product’s manufacture or construction, the product’s design or formulation, adequate warnings or instructions, and representations when the claimant’s injury results from an alleged defect in an aspect of the product for which there is an applicable government safety or performance standard. Ohio Rev. Code § 2307.80.
- 29 Or. Rev. Stat. § 30.927.
- 30 Utah Stat. § 78-18-2.

ALEC Model Regulatory Compliance Congruity with Liability Act

SECTION 1. {TITLE}

This Act may be known as the Regulatory Compliance Congruity With Liability Act.

SECTION 2. {PURPOSE}

The purpose of this Act is to assure that a state's civil justice system is congruent with applicable regulatory systems and that these two principal areas of law do not work at cross purposes.

SECTION 3. {DEFINITIONS}

For the purpose of this Act:

- A. "Clear and convincing evidence" means a measure or degree of proof that will produce in the mind of the trier of fact a firm belief or conviction as to the allegations sought to be established. This level of proof is greater than mere "preponderance of the evidence," but less than proof "beyond a reasonable doubt."
- B. "Government agency" means this State or the United States, or any agency of thereof, or any entity vested with the authority of this State or of the United States to issue rules, regulations, orders, or standards concerning the design, manufacture, packaging, labeling, or advertising of a product or provision of a service.
- C. "Manufacturer" means any person who is engaged in a business to produce, create, make, or construct any product (or component part of a product) and who: (1) designs, manufactures, or formulates the product (or component part of the product); or (2) has engaged another person to design, manufacture, or formulate the product (or component part of the product).
- D. "Product" means any object possessing intrinsic value, capable of delivery either as an assembled whole or as a component part or parts, and produced for introduction into trade or commerce.
- E. "Seller" means a person who in the course of a business conducted for that purpose: (1) sells, distributes, rents, leases, prepares, blends, packages, labels, or otherwise is involved in placing a product or service in the stream of commerce; or (2) installs, repairs, refurbishes, reconditions, or maintains a product.
- F. "Service" means all activities engaged in for other persons for a consideration, which activities involve predominantly the performance of a service as distinguished from manufacture or sale of a product and that are regulated, approved, or licensed by a government agency. Services include, but are not limited to financial services and the provision of insurance.

SECTION 4. {EFFECT OF REGULATORY COMPLIANCE ON CIVIL LIABILITY}

Option 1 – No Liability

- A. A manufacturer or seller is not subject to liability as a matter of law, if:
 - 1. The product alleged to have caused the harm was designed, manufactured, packaged, labeled, sold, or represented in relevant and material respects in accordance with the terms of an approval, license or similar determination of a government agency; or
 - 2. The product was in compliance with a statute of this State or the United States, or a standard, rule, regulation, order, or other action of a government agency pursuant to statutory authority, where such statute or agency action is relevant to the event or risk allegedly causing the harm and the product was in compli-

ance at the time the product left the control of the manufacturer or seller.

3. The act or transaction forming the basis of the claim involves terms of service, contract provisions, representations, or other practices authorized by, or in compliance with, the rules, regulations, standards, or orders of, or a statute administered by, a government agency.

This paragraph shall not extend to a product that departs from its intended design due to a flaw created during the manufacturing process, even though the product manufacturer or seller has complied with all applicable state and federal standards or regulations.

- B. This section does not apply if the claimant establishes that the manufacturer or seller at any time before the event that allegedly caused the harm did any of the following:
 1. Sold the product or service after the effective date of an order of a government agency to remove the product or service from the market, to withdraw its approval, or to substantially alter its terms of approval in a manner that would have avoided the claimant's alleged injury;
 2. Intentionally, and in violation of applicable regulations, withheld from or misrepresented to the government agency information material to the approval or maintaining of approval of the product or service, and such information is relevant to the harm which the claimant allegedly suffered; or
 3. Made an illegal payment to an official or employee of a government agency for the purpose of securing or maintaining approval of the product or service.

Option 2 – Rebuttable Presumption

- A. There shall be a rebuttable presumption that a manufacturer or seller is not subject to liability as a matter of law, if:
 1. The product alleged to have caused the harm was designed, manufactured, packaged, labeled, sold, or represented in relevant and material respects in accordance with the terms of an approval, license or similar determination of a government agency; or
 2. The product was in compliance with a statute of this State or the United States, or a standard, rule, regulation, order, or other action of a government agency pursuant to statutory authority, where such statute or agency action is relevant to the event or risk allegedly causing the harm and the product was in compliance at the time the product left the control of the manufacturer or seller.
 3. The act or transaction forming the basis of the claim involves terms of service, contract provisions, representations, or other practices authorized by, or in compliance with, the rules, regulations, standards, or orders of, or a statute administered by, a government agency.

This paragraph shall not extend to a product that departs from its intended design due to a flaw created during the manufacturing process, even though the product manufacturer or seller has complied with all applicable state and federal standards or regulations.

- B. The claimant may rebut the presumption in Subsection A by establishing through clear and convincing evidence that:
 1. The government standards or regulations applicable to the product or service were wholly inadequate to protect the public from unreasonable risks of injury or damage; or
 2. The manufacturer or seller of the product or service, either before or after placing the product or service in the stream of commerce, intentionally, and in violation of applicable regulations, withheld from or misrepresented to the government agency information material to the approval or maintaining of approval of the product or service, and such information is relevant to the harm which the claimant allegedly suffered; or

3. The manufacturer or seller made an illegal payment to an official or employee of the government agency for the purpose of securing or maintaining approval of the product or service.

Option 3 – No Punitive or Exemplary Damages When Compliant

- A. A manufacturer or seller shall not be liable for exemplary or punitive damages if:
 1. The product alleged to have caused the harm was designed, manufactured, packaged, labeled, sold, or represented in relevant and material respects in accordance with the terms of an approval, license or similar determination of a government agency; or
 2. The product was in compliance with a statute of this State or the United States, or a standard, rule, regulation, order, or other action of a government agency pursuant to statutory authority, where such statute or agency action is relevant to the event or risk allegedly causing the harm and the product was in compliance at the time the product left the control of the manufacturer or seller.
 3. The act or transaction forming the basis of the claim involves terms of service, contract provisions, representations, or other practices authorized by, or in compliance with, the rules, regulations, standards, or orders of, or a statute administered by, a government agency.
- B. This section shall not apply if the claimant establishes that the manufacturer or seller at any time before the event that allegedly caused the harm did any of the following:
 1. Sold the product or service after the effective date of an order of a government agency to remove the product from the market, to withdraw its approval of the product or service, or to substantially alter its terms of approval of the product or service in a manner that would have avoided in the claimant's alleged injury; or
 2. Intentionally, and in violation of applicable regulations, withheld from or misrepresented to the government agency information material to the approval or maintaining of approval of the product or service, and such information is relevant to the harm which the claimant allegedly suffered; or
 3. Made an illegal payment to an official or employee of a government agency for the purpose of securing or maintaining approval of the product or service.

SECTION 4. {RULES OF CONSTRUCTION}

Nothing in this Act shall be construed to:

- A. Expand the authority of any state agency or state agent to adopt or promulgate standards or regulations where no such authority previously existed; or
- B. Reduce the scope of any limitation on liability based on compliance with the rules or regulations of a government agency applicable to a specific act, transaction, person, or industry.
- C. Affect the liability of a service provider based on rates filed with and reviewed or approved by a government agency.

{Severability Clause}

{Repealer Clause}

{Effective Date}

Adopted by ALEC's Civil Justice Task Force at the Spring Task Force Summit, April 2007; amended at the Annual Meeting, July 27, 2007. Approved by full ALEC Board of Directors in August 2007.

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