



By the Center for Media and Democracy www.prwatch.org



DID YOU KNOW? Corporations VOTED to adopt this. Through ALEC, global companies work as "equals" in "unison" with politicians to write laws to govern your life. Big Business has "a VOICE and a VOTE," according to newly exposed documents. **DO YOU?**

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 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. 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:

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- 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.

Section 5. {Severability Clause}

Section 6. {Repealer Clause}

Section 7. {Effective Date}

Endnotes

State legislatures and Congress have charged certain government agencies with ensuring that products are safe for public use and that services are provided in a manner that adequately protects consumers. Government regulations provide standards for the design of automobiles, airplanes, construction equipment, bicycle helmets, swimming pools, lawn mowers, automatic

garage doors, ladders and scaffolding, workplace protection, pacifiers and rattles, and even matchbooks. The Food and Drug Administration (FDA) specifically approves each prescription drug and medical device as safe and effective before patients can benefit from what can be life-saving treatments. Insurers, public utilities, financial services, and other industries are subject to extensive government oversight.

Nevertheless, even the most closely regulated businesses face lawsuits advancing theories of liability that create tension with the reasoned decisions of government regulators. Such claims impose liability, sometimes even punitive damages, on businesses that faithfully comply with the law. Lawsuits that conflict with the orders, regulations, or approvals of government agencies result in unpredictability in the civil justice system and confusion among manufacturers and service providers as to their legal obligations. It also can act at cross purposes with the work of experts at government agencies who are charged by legislatures with protecting the public, and may conflict with those many instances in which an administrative agency establishes remedies for identified concerns with a regulated industry (such as in the instance of ratemaking).

ALEC's model Regulatory Compliance Congruity With Liability Act assures that a state's regulatory system is congruent with its civil justice system and that these two principal areas of law do not work against each other. It accomplishes this objective through providing several options for consideration of state legislatures. Each option provides a different approach instructing courts as to how they should weigh a product's or service's compliance with regulatory standards or approval by government agencies in deciding civil lawsuits, such as negligence, product liability, and consumer protection claims. These options are drawn from existing state laws that aim to achieve congruence between regulatory compliance and product liability actions. The options also find support in state laws that preclude lawsuits alleging unfair or deceptive trade practices when the conduct at issue is permitted by a regulatory agency.

The model act does not give a free pass from liability to a business whose product or service causes harm. Rather, this legislation creates a supposition of propriety when producers meet existing government standards and regulations. If the regulatory decision making process was compromised by misconduct of the defendant, such as through a material misrepresentation or omission of required information, claimants may overcome the reasonable safeguards provided by the model act and pursue their claims. In short, the model act attempts to re-focus liability on those manufacturers and service providers that do not follow the law, and, as a corollary, provide an incentive for producers to comply with all regulatory

In sum, by adding congruity between 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. By the Center for Media and Democracy www.prwatch.org

Option 1 - No Liability

Option 1 provides for full congruence between regulatory compliance and liability. In other words, if a product or service is in compliance with regulatory standards or was approved by a government agency, its manufacturer or provider is not subject to liability for claims related to the aspect of the product or service that is in line with government regulations. Not included within the scope of this provision are claims resulting from defects in the manufacturing process, where a product does not conform to the manufacturer's own specifications. Manufacturing defects, which may occur randomly or due to error in a small percentage of products, such as a foreign object inside a soda bottle, are and would remain subject to strict liability. Full liability would also continue to apply if 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. Nor would the liability protection apply to an unintended flaw in a product that occurred during the manufacturing process, i.e. broken glass in 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. These exceptions are consistent with the purpose of obtaining full congruence between regulatory compliance and liability.

The policy objectives underlying this option are to encourage producers of products and services to comply with the law in all respects and to give proper respect to such compliance in court. Compliance with regulatory standards and approvals may require considerable business expenditures. The liability protection provided by the model act places compliance with regulatory standards and approvals firmly in a business's self interest. Further, the provision aims to promote compliance as a paramount business consideration, and one that businesses can ill-afford to disregard.

Option 2 - Rebuttable Presumption

Option 2 establishes a "rebuttable presumption" for manufacturers or service providers that comply with applicable government standards or approvals. In other words, it would be presumed in court that a product or service that complies with government regulations is not subject to liability unless a plaintiff provides proof that overcomes that presumption. As well as including Option 1's exceptions for misconduct during the regulatory process, this alternative provides that a manufacturer or service provider may still be subject to liability despite its compliance with government regulations if a plaintiff can clearly show that the regulations at issue were wholly inadequate to protect the public from the harm at issue. As is true with Option 1, abnormalities in a product occurring due to a flaw in the manufacturing process are also excluded from coverage.

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

Option 3 - No Punitive or Exemplary Damages When Compliant

Option 3 embraces what should be a universally accepted principle: a person or business should not be punished when it follows the law. Unlike Options 1 and 2, this alternative does not affect a manufacturer's or service provider's liability for compensatory damages, such as medical expenses, lost wages or other economic loss, or pain and suffering, stemming from a regulated product or service. Evidence of compliance with regulatory standards would remain admissible in determining liability, per applicable state law, but this alternative would provide for no particular degree of deference in a liability determination. Rather, 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 government standards.

Under Option 3, punitive damages would not be available if a product or service was manufactured, sold, or represented in relevant and material respects in accordance with the terms of government standards or approvals. As with the other alternatives, Option 3 would not preclude punitive damages if a manufacturer or service provider engaged in misconduct during the regulatory process.

Several states, including Arizona, New Jersey, Ohio, Oregon, and Utah, 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. Option 3 applies this sound and fair

principle to all products and services that are in compliance with government approvals, regulations, or standards.

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.

Did you know that Victor Schwartz--a lawyer who represents companies in product litigation--was the corporate co-chair in 2011?

Center for Media and Democracy quick summary

This bill gives corporations more defenses in product liability cases. It creates a rebuttable presumption in favor of the corporate defendant when it can show compliance with governmental standards and recommendations, making it easier to escape liability, even though the American consumer may be injured or killed.

The proposal ignores the possibility that governmental standards and recommendations can be out of date as well as the probability that the standards were created at the insistence of those who manufacture the products influencing agencies.

In Wisconsin, this option was adopted in 2011 Wis Act 2 (895.047(3)(b)). It overlaps with the "Product Liability Act."

ALEC EXPOSED

"ALEC" has long been a secretive collaboration between Big Business and "conservative" politicians. Behind closed doors, they ghostwrite "model" bills to be introduced in state capitols across the country. This agenda-underwritten by global corporationsincludes major tax loopholes for big industries and the super rich, proposals to offshore U.S. jobs and gut minimum wage, and efforts to weaken public health, safety, and environmental protections. Although many of these bills have become law, until now, their origin has been largely unknown. With ALEC EXPOSED, the Center for Media and Democracy hopes more Americans will study the bills to understand the depth and breadth of how big corporations are changing the legal rules and undermining democracy across the nation.

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For more on these corporations, search at www.**SourceWatch.org**.

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