Drug Liability Act

Summary

This Act establishes in statutory form certain clear limitations with respect to the imposition of liability in actions for damages alleged to have been caused by certain drugs.

Model Legislation

Section 1. This Act may be cited as the Drug Liability Act.

Section 2. The legislature finds and reports that there is a need for remedial legislation to establish in statutory form certain clear limitations with respect to the imposition of liability in actions for damages alleged to have been caused by certain drugs. The legislature also finds and declares that the lack of such limitations has severely harmed the public interest by creating disincentives for the research and development of new pharmaceutical products and by delaying or preventing the introduction into the market of products that could prolong or even save the lives of individuals suffering from severe illnesses, including AIDS and human immunodeficiency virus infection.

Section 3. The manufacturer or seller of a drug is not liable for punitive damages if the drug alleged to cause harm either:

(A) Was manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the Federal Food and Drug Administration under the Food, Drug, and Cosmetic Act (21 United States Code Section 301, et seq.) or the Public Health Service Act (42 United States Code Section 201 et seq.) or

(B) Is generally recognized as safe and effective pursuant to conditions established by the federal Food and Drug Administration and applicable regulations, including packaging and labeling regulations.

Section 4. Notwithstanding Section 2, punitive damages may be awarded if the plaintiff proves, by clear and convincing evidence, that the defendant, either before or after making the drug available for public use, knowingly, in violation of applicable federal Food and Drug Administration regulations, withheld from or misrepresented to the Administration information known to be material and relevant to the harm which the plaintiff allegedly suffered.

Section 5. {Severability clause}

Section 6. {Repealer clause}

Section 7. {Effective date}