

Punitive Damages Limits for Government-Approved Products

by Kelly W. MacHenry

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A new Arizona law, Ariz. Rev. Stat. § 12-689, provides an exemption from punitive damages in Arizona product liability cases for virtually any kind of product that was government-approved or that complied with government regulations. Section 12-689 takes effect on August 1, 2012.

Section 12-689 safeguards product manufacturers and sellers from punitive damages as a matter of law where the product at issue was manufactured according to the terms of a government agency approval, or if the product complied with all regulatory requirements when it left the control of the manufacturer. Specifically, product manufacturers and sellers are not liable for punitive damages if: the product was designed/manufactured/sold according to the terms of government approval, or the product complied with all state or U.S. government regulations when the product left the control of the manufacturer/seller, or the act or transaction forming the basis of the claim involves practices authorized by or in compliance with government regulations.

The exemption from punitive damages does not apply in certain circumstances. It does not apply if the product was sold after the government ordered the product removed from market or withdrew or substantially altered its approval, or if the government later found the manufacturer/seller knowingly violated applicable regulations requiring reporting of risks of harm. It does not apply if illegal payments were made to the government to gain approval, or if the manufacturer/seller intentionally and in violation of regulations withheld from or misrepresented relevant information to the government.

“Product” has an expansive definition under the law. It 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.” “Seller” includes any person who distributes, rents, blends, packages, labels or places a product in the stream of commerce. Compliance with “regulations” means government-mandated regulations, not merely industry regulations or guidelines.

The Arizona legislature based § 12-689 on a parallel statute, Ariz. Rev. Stat. § 12-701 which, since 1989, has limited punitive damages against drug manufacturers in Arizona cases if the drug was manufactured and labeled in accordance with FDA regulations and was approved by the FDA. That statute has been analyzed and upheld by Arizona’s federal court. *Kobar ex rel. Kobar v. Novartis Corp.*, 378 F. Supp. 2d 1166 (D. Ariz. 2005). A handful of states (New Jersey, Ohio and Oregon) have similar laws that limit punitive damages against drug or device manufacturers. Arizona’s new law expands this exemption to all kinds of products.

This is a different type of limit than those in Texas, Wisconsin, Utah, Alaska, and Virginia, which have set monetary limits or caps on the amount of punitive damages that can be recovered. Certain other states (Washington, Michigan, Nebraska and South Carolina) generally do not allow punitive damages in product liability cases. By contrast, many states have no restrictions or caps on punitive damages.



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