

# Fifty State Survey of FDCA-Related Tort Causes of Action

A Report of the Pharmaceuticals and Biologicals Subcommittee  
Products Liability Committee

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## MISSOURI LAW REGARDING FDCA-RELATED TORT CLAIMS

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Although Missouri courts have yet to address Food, Drug & Cosmetic Act ("FDCA")-related causes of action, the likely response of Missouri courts is inferable from several areas of well-settled negligence and product liability law. Missouri closely examines legislative intent and expression to determine whether a private cause of action is created by statutory prohibition and draws on such an analysis to decide if negligence per se may be established and whether state law claims are preempted by federal law. Based on such an examination, it is unlikely that Missouri courts would allow a private cause of action or find negligence per se based solely on the FDCA.

### Private FDCA Rights of Action

Missouri courts look to legislative intent to determine where a private cause of action lies under a statutory regime. Absent an express intent within the legislation, Missouri courts do not favor a private right of action. Shqeir v. Equifax, Inc., 636 S.W.2d 944, 947 (Mo. *en banc* 1983) (noting that "the trend is away from judicial inferences that a statute's violation is personally actionable"). Missouri courts are also unlikely to find a private cause of action within the contours of the FDCA, because the FDCA allows for the imposition of penal sanctions: "We think it may be correctly stated that a statute which creates a criminal offense and provides a penalty for its violation, will not be construed as creating a new civil cause of action independently of the common law, unless such appears by express terms or by clear implication to have been the legislative intent." Christy v. Petrus, 365 Mo. 1187, 295 S.W.2d 122, 126 (1956) (holding that the Workman's Compensation law did not create a private cause of action). Given the criminal sanctions available under the FDCA and its explicit provision that only the United States Government is authorized to enforce the FDCA in 21 U.S.C. §337(a), it is likely that Missouri courts would not allow a private cause of action to issue from the prohibitions set forth in the FDCA.

### FDCA-Based Negligence Per Se

Closely linked to Missouri's position on private causes of action based on statutory requirements is its stance concerning the violation of a statutory standard as sufficient to establish negligence per se. Missouri recognizes that a violation of a statute that is the proximate cause of an injury is negligence per se. Downing v. Dixon, 313 S.W.2d 644, 650 (Mo. 1958); see also, Imperial Premium Finance, Inc. v. Northland Insurance Co., 861 S.W.2d 596, 599 (Mo. App. 1993). More specifically, if the party injured is within the class of persons intended to be protected by the statute and the violation is the proximate cause of the injury, then the statutory violation will usually constitute actionable negligence. Endicott v. St. Regis Investment Co., 443 S.W.2d 122, 125 (Mo. 1969). The exception to such a rule flows from Missouri's reluctance to allow a private cause of action absent

an expressed or strongly implied legislative intent: “[w]hen the Legislature has established other means of enforcement, we will not recognize a private right of action unless such appears by clear implication to have been the legislative intent.” Shqeir, 636 S.W.2d at 948. Additionally, if the statute at issue does not impose a particular duty of care to protect the allegedly injured party, then negligence per se, based on the statutory requirement, will not be found. See, e.g., Imperial Premium Finance, 861 S.W.2d at 599. Consequently, negligence per se would, in Missouri, only be applicable under provisions of the FDCA which state duties to others with particularity; broad prohibitions established for the common good or for public safety generally do not impose a specific duty under which negligence per se could be ascribed.

### FDCA Preemption of State Tort Claims

Although the FDCA would likely not arm a plaintiff with a private cause of action or an easy case of negligence per se, it may provide a limited shield for potential defendants. Missouri courts will construe the scope of preemption to be quite narrow when considering areas, such as public health and safety, which the state has traditionally governed through its police powers. See Ard v. Jensen, 996 S.W.2d 594, 597 (Mo. App. 1999) (holding that the Federal Boat and Safety Act did not preempt tort claims for defective design). Nevertheless, Missouri courts have recognized that where federal regulatory power exists and is plenary, states may be limited in their abilities to impose additional requirements. See Silvey v. Mallinckrodt, Inc., 976 S.W.2d 497, 500 (Mo. App. 1998). In other words, common law tort claims may not impose greater requirements than those established under federal law (see, e.g., 21 U.S.C. §360k(a)(1) of the Medical Device Act). Any use of the FDCA as a preemptive shield to state tort claims would require that the statute regulate the activity with particularity and would be construed by the courts quite narrowly. See, e.g., Northip v. International Playtex, Inc., 750 F. Supp. 402 (W.D. Mo. 1989) (holding that federal requirements for labeling under the Medical Device Amendments to the FDCA do not preempt state tort claims which are distinct from labeling and warning requirements).

Recently, the Eighth Circuit has held, in a non-Missouri case, that common law claims involving medical devices can be preempted, but only as to premarket approved devices, and only where there is an actual conflict between the plaintiff’s claim in a particular case and an FDA requirement. Brooks v. Howmedica, Inc., 2001 WL 21230 (8th Cir. 2001).

### Other Issues

Due to differences in burdens of proof, FDA regulatory determinations cannot support the admissibility of expert testimony in tort litigation under Daubert. Glastetter v. Novartis Pharmaceuticals Corp., 107 F. Supp. 2d 1015, 1035-37 (E.D. Mo. 2000).