## Products Liability/Preemption of State Law
## *King v. Collagen Corp.*, 183 F. 2d 1130 (1st Cir. 1993)

The plaintiff sought Zyderm treatment in 1987, a treatment that consists of injecting processed cow tissue directly under the skin. The cosmetic medical device is used to correct wrinkles and other skin deformities.

The plaintiff's physician injected a test dose, and the plaintiff developed muscle and joint pains as well as other symptoms. The doctor diagnosed her condition as dermatomyositis/polymyositis, an autoimmune disease.

The plaintiff filed a complaint against Collagen, which was subsequently amended. While there was some controversy as to whether the amended complaint was properly allowed, the District Court proceeded to grant summary judgment on the basis of the original complaint. However, the appellate court discussed the amended complaint, which alleged that (1) the defendant was strictly liable, (2) liable because the product was not safe and fit for the purpose intended and therefore in breach of a warranty of merchantability, (3) negligent in the design, manufacture, and marketing of the product, (4) that the product was misbranded and/or mislabeled, (5) that the defendant made misrepresentations of material fact in selling the product to her, (6) that the defendant failed to warn of any defective condition, and (7) that the defendant fraudulently obtained Food and Drug Administration approval.

The court, in an opinion by Judge Torruella in which two other judges joined in the result, detailed the approval process regarding Zyderm. The court noted that Zyderm falls within the scope of the Medical Device Amendments Act of 1976 (MDA) and thus must be approved and regulated by the Food and Drug Administration. This item is a class III medical device and is subject to the "most extensive pre-marketing approval requirements imposed by the MDA and to similarly extensive regulation post-approval." The court noted that federal law is the supreme law of the land and that state laws that conflict with federal laws and regulations are preempted. The court then discussed how to determine whether such a conflict exists. The court wrote that federal preemption of state law does not occur unless Congress intended it to occur and that such intent may be expressed or it may be implied when conflict between state and federal law makes compliance with both impossible, or when state law would frustrate the purpose and objectives of the federal law.

The court distinguished this case from *Cipollone v. Liggett Group, Inc.*, which dealt with the requirement that cigarette manufacturers include a brief health warning in their advertisements. The Judge wrote that the warning did not affect cigarette advertisements in any way and that the manufacturers are free to make any claims that they wish, including express warranties. The court contrasted this with the Zyderm instance, where the federal law imposed much more extensive regulation upon class III device manufacturers, and noted that the Food and Drug Administration retained rigid control over the entirety of the labeling and packaging of class III products "largely displacing the ability of manufacturers to make additional claims. The high level of control contrasts with the low level of control in Cipollone, and insures that manufacturers will

not be held liable for packaging or labeling imposed by the FDA." The Judge concluded that the MDA expressly preempted the state law tort claims and thus affirmed the holding of the District Court. It is noted that the district court granted the defendant summary judgment relying on a similar case from the Southern District of Texas, *Stamps v. Collagen Corp.*, 1991 U.S. District, LEXIS 20666 (S.D.Tex. 1991). On February 19, 1993, the 5th U.S. Circuit Court of Appeals in New Orleans affirmed the District Court holding in the Stamps case.

The applicability of this case to other devices such as breast implants was not addressed. However, a distinguishing characteristic is that breast implants apparently were never officially approved by the FDA.