

# PRO TE: *Refero*

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## **Absence of Reliance Element in Fraud Claim Not Enough to Certify Class**

In *In Re: St. Jude Medical, Inc.*, --- F.3d ----, 2008 WL 942274 (8th Cir. 2008), the Court addressed the attempted class certification, sited in Minnesota, of a group of consumers implanted with prosthetic heart valves. The Court had previously rejected certification of a subclass of "medical monitoring" cases. Following remand, the district court proceeded to recertify a "consumer protection" class under Minnesota's Consumer Fraud Act. Defendant challenged on the predominance element of the Rule 23 calculus, arguing that common questions of law and fact did *not* predominate over the individual issues.

The Court pointed out that typically fraud cases are unsuitable for class treatment, chiefly because such claims incorporate elements of a plaintiff's reliance upon a defendant's representation. See, e.g. Fed. R. Civ. P. 23 advisory committee notes ("[A]lthough having some common core, a fraud case may be unsuited for treatment as a class action if there was material variation in the representations made or in the kinds or degrees of reliance by the persons to whom they were addressed"). In this case, however, the Minnesota fraud statute did not include an element of reliance.

The Court examined the state's Supreme Court decision in *Group Health Plan, Inc. v. Phillip Morris Inc.*, 621 N.W.2d 2 (Minn. 2001) delineating a "relaxed" traditional common law reliance requirement. However, the Court held that even if plaintiffs were not required to prove reliance directly, a defendant was not foreclosed from offering such evidence in defense of a fraud claim. "When such evidence is available,

then it is highly relevant and probative on the question whether there is a causal nexus between alleged misrepresentations and any injury." *St. Jude*, 2008 WL 942274 at \*3. Consequently, the Court determined that the necessity of "plaintiff-by-plaintiff determinations" rendered common questions subordinate to individual issues. *Id.* The predominance element was not satisfied; the class was not appropriate for certification.

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### **FDA Proposes Draft Guidance for Section 402(j) Certifications**

In an effort to provide a mechanism for the public to learn about clinical trials that are being conducted, as well as the results of those trials, Congress enacted Section 402(j) of The Public Health Service Act. This section requires a certification to accompany certain human drug, biological product and device applications and submissions to the Food and Drug Administration ("FDA"). These certifications not only encourage industry submissions to comply with the new law, they trigger actions within the government that "eventually will allow FDA to help the public more easily correlate various reports, medical reviews, advisories, health alerts, advisory committee actions, and other materials with specific applicable clinical trials registered with ClinicalTrials.gov." *See attached*, 73 Fed. Reg. 76 at 21143.

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Since the certification requirement went into effect in December 2007, numerous inquiries from industry sectors, researchers, and investigators have sought guidance for certification requirements for certain submissions. The FDA has prepared a draft guidance reflecting its "current thinking regarding specific types of information and documents submitted . . ." (73 Fed. Reg. 76 at 21143) which can be found at: [http://www.fda.gov/oc/initiatives/fdaaa/guidance\\_certifications.html](http://www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html).

Among the categories for which a certification need not accompany a submission are (1) **investigational applications/submissions**, including: chemistry and manufacturing amendments to investigational new drug applications (INDs), non-clinical pharmacology/toxicology amendments to INDs, and meeting requests; and (2) **marketing and post-marketing applications/submissions**, including: humanitarian device exemptions (HDEs) and premarket approval application (PMA) 30 day notices, biologics license applications (BLAs) and new drug applications (NDAs) safety reports and 510(k)s that contain no clinical data.

Comments will be accepted through June 17, 2008.

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