

## Massachusetts Supreme Judicial Court Dismisses Medical Device Suit

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*Product Liability Alert*

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Last week, in *Dunn v. Genzyme*,<sup>[1]</sup> the Massachusetts Supreme Judicial Court (SJC) provided clarification as to the pleading standard that applies to state product liability claims against medical device manufacturers. Under *Riegel v. Medtronic*,<sup>[2]</sup> such claims survive federal preemption under the Medical Device Amendments (MDA) of the Food, Drug, and Cosmetic Act, so long as the state claims parallel (and do not supplement or conflict with) federal law.

But courts have reached conflicting results as to whether the alleged “parallel” violation of federal law must be pleaded with specificity. Some courts require detailed pleading where they will dismiss a complaint unless the plaintiff “allege[s] that the defendant violated a particular federal specification relating to the device at issue.”<sup>[3]</sup> Other courts are more lenient, where they do not require that plaintiffs “specify the precise defect or specific federal regulatory requirements that were allegedly violated.”<sup>[4]</sup>

Wading into this dispute, the SJC aligned itself with the more lenient approach; it found that state law claims are not subject to a heightened pleading standard. However, it ultimately dismissed the plaintiffs’ claim, on grounds that the allegations of the complaint failed to meet even the less stringent standards the court was willing to adopt.

### Background

The plaintiff in *Dunn* received injections of Synvisc-One, a Class III medical device approved by the FDA in 2009 to treat pain associated with osteoarthritis of the knee. Complications ensued and the plaintiff sued Genzyme, the manufacturer of the device. Genzyme moved to dismiss, arguing that plaintiffs’ claims were preempted because the device was subject to FDA premarket approval and other regulatory requirements.

In cases of this nature, *Riegel* instructs courts to consider whether the state claims were “different from, or in addition to, [the] requirement applicable to the device” under federal law. To the extent the state claims simply parallel federal requirements, and do not supplement or conflict with those requirements, they may be permissible.

### The Court's Decision

Here, the court found the plaintiff’s claims under Massachusetts law – for negligent failure to warn, breach of warranty, negligent manufacture, products liability, and violations of M.G.L. ch. 93A – could “be interpreted as coextensive with the comprehensive federal requirements imposed on Genzyme under the MDA, such as, for example, those regulating production and process controls ... and packaging and labeling ...” The court found, in other words, that these state law obligations might parallel, rather than adding to, federal requirements.

But it remained to be determined whether the plaintiff had adequately pled out her claims under state law. Genzyme argued that the plaintiff’s complaint was insufficient to survive dismissal, under *Iannachino v. Ford Motor Co.*, 451 Mass. 623 (2008), because it did not describe in detail the “parallels” with federal law. Among other things, the complaint “never state[d] which [premarket approval] requirements Genzyme purportedly violated, nor ... how Genzyme allegedly violated them.”

The SJC found this level of detail was unnecessary:

Plaintiffs asserting parallel state-law claims based upon a violation of FDA regulations must articulate only 'factual allegations plausibly suggesting (not merely consistent with) an entitlement to relief .... Plaintiffs need not point to conclusive or specific evidence of such violations, as would be required under a heightened pleading standard.

What was necessary, however, was a specific assertion of how Genzyme's purportedly tortious activities, under state law, had caused the plaintiff's injuries. And on this dimension, the court found the plaintiffs' complaint failed. The court found the plaintiffs' allegations to be wholly vague and conclusory; they consisted largely of allegations like:

- "the reasonably foreseeable use of Synvisc-One involved significant dangers not readily obvious to the ordinary user of the product;"
- Synvisc-One posed "known or reasonably knowable dangers;" and
- the "Syniovisc-One that was ultimately injected into [the plaintiff] was adulterated and defectively manufactured, distributed, marketed, and sold" by Genzyme.

The court described these as mere "labels and conclusions." It said the plaintiff had "invoke[d] no facts – regulatory, medical, or otherwise – that connect[ed any of] Genzyme's actions with the purported harm."

In the end, while the court was prepared to accept a relatively low level of pleading specificity for claims involving federally regulated devices, it ordered dismissal because the plaintiff was not even able to meet the lower standard the court signaled it willing to accept.

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[1] No. SJC-12904, 2021 Mass. LEXIS 84 (Jan. 29, 2021).

[2] 552 U.S. 312, 330 (2008).

[3] *Wolicki-Gables v. Arrow Intl., Inc.*, 634 F.3d 1296 (11<sup>th</sup> Cir. 2011)

[4] *Bausch v. Stryker Corp.*, 630 F.3d 546, 560 (7<sup>th</sup> Cir. 2010), cert denied, 565 U.S. 976 (2011).

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