

Product Liability Litigation Update

Recent Developments in the Law

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Proposition 65: Companies Win Trial Involving Lead in Fruit Juice and Baby Food Products

In *Environmental Law Foundation v. Beech-Nut Nutrition Corp.*, No. RG11597384 (Alameda Cnty. Cal. Super. Ct. July 31, 2013), Judge Steven Brick ruled in favor of the defendant companies and held that any alleged exposures to lead in fruit juice and baby food products did not exceed the “safe harbor” level triggering a requirement to warn under Proposition 65. In doing so, the court ruled on a key issue that had not previously been litigated in any other Proposition 65 trial involving lead -- whether or not the “safe harbor” limit for lead exposure should be calculated on the basis of average exposure or maximum daily exposure.

Environmental Law Foundation, a private plaintiff that has been an active Proposition 65 enforcer for nearly two decades, conceded that the products are consumed intermittently, not every day, so that average lead exposure over long periods of time fell within the safe harbor limits. But Plaintiff argued that exposure to lead on any given day of consumption exceeds those safe harbors and therefore triggers the requirement to warn under Proposition 65. Rejecting Plaintiff’s theory, the court found that it is appropriate to average exposures to lead over more than a single day based on the evidence and expert testimony presented in the case. In particular, the court agreed with the defense experts, who testified that the lead levels in the products would not cause any increase in blood lead levels based on average consumption patterns. The court thus determined that none of the exposures exceeded the safe harbor level for lead. The court’s ruling provides important guidance to other food, beverage, and dietary supplement companies on how to measure exposures to low levels of lead in products under Proposition 65.

In finding for the companies on the “safe harbor” defense, the court also rejected Plaintiff’s argument that the court should defer to the principal agency for Proposition 65, the California Office of Environmental Health Hazard Assessment (OEHHA), which has a policy against averaging exposures to lead over more than a day. The court found that the opinions expressed in a 1991 declaration by an OEHHA staff person did not constitute a policy entitled to deference and should not be given any weight. In particular, the court noted that the declaration was not issued with any opportunity for public notice and comment.

The court also ruled against the companies on other defenses presented -- namely federal preemption and a defense that the lead in the products was naturally occurring. Under Proposition 65, naturally occurring levels of listed chemicals in foods are exempt. The court found that the companies failed to meet their burden to show that the lead was naturally occurring and did not adequately quantify how much lead was attributable to non-human as opposed to human sources.

As Proposition 65 cases generally settle before trial, this opinion is significant because of its ruling on issues involving the determination of average lead exposures that had not previously been litigated.

Preemption: Pennsylvania Superior Court Narrows Generic Drug Preemption and Expands RLD Liability

In a series of recent decisions involving metoclopramide, the Pennsylvania Superior Court found that various claims against generic manufacturers under Pennsylvania law were not preempted pursuant to the Supreme Court's *Mensing* and *Bartlett* cases. *Hassett v. Dafoe*, --- A.3d ---, 2013 WL 3874882 (Pa. Super. Ct. July 29, 2013) and *In re Reglan/Metoclopramide Litigation (Appeal of Teva Pharmaceuticals USA, Inc.)*, --- A.3d ---, 2013 WL 3874905 (Pa. Super. Ct. July 29, 2013). The court also held for the first time in *In re Reglan/Metoclopramide Litigation (Appeal of Morton Grove Pharmaceuticals Inc.)*, --- A.3d ---, 2013 WL 3874931 (Pa. Super. Ct. July 29, 2013) that a generic manufacturer designated as the Reference Listed Drug (RLD) holder may be liable under a failure-to-warn theory.

The court in *Hassett* acknowledged that the plaintiffs' failure-to-warn claims were preempted under *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011). However, it rejected the defendants' argument that the other claims plaintiffs brought -- strict liability design defect, negligence, breach of express and implied warranty, fraud, and misrepresentation in drug advertising and promotion -- were essentially warnings-based claims and therefore preempted under *Mensing's* rationale. The court instead relied on express preemption cases in non-pharmaceutical contexts to find that such claims based on false advertising and promotion, failure to test, and breach of warranty involve types of communications other than labeling, and accordingly are not preempted. The court also discussed whether Pennsylvania's design defect claim imposed "absolute liability" of the type that might not pose an impossibility conflict under *Bartlett*. But the court chose not to directly address that issue, instead holding that "without a careful analysis of the applicable state law, preemption of all design defect claims [was] premature." *Id.* at *11.

In the companion case, *In re Reglan/Metoclopramide Litigation (Appeal of Morton Grove Pharmaceuticals Inc.)*, the court held that a generic manufacturer designated as the RLD holder following the brand-name manufacturer's withdrawal of the brand-name product can be liable for failing to change the drug label. If the holder of an NDA ceases marketing a drug, then FDA may appoint another company as the RLD. The question presented here was whether a generic company designated as an RLD has the power to change a drug's label and accordingly to be held liable for failure-to-warn. Although multiple state and federal courts have rejected the RLD theory of liability, the court agreed with the plaintiffs' argument that Morton Grove stepped into the shoes of the brand-name manufacturer and assumed the authority to update the drug's label. The court first explained that neither *Wyeth v. Levine*, 555 U.S. 555 (2009), nor *Mensing*, addressed whether a generic holder which is subsequently designated as the RLD can unilaterally change its label. The court then concluded there was "no indication that only brand-name manufacturers that obtained NDA approval, rather than RLDs generally," can change the label. 2013 WL 3874931, at * 6. Absent authority that the RLD holder was powerless to change the label, preemption did not apply.

Battles like these about the scope of preemption under various state laws will continue to play out in the wake of *Bartlett* and *Mensing*.

Preemption: Minnesota Court Rules that Fraud Claims Against Device Manufacturer May Fit Into Narrow Preemption Gap

In *Lawrence v. Medtronic Inc.*, No. 27-cv-13-1197, slip op. (Minn. D. Ct. 4th July 7, 2013), a Minnesota state trial court ruled that the plaintiff's fraud claims may fit into a narrow gap in the preemption doctrine established by the U.S. Supreme Court's decisions in *Riegel v. Medtronic*, 552 U.S. 312 (2008), and *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). But the court nonetheless dismissed those claims on the basis of pleading insufficiency.

The plaintiff claimed that he was injured after being implanted with Medtronic's bone graft device through an unapproved surgical procedure alleged promoted by Medtronic. Plaintiff sued on numerous state law grounds including negligence, negligence per se, strict liability, breach of warranty, fraud and constructive fraud, and violation of state consumer protection statutes. The court found all but the fraud-based claims either expressly or impliedly preempted under *Riegel* and *Buckman*.

With respect to the fraud claims, the court noted that a plaintiff may "navigate carefully" to fit into a "narrow gap . . . [between] express or implied preemption." *Lawrence*, slip op. at 7. A state law claim can survive preemption, the court said, when it is premised on conduct that "(1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA." *Id.* The court recognized that to the extent plaintiff claimed Medtronic "provided false and misleading information to them in the process of promoting the off-label use of the [bone graft] device, and that [plaintiff] relied upon such misrepresentations, . . . [plaintiff's] fraud-based claims have the potential to escape both express and implied preemption." *Id.* at 13. Ultimately,

however, the court dismissed plaintiff's fraud claims without prejudice (and with leave to amend) for failure to plead with requisite particularity. *Id.* at 15.

The *Lawrence* case is a reminder of the importance of coupling preemption motions with pleadings arguments. Even if there is room between *Riegel* and *Buckman* for a theoretical claim to survive preemption, plaintiffs must actually plead a valid and sufficient cause of action to survive dismissal.

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