No Preemption for the Common Cold Remedy

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Since the first sneeze, people have been trying to cure the common cold. While the cure remains elusive, everyone has a remedy for its symptoms – chicken soup, salt water gargle, fresh chopped garlic on crackers and, our personal favorite, the hot toddy. But, do any of them really work? And, if they don't, who is to blame – your Great Aunt Martha? So, what if you take a homeopathic remedy, put it in a bottle with a label that identifies its ingredients, directions for use and indications for usage and put it on a shelf in a drug store? Now, who can you blame if it doesn't work – the manufacturer of course. Well, the court in Delarosa v. Boiron, Inc., 2011 U.S. Dist. LEXIS 80562 (C.D. Cal. Jul. 25, 2011), at least thought plaintiffs should get a chance to make that claim.

This case caught our attention because we have never seen a preemption argument advanced concerning an over-the-counter homeopathic product before and while the decision goes against the defendant, we thought it warranted a passing mention – primarily because no one, including the FDA, seems to know what to do with homeopathic remedies.

Plaintiff alleges that she purchased and used an over-the-counter homeopathic cold remedy called Children's Coldcalm based on the product's labeling and advertising that it relieved symptoms of the common cold including "sneezing, runny nose, nasal congestion, sinus pain, headaches, and sore throat." Delarosa, 2011 U.S. Dist. LEXIS 80562 at *3. Sound too good to be true – plaintiff thinks so. Plaintiff claims she did not obtain the advertised relief or any other benefit from the product and therefore did what so many others have done – filed a class action under California's notorious consumer protection statutes (and alleging common law fraud, too). Id. at *4. The defendant filed a motion to dismiss based on both express and implied preemption.

Putting aside the complexities of preemption law, the crux of the court's decision can be summed up by its comparison of the FDA's regulation of OTC drugs versus what the court deemed "quasi-regulation" of homeopathic OTC drugs. Id. at *4-12. First and foremost – according to the court – homeopathic OTC drugs "are not evaluated by the FDA at all." Id. at *8.

"[T]he FDA allows a private organization [Homeopathic Pharmacopoeia of the United States ("HPUS")] to designate which homeopathic drugs meet certain (and unknown) standards for strength, quality and purity. . . . [T]he FDA did not review any studies or information on homeopathic drugs ."

Id. at *21-22. While HPUS governs how ingredients are prepared for homeopathic use, it does not dictate indications for use, nor does it set forth any standards to ensure that homeopathic OTC drugs are safe and effective. Id. at *8-9, *11.

"The FDA does not impose additional standards for strength, purity, quality, safety, or efficacy on homeopathic OTC remedies. Indeed, the FDA has advised that unless a homeopathic remedy is being offered for use (or promoted) significantly beyond recognized or customary practice of homeopathy, federal policies on health fraud do not apply. And perhaps most significant, a product's compliance with requirements of the HPUS . . . does *not* establish that it has been shown by appropriate means to be safe, effective, and not misbranded for its intended use.:"

Id. at *11-12 (citations and quotation marks omitted).

So, confronted with what amounts more to a lack of regulation, it is not altogether surprising that the court was reluctant to find preemption in the context of a homeopathic OTC … umm … drug. (Actually, we have a hard time even calling the product at issue here a "drug" when its ingredients are "various flowers, vegetables, insects, metals, and poison" – id. at *3 – *seriously*?).

As to express preemption, we won't bore you with a reiteration of the court's very detailed analysis, but suffice it to say that the court found that homeopathic drugs are excepted from the express preemption provisions for non-prescription drugs. See id. at *14-24. So, the court was essentially left with conflict preemption – but can there be a conflict if there is no regulation? The court continued its focus on the difference between non-homeopathic drugs and homeopathic drugs, finding that as to the former

"The . . . decision to defer to the FDA's labeling regulations relie[s] in no small part on the FDA's comprehensive process that test[s] the safety and efficacy of the drugs which it regulate[s]."

Id. at *29-30. Absent such a process for homeopathic drugs, the court was unwilling to conclude "that inclusion in the HPUS is sufficient to guarantee the efficacy and safety of a homeopathic OTC drug." Id. at *29. Since the efficacy of homeopathic drugs is not regulated

by the FDA and the FDA has said that compliance with HPUS does not establish that a product is effective or correctly labeled -- a state law fraud claim, which if proven true, would "simply require Defendant to truthfully state its efficacy" is not different than or in conflict with the requirements of the FDCA. Id. at *30-31.

While we may have come a long way from Dr. Kilmer's Swamp Root and Clark Stanley's Snake Oil Liniment -- we, like the court and apparently the FDA, are left scratching our heads about what is actually regulated about homeopathic drugs. So, for now, at least where the alternative is apparently "flowers, vegetables, insects, metals, and poison" – we'll just stick with the hot toddy.