Legal Opinion Letter

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COURT RULES CALIFORNIA'S PROP 65 SUPERSEDES FEDERAL DRUG RULES

by
Gene Livingston

A California court of appeal has ruled that Proposition 65 supersedes conflicting mandates from the Food and Drug Administration (FDA) about warnings on over-the-counter drugs. *Dowhal v. SmithKline Beecham Consumer HealthCare, et al.*, 100 Cal.App.4th 8 (2002). This decision adamantly refuses to consider that FDA-regulated entities may find it actually impossible to satisfy both the FDA and Proposition 65. Rather, the decision simply assumes away any potential conflicts, stating that the FDA should be flexible enough to allow labels to comply with Proposition 65 — and giving no guidance if it is not.

The decision grew out of an action filed by a private plaintiff against manufacturers of nicotine patches and other smoking cessation products. The plaintiff asserted that the product labels fail to provide a Proposition 65 warning that nicotine is known to cause reproductive toxicity. The warning mandated by FDA as part of its new drug application procedure was generally as follows: *Nicotine can increase your baby's heart rate; if you are pregnant or nursing your baby, seek the advice of a health professional before using this product.*

FDA and its independent Nonprescription Drugs Advisory Committee gave this warning substantial consideration. FDA was committed to communicating the potential harm from the smoking cessation products against the known harms of smoking for pregnant and nursing women, and sought to ensure an accurate warning, but one that did not discourage such women from using the products to stop smoking.

FDA's commitment to maintaining a balanced warning on the OTC products was emphasized numerous times. Before this was filed, one of the manufacturers sought permission from FDA to add the Proposition 65 safe harbor warning to its label. The proposed label change would have added, "This product contains nicotine, a chemical known to the State of California to cause birth defects or other reproductive harm." FDA emphatically denied the request.

The California Attorney General had also sought an explanation from FDA concerning its position on the nicotine patch warning. FDA responded that the Proposition 65 warning would be "inaccurate and could possibly render the products misbranded."

After the private plaintiff filed his lawsuit, the product manufacturers sought further advice from FDA. In each and every instance, FDA instructed the manufacturers to continue using the warning it had approved. The private plaintiff not only filed an action against the product manufacturers, but he also filed a citizen's petition with FDA. In the petition, he urged FDA to modify its warning and to order all manufacturers to include a warning that generally states, "nicotine, whether from smoking or medication, can harm your baby."

Gene Livingston is a Principal at the Sacramento law firm Livingston & Mattesich.

In response to the citizen petition, FDA again emphasized the importance of a balanced warning. It agreed that the warning it had previously ordered the manufacturers to use, referring to an increase in the baby's heart rate is not sufficient. However, it also concluded that the "harm your baby" warning "overstates what is actually known about nicotine and its effect on the unborn child." FDA was particularly concerned that the "harm your baby" warning implies that the harm from the smoking cessation products is equal to the harm from smoking. FDA concluded that it would order all manufacturers to change the pregnancy warning to:

> **If you are pregnant or breast-feeding, only use this medicine on the advice of your health care providers.** Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known.

FDA's actions caused the trial court to conclude that the Proposition 65 claim was preempted under the doctrine of conflict preemption. The manufacturers could not comply with both FDA's demand to avoid over warning and the private plaintiff's demand that they add a Proposition 65 warning. Accordingly the trial court granted the manufacturers' motion for summary judgment. Plaintiff's subsequent appeal resulted in the decision described above. The court, relying on the Food and Drug Administration Modernization Act of 1997, concluded that Congress authorized the State of California to act in conflict with the Food, Drug and Cosmetic Act (FDCA) and FDA's implementation of it.

In 1997, Congress reauthorized FDA and in doing so amended the FDCA. It expressly stated its intent to establish uniformity for labeling of non-prescription drugs and to preempt state law with respect to labeling. 21 U.S.C. § 379r(a)(2) provides that "[No] State…may establish or continue in effect any requirement…(2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this Act…." At the same time, Congress enacted subdivision 379r(d) to provide, "This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997."

The court correctly acknowledged that federal preemption falls into three categories, "State action may be foreclosed by express language in a congressional enactment, by implication from the depth and breath of a congressional scheme that occupies the legislative field, or by implication because of a conflict with a congressional enactment. Nevertheless, the court engaged in only an express preemption analysis. It discussed the provisions of the Modernization Act and concluded that the saving clause in subdivision 379r(d) applies not only to the express provision set out in subdivision 379r(a), but also saves the Proposition 65 claim from conflict preemption. The court's opinion ignores the fact that the saving provision saves only the preemption provided by "this section." In addition, the court distorts what was considered an explicit ruling by the United States Supreme Court in *Geier v. American Honda Motor* 529 U.S. 861 (2000).

In *Geier,* the question was whether the Department of Transportation regulations preempted a common law tort claim based on a car manufacturer's failure to install an air bag. Federal regulations included both an express preemption clause and a saving clause preserving certain tort claims. The Supreme Court held that neither the express preemption nor the saving clause suggests that Congress intends to "bar the ordinary working of conflict preemption principles."

The majority opinion in the instant case construed *Geier* narrowly, saying that the particular saving clause was limited to the express preemption and that neither applied to the specific tort claim involved in the case. On the other hand, according to the court, Congress, in the Modernization Act, saved the precise claim that is involved in the instant case. In other words, the court concluded that Congress intended to save Proposition 65 from all three categories of preemption and not just the express preemption.

The issue of conflict preemption in the context of nicotine patches is far from being concluded. On October 23, 2002, the California Supreme Court granted the manufacturer's *cert* petition in the *Dowhal* case, setting up what proves to be a contentious and precedent-setting review.

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