

FEDERAL DRUG LAW PREEMPTS CALIFORNIA'S PROPOSITION 65

by
Gene Livingston and Dan Fuchs

How much “conflict” is needed for a federal labeling requirement to preempt the warning requirement of California’s infamous Proposition 65? The California Supreme Court answered that question in *Dowhal v. SmithKline Beecham Consumer Healthcare et al*, 32 Cal. 4th 910 (2004).

Proposition 65 requires any business exposing Californians to chemicals which appear on a list of substances “known to the state to cause cancer or reproductive toxicity” to provide a written warning. Consumer activist Paul Dowhal sued manufacturers of nicotine gum and patches — over-the-counter products designed to help people quit smoking through nicotine replacement therapy (NRT) — for failing to warn consumers about nicotine, which is listed as a Proposition 65 developmental toxin.

The federal Food, Drug, and Cosmetic Act gives the Food and Drug Administration (FDA) authority to regulate the labels of over-the-counter drugs such as the nicotine patches and gum at issue. A product can be deemed “misbranded” and prohibited from legal sale if the FDA disapproves of any part of the label. The NRT products underwent an unusually long label approval process, as the FDA struggled to balance the need to warn consumers about their nicotine content against the desire to encourage their use to decrease smoking. As the Court noted, “Smoking is even more dangerous to the fetus, because it may deliver more nicotine than the products, and also exposes the smoker to carbon monoxide and other harmful chemicals.”

The warning FDA ultimately mandated as part of the agency’s New Drug Application procedure does not state that nicotine can cause reproductive harm. Rather, it requires the product label to state: “If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider. 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 commitment to maintaining a balanced warning on the NRT products was emphasized numerous times. In January 1997, before Dowhal filed his lawsuit, one of the defendants specifically asked the FDA for permission to change the label for its NRT product to add the Proposition 65 “safe harbor” warning: “This product contains nicotine, a chemical known to the State of California to cause birth defects or other reproductive harm.” The FDA denied the request, telling the company that it “[m]ust use the labeling that was approved at the time of . . . approval.”

Gene Livingston is a Principal at the Sacramento law firm Livingston & Mattesich. **Dan Fuchs** is a senior associate with the firm.

Then, in November 1999, while the case was pending, the FDA granted permission to a new entrant in the NRT field. Although the new company's product was identical to some of the defendants' products in nicotine content, indication for use, and method of administration, the company used a slightly different warning: "Nicotine, whether from smoking or medication, can harm your baby."

Nonetheless, in 2000, the FDA informed the manufacturers of the existing NRT products that those products "must" carry the pregnancy warning that had been specified when they were approved.

In March 2001, the FDA told them that even though one product carried a different warning, the instructions concerning defendants' products remained unchanged: "The agency is currently reviewing its position regarding the pregnancy/nursing warning on [over-the-counter] nicotine replacement products. [] . . . As we have stated previously, until the agency's review is complete, all sponsors of [over-the-counter] nicotine replacement products should continue to use the pregnancy/nursing warning that was approved by the agency as part of their [new drug approval]. *Any additional or modified warning may render the product misbranded.*" (Italics added.)

Notwithstanding the lengthy history of FDA involvement, Dowhal continued to argue that to conform to Proposition 65, the NRT products must carry the warning, "This product contains nicotine, a chemical known to the state of California to cause reproductive harm," or words to that effect.

The Supreme Court concluded, however, that if a defendant were to add a Proposition 65 warning to its label, it would violate the FDA's determination and would risk legal sanctions. The Court held that the FDA's rejection of the Proposition 65 warning language created a direct conflict with Proposition 65. In effect, said the Court, any warning that would meet FDA approval could not meet the Proposition 65 requirements, and, thus, the FDA labeling requirements effectively barred all Proposition 65-compliant warnings on NRT labels.

Dowhal asserted that a product could not be "misbranded" if the proposed wording is truthful, and that nicotine is undeniably a developmental toxin. However, the Court found that the FDA could prohibit even truthful statements on a product label if they are "misleading" or are not stated in "such manner and form, as are necessary for the protection of users." The Court further found that the FDA had rejected the Proposition 65 warning on the NRT products because the risk communicated by the proposed warning was outweighed by the greater risk that a warning would "scare consumers into foregoing use of a product that in most cases will be to their benefit." Thus, the Court concluded, the FDA had preempted Proposition 65.

In reaching this conclusion, the Court considered the three forms of preemption: (1) when the federal law expressly preempts the state law; (2) when the federal law or agency completely occupies the field, so there is no room for a contrary state law; and (3) when there is "direct preemption" — i.e., "it is impossible for a private party to comply with both state and federal requirements."

The first and second forms clearly did not apply because the 1997 FDA Modernization Act contains a special provision exempting Proposition 65. However, the Court held that the third form, direct preemption, does apply in this situation. The Court held that because the products are designed to help people stop smoking, and it is worse for a pregnant woman to smoke than to use the products, the FDA-approved warning should prevail. "The risk of harm may be so remote that it is outweighed by the greater risk that a warning will scare consumers into foregoing use of a product that in most cases will be to their benefit," the Court said, adding that the stricter wording of the state warning may lead some women "overly concerned about those risks, to continue smoking."

FDA's specific rejection of the Proposition 65 regulatory warning and its repeated direction to continue using the warning it approved, combined with its concern about Proposition 65 upsetting the public health balance that it sought to achieve, formed the conflict which gave rise to preemption. Were these unique circumstances? Perhaps, but other Proposition 65 cases are pending that potentially raise comparable issues. The *Dowhal* decision will undoubtedly be cited soon.