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FIFRA Label Preemption and the RoundUp Litigation

By

Pesticides, like human and animal drugs, are highly regulated products. Before any pesticide may be sold, it must be "registered" (*i.e.*, licensed) by the U.S. Environmental Protection Agency (EPA) under the Federal Fungicide, Insecticide and Rodenticide Act (FIFRA). To obtain a registration, the pesticide producer must provide extensive health, safety and environmental data concerning its product. Based on these data, EPA then determines the appropriate warnings, directions for use, and other information to be included on the pesticide label. It is unlawful to sell a pesticide without its EPA-approved label or that is otherwise "misbranded." FIFRA defines a "misbranded" pesticide as one bearing a label that is "false or misleading in any particular."

EPA's authority over the contents of pesticide labels is nearly exclusive. In a section entitled "Uniformity," FIFRA expressly preempts U.S. states from imposing any requirements for labeling "in addition to or different from" those imposed under FIFRA. It is well-settled through case law that this prohibition applies not only to labeling requirements imposed by state law but also to "failure to warn" claims under state law that may be asserted in litigation. A "failure to warn" claim is one in which a plaintiff injured by a product seeks an award of damages because the seller (allegedly) had a duty to, but failed to, warn of a potential risk. Courts reasoned that "failure to warn" claims against pesticide producers were, in effect, challenges to the adequacy of the warnings on the EPA-approved label and therefore were preempted under FIFRA. Needless to say, pesticide producers view FIFRA label preemption as an important defense against efforts by private plaintiffs and state governments to second-guess EPA's expert judgments as to the appropriate warnings and other information to be included on labels for the products they sell.

The ability to defeat state law claims based on FIFRA preemption, however, was narrowed in 2005, with the U.S. Supreme Court's decision in *Bates v. Dow*, 544 U.S. 431, 447 (2005). In *Bates*, the Supreme Court recognized an exception to EPA's exclusive authority over pesticide labels. In particular, the Court ruled that U.S. states remain free to enforce state labeling requirements that are "equivalent" to the "misbranding" standard set forth in FIFRA. Although facially narrow, the *Bates* exception has been interpreted by some lower courts to permit a range of "failure to warn" claims that likely would have been deemed preempted prior to *Bates*.

A good illustration of the impact of the *Bates* exception is provided by the recent litigation involving Monsanto's popular weedkiller, RoundUp®, containing the pesticide active ingredient, glyphosate. Thousands of private plaintiffs have sued Monsanto for compensatory and punitive damages, alleging that use of the product caused their (or a family member's) non-Hodgkin lymphoma, an often fatal blood cancer. To date, four plaintiffs have obtained verdicts in three jury trials totaling more than $2.4 billion in damages (subsequently reduced by the presiding judge in each case to a total of about $189 million).

The central assertion made by the plaintiffs in these cases is that Monsanto should have warned them of the cancer risks posed by the product. Prior to *Bates*, this claim likely would have been dismissed as preempted by FIFRA. The plaintiffs in these RoundUp cases, however, exploited the *Bates* exception, arguing that Monsanto withheld from EPA relevant evidence in its possession regarding the cancer risks posed by RoundUp – evidence that only came to light as a result of the litigation. This additional evidence, plaintiffs contend, demonstrates that RoundUp is indeed misbranded under FIFRA's standard and that therefore their state law failure to warn claims are not preempted.

As explained in a companion blog, EPA has recently has spoken to this issue. In 2017 (prior to any of the jury verdicts), EPA conducted yet another scientific review of glyphosate and concluded, again, that RoundUp can be used safety and is not a carcinogen. Then, in August 2019, EPA issued a statement announcing that will not approve glyphosate product labels bearing a cancer warning because such a warning, in EPA's judgement, would be false and misleading. It is not entirely clear whether EPA reviewed the putative additional evidence on carcinogenicity used by the plaintiffs in the litigation prior to issuing this statement. The context, however, strongly suggests that EPA was aware of this additional

evidence and has concluded that it does not change its assessment that glyphosate/RoundUp is not a carcinogen and should not bear a cancer warning on the label.

EPA's public statement that a cancer warning for RoundUp would be false and misleading significantly changes the calculus on the FIFRA label preemption defense in the ongoing RoundUp litigation. Whereas before plaintiffs were able to avoid preemption by arguing that EPA was not aware of evidence in Monsanto's possession showing that RoundUp posed a cancer risk, EPA's 2019 statement casts doubt on plaintiffs' ability to make this argument successfully in the future.

