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Another RoundUp® RoundUp

By

The saga concerning RoundUp®, the world's most popular weedkiller, continues apace. Litigation over the product first erupted after the World Health Organization's International Agency for Research on Cancer (IARC) declared in 2015 that the active ingredient in RoundUp, glyphosate, is "probably carcinogenic to humans." Thereafter, Monsanto – now part of Bayer – lost three successive jury trials in California involving claims that Bayer should have, but failed to warn users of the risk of cancer (specifically, non-Hodgkins lymphoma (NHL)), resulting in awards totaling nearly $190 million in compensatory and punitive damages. Bayer promptly filed appeals in all three cases. Nevertheless, by the end of 2019, Bayer was facing over 125,000 additional cancer claims against RoundUp.

In June 2020, Bayer entered into a $9.6 billion settlement agreement to resolve nearly all of these claims. The settlement also included $1.25 billion to resolve future claims, but the California federal court presiding over the cases rejected that portion of the settlement as unfair to future plaintiffs. Thereafter, Bayer negotiated a new settlement agreement worth $2 billion to resolve future claims. In May 2021, however, the same federal court rejected Bayer's new proposal as "clearly unreasonable," seeding doubts whether Bayer will ever be able to put together a settlement on future claims that will satisfy the court's concerns. Without a settlement in hand, Bayer indicated that it may withdraw RoundUp from the residential market, limiting its use to commercial agriculture.

Further, in June 2021, Bayer agreed to pay up to $45 million to resolve a nationwide class action in Delaware federal court that accused Bayer of defrauding consumers by offering RoundUp without a cancer warning.

Despite its $9.6 billion settlement for current claims, its willingness to pay $2 billion more to settle future claims, and its agreement to settle the consumer fraud class action, Bayer has steadfastly maintained that RoundUp is safe and not carcinogenic. Bayer's position is buttressed by several other scientific agencies around the world that have reviewed the extensive database on glyphosate and concluded, contrary to IARC, that RoundUp is not carcinogenic. In the U.S., the Environmental Protection Agency (EPA) strictly regulates pesticides under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA). After the IARC declaration, EPA conducted another scientific review and concluded once again that RoundUp can be used safely and is not a human carcinogen. Further, in August 2019, EPA issued a press release and letter making clear that it will not approve glyphosate product labels that include a cancer warning because it would be "false and misleading," in violation of FIFRA's "misbranding" standard.

Bayer's position that RoundUp is not carcinogenic is also buttressed by its victory in a lawsuit involving California's "Prop 65" list of "known carcinogens." Under the provisions of Prop 65, IARC's determination that glyphosate is "probably carcinogenic to humans" automatically triggered a requirement that sellers of glyphosate products in California provide a warning (albeit not necessarily on the product label) that the active ingredient in RoundUp is a "known carcinogen." Bayer challenged this requirement in federal court in California as violating its First Amendment rights to truthful speech. In June 2020, the court agreed and issued a permanent injunction against the requirement, based on "the heavy weight of evidence in the record that glyphosate is not in fact known to cause cancer." The court explained that the requirement for such a warning "undermines California's interest in accurately informing its citizens of health risks." The case is currently on appeal.

In light of EPA's public position in support of the current RoundUp label, and Bayer's victory in the Prop 65 litigation, Bayer has had good reason to hope that its appeals of the three adverse jury verdicts in California ultimately would be successful. As discussed in a prior blog, a core legal issue in these appeals is whether the plaintiffs' "failure to warn" claims are *preempted* under FIFRA, which prohibits states from imposing any labeling requirement "in addition to or different from" those imposed under FIFRA. In *Bates v. Dow*, 544 U.S. 431, 447 (2005), the Supreme Court ruled that only state labeling requirements – which would include state law "failure to warn" claims – that are "equivalent" to the "misbranding" standard in FIFRA are *not* preempted. Given EPA's public declaration that a cancer warning on the RoundUp label would render the product misbranded, Bayer could forcefully argue that plaintiffs' "failure to warn" claims are preempted.

In March 2021, however, a state appeals court rejected Bayer's preemption argument in *Johnson v. Monsanto*. (For case-specific reasons, Bayer stated that it would not appeal this decision.) Then, in May 2021, Bayer lost its appeal in a second case involving the same issue, *Hardeman v. Monsanto*, before the U.S Court of Appeals for the Ninth Circuit. In *Hardeman*, the Ninth Circuit expressly rejected Bayer's preemption defense based on EPA's August 2019 letter declaring that a cancer warning for RoundUp would violate FIFRA. The court reasoned that EPA's letter did not "carry the force of law," because it was not issued as part of a formal administrative proceeding, was not published in the Federal Register, did not provide for a hearing or other opportunity to respond, and lacked any sort of dispute-resolution process. An appeal in a third case involving the question of whether "failure to warn" claims are preempted by FIFRA is still pending.

The Ninth Circuit's decision in *Hardeman* stands for the proposition that even an EPA-approved pesticide label could be deemed "misbranded" by a court (or jury) adjudicating a "failure to warn" claim. It also means that, to avoid liability, pesticide manufacturers may have to seek to add an unapproved warning to the product label, even when EPA has made clear that the warning would violate FIFRA. For this reason, the pesticide industry finds the *Hardeman* decision deeply troubling.

Needless to say, it would be helpful for the U.S. Supreme Court to weigh in on whether plaintiffs' "failure to warn" claims are preempted under FIFRA and provide some certainty and finality to the issue. Bayer can and almost certainly will petition for Supreme Court review of the Ninth Circuit's decision in *Hardeman* . However, Supreme Court review is discretionary, so whether it will accept review of *Hardeman* is far from assured.

Supreme Court review is more likely if different federal courts of appeal are split on whether "failure to warn" claims are preempted by FIFRA. Recent court filings indicate that this could occur. Of note are decisions by courts in the Eleventh Circuit, which have been more receptive to defenses based on federal preemption of state law claims. For example, in *Kuenzig v. Hormel Foods Corp.*, the Eleventh Circuit ruled that a claim concerning an allegedly false or misleading food label was barred by a preemption provision in a federal law regulating food labels that is analogous to FIFRA's preemption provision. Similarly, in *Ezcurra v. Bayer*, a lower court in the Eleventh Circuit followed *Kuenzig* in dismissing a Florida consumer fraud suit concerning the RoundUp label based on a provision of the Florida statute that bars claims concerning acts permitted by federal law. The appeal of this decision is pending in the Eleventh Circuit.

Perhaps most important is a pending appeal in the Eleventh Circuit in *Carson v. Monsanto.* In that case, the lower court ruled that plaintiff's claim that Bayer failed to provide a cancer warning on the RoundUp label was preempted by FIFRA. Thereafter, Bayer settled with the plaintiff. Although the settlement is confidential, some of its terms have been disclosed. The plaintiff, Carson, received an initial payment of $100,000, but the settlement requires him to appeal the lower court's preemption ruling – in which Bayer prevailed – to the Eleventh Circuit, which the plaintiff has done. If Carson had declined to file the appeal, or if he withdraws the appeal, he forfeits nearly all of the $100,000. If Carson prevails in his appeal, he will receive "substantial" additional funds.

It appears that Bayer hopes that the Eleventh Circuit will uphold the lower court's ruling that Carson's "failure to warn" claim is preempted under FIFRA, creating a split between the Eleventh and Ninth Circuits. Regardless of which side prevails in the *Carson* appeal, the other side is likely to seek Supreme Court review of its decision. Thus, even if the Supreme Court elects not to review the *Hardeman* decision, the Court may well accept review of the *Carson* case if Bayer ultimately prevails in order to resolve the disagreement between the Ninth and Eleventh Circuits.

The Roundup saga continues.

