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Durnell v. Monsanto Oral Argument Before the Supreme Court
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The Supreme Court agreed to hear an appeal of the plaintiff verdict in the John Durnell versus Monsanto non-Hodgkin lymphoma (NHL) cancer case that had been tried in the State of Missouri.

The issue before the Court is stated on the SCOTUS website as:

> "Whether the Federal Insecticide, Fungicide, and Rodenticide Act preempts a label-based failure-to-warn claim where EPA has not required the warning."

The appeal challenged the "failure to warn" cause of action in the *Durnell v. Monsanto* case involving Roundup and NHL on the grounds that the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) preempts (overrules) state-law based "failure to warn" claims.

Bayer/Monsanto's appeal asserts that because federal EPA did not require Monsanto to add a cancer warning on the label of the Roundup products bought by Mr. Durnell, the judge in that trial should not have allowed the jury to consider the "failure to warn" cause of action. Durnell's defense is that both federal and state law prohibit the sale of a pesticide with a false or misleading label—meaning the requirements are identical and nothing is preempted.

As the plaintiff verdict in *Durnell* progressed through the appeal process, and eventually reached the SCOTUS, the primary justification advanced by lawyers for Bayer/Monsanto was that Monsanto could not add a cancer warning onto the Roundup products sold in Missouri, because doing so would impose an added, state-law driven labeling requirement that was "in addition to" the provisions contained in the EPA-approved Roundup label.

The *Bates v. Dow Agrosciences* (2005) decision established existing SCOTUS precedent governing failure to warn claims. In that ruling, the Supreme Court determined that as long as state law parallels federal requirements, it is not preempted.

The key question at the heart of this case and other pesticide preemption cases has become whether a pesticide product can be registered and still "misbranded" under FIFRA. A pesticide product is "misbranded" if its labeling, when adhered to, fails to avoid "unreasonable adverse effects on man or the environment".

If the Supreme Court holds that a registered pesticide with an EPA-approved label can nevertheless be misbranded, then a state-law based misbranding claim would not be in addition to what is required by FIFRA for two reasons:

- First, the requirement to avoid "unreasonable adverse effects" is shared, or common, under FIFRA and state law, and
- Second, FIFRA states that federal registration (i.e. an approved EPA label) "shall not be a defense" against misbranding.

If the justices follow this logic, then *Durnell* should stand. If the justices are persuaded that EPA's registration decision forecloses a finding that the product is misbranded, then Monsanto will likely win.

In recent years, the preemption defense has been advanced, and rejected, in most pesticide liability cases involving Roundup and NHL, paraquat and Parkinson's disease, and other pesticide litigation involving:

- An adverse human health outcome,
- Unacceptable product performance, or
- Collateral economic damage (e.g. herbicide carryover and damage to a subsequent crop, pesticide drift, harm to personal property like honey bees or livestock).

Appearances in *Durnell v. Monsanto* during oral argument were made on behalf of petitioner Bayer/Monsanto by Paul Clement; by Sarah Harris on behalf of the government and in support of Bayer/Monsanto; and, by Ashley Keller on behalf of respondent, Mr. John Durnell.

I attended the oral argument and offer these comments on key passages and points that arose during the oral argument. An effort is made to explain the relevance of references made to prior SCOTUS cases and rulings that were a primary focus throughout the oral argument. Thanks to Daniel Hinkle, Senior Counsel for Policy and State Affairs of the American Association for Justice, for assistance in explaining the relevance and impact of prior SCOTUS cases and rulings.

Below you will find comments made in response to certain passages in the *Durnell v. Monsanto* Oral Argument transcript identified by page and line number. Access the full transcript at: https://www.supremecourt.gov/oral_arguments/argument_transcripts/2025/24-1068_fcgj.pdf

The Oral Argument

In his brief opening statement, Mr. Clement claims that FIFRA preempts state-law based failure to warn claims via the "express terms of FIFRA" that "forecloses state labeling claims that are in addition to or different from those imposed by FIFRA." He claims that arguing otherwise "defies common sense" and cites the Court's 8-1 judgment in *Riegel v. Medtronic* (2008).

In the *Riegel v. Medtronic* case, a patient was injured when an FDA-approved heart catheter burst. Mr. Riegel sued Medtronic under state law. The Supreme Court ruled 8-1 for the manufacturer. SCOTUS concluded that once the FDA approves a medical device through its rigorous premarket review process, state juries can't impose new or different requirements by holding medical-device manufacturers liable under state tort law.

A key factor leading to the *Riegel v. Medtronic* ruling was the wording in the Medical Device Amendments, which ***explicitly preempts*** any state-law requirement that is “different from, or in addition to” federal requirements (such “explicit”, or stated preemption, is termed “express” preemption in court proceedings). In *Riegel*, the federal approval sets the requirements and expressly preempts state law.

Mr. Clement and Monsanto argued that FIFRA works the same way:

- FIFRA’s explicit preemption provision prohibits state-law requirements that are “different from, or in addition to” those requirements imposed by FIFRA;
- Registrants must use label language that the EPA has approved, and cannot unilaterally make substantive changes in most label provisions;
- The EPA had approved Roundup labels without a cancer warning, and therefore;
- A Missouri jury saying "you should have added a cancer warning” is a state requirement "in addition to" what EPA decided was necessary and, therefore, is preempted.

However, as the *Durnell* case moved through the appeals process and during the SCOTUS oral argument, counsel for Mr. Durnell argued that this line of argument, and the Court’s reasoning in *Riegel,* does not apply given the law governing *Durnell v. Monsanto*. FIFRA contains a provision lacking in medical device law—a section establishing that EPA registration "shall not be a defense" against misbranding claims (Section 136a(f)(2) in FIFRA).

One other point is key in this context – registrants are responsible for writing most of the content on pesticide product labels. The EPA almost always accepts the label language proposed by registrants. If a pesticide product label lacks a cancer warning, that reflects the judgment of the manufacturer that such a warning is not warranted.

But if a registrant is aware of data and science suggesting a risk of cancer, or some other harmful outcome, yet chooses to not add a warning and/or label directions designed to avoid such an adverse effect, the manufacturer may face litigation based on a “failure-to-warn” and/or negligence claim. If a registrant also takes steps to unlawfully hide or obscure data suggesting possible cancer risk, or other harm, from the EPA, such information can influence the outcome of trials and magnitude of damage awards. Such information has been presented to juries in all Roundup-NHL trials carried out to date.

Page 8, lines 1-9. Justice Jackson raises a key point that comes up several times during the oral argument. She asks Mr. Clement whether new information can emerge on a pesticide that turns a lawfully registered -- and ***not misbranded*** product -- into a ***misbranded one*** if the new information does not lead to label changes sufficient to avoid “unreasonable adverse effects” (the trigger for misbranding). Later, on p. 20, lines 17-20, Justice Jackson adds:

> “But there’s a 15-year window between when that product has to be reregistered again, and lots of things can happen in science in terms of developments about the product.”

Page 8, lines 10-15. Mr. Clement takes "...issue with that with respect to safety. Efficacy, as I think you know, is different, and that's why I think the *Bates* case is quite distinguishable [from *Durnell*] because the agency actually doesn't have to evaluate efficacy..."

This assertion regarding efficacy is factually wrong, and an attempt to steer the focus of the Court in this *Durnell* appeal away from product safety issues. The *Bates* case was not about the efficacy of Strongarm herbicide. This Dow Agrosciences herbicide worked well and controlled the weeds in the peanut fields of Texas farmers. But it persisted longer in the high pH soils common in the region, and as a result, did not break down as fast as it would in other soils.

As a result, the herbicide damaged the peanut crops and/or rotational crops, imposing economic losses on farmers deemed to be "unreasonable". The *Bates v. Dow Agrosciences* litigation was focused on whether FIFRA preempts the obligation of Dow to warn the Texas peanut farmers that the herbicide might damage treated crops planted in high pH soils.

The farmer's position prevailed. This established current SCOTUS precedent and guidance to state courts regarding defense challenges to failure-to-warn causes of action. In response to the SCOTUS ruling in *Bates*, Dow sought and secured from state regulators approval of Strongarm supplemental label language that prohibits applications on high-pH soils in Texas, Oklahoma, and New Mexico. EPA approved this supplemental labeling in accord with normal procedures, and the new language became part of the federal label. That is how FIFRA is supposed to work when unique issues arise or are recognized in a state.

P. 8, lines 20-23. Mr. Clement acknowledges that registrants have an obligation "to bring adverse information to the agency" but he does not acknowledge, nor discuss the consequences of, multiple instances in which Monsanto failed to do so years before Mr. Durnell purchased, applied, and was exposed to Roundup (e.g., Monsanto research on the genotoxicity of Roundup, and on the rate at which Roundup moves through skin). While Mr. Clement and the Government acknowledge this requirement, their interpretation of FIFRA would still preempt state failure to warn claims even if a company knowingly violated this obligation.

Such undisclosed new information would have been relevant in EPA's assessment of the adequacy of the directions for use, requirements for Personal Protective Equipment, and warnings on the label of the Roundup-brand, lawn and garden products bought and applied by Mr. Durnell.

P. 9, lines 18-23. Justice Jackson returns to issues arising from new information that emerges after the EPA has approved a label, and before a regularly scheduled, every-15-year reregistration review. Justice Jackson asks whether new information could render a product misbranded because of no, or an inadequate, response to "... a new research study". Mr. Clement responds:

> "So I disagree with that ... You know, the government may have a different view. I think the way you deal with that and the way the agency deals with that is either through amended registration or some cancellation process..."

Mr. Clement tries to steer clear of the issue brought up by Justice Jackson's questions. His suggestion that an "amended registration" is how the agency and registrants deal with such a circumstance is correct. When new risk concerns arise, registrants have a continuing obligation to propose new or different label directions, and/or add a warning, to avoid "unreasonable adverse effect". The EPA almost always accepts such proposed, new label language via approval of an "amended registration" application submitted by registrants.

But contrary to Mr. Clement's assertion, the cancellation process is rarely used to meet the need for revised label provisions to avoid misbranding. This is because the cancellation process takes years, is extremely resource intensive, and is pursued rarely by EPA as a result. Plus, any product formulation or label changes are typically delayed to the end of a multi-year cancellation process. In the interim, the product remains on the market, and typically with an inadequate label rendering the product arguably misbranded.

P. 12, line 23 to line 14, p. 13. Chief Justice Roberts asks about when a state reacts to new information "more quickly than the federal government..."

Mr. Clement responds (p. 13, lines 19-21) "...and the way they [a state] manifest their responsiveness is to mandate an additional or a different label requirement, I think that walks them in directly to the plain text of the express preemption in FIFRA."

But it does not. FIFRA grants states the authority to ban or restrict one or more, or all of the uses of a pesticide approved on its EPA label when a state sees a need to do so under state law to avoid "unreasonable adverse effects". This assertion, and related issues, arises again later in the oral argument.

P. 21, line 20. Justice Sotomayor begins an exchange with Mr. Clement to "pin down" the issue of whether a pesticide can be legally labeled but also misbranded.

She begins by noting "I too [along with justices who spoke earlier] believed that misbranding and registration were not inconsistent." Mr. Clement disagrees, and limits misbranding to a situation in which a registrant adds some language onto a product label that was not included in a previously approved label. He asserts that new information, or recognition of new risks that emerge after an EPA registration decision, cannot be the basis for misbranding. Justice Sotomayor then paraphrases her understanding of Mr. Clement's argument (p. 22, lines 9-14): "...if it's a failure to warn of something you should be warning, that would not be a misbranding claim; it would be a violation of a FIFRA obligation to disclose that information and ask for a change [in the label]."

Mr. Clement responds (p. 22, lines 15-19) "Absolutely." He then asserts that this analysis makes the FIFRA "regime" mirror the regime governing preemption in the case of medical devices. Justice Sotomayor then states "I think the problem [with Clement's analysis] is 136a(f)(2) because it also says a valid registration, however, is *prima facie* evidence [i.e., evidence that is

sufficient to establish a fact, or support a case, unless contradicted by opposing evidence] that the pesticide's labeling and packaging comply with the registration provisions of FIFRA. But that's prima facie. It's not presumptive. And so it seems to me, if its prima facie, it could be rebutted" (p. 23, lines 9-17).

In response, Mr. Clement brings up the *Pliva v. Mensing* (2011) case involving a patient made ill by a generic prescription drug. An individual sued a generic drug maker for failing to warn about dangerous side effects. The Court ruled 5-4 for the manufacturer because federal law required generic products to carry the ***exact same label*** as the brand-name drug—making it ***impossible*** for the generic manufacturer to add the warning. When federal law makes compliance with both state and federal rules impossible, the Constitution requires state law to give way. This is the scenario leading to assertions of "impossibility" preemption in a number of areas of law, including pesticide regulation.

In *Durnell*, Mr. Clement argues that Monsanto is in the same situation as a generic drug manufacturer like Mensing because Monsanto is required by FIFRA to carry the exact same EPA approved label when marketing a product in a state. Mr. Clement buttresses this argument by asserting that EPA regulations purportedly forbid Monsanto from unilaterally changing Roundup's label to add a cancer warning. Mr. Clement contends the company is stuck — and under *Pliva*, that means preemption.

However, Mr. Clement's assertions based on *Pliva* were challenged in *Durnell v. Monsanto*. The EPA/FIFRA framework governing label changes is much more flexible and fluid than the FDA framework for generic drugs, and was so designed to accommodate new information as experience is gained from real-world pesticide uses. Plus, the scope and depth of the premarket approval process for drugs is much more extensive and rigorous than the pre-market testing of pesticides, and includes human clinical trials and post-approval surveillance of efficacy and adverse reactions.

The process and data required by the Federal Food, Drug, and Cosmetic Act (FDCA) to change the uses and contraindications required on drug labels is rigorous and demanding. Under FIFRA, pesticide registrants are free to propose label changes when new information emerges or the need for a new use arises, and the EPA approves such changes via label amendments on essentially an annual basis. Plus, the "impossibility" argument is undermined by the fact that the EPA has approved cancer warnings on product labels—including one case where Bayer added a cancer warning through a simple notice process, and another example in which EPA approved a cancer warning on a generic glyphosate-based herbicide.

Under FIFRA, a company cannot sell a misbranded pesticide, and registration does not render misbranding "impossible". Under state law, a company cannot sell a misbranded pesticide either. In addition, FIFRA provides states with clear authority, and a processes, to impose additional requirements and restrictions on pesticide uses that are imposed via label changes, including even banning certain, or all, federally approved uses.

Why did Congress grant states such a role and authority? Congress recognized that the EPA and a state regulator might reach different factual conclusions over whether a federally labeled product can be used in a state without imposing "unreasonable adverse effects." For example over the years, California and some other states have periodically recognized the need for additional labeling to protect farm workers present in or near treated fields, and imposed new worker-protection provisions via supplemental labeling.

FIFRA allows states to impose new ***restrictions*** that reduce risks via state supplemental labels when deemed necessary by the state to avoid "unreasonable" effects. States must simply inform the EPA when such supplemental labeling is issued and in effect; the EPA rarely requests any data to support such changes, and almost never challenges such changes. Unless challenged by the EPA, such supplemental state labeling remains in effect.

But FIFRA clearly prohibits states from unilaterally adding new uses, or altering how a pesticide can be applied, ***if such changes would be expected to increase exposures***, and hence risk. States can request EPA to approve changes that pose new or heightened risks through a Section 18 "emergency exception" and Section 24 "special local need" supplemental label. However, states may not authorize such uses until approved by EPA.

The statute does not appoint the EPA Administrator as the ultimate fact finder on pesticide label accuracy -- and adequacy -- under the myriad conditions of use that arise across all 50 states. The nation's constitutional system tolerates differing federal versus state factual decisions about whether a product is "safe" or not, and whether it is misbranded, or not.

Differing federal vs. state risk assessment methods and data can cut both ways. A pesticide product labeled by EPA under FIFRA can be judged in a state as posing "unreasonable" risk under state law, and hence would be misbranded for use within the state in the absence of state supplemental labeling.

Alternatively, a pesticide use or application method not allowed on a federal, EPA label can be deemed by state regulators as not posing any "unreasonable" risks. Such a use can then be approved under state-specific, supplemental labeling that is subject to EPA review. EPA generally approves new uses pursued by states without any further analysis, unless the EPA foresees a substantial increase in exposures, and hence risk. In such cases, the EPA will typically require states to provide some additional data to update agency risk assessments. This process usually leads to approval in conjunction with different use directions, PPE, and/or warnings to mitigate possible, high-risk application scenarios.

P. 26, lines 23-24. In advancing his case that a labeled product cannot be misbranded, Mr. Clement asserts "...when it comes to misbranding, that's very specific...", citing the clear example of a registrant not placing on a label something that is required by EPA. But a pesticide product can be misbranded for a variety of other reasons that can lead to "unreasonable adverse effects" on people or the environment, including adverse economic impacts.

On page 28 (lines 12-15), Clement states further that when the EPA approves a label "... the agency is giving us a green light that we can go forward and market it as a pesticide or a herbicide as labeled and not have to worry about a misbranding offense."

This assertion assumes that, upon approval of a label by EPA, the registrant adheres continuously to all ongoing requirements in FIFRA, including adding limits on use and warnings sufficient to avoid "unreasonable" adverse effects when new information becomes available pointing to the need for label changes, as it did, for example, in the case of Roundup and cancer.

P. 29, lines 7-16. Justice Kavanaugh raises concern over classifying a use "misbranded" retroactively when new science emerges, and is deemed sufficient to justify changes in label directions and warnings. In reference to how the EPA is supposed to respond to new information, Mr. Clement adds that "... the real way you [EPA and registrants] sort of change warnings or take a pesticide off the market is through the cancellation proceedings."

This is factually incorrect. As noted before, cancellation proceedings rarely occur; and, warnings are changed routinely via the annual label amendment process. Label amendments are usually requested by registrants and approved with little or no assessment by EPA, as long as the change is not expected to increase exposures, and hence risks.

FIFRA establishes a continuing obligation on registrants to properly test their products, and provide any new, adverse information to the EPA. When registrants fail to do so, their products can become misbranded by virtue of inability to avoid "unreasonable adverse effects" under routine, labeled patterns of use.

In *Durnell*, there was new information in Monsanto's possession that was not presented to EPA, but was presented to the jury. The jury was informed that Monsanto was obligated by FIFRA to provide such information to the EPA in a timely manner (typically within 120 days), but did not do so.

One plausible reading of the jury's verdict in favor of Mr. Durnell is that the jury did feel there was adequate information in Monsanto's possession at the time Durnell was buying and applying Roundup to justify some PPE requirements and warnings.

P. 32, lines 9-12. Mr. Clement acknowledges that "design defect" causes of action under state law are not preempted, but then asserts that they are preempted if they involve a "back door" failure to warn claim. SCOTUS and appeal courts have ruled in past cases that a product's labeling and packaging are part of the design of the product.

Multiple design defect claims played a role in most Roundup-NHL cases. These include failure to require use of commonsense PPE (e.g., "wear gloves" when applying the product), wash spray solution off skin as soon as possible, and to be careful when repairing leaking equipment.

P. 33, line 23-line 2 p. 34. Mr. Clement argues that any state requirement that goes beyond the EPA label is preempted.

Not true, as explained previously. States are free to ban or restrict the use of a pesticide approved by EPA, and can also impose PPE requirements and label warnings that are not on federal labels. Such label changes advanced by states via supplemental labeling are quickly and routinely approved by EPA.

However, as noted above, states may not approve additional uses of a pesticide that lead to new or additional risks without EPA assessment and concurrence.

P. 35, line 21 – line 9, p. 37. Justice Jackson frames the retroactivity issue brought up by Justice Kavanaugh, with focus on what the *Bates* order calls for in terms of state law obligations that do, and do not trigger preemption. She asks for Mr. Clement's view of this issue

Mr. Clement's answer is largely unresponsive. He points out the obvious -- that a state label is preempted that calls for a "caution" signal word on a label where the EPA label includes the more serious "danger" signal word.

P. 38, lines 5-15. Justice Jackson returns to how the "FIFRA scheme" is designed to deal with new information and science that emerges in the 15 years between FIFRA-mandated reregistration reviews carried out by EPA. In reference to when new information emerges, she states "...I'm trying to understand why it couldn't be that both the EPA and state tort law can enforce the misbranding requirement in the interregnum."

Mr. Clement's response again fails to acknowledge that Monsanto possessed important, new information relevant to the evaluation of Roundup and cancer, but failed to inform EPA of such information as required by FIFRA. Unknown to the justices, some of this undisclosed information was discussed in considerable detail during the *Durnell* trial. In addition, the jury in *Durnell* learned of multiple steps Monsanto took over decades to: (1) twist or obscure the results of toxicology studies, (2) not share germane information with the EPA, (3) infuse the peer-reviewed scientific literature with ghost-written papers spinning science in a way that minimized the linkages between Roundup and cancer, and (4) attack scientists and organizations raising concerns about the genotoxicity and oncogenicity of Roundup.

The jury in *Durnell* likely concluded that the content of the labels on the Roundup products Durnell bought was deficient in terms of the need to avoid spray solution getting on his skin, as well as how to minimize exposures (e.g., "wear gloves when applying this product"), and what to do when exposures occur (e.g., "wash thoroughly with soap and water").

P. 44, lines 13-16. Ms. Harris, presenting for the government, states that the government does not see *Durnell* as a "new information" case.

But in fact "new information" played a major role in *Durnell*. This is because Monsanto failed to provide substantial new information to EPA that it came into possession of, and that FIFRA required the company to provide to the EPA on a timely basis.

Ms. Harris is correct in arguing that had Monsanto followed the law by providing the new information to EPA, and then worked with the agency to update applicator exposure estimates and augment label requirements accordingly, the company would have purportedly met its continuing obligations under FIFRA to avoid "unreasonable adverse effects". But that did not happen. During the trial, Durnell's lawyers asked the jury to consider the impact of Monsanto's systematic efforts to control the flow of scientific information on EPA's understanding of applicator exposures to Roundup, and the resulting risk of NHL.

P. 45, lines 1-5. Ms. Harris lays out what the EPA is supposed to do, and sometimes does, in addressing applicator exposures and risk, but did not do in the case of the labels on lawn and garden Roundup products bought and applied by Mr. Durnell.

In the ongoing glyphosate reregistration process that started in 2008, EPA decided to not even conduct an applicator exposure and risk assessment. Moreover, EPA openly acknowledges it lacks the essential data to do such an assessment (e.g., a valid dermal penetration study using Roundup, rather than pure glyphosate; and, a cancer study testing the oncogenic response following exposure to Roundup, and not just its active ingredient, glyphosate).

This is one of the reasons why EPA's "not likely" to pose cancer risk classification decision regarding glyphosate residue in food does little to inform cancer risks stemming from Roundup spray solution landing on an applicator's skin.

P. 48, lines 12-18. Ms. Harris explains that "...states, with respect to labeling, cannot propose their own labeling. States, of course, remain free to restrict the use of the pesticides under 136v(a). So, if a state said, look, within my borders, I just don't think this pesticide is safe, don't use it, they're free to do that." This key passage needs translation.

Ms. Harris and Mr. Clement agree that FIFRA grants states the authority, and right, to ban a specific use of a pesticide, or all uses. States may also impose restrictions on how a pesticide can be used in a state, including the addition of new PPE requirements and warnings.

But all state-driven changes in how, when, and where a pesticide is applied obviously require changes relative to what is on the EPA label. Such changes clearly fall outside of FIFRA's uniformity provision and ***are not preempted by FIFRA***. Such changes start out typically as a component of state-approved supplemental labels, and often soon become part of the federal label. Once on the federal label, the state-specific supplemental label provisions are no longer needed and are generally not renewed.

In response to Ms. Harris's point, Justice Gorsuch raises a key point (p. 48, lines 20-22). FIFRA provides states authority to stop the use of a pesticide approved by EPA when a state considers

the risks to be too great, so why would Congress deny states the right to impose tort liability if a pesticide was sold in violation of state law?

This question by Justice Gorsuch gets to the heart of the issues in *Durnell* and how existing law envisions the FIFRA "scheme" working to achieve its basic goal – "safe" use of pesticides that avoid unreasonable adverse effects.

P. 51, lines 11-17. Ms. Harris explains that when a cancellation proceeding is underway, or a high-risk application scenario is under review, EPA can ask the registrant to "please" make changes to reduce exposures.

Yes, indeed it can, and did in the 1986 Glyphosate Registration Standard document (the first "reassessment" of the science base supporting Roundup tolerances and labels after initial approvals in 1974).

In that 1986 EPA document, the agency imposed mandatory requirements for additional PPE and cautionary statements relative to Roundup dermal exposures. Monsanto refused to adopt most of them, and labels to this day do not include several commonsense exposure reduction measures called for by EPA in 1986.

P. 54, lines 12-17). Justice Sotomayor asks Ms. Harris about the 2022 agreement between EPA and California over language for a cancer warning on Roundup products sold in California that is both compliant with FIFRA and Proposition 65. Ms. Harris responds in error "Respectfully, that's from 2012..." The agreement between EPA and the State of California over a cancer warning on certain Roundup labels was reached in 2022.

Concluding Thoughts

Monsanto's legal strategy rests primarily on two earlier Supreme Court decisions regarding preemption: *Riegel v. Medtronic* and *Pliva v. Mensing*. Together, these cases are the best precedent that Monsanto could point to that supports their position that when federal regulators approve a product, state lawsuits can't second-guess EPA judgments.

But significant differences were highlighted by justices during oral argument in the laws governing medical device and generic drug approvals by the FDA, in contrast to what EPA and pesticide registrants are required to do under FIFRA.

Throughout the oral argument, Mr. Clement and Ms. Harris rejected the notion that an EPA approved product could simultaneously be misbranded. Their argument and assertions encompassed cases where "an unreasonable adverse effect" occurs in just some places in one or a few states (the high pH soils in *Bates*), and/or when new science points to the need for additional label directions and warnings (as in *Durnell*).

A disconnect loomed large throughout the oral arguments between Congressional intent, the "theory" of how FIFRA is supposed to work, and how it actually works in practice. The assertion by Mr. Clement and Ms. Harris that the Roundup products bought by Mr. Durnell were not misbranded rests on the presumption that the EPA approved label effectively instructed users of Roundup how and why to avoid "unreasonable adverse effects".

But facts presented to the jury over the course of the *Durnell* trial pointed out instances where Monsanto had kept the EPA, the scientific community, and users in the dark over possible Roundup risks. As a result, Monsanto hid potential "unreasonable adverse effects" that could have been mitigated by reformulation and simple label changes and warnings. The fact that such risks were recognized by European regulators, and minimized to a significant extent through routine regulatory processes in the European Union, likely was a factor taken into account by the jury in *Durnell*.

The SCOTUS ruling and opinion in *Durnell v. Monsanto* is expected in early summer, 2026. One prediction can be made with confidence -- some key passages in the FIFRA statute will need to be clarified to more clearly delineate state-versus-federal roles and responsibilities in pesticide regulation. The Heartland Health Research Alliance will be among the organizations working to craft amendments to FIFRA that will hopefully avoid the need for a third round of SCOTUS review of the core issues that gave rise to the *Durne*ll appeal.