

# More Individualized and Easier to Follow: A Case for Changes to the Production of Pesticide Warning Labels

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*To fulfill its statutory mandate under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the U.S. Environmental Protection Agency (EPA) should provide information about risk factors for developing cancer, both in terms of individual risk profiles and making the results of the registration and re-registration reviews more accessible to the public. Most people in the United States are unaware of risk factors for developing cancer, and the language of EPA's registration and re-registration processes for pesticide warning labels remains opaque. By remedying these issues of access to both consumers' risk profiles for developing cancer and EPA's own deliberative process for approving pesticide warning labels, EPA can create a regulatory regime in which consumers will have more information with which to choose how they approach using pesticides and pesticide manufacturers are less likely to face failure to warn lawsuits from consumers. These benefits would occur even though the ultimate disposition of the Eleventh Circuit case Carson v. Monsanto, which addresses whether FIFRA overrides state law failure to warn claims, is uncertain.*

|   |     |
|---|-----|
| Introduction .....  | 350 |
| I. Confusion About Federal Preemption of State Tort Law .....           | 353 |
| II. The Link Between Regulatory Standards and the State Failure to Warn |     |
| Tort .....  | 357 |
| A. EPA Registration and Re-registration Under FIFRA.....                | 357 |
| 1. Statutory and Regulatory Standards .....                             | 357 |
| 2. The Difficult Case of Glyphosate .....                               | 359 |

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|      |   |     |
|------|---|-----|
| B.   | The State Law Failure to Warn Tort .....  | 360 |
| 1.   | Elements of the Claim .....   | 360 |
| 2.   | Caselaw that Illustrates Failure to Warn Requirements for<br>Pesticide Labeling ..... | 361 |
| 3.   | How the Regulatory Standards Influence State Failure to<br>Warn Cases .....           | 363 |
| III. | Adding Cancer Risk Factors and Other EPA Data to Pesticide Labels ..                  | 364 |
| A.   | How EPA Can Make this Addition .....  | 364 |
| B.   | What this Would Mean for Glyphosate Standards and Failure<br>to Warn Claims .....     | 367 |
| C.   | Potential Drawbacks and Benefits for Both Consumers and<br>Manufacturers .....        | 367 |
|      | Conclusion .....  | 371 |

#### INTRODUCTION

John D. Carson had been using Roundup on his lawn for thirty years before he was diagnosed with malignant fibrous histiocytoma in 2016.<sup>1</sup> In response to his diagnosis, Carson sued Monsanto, the manufacturer of Roundup.<sup>2</sup> His cause of action rests on a state “failure to warn” claim.<sup>3</sup> Failure to warn claims are tort claims through which plaintiffs can, under certain conditions, hold manufacturers liable for not having given adequate notice about the risks of using their products.<sup>4</sup> Carson maintains that Monsanto did not warn him sufficiently about the risks of using Roundup in the label that Monsanto registered with the U.S. Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and then placed on Roundup’s packaging.<sup>5</sup>

The ultimate outcome of Carson’s case remains unsettled, and the case is currently on appeal at the Eleventh Circuit.<sup>6</sup> Regardless of the Eleventh Circuit’s decision after rehearing, there remains another viable option for EPA to give individual pesticide consumers the tools they need to have more control over how much risk they take on by using a given pesticide.<sup>7</sup> To better fulfill its existing obligations under FIFRA, EPA should use the warning labels that FIFRA requires for pesticide labels to more effectively inform consumers about the risk factors that make a person more likely to develop cancer from using a

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1. Carson v. Monsanto Co. (*Carson I*), 39 F.4th 1334, 1337 (11th Cir. 2022).

2. *Id.*

3. *Id.*

4. RESTATEMENT (SECOND) OF TORTS § 388 (AM. L. INST. 1965).

5. *Carson I*, 39 F.4th at 1337.

6. Order of the Court, Carson v. Monsanto, No. 21-10994 (11th Cir. Dec. 19, 2022), ECF No. 113-2 (granting rehearing en banc).

7. For the sake of this Note, consumers are people who apply a pesticide.

given pesticide. Through this change, consumers will be able to modulate their usage of pesticides to reduce their health risks.

Consumers do not all have the same risk profile for developing cancer.<sup>8</sup> Factors specific to each person can contribute to how much risk each person has.<sup>9</sup> In addition, different kinds of personal protective equipment (PPE) can change the amount of that pesticide to which the person is exposed.<sup>10</sup> EPA's warning labels currently do not inform people of these individualized risk factors, but instead offer what amounts to a one-size-fits-all approach.<sup>11</sup> EPA should instead require pesticide manufacturers to give consumers access to such individualized information through warning labels.

If EPA makes this regulatory change, it would benefit both consumers and pesticide manufacturers, albeit for distinct reasons. EPA would create a regulatory regime in which pesticides may cause consumers less harm because consumers would be more informed about how to reduce their risk of pesticide-induced harms. If consumers who read the warning labels have a better idea of their individual risk factors for cancer and ways to apply a pesticide that reduce their exposure to that pesticide, they will be able to adjust their behavior to protect their health, at least in principle (due to how PPE is provisioned at workplaces,<sup>12</sup> this adjustment may become a bit complicated in practice). Manufacturers, for their part, will have a more cogent idea of what precisely they need to include on pesticide warning labels to warn the public about their products. This clarity may become increasingly important because the framework on FIFRA preemption of state failure to warn claims may become even more unsettled than it is presently.<sup>13</sup> Since consumers who have a choice over how much pesticide they apply will be able to exercise that choice with more relevant information and pesticide manufacturers will have a clearer sense of what they need to put in their warning labels, those manufacturers will be less vulnerable to lawsuits on state failure to warn claims. This Note argues these positive effects would still happen even after the Eleventh Circuit's decision

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8. AM. INST. FOR CANCER RSCH., 2019 AICR CANCER RISK AWARENESS SURVEY 3–4 (2020), <https://www.aicr.org/assets/can-prevent/docs/2019-Survey.pdf>.

9. *Id.*

10. Ewan MacFarlane et al., *Dermal Exposure Associated with Occupational End Use of Pesticides and the Role of Protective Measures*, 4 SAFETY & HEALTH WORK 136, 139 (2013) (showing that even among a given kind of personal PPE (e.g., gloves and coveralls), the kind of material the PPE is made of affects its efficacy in protecting the wearer from pesticide exposure).

11. *See, e.g.*, SHAJA B. JOYNER, EPA, NOTIFICATION PER PRN 98-10 – CHANGING CONTAINER ‘DISPOSAL’ TO ‘HANDLING’ AND CHANGING TRADE NAMES OF TANK MIX 2–3 (Nov. 25, 2015), [https://www3.epa.gov/pesticides/chem\\_search/ppls/034704-00854-20151125.pdf](https://www3.epa.gov/pesticides/chem_search/ppls/034704-00854-20151125.pdf) (showing a fairly ordinary pesticide warning label that takes a one-size-fits-all approach to risks that the pesticide produces, instead of including a warning that includes individualized risk factors for cancer development).

12. *See* Training Requirements for Handlers, 40 C.F.R. § 170.501(c)(3)(x) (2023).

13. Although the Eleventh Circuit held that FIFRA does not preempt all state law failure to warn claims about pesticide warning labels in *Carson I* and kept that holding in *Carson II*, the court vacated this holding in December 2022 pending rehearing. *Carson I*, 39 F.4th at 1337; *see Carson v. Monsanto Co. (Carson II)*, 51 F.4th 1358, 1361 (11th Cir. 2022); *see* Order granting rehearing en banc, *Carson v. Monsanto*, *supra* note 6, at 2.

upon rehearing *Carson* in July 2023 (and no matter how the Eleventh Circuit or U.S. Supreme Court potentially decide *Carson* in the future).

Part I of this Note explains the current state of confusion about federal preemption of state failure to warn claims. To achieve that aim, Part I describes the increasingly complex case history of *Carson v. Monsanto*. As of late 2023, the outcome of this case is unsettled,<sup>14</sup> and the case's disposition has gotten more complicated since the Eleventh Circuit issued *Carson I* in mid-2022.<sup>15</sup> In the midst of this confusion, it may soon become unclear whether EPA's processes for registering and re-registering pesticide warning labels satisfy state law failure to warn requirements.

Part II of this Note delves into the link between regulatory standards for pesticides and the tort of failure to warn. Part II begins by discussing EPA's registration and re-registration processes<sup>16</sup> for pesticide warning labels, with glyphosate as an (imperfect) case study in how that process works. Part II then explains the tort of failure to warn, including the elements of a successful failure to warn claim, the national picture of failure to warn claims, and how changing regulatory standards have the potential to affect these claims.

Finally, Part III addresses what a regulatory regime that better informs consumers of their individual risk profiles might look like in practice. Part III does so in two parts. First, Part III discusses what this change in EPA's regulatory regime would look like and how EPA could go about implementing it, both administratively and practically. Because of advances in technology and databases that EPA already has, EPA can already make such information both relatively easily available and more accessible to the general public.<sup>17</sup> Part III also contains some other ideas on how EPA could make the system even more available to members of the public who would otherwise have trouble accessing this informational system.

The second half of Part III describes potential drawbacks to the proposed regulatory regime and explains how the provision of individualized risk information can benefit both consumers and pesticide manufacturers. Consumers who read pesticide warning labels under this modified regime will have a more accurate idea of how much of a pesticide they can use before being at elevated risk of serious illness or death. These consumers will therefore be able to make more informed decisions about their pesticide use, which will result in (1) less injury from pesticide usage and (2) less litigation against pesticide manufacturers on failure to warn claims. Pesticide manufacturers will also have a more accurate

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14. Order granting rehearing en banc, *Carson v. Monsanto*, *supra* note 6, at 2.

15. See *Carson I*, 39 F.4th at 1334; *Carson II*, 51 F.4th at 1361; Order granting rehearing en banc, *Carson v. Monsanto*, *supra* note 6, at 2.

16. This Note refers to both the registration and re-registration processes for pesticide warning labels as the "registration process."

17. See *infra* Subpart III.A; see *Pesticide Product Label System (PPLS): More Information*, EPA (2022), <https://www.epa.gov/pesticide-labels/pesticide-product-label-system-ppls-more-information>.

idea of what they need to put on the warning labels, which will help them avoid consumer lawsuits.

#### I. CONFUSION ABOUT FEDERAL PREEMPTION OF STATE TORT LAW

In *Carson I*, the Eleventh Circuit held that FIFRA did not override state failure to warn claims that required either less than or the same amount of warning as what FIFRA required for pesticide packaging.<sup>18</sup> The Eleventh Circuit also held that on that basis, FIFRA did not expressly override Carson’s failure to warn claim against Monsanto under Georgia common law.<sup>19</sup> In a separate case, the Ninth Circuit agreed with the Eleventh Circuit on the scope of FIFRA preemption of state law failure to warn claims,<sup>20</sup> and the Supreme Court recently denied certiorari to both that case and another court case with the same holding.<sup>21</sup> With no contrary ruling from the Supreme Court or other circuit courts, the Eleventh Circuit’s holding in *Carson I* had seemed relatively secure.

The Eleventh Circuit’s reasoning in *Carson I* consisted of two main prongs. First, the court held that registration with EPA is prima facie evidence that the manufacturer followed FIFRA’s registration requirement.<sup>22</sup> In other words, proof of such registration is not proof that the manufacturer followed FIFRA’s packaging and labeling requirements.<sup>23</sup> Rather, proof of registration is only proof that the registration happened—it is not proof that the warning was adequate notice for consumers.<sup>24</sup> Second, the court reasoned that although EPA had produced various documents evaluating glyphosate’s carcinogenicity in the course of the re-registration process, EPA had not produced these documents that informed the Interim Registration Review Decision via “notice-and-comment rulemaking” or by any other kind of “formal adjudication,”<sup>25</sup> so these documents did not have the force of law and therefore could not expressly preempt state law failure to warn claims.<sup>26</sup> Furthermore, the court found that the registration process itself was not “formal” enough to be “notice-and-comment rulemaking,” since it only created a “rebuttable presumption” that a manufacturer followed EPA’s registration guidelines “and nothing more.”<sup>27</sup>

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18. See *Carson I*, 39 F.4th at 1339–40 (citing 7 U.S.C. § 136a(f)(2)).

19. See *id.* at 1340.

20. See *Hardeman v. Monsanto Co.*, 997 F.3d 941, 950 (9th Cir. 2021), *cert. denied*, 142 S. Ct. 2834 (2022).

21. *Id.*; Amended Brief of U.S. Chamber of Com., Pharm. Rsch. & Mfrs. of America, & Prods. Liab. Advisory Liab. Council, Inc. as Amici Curiae in Support of Petition for Rh’g. En Banc, at 3–4, *Carson v. Monsanto Co. (Carson II)*, 51 F.4th 1358 (11th Cir. 2022) (No. 21-10994), 2022 WL 4182567.

22. *Carson I*, 39 F.4th at 1339–40 (citing 7 U.S.C. § 136a(f)(2)).

23. *Id.*

24. See *id.*

25. This Note discusses what notice-and-comment rulemaking and formal adjudication are in more detail in Subpart II.A, *infra*.

26. *Carson I*, 39 F.4th at 1339–40 (citing 7 U.S.C. § 136a(f)(2)).

27. *Id.*

Although the future of *Carson I*'s holding was by all appearances secure in the summer and early autumn of 2022, the situation has become more unsettled as of 2023. On August 10, 2022, industry actors including the U.S. Chamber of Commerce filed an amicus brief that encouraged the Eleventh Circuit to reconsider its opinion in *Carson I* en banc.<sup>28</sup> The amicus brief urged the court to rehear the case on one of the grounds that Monsanto argued in *Carson I* and that the court specifically repudiated in its initial ruling.<sup>29</sup> The industry coalition argued that FIFRA categorically overrode state law failure to warn claims and the plaintiff therefore could not prevail in his suit against Monsanto.<sup>30</sup>

On October 28, the Eleventh Circuit responded to the amicus brief by withdrawing and reissuing its opinion in *Carson v. Monsanto*.<sup>31</sup> The second ruling was not a reversal of *Carson*.<sup>32</sup> On the contrary, this second ruling, which this Note refers to as *Carson II*, was a continuation of *Carson I* in substance.<sup>33</sup> The Eleventh Circuit's ruling in *Carson II* had precisely the same core holding as *Carson I*,<sup>34</sup> and the reissued holding only featured minor changes in sentence order and wording from its predecessor opinion.<sup>35</sup> Then, on November 14, the same industry coalition refiled the amicus brief that they originally filed on August 10.<sup>36</sup> The brief's purpose was once again to urge the Eleventh Circuit to rehear the case en banc, principally on the rationale that FIFRA's labeling provisions do in fact preempt state failure to warn claims concerning pesticide warning labels.<sup>37</sup>

On December 19, the Eleventh Circuit took a step towards granting the request for rehearing, and the court announced that based on an internal poll of its constituent judges, the court would agree to rehear *Carson v. Monsanto* en banc.<sup>38</sup> In the meantime, the Eleventh Circuit vacated the entirety of its holding in *Carson I* pending rehearing.<sup>39</sup> As of late 2023, *Carson I* is no longer good (i.e., current) law.<sup>40</sup> The Eleventh Circuit issued a new ruling in July 2023 (which this Note refers to as *Carson III*), determining that the canons of statutory

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28. Amended Brief of U.S. Chamber of Com., Pharm. Rsch. & Mfrs. of America, & Prods. Liab. Advisory Liab. Council, Inc. as Amici Curiae in Support of Petition for Rh'g. En Banc, at 3–4, *Carson v. Monsanto Co.* (*Carson II*), 51 F.4th 1358 (11th Cir. 2022) (No. 21-10994), 2022 WL 4182567.

29. *Id.*

30. *Id.*

31. *Carson II*, 51 F.4th at 1358.

32. *See generally id.*

33. *Compare Carson II*, 51 F.4th at 1358, with *Carson I*, 39 F.4th at 1340.

34. The Eleventh Circuit held in *Carson I* that FIFRA did not expressly preempt state failure to warn claims regarding pesticide warning labels. *Carson I*, 39 F.4th at 1339–40.

35. *Compare Carson II*, 51 F.4th at 1358, with *Carson I*, 39 F.4th at 1340.

36. Motion to Consider Previously-Filed Brief of Amici Curiae in Connection with Renewed Petition for Rh'g. En Banc, *Carson v. Monsanto*, (11th Cir. 2022) (No. 21-10994), 2022 WL 17090586.

37. *Id.*

38. Order granting rehearing en banc, *Carson v. Monsanto*, *supra* note 6, at 2.

39. *Id.* Since the holding of *Carson I* is not substantively different from the court's slightly edited holding in *Carson II*, this Note refers to the holding of both decisions as the *Carson I* holding. *Compare Carson II*, 51 F.4th at 1358, with *Carson I*, 39 F.4th at 1340.

40. *See* Order granting rehearing en banc, *Carson v. Monsanto*, *supra* note 6, at 2.

interpretation are what decide whether FIFRA preempts Georgia's failure to warn law for pesticide warning labels.<sup>41</sup> However, the court did not decide whether those interpretative canons actually meant that the state law was preempted in this instance.<sup>42</sup> Instead, the court remanded the case to the district court to resolve that question.<sup>43</sup>

This turn of events leaves vague whether FIFRA will preempt a given state's law on pesticide warning labels, and eventually this case could conceivably come before the Eleventh Circuit once again. At that point, Georgia's failure to warn provision may become uncertain, and it is possible that the Eleventh Circuit could eventually hold that FIFRA does preempt Georgia's failure to warn law on pesticide warning labels—in effect, wholly repudiating *Carson I*. The extent to which the Eleventh Circuit might reverse itself if it reconsiders this case is unclear. For example, the court could maintain the current regulatory regime after *Carson III* in which FIFRA only overrides some state failure to warn claims and not others. On the other extreme, though, the Eleventh Circuit could reverse *Carson I* and conclude that FIFRA overrides state failure to warn claims in all instances.

A full Eleventh Circuit reversal of the holding of *Carson I* would have at least two main consequences. First, it would be a fatal setback for Carson's case against Monsanto. If FIFRA's pesticide warning label provisions override all state common law failure to warn claims, Georgia's failure to warn law would no longer apply to pesticide warning labels, so Carson would no longer have this cause of action available to sue Monsanto. More broadly, a full-scale reversal of *Carson I* by the Eleventh Circuit would spread confusion for consumers and pesticide manufacturers alike because it would create a split in the federal circuit courts on the issue. The Ninth Circuit, for instance, has held that FIFRA's pesticide warning label provisions do not preempt state failure to warn claims.<sup>44</sup>

This split would thus create an awkward situation in which a federal law would have different effects in different parts of the country. Unless the Supreme Court were to take up the issue, this area of law would become even more unsettled than its present state. The U.S. Constitution requires that certain cases (such as those with states as parties or cases involving ambassadors) be sent directly to the Supreme Court, but a case such as *Carson* is not one of them.<sup>45</sup> The Supreme Court has discretion to decide when, if at all, to examine *Carson*.<sup>46</sup> Therefore, if the Eleventh Circuit reverses itself in *Carson*, there would be no way of knowing how long the ensuing regulatory turbulence might last.

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41. *Carson III*, 72 F.4th at 1267–68.

42. *Id.* at 1268.

43. *Id.*

44. *See Hardeman v. Monsanto Co.*, 997 F.3d 941, 950 (9th Cir. 2021), *cert. denied*, 142 S. Ct. 2834 (2022).

45. *See* U.S. Const., Art. III, § 2, cl. 2.

46. *See id.*

The overall balance of legal authority, however, suggests that even if the Eleventh Circuit reverses its position in *Monsanto*, the reversal might neither endure for long in the Eleventh Circuit nor take hold nationally. First, although information regarding the other circuits' opinion on the subject is limited, the one other circuit that has ruled on this issue was of the same opinion as the Eleventh Circuit in *Carson I*—in other words, the other circuit court to rule on the issue found that FIFRA does not override state law failure to warn claims.<sup>47</sup> Second, the Supreme Court has already held that FIFRA does not constitute a blanket express override of state failure to warn laws about pesticide warning labels in its 2005 holding in *Bates v. Dow*.<sup>48</sup> The third and potentially most compelling reason is that the Supreme Court might already approve of the Eleventh Circuit's opinion in *Carson I*. In the summer of 2022, the Supreme Court denied petitions for certiorari for state and lower federal court cases that came to the same holding as the Eleventh Circuit in *Carson I*.<sup>49</sup>

The Court's specific motivation for denying certiorari for those two cases remains inscrutable for the time being.<sup>50</sup> The denials of certiorari do not necessarily say anything about the Court's motivations in those cases.<sup>51</sup> It could be that the Court simply did not have the necessary space on their docket to delve into this issue absent a clear split in the circuits. On the other hand, the Court could have already agreed with the outcomes of those cases in the state and lower federal courts and denied certiorari because it saw no error in their decisions. If the Eleventh Circuit reverses its ruling in *Carson I*, then there will be a split between the Eleventh Circuit and the Ninth Circuit, creating a situation where the Supreme Court's resolution will be necessary. It could be that a majority of the Court is in accord with the Eleventh Circuit's ruling in *Carson I*, but this outcome is not assured by any means.

If the denials of certiorari indicate that the Supreme Court agrees with the state and lower federal courts' opinions on FIFRA preemption, the long-term path of the issue of FIFRA preemption of state law failure to warn claims is likely clear enough. Although there may well be a split between the circuits on the matter soon, the emergence of such a split will make the issue more likely to reach the Supreme Court, especially if the split is in completely opposite directions. If a majority of the Supreme Court justices are in favor of the Eleventh Circuit's initial holding in *Carson I*, then the Court will have occasion to bring back that holding and apply it to *Carson's* case. FIFRA would continue its status of not overriding state law failure to warn claims, and the basis for corporate and individual behavior on pesticide warning labels would be on firmer ground than it is at present.

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47. See *Hardeman*, 997 F.3d at 950.

48. See *Bates v. Dow Agrosociences LLC*, 544 U.S. 431, 444 (2005) (citing 7 U.S.C. § 136v(b)).

49. See *Hardeman*, 997 F.3d at 950; *Pilliod v. Monsanto Co.*, 67 Cal. App. 5th 591, 600–01 (Cal. Ct. App. 2021), *cert. denied*, 142 S. Ct. 2870 (2022); see generally *Carson I*, 39 F.4th.

50. See *Hardeman*, 997 F.3d at 950; see *Pilliod*, 67 Cal. App. 5th at 600–01.

51. See *Hardeman*, 997 F.3d at 950; see *Pilliod*, 67 Cal. App. 5th at 600–01.



At the same time, the Supreme Court could, in principle, reinstate FIFRA preemption of state failure to warn claims for pesticide warning labels. In addition, the public does not yet know what the Supreme Court justices' views on the subject are (or, indeed, if they have opinions on the subject yet, given that nearly two decades have passed since the Court's ruling in *Bates v. Dow*). A majority of Supreme Court justices could already disagree with the holding of *Carson I*, or they may be waiting for a case to come before them to formulate their point of view fully. In any event, a circuit split would provide the justices with an opportunity to make known their opinion on this area of law.

## II. THE LINK BETWEEN REGULATORY STANDARDS AND THE STATE FAILURE TO WARN TORT

Part II of this Note begins by examining how this current landscape of federal preemption of state failure to warn claims intersects with federal pesticide warning label laws. From there, Part II lays out what a failure to warn tort is, what a successful claim looks like, and how changing regulatory standards might affect state law failure to warn claims on pesticide warning labels.

### A. EPA Registration and Re-registration Under FIFRA

Under FIFRA, manufacturers of pesticide products must follow a registration process, which includes requirements for warning labels.<sup>52</sup> The subsection below covers the general statutory and regulatory framework for failure to warn, as well as why that framework is insufficient for regulating pesticides such as glyphosate.

#### 1. Statutory and Regulatory Standards

For EPA to approve a pesticide's registration, the manufacturer of that pesticide must provide a warning label on the pesticide's packaging when such a label "may be necessary and if complied with . . . is adequate to protect health and the environment."<sup>53</sup> Since 2007, Congress has required EPA to review a given pesticide's registration every fifteen years, with the first reviews of pre-2007 warning label registrations due by October 1, 2022.<sup>54</sup>

EPA's process for registering and re-registering pesticide warning labels follows a form that has procedural elements of notice-and-comment rulemaking, even though the Eleventh Circuit found in *Carson I* that the process itself was not notice-and-comment rulemaking because it only provided a "rebuttable

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52. 7 U.S.C. § 1336a(a).

53. 7 U.S.C. § 136(q)(1)(G).

54. 7 U.S.C. § 136a(g)(1)(A).

presumption of [a manufacturer's] compliance with FIFRA's registration processes."<sup>55</sup>

EPA does not conduct notice-and-comment rulemaking for its pesticide registration process under FIFRA, but it does allow the public to comment on proposed decisions.<sup>56</sup> The process of reevaluating glyphosate's warning label<sup>57</sup> began in 2015, when EPA conducted a review of "epidemiological, animal carcinogenicity, and genotoxicity studies" relating to glyphosate.<sup>58</sup> EPA then brought the issue of glyphosate's carcinogenicity before the FIFRA Scientific Advisory Panel (SAP).<sup>59</sup> Once the FIFRA SAP issued its report,<sup>60</sup> EPA issued a response paper<sup>61</sup> and edited its findings about glyphosate's carcinogenicity to take the FIFRA SAP's findings into account.<sup>62</sup>

From this point, EPA began to bring industry actors and members of the public into the decision-making mix. EPA held a sixty-day public comment period for glyphosate's "preliminary risk assessments," during which 238,290 comments comprising 2,244 "unique submissions" came through to EPA.<sup>63</sup> After considering those public comments, EPA issued its first Proposed Interim Registration Review Decision in April 2019.<sup>64</sup> This proposed decision addressed both the distinct comments that came through about its preliminary risk assessments and EPA's findings about different aspects of glyphosate's risk, including risk from occupational use, non-occupational use, and aggregate

55. *Carson I*, 39 F.4<sup>th</sup> at 1339–40 (citing 7 U.S.C. § 136a(f)(2)). It remains to be seen, however, if the Eleventh Circuit will maintain this categorization of the registration process after rehearing *Carson*. Under notice-and-comment rulemaking, an agency first issues a "general notice of proposed rulemaking," which provides the public with the opportunity to give comments about that notice. 5 U.S.C. §§ 553(b)-(c). The agency must consider each comment that the public submits. § 553(c). After at least thirty days during which the public has had the opportunity to submit comments and the agency has had the opportunity to respond to those comments, the agency can send out a notice of the final rule. *Id.* § 553(d).

56. *Carson I*, 39 F.4<sup>th</sup> at 1340 (citing 7 U.S.C. § 136a(f)(2)).

57. The process for reevaluating glyphosate is typical of the process that EPA has followed for other pesticide warning label reevaluations. *Compare Glyphosate*, EPA (Sept. 23, 2022), <https://www.epa.gov/ingredients-used-pesticide-products/glyphosate>, with *Registration Review Process*, EPA (Nov. 16, 2022), <https://www.epa.gov/pesticide-reevaluation/registration-review-process>.

58. *Glyphosate*, *supra* note 57.

59. *Id.*

60. See generally STEVEN M. KNOTT, EPA, TRANSMISSION OF MEETING MINUTES & FINAL REPORT OF THE DEC. 13-16, 2016 FIFRA SAP MEETING HELD TO CONSIDER & REVIEW SCIENTIFIC ISSUES ASSOCIATED WITH EPA'S EVALUATION OF THE CARCINOGENIC POTENTIAL OF GLYPHOSATE, EPA-HQ-OPP-2016-0385-0526 (2017), <https://downloads.regulations.gov/EPA-HQ-OPP-2016-0385-0526/content.pdf>.

61. See generally GREGORY ACKERMAN & MONIQUE M. PERRON, EPA, RESPONSE TO THE FINAL REPORT OF THE FEDERAL INSECTICIDE, FUNGICIDE, & RODENTICIDE ACT SCIENTIFIC ADVISORY PANEL (FIFRA SAP) ON THE EVALUATION OF THE HUMAN CARCINOGENIC POTENTIAL OF GLYPHOSATE (2017), <https://downloads.regulations.gov/EPA-HQ-OPP-2016-0385-0527/content.pdf>.

62. OFF. OF PESTICIDE PROGRAMS, EPA, REVISED GLYPHOSATE ISSUE PAPER (2017), <https://www.regulations.gov/document/EPA-HQ-OPP-2009-0361-0073>.

63. PESTICIDE RE-EVALUATION DIV., EPA, GLYPHOSATE PROPOSED INTERIM REGISTRATION REVIEW DECISION CASE NUMBER 01785 (2019), <https://www.regulations.gov/document/EPA-HQ-OPP-2009-0361-2344>.

64. *Id.* at title page.

exposure (i.e., overall exposure that a person could get from multiple pathways at once, such as from food and from water).<sup>65</sup> In January 2020, EPA proceeded to issue its Interim Registration Review Decision for glyphosate.<sup>66</sup>

## 2. *The Difficult Case of Glyphosate*

EPA's stance on glyphosate is that it is unlikely to be carcinogenic when consumers use it in accordance with the pesticide's warning labels.<sup>67</sup> In July 2022, the Ninth Circuit held that EPA needed to redo its registration of glyphosate's warning label by October of that year<sup>68</sup> because in the lead-up to EPA releasing its interim re-registration decision for glyphosate, EPA had not followed its own "Guidelines for Carcinogen Risk Assessment" when developing its findings.<sup>69</sup> Although EPA mentioned the guidelines frequently in its decision, it did not describe sufficiently in its decision how those guidelines factored into EPA's logic.<sup>70</sup> This lack of explanation rendered EPA's decision "arbitrary," which was fatal for the ecological and human health portions of its decision as it stood.<sup>71</sup> The court ordered the agency to reissue its whole interim decision by October 1, 2022.<sup>72</sup>

EPA proved unable to meet this deadline,<sup>73</sup> so the agency withdrew its Interim Registration Review Decision.<sup>74</sup> According to the agency, it failed to meet the Ninth Circuit's deadline because it had not yet completed the ecological review section of its revised interim registration review decision.<sup>75</sup> As of September 2022, however, EPA had not changed its stance that glyphosate was unlikely to be a human carcinogen when used in the ways prescribed by the warning label.<sup>76</sup>

The urgency of getting the process right may be particularly salient for glyphosate, given its increasingly widespread usage in the United States. Since EPA approved glyphosate for use in Roundup in 1974, the use of glyphosate on

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65. *Id.* at 19–23.

66. *See generally* PESTICIDE RE-EVALUATION DIV., EPA, GLYPHOSATE INTERIM REGISTRATION REVIEW DECISION CASE NUMBER 0178 (2020), <https://downloads.regulations.gov/EPA-HQ-OPP-2009-0361-14442/content.pdf>.

67. CATHRYN BRITTON, EPA, WITHDRAWAL OF THE GLYPHOSATE INTERIM REGISTRATION REVIEW DECISION 5 (2022), <https://www.regulations.gov/document/EPA-HQ-OPP-2009-0361-14447>.

68. *Nat. Res. Def. Council v. EPA (NRDC)*, 38 F.4th 34, 45–46, 61 (showing that the plaintiffs' challenge was primarily focused on the ecological portion of EPA's decision, but also considered the human health portion as well, so the court considered both in turn.)

69. *NRDC*, 38 F.4th at 51.

70. *Id.*

71. *Id.* at 45–46.

72. *Id.* at 40, 61–62 (referring to FIFRA's October 2022 deadline, which translates to October 1, 2022).

73. BRITTON, *supra* note 67, at 1.

74. *Id.* at 4–5.

75. *Id.*

76. *Id.*

crops has increased by about 100 times.<sup>77</sup> Use of glyphosate accelerated in the years following the 1996 introduction of crops genetically modified to be resistant to glyphosate.<sup>78</sup> As a result of consumers and companies using glyphosate in greater amounts, the pesticide's residues have become more common on food products such as soybeans.<sup>79</sup>

## B. *The State Law Failure to Warn Tort*

### 1. *Elements of the Claim*

Failure to warn is a type of products liability tort that allows consumers to receive compensation from manufacturers when those manufacturers have not given consumers adequate warning of the risk of their product. Under the Second Restatement of Torts Section 388 (Section 388), a manufacturer has committed failure to warn when that manufacturer's conduct on a given product meets three conditions.<sup>80</sup> The first is that the manufacturer "(a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied."<sup>81</sup> If a manufacturer neither knows its product is hazardous nor had any reasonable way of knowing its product was hazardous or could be hazardous, then that manufacturer cannot meet all three conditions to be liable for failure to warn under Section 388.

The second Section 388 requirement for a consumer to bring a successful failure to warn claim is that the manufacturer "(b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition."<sup>82</sup> A manufacturer, in other words, cannot meet all three elements for failure to warn liability under Section 388 if the manufacturer has reason to think that the average consumer would know of the product's hazardousness.<sup>83</sup> In the case of a given pesticide, an average consumer will not necessarily know that it is dangerous if the pesticide manufacturer does not alert the consumer to the product's dangerousness. Therefore, this second requirement for a successful failure to warn suit is generally satisfied when it comes to pesticide products. The products are not hazardous on their face, so the manufacturers must give some kind of warning to the public about them.

The third Section 388 requirement for a consumer to bring a successful failure to warn claim is that the manufacturer "(c) fails to exercise reasonable care to inform [consumers] of [the product's] dangerous condition or of the facts

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77. John Peterson Myers et al., *Concerns Over Use of Glyphosate-Based Herbicides and Risks Associated with Exposures: A Consensus Statement*, 15 ENV'T HEALTH 1, 5 (2016).

78. *Id.* at 2.

79. *See id.* at 5.

80. RESTATEMENT (SECOND) OF TORTS § 388 (1965).

81. *Id.*

82. *Id.*

83. *See id.*

which make [the product] likely to be dangerous.”<sup>84</sup> What is “reasonable” is not defined in the text of Section 388, so the definition of that word is therefore both product- and industry-dependent.<sup>85</sup> In the case of pesticide warning labels, a sufficiently informative and comprehensible label could conceivably do enough to warn consumers in the way that FIFRA requires.<sup>86</sup> Given the lack of case history on reasonableness of pesticide warning labels as a mechanism, however, a case could arise that challenges the pesticide warning labels on that basis.

Crucially, the manufacturer’s conduct must satisfy all three of the above conditions for the manufacturer to be liable for a failure to warn under Section 388.<sup>87</sup> Since the second requirement for failure to warn under Section 388—that the product not be clearly hazardous on its face<sup>88</sup>—is generally satisfied in the case of pesticides, it is the first and third requirements that have the potential to be at issue in a failure to warn case about pesticide warning labels.

The Section 388 framework for failure to warn is not in place verbatim across the country, but the state-level legal landscape on failure to warn is not as varied as one might suppose. As of a 2022 Westlaw national survey of state-level products liability laws in the United States, eight states feature the failure to warn tort in statute rather than through common law restated in Section 388.<sup>89</sup> Even within those eight states, however, the failure to warn tort remains consistent in substance with the Section 388 failure to warn tort.<sup>90</sup> Thus, the national state law picture of failure to warn is not fifty disparate failure to warn regimes. On the contrary, the states are broadly in agreement on the basics of what the failure to warn tort entails, regardless of whether they adopt the exact wording of Section 388 in their common law or statutes.

## *2. Caselaw that Illustrates Failure to Warn Requirements for Pesticide Labeling*

From FIFRA’s passage until 2005, consumers were unable to bring state law claims against manufacturers for their pesticide warning labels, even if they had the evidence to prove all three elements of a Section 388-style failure to warn claim. In the years leading up to the Supreme Court’s 2005 decision in *Bates v.*

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84. *Id.*

85. *Id.*

86. *See* 7 U.S.C. § 136(q)(1)(G).

87. RESTATEMENT (SECOND) OF TORTS § 388 (1965).

88. *Id.*

89. *See 50 State Statutory Surveys: Civil Laws: Torts: Products Liability*, THOMPSON REUTERS (Apr. 2022), [https://1.next.westlaw.com/Document/I904cd01a5afa11de9b8c850332338889/View/FullText.html?transitionType=UniqueDocItem&contextData=\(sc.Default\)&userEnteredCitation=0020+SurvEys+29](https://1.next.westlaw.com/Document/I904cd01a5afa11de9b8c850332338889/View/FullText.html?transitionType=UniqueDocItem&contextData=(sc.Default)&userEnteredCitation=0020+SurvEys+29) (stating that Arizona, Michigan, Missouri, Nebraska, New York, North Dakota, and Oregon all have the concept of failure to warn in statute in some capacity).

90. *See, e.g.*, Mich. Comp. Laws Ann. § 600.2948(2). The section does not spell out the elements of failure to warn in full, but specifies that in order for a product’s danger to be worth warning about, it cannot be “obvious” to a reasonable consumer of that product—a requirement that remains consistent with the second element of failure to warn as defined by Section 388.

*Dow*, there was general agreement among the circuit courts that FIFRA preempted state law failure to warn claims regarding pesticide warning labels.<sup>91</sup> Even though FIFRA preempted state law failure to warn claims, FIFRA did not supply any cause of action by which consumers could seek compensation from pesticide manufacturers when those pesticides failed to warn them about negative health outcomes associated with exposure.<sup>92</sup> Such prospective plaintiffs, in short, did not have legal recourse for the health-related harms they experienced due to inadequate warning labels.<sup>93</sup>

In 2005, however, the Supreme Court ended FIFRA's wholesale express preemption of state law failure to warn claims regarding pesticide warning labels in *Bates v. Dow*.<sup>94</sup> This case concerned Texas peanut farmers who alleged that a pesticide manufacturer did not adequately warn them about possible damage that their pesticide could inflict on peanut crops.<sup>95</sup> The Court ruled that FIFRA only overrides a state law about pesticide packaging if the state law (1) relates to packaging and labeling and (2) is more stringent than or different from FIFRA's requirements.<sup>96</sup> This ruling opened the door to the possibility that FIFRA did not expressly override all state law failure to warn claims about pesticide warning labels, but it remained unclear whether FIFRA preempted "particular" kinds of common law claims, such as that of failure to warn.<sup>97</sup>

During the summer and early autumn of 2022, this ambiguity seemed to finally start on its way towards becoming resolved. If the logic of the Eleventh Circuit's ruling in *Carson I* were applied to other states, FIFRA would not override state law failure to warn claims when it comes to pesticide warning labels.<sup>98</sup> The *Carson I* ruling made Georgia tort law controlling on the question of whether Monsanto could be held liable for not sufficiently warning consumers about glyphosate's level of safety.<sup>99</sup> The registration process reflects only that the manufacturer followed EPA's requirements for those processes,<sup>100</sup> and the Eleventh Circuit ruled in *Carson I* that the studies that EPA had produced about glyphosate's level of safety (along with EPA's registration decisions themselves) are not the product of notice-and-comment or adjudicatory rulemaking.<sup>101</sup> Since the studies that EPA had issued and the registration decisions do not have the

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91. Sherrie M. Flynn, *FIFRA's Puzzling Failure-to-Warn Preemption: Pesticide Use and the Right-to-Know*, 13 SAN JOAQUIN AGRIC. L. REV. 173, 176 (2003).

92. *Id.*

93. *See id.*

94. *Bates v. Dow Agrosiences LLC*, 544 U.S. 431, 443 (2005) (citing 7 U.S.C. § 136v(b)).

95. *Id.* at 434.

96. *Id.* at 444 (citing 7 U.S.C. § 136v(b)).

97. *See id.* at 443, 447 (holding that state "common law duties" are not necessarily preempted by FIFRA, but declining to hold whether any "particular [state] common law duties" are preempted by FIFRA).

98. *Carson I*, 39 F.4th at 1340.

99. *Id.*

100. *See* 7 U.S.C. § 136a(f)(2).

101. *Carson I*, 39 F.4th at 1340.

force of law under *Carson I*, they cannot preempt failure to warn claims under Georgia state law about pesticide warning labels under that precedent.<sup>102</sup>

### 3. How the Regulatory Standards Influence State Failure to Warn Cases

If FIFRA does not preempt state law failure to warn claims, pesticide manufacturers will need to prove that they adequately warned consumers about the risks of using their products. If EPA having registered a pesticide does not expressly preempt state law failure to warn claims about pesticide warning labels, as the Eleventh Circuit ruled regarding Georgia law and glyphosate in *Carson I*,<sup>103</sup> pesticide manufacturers will have to communicate an adequate amount of information to consumers in order to avoid being held liable under states' failure to warn laws.

The failure to warn tort under Section 388 requires manufacturers to “exercise reasonable care to inform [consumers] of [the product’s] dangerous condition or of the facts which make [the product] likely to be dangerous” in order to avoid being liable.<sup>104</sup> For pesticides such as diuron, which EPA classifies as a “[k]nown/[l]ikely” carcinogen,<sup>105</sup> the warning label gives consumers neither information about each consumer’s risk levels nor the chain of research and reasoning that EPA employed to classify the pesticide that way.<sup>106</sup>

Since the pesticide warning labels that FIFRA mandates are already a means by which pesticide manufacturers communicate information to consumers, the labels can also be adapted to satisfy states' failure to warn laws in a time when caselaw is not altogether clear on what adequate warning would look like in the context of pesticide warning labels. If consumers have a reasonably wide array of information about the possible risks of a given pesticide in general and the risk factors that could exacerbate those risks, then consumers can decide which kinds of PPE they want to wear, as well as whether or not to use that pesticide at all. With a more informative warning, in other words, consumers will have more relevant information with which to decide how to pattern their use of a given pesticide.

Knowledge of risk factors for developing cancer can be a helpful tool for individual consumers to inform their behavioral decisions.<sup>107</sup> That knowledge is

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102. *Id.*

103. *Id.*

104. RESTATEMENT (SECOND) OF TORTS § 388(c) (1965).

105. LINDA L. TAYLOR & ESTHER RINDE, EPA, CARCINOGENICITY PEER REVIEW OF DIURON I (1997), [https://www3.epa.gov/pesticides/chem\\_search/cleared\\_reviews/csr\\_PC-035505\\_8-May-97\\_042.pdf](https://www3.epa.gov/pesticides/chem_search/cleared_reviews/csr_PC-035505_8-May-97_042.pdf).

106. *See, e.g.,* JOYNER, *supra* note 11, at 2 (including an enclosed warning label for a version of diuron did not include any of EPA’s regulatory documents that informed the agency’s approval of the warning label).

107. *See* AM. INST. FOR CANCER RSCH., *supra* note 8, at 2.

far from thorough for many in the United States.<sup>108</sup> As of 2019, the American Institute for Cancer Research (AICR) found that a majority of the U.S. public did not know of the relative importance of a number of risk factors for developing cancer such as diets low in fruits and vegetables and high alcohol consumption.<sup>109</sup> If U.S. consumers are generally uninformed about cancer risk factors relating to diet and alcohol consumption, they may not know the risks of certain pesticide usage, either.

In addition, the pesticide warning labels do not link to EPA's most important regulatory documents about the carcinogenic risk of pesticides, even in a summary form.<sup>110</sup> For those who want to learn more about what EPA thinks of a pesticide's carcinogenicity (or lack thereof), the pesticide warning label does not give insight into EPA's process for reaching its conclusions.<sup>111</sup> Regardless of whether *Carson I* becomes good law again,<sup>112</sup> the warning labels that EPA approves through its registration process do not give consumers adequate information to evaluate EPA's reasoning for themselves.<sup>113</sup> EPA can and should change this situation. A given consumer may not wish to evaluate EPA's reasoning for a given pesticide, but if EPA makes access to (1) its reasoning in the registration process and (2) the informational documents that EPA produces that make that process more legible to non-expert consumers, then consumers can be better prepared to assess EPA's reasoning for themselves.

### III. ADDING CANCER RISK FACTORS AND OTHER EPA DATA TO PESTICIDE LABELS

#### A. *How EPA Can Make this Addition*

To make pesticide warning labels both more individualized and more accessible, EPA should require pesticide manufacturers to provide consumers with more specific information about (1) the range of factors that can contribute to a person's overall cancer risk profile and (2) EPA's most up-to-date registration or re-registration findings about the pesticide in question. These more specific warning labels would allow consumers to better estimate how much pesticide exposure during application could be safe for them. There would be no need to stop using the current pesticide warning labels with their instructions on how to use each pesticide. Rather, consumers could take note of their specific risk factors and the latest available research that EPA has considered to determine whether they should use the recommended amount of

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108. *Id.* at 14–15.

109. *Id.*

110. *See, e.g.,* JOYNER, *supra* note 11 (including an enclosed warning label for a version of diuron did not cite EPA regulatory decisions).

111. *See id.*

112. In December 2022, the Eleventh Circuit vacated its *Carson I* opinion pending rehearing en banc. *See* Order granting rehearing en banc, *Carson v. Monsanto*, *supra* note 6, at 2.

113. *See id.*



pesticide or less, depending on each consumer's specific risk factors for developing cancer. In this way it would be somewhat analogous to California's Proposition 65 labels for chemicals "known to the State of California" to cause certain health harms, in that the labels would be giving consumers information that they could use to change their product use patterns if they see fit.<sup>114</sup> The modified warning label registration system would be different from the Proposition 65 labels in a couple of key ways. The modified warning label registration system would include individualized risk factors for consumers, which the Proposition 65 system does not.<sup>115</sup> In addition, the modified warning label registration system would not necessarily have the certainty of claiming that a given pesticide is known to cause a given health-related harm, unlike the Proposition 65 system, which presents more certainty in its labels.<sup>116</sup>

Under this proposed new labeling regime, pesticide manufacturers would include information on labels based on documents that EPA makes available in its pesticide warning label registration process. When EPA adds regulatory documents to Regulations.gov, pesticide manufacturers would be required to add the information to the pesticide warning labels. In addition, pesticide manufacturers would add information about cancer risk factors if and when the science linking risk factors to cancer becomes more developed.

Since such a change to EPA's system of pesticide warning labels would be a novel implementation of a statutory scheme that Congress already set forth in FIFRA, EPA would have the advantage of implementing the change through regular notice-and-comment rulemaking under the Administrative Procedure Act (APA).<sup>117</sup> Setting forth this change via notice-and-comment rulemaking would not be instantaneous: EPA would still have to abide by the notice-and-comment timeline to which the APA requires that agencies adhere.<sup>118</sup> This administrative route towards regulatory change would, however, place the initiative on EPA rather than with Congress (which could also make the change by amending FIFRA). Given that Congress remains gridlocked and is unlikely to pass such substantive legislation in the near future,<sup>119</sup> EPA would likely be able to make this change to its regulations more quickly than Congress could do via a revision to FIFRA itself.

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114. See *Proposition 65 Warnings Website – Your right to know.*, CAL. OFF. OF ENV'T'L HEALTH HAZARD ASSESSMENT (2023), <https://www.p65warnings.ca.gov/> (describing the purpose of the warnings in terms of better informing people in California about health risks from exposure to various chemicals).

115. See *id.*

116. See *id.*

117. See 5 U.S.C. §§ 553(b)-(c) (setting forth the general requirements for notice-and-comment rulemaking).

118. See *id.*

119. See, e.g., Sara Savat, *WashU Expert: Next two years will be marked by gridlock, vetoes*, WASH. UNIV. IN ST. LOUIS NEWSROOM (Jan. 13, 2023), <https://source.wustl.edu/2023/01/washu-expert-next-two-years-will-be-marked-by-gridlock-vetoes/>.

This additional information can go onto the pesticide warning label without making the already booklet-sized document<sup>120</sup> substantially longer. Pesticide warning labels are already available on the internet through EPA's Pesticide Product Label System (PPLS).<sup>121</sup> Thus, under the new labeling regime, pesticide manufacturers can place new regulatory documents and various cancer risk factors on PPLS and place a link to that part of PPLS on the pesticide labels. The pesticide packaging can include a link to the specific warning labels for that particular pesticide on the PPLS system without taking up an inordinate amount of room on that packaging's surface.

If all this additional pesticide warning label information were only available to consumers via PPLS, however, the new warning label system would not be accessible for all people who apply pesticides. As of early 2023, not all residents of the U.S. have internet access.<sup>122</sup> Furthermore, even some people who do have access to the internet have difficulty with basic internet-related tasks, let alone with accessing the pesticide warning label that best fits their circumstances.<sup>123</sup> People who experience barriers to internet access, internet proficiency, or both would face challenges in accessing PPLS and the more specific warning labels that could assist them with avoiding health-related harm.

Putting the additional warning label information in other media apart from PPLS, such as establishing a publicly available printed library or on a dedicated phone line, could be a tool for making this additional information on pesticide warning labels more easily searchable for a wider range of consumers. Any single additional medium for communicating this information, however, would likely come up short in some capacity (e.g., not everyone would necessarily have access to a phone to call the dedicated phone line). EPA could also mandate the translation of warning labels into commonly spoken languages in the U.S. such as Spanish, which is the "predominant" language of 62 percent of the country's agricultural workforce.<sup>124</sup> In addition, EPA could use the warning label weblink

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120. See, e.g., BAYER CROPS SCIENCE LP, ROUNDUP POWERMAX HERBICIDE (2020), [https://cs-assets.bayer.com/is/content/bayer/Roundup\\_PowerMAX\\_Herbicide\\_Bayer\\_Label2pdf](https://cs-assets.bayer.com/is/content/bayer/Roundup_PowerMAX_Herbicide_Bayer_Label2pdf) (consisting of a label for Roundup PowerMAX herbicide that is twenty-five pages long).

121. *Pesticide Product Label System (PPLS): More Information*, *supra* note 17.

122. Joyce Winslow, *America's Digital Divide*, PEW CHARITABLE TRUSTS (Jul. 26, 2019), <https://www.pewtrusts.org/en/trust/archive/summer-2019/americas-digital-divide>.

123. SAIDA MAMEDOVA & EMILY PAWLOWSKI, AMER. INSTS. FOR RSCH., A DESCRIPTION OF U.S. ADULTS WHO ARE NOT DIGITALLY LITERATE 3 (2018), <https://nces.ed.gov/pubs2018/2018161.pdf>.

124. AMANDA GOLD ET AL., JBS INT'L, FINDINGS FROM THE NATIONAL AGRICULTURAL WORKERS SURVEY (NAWS) 2019-2020: A DEMOGRAPHIC & EMPLOYMENT PROFILE OF UNITED STATES FARMWORKERS (2022), available at <https://www.dol.gov/sites/dolgov/files/ETA/naws/pdfs/NAWS%20Research%20Report%2016.pdf>; see Anne Marshall-Chalmers, *Most Farmworkers Speak Spanish, but Pesticide Safety Labels are Often Only Printed in English*, CIV. EATS (Aug. 30, 2022), <https://civileats.com/2022/08/30/pesticide-safety-labels-farmworker-health-safety-data-sheets-english-spanish/>; see also EMILY SCHMIDT, EPA, LABEL AMENDMENT – UPDATE DIRECTIONS FOR USE, LABEL CLAIMS, AND LABEL FORMAT FOR CONSISTENCY 10 (Jan. 28, 2021), [https://www3.epa.gov/pesticides/chem\\_search/ppls/071995-00025-20210128.pdf](https://www3.epa.gov/pesticides/chem_search/ppls/071995-00025-20210128.pdf), (including an enclosed glyphosate warning label allows for an option for the label to be translated into Spanish but does not require such translation).

to provide consumers direct access to fact sheets about its registration process for given pesticides, which are texts EPA already has experience writing for glyphosate.<sup>125</sup> Therefore, a combination of approaches would probably be required to expand access to the specific warning labels as much as is feasible given economic and practicability constraints.

*B. What this Would Mean for Glyphosate Standards and Failure to Warn Claims*

This new regulatory requirement would not change EPA's determinations of whether glyphosate (or any other pesticide) causes cancer. The regulatory change would instead entail information that is already public knowledge in the form of risk factors for cancer and the rulemaking documents that EPA already produces and evaluates in the pesticide warning label registration process. Even the web pages that sum up EPA's rulemaking processes are information that EPA already creates,<sup>126</sup> so adding to those resources would require minimal expenditure. The only need for extra staffing or funding would be for providing information in accessible media and in commonly spoken languages.

For the state law failure to warn claims, this regulatory change would give consumers more comprehensive and readily understandable ways of discerning their individual risk factors for cancer and how those risk factors interact with EPA's findings about each pesticide's carcinogenicity. In turn, those consumers will be able to alter their behavior—whether they apply a pesticide or which PPE they use—to minimize their individual risk of cancer. In a situation where consumers have more knowledge to make an informed choice about their pesticide use, there will be less reason (and less of a basis) to claim that pesticide manufacturers did not warn them of the carcinogenic risks of using a particular pesticide.

*C. Potential Drawbacks and Benefits for Both Consumers and Manufacturers*

Whichever way the Eleventh Circuit rules on whether FIFRA preempts state law failure to warn claims, EPA's new warning label registration process will advantage both consumers and pesticide manufacturers. Consumers will have the benefit of increased safety when it comes to controlling how much pesticide they are exposed to, even though this increased safety would not be perfect. At the same time, pesticide manufacturers will have the benefit of knowing what they are supposed to include on pesticide labels in a legal environment that might rapidly become much more complex. Thus, pesticide manufacturers would have

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125. See generally *Glyphosate*, *supra* note 57; EPA, GLYPHOSATE: REREGISTRATION ELIGIBILITY DECISION (RED) FACT SHEET (1993), [https://www3.epa.gov/pesticides/chem\\_search/reg\\_actions/reregistration/fs\\_PC-417300\\_1-Sep-93.pdf](https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/fs_PC-417300_1-Sep-93.pdf).

126. See *id.*

the opportunity to avoid at least some state law failure to warn litigation that they might have arisen otherwise.

Since consumers who read more specific pesticide warning labels will be able to adjust how they use a pesticide to fit their particular circumstances, these consumers will be able to adjust their behavior. Consumers who are considering applying an insecticide to prevent mosquito bites, for instance, would be able to use the PPLS system to look up their own risk factors for cancer and EPA's chain of reasoning in approving the pesticide's warning label. With that information, consumers could choose to have more protective PPE, they could choose not to use the pesticide at all, or they could choose not to do anything with the additional information. By using this additional warning label information, consumers may reduce their risk of developing cancer, but in any event they will have more information with which to make decisions about their behavior.

This regulatory change would not get rid of the problem of pesticide exposure completely for consumers, though. Additionally, the regulatory change would not necessarily reduce the amount of a given pesticide that is already present in the environment, especially in cases where a pesticide has a long half-life. This means that consumers and the general public would still experience environmental background exposures. If background exposure to a particular pesticide is already especially high in an area, then having more specific information on the warning labels would not reduce that environmental exposure. Rather, the proposed regulatory change would simply give consumers the knowledge necessary to avoid exposing themselves unnecessarily to that pesticide through their own voluntary activities. In other words, the regulatory change would put the onus on consumers to protect themselves rather than on pesticide manufacturers to produce pesticides that are less dangerous to people. Addressing the background environmental exposure would require further statutory or regulatory change aside from improving pesticide warning labels.

In addition, for this regulatory change to succeed, the public must be aware of it and informed on how to navigate the PPLS system to see their risk factors for developing cancer. EPA can take steps to make the specific warning labels more accessible to more of the population, such as by keeping printed versions of the specific pesticide warning labels and making the information on the labels available over the phone. That being said, such steps are unlikely to serve as a panacea to the issue and continued improvement on accessibility would be necessary to ensure that the specific warning labels reach their targeted audience.

Another drawback of this regulatory change is that it would only affect people who actually read the pesticide warning labels before using pesticides. If a consumer does not read the labels to begin with or only reads them in a cursory way, this administrative change will not help protect that person. At this point, it is difficult to know how significant this issue would be. There is a lack of scholarly literature that examines (1) how many pesticide consumers look at pesticide labels when buying pesticides and (2) how thoroughly consumers who do look at the labels actually read them. There is also a lack of scholarly literature

that looks into how many consumers follow the instructions on a pesticide's warning label even if they do read the label carefully.

If few consumers look at pesticide warning labels (or if not many of the people who do look at pesticide warning labels read them carefully or follow their instructions), EPA could attempt to change people's approach to the warning labels. These efforts could take a number of forms. For instance, EPA could start a public campaign to encourage reading the labels. Or EPA could increase the messaging it puts forth about the pesticide warning labels' terminology so that consumers can learn more easily about how to understand the labels' content. If the labels include weblinks to EPA's informational fact sheets,<sup>127</sup> EPA could use those links to avoid having so much information on the label itself that consumers become more likely to disengage from the label's content. Having more insight into statistics about consumers' approach to pesticide warning labels could inform agency decisionmakers' efforts to make the warning label information as effective as possible in alerting the public.

In addition, there is the issue that the current agricultural PPE system does not make it easy for agricultural workers in the United States (at least those who are not self-employed) to choose which kind of PPE they use. Under current federal regulations, it is agricultural employers' responsibility to provision PPE for their employees.<sup>128</sup> Thus, agricultural workers who are working for an employer are not in a position to directly choose which PPE they use in the course of their work.

For those employees to have more of a say in which PPE they use in response to the modified registration and labeling system, at least two elements would have to go along with that system's rollout. For one, there would need to be a mechanism for employees to register their choice of PPE with their employer, be it through labor unions and/or by some other dedicated medium of communication. Second, there would need to be a continued requirement for employers to pay for that PPE so the workers themselves do not incur an infeasible financial burden in trying to keep themselves safe.

Even with these challenges, the regulatory change would have benefits that apply not only to consumers, but also to pesticide manufacturers. By making individual risk factors and EPA's decision-making process part of the pesticide warning labels, EPA will give pesticide manufacturers more clarity on what they must do to try (1) to avoid harm to consumers and (2) to warn consumers sufficiently under failure to warn laws. The ongoing litigation in the *Carson* case leaves pesticide manufacturers in a precarious spot in terms of their pesticide warning labels. The crux of the uncertainty is whether the Eleventh Circuit overrules itself and whether the Supreme Court steps in afterwards.

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127. See, e.g., GLYPHOSATE: REREGISTRATION ELIGIBILITY DECISION (RED) FACT SHEET, *supra* note 125.

128. Training requirements for handlers, 40 C.F.R. § 170.501(c)(3)(x) (2023).

If the Eleventh Circuit overrules its own recent holding in *Carson I*, manufacturers will be in a confusing position. It will not be clear if FIFRA overrides state failure to warn claims, and if so, to what extent. If the Eleventh Circuit reverses itself, then in the states under the Eleventh Circuit's jurisdiction (i.e., Georgia, Florida, and Alabama<sup>129</sup>), FIFRA would preempt state failure to warn claims, but the opposite would be true in the Ninth Circuit, which ruled that FIFRA does not preempt such failure to warn claims.<sup>130</sup> Where either FIFRA preempts and the manufacturers do not need to be concerned about state law failure to warn claims, or FIFRA does not preempt and the manufacturers do need to be concerned about those claims, manufacturers will need to pay attention to the state of each circuit court's rulings on the subject unless and until the Supreme Court intervenes. There is no way of telling when the Supreme Court would take up the subject.

In this uncertain situation, pesticide manufacturers will be unsure exactly what they must do to give sufficient warning to consumers and avoid state law failure to warn litigation. Pesticide manufacturers could add more information to pesticide warnings on their own initiative, spending an uncertain amount of money to figure out an alternative system. The manufacturers would have no guarantee that EPA or the judiciary will approve of the new warning label system.

Conversely, pesticide manufacturers could simply maintain the pesticide warning label system as it is now. This option would save pesticide manufacturers the additional costs of revising their pesticide warning label system. The downside for manufacturers would be that they would leave themselves potentially open to a flood of failure to warn litigation in each state where the circuit courts have not found that FIFRA preempts state failure to warn provisions for pesticide warning labels. There could also be potentially diverging state and circuit court rulings on what constitutes adequate failure to warn. The pesticide manufacturers could go from a situation<sup>131</sup> where FIFRA overrides state failure to warn claims on pesticide warning labels, to a situation where different parts of the country have different rules on whether FIFRA overrides such claims.

By mandating more specific pesticide warning labels, EPA has the opportunity to step in and allow both consumers and pesticide manufacturers to avoid this regulatory and litigatory debacle before it begins. It will likely not cost pesticide manufacturers much to add weblinks to information that is already

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129. *About the Court*, U.S. CT. OF APP. FOR THE ELEVENTH CIR., <https://www.ca11.uscourts.gov/about-court> (last visited Apr. 14, 2023).

130. *Hardeman v. Monsanto Co.*, 997 F.3d 941, 950 (9th Cir. 2021), *cert. denied*, 142 S. Ct. 2834 (2022).

131. This situation is current as of early 2023, when the Eleventh Circuit vacated its *Carson I* holding. *See* Order granting rehearing en banc, *Carson v. Monsanto*, *supra* note 6, at 2; *see also* Flynn, *supra* note 91, at 176.

publicly available.<sup>132</sup> In addition, given the fact that the current regulatory ground might rapidly give way depending on future court rulings, EPA requiring more individualized health information on pesticide warning labels would give manufacturers greater certainty on the information they need to provide to adequately warn consumers. There might be (at least for a time) numerous different standards on what information manufacturers must put on the warning labels, but by following EPA's requirements, manufacturers would be able to attempt to satisfy all of them at once. Even if pesticide manufacturers are unable to know the extent to which FIFRA preempts state failure to warn claims (unless and until the Supreme Court intervenes), EPA can implement a system by which pesticide manufacturers are on reasonably solid footing no matter where federal circuit courts and the Supreme Court land on the subject.

#### CONCLUSION

In response to both preexisting statutory responsibilities and more recent legal uncertainties, EPA should change how it registers and re-registers pesticide warning labels under FIFRA. EPA should no longer use a "one-size-fits-all" approach in the registration and re-registration processes. With new technologies that are available and the PPLS database that is publicly accessible online, EPA can fashion a system by which pesticide manufacturers give consumers pesticide warning labels that empower individual consumers to consider (1) their individual cancer risk profile and (2) which PPE they are comfortable with using.

By adopting this change in how it registers and re-registers pesticides, EPA will accomplish three things at once. First, EPA will better fulfill its statutory requirements under FIFRA to require pesticide warning labels when those pesticides present a risk to people's wellbeing. Second, EPA will more comprehensively protect the public than under its current pesticide warning label registration requirements. Finally, EPA will let the pesticide industry know, in legally uncertain times, what they need to include on warning labels to avoid liability. In an environment where the judicial outcome is ambiguous and congressional resolution to that ambiguity is unlikely to arrive anytime soon, EPA can bring order and increased safety to the table.

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132. See, e.g., PESTICIDE RE-EVALUATION DIV., *supra* note 66, at 1 (featuring an example of such a document that EPA produces already—in this instance, EPA's Interim Registration Review Decision for glyphosate that the agency issued in 2020).

