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Nos. 19-16636, 19-16708

#### IN THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

#### EDWIN HARDEMAN, Plaintiff-Appellee/Cross-Appellant,

v.

#### MONSANTO COMPANY, Defendant-Appellant/Cross-Appellee.

On Appeal from the United States District Court for the Northern District of California, Nos. 16-cv-00525 & 16-md-02741 (Chhabria, J.)

#### BRIEF OF AMICI CURIAE STATES OF NEBRASKA, IDAHO, LOUISIANA, NORTH DAKOTA, SOUTH DAKOTA, TEXAS, AND UTAH IN SUPPORT OF DEFENDANT-APPELLANT/CROSS-APPELLEE MONSANTO COMPANY SEEKING REVERSAL

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The States of Nebraska, Idaho, Louisiana, North Dakota, South Dakota, Texas, and Utah ("*amici* States") file this *amicus curiae* brief in support of Defendant-Appellant/Cross-Appellee Monsanto Company seeking reversal of the judgment of the U.S. District Court for the Northern District of California. In particular, the *amici* States' brief focuses on the district court's Pretrial Orders Denying Monsanto Company's Summary Judgment and *Daubert* Motions on General Causation (ER49) and Motion for Summary Judgment on Specific Causation (ER33).<sup>1</sup>

#### **IDENTITY AND INTEREST OF THE AMICI STATES**

*Amici* are the States of Nebraska, Idaho, Louisiana, North Dakota, South Dakota, Texas, and Utah. Agriculture is important in these States. The *amici* States are home to over 400,000 farms and ranches covering over 280 million acres. Last year, their farmers produced more than three billion bushels of corn and over 800 million bushels of soybeans adding billions to the economy. These farmers and

<sup>&</sup>lt;sup>1</sup> Pursuant to Federal Rule of Appellate Procedure 29(a)(2), the *amici* States are permitted to file an amicus brief without consent of the parties to the appeal or leave of the Court. All citations to the record are designated by "ER" and pertain to the Excerpts of Record filed by Monsanto Company in this appeal.

the crops they grow help feed a growing population, contribute to rural, state, and national economies, and directly and indirectly employ millions of people. The herbicide at issue in this case—glyphosate helped farmers in these States, and across the country, accomplish these feats.

Glyphosate is an essential herbicide for farmers in the *amici* States. Glyphosate can control 300 different weeds and can be applied directly to growing crops engineered to be resistant to it. With glyphosate, farmers can manage weeds more effectively in less time and for less money. Better weed management also positively impacts crop yields by allowing the growing crops to reach yield potential. Producing higher yields with fewer costs not only benefits farmers in the *amici* States, but also related industries and downstream consumers. The *amici* States benefit because of the impact of agriculture on their economies and, especially, the economies in their rural areas.

Glyphosate also benefits the environment in the *amici* States. Glyphosate paired with glyphosate-resistant crops encourages the adoption of conservation tillage by farmers. The *amici* States benefit from conservation tillage because there is less soil erosion and runoff

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from fields into surface waters of the States. Glyphosate is also less toxic and harmful than many other herbicides. Simply, glyphosate greatly benefits agriculture in the *amici* States and, in turn, the economies, environment, and people in those States.

Glyphosate has been used safely and effectively as a weed management tool in agriculture for over forty years. The overwhelming consensus from research and regulatory bodies is that glyphosate does not cause cancer or non-Hodgkins lymphoma ("NHL") in humans. The U.S. Environmental Protection Agency ("EPA") has repeatedly determined glyphosate is not likely to be carcinogenic to humans and is in the process of again renewing that determination. Regulatory bodies in other countries have reached similar determinations. But in 2015, the International Agency for Research on Cancer ("IARC")—seemingly out of nowhere—classified glyphosate as "probably carcinogenic to humans" and precipitated this case and thousands like it.

In this case, the plaintiff, Hardeman, presented experts who opined that glyphosate not only causes NHL in humans, but specifically caused Hardeman's NHL. The district court was skeptical and called these opinions "rather weak" and "shaky" but nonetheless found them

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admissible under Federal Rule of Evidence 702 and the *Daubert* standard. The jury heard this expert evidence and, ultimately, rendered a verdict for Hardeman and against Monsanto Company.

Although the overwhelming evidence from national and international research and regulatory bodies shows glyphosate is not carcinogenic to humans, the judgment in this case threatens to undermine that evidence and curtail glyphosate from agricultural use in the *amici* States and the Nation. In response, farmers may have to resort to less effective, more expensive, and more toxic herbicides. This could impact crop yields, the economy, and the environment in the *amici* States. For these reasons, the *amici* States request this Court reverse the district court's judgment.

#### ARGUMENT

## I. THE DISTRICT COURT ERRED WHEN IT MISAPPLIED THE *DAUBERT* STANDARD AND ALLOWED THE JURY TO HEAR UNRELIABLE EXPERT OPINIONS.

Production agriculture makes up the vast majority of glyphosate usage because of the economic, environmental, and time-saving benefits. If glyphosate were curtailed, agriculture in the *amici* States would be adversely impacted. The district court's decisions on the

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admissibility of expert testimony on glyphosate being carcinogenic go

beyond just this case because other users, like farmers in the amici

States, greatly rely on glyphosate.

The admissibility of expert testimony is governed by Federal Rule

of Evidence 702 and Daubert v. Merrell Dow Pharmaceuticals, Inc., 509

U.S. 579 (1993) ("Daubert I"). Federal Rule of Evidence 702 provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. District courts play an important role in analyzing the relevancy and reliability of expert evidence before a jury hears the evidence at trial. *See Daubert I*, 509 U.S. at 589, 595.

In the case below, the district court engaged in two *Daubert* analyses at the general causation and specific causation phases. The district court repeatedly recognized the uphill battle Hardeman faced given the substantial evidence showing glyphosate was not carcinogenic to humans. Yet, each time, the district court opened the door for Hardeman to present "shaky" and "rather weak" expert opinions to the jury. As demonstrated below, the district court erred at the general and specific causation phases based on the misapplication of the *Daubert* standard in this Circuit. If the district court's erroneous decisions admitting unreliable expert evidence are allowed to stand, then agriculture in the *amici* States will bear the brunt of these errors.

#### A. The District Court Erroneously Admitted "Shaky" And "Rather Weak" Expert Evidence On General Causation.

To determine the admissibility of expert testimony, the district court analyzes whether the expert testimony is sufficiently relevant and reliable under Federal Rule of Evidence 702 and the *Daubert* standard. *See Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1315 (9th Cir. 1995) ("*Daubert II*"). Although Federal Rule of Evidence 702 "*should* be applied with a 'liberal thrust' favoring admission", it "*requires*" that expert testimony "be both relevant and reliable." *Messick v. Novartis Pharmaceuticals Corp.*, 747 F.3d 1193, 1196 (9th Cir. 2014) (internal quotations omitted) (all emphasis added). Determining whether expert evidence is both relevant and reliable is key because "[e]xpert evidence can be both powerful and quite misleading because of the difficulty in evaluating it." *Daubert I*, 509 U.S. at 595 (internal quotations omitted). In this regard, the district court "act[s] as a gatekeeper to exclude junk science that does not meet Federal Rule of Evidence 702's reliability standards." *Messick*, 747 F.3d at 1197.

This Circuit recognizes the importance of the task a district court confronts in determining whether scientific expert testimony is relevant and reliable. *See Daubert II*, 43 F.3d at 1315. Reliability requires the district court to "determine ... whether the experts' testimony reflects 'scientific knowledge,' whether their findings are 'derived by the scientific method,' and whether their work product amounts to 'good science." *Id.* (quoting *Daubert I*, 509 U.S. at 590). This task may be more difficult when "the dispute concerns matters at the very cutting edge of scientific research, where fact meets theory and certainty dissolves into probability." *Daubert II*, 43 F.3d at 1316. Nonetheless, this Court explained:

Our responsibility ... is to resolve disputes among respected, well-credentialed scientists about matters squarely within their expertise, in areas where there is no scientific consensus as to what is and what is not "good science," and occasionally to reject such expert testimony because it was not "derived by the scientific method."

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*Id*. In a post-*Daubert* world, a federal judge's duty to act as a gatekeeper is essential.

This case, however, does not present a difficult dispute over a matter at the "very cutting edge of scientific research" or without "scientific consensus." Glyphosate has been "commercially available" since 1974 and is "widely used across the United States and much of the world." ER52. There have been a large number of scientific studies on the carcinogenicity of glyphosate-from case-control studies and metaanalyses to laboratory studies to a large cohort study. See ER62-ER73. The most recently published studies, the 2005 study and 2018 update to the Agricultural Health Study ("AHS"), which was a cohort study of more than 57,000 licensed pesticide applicators, found no association between glyphosate and NHL. See ER73 & ER88-ER89. The EPA also "does not currently consider glyphosate likely to cause cancer" and neither do other regulatory bodies, including those in Canada and parts of Europe.<sup>2</sup> The overwhelming majority of studies and regulators have found glyphosate is not carcinogenic to humans.

<sup>&</sup>lt;sup>2</sup> See U.S. Environmental Protection Agency, *Glyphosate—Human Health*, https://www.epa.gov/ingredients-used-pesticideproducts/glyphosate (last visited Dec. 20, 2019).

Yet, the IARC classified glyphosate as "probably carcinogenic to humans" in 2015, which spawned the current litigation and thousands of other cases. See ER52-ER53. In this case, Hardeman relied "heavily" on this IARC classification and the district court recognized such reliance as problematic. ER49 & ER57. The district court explained IARC's classification of glyphosate as "probably carcinogenic to humans" meant there was only "limited" evidence that glyphosate causes cancer in humans and "sufficient" evidence in animals. ER58-ER59. Given the IARC classification was "too limited" and "too abstract," the district court correctly closed the gate to Hardeman's experts who only parroted the IARC's examination. ER60-ER61. The district court, however, further analyzed Hardeman's three remaining experts on the basis that these experts "went beyond" the IARC classification. ER51.

After the expert reports were exchanged but a few months before the *Daubert* hearing on general causation, the 2018 update to the AHS was published. *See* ER74. With this update, the district court had even greater evidence of "scientific consensus." As the district court stated, the update showed glyphosate was not likely causing NHL in humans:

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There is one large cohort study (the AHS), with results recently published in a well-regarded scientific journal, suggesting no association between glyphosate use and NHL. There is a series of case-control studies arguably suggesting an association, but a fairly weak one. There are limited data indicating that the association strengthens with greater exposure to glyphosate, but also data to the contrary. And there are legitimate concerns about the reliability of the data from all the studies. *Under these circumstances, all one might expect an expert to conclude is that glyphosate exposure is cause for concern, but not that glyphosate is likely causing NHL at realistic human exposure levels.* 

ER88-ER89 (emphasis added). With regard to the evidence as a whole, the district court stated "the evidence of a causal link between glyphosate exposure and NHL in the human population seems rather weak" and "[t]he evidence, viewed in its totality, seems too equivocal to support any firm conclusion that glyphosate causes NHL." ER50. Because of this, the district court correctly described Hardeman's expert evidence as "shaky" and "rather weak". ER50, ER88-ER89, ER115.

The district court further described Hardeman's experts' opinions as being based on their identification of "at least a few statistically significant elevated odds ratios from case-control studies and metaanalyses" and "what they deem to a be a pattern of odds ratios above 1.0 from the case-control studies, even if not all are statistically significant[.]" ER116. Yet somehow, the district court called admissibility a "close question" and admitted the expert testimony because Federal Rule of Evidence 702 "should be applied with a liberal thrust." *Messick*, 747 F.3d at 1196 (internal quotations omitted); ER56-ER57, ER115.

The district court misapplied this Court's *Daubert* standard, thereby lowering the bar for reliability. When there is only a "scintilla of evidence" or "a few statistically significant" studies that support a position, a district court should, as a gatekeeper, exclude those expert opinions as junk science—especially when the district court finds such opinions to be rather weak and shaky. See Daubert I, 509 U.S. at 596 ("[I]n the event the trial court concludes that the scintilla of evidence presented supporting a position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true, the court remains free to direct a judgment ... and likewise grant summary judgment ...."); Fed. R. Evid. 702 (requiring expert testimony to be based on "sufficient" data). The district court should have excluded all of Hardeman's expert testimony at the general causation phase as unreliable based on the overwhelming evidence showing no association between glyphosate and NHL. The district court's error gave credibility

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to these unreliable expert opinions thereby threatening the agricultural use of glyphosate in the *amici* States.

## B. The District Court Erroneously Admitted Expert Opinions On Specific Causation By Wrongly Elevating Art Over Science.

By opening the gate for junk science on glyphosate at the general causation phase, Hardeman's experts were able to "rule-in" glyphosate as a potential cause of his NHL at the specific causation phase. ER34-ER35. The district court, then, lowered the reliability bar even more at the specific causation phase.

At the specific causation phase, the district court again voiced skepticism and called it a close question that glyphosate caused Hardeman's NHL. ER33, ER38. And yet again the district court concluded the expert testimony was admissible:

The Court may be skeptical of [Hardeman's experts'] conclusions, and *in particular of the assumption built into their opinions from the general causation phase about the strength of the epidemiological evidence*. But their core opinions—that [Hardeman has] no other significant risk factors and w[as] exposed to enough glyphosate to conclude that it was a substantial factor in causing [his] NHL—are admissible.

ER38 (emphasis added). The district court relied on *Messick* and *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227 (9th Cir. 2017) as the

basis for admitting the expert evidence. ER36-ER37. The district court explained that while Hardeman presented "borderline expert opinions" such opinions were admissible in the Ninth Circuit because of a tolerance for specific causation opinions that "lean strongly toward the 'art' side of the spectrum" rather than the science side. ER37. The district court, however, misapplied *Messick* and *Wendell*.

Messick and Wendell dealt with different scenarios than the case at hand. In Messick, the expert relied "on his extensive clinical experience[,]" as well as "examination of the [plaintiff's] records, treatment, and history" to determine whether the plaintiff's condition met the "unique features" defining that particular medical condition. 747 F.3d at 1196-98. In reversing the district court's exclusion of this expert's testimony, this Court stated "[m]edicine partakes of art as well as science, and there is nothing wrong with a doctor relying on extensive clinical experience when making a differential diagnosis." *Id.* at 1198.

In *Wendell*, the plaintiff had "an exceedingly rare cancer, with only 100 to 200 cases reported since it was first recognized." 858 F.3d at 1236. Moreover, this type of cancer was not widely studied. *Id*. ("It

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is not surprising that the scientific community has not invested substantial time or resources into investigating the causes of such a rare disease."). In reversing the district court, this Court explained that sometimes there may not be "a plethora of peer reviewed evidence" especially with a "rare disease" and, thus, *Daubert* should not bar the testimony of "two doctors who stand at or near the top of their field and have extensive clinical experience with the rare disease or class of disease at issue ...." *Id.* at 1238.

Unlike the scenarios in *Messick* and *Wendell*, NHL is not a rare disease—there were over 74,000 new cases in 2019.<sup>3</sup> NHL is, unfortunately, a common type of cancer and has a number of known risk factors.<sup>4</sup> Moreover, unlike *Wendell*, glyphosate is a well-studied herbicide and there is a "plethora of peer reviewed evidence" that glyphosate does not cause cancer or NHL. *See* ER65-ER82, ER88-ER89.

The district court misapplied this Circuit's *Daubert* standard at both phases. The district court was not presented with a case where the

<sup>3</sup> American Cancer Society, *Key Statistics for Non-Hodgkin Lymphoma*, https://www.cancer.org/cancer/non-hodgkin-lymphoma/about/keystatistics.html (last visited Dec. 20, 2019). <sup>4</sup> *Id*. disease was unique or rare or did not have a number of peer reviewed studies finding no association between glyphosate and NHL and, in turn, Hardeman's NHL. There was no reason for an expert's "art" to take precedence over "science" or "scientific consensus". The district court should have excluded Hardeman's expert testimony instead of opening the gate to shaky, weak, and unreliable opinions that glyphosate causes NHL and, more specifically, caused Hardeman's NHL. By admitting this unreliable expert testimony, the district court failed to protect the jury from misleading expert evidence and, thus, has adversely affected agriculture and farmers in the *amici* States.

#### II. THE DISTRICT COURT'S MISAPPLICATION OF THIS COURT'S *DAUBERT* STANDARD WILL HAVE REAL WORLD IMPACTS ON AGRICULTURE.

The district court's errors in admitting unreliable expert evidence that glyphosate causes cancer in humans has real world effects. The use of glyphosate paired with glyphosate-resistant crops is critically important as a weed control tool in agriculture. As demonstrated below, agriculture is vital to the country and the *amici* States. Because the district court let the jury be misled by unreliable expert testimony that glyphosate causes cancer, agriculture and farmers in the *amici* States will bear the costs of the district court's erroneous evidentiary decisions.

# A. Agriculture Is Important To The *Amici* States And Abroad.

From coast to coast, America's farmers and ranchers produce and raise crops and livestock on over 2 million farms covering more than 900 million acres.<sup>5</sup> Every person living in the United States benefits from agriculture and the industries related to it. The benefits of agriculture are many and far-reaching—from the economy to the kitchen table.

Agriculture significantly contributes to the national economy. In 2017, America's farmers contributed \$132.8 billion to the United States' gross domestic product.<sup>6</sup> This number, however, does not include related industries. Related industries range from food and beverage manufacturers, retailers, and restaurants to textiles and apparel

<sup>&</sup>lt;sup>5</sup> U.S. Dep't of Agric., 2017 Census of Agriculture, 7 (Table 1).

<sup>&</sup>lt;sup>6</sup> U.S. Dep't of Agric., Econ. Research Serv., *Ag and Food Sectors and the Economy*, https://www.ers.usda.gov/data-products/ag-and-food-statistics-charting-the-essentials/ag-and-food-sectors-and-the-economy/ (last visited Dec. 20, 2019).

manufacturers and stores.<sup>7</sup> If these related industries are included, the overall contribution of the agricultural sector is higher—

1.053 trillion in 2017.<sup>8</sup> In turn, if America's farmers and ranchers are doing well, then the downstream consumers and their pocketbooks benefit.<sup>9</sup>

Likewise, agriculture benefits the global economy. In 2018, the United States exported \$140 billion in agricultural products.<sup>10</sup> These exports resulted in a trade surplus, which has been ongoing since 1960.<sup>11</sup> The majority of agricultural goods exported are grains/feed, soybeans, livestock products, and horticulture products.<sup>12</sup>

There is also room for increases in agricultural exports. The world's population is expected to continue to increase from 7.7 billion

 $<sup>^{7}</sup>$  Id.

<sup>&</sup>lt;sup>8</sup> Id.

 $<sup>^9</sup>$  In 2018, Americans spent 12.9% of their household expenditures on food. See id.

<sup>&</sup>lt;sup>10</sup> U.S. Dep't of Agric., Econ. Research Serv., *Agricultural Trade*, https://www.ers.usda.gov/data-products/ag-and-food-statistics-charting-the-essentials/agricultural-trade (last visited Dec. 20, 2019).

<sup>&</sup>lt;sup>11</sup> Id.; U.S. Congress, Joint Econ. Comm., *The Economic Contribution of America's Farmers and the Importance of Agricultural Exports*, 1 (Sept. 2013).

 $<sup>^{12}</sup>$  Supra note 10.

persons today to 9.7 billion persons in 2050.<sup>13</sup> Due to the increases, there will likely be a larger demand for agricultural products and, thus, an increase in exports to those growing countries.<sup>14</sup>

Agriculture also creates and supports millions of employment opportunities in many different areas. These areas include insurance, transportation, technology, engineering, sales, repairs, and the food industry. In 2017, 21.6 million jobs were related to the agriculture and food sectors, which amounted to 11.0% of all employment in the United States.<sup>15</sup> This number includes approximately 2.6 million on-farm jobs.<sup>16</sup>

States also depend on agriculture for their economies. Every state has some type of agricultural production. Crop production, however, is

<sup>&</sup>lt;sup>13</sup> Press Release, Dep't of Econ. & Soc. Affairs, Growing at a slower pace, world population is expected to reach 9.7 billion in 2050 and could peak at nearly 11 billion around 2100, U.N. Press Release (June 17, 2019).

<sup>&</sup>lt;sup>14</sup> Supra note 11 at 1 ("Ninety-five percent of the world's potential consumers live outside of the United States, and population growth in the decades ahead will be concentrated in developing countries. As these countries grow and their citizens' incomes rise, their demand for meat, dairy and other agricultural products will increase.").

<sup>&</sup>lt;sup>15</sup> Supra note 6.

 $<sup>^{16}</sup>$  Id.

mostly centered in the Midwest.<sup>17</sup> The top five States with the most crop sales are California, Iowa, Illinois, Minnesota, and Nebraska.<sup>18</sup> California's crop sales mostly come from horticulture, while the Midwest's crop sales mostly come from grains and oilseeds—corn and soybeans.<sup>19</sup> These crops also support livestock and poultry production by providing feed.<sup>20</sup> The top five States with the most livestock sales are Texas, Iowa, California, Nebraska, and Kansas.<sup>21</sup>

Agriculture is particularly important in the *amici* States. Nebraska, known as the Cornhusker State and the Beef State, is defined by agriculture.<sup>22</sup> Nebraska is home to 47,400 farms and ranches covering 91% of the State's total land area.<sup>23</sup> In 2017, Nebraska farmers and ranchers contributed \$21 billion to the state's

<sup>&</sup>lt;sup>17</sup> U.S. Dep't of Agric., Econ. Research Serv., *Agricultural Production and Prices*, https://www.ers.usda.gov/data-products/ag-and-food-statistics-charting-the-essentials/agricultural-production-and-prices/ (last visited Dec. 20, 2019).

 $<sup>^{18}</sup>$  Id.

 $<sup>^{19}</sup>$  *Id*.

<sup>&</sup>lt;sup>20</sup> Nebraska Dep't of Agric., Nebraska Ag Facts Brochure, 17, https://nda.nebraska.gov/publications/ne\_ag\_facts\_brochure.pdf.

 $<sup>^{21}</sup>$  Supra note 17.

 $<sup>^{\</sup>rm 22}$  Supra note 20 at 14.

<sup>&</sup>lt;sup>23</sup> Nebraska Dep't of Agric., Nebraska Agriculture Fact Card (Feb. 2019), https://nda.nebraska.gov/facts.pdf.

economy, which was 5.7% of the United States' total.<sup>24</sup> Nebraska also had \$6.4 billion in agricultural exports, which translated into \$8.9 billion in additional economic activity.<sup>25</sup> Nebraska agriculture also supports 1 in 4 jobs in the state.<sup>26</sup>

Nebraska's top agricultural commodities are corn and cattle, which go hand in hand—corn is used as feed for many cattle operations.<sup>27</sup> Corn is an important feed for finishing cattle before processing because it improves the final beef product.<sup>28</sup> Iowa, Illinois, Nebraska, Minnesota, Kansas, and Indiana had the largest corn area forecasted to be planted and harvested in 2019.<sup>29</sup>

Like corn and cattle, soybeans are an important commodity. For 2019, Illinois, Iowa, Minnesota, North Dakota, Indiana, and Missouri had the largest soybean area forecasted to be planted and harvested.<sup>30</sup>

 $^{27}$  Id.

 $<sup>^{24}</sup>$  Id.

 $<sup>^{25}</sup>$  Id.

 $<sup>^{26}</sup>$  Id.

 $<sup>^{28}</sup>$  Supra note 20 at 12.

<sup>&</sup>lt;sup>29</sup> U.S. Dep't of Agric., Nat'l Agric. Statistics Serv., Acreage (June 2019),6 (June 28, 2019).

<sup>&</sup>lt;sup>30</sup> *Id*. at 15.

Soybeans are not only used in human food products, but also as feed for livestock and poultry.<sup>31</sup>

Another important crop is sugar beets. Sugar beets are used for sugar production.<sup>32</sup> Over half of the sugar produced in the United States comes from sugar beets.<sup>33</sup> Minnesota, North Dakota, Idaho, Michigan, Nebraska, and Montana are the largest sugar beet producers in the country producing millions of tons of sugar beets every year to be used in a wide range of products.<sup>34</sup>

Agriculture plays not only an important role in our country's history, but is essential to our country's and the *amici* States' futures. Agriculture and related industries in the *amici* States put food on the table, employ millions, and significantly contribute to the economy at all levels. It is imperative that agriculture and the inputs that fuel it be protected.

 $<sup>^{\</sup>scriptscriptstyle 31}$  Supra note 20 at 18.

 $<sup>^{32}</sup>$  Supra note 20 at 24.

 $<sup>^{33}</sup>$  Id.

 $<sup>^{34}</sup>$  Supra note 29 at 23.

## B. Glyphosate Provides Numerous Benefits To Agriculture In The *Amici* States.

Glyphosate benefits agriculture in a substantial number of ways. Glyphosate was commercially introduced in 1974 and is now the most widely used herbicide in the world.<sup>35</sup> Part of its success has been the development of transgenic, glyphosate-resistant crops, which were introduced in 1996.<sup>36</sup> Glyphosate-resistant crops include alfalfa, canola, corn, cotton, soybeans, and sugar beet varieties.<sup>37</sup> Glyphosate-resistant crops allow a farmer to spray glyphosate on his or her fields to manage weeds without damaging the crops.<sup>38</sup> Weed management is essential to good and sustainable agriculture because pests, like weeds, "can reduce

<sup>&</sup>lt;sup>35</sup> Stephen O. Duke & Stephen B. Powles, *Mini-review Glyphosate: a once-in-a-century herbicide*, 64 Pest Mgmt. Sci. 319, 319 (2008).
<sup>36</sup> Id.

<sup>&</sup>lt;sup>37</sup> U.S. Dep't of Agric., ERR-184, The Economics of Glyphosate Resistance Management in Corn and Soybean Production, 1 (April 2015).

<sup>&</sup>lt;sup>38</sup> U.S. Dep't of Agric., EIB-208, Agricultural Resources and Environmental Indicators, 2019, 30 (May 2019) ("Herbicide-tolerant ... crops are not damaged when they are sprayed with broad-spectrum herbicides (such as glyphosate or glufosinate) that damage most conventional varieties. Planting [herbicide-tolerant] crops allows farmers to use nonselective, broad-spectrum herbicides throughout the growing season (even after crop emergence).").

crop yields or the quality of production ...."<sup>39</sup> Weeds reduce crop yields or quality by competing with crops for the same resources of water, nutrients, sunlight, and space. The development of glyphosateresistant crops "made weed management easy, efficient, economical and environmentally compatible—exactly what growers wanted."<sup>40</sup> Due to these benefits, the vast majority of the corn and soybeans planted are glyphosate-resistant.<sup>41</sup> For example, Nebraska farmers used some form of glyphosate on 85% of the area planted with corn and 92% of the area planted with soybeans in 2018.<sup>42</sup> And, most if not all, sugar beets planted are glyphosate-resistant.<sup>43</sup>

<sup>&</sup>lt;sup>39</sup> *Id.* at 35.

<sup>&</sup>lt;sup>40</sup> Jerry M. Green, *The benefits of herbicide-resistant crops*, 68 Pesticide Mgmt. Sci. 1323, 1323 (May 2012).

 $<sup>^{41}</sup>$  Supra note 38 at v & 30.

<sup>&</sup>lt;sup>42</sup> U.S. Dep't of Agric., Nat'l Agric. Statistics Serv., Quick Stats for Nebraska Soybeans-Treated, Measured in Percentage of Area Planted, Average (2018), https://quickstats.nass.usda.gov/data/printable/
3496DCDD-6C83-3E4F-A4E1-AAF41FC5DC78 (last visited Dec. 20, 2019); see also U.S. Dep't of Agric., Nat'l Agric. Statistics Serv., Quick Stats for Nebraska Corn-Treated, Measured in Percentage of Area Planted, Average (2018), https://quickstats.nass.usda.gov/data/
printable/A18FA0E1-F27F-350E-B3B7-3B52B69B4B0C (last visited Dec. 20, 2019).

<sup>&</sup>lt;sup>43</sup> Memorandum from Caleb Hawkins, Charmaine Hanson, & Dexter Sellers, EPA, to Khue Nguyen, EPA, 7 (Apr. 18, 2019), https://www.epa.gov/sites/production/files/2019-04/documents

Glyphosate paired with glyphosate-resistant crops has helped increase yields and lower production costs. The use of glyphosateresistant crops allowed for easy, effective weed control and, in turn, resulted in better yields.<sup>44</sup> For example, Nebraska farmers harvested 111 bushels/acre of corn and 33 bushels/acre of soybeans in 1995 (prior to glyphosate-resistant crop introduction) compared to 182 bushels/acre of corn and 57 bushels/acre of soybeans in 2019, which is attributable to glyphosate and other variables.<sup>45</sup> Sugar beet yield increased 30% since glyphosate-resistant sugar beets were introduced.<sup>46</sup> These yield increases support more livestock and poultry to feed a growing world and, also, are used to make other human food products.

<sup>/</sup>glyphosate-response-comments-usage-benefits-final.pdf.
<sup>44</sup> U.S. Dep't of Agric., ERR-162, Genetically Engineered Crops in the United States, 12 (Feb. 2014) ("[B]y protecting the plant from certain pests, [genetically engineered] crops can prevent yield losses to pests, allowing the plant to approach its yield potential."); *supra* note 38 at 32.
<sup>45</sup> U.S. Dep't of Agric., Nat'l Agric. Statistics Serv., *Quick Stats for Nebraska Corn, Grain & Soybeans-Yield, Measured in Bushels/Acre (1995)*, https://quickstats.nass.usda.gov/results/A3BAB75C-BEFF-3665-8DEF-8D0CBB7674D4 (last visited Dec. 20, 2019); U.S. Dep't of Agric., Nat'l Agric. Statistics Serv., *Quick Stats for Nebraska Corn, Grain & Corn* 

Soybeans-Yield, Measured in Bushels/Acre (2019), https://quickstats. nass.usda.gov/results/A490EBB2-26AD-383A-87F2-0944B690543B (last visited Dec. 20, 2019).

 $<sup>^{46}</sup>$  Supra note 43 at 7.

Prior to glyphosate-resistant crops, glyphosate could not be directly sprayed onto growing crops because it would not only kill the weeds, but the crops.<sup>47</sup> Direct spraying of glyphosate onto glyphosateresistant crops enabled farmers to better control weeds in an economical and environmentally-friendly way.<sup>48</sup> Farmers using this method saved money and time because glyphosate could be applied to control "essentially all weeds—300 weed species—at a wide range of growth stages with no recropping restrictions."<sup>49</sup> When the patent for glyphosate expired, the price fell as generics came on the market thereby resulting in more savings for farmers.<sup>50</sup>

Moreover, farmers saved on fuel and equipment. Because glyphosate covers a broad spectrum of weeds, farmers were able to

 $<sup>^{\</sup>rm 47}$  Supra note 40 at 1324.

<sup>&</sup>lt;sup>48</sup> For example, farmers are able to use spraying equipment to apply glyphosate after the crop has emerged from the soil instead of only being able to spray prior to crop emergence or having to use row cultivators after crop emergence.

 $<sup>^{49}\</sup> Supra$  note 40 at 1325.

 $<sup>^{50}</sup>$  Supra note 38 at 38; supra note 37 at 1.

control weeds with "a single timely application ...."<sup>51</sup> As such, the use of glyphosate may save passes over a field,<sup>52</sup> but even if:

[Glyphosate-resistant] crops do not necessarily save passes over a field, ... they do substitute herbicide applications for more expensive and more fuel intensive methods of weed management, such as intensive tillage practices or the use of herbicides that require physical incorporation into the soil. Also, with potentially fewer passes over the field, tractor and spraying equipment lasts longer, and this results in savings in machinery and equipment costs over the long term.<sup>53</sup>

These cost-savings are, in turn, passed down to other consumers

and users. For example, "[l]ivestock producers constitute a large

percentage of corn and soybean buyers and therefore are major

beneficiaries of any downward pressure on crop price due to adoption of

[genetically-engineered] crops." $^{54}$  If farmers have cost-savings, then

those cost-savings are passed on to livestock producers and consumers.

<sup>&</sup>lt;sup>51</sup> Nat'l Research Council, The Impact of Genetically Engineered Crops on Farm Sustainability in the United States, 32 (The National Academies Press, 2010).

<sup>&</sup>lt;sup>52</sup> Passes over a field refers to the number of times a farmer uses machinery—whether spraying or tilling—to accomplish a task. For example, spraying machinery may cover more ground than cultivators (spray booms versus cultivator wings), which means fewer passes over a field and less soil compaction or a farmer may have to be in the field fewer times to manage weeds.

 $<sup>^{\</sup>rm 53}$  Supra note 51 at 151-52.

 $<sup>^{54}\</sup> Supra$  note 51 at 11, 166.

This is particularly important because, on average, Americans spend 12.9% of their household expenditures on food.<sup>55</sup>

The use of glyphosate-resistant crops has also benefited the environment. Glyphosate-resistant crops "have had fewer adverse effects on the environment than non-[glyphosate-resistant] crops produced conventionally."<sup>56</sup> By being able to spray glyphosate directly on glyphosate-resistant crops, farmers are able to eliminate the use of row cultivators to control weeds during the growing season and reduce the use of intensive cultivation practices after harvest or before planting.<sup>57</sup> Rather, farmers can engage in conservation tillage:

Conservation tillage maintains a soil cover with crop residues, which has many positive environmental benefits, including reduced soil erosion and water pollution from nutrient and sediment run-off, protection from wind erosion and improved habitat for birds, mammals and microorganisms, as well as less consumption of fossil fuels and lower carbon dioxide emissions.<sup>58</sup>

 $<sup>^{55}</sup>$  Supra note 6.

 $<sup>^{56}</sup>$  Supra note 51 at 3.

<sup>&</sup>lt;sup>57</sup> Supra note 51 at 64 ("[T]he use of glyphosate allowed weeds to be controlled after crop emergence without the need for tillage to disrupt weed development before or after planting."). If a farmer could not directly spray crops after emergence, then row cultivators would be used to break up the soil between the rows of crops thereby uprooting weeds.

 $<sup>^{58}</sup>$  Supra note 40 at 1326.

One form of conservation tillage is no-till, where "the soil and surface residue from the previously harvested crop are left undisturbed as the next crop is seeded directly into the soil without tillage."59 The crop residue leftover, by conservation tilling, "builds organic matter, and there is less soil compaction because [herbicide-resistant] crop growers make fewer passes through the field with tractors than non-[herbicideresistant] crop growers."60 Conservation tillage "reduces soil loss from erosion, increases water filtration, and can improve soil quality and moisture retention ....."<sup>61</sup> By increasing water filtration, conservation tillage reduces the amount of sediment and chemicals that runoff into surface waters.<sup>62</sup> Conservation tillage is used on 70% of soybean acres and 65% of corn acres.<sup>63</sup> Glyphosate and glyphosate-resistant crops have helped increase the use of conservation tillage, as well as crop production.64

- $^{62}$  Supra note 51 at 69.
- $^{63}$  Supra note 38 at VI.
- $^{64}$  Supra note 40 at 1326.

<sup>&</sup>lt;sup>59</sup> Supra note 51 at 63.

 $<sup>^{60}\</sup> Supra$  note 40 at 1326.

 $<sup>^{\</sup>rm 61}$  Supra note 51 at 68.

An added benefit of less tilling is using less fuel resulting in fewer emissions.<sup>65</sup> For example, moldboard plowing may use 5.29 gallons per acre of fuel whereas no-till practices may use 1.40 gallons per acre of fuel.<sup>66</sup> On a 120-acre field, moldboard plowing may use 635 gallons of fuel and no-till practices may use 168 gallons.

Glyphosate has other environmental benefits. Glyphosate is "more environmentally benign than the herbicides that it has replaced …."<sup>67</sup> It has "very low toxicity to mammals, birds, and fish" because "they do not have a shikimate pathway for protein synthesis …."<sup>68</sup> Glyphosate also "has low soil and water contamination potential because it binds readily to soil particles and has a relatively short halflife in soil …."<sup>69</sup>

Glyphosate is an important tool as part of an integrated and diverse weed management system.<sup>70</sup> Even with the emergence of

<sup>&</sup>lt;sup>65</sup> *Id*.

 $<sup>^{66}</sup>$  *Id.*; *see also supra* note 51 at 151. A moldboard plow is a piece of equipment with curved metal plates pulled by a tractor to turn over the soil.

 $<sup>^{67}</sup>$  Supra note 51 at 62.

<sup>&</sup>lt;sup>68</sup> Supra note 51 at 29, 62.

 $<sup>^{69}</sup>$  Supra note 51 at 29 & 70.

 $<sup>^{70}\</sup> Supra$  note 40 at 1328.

relatively few glyphosate-resistant weeds, glyphosate-resistant crops will be a mainstay because "[w]eeds that have evolved resistance to glyphosate have not eliminated the ability of glyphosate to control other weeds."<sup>71</sup> Because of its effectiveness on a broad spectrum of weeds, glyphosate will continue to be an herbicide that is part of a weed management system where resistance can be slowed or removed for the remaining 200+ weeds that glyphosate covers.<sup>72</sup> It is also cheaper and environmentally safer. Glyphosate will remain an important and effective weed management tool for farmers in the *amici* States.

Glyphosate has a beneficial impact on farmers, the economy, the environment, and the way of life in the *amici* States. If glyphosate were curtailed as a result of this case and the thousands of cases like it, there would be a palpable and adverse effect on agriculture in the *amici* States and abroad.

 $<sup>^{71}</sup>$  Supra note 40 at 1329.

<sup>&</sup>lt;sup>72</sup> Supra note 44 at 32; Univ. of Nebraska-Lincoln, Inst. of Agric. & Nat. Res., Multiple Herbicide Resistant Weeds and Challenges Ahead, https://cropwatch.unl.edu/multiple-herbicide-resistant-weeds-andchallenges-ahead#:~:targetText=By%202014%2C%2029%20weed%20 species,species%20in%20the%20United%20States (last visited Dec. 20, 2019) (providing there were 15 weed species resistant to glyphosate in the United States in 2014).

## C. The District Court's Erroneous Evidentiary Decisions Threaten To Curtail The Important Use Of Glyphosate In Agriculture.

The importance of glyphosate in agriculture is undeniable. The beneficial impacts of glyphosate not only accrue to farmers and the *amici* States, but to the country and the world as a whole. The shelf life of glyphosate, however, may be limited if the district court's decisions to open the gate to unreliable and misleading expert testimony on the carcinogenicity of glyphosate on humans is left standing. As demonstrated below, the curtailment of glyphosate from agriculture will have real impacts not only to farmers and agriculture in the *amici* States, but the ripple effects of these impacts will be felt by every person.

Glyphosate is the most widely used herbicide in the country and the *amici* States. Because of its broad applicability, effectiveness, price, and environmental benefits, it is the herbicide of choice for most farmers in the United States. In 2018, farmers used some form of glyphosate on the vast majority of the areas planted with corn and soybeans.<sup>73</sup>

<sup>&</sup>lt;sup>73</sup> *E.g.*, *supra* note 42.

Many herbicide-resistant crops, like corn and soybeans, are engineered to be resistant to only glyphosate.<sup>74</sup> Without glyphosate as a weed management tool, farmers in the *amici* States will have to resort to another herbicide or more likely a mixture of herbicides. These herbicides may be less environmentally-friendly and less effective on a broad spectrum of weeds, meaning farmers may need to use more herbicides to fill the gap left by glyphosate or make additional passes in the field. These other herbicides may also be more expensive and more difficult to use than glyphosate. This is because choosing "[glyphosate] often means reducing the use of less effective, more costly, and possibly more toxic herbicides although exceptions occur .... That substitution effect can produce cost savings as well as reductions in environmental and human health risks associated with chemical applications ...."<sup>75</sup>

<sup>&</sup>lt;sup>74</sup> Supra note 51 at 29; but see supra note 38 at 33 ("Recently, new varieties of [genetically engineered] seeds that are tolerant of the herbicidal active ingredients dicamba and 2,4-D have been commercialized. It remains to be seen how the introduction of these technologies will affect the herbicide use and weed control decisions of U.S. farmers.").

<sup>&</sup>lt;sup>75</sup> Supra note 51 at 149; see also, supra note 44 at 25 ("[G]lyphosate is significantly less toxic and less persistent than traditional herbicides ...."); U.S. Dep't of Agric., AER-801, Adoption of Bioengineered Crops, 28 (May 2002) ("The herbicides that glyphosate replaces are 3.4 to 16.8 times more toxic" and "glyphosate has a half-life in the environment of

Additionally, farmers will have to change up their weed management program, which may take additional time and cost additional money.

The change to other herbicides may not only impact the environment, but also the economy. Farmers would likely need to spend more on herbicides for weed management, which in turn impacts downstream consumers of agricultural products, such as livestock and poultry producers, manufacturers, and supermarkets. In the alternative, if the market would not adjust to the increased costs of farmers' inputs, then the economies in the *amici* States—especially in the rural areas—may suffer.

Agriculture in this country, and the *amici* States, plays a prominent role in feeding the world and conserving the environment. "Agriculture must take advantage of any technology that provides more food to a hungry world by enabling better control of weeds and does not hurt the environment or human health."<sup>76</sup> Glyphosate is a jack of all trades in that regard—yields have increased since the introduction of glyphosate-resistant crops, the environment has benefitted, the

 $<sup>47~{\</sup>rm days}\ldots$  compared with 60-90 days for the herbicides it commonly replaces.").

 $<sup>^{76}</sup>$  Supra note 40 at 1330.

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economy has benefited, and it is safer than other herbicides. All of these benefits are important to the *amici* States where agriculture is a valuable component of their identities.

Glyphosate is one of the most studied herbicides. It has repeatedly been found not likely to be carcinogenic to humans by the EPA, other regulatory bodies, and many scientific researchers. Tens of thousands of farmers have been using glyphosate as their herbicide of choice for over twenty years and maybe longer. Farmers in the *amici* States should not have to worry that glyphosate will disappear because the district court and the jury in this case bought into junk science. The district court's erroneous evidentiary decisions threaten the continued vitality of agriculture in the *amici* States. This Court should reverse the district court's judgment and exclude Hardeman's expert testimony on general and specific causation.

#### CONCLUSION

The district court's judgment should be reversed.

Dated: December 20, 2019.

Respectfully submitted,

STATE OF NEBRASKA, Amicus Curiae

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#### UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

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