1	WILKINSON WALSH + ESKOVITZ LLP	ARNOLD & PORTER KAYE SCHOLER
2	Brian L. Stekloff (<i>pro hac vice</i>) (bstekloff@wilkinsonwalsh.com)	LLP Pamela Yates (CA Bar No. 137440)
3	Tamarra Matthews Johnson (pro hac vice)	(Pamela.Yates@arnoldporter.com)
4	(tmatthewsjohnson@wilkinsonwalsh.com) Rakesh Kilaru (<i>pro hac vice</i>)	777 South Figueroa St., 44th Floor Los Angeles, CA 90017
	(rkilaru@wilkinsonwalsh.com)	Tel: 213-243-4178
5	2001 M St. NW 10 th Floor	Fax: 213-243-4199
6	Washington, DC 20036	
7	Tel: 202-847-4030 Fax: 202-847-4005	
8	1 ux. 202 047 4003	
9	HOLLINGSWORTH LLP Eric G. Lasker (pro hac vice)	COVINGTON & BURLING LLP
10	(elasker@hollingsworthllp.com) 1350 I St. NW	Michael X. Imbroscio (pro hac vice) (mimbroscio@cov.com) One City Center
11	Washington, DC 20005	850 10th St. NW
	Tel: 202-898-5843 Fax: 202-682-1639	Washington, DC 20001 Tel: 202-662-6000
12	Fax: 202-082-1039	Tel: 202-002-0000
13	Attorneys for Defendant MONSANTO COMPANY	
14		
15	UNITED STATES DISTRICT COURT	
16	NORTHERN DISTRICT OF CALIFORNIA	
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18	IN RE: ROUNDUP PRODUCTS)) MDL No. 2741
19	LIABILITY LITIGATION	
20		Case No. 3:16-md-02741-VC
21	Gebeyehou v. Monsanto Co., et al., 3:16-cv-05813-VC	MONSANTO COMPANY'S MOTION FOR DIRECTED VERDICT
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MOTION FOR DIRECTED VERDICT

As conveyed on the record at the close of Plaintiff's case and at the conclusion of all evidence, Monsanto moves for a directed verdict in Phase 1 of this trial. Based on the evidence presented at Phase 1 of the trial, Monsanto is entitled to a directed verdict on the question of causation. Monsanto reserves the right to seek a directed verdict on all Phase 2 questions should the need arise. The bases for this Motion are set forth below.

- 1. Mr. Hardeman has presented insufficient general causation evidence. Understanding the complexities of the general causation inquiry, as thoroughly outlined in the Court's Pretrial Order No. 45, Monsanto maintains its position that Mr. Hardeman has presented insufficient evidence at trial to support a finding that Roundup can cause NHL and hereby incorporates all its prior briefing and argument on this subject.
- 2. Mr. Hardeman has failed to present sufficient reliable evidence that Roundup was a substantial factor in causing Mr. Hardeman's NHL. Monsanto hereby incorporates all its prior briefing and argument on this subject, but specifically identifies a number of deficiencies in Mr. Hardeman's specific causation evidence that makes a directed verdict particularly appropriate.
- 3. Mr. Hardeman presented just one specific causation expert, Dr. Weisenburger, whose opinion was based purely on his subjective beliefs, 2/11/19 Tr. at 384:7–10, an untested methodology, Trial Tr. at 1220:25–1221:10, and inadequate science. Dr. Weisenburger's opinion cannot withstand scrutiny for a number of reasons outlined below and therefore is not a sufficient basis for Mr. Hardeman's specific causation case.
- 3. Dr. Weisenburger admitted he had never before used the differential diagnosis he employed in this case to determine the cause of Mr. Hardeman's NHL. Trial Tr. at 1220:25–1221:10. All of the other specific causation experts in this case testified that they do not use Dr. Weisenburger's differential diagnosis in their own work, they do not know of any other doctors who use this methodology, and they do not think it is a scientifically valid methodology. Trial Tr. at 1595:21–1596:20 (Dr. Levine); 1785:8–1787:22 (Dr. Arber). Dr. Weisenburger cannot reliably base his opinion in this case on an untested methodology that he crafted for litigation.

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- 4. Dr. Weisenburger failed to adequately consider whether Mr. Hardeman's NHL was idiopathic. It is undisputed that 70 to 90 percent of NHL cases are idiopathic. Considering this fact, the Court specifically held that to assist the jury in this case, a specific cause expert "must have a way to differentiate Roundup users who developed NHL because they used the product from Roundup users who would have developed NHL regardless." Pretrial Order 85, at 4. Dr. Weisenburger did not do so. After improperly disregarding a number of risk factors and unreliably ruling out several so-called "causative" risk factors, Dr. Weisenburger concluded Roundup was the cause of Mr. Hardeman's NHL simply because there was no other causative risk factor present. Trial Tr. at 11:57:9–11:58:8; 1164:1–4. This analysis completely ignores the possibility of an idiopathic case of NHL, even though Dr. Weisenburger admits Mr. Hardeman could have contracted NHL without ever using Roundup. Trial Tr. at 1305:5-10. In fact, Dr. Weisenburger testified that the presence of any risk factor associated with NHL will automatically lead him to disregard the possibility that a patient's NHL is idiopathic. Trial Tr. at 1218:4–22. This testimony is inconsistent with the consensus among experts regarding the idiopathic nature of NHL. Dr. Weisenburger's opinion is not saved by a biomarker or genetic signature associated with Roundup. In fact, he openly admits one does not exist. Trial Tr. at 1290:4–20.
- 5. The only basis Dr. Weisenburger offered for concluding that Roundup was a potential cause for Mr. Hardeman was his analysis of certain epidemiological studies. But those studies are unreliable and inadequate to support his conclusions. Dr. Weisenburger relied on the McDuffie and Eriksson studies for the proposition that there is increased risk of developing NHL for people exposed to glyphosate more than two days a year or ten days in a lifetime. *Id.* at 1089:6–1090:5. The Court has recognized that the glyphosate figures from those studies are "based on unadjusted data" and amount to junk science that cannot form the basis of a reliable specific cause opinion. PTO 85, at 7–8; PTO 45, at 24. Moreover, when NHL's 20 year latency period is factored in, the impact of the failure to adjust for other pesticides is even more apparent. For example, the McDuffie study examined individuals who were diagnosed with NHL between 1991 to 1994. Twenty years prior to these individual's diagnoses (1971-1974), Roundup was not yet available or was just coming on the market. Thus, it is likely the individuals studied in McDuffie were using

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other pesticides much more frequently than Roundup, and these other pesticides were not accounted for in the data.

- 6. Dr. Weisenburger's reliance on DeRoos 2003 is also improper and does not save his specific causation opinion. Dr. Weisenburger stated, based on DeRoos 2003's logistic regression, that "people who were exposed to Roundup were twice as likely to develop non-Hodgkin's lymphoma as people who weren't exposed to Roundup." Trial Tr. at 1086:7–9. DeRoos 2003 taken as a whole does not reliably support this statement; accordingly, this doubling of the risk statement was not distinguishable from similar statements ruled impermissible under the Court's prior orders. See PTO 85, at 7. Although DeRoos 2003 adjusted for 47 other pesticides, this fact is actually detrimental to its findings. There were only 36 exposed cases and 61 controls in that study. To yield reliable results, there should have been "five exposed cases for every variable" the authors adjusted for. Trial Tr. at 1453:17-21. There were far too few exposed cases in DeRoos considering the number of pesticides the authors adjusted for. Acknowledging this fact, the authors then conducted a hierarchical regression to correct for the low numbers, and it yielded a odds ratio of 1.6 that was not statistically significant. Trial Tr. at 1453:22–1454:2. Such an odds ratio cannot establish specific causation. DeRoos 2003's glyphosate specific data also falls apart when latency is considered. DeRoos 2003 analyzed three studies that examined individuals who were diagnosed with NHL between roughly 1979 and 1986. Twenty years prior to these individual's diagnoses (1959-1966) was well before glyphosate was commercially available.
- 7. Even if DeRoos 2003 were reliable, it cannot be the only information upon which Dr. Weisenburger bases his specific causation opinion. DeRoos 2003 contains no discussion of a dose response and thus provides no basis for Dr. Weisenburger's conclusion that Mr. Hardeman falls into the category of Roundup users who are at an elevated risk for developing NHL. See PTO 85, at 6. Moreover, because DeRoos analyzed ever/never data, it does not allow Dr. Weisenburger to provide the type of analysis necessary to distinguish idiopathic cases of NHL amongst Roundup users from cases of NHL caused by Roundup. Such analysis is necessary under the Court's prior rulings. Id. at 4.

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- 8. Dr. Weisenburger's reliance on the North American Pooled Project (NAPP) is completely impermissible. Dr. Weisenburger cherry-picked one slide out of one presentation of unpublished data to support his opinion, while ignoring subsequent presentations of the same data showing updated statistics that did not support his opinion. Trial Tr. at 1244:10–20. Such cherrypicking cannot reliably support a specific causation opinion.
- 9. Dr. Weisenburger had no reliable basis for his dose-response opinion—which represented his sole effort to distinguish Mr. Hardeman from anyone else exposed to Roundup. McDuffie and Eriksson were the only studies that provided dose-response analyses. As discussed above, because these cases did not adjust for the use of other pesticides, Dr. Weisenburger cannot reliably rely upon them. Dr. Weisenburger's other statements regarding dose-response, that Roundup was a substantial contributing factor to Mr. Hardeman's NHL because "he used [Roundup] frequently and had high exposures," Trial Tr. at 1145:20–22, are unsupported and purely subjective. Dr. Weisenburger admitted as much at the February 11, 2019 Daubert hearing. 2/11/19 Tr. at 387:18–22; 430:5–19.
- 10. Dr. Weisenburger failed to reliably rule out Mr. Hardeman's other causative risk factors including hepatitis B and hepatitis C. The evidence shows Mr. Hardeman was actively infected with hepatitis C for an extended period of time. The scientific literature indicates hepatitis C can cause irreversible genetic mutations; when accounting for latency, there is strong evidence this genetic mutation caused Mr. Hardeman's NHL. Dr. Weisenburger did not adequately account for and refute this evidence.
- For all the foregoing reasons, as well as those stated in Monsanto's prior briefing, 11. expressly incorporated herein, the Court cannot allow Phase 1 of this case to proceed to a jury.

1 **DATED:** March 12, 2019 Respectfully submitted, 2 3 /s/ Brian L. Stekloff 4 Brian L. Stekloff (pro hac vice) (bstekloff@wilkinsonwalsh.com) Tamarra Matthews Johnson (pro hac vice) 5 (tmatthewsjohnson@wilkinsonwalsh.com) 6 Rakesh Kilaru (pro hac vice) (rkilaru@wilkinsonwalsh.com) 7 WILKINSON WALSH + ESKOVITZ LLP 2001 M St. NW, 10th Floor 8 Washington, DC 20036 Tel: 202-847-4030 9 Fax: 202-847-4005 10 Pamela Yates (CA Bar No. 137440) (Pamela. Yates@arnoldporter.com) 11 ARNOLD & PORTER KAYE SCHOLER 777 South Figueroa St., 44th Floor 12 Los Angeles, CA 90017 13 Tel: 213-243-4178 Fax: 213-243-4199 14 Eric G. Lasker (pro hac vice) 15 (elasker@hollingsworthllp.com) HOLLINGSWORTH LLP 16 1350 I St. NW 17 Washington, DC 20005 Tel: 202-898-5843 18 Fax: 202-682-1639 19 Michael X. Imbroscio (pro hac vice) (mimbroscio@cov.com) 20 COVINGTON & BURLING LLP 21 One City Center 850 10th St. NW 22 Washington, DC 20001 Tel: 202-662-6000 23 24 Attorneys for Defendant MONSANTO COMPANY 25 26 27 28

CERTIFICATE OF SERVICE I HEREBY CERTIFY that on this 12th day of March 2019, a copy of the foregoing was filed with the Clerk of the Court through the CM/ECF system which sent notice of the filing to all appearing parties of record. /s/ Brian L. Stekloff