UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE: ROUNDUP PRODUCTS LIABILITY LITIGATION	MDL No. 2741 Case No. 16-md-02741-VC
This document relates to: ALL ACTIONS	

PLAINTIFFS' CASE MANAGEMENT STATEMENT

Pursuant to the Court's Pretrial Order No. 1, Plaintiffs submit this joint case management statement.

I. Plaintiffs Have Reached Consensus Regarding Plaintiffs' Leadership and Coordination Structure.

A. Co-Lead Counsel.

The demands of this case warrant a co-lead structure. All Plaintiffs request a three-person, co-lead counsel structure as follows: [redacted]. As their applications illustrate, these counsel have the experience, dedication, staff, and financial resources to litigate this MDL efficiently and effectively for the benefit of all Plaintiffs. More importantly, [redacted] have been the *de-facto* leaders of this litigation for some time and have built strong relationships and consensus among the numerous Plaintiffs' counsel litigating these matters.

B. Executive Committee.

The case also demands additional firms to assist in the financial and attorney requirements of the MDL. Plaintiffs agree that a six-person Executive Committee, composed of the three co-lead counsel named above and the following attorneys, would best serve this MDL and Plaintiffs: Michael Baum, Yvonne Flaherty, and Hunter Lundy. Like the proposed co-leads, Mr. Baum, Ms. Flaherty, and Mr. Lundy have been instrumental in developing and supporting this litigation thus far. They bring a wealth of experience and know-how to the table. Incorporation of these six counsel into an Executive Committee will greatly facilitate

coordination among Plaintiffs.

C. Plaintiffs' Steering Committee.

Finally, Plaintiffs' counsel agree that the financial and work demands of this MDL would also benefit from the formation of a Plaintiffs' Steering Committee ("PSC"), with members nominated by Plaintiffs' leadership and confirmed by the Court. If the Court agrees, Plaintiffs propose to submit a list of attorneys and their applications for nomination to a PSC within five (5) business days from the date the Court appoints leadership.

D. Roles and Responsibilities of Co-Lead Counsel.

The Co-Lead Counsel would have the authority and duty to coordinate and oversee the Executive Committee's and the PSC's responsibilities, as set forth below:

1. To propose agenda items for and to appear at periodic Court-noticed status conferences and hearings;

2. To schedule and set agendas for PSC meetings and to keep minutes or transcripts of these meetings;

3. To draft case management orders for the orderly and efficient litigation of this case, including a case management order that provides for the duties and responsibilities of the MDL leadership structure as set forth herein;

4. To enter into stipulations with Defendants;

5. To sign and file all pleadings relating to all actions in the MDL;

6. To determine and present in pleadings, briefs, motions, oral argument, or such other fashion as may be appropriate, personally or by a designee, to the Court and opposing parties the position of Plaintiffs on matters arising during the pretrial proceedings;

7. To coordinate and conduct discovery on behalf of Plaintiffs consistent with the requirements of the Federal Rules of Civil Procedure and the Local Rules of Practice for the Northern District of California;

8. To schedule and engage in settlement negotiations with Defendants, and if there is a settlement, propose a claims protocol and/or plan of allocation;

9. To liaise with defense counsel;

10. To liaise with and keep informed Plaintiffs' attorneys who file cases in this MDL and who are not appointed to leadership in this MDL;

11. To consult with and employ expert witnesses;

12. To enter into contracts and other agreements with vendors necessary to litigate this MDL, such as a document depository vendor, court reporting services, and expert witnesses;

13. To establish protocols for common benefit billing and disbursements, to maintain records of such billing and disbursements advanced by Executive Committee and PSC members, and to report periodically to the Executive Committee and PSC concerning disbursements and receipts;

14. To maintain and collect time and expense records for work performed, time billed, costs incurred and other disbursements made by all Plaintiffs' counsel whose work has been specifically authorized, and submit at the Court's request in writing, *ex parte* and *in camera* reports to the Court regarding time billed in the prosecution of this action;

15. To retain the services of any attorney not part of the Executive Committee or PSC to perform any common benefit work, provided the attorney so consents and is bound by the compensation structure established in this MDL;

16. To establish and maintain a depository for orders, pleadings, hearing transcripts, and all documents served upon Plaintiffs' counsel, and to make such papers available to Plaintiffs' counsel upon reasonable request;

17. To otherwise coordinate the work of all Plaintiffs' counsel, and perform such other duties as the Co-Lead Counsel deem necessary, in order to advance the litigation or as authorized by further Order of the Court; and

18. To perform any other necessary administrative and logistic functions of the Executive Committee and the PSC and to carry out any other duty as the Court may order.

E. Appointment of Liaison Counsel.

Plaintiffs' counsel met and have consensus on the recommendation of Plaintiffs' Liaison Counsel pursuant to the Court's Pretrial Order No.1. Plaintiffs propose the appointment of Lori Andrus and Mark Burton as Co-Liaison, subject to the Court's approval. Ms. Andrus and Mr. Burton will file a joint application for the position of Co-Liaison in the MDL docket.

F. Other Administrative Matters.

Plaintiffs attach as Exhibit A a proposed schedule for the submission of case management orders that are necessary for the efficient and effective adjudication of this MDL. The proposed deadlines in Exhibit A reflect the fact that counsel comprising the proposed Co-Lead Counsel and Executive Committee structure have been negotiating these matters with counsel for Monsanto for several months.

II. Circumstances Since the Phased Discovery Order in the *Hardeman* Case Indicate that Phased Discovery Is Not Warranted.

A. Phased Discovery Will Not Advance the Speedy Resolution of This MDL.

At the heart of Monsanto's phased discovery proposal is the hope that Monsanto will be able to exclude *all* of Plaintiffs' general causation experts under *Daubert* as being "unreliable" and then, in turn, prevail on summary judgment by arguing that Plaintiffs cannot submit admissible evidence that Roundup® exposure causes NHL. Thus, the wisdom of phased discovery turns on whether there is any reasonable probability that Monsanto will be successful in excluding all of Plaintiffs' experts under *Daubert*. And, in light of the prevailing science, there is simply no reasonable probability that Monsanto will accomplish this Herculean task. There is already a disputed issue of fact regarding whether Roundup® exposure can cause NHL; it has been so deemed by a source that is unquestionably reliable.

The World Health Organization's International Agency for Research on Cancer ("IARC") concluded that glyphosate is a human carcinogen and that there is a strong association between glyphosate exposure and NHL. Simply put, IARC is the most preeminent cancer-assessment authority in the world. Several federal and state laws specifically rely on IARC monograph assessments. For example, under the Toxic Substances Control Act of 1976, as interpreted by the EPA, "[a] chemical is considered to be a known or potential human carcinogen, for purposes of TSCA section 12(b) export notification, if that chemical is . . . classified as . . . 'probably carcinogenic to humans' (Group 2A) . . . by the World Health Organization International Agency for Research on Cancer (IARC)[.]" 40 C.F.R. § 707.60(2)(c).

Similarly, the U.S. Consumer Product Safety Commission ("CPSC") and the Occupational Safety and Health Administration ("OSHA") both recognize and accept the authority of IARC in assessing the potential cancer hazard of an agent. *See* 16 C.F.R. § 1500.135(a)(1)-(3) (describing similarities between IARC and EPA assessments); 29 C.F.R. § 1910.1450(b) (defining carcinogen as any substance identified as such by IARC). And, in California, by law, any substance listed as a probable carcinogen by IARC (like glyphosate) is presumed to be a carcinogen by the State of California—and the State of California is presently embroiled in litigation with Monsanto because it intends to list glyphosate as a substance known to cause cancer. *See* Cal. Lab. Code § 6382(b)(1); *California Chamber of Commerce v. Brown*, 196 Cal. App. 4th 233, 242, 126 Cal. Rptr. 3d 214, 219 (Ct. App. 2011).

Putting aside the respect and deference afforded IARC cancer assessments by Congress, EPA, CPSC, OSHA, and the State of California, the Federal Judicial Center ("FJC") specifically lists IARC as one "of the most well-respected and prestigious scientific bodies." Reference Manual on Scientific Evidence (Third) at 20 (2011). In discussing the IARC monograph process, the FJC explains that IARC "evaluates the human carcinogenicity of various agents" by reviewing "all of the relevant evidence, including animal studies as well as any human studies" and "[o]n the basis of a synthesis and evaluation of that evidence, IARC publishes a monograph containing that evidence and its analysis of the evidence and provides a categorical assessment of the likelihood the agent is carcinogenic." *Id.* at 564 n.46.

The likelihood of Monsanto's prevailing on a *Daubert* challenge is, thus, remote. Monsanto would have to convince this Court to ignore the IARC assessment and reject a near-unanimous agreement by regulators, legislatures, and the judiciary that IARC's method for hazard assessment sets the standard. Because the wisdom of phased discovery turns on whether Monsanto will be able to convince this Court that IARC, and the peer reviewed epidemiology, should be ignored, requiring phased discovery will only delay the resolution of this MDL. There is no need to shackle discovery with any restriction; it makes sense to allow this matter to proceed with general full-bore discovery consistent with the practice of nearly all other MDLs.

B. Recent Discovery Shows that Separating General Causation Discovery from other Forms of Monsanto-Specific Discovery is Not Feasible.

The creation of the MDL and the documents produced so far warrant reassessment of phased discovery in this litigation because 'general causation' discovery cannot be isolated from other Monsanto-specific discovery.[1] In this case, 'general causation' is not a simple term of merely reading/interpreting the published articles and scientific literature. Instead, Plaintiffs must actually discover *how* each article and study was conducted and *who* was involved. In the limited productions received so far, it is evident that Monsanto facilitated the "ghostwriting" of key articles and studies concerning Roundup's® safety and participated in the perpetuation of academic fraud about Roundup's® safety. These activities call into question the reliability of Monsanto's and other scientists' studies about Roundup® exposure and human health—studies Monsanto's boldly cites as "independent" in defending claims that Roundup® causes cancer. As a result, the issue of general causation is inextricably interwoven with other liability discovery.

Moreover, given the manner in which Monsanto maintains its ESI, most document discovery involves the production of individual custodial files. Monsanto lacks the capability of searching for documents across all files. Therefore, the only way to respond to document requests is for Monsanto to conduct targeted searches for *each* custodian (which is another reason to deny Monsanto's attempt to limit production of custodial files). Thus, it makes little sense, to stage or limit discovery. Once Monsanto has begun searching a custodian's files, why not conduct a complete search for all relevant documents instead of bickering about the actual

[1] The law does not favor bifurcation; unitary proceedings are the norm. Indeed, when considering bifurcation, a court must balance the "potential savings against the risk of later duplicative discovery should it be necessary to resume the deposition of a witness or the production of documents." MANUAL FOR COMPLEX LITIGATION § 11.422 (4th ed. 2004). Bifurcation of discovery is permitted only when it promotes fairness and efficiency. *See In re Plastics Additives Antitrust Litig.*, No. 03-CV-2038, 2004 WL 2743591, at *2 (E.D. Pa. 2004). "[I]t is clear that in most instances, regular—that is, unbifurcated—discovery is more efficient." *Central Transp. Intl., Inc., v. Gen. Elec. Co.*, No. 3:08-CV-136-C, 2008 WL 4457707, at *3 (W.D.N.C. Sep. 30, 2008); *see Awalt v. Marketti*, 75 F. Supp. 3d 777, 779 n.2 (N.D. Ill. 2014) ("bifurcation [of discovery] is now heavily disfavored" (internal quotation marks and citation omitted)); *Charter Oak Fire Ins. Co. v. Am. Capital, Ltd.*, No. 09-CV-0100, 2011 WL 6000562, at *1 (D. Md. Nov. 29, 2011); *cf. In re Bendectin Litig.*, 857 F.2d 290, 307 (6th Cir. 1988) ("The piecemeal trial of separate issues in a single suit is not to be the usual course."); *Monaghan v. SZS 33 Assocs., L.P.*, 827 F. Supp. 233, 246 (S.D.N.Y. 1993) ("fundamental presumption" against bifurcation of trials); *Patten v. Lederle Labs*, 676 F. Supp. 233, 238 (D. Utah 1987) (single trial tends to lessen delay, expense, and inconvenience).

scope of the phased discovery and then, later, re-search that same custodian's files once the first phase of discovery is complete. Indeed, it is difficult to agree on the scope of the proposed phased discovery—one side will read the scope broader than the other—and an order phasing discovery will almost certainly inject needless delay as the parties "litigate" those disputes.

Since the time that this Court phased discovery in *Hardeman*, Monsanto has used the *Hardeman* Order as a shield from producing additional custodial files, even when Plaintiffs show that additional custodial files have relevant, and even vital, information about whether exposure to Roundup® (including its surfactants) causes NHL and Monsanto's knowledge of those dangers.[2] Monsanto's refusal centers on a dispute about an arbitrary number of potential custodians it should search,[3] notwithstanding the fact that this Court specifically denied Monsanto's request to limit production to 5 custodial files and held that the "plaintiffs may make any reasonable discovery request of Monsanto about whether Monsanto's product can cause non-Hodgkin's lymphoma, about Monsanto's knowledge on the issue, about any communication Monsanto has made on the issue, and about any scientific studies in which Monsanto may have been involved." *Hardeman v. Monsanto Co.*, No. 3:16-cv-525, Doc. 66, June 16, 2016. This discovery dispute exists because the parties are operating under a phased discovery order, illustrating why phased discovery creates more problems than it solves. What is more, there is no need for such disputes. Monsanto is already under a legal obligation in two cases to produce discovery on ***all*** issues. In *Kennedy v. Monsanto Co.*, No. 16CM-CC00001, another Roundup®-NHL case, the Circuit Court in Camden County, Missouri, denied "bifurcation" of discovery on June 27, 2016. *See* **Exhibit C**. Likewise, on August 30, 2016, the Philadelphia County Court of Common Pleas denied Monsanto's motion to permit discovery only on the issue of general

[2] *See,* Discovery Letter No. 2, filed October, 24, 2016, [ECF 14]. Each of the 11 requested custodians is currently on a legal hold, as initiated by Monsanto. Attached as **Exhibit B**. Monsanto filed a Response on October 27, 2016, also included in **Exhibit B.**

[3] If discovery is allowed to proceed as Monsanto proposes, this Court's order in *Hardeman* would be violated and Monsanto would essentially be in control of deciding which custodial files Plaintiffs should receive before the *Daubert* hearing. This would leave Plaintiffs with incomplete information about Monsanto's knowledge of Roundup's® dangers and the accuracy, reliability, and efficacy of the "scientific" studies upon which Monsanto intends to rely.

causation. *Schrack v. FMC Corp. et al.*, No. 160400812. *See* **Exhibit D.** As a practical matter, given Monsanto's refusal to produce the documents in *Hardeman* because of the phased discovery order, the eleven custodial files in dispute had to be subsequently requested in the *Kennedy* matter, which allows only one MDL law firm access to those documents. Nothing is gained by denying MDL Plaintiffs access to documents and depositions that are available to the Missouri and Pennsylvania plaintiffs who also allege that exposure to Roundup® and its surfactants caused their NHL.

C. Phased Discovery Will Cause Delays, Disputes, and Inefficiencies.

Monsanto contends that phased discovery will lead to the effective and efficient resolution of this litigation. Plaintiffs disagree. Simply, phased discovery invites unnecessary discovery disputes and motion practice on, among other things, questions over whether a discovery request or deposition question relates to "general causation," liability, or another issue. Particularly in this litigation, these are wasted resources as Monsanto already is under a legal obligation for full discovery in the *Kennedy* and *Schrack* matters. The time and effort that would need to be expended on these disputes by the Court and the parties further illustrate why bifurcation is inappropriate. *See True Health Chiropractic, Inc. v. McKesson Corp.*, No. 13-CV-02219-JST, 2015 WL 273188, at *2 (N.D. Cal. Jan. 20, 2015) ("[B]ifurcation has the potential to further complicate this litigation—even if Defendants are correct [regarding the bifurcated issue]—because … the line between [bifurcated categories] can be difficult to discern."); *Surcharge Anti-Trust Litig.*, 258 F.R.D. 163, 173 (D.D.C. 2009) ("Courts must consider the degree to which the [bifurcated] evidence is closely intertwined with, and indistinguishable from, the [other] evidence in determining whether bifurcation is appropriate."); *id.* at 172 ("Because the Court may be forced to spend time and resources resolving discovery disputes … bifurcated discovery 'belies the principles of judicial economy.'" (internal quotation marks and citation omitted)); *Arocho v. Nafzinger*, No. 07-CV-02603-REB-KLM, 2008 WL 5101701, at *1 (D. Colo. Dec. 1, 2008) ("[P]retrial stays or bifurcated discovery have proven to be an inefficient process, leading to confusion of the parties about the type of discovery permitted during the stay and, consequently, discovery disputes which cannot be resolved without court assistance.");

Trading Techs. Intern., Inc. v. eSpeed, Inc., 431 F. Supp. 2d 834, 840 (N.D. Ill. 2006) ("[W]e would not be surprised if the parties engaged in extensive motion practice wrangling over whether certain pieces of discovery were applicable to the liability case or the willfulness/damages case."); *see also* MANUAL FOR COMPLEX LITIGATION § 11.424 (4th ed. 2006). ("Discovery disputes, with their potential for breeding satellite litigation, are a major source of cost and delay.").

Moreover, courts addressing phased discovery, as proposed by Monsanto, have often experienced difficulty implementing such a limitation. *In re Incretin Mimetics Prods. Liab. Litig. ("Incretin")*, No. 3:13-md-02452-AJB-MDD, 2014 WL 2532315, at *2 (S.D. Cal. Feb 18, 2014), a case cited by Monsanto, perfectly illustrates the impracticality of bifurcation. Less than three months after entering an order limiting the first phase of discovery to general causation, "the Court was alerted to a dispute as to the scope of [the limitation] as well as issues regarding the timely and complete production of discovery." *Id.* at *2. The court was forced to grant "additional discovery and expand[] the scope of inquiry to include facts relevant to preemption," as well as decide multiple issues regarding whether discovery sought by the plaintiffs fell within the scope of the bifurcated discovery. *Id*. at *1, *4.

Bifurcation impracticalities led a federal court in California to state that "[t]he theory and the benefits of bifurcation, when placed in actual practice, will prove to be ephemeral." *In re Paxil Litig.*, 212 F.R.D. 539, 547 (C.D. Cal. 2003) (internal citations omitted) (declining to bifurcate general causation); *see also Trading Techs.*, 431 F. Supp. 2d at 841 ("[B]ifurcation can lead to additional discovery disputes that actually add time and energy to a litigation."); *Ikonen v. Hartz Mountain Corp.*, 122 F.R.D. 258, 265 (S.D. Cal. 1988) (determining arguments for generic causation issues "not persuasive"). These impracticalities have already manifested themselves in the instant litigation. Monsanto has objected to the production of documents concerning carcinogenicity studies, oxidative stress, and other plainly relevant evidence on the grounds that such requests exceeded the bounds of the Court's order.

Monsanto makes the puzzling argument that it would be inefficient to stop the progress made to date since it already has produced a substantial amount of general causation discovery.

Br. at 3–5. But, in fact, simply expanding the scope of allowable discovery to include *more* documents would have no effect on documents already produced and would perhaps resolve future inefficiencies and disputes over how to properly categorize documents. Further, as set forth in Sections III and VII below, Monsanto's productions to date have been incomplete and need to be re-done.

In any event, as stated above, Monsanto is already under an obligation to conduct full discovery in two separate state court litigations. Further, Monsanto has not submitted an affidavit as to the expected cost related to standard liability discovery, nor did it explain how the rules in the state court cases differ for purposes of the courts there denying phased discovery. Thus, irrespective of the Court's decision to continue or expand phased discovery, Monsanto will have to produce documents about glyphosate and its knowledge of glyphosate, other product ingredients, and Roundup's® propensity to cause injury in the Missouri and Pennsylvania state court cases. Monsanto's argument that the potentially voluminous document production in this case would be unduly burdensome and expensive—because of the number of plaintiffs potentially involved—is therefore unpersuasive.

D. General Causation Is Difficult to Isolate from Specific Causation.

The bulk—if not the entirety—of Monsanto documents about Roundup® will relate to issues of general causation. Indeed, other than a plaintiff who worked at a Monsanto facility where he was exposed to Roundup® or glyphosate, Monsanto is unlikely to have documents relating to an individual plaintiff's actual exposure to Roundup®. Thus, the majority of discovery of Monsanto is essentially discovery of information that goes to the heart of general causation. That said, even though Monsanto's records largely concern general causation, courts recognize that general causation cannot be separated from specific causation.

In response to similar arguments made by Monsanto thirty years ago, an MDL Court held that "[G]eneric causation and individual circumstances concerning each plaintiff and his or her exposure" are often "inextricably intertwined." *In re Agent Orange Prod. Liab. Litig*. MDL No. 381, 818 F.2d 145, 164–65 (2d Cir. 1987). As a result, if separated, Plaintiffs' experts would be challenged twice—on the question of the exposure necessary to cause cancer generally and again

on the question of Plaintiff's exposure. Hence, multiple depositions would be necessary, creating inefficiencies and the possibility that issues addressed in the first deposition could be re-addressed in the latter deposition. *See In re Heparin Products Liab. Litig*., No. 1:08-hc-60000, 2011 WL 1097637, at *3 (N.D. Ohio Mar. 22, 2011) ("If I were to bifurcate, plaintiffs would have to put on product identification evidence not once, but twice; first to prove causation and second to prove liability."); *Patten v. Lederle Labs*., 676 F. Supp. 233, 238 (D. Utah 1987) (denying bifurcation because the plaintiff's expert would have had to testify twice, once to explain the toxic properties of the chemical at issue and again to explain the known actions of this toxin in the human body); *Agent Orange*, 818 F.2d at 165. Trying to parse general and specific causation opinions and the real risk of unfairly giving Monsanto two bites at the apple in challenging Plaintiffs' experts, further militates against staged discovery.

III. Status of Current Discovery.

Contrary to Monsanto's assertions, discovery is in its infancy. The document productions so far are incomplete and inadequate. Prior to resolving the remaining discovery concerns set forth below, there are two key issues that require the Court's immediate guidance and intervention: (1) incomplete productions using inadequate search terms and (2) inappropriate three-tier responsiveness searches. Each issue is described in detail, below, in sections VII (B) and VII (C).

Because of the incomplete productions, no depositions have taken place of key Monsanto employees. Monsanto offered dates in October but had not certified that any of the custodial productions are complete. Not wishing to have to take the depositions twice, Plaintiffs' counsel postponed them until Monsanto certified the produced custodial files are complete.

Additionally, in a discovery dispute currently before the Court, Plaintiffs' counsel requested the production of eleven key employees' files that Monsanto has refused to produce, even though preliminary review of the custodial files produced to date reveal that these additional eleven employees are central to general causation issues. *See,* **Exhibit B**. That dispute will have to be resolved, and, further production is expected. In all, should the Court decide phased discovery will govern the MDL, Plaintiffs expect to depose dozens of witnesses, solely in

the "phase one" portion of phased discovery. Plaintiffs anticipate these depositions can be accomplished in a timely manner, but production and a meaningful review of the material must be completed first.

Lastly, Plaintiffs object to Monsanto's vague request for "limitations on written discovery" as premature. Discovery has already been limited, at Monsanto's request, for phase one of the litigation in cases prior to this MDL. The principle of "proportionality" under Rule 26(b)(1), cited by Monsanto, is an apt one to examine in this context. Thousands of users have developed NHL following exposure and have filed suit or retained attorneys to do so. A similar MDL for a cancer-causing product recently oversaw a global settlement totaling $2.4 Billion (MDL 2299, In re: Actos Products Liability, Western District of Louisiana). *See also e.g., In re: EI DuPont de Nemours and Company C-8 Personal Injury Litigation*, 2016 WL 5884964 (S.D. Ohio Oct. 7, 2016) (holding where many plaintiffs alleged injury from defendant's chemical, "the importance of the issues at stake cannot be overstated for these thousands of plaintiffs … further, the amount in controversy is substantial, with two of the 270 cancer cases resulting in over $7 million in jury verdicts"; the court denied the defense-suggested limits on discovery and held the requested discovery was proportional to the large number of claimants and extremely large potential amount in controversy). As such, the principle of "proportionality" as argued by Monsanto should not limit discovery.

IV. Plaintiffs Disagree with the "Science" Contained in Monsanto's Case Management Statement.

Monsanto is requesting the Court phase discovery and conduct early *Daubert* hearings on general causation. The Court's role in a *Daubert* analysis is to determine "whether an expert's testimony has 'a reliable basis in the knowledge and experience of the relevant discipline,'" not to weigh the evidence directly. *Estate of Barbarin v. AstenJohnson, Inc.*, 740 F.3d 457, 463 (9th Cir. 2014) (internal citations omitted). In other words, it is not the Court's responsibility to determine the ultimate issue of general causation; that is a jury question. As such, Plaintiffs object to Monsanto's use of the Case Management Statement to argue the merits of general causation, as the statement was intended to address procedural and scheduling issues. In fact,

discovery produced so far indicates that Monsanto has exerted inappropriate influence over the very "authorities" Monsanto cites.

Although Plaintiffs do not believe general causation *Daubert* hearings should be prioritized above all other issues, Plaintiffs will be prepared to present reliable evidence from qualified experts that exposure to Roundup®, comprised of glyphosate plus surfactants, causes NHL at any *Daubert* hearing. That said, Plaintiffs confront some of the information about Roundup® and glyphosate that Monsanto included in its Case Management Statement, as it is both one-sided and misleading. Indeed, there is already a body of peer-reviewed, published epidemiology, the greater weight of which shows a positive, statistically significant causal relationship between exposure to glyphosate and the incidence of NHL, *including Monsanto-sponsored epidemiological studies.*

A. The EPA's Office of Pesticide Programs ("OPP") Has Never Considered Whether Roundup® Is a Carcinogen.

IARC reviewed glyphosate in the manner in which it is used in the real-world—as one of the ingredients of the herbicide Roundup®. Thus, when evaluating the risk of exposure to glyphosate, IARC looked at the epidemiology of glyphosate in combination with the other chemicals used in the Roundup® formulation(s) to increase glyphosate's penetration and toxicity, *i.e.,* surfactants. In contrast, the EPA does not make such a determination of the carcinogenicity of Roundup® which is a combination of glyphosate with surfactants. The EPA, pursuant to its regulatory authority, is limited to analyzing glyphosate in isolation and only on its effects on non-human animals. The EPA assessment is therefore of limited relevance to Plaintiffs who were exposed to Roundup® as a product, which in fact contains other carcinogens in addition to glyphosate. For example, Roundup® contains formaldehyde, which IARC classifies as a group 1 carcinogen (carcinogenic to humans). Roundup® also contains 1,4-Dioxane, which IARC classifies as a group 2b carcinogen (possibly carcinogenic to humans), and which California has categorized as a chemical known to cause cancer. Roundup® contains n-nitroso-glyphosate, which has not been assessed by regulatory authorities, but is in a class of compounds that IARC has found to be carcinogenic. Roundup® contains ethylene glycol (anti-freeze), which the

National Toxicology Program ("NTP") has found to be mutagenic. Finally Roundup® contains polyethoxylated tallow amine ("POEA") which has been found to be genotoxic and cytotoxic and to increase the toxicity of glyphosate when used in combination with it. The European Union recently has decided to ban the use of POEA in Roundup® products. It is for these and other reasons that Monsanto cannot in good faith tell this Court that Roundup® is conclusively not a carcinogen.

B. The EPA Office of Pesticides Program Has Ties to Monsanto Over Glyphosate.

While EPA is of limited relevance to the instant matter in light of its confined review, the following has transpired recently relating to glyphosate. The EPA Office of Pesticides Program ("OPP") explicitly notes the limits of its review in the recent draft assessment to which Monsanto cites. The draft assessment was supposed to be submitted for peer review in October, 2016, but that deadline has been postponed indefinitely. In the draft assessment, the OPP remarks that dozens of studies considered by IARC were not reviewed by the OPP because the OPP's "evaluation focused on studies on the active ingredient glyphosate" and that "additional research could also be performed to determine whether formulation components, such as surfactants, influence the toxicity of glyphosate formulations." OPP draft assessment, p. 141. The OPP notes that it rejected studies that used Roundup® instead of isolated glyphosate because "[g]lyphosate formulations contain various components other than glyphosate and it has been hypothesized these components are more toxic than glyphosate alone." *Id.* at 70. In its charge to the FIFRA Scientific Advisory Panel ("SAP"), established to peer review the OPP draft assessment, the OPP notes that "[a]lthough there are studies available on glyphosate-based pesticide formulations, the agency is soliciting advice from the FIFRA Scientific Advisory Panel (SAP) on this evaluation of human carcinogenic potential for the active ingredient glyphosate only at this time."[4] The OPP draft assessment is therefore of limited relevance as it does not

[4] https://www.epa.gov/sites/production/files/2016-09/documents/glyphosate_sap_charge_questions_-final.pdf

actually consider the product at issue in this litigation or, more importantly, how glyphosate, in conjunction with surfactants and other chemicals, affects carcinogenicity.

Furthermore, the OPP is not the EPA; it is merely a subdivision of the EPA. As limited discovery to date has shown, the OPP draft assessments are inherently unreliable and biased. The OPP conducts no independent testing of glyphosate and relies more heavily on unpublished data submitted by Monsanto than it does publications subjected to a rigorous peer-review process. Indeed, discovery to date has revealed disturbingly close relationships between employees working at the OPP and Monsanto. In effect, documents suggest that the OPP coordinates with Monsanto behind closed doors to facilitate Roundup® remaining on the market. Unlike IARC, OPP assessments have never been cited by any federal or state court as an authority or reliable source on cancer causation, nor does the committee contain renowned international experts on cancer causation.

An earlier draft of the OPP report on glyphosate was leaked by someone within EPA in May 2016. EPA promptly retracted the report and disavowed its conclusions. *Reuters* reported that:

> The EPA took down the report and other documents on Monday afternoon [May 2, 2016], saying it did so "because our assessment is not final," in an emailed statement to Reuters. The agency said the documents were "preliminary" and that they were published "inadvertently."
>
> The EPA said its documents are part of its broader registration review, which began in 2009, of glyphosate and its potential human health and environmental risks.
>
> "EPA has not completed our cancer review," the EPA told Reuters in a statement. "We will look at the work of other governments as well as work by (the U.S. Department of Health and Human Services') Agricultural Health Study as we move to make a decision on glyphosate."
>
> The EPA said its assessment will be peer reviewed and completed by the end of 2016.[5]

Documents have since indicated that the reliability of the OPP's October 15, 2015, report

[5] P.J. Huffstutter, *EPA takes Offline Report that Says Glyphosate Not Likely Carcinogenic*, Reuters May 2, 2016 *available at:* http://www.reuters.com/article/us-usa-glyphosate-epa-idUSKCN0XU01K.

is highly questionable. For instance, in documents released pursuant to a FOIA request, Michael L. Goodis, Associate Director, Pesticide Re-evaluation Division, stated in an email dated March 23, 2015:

> As you can see, I received a call from Dan Jenkins of Monsanto regarding the cancer determinations coming out of the IARC. Monsanto's position is that the report misrepresents the science and EPA's position and that he talked with Jess [Jess Rowland Chair, Cancer Assessment Review Committee ("CARC")] and Rick about it and asked whether we would be correcting the record. I told him that I was not aware of EPA sending out a specific message of "correcting the record," but that our draft risk assessment would contain the full body of the science. He sent the attached talking points and other information as an FYI.[6]

The "talking points" sent by Monsanto to the author of the CARC draft report are remarkably similar to the version of the CARC draft report that leaked to the public. The "talking points" were submitted outside of the docket and comment period for the re-registration of glyphosate.[7] Such informal access to and *ex parte* contacts with scientists drafting a supposedly independent review of glyphosate are contrary to sound, unbiased science. IARC prohibits such inappropriate influence by interested parties and values impartiality. See Monograph Preamble (Jan. 2006), p. 5, http://monographs.iarc.fr/ENG/Preamble/currenta5participants0706.php. Further discovery will likely uncover additional biased, improper contacts between EPA personnel and Monsanto.

The OPP goes so far as to advocate for Monsanto by seeking to suppress the study of Roundup® by other federal agencies. One such agency is the Agency for Toxic Substances and Disease Registry ("ATSDR"), which is part of the Department of Health and Human Services, and is charged with "using the best science, taking responsive public health actions, and providing trusted health information to prevent harmful exposures and diseases related to toxic substances."[8] Pursuant to documents released via a FOIA request, Jack Housenger, head of the

[6] March 23 Email string including Dan Jenkins from Monsanto and Jess Rowland, lead author of CARC report. *Available at*: https://foiaonline.regulations.gov/foia/action/public/view/record?objectId=090004d280a434c6.

[7] Monsanto's Talking Points on IARC. *Available at:* https://foiaonline.regulations.gov/foia/action/public/view/record?objectId=090004d280a18c0f.

[8] http://www.atsdr.cdc.gov/.

OPP, requested that the ATSDR stop its efforts to review the dangers of glyphosate. [9] Unfortunately for the public, Housenger was successful in his efforts to quash ATSDR's review of glyphosate.

Another example of the OPP's overly intimate connection with Monsanto is found in the OPP's *Glyphosate Issue Paper: Evaluation of Carcinogenic Potential*, prepared for the SAP before the SAP hearing was continued indefinitely. The paper rejects a causal connection between glyphosate and NHL, stating that if a true association existed one would expect to see higher "effect rates" of NHL where individuals are more exposed to glyphosate, such as in the United States and Canada. The "evidence" for this statement is footnote 12, which states: "Components in glyphosate formulations in the US and abroad are similar according to personal communications with Monsanto." In short, the underpinning of this aspect of the OPP's conclusion is based on unspecified "personal communications" with the company that makes the product.

For these reasons, Monsanto is resisting a comprehensive, independent review of glyphosate or Roundup® free from its industry influence. Under FIFRA, the EPA has established a procedure to seek independent advice about a complex regulatory decision through a SAP. 7 U.S.C. § 136w. The EPA scheduled a four-day SAP to peer-review the OPP's draft assessment of glyphosate for the week of October 17, 2016. However, on October 12, 2016, Monsanto's lobbying group CropLifeAmerica successfully derailed the SAP by accusing two of the panelists as biased against industry.[10] The SAP meeting is now "postponed" to a later as-yet undetermined date, again delaying the EPA's final review of glyphosate.[11]

The State of California, in contrast, has not allowed its assessment of Roundup® to be derailed, despite Monsanto's best efforts to do so. The State has added Roundup® to the list of

[9] https://foiaonline.regulations.gov/foia/action/public/view/record?objectId=090004d280b5d6b3.

[10] Letter from CLA to EPA, available at: http://191hmt1pr08amfq62276etw2.wpengine.netdna-cdn.com/wp-content/uploads/2016/01/CLA-Comments-on-SAP-Disqualification-10-12-16.pdf.

[11] *EPA Bows to Chemical Industry in Delay of Glyphosate Cancer Review* , Huffington Post http://www.huffingtonpost.com/carey-gillam/epa-bows-to-chemical-indu_b_12563438.html.

Proposition 65 products in response to the IARC's conclusion that glyphosate is a probable human carcinogen. In response, Monsanto sued the State of California to prohibit it from warning its citizens that Roundup® is carcinogenic. The California Attorney General has filed a motion for judgment on the pleadings to that challenge, emphasizing the State of California's position about the importance and credibility of IARC assessment. According to the California A.G., "IARC's scientific determinations are the gold standard in carcinogen identification." Brief, p. 2. In describing the IARC process, the California AG notes:

> Further, IARC classifies carcinogens through a rigorous process of peer review that includes numerous procedures designed to promote the scientific integrity of its decisions. The IARC procedure for evaluating chemicals is thorough, impartial, expert, and open. Members of the Working Groups who study and classify each chemical and who publish the Monographs have typically published significant research on the subject chemicals. … Working Group members are free of outside influence that would constitute a conflict of interest, and the process is transparent and open to interested parties, including parties such as Monsanto. IARC therefore has strong safeguards in place that are sufficient to assure the integrity of its scientific review. Given IARC's stature and expertise, as well as its thorough and open review process, the voters were entitled to rely on this scientific review process, without the need to add additional provisions to the statute either relating to IARC's work or requiring review of IARC's work.

Id. at 31.

Clearly, the question of whether Roundup® is a carcinogen will not be resolved in the context of a case management statement. That said, Monsanto's transparent effort to poison the well by citing to preliminary reports by regulatory agencies must be understood in the context of the control that Monsanto exerts over the executive branch of the deferral government and much of the scientific community and the retaliation Monsanto pursues against anyone, including IARC, who concludes that Roundup® causes cancer.

Finally, Monsanto cherry-picks some other foreign regulatory authorities that allow the sale of Roundup®. However, several Countries are banning and restricting the use of Roundup. For Example, based on "concerns about the carcinogenicity and endocrine disruptive properties of the herbicide glyphosate" the European Parliament voted to restrict the re-authorization and use of glyphosate in an attempt to minimize human exposure to the

carcinogenic chemical. *Id.* Countries such as "France, the Netherlands and Sweden have all said they will not support an assessment by the European food safety authority (Efsa) that glyphosate is harmless" and "[g]lyphosate use has been banned or restricted in large parts of Europe."[12] (Arthur Nelson, EU states rebel against plans to relicense weedkiller glyphosate, The Guardian, 3/4/2016 available at: http://www.theguardian.com/environment/2016/mar/04/eu-states-rebel-against-plans-to-relicense-weedkiller-glyphosate.) Glyphosate has additionally been banned in Sri Lanka, Argentina, and Malta. The European Union will be enacting a blanket ban on the current formulation of Roundup®, which contains POEA, beginning next year.

V. Plaintiffs' Proposed Discovery and Case Schedule.

If the Court decides to proceed with a general causation *Daubert* hearing in advance of adjudication of the overall case, Plaintiffs are in substantial agreement with Monsanto on many aspects of its proposed discovery schedule. Nevertheless, Plaintiffs propose several important changes to encourage efficiency and fairness.

- Proposed orders on deposition and written discovery protocol due by November 30, 2016 (agreed)
- Identification of additional custodians for document production by December 2, 2016, objections thereto by December 9, 2016 (agreed)[13]
- Monsanto certifies completion of first five custodial files by December 14, 2016
- First five custodians deposed by January 31, 2017
- Production of additional custodial files certified complete by February 3, 2017 (agreed)
- Plaintiffs identify five trial plaintiffs by March 1, 2017

[12] Arthur Nelson, EU states rebel against plans to relicense weedkiller glyphosate, *The Guardian,* 3/4/2016 *available at:* http://www.theguardian.com/environment/2016/mar/04/eu-states-rebel-against-plans-to-relicense-weedkiller-glyphosate

[13] Plaintiffs will be requesting many more custodians in "phase two" but have agreed to these limits in phase one in order to efficiently move beyond general causation issues.

- Deposition of additional non-expert witnesses accomplished by May 1, 2017
- Parties' expert reports due June 30, 2017
- Parties' expert reports due June 30, 2017
- Parties' rebuttal expert reports due July 31, 2017
- Close of expert discovery September 29, 2017
- Motions for summary judgment/ *Daubert* motions due October 30, 2017
- Oppositions to motions due November 30, 2017
- Parties' reply due December 15, 2017
- Trial on all issues: February 2018

VI. Plaintiffs Agree that an Independent Expert Is Not Necessary.

Plaintiffs are developing their experts and anticipate Monsanto is doing the same; there are likely to be experts in over a dozen specialties on both sides. Accordingly, Plaintiffs do not believe the addition of an "independent" expert would aid the Court's analysis or resolution of this matter. Plaintiffs again object to Monsanto's arguing its position on the substance of the case, but largely agree with Monsanto that a court-appointed expert is not needed, albeit for vastly different reasons.

The peer-reviewed, publicly available, published scientific literature overwhelmingly supports a significant relationship between Roundup® exposure and lymphoma. The WHO has already deemed glyphosate a "probable human carcinogen." Although Monsanto disagrees with and criticizes this classification, Monsanto cannot point to a more widely-respected authority on carcinogenicity. Indeed, the State of California considers IARC to be the ultimate authority on the subject, having adopted its conclusions by force of law with Proposition 65.

VII. Other Matters.

A. Production of Custodial Files.

Monsanto refuses to produce 11 custodial files as requested by Plaintiff Hardeman. Each of the requested 11 custodians is currently under a legal hold, initiated by Monsanto. On October 24, 2016, Plaintiff Hardeman filed his Discovery Dispute Letter No. 2, **Exhibit B**. Because Monsanto is using the *Hardeman* phased discovery order to refuse production, and in the interest

of moving the litigation forward, the 11 custodial files in dispute had to be subsequently requested by the Miller firm in the *Kennedy* matter (a case in which phased discovery was denied), which allows only one MDL law firm access to those documents.

B. Search Terms.

To date, Monsanto has produced documents based on a set of search terms requested by one of the lead Plaintiffs' firms. The list was compiled before Plaintiffs had an opportunity to review any of the produced documents. At the time, Plaintiffs had specifically negotiated the right to supplement these search terms as discovery continued.

For example, during an informal ESI meeting in St. Louis, Missouri, on August 17, 2016, Plaintiffs learned for the first time that glyphosate/Roundup® are commonly referred to by Monsanto/outside scientists and some non-scientist Monsanto employees by a MON number, CP code, and/or PN code. Since that date, undersigned counsel has actively requested the universe of those codes/numbers and that they be included in the search terms. Monsanto has yet to produce a complete list and has refused to include them in search terms. On or about August 1, 2016, Monsanto began producing its initial custodial files. Because no productions to date utilized the MON number, CP code, and PN code as search terms, every production is incomplete and should be re-done.

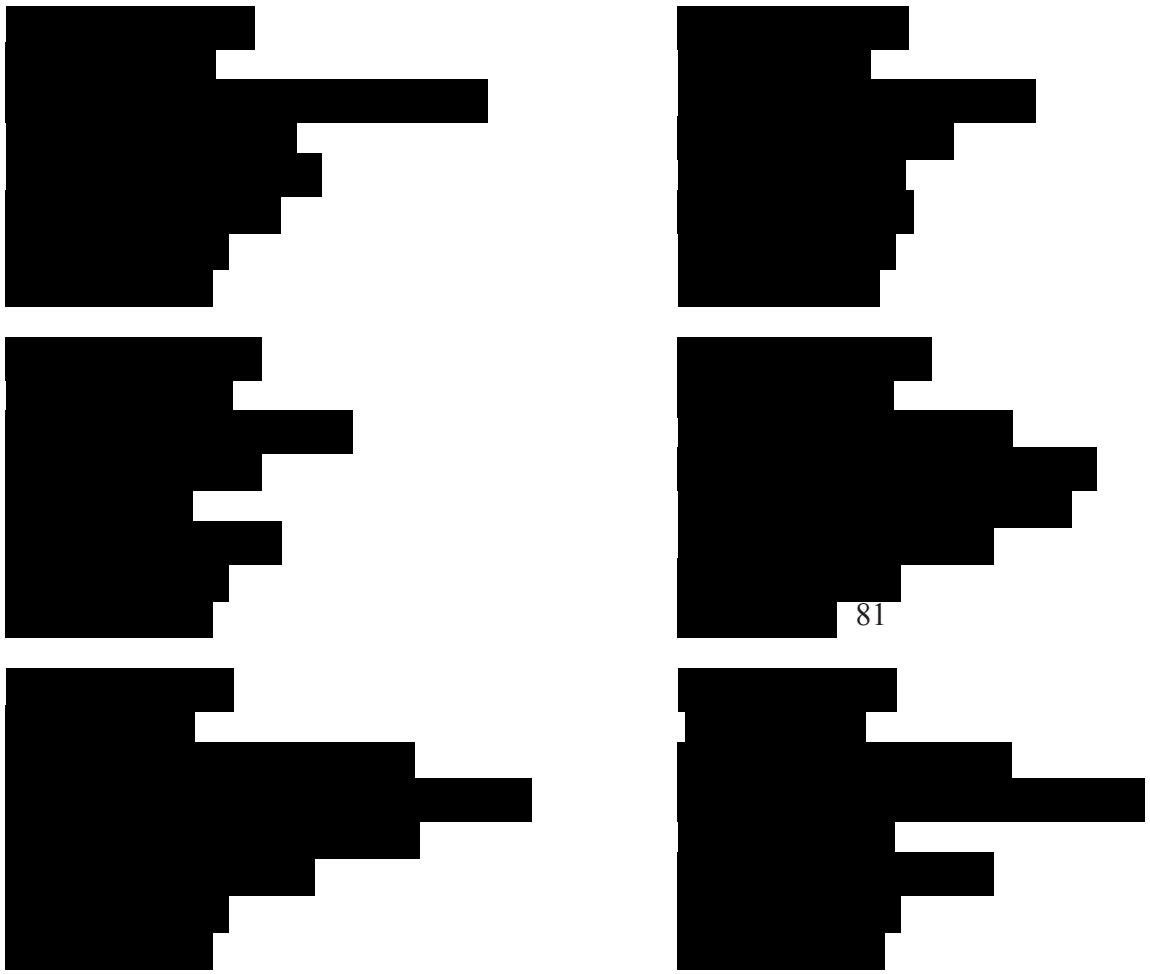
C. Responsiveness Searches.

The parties have an ongoing dispute regarding the process of Monsanto's "responsiveness searches." Currently the Monsanto document search process employs a two-tiered search; meaning, there are two separate search term lists and a document must contain a "hit" on **each** list before it is included in a production. The reason for requiring a document hit on both lists is to ensure that documents are relevant to this litigation. If a document hits on both search term lists, it should be included in the custodial file and produced. However, it is not. Unbeknownst to Plaintiffs, Monsanto has been engaging in a third tier review for

"responsiveness." Once a document hits on both search term lists, instead of producing the document, Monsanto is further restricting production by making subjective determinations of responsiveness. Monsanto represents that approximately 25% of documents containing two search terms are eliminated and withheld due to their improper third tier review. That third review is likely resulting in relevant documents being withheld. Accordingly, Plaintiff requests the Court order Monsanto to produce those documents withheld by the third tier "responsiveness" review. Alternatively, Plaintiffs propose that a random sample of documents withheld by Monsanto's third tier review be produced so that a determination can be made as to whether Monsanto's review results in the withholding of relevant documents.

DATED: October 27, 2016

Respectfully submitted,



ECF CERTIFICATION

Pursuant to Civil L.R. 5-1(i)(3), the filing attorney attests that she has obtained concurrence regarding the filing of this document from the signatories to the document.

DATED: October 27, 2016

ANDRUS WAGSTAFF, PC

[redacted]

EXHIBIT A

EXHIBIT A

Plaintiffs propose that the following Case Management Orders are necessary at the outset of this coordinated litigation to ensure the efficient and effective adjudication of MDL 2741, to include dates to submit proposed Orders (either joint or competing), when applicable, to the Court:

1. Protective Order[1]	November 30, 3016
2. Electronically Stored Information ("ESI")	November 30, 2016
3. Privilege Log Order	November 30, 2016
4. Deposition Protocol	December 7, 2016
5. Submission of Master (Administrative) Complaint	December 16, 2016
6. Submission of a Short Form Complaint	December 16, 2016
7. Direct Filing Order	December 16, 2016
8. Submission of proposed fact sheets/profile forms	December 20, 2016
9. Fact Sheet/Profile Form Order	December 20, 2016
10. Monsanto Answers Master (Administrative) Complaint	January 20, 2017

[1] Monsanto requests the entry of a Protective Order. Plaintiffs do not believe a Protective Order is necessary or required but do not oppose the entry of one if the Court believes it necessary.

EXHIBIT B

[redacted]

[redacted]

October 24, 2016

FILED VIA ECF
Honorable Vince Chhabria
United States District Court, Northern District of California

RE: *Edwin Hardeman v. Monsanto Company*, *et. al* - Case No: 3:16-cv-00525-VC

To the Honorable Vince Chhabria,

The Parties have reached an impasse with respect to a discovery dispute, and this joint letter is filed pursuant to paragraph 15 of the Court's Standing Order for Civil Cases Before Judge Vince Chhabria.

Meet and Confer: Undersigned counsel sent to Monsanto attorneys Joe Hollingsworth and Rosemary Stewart Plaintiff's position, below, on October 16, 2016 and requested a response by Friday, October 21, 2016. That Friday morning, undersigned received an e-mail stating that, "[w]e decline to join your proposed Discovery Dispute Letter with respect to 11 more Monsanto employee custodians." The e-mail continued for two additional paragraphs. Undersigned counsel sent three separate follow up e-mails to Mr. Hollingsworth and Ms. Stewart indicating a desire to file this dispute letter last Friday, October 21, and requesting direction on whether to 'cut and paste' the entire 2 paragraph e-mail as Monsanto's position or instead just indicate that Monsanto declines to join the letter. Undersigned has received no response to any of the three e-mails. After waiting three days for a response, Plaintiff believes it time to file this dispute letter.

Plaintiff's Position

Monsanto refuses to produce custodial files for eleven individuals, each of whom possess unique information critical to whether exposure to Roundup® causes cancer, Monsanto's knowledge of that causal link, communications Monsanto made on the issue, and the relevant science[1]. Monsanto's refusal to produce the custodial files is unnecessarily delaying discovery, this Court's current expert disclosure order, and is premised on two arguments; that the requests are untimely and that the requested custodial files are not necessary. *See* Supplemental Case Management Statement, ECF No. 81 at 6. The 'untimely objection' is now moot given the consolidation of the Hardeman case into MDL No. 3:16-md-2741 VC. The 'unnecessary objection' is wrong as the identified custodians have relevant and unique discoverable materials

[1] This request was made pursuant to the Court's June 16, 2016 Order that allowed discovery "about whether Monsanto's product can cause non-Hodgkin's lymphoma, about Monsanto's knowledge on the issue, about any communications Monsanto has made on the issue, and about any scientific studies in which Monsanto may have been involved." ECF 66.

that are specifically allowed by this Court's June 16, 2016 Order, the federal rules of civil procedure, and due process. The relevant facts are as follows:

1. Roundup® has been on the market since the 1970s. The organizational charts produced by Monsanto invite more questions than answers with respect to custodial files as they identify hundreds of Monsanto employees involved with the manufacture and sale of Roundup®, and the organizational structure appears to change often over time.

2. Monsanto served Initial Disclosures on May 17, 2016 and identified only four persons – all current employees. Later, Monsanto identified a fifth custodian.

3. On June 16, 2016, this Court specifically denied Monsanto's request to limit its production to the 5 custodial files hand selected by Monsanto. ECF No. 66.

4. Two weeks later, on June 30, 2016, Monsanto made its first production in this matter that consisted of non-custodial, public documents (*i.e.* EPA documents).

5. On August 2, 2016, Monsanto made its first partial production of the 5 custodians that were hand selected by Monsanto. The production of those 5 custodial files was not complete until September 30, 2016.

6. Plaintiff Stevick, through his counsel and without consultation by Mr. Hardeman or his counsel, requested an additional 7 custodial files. Monsanto agreed to produce those custodial files and agreed to produce 5 more files as selected by Mr. Hardeman.

7. After having a reasonable amount of time to review the produced documents, and prior to the completion of the production of **any** custodial file, on September 16, 2016, Mr. Hardeman made his initial request for the production of 11 custodial files. These were the first custodial files requested by Mr. Hardeman. During a meet and confer, Monsanto offered a partial production of 3 custodians by a date past the production deadline. Plaintiff's counsel requested Monsanto's position in writing, which was never received. Mr. Hardeman made an official discovery request on October 1, 2016.

8. On October 13, 2016, Monsanto informed undersigned counsel that it does not intend to produce the 11 custodial files absent direction from the Court. As such, this matter is ripe for judicial assistance. Mindful of the Court's encouragement to keep discovery moving prior to the first MDL hearing, and Monsanto's representation of the laborious process to produce documents, it is appropriate and timely to raise these issues now.

Custodial Files at Issue

1. **John Acquavella** was Monsanto's chief epidemiologist from 1989 to 2004. Over that period Dr. Acquavella analyzed and responded to the epidemiological studies showing an increased risk of non-Hodgkin's lymphoma caused by Roundup®. Epidemiology is critical to the general causation analysis. Additionally, Dr. Acquavella returned to work as a consultant for Monsanto in October of 2014 to help Monsanto respond to IARC's assessment of glyphosate.

Since that time, Dr. Acquavella transitioned to becoming an "independent" expert on Monsanto's Intertek panel that reviewed the work of IARC.

2. **Katherine Carr** has worked at Monsanto since 1982 in various roles. Her last 19 years at Monsanto were spent as an Environmental Assessment Specialist and then Senior Environment Assessment Specialist. As part of her job, she prepared detailed environmental fate, environmental exposure, human exposure, and ecological risk assessment reports to address registration of Roundup®. The environmental fate and human exposure of Roundup® is relevant to general causation.

3. **Eric Haupfear** has been the director of "Process Technology" and "Process Chemistry" at Monsanto since at least 1997. Process technology involves the production of consumer goods from raw material and is vitally important to demonstrating a feasible alternative design as required by some states. Furthermore, the production of glyphosate and surfactants produce byproducts such as formaldehyde and 1,4 dioxane, which are known carcinogens. Access to documents that may reveal the presence of these additional carcinogens in Roundup® is relevant to general causation.

4. **Joel Kronenberg** is a senior scientist and toxicologist. As part of the Food & Chemical Toxicology team, his principle charge is to maintain and enhance worldwide glyphosate business. He holds meetings with the EPA to discuss toxicology profiles; counters allegations that glyphosate is unsafe; meets with outside experts to develop a network of paid consultants to address future issues with glyphosate and surfactants, and has initiated dozens of studies to support glyphosate reregistration. Dr. Kronenberg has worked at Monsanto since at least 2004.

5. **Michael Koch** is a toxicologist, pharmacologist and "new technologies in toxicology lead" who has worked at Monsanto from 2010-present. Michael Koch is currently the vice-chair of the toxicology forum responsible for addressing toxicological issues arising in the safety assessments of Monsanto's products, including Roundup®. He also plays a key role in Monsanto's attempts to counter IARC's safety assessment of glyphosate.

6. **Eric Sachs** is the Science, Technology & Outreach Lead at Monsanto. He has worked at Monsanto for 38 years. His job involves shaping public opinion about Roundup® and IARC, through reaching out to scientists to influence policy makers, opinion leaders and the public. The documents produced so far indicate that he is heavily involved in attempts to manipulate the scientific literature.

7. **Xavier Belvaux** is currently a Regulatory Affairs Lead at Monsanto Europe and has worked at Monsanto from 1992-present. The documents produced thus far demonstrate that research, investigation and suppression of information about the carcinogenicity of Roundup® was occurring both independently in Europe and in connection with U.S. employees. Monsanto also touts the assessments by European regulatory agencies as evidence in favor of the non-carcinogenicity of Roundup®. Additionally, to the extent that Monsanto intends to rely on EFSA, plaintiffs are entitled to view the custodial files of employees' interactions with EFSA.

8. **Richard Garnett** is the Crop Protection Regulatory Affairs Lead for Monsanto Europe from at least 2003 – present. Additionally, he leads the Glyphosate task force in Europe which is a consortium of European companies which manufacture glyphosate and is charged with re-registering glyphosate in Europe through the manufacture of data and through interactions with regulatory authorities.

9. **Christophe Gustin,** has been the Europe, Middle East and Africa (EMEA) crop protection regulatory affairs lead in Europe since 2005. In his current role he is responsible for regulatory affairs related to glyphosate and the Ag-chem formulations. In this role he is

responsible for implementing the regulatory aspects of the glyphosate business strategy. In addition, he is responsible for the European re-registration of glyphosate, which is effectuated within a taskforce of currently 25 companies. He is the coordinator of the technical and regulatory activities within this taskforce. From 2000 – 2005, Dr. Gustin worked in St. Louis where he was responsible for Monsanto's exposure and environmental risk assessments.

10. **Manda Sansom** is a technology Development Lead for Monsanto in Ireland and the UK from 1998 to December 2013. Dr. Sansom played a central role in responding to issues raised by European governments related to the safety and toxicity of glyphosate and glyphosate formulations.

11. **Steven Levine** is Monsanto's global lead for ecotoxicology and environmental risk assessment. He has worked for Monsanto since approximately 2000, nearly exclusively in the field of ecotoxicology. Dr. Levine is instrumental in Monsanto's study design and data analysis. Dr. Levine is also involved in Monsanto's external product safety outreach efforts and is a member of Crop Life America's Endocrine disruption Working Group.

Conclusion

The documents produced thus far demonstrate Monsanto's early knowledge, its lack and/or manipulation of Roundup® testing, and its engagement in scientific misinformation. Upon best information and belief, Monsanto Europe is under the umbrella of the Monsanto worldwide headquarters in St. Louis. Indeed, Monsanto Europe routinely shared information with Monsanto St. Louis, and it was expected to do so. Each one of the requested custodians was carefully selected after reviewing the first batch of documents Monsanto produced, and each one is directly relevant to whether Roundup® causes non-Hodgkin's lymphoma, Monsanto's knowledge on the issue, communications Monsanto has made on the issue, and any scientific studies in which Monsanto may have been involved. As such, Mr. Hardeman requests the Court order production of the same.

Monsanto's Position

See Meet and Confer, above.

Dated: October 24, 2016

Respectfully submitted,

[redacted]

October 27, 2016

Filed via ECF

The Honorable Vince Chhabria
United States District Court, Northern District of California

Re: *Hardeman v. Monsanto Co.*, No. 3:16-cv-00525-VC

Dear Judge Chhabria:

Defendant Monsanto Co. hereby files its Objections to the plaintiff's Discovery Letter Brief, filed on October 24, 2016 (ECF No. 85) ("Pl's Discovery Letter"). While Monsanto's counsel understands that the Court requires "discovery disputes" to be addressed in a short letter in which both parties express their views about the dispute, Monsanto submits that Mr. Hardeman's counsel has not identified a legitimate discovery dispute at all. Instead, plaintiff's counsel is attempting an improper end-run around this MDL Court's initial steps to coordinate discovery on behalf of all plaintiffs in the MDL.

In Plaintiff's Discovery Letter, Mr. Hardeman's counsel asks that her law firm be allowed to select 11 Monsanto employee custodians before the MDL court even addresses the key question of how many custodians *the entire group of plaintiffs' counsel* should be permitted to select. Counsel claims that these are her "first" selections, Pl's Discovery Letter at 2, but such claim is belied by the June 2016 joint email to the Court from her firm and Mr. Stevick's counsel (MDL ECF No. 9-3), requesting production of the custodial files for seven (7) Monsanto employees, in addition to the five (5) employee custodians identified long ago by Monsanto – and in response to which Monsanto spent months collecting and producing voluminous records. In addition, in an application filed last week with this Court, [redacted] said that she and other plaintiffs' counsel have been meeting and working together for a year on the development of many aspects of this litigation, including document review, which presumably entailed discussing possible document custodians. *See* Letter from [redacted] Regarding Application for Appointment of Lead Counsel (MDL ECF No. 11) at 1. That [redacted] herself now seeks 11 *additional* custodian requests beyond those made by her firm and other plaintiffs' counsel with whom she states she has had a close and "seamless" working relationship prior to creation of the MDL – in addition to any joint requests the MDL Court may later grant to all plaintiffs as a group – is an abuse of the MDL process.

This is not a discovery dispute unique to the *Hardeman* case, but a ploy designed to obtain an advantage that is unfair to Monsanto as well as contrary to the goals of efficient

coordination, the very reason for the MDL process. As a result, Monsanto respectfully requests that the Court direct Plaintiff's Discovery Letter to be withdrawn.

A. Background Facts

Just prior to Monsanto's last document production (now totaling well over 3.5 million pages) in the *Hardeman* and *Stevick* cases – which includes hundreds of thousands of pages of scientific and regulatory files from Monsanto's non-custodial corporate files and millions of pages of custodial files of 12 Monsanto employee custodians – Mr. Hardeman's counsel also requested that Monsanto collect and produce documents from 11 additional custodians. This request was made without any explanation of these custodians' purported relevance to "general causation," which was the only question at issue in the *Hardeman* stage of discovery. *See* Order Granting Mot. for Bifurcation, dated June 16, 2016 (ECF No. 66) ("plaintiffs may make any reasonable discovery request of Monsanto about whether Monsanto's product can cause non-Hodgkin's lymphoma . . . ."). [1] Indeed, some of the 11 individuals identified by [redacted] have absolutely no relevant knowledge of the science or the testing of glyphosate-based herbicide ("GBH") products related to human health and safety. As a result, Monsanto objected to this request, noting that the individuals were not appropriate document custodians and that Plaintiffs' counsel had waited until it was too late to collect, review, and produce documents from additional custodians before the then existing deadline of October 15 to produce custodial files.

The timing of Mr. Hardeman's counsel's request for the 11 additional custodians was particularly suspect because the same Plaintiff's counsel had already filed the initial motion seeking consolidation of the Roundup cases into an MDL. And Plaintiff's October 24 Discovery Letter is equally suspect in attempting to gain an advantage before the commencement of the orderly processes of pretrial activities in the MDL, which is the first objection stated here. Monsanto also objects on additional grounds, including that discovery from these 11 additional custodians is not likely to produce material relevant to the question of general causation. In fact, any potentially relevant material is likely to be cumulative and/or duplicative, and the scant merit of such additional material is far outweighed by the expected burden of producing it.

B. The Identification of and Discovery from Additional Custodians Should Be Determined in the Context of the MDL.

The MDL Court's Pretrial Order No. 1 contemplates the appointment of both a plaintiffs' liaison counsel and a plaintiffs' lead counsel "to coordinate and conduct pretrial activities."

[1] Although Plaintiff's Discovery Letter now attempts to explain the relevancy of each of the 11 requested custodians, the stated descriptions are plainly incorrect for several of the individuals. Moreover, four of the individuals are not employed by the defendant Monsanto Company but by subsidiary corporations located in Europe. Monsanto's counsel renews their offer made previously to Plaintiff's counsel to discuss the background and experience of additional individuals whom plaintiffs are considering as potential custodians *after* the MDL Court determines the appropriate number of custodians for all plaintiffs and *after* the Court determines which plaintiffs' counsel should be conducting such discussions.

Pretrial Order No. 1 (MDL ECF No. 2) ¶¶ 6-7. The question of how many additional document custodians *the entire group of plaintiffs' counsel* will be permitted to identify (if any) is exactly the kind of "pretrial activity" that will need to be coordinated in the larger context of the MDL and under the supervision of this Court. Indeed, it is likely to be one of the key initial issues for this Court to resolve following the parties' submissions and the first MDL hearing on November 16. It is not an issue that should be addressed now or solely in the context of the *Hardeman* case or solely with one of the many law firms representing plaintiffs in this MDL proceeding. In its MDL Case Management Statement, filed on October 20, 2016, Monsanto proposed that the parties seek to negotiate reasonable limitations on written discovery and that plaintiffs *as a group* should be limited to selecting no more than 10 additional general causation document custodians. *See* Monsanto Co.'s Case Management Statement (MDL ECF No. 9) at 11, 13. Yet Mr. Hardeman's counsel filed her October 24 Discovery Letter several days after Monsanto made this proposal to the MDL Court.

The MDL Court's October 6, 2016 Orders encouraged discovery in *Hardeman* and *Stevick* to continue "to the extent possible" and "[t]o the extent the parties conclude it is practical." *Hardeman*/*Stevick* Order Re Discovery Letter (MDL ECF No. 3); Pretrial Order No. 1, ¶ 11. To that end, Monsanto has proceeded with other appropriate and practical discovery in *Hardeman* and *Stevick*. For example, on October 15, after the date of the MDL Court's initial Pretrial Orders, and even though previous deadlines had been lifted, Monsanto made its last planned production for 12 employees' custodial files (comprising more than 300,000 pages of additional records), along with a privilege log. Monsanto also will be responding to the October 12 interrogatories and document requests served in the *Hardeman* case because some of these requests address subjects already discussed and agreed upon earlier between the parties' counsel. But what Mr. Hardeman's counsel now seeks is not the continuation of existing discovery efforts; nor is it a "practical" request to the defendant. It is instead a massive expansion of the entire field of general causation discovery, in direct contradiction to the efficient and proportional discovery required by the federal rules. Further, by issuing their request for 11 custodians *after seeking an MDL* – and filing their Discovery Letter *after the creation of the MDL* – Mr. Hardeman's counsel is attempting to short-circuit the very process she requested: coordination of discovery on behalf of all plaintiffs.

C. Most of the 11 Additional Custodians Identified by Plaintiff Have No Meaningful or Unique Information with Respect to General Causation.

As cited above, this Court has previously limited discovery in the *Hardeman/Stevick* cases to "whether Monsanto's product can cause non-Hodgkin's lymphoma." And the only relevant issue for such a general causation inquiry is what the science reveals.[2] In this case, the

[2] *See* Order on J. Mot. for Determination of Disputes Related to the Scope of the Written Discovery Related to Gen. Causation at 2, *In Re: Incretin Mimetics Prods. Liab. Litig.*, No. 3:13-md-02452-AJB-MDD, Doc. 377 (S.D. Cal. Mar. 25, 2014) (agreeing "that general causation . . . is a matter of science, and therefore, scientific documents and/or scientific evidence frame the universe of contemplated discovery").

science is increasingly clear. For example, just last month, EPA's Office of Pesticide Programs ("OPP") issued a 227-page evaluation of glyphosate's carcinogenic potential, concluding that "[t]he strongest support is for [the description] 'not likely to be carcinogenic to humans' at doses relevant to human health risk assessment."[3]

Most of the individuals on Plaintiff's list of 11 additional custodians have no meaningful or unique information with respect to general causation, making them inappropriate custodians.[4] Monsanto will be prepared to address the relevancy of proposed custodians in detail at the MDL case management conference – or later with the plaintiffs' designated lead counsel – as the Court desires, but there are many general reasons why the 11 individuals identified by [redacted] are inappropriate. For example, most of the identified custodians have never been responsible for any kind of testing or analysis of the human health safety of glyphosate or GBH products (including Xavier Belvaux, Katherine Carr, Richard Garnett, Christophe Gustin, Eric Haupfear, and Manda Samson). Not one of the 11 is a medical doctor or scientist who can address the possible cause of non-Hodgkin's lymphoma. And three of the 11 (Messrs. Belvaux, Garnett, and Gustin) do regulatory (not science) work, relying on the same animal studies already produced to plaintiffs in this litigation – and about which Monsanto is voluntarily producing scientific witnesses to discuss. Still others (*e.g.*, Michael Koch, Joel Kronenberg, and Eric Sachs) are clearly duplicative of (and less informed than) the "first five" Monsanto employee custodians whose files already have been produced to the plaintiffs and who already have been offered for deposition.

D. Discovery of the 11 Additional Custodians Is Not Proportional to the Needs of the Case.

For the reasons discussed in the preceding section, Plaintiff has not and cannot meet his burden to establish "that the discovery sought is proportional to the needs of the case." *Gilead*

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[3] EPA's Office of Pesticide Programs, *Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* at 141 (Sept. 12, 2016), https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0094. The OPP's report includes a study-by-study evaluation of each of the three bodies of scientific evidence for glyphosate – epidemiological studies, animal carcinogenicity studies, and genotoxicity studies, and concludes that "[t]he available data at this time do no[t] support a carcinogenic process for glyphosate." *Id.* at 140. At the same time, EPA posted an October 2015 final report by its standing Cancer Assessment Review Committee ("CARC") in which CARC endorsed EPA's existing classification of glyphosate as "Not Likely to be Carcinogenic to Humans." Cancer Assessment Review Committee, Health Effects Division, Office of Pesticide Programs, U.S. Environmental Protection Agency, *Cancer Assessment Document – Evaluation of the Carcinogenic Potential of Glyphosate* at 10, 77 (Final Report, Oct. 1, 2015), https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0014.

[4] *See Allen v. Neighborhood Housing Servs. Silicon Valley*, No. 12-1656 PSG, 2012 WL 5954213, at *2 (N.D. Cal. Nov. 28, 2012) (denying motion to compel when plaintiff "cannot establish how the requested information is relevant" to the issues at hand).

Sciences, Inc. v. Merck & Co., Inc., No. 5:13-cv-04057-BLF, 2016 WL 146574, at *1 (N.D. Cal. Jan. 13, 2016). And for similar reasons, Mr. Hardeman's request is "unreasonably cumulative or duplicative," and seeks information that "can be obtained from some other source that is more convenient" and for which "the burden or expense of the proposed discovery outweighs its likely benefit." *Allen*, 2012 WL 5954213, at *2.

Any relevant documents contained in the files of the 11 additional custodians proposed by Mr. Hardeman's counsel are likely to be duplicative and/or cumulative of the millions of pages Monsanto has already produced from its voluminous non-custodial files and the twelve custodians referenced above, making them inappropriate for compelled disclosure. *See* Fed. R. Civ. P. 26(b)(1), (b)(2)(C); Fed. R. Civ. P. 34(b)(2)(E)(iii). Requiring Monsanto to engage in the lengthy, laborious, and expensive process of searching for, collecting, processing, reviewing, and producing these 11 custodial files would place an undue burden on the company. Based on Monsanto's experience with production in this litigation so far, the entire process to produce the 11 additional custodial files will consume about three months at an excessive cost.[5] Monsanto already has produced more than plaintiffs' experts could reasonably need to assess the science of whether glyphosate can actually cause non-Hodgkin's lymphoma – the only real question at this stage of the *Hardeman* litigation. Plaintiff's counsel's mere assertions that the 11 custodians possess "unique" and relevant documents are insufficient to justify the tremendous burden of producing these additional files.[6]

Additional considerations weigh against producing files of foreign custodians. As noted above, four of the 11 custodians identified by Plaintiff live and work in Europe, not in the United States. These individuals are employed not by the defendant Monsanto Company, but by subsidiary corporations established under the laws of Belgium and the United Kingdom.[7] Plaintiff has failed to establish that any of these four European custodians possess documents that are relevant to the claims of the plaintiffs in this litigation, who were allegedly exposed to GBH products in the United States.[8] Monsanto Company is based in St. Louis, Missouri, and, as

[5] This assumes no discovery from foreign countries, which may be restricted or delayed due to foreign data protection laws if such discovery is permitted. Plaintiff does not allege product exposure outside the United States so such discovery also is irrelevant and unduly burdensome, as discussed herein.

[6] *See Florer v. Johnson-Bales*, No. C06-5561 RJB/KLS, 2010 U.S. Dist. LEXIS 20934, at *16 (W.D. Wash. Feb. 16, 2010) (denying motion to compel production when "[t]he value of the requested documents in helping Plaintiff to prove his claim . . . is questionable" but "the request places considerable time and expense burdens on the Defendants").

[7] The four custodians are: Xavier Belvaux, Richard Garnett, and Christophe Gustin, who work for Monsanto Europe S.A., headquartered in Brussels, and Manda Sansom, a consultant who works for Monsanto UK Ltd. in England.

[8] *See In re Benicar (Olmesartan) Prods. Liab. Litig.*, No. 15-2606 (RBK/JS), 2016 WL 5817262, at *6 (D.N.J. Oct. 4, 2016) ("the Court is skeptical that meaningful discovery regarding any alleged causal connection between defendant's [product] and plaintiffs' symptoms is singularly possessed by [the two German employees], or even Daiichi Europe"); *Bard*, 2016 WL 4943393, at *4 (finding discovery of

described above, the relevant scientific and regulatory files are maintained in non-custodian-based collections in the United States. The potential for discovery of relevant, non-privileged, non-cumulative information in additional custodial files is very small, especially in comparison to the burden – in addition to the general burden of producing 11 additional custodial files – of searching for, collecting, reviewing, and producing four custodial files located in Europe.[9] Plaintiffs' broad-sweep requests – made without even the attempt to identify what specific, relevant, "unique" information each of these four custodians might possess – violate the mandate for proportionality in all pre-trial discovery.[10]

E. Conclusion

For the reasons outlined above, Monsanto respectfully requests that the Court direct the *Hardeman* plaintiff's counsel to withdraw the October 24 Discovery Letter Brief because it is an inappropriate request in light of the commencement of the MDL for the Roundup litigation of which the *Hardeman* case is clearly a part.

Dated: October 27, 2016

Respectfully submitted,

/s/ Rosemary Stewart
Rosemary Stewart
HOLLINGSWORTH LLP
rstewart@hollingsworthllp.com

Counsel to Defendant Monsanto Company

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foreign regulatory communications was "only marginally relevant" given that there were "no foreign-based Plaintiffs" and any possible relevance was "more hope than likelihood").

[9] Any disputes regarding whether defendant Monsanto Company has legal control of the requested records of Monsanto Europe S.A. or Monsanto UK Ltd. and, if so, whether European laws such as E.U. privacy laws nevertheless restrict production of those documents, are complex issues that this Court does not need to reach because Mr. Hardeman's counsel's request circumvents the MDL process and, in any event, the four European citizens at issue are not proper custodians.

[10] *See Benicar*, 2016 WL 5817262, at *6 (refusing to compel discovery of foreign affiliate employees and files when "it is likely the bulk of the relevant causation knowledge possessed" by the employees "has or could have been obtained" from prior discovery); *Bard*, 2016 WL 4943393, at *5 (holding defendant Bard "need not search the ESI of foreign Bard entities" because "the burden and expense" of the search "outweighs the benefit of the proposed discovery"); *see also Burnett v. Ford Motor Co.*, No. 3:13-cv-14207, 2015 WL 4137847, at *12 (S.D. W.Va. Jul, 8, 2015) (noting that "more focused discovery needed to be completed in North America before a final determination could be made about the need for the parties to collect documents housed overseas").

EXHIBIT C

Style of Case	Page No.
	16CV-CC00001

DATE	DOCUMENTS FILED/ACTION TAKEN IN CASE
6-27-16	Defendant Monsanto Company's Motion To Dismiss Plaintiffs Petition For Failure To State A Claim is denied. Plaintiff Phyllis Kennedy's Motion To ~~Strike Exhibits For Argument~~ Strike Exhibits and References to Exhibits In Defendant Monsanto's Reply Brief is denied. Defendant Monsanto's Motion For Scheduling Order Regarding General Causation is denied.

EXHIBIT D

LINDA M. SCHRACK
And
MYRON E. SCHRACK

Plaintiffs,

v.

FMC CORPORATION; UNITED PHOSPHORUS, INC., and MONSANTO COMPANY

Defendants.

COURT OF COMMON PLEAS
PHILADELPHIA COUNTY

April Term 2016

Case No. 0812

DEMAND FOR A JURY TRIAL

ORDER

AND NOW, this 2nd day of Sept., 2016, upon consideration of the Defendant Monsanto Company's Motion for Scheduling Orer Regarding General Causation, and all responses thereto, it is ORDERED that said Motion is DENIED.

BY THE COURT:

J.

Case ID: 160400812
Control No.: 16081258

Schrack Etal Vs Fmc Cor-ORDER

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