EXHIBIT 16

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	

Supplemental Report of Dr. Dennis D. Weisenburger, M.D.

Pursuant to PTO No. 34 and In Support of General Causation

On Behalf of Plaintiffs

In this supplemental report, I will comment on the recently-published update of the Agricultural Health Study (AHS) (1). I have previously commented on an unpublished draft update of the AHS (2) in my deposition. The most recent update (1) has added approximately 11 years of follow-up to the cohort and has significantly increased the number of non-Hodgkin lymphoma (NHL) cases (n = 575). The study also includes more recent exposure data from a follow-up survey administered to cohort members in 1999 – 2005 to update the original exposure information obtained at enrollment in 1993 – 1997. Although the study continues to show no association of glyphosate use and risk of developing NHL, it suffers from a number of significant issues and flaws which have likely resulted in a negative finding, and which call into question its validity and the weight that should be attributed to this study in an analysis of general causation.

In an industry-sponsored critical review of the design of the AHS in 2000 (3), the authors noted that the success of the study would depend on follow-up surveys of the cohort to determine how exposures change over time, and raised the issues of potential selection bias and exposure misclassification in the study if the response rates to the follow-up surveys were low. For example, only 44% of the enrolled applicators completed and returned a supplemental questionnaire following initial enrollment. A significant concern regarding the updated AHS (1) is the poor response to the first follow-up survey in 1999 – 2005, in which 37% of the applicators failed to respond and for whom no actual recent data on exposures was available for analysis. For the responders, pesticide use data was only obtained for the last year of farming prior to the follow-up survey, thus leaving a data gap of 6 – 12 years for actual pesticide use from the time of initial enrollment.

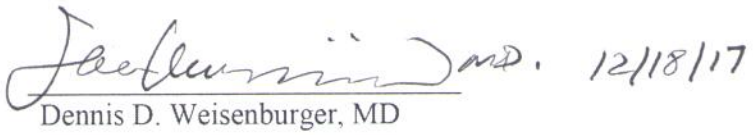
To further complicate matters, a dramatic increase in the use of glyphosate started in 1996 – 1997 after the introduction of glyphosate-resistant crops. This occurred during the latter part of the enrollment period of the AHS (1993 – 97) and usage continued to increase dramatically during the follow-up period, very likely resulting in significant misclassification of many applicators with regard to exposure. This dramatic change in the use of glyphosate was unique when compared to the use of other pesticides in this study (2, 4).

Because 37% of the applicators failed to complete the follow-up survey, the AHS researchers decided to use a complicated imputation method (5) to guesstimate the exposures for the nonresponders based on their prior exposures and the data obtained from the responders. However, this method also may lead to significant exposure misclassification if these

guesstimates are incorrect, which is likely since nonresponse was dependent on a variety of demographic and lifestyle factors as well as personal pesticide use (6). Furthermore, the imputation method underestimated glyphosate usage by 8% (5). Thus, the imputation of exposures likely further compounded the exposure misclassification problem in the AHS. Since all of these various errors in exposure classification were nondifferential, they would result in a bias toward the null and attenuate or obliterate any true positive effect. Thus, this type of misclassification will reduce the power of a study to detect any genuine cause-effect relationship and, thus, reduces the validity of the study findings.

Other issues of concern in the AHS include the high frequency of exposure to glyphosate and the relatively small number of lifetime years of use. In the AHS (1), 83% of the applicators used glyphosate and only 17% did not use it. Since the greatest power to detect a significant association is generally achieved when approximately 50% of the cohort is exposed and 50% is unexposed, it becomes difficult to estimate true effects with an unbalanced exposure distribution such as seen here. Additionally, the median lifetime years of glyphosate use in the study was only 8.5 years (range, 6 – 14 years) with a median follow-up time of only about 18 years, which may not be enough exposure and/or follow-up time to demonstrate an effect. At best, the current study is an interim analysis and the AHS will not be completed until most of the enrollees have died and the collected data on cancer outcomes has been fully analyzed (3, 7).

In conclusion, my opinion on the role of glyphosate as a cause of NHL has not changed based on the recently-published update of the AHS (1). Because of the significant issues and flaws in this study, it should not be given disproportionate weight compared to the case-control studies. Certainly, the results of one questionable negative study cannot be used to negate the results of multiple positive epidemiologic studies. Based on my expertise, and my review and evaluation of the literature on this subject, I conclude with a reasonable degree of medical certainty that glyphosate and glyphosate-based formulations (including Roundup) can cause NHL in humans exposed to these chemicals in the workplace or environment.



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