CORRECTED

EXHIBIT 19

Report of Michael L. Grossbard, MD

RE: Edwin Hardeman

Michael L. Grossbard, MD
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240 East 38th St.
19th Floor

November 26, 2018

Personal Qualifications/Experience:

I am a medical oncologist and a Professor of Medicine at NYU School of Medicine. Between January 2015 and December 2016, I served as the interim Co-Chief of the Division of Hematology and Oncology at NYU Langone Health. I have an active practice in Medical Oncology with a focus on hematologic malignancies. I am currently the Section Chief for Hematology at NYU Langone Health and the Perlmutter Cancer Center as well as the Section Chief, Hematology/Oncology, Tisch Hospital.

Between April 2000 and August 2014, I served as Chief of Hematology/Oncology at both St. Luke's-Roosevelt Hospital Center and Beth Israel Medical Center in New York, NY. From 2000 until 2007, I was an Associate Professor of Clinical Medicine at Columbia University College of Physicians and Surgeons. In 2007, I was promoted to Professor of Clinical Medicine and subsequently to Professor of Medicine. In 2013, SLRHC and BIMC merged with Mt. Sinai Hospital and I became a Professor of Medicine at the Icahn School of Medicine.

I am a summa cum laude graduate of Harvard College and a cum laude graduate of Yale University School of Medicine. I completed an internship and residency at Massachusetts General Hospital and a fellowship in Medical Oncology at Dana-Farber Cancer Institute. Until April 2000, I was a staff medical oncologist at Massachusetts General Hospital and an Assistant Professor of Medicine at Harvard Medical School. At Massachusetts General Hospital, I directed the Lymphoma Program from 1993-2000 and served as medical oncology directory of the Gastrointestinal Cancer Program from 1998-2000. In addition, I was an active participant in the Melanoma, Breast Cancer and Thoracic Oncology Programs at Massachusetts General Hospital.

I am board certified in Internal Medicine (1989) and in Medical Oncology (1991; re-certified 2001 and 2011).

I have published extensively in the area of non-Hodgkin's lymphoma and also have published in the areas of breast cancer, gastrointestinal oncology, thoracic oncology and melanoma. I have served on several editorial boards in the past, including as a member of the editorial boards of *The Oncologist* (section editor, Lymphoma) and *Clinical Lymphoma*.

I have authored or co-authored more than 100 primary articles and review articles, many of which are related to the therapy and management of lymphoma. I have edited two books, one on Monoclonal Antibody Therapy of Cancer, and a second book on Lymphoma. I have been listed in Best Doctors in America since 1998. I also have been listed in Top Doctors in New York and Top Doctors in America since 2001. My curriculum vitae is attached as Ex. A.

Along with my current positions in administration, I evaluate and treat 200-250 new patients with non-Hodgkin's lymphoma each year and remain as the primary oncologist for hundreds of other patients with lymphoma who have previously completed therapy. I am actively involved in teaching of both Hematology/Oncology fellows and Internal Medicine Residents and also teach medical students both in the classroom and at the bedside. Over the past year, I have served as the Hematology/Oncology Fellowship Training Program director for NYU Langone Health.

I am paid $600 per hour for medical record review and report preparation and $5000 per day for testimony at depositions and at trial. A list of my testimony over the past four years is attached as Ex. B. A list of materials that I have reviewed is attached as Ex. C. A list of medical and scientific references that I have considered is attached as Ex. D.

In addition, I am relying on my extensive personal academic and clinical experience in the treatment of lymphoma, including my leadership of academic lymphoma programs from 1993 through 2014. I also have relied on standard sources of medical information including DeVita, Hellman and Rosenberg's Cancer: Principles & Practice of Oncology, 10th Edition (2015) and Up to Date, an on-line textbook of medicine.

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obese individuals compared with people of normal weight. The RR in overweight individuals was 1.14 (95% CI 1.04-1,24), and the RR in obese individuals was 1.29 (95% CI 1.16-1.43).

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Multiple published studies have documented a role for HCV infection in the causation of NHL. Literature dating back more than 15 years demonstrates an increased risk of NHL in patients with HCV infection with common subtypes including marginal zone lymphoma, lymphoplasmacytoid lymphoma and DLBCL (Turner, 2003; Mihalia, 2016). Several mechanisms have been postulated whereby chronic HCV infection can induce the proliferation of B-lymphocytes. Subsequent molecular alterations in these proliferating lymphocytes may play a role in a multi-step process of malignant transformation. For example, even in the absence of overt lymphoma, circulating lymphocytes in HCV infection have been shown to have a high incidence of the t(14;18) resulting in over-expression of BCL-2. Furthermore, there is evidence that HCV infects and replicates in the B-cells of patients with chronic HCV and that peripheral B cells serve as a reservoir of hepatitis C infection (Ito, 2011). Clearance of virus from plasma by interferon and ribavirin may not eliminate virus from peripheral blood B-cells. Ultimately, the B-cell proliferation process/lymphoma is independent of active viral infection (Tasleem, 2015). Exposure of B-cells to HCV in vitro has been associated with a five to ten-fold increase in

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In 2006, Dal Maso and Franceschi published a meta-analysis assessing 15 case control studies and three prospective studies to assess the risk of lymphoma and other lymphoid neoplasms in patients with hepatitis C infection. Only studies with greater than 100 cases were included. The pooled relative risk of lymphoma in HCV positive individuals was 2.5 (95% C.I. 2,1-3.0). In fact, an elevated relative risk was observed in all 15 of the included case control studies.

Allison et al (2015) followed 12,126 individuals who were chronically infected with hepatitis C and assessed the incidence of cancer as compared with individuals in 13 SEER registries. With respect to the age adjusted incidence of NHL, the standardized rate ratio was 1.6 (95% CI 1.2-2.1).

Mele et al reported a case control study demonstrating the existence of an association between hepatitis C infection and lymphoma. They compared 400 lymphoma patients with 396 controls and identified an odds ratio (OR) of 3.1 (95% CI 1.8-5.2) for the development of NHL, adjusted by age, sex, level of education and place of birth. 19% of the 205 cases of DLBCL in this study were positive for hepatitis C virus. The OR for the development of aggressive NHL (most aggressive lymphomas in this study were DLBCL) was 3.9 (95% CI 2.3-6.7) with an adjusted OR 3.5 (95% CI 2.0-6.3).

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lymphoma. BCL6 translocations and mutations are known to contribute to the development and

I also have reviewed the epidemiologic literature related to glyphosate, the active herbicidal agent in Roundup. I am aware that IARC published a monograph related to glyphosate in March 2015, stating: "There is *limited evidence* in humans for the carcinogenicity of glyphosate. A positive association has been observed for non-Hodgkin lymphoma." As a clinician with a particular expertise in the diagnosis and management of lymphoma, I am aware that the terms "limited evidence" and "association" do not establish causation. Beyond that terminology, it is critical to assess the evidence that IARC used to arrive at its conclusions.

IARC's assessment relied on numerous epidemiologic studies, with the largest studies involving agricultural workers and workers involved in pesticide application. Hence, findings from these studies would have limited relevance to the case of Mr. Hardeman who applied Roundup in a residential setting and would have a significantly lower exposure to Roundup or any other pesticide. Several of the key studies cited in the IARC document are summarized in the following paragraphs.

De Roos et al. (2005) conducted a prospective cohort study in 57,311 pesticide applicators in Iowa and North Carolina to evaluate associations between glyphosate exposure and cancer incidence. Ninety-two cases of NHL were identified, and the RR adjusted for age was 1.2 (95% CI 0.7-1.9). The RR adjusted for age, demographic and lifestyle factors and other pesticides was 1.1 (95% CI 0.7-1.9). Further analysis failed to show an increased RR with increased exposure days or intensity weighted exposure days. Again, these workers had a different magnitude of glyphosate exposure than Mr. Hardeman.

In an earlier study, De Roos et al (2003) pooled data from three case control studies to examine the risk of NHL in 3147 farmers with pesticide exposure. In that study, the logistic regression OR was 2.1 (95% CI 1.1-4.0) for glyphosate but the hierarchical regression OR was 1.6 (95% CI 0.9-2.8). Given that the latter result accounts for multiple herbicides/pesticides, and lacks statistical significance, it is impossible conclude that even high degrees of glyphosate exposure in farmers increases the risk of NHL.

In a case control study conducted in Sweden, Hardell et al (2002) assessed the risk of NHL following exposure to pesticides and herbicides. For glyphosate exposure, the OR was 3.04 (95% CI 1.08-8.52), based on only 8 exposed cases and 8 controls. However, after controlling for exposure to other pesticides the risk decreased by 85% and was not statistically significant.

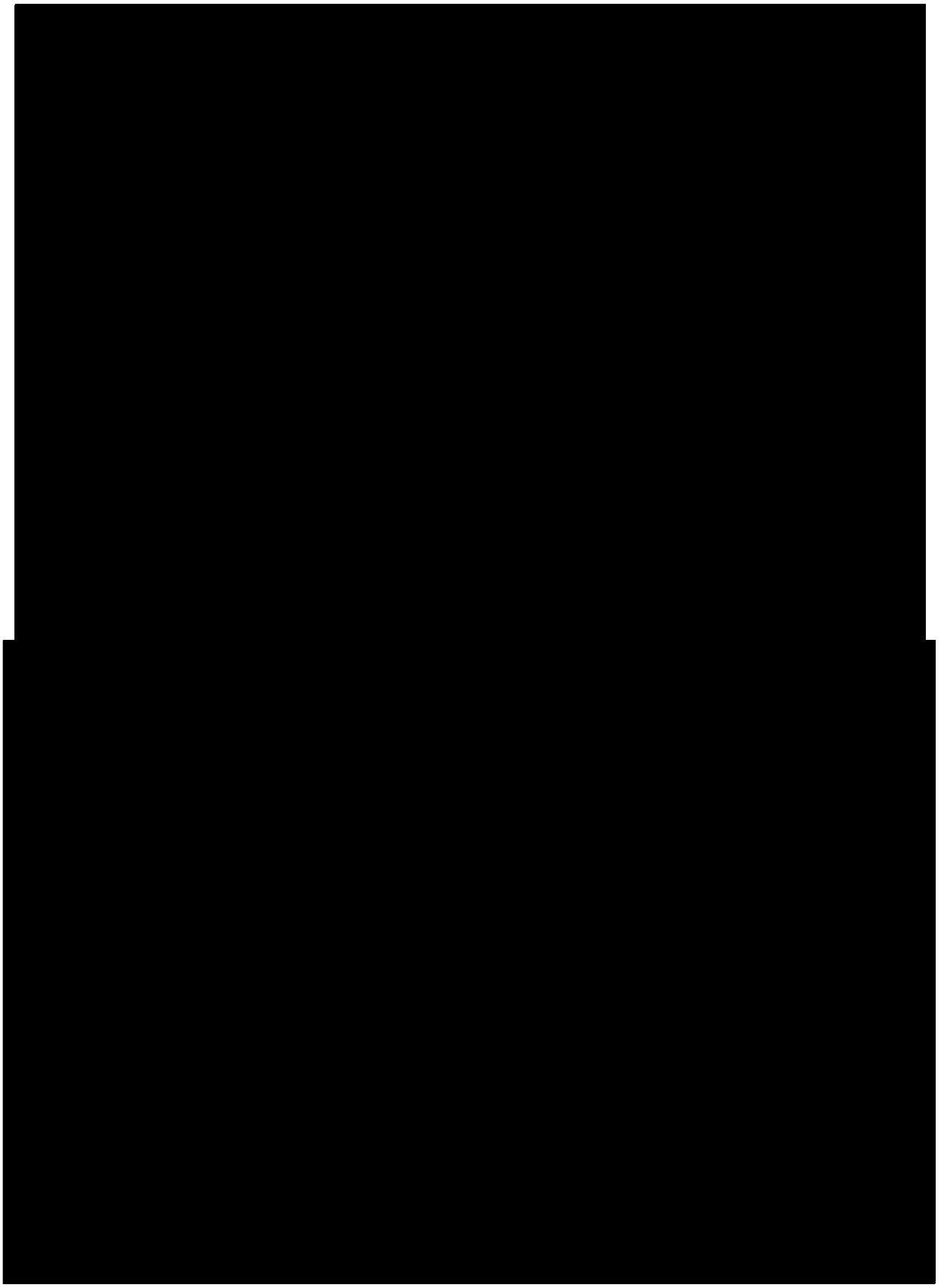
Eriksson et al (2008) reported a population based case-control study assessing exposure to pesticides as a risk factor for NHL. Patients with NHL (910) were matched with controls (1016) from the national population registry in Sweden. The OR for exposure to glyphosate for $\leq$ 10 days was 1.69 (95% CI 0.70-4.07) and for > 10 days was 2.36 (95% CI 1.04-5.37). Importantly, after controlling for exposure to other pesticides, there was not a statistically significant increased risk. For B-cell lymphomas, the OR was 1.87 but did not achieve statistical significance with the 95% CI 0.998-3.51. Likewise, for the 239 cases of DLBCL, the OR for glyphosate was 1.22, but was not statistically significant with the 95% CI 0.44-3.35.

McDuffie et al (2001) conducted a case control study in Canada to investigate the association of multiple pesticides and herbicides with the development of NHL. 517 NHL patients were assessed along with 1506 controls. For glyphosate, the OR adjusted for age and province of residence was 1.26 (95% CI 0.87-1.80) and the OR adjusted for additional variables including family history of cancer was 1.20 (95% CI 0.83-1.74). Thus, glyphosate exposure did not lead to a statistically significant increase in the risk of lymphoma.

Finally, Andreotti et al (2018) published a detailed and updated report from the Agricultural Health Study. This is by far the largest (more than 50,000 participants) and most scientifically rigorous study that has been conducted. Glyphosate exposure was not statistically significantly associated with cancer at any site. With respect to NHL, regardless of the extent of exposure to glyphosate the RR was 0.83-0.88. Similar findings were reported for B-cell lymphoma with RR ranging from 0.76-0.88. The size and detail of the study with the duration of follow up makes it the most important study for the assessment of glyphosate risk and strongly suggests that there is no relationship between glyphosate exposure and the development of B-cell lymphoma.

In sum, the epidemiologic studies do not indicate an increased risk of NHL associated with glyphosate exposure.

Response to Plaintiff's Expert Reports:



These represent my conclusions based on the records made available to me. I reserve the right to modify my opinion based on additional information that may be made available to me. I also reserve the right to use graphics and demonstratives to illustrate and explain my opinions and bases for those opinions.

Michael L. Grossbard, MD
November 26, 2018

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