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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

EAGLE PHARMACEUTICALS, INC., Plaintiff, v. MRIGLOBAL, Defendant.	Civil Action No. 3:21-cv-20145 **COMPLAINT AND DEMAND FOR JURY TRIAL** *DOCUMENT FILED ELECTRONICALLY*

Plaintiff Eagle Pharmaceuticals, Inc. ("Eagle"), by and through its undersigned counsel, Troutman Pepper Hamilton Sanders LLP, hereby files this Complaint against defendant MRIGlobal and states as follows:

INTRODUCTION

1. Eagle brings this action to recover amounts due and owing based on MRIGlobal's admitted material breaches of a Master Services Agreement ("MSA") that the parties entered into in 2017.

2. The MSA applied to certain preclinical studies that MRIGlobal agreed to conduct with respect to Eagle's efforts to obtain FDA approval of a new indication for its medication, Ryanodex, to prevent or treat the effects of exposure to chemical agents that cause neurological damage.

3. MRIGlobal wrote the study protocols at issue in this case, but then failed to follow its own instructions.

4. As a result, more than four years after entering into the MSA with MRIGlobal and paying more than $1.8 million, Eagle lacks critical preclinical data required by FDA to obtain approval of a new indication for Ryanodex.

THE PARTIES

5. Eagle is a specialty pharmaceutical company working to advance safe and efficient injectable treatments for patients across critical care and other diseases. Eagle is a Delaware corporation with its principal place of business at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey 07677.

6. MRIGlobal is a contract research organization with expertise in medical countermeasures designed to protect against threats to public health, including exposure to chemical agents. That expertise includes the conduct of preclinical safety and efficacy studies compliant with regulatory requirements. MRIGlobal is a Missouri nonprofit corporation with its principal place of business at 425 Dr. Martin Luther King Jr. Boulevard, Kansas City, Missouri 64110.

VENUE AND JURISDICTION

7. This Court has jurisdiction pursuant to 28 U.S.C. § 1332 because the parties are of diverse citizenship and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

8. This Court has personal jurisdiction over the Defendant because, at all relevant times, MRIGlobal conducted regular and sustained business in New Jersey, engaged in substantial commerce and business activity in New Jersey, including in Bergen County, and the claims at issue arise from MRIGlobal's business activities.

9. Venue is proper in this District pursuant to 28 U.S.C. § 1391(a) because a substantial part of the events or omissions giving rise to the claim occurred in the State of New Jersey.

FACTUAL ALLEGATIONS

10. As part of its mission, Eagle develops medications that can treat or prevent serious or life-threatening conditions caused by exposure to lethal or permanently disabling toxic substances.

11. Eagle is studying one of its medications, Ryanodex, to evaluate its potential for treating or preventing neurological damage in people exposed to chemical nerve agents. Ryanodex is currently approved by FDA for treatment of malignant hyperthermia in conjunction with appropriate supportive measures and prevention of malignant hyperthermia in patients at high risk.

12. Because of the purpose for which Ryanodex is being studied, it would not be ethical to conduct studies in humans, and field trials after accidental or deliberate exposure are not feasible.

13. Eagle is, therefore, proceeding under FDA's Animal Rule. *See* 21 C.F.R. § 314.600-650; FDA Guidance for Industry, Product Development Under the Animal Rule (October 2015) ("FDA Animal Rule Guidance").

14. Under the Animal Rule, FDA may grant approval for use in humans "based on adequate and well-controlled animal efficacy studies when the results of those studies establish that the drug is reasonably likely to produce clinical benefit in humans." FDA Animal Rule Guidance, at 2.

15. For the preclinical studies necessary to obtain FDA approval of Ryanodex under the Animal Rule, Eagle entered into a Master Services Agreement ("MSA") with MRIGlobal, effective March 28, 2017 (attached as Exhibit 1).

16. In entering into this MSA with MRIGlobal, Eagle relied on MRIGlobal's representations about its extensive preclinical experience testing medical countermeasures to chemical agents, in compliance with the Animal Rule.

17. The MSA provides that the delivery of research services will be further described in Statements of Work ("SOWs"), prepared by MRIGlobal and submitted to Eagle for approval. MSA ¶ 1.

18. Initially, the parties agreed that MRIGlobal would conduct preliminary studies of Ryanodex in a rodent model.

19. MRIGlobal completed its studies of Ryanodex in the rodent model in 2017.

20. After other work related to Ryanodex not performed by MRIGlobal, Eagle and MRIGlobal executed Project Change Order No. 4 (attached under seal as Exhibit 2), which had an effective date of September 4, 2020. The purpose of this change order was to get Eagle's

approval of the additional Scope of Work – i.e., the drafting of protocols in nonhuman primates (NHPs) – and related price increase.

21. Soon after, Project Change Order No. 5 (attached under seal as Exhibit 3), which had an effective date of November 20, 2020, identified five NHP studies needed for Eagle's planned Ryanodex Investigational New Drug Application submission to FDA for approval under the Animal Rule.

22. Each of the five NHP studies had a different purpose, and each provided necessary information for the studies that followed it.

23. These precursor studies were intended to lead to a pivotal efficacy study that would support an Investigational New Drug Application for FDA approval of Ryanodex for treatment or prevention of neurological damage in people exposed to chemical nerve agents.

24. MRIGlobal was responsible for drafting the protocols for each of the five NHP studies in the SOWs.

25. The protocols for the five NHP studies that MRIGlobal prepared were the executable Statement of Work. The agreed-on scope of this SOW was the conduct of the studies.

26. Each study protocol and any amendments thereto had to be approved by MRIGlobal's study director and Eagle, as the study sponsor, with the study director being the last to sign.

27. MRIGlobal's study director was required to promptly communicate to Eagle, as the study sponsor, all unplanned changes to the study, also known as protocol deviations. The study director was also required to determine the importance of any deviation and its impact on the study, including data generated, results, and conclusions.

DOCKET ALARM

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