\*\*Deposition of Karen Newford\*\*

\*\*Date:\*\* August 1, 2024

\*\*Time:\*\* 10:45 AM

\*\*Location:\*\* Dechert LLP, Conference Room C

\*\*Attorneys Present:\*\*

- \*\*For Plaintiff:\*\* Janet Robbens, Esq.

- \*\*For Defendant:\*\* Will Sams, Esq.

\*\*Court Reporter:\*\* Emily Davis

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\*\*Janet Robbens, Esq.:\*\* Good morning, Ms. Newford. Could you please state your full name for the record?

\*\*Karen Newford:\*\* My name is Karen Elizabeth Newford.

\*\*Janet Robbens, Esq.:\*\* Thank you. Ms. Newford, where do you currently reside?

\*\*Karen Newford:\*\* I live at 456 Oak Avenue, Boston, Massachusetts.

\*\*Janet Robbens, Esq.:\*\* Let's start with your professional background. Where are you currently employed?

\*\*Karen Newford:\*\* I am currently employed at PharmaTech Solutions as the Director of Clinical Research.

\*\*Janet Robbens, Esq.:\*\* How long have you been with PharmaTech Solutions?

\*\*Karen Newford:\*\* I joined PharmaTech Solutions on June 1, 2012.

\*\*Janet Robbens, Esq.:\*\* Can you describe your responsibilities at PharmaTech Solutions?

\*\*Karen Newford:\*\* I oversee all clinical trials, manage a team of researchers, and ensure compliance with FDA regulations.

\*\*Janet Robbens, Esq.:\*\* Were you involved in the development of the medication known as MedicaRelief?

\*\*Karen Newford:\*\* Yes, I was the lead researcher for the MedicaRelief project.

\*\*Janet Robbens, Esq.:\*\* When did the development of MedicaRelief begin?

\*\*Karen Newford:\*\* The initial research phase began on January 10, 2015.

\*\*Janet Robbens, Esq.:\*\* Can you outline the key milestones in the development of MedicaRelief?

\*\*Karen Newford:\*\* Certainly. The preclinical trials started on March 15, 2015, and were completed by September 30, 2015. We received FDA approval to begin Phase I clinical trials on November 20, 2015.

\*\*Janet Robbens, Esq.:\*\* When did the Phase I clinical trials begin?

\*\*Karen Newford:\*\* Phase I trials began on December 1, 2015, and concluded on February 28, 2016.

\*\*Janet Robbens, Esq.:\*\* What were the results of the Phase I trials?

\*\*Karen Newford:\*\* The results were promising, showing a high safety profile and minimal side effects.

\*\*Janet Robbens, Esq.:\*\* When did you proceed to Phase II trials?

\*\*Karen Newford:\*\* Phase II trials started on April 15, 2016, and ended on October 15, 2016.

\*\*Janet Robbens, Esq.:\*\* Were there any significant findings during Phase II?

\*\*Karen Newford:\*\* Yes, we observed a significant improvement in patient symptoms, with a 70% efficacy rate.

\*\*Janet Robbens, Esq.:\*\* When did Phase III trials commence?

\*\*Karen Newford:\*\* Phase III trials began on January 5, 2017.

\*\*Janet Robbens, Esq.:\*\* How long did Phase III trials last?

\*\*Karen Newford:\*\* They lasted until December 20, 2017.

\*\*Janet Robbens, Esq.:\*\* Were there any challenges during Phase III?

\*\*Karen Newford:\*\* We encountered a few challenges, including a higher dropout rate, which we addressed by increasing patient support and follow-up.

\*\*Janet Robbens, Esq.:\*\* When did you submit the New Drug Application (NDA) to the FDA?

\*\*Karen Newford:\*\* We submitted the NDA on March 1, 2018.

\*\*Janet Robbens, Esq.:\*\* When did the FDA approve MedicaRelief?

\*\*Karen Newford:\*\* The FDA approved MedicaRelief on September 15, 2018.

\*\*Janet Robbens, Esq.:\*\* Were there any post-approval studies conducted?

\*\*Karen Newford:\*\* Yes, we conducted post-marketing surveillance studies starting on October 1, 2018, to monitor long-term safety and efficacy.

\*\*Janet Robbens, Esq.:\*\* Have there been any significant findings from these post-marketing studies?

\*\*Karen Newford:\*\* We found that MedicaRelief maintained its efficacy over a two-year period, with no new safety concerns reported.

\*\*Janet Robbens, Esq.:\*\* Were there any recalls or safety alerts issued for MedicaRelief?

\*\*Karen Newford:\*\* No, there have been no recalls or safety alerts for MedicaRelief to date.

\*\*Janet Robbens, Esq.:\*\* Thank you, Ms. Newford. I have no further questions at this time.

\*\*Will Sams, Esq.:\*\* I have a few questions. Ms. Newford, can you describe the nature of the side effects observed during the clinical trials?

\*\*Karen Newford:\*\* The most common side effects were mild headaches and nausea, which were reported by less than 10% of participants.

\*\*Will Sams, Esq.:\*\* Were there any serious adverse events reported?

\*\*Karen Newford:\*\* There were two serious adverse events reported during Phase III, both of which were determined to be unrelated to MedicaRelief.

\*\*Will Sams, Esq.:\*\* How did you ensure compliance with FDA regulations throughout the development process?

\*\*Karen Newford:\*\* We followed all FDA guidelines, conducted regular audits, and maintained detailed documentation of all trial activities.

\*\*Will Sams, Esq.:\*\* Were there any inspections by the FDA during the clinical trials?

\*\*Karen Newford:\*\* Yes, the FDA conducted inspections on June 10, 2016, and August 15, 2017, both of which we passed without any major findings.

\*\*Will Sams, Esq.:\*\* Thank you, Ms. Newford. No further questions.

\*\*Court Reporter:\*\* The time is now 12:15 PM. This concludes the deposition of Karen Newford.