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

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.