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Exosomes

The FDA is raising public awareness about reports of non-FDA approved treatments with exosome therapies which may result in serious adverse drug events.

What are exosomes? Exosomes are extracellular vesicles that are believed to mediate intracellular communication. They are currently being investigated in a variety of potential roles for drug delivery and as treatments for certain diseases. Exosomes have been studied for many years but the biological significance and effects of exosomes remains largely unknown.

The Issue: There are reports that certain clinics in Nebraska and possibly other states, are offering exosome treatments for a variety of diseases that have not received FDA approval. As a result, there have been multiple reports of serious adverse drug events experienced by patients who were treated with these products. Any treatment with an exosome would require FDA review and approval. At this time, the FDA has not approved any exosome products.

Recommendations: The FDA is encouraging patients who are offered exosome therapy to confirm that they will be receiving an FDA approved product to reduce the risk of inappropriate treatment with non-approved substances.

The FDA drug safety alert can be read in its entirety [online by clicking this link](#).