

CLIENT ALERT

Attorneys General Target Unsupported Medical Treatment Claims

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Although COVID-19 is occupying a lot of regulatory resources, Attorneys General are continuing their consumer protection mission, including watching out for deceptive claims related to stem cell therapy and other medical treatments. Attorneys General are particularly concerned about businesses making unsupported claims suggesting their services or procedures can treat or cure disease.

On July 15, 2020, Iowa Attorney General Tom Miller sued stem cell therapy entities Regenerative Medicine and Anti-Aging Institutes of Omaha, Omaha Stem Cells LLC, and Stem Cell Centers of Anchorage, Alaska, as well as their owners in their individual capacities, for allegedly making unfounded claims that their treatments could reverse aging and cure, prevent, or treat medical conditions. The defendants allegedly claimed their services could cure, treat, or prevent conditions such as neuropathy, Alzheimer's disease, and chronic obstructive pulmonary disease. They allegedly targeted older Iowans through advertisements and live events, persuading them to purchase treatments that ranged in cost from \$1,400 to over \$27,000 and that were not covered by health insurance. The lawsuit seeks injunctive relief, restitution, and civil penalties of up to \$40,000 per violation of the Consumer Fraud Act. It also seeks \$5,000 for every violation of the Older Iowans Law.

Nebraska Attorney General Doug Peterson also filed a lawsuit against the same defendants based on their actions against consumers in Nevada. In regard to the lawsuit, Attorney General Peterson stated, "Consumers are entitled to accurate and truthful information about any product or service, but especially those products that affect their health and wellbeing. With today's filing, we remind all healthcare providers and other businesses that they will be held accountable for the representations they make to consumers."

The U.S. Food and Drug Administration (FDA) has approved stem cell therapy for the limited purpose of treating those with hematopoietic system disorders. However, this method of treatment is still in its early stages for other medical issues, and though it has potential, it has not yet been proven safe and effective.

The Iowa and Nevada lawsuits come only a few months after the FDA issued a public safety notification in December 2019 warning against products advertised as containing exosomes, after several patients in Nebraska experienced "serious adverse events." The FDA notification explains that, as of the time of its issuance, there are "no FDA-approved exosome products," though some clinics, including a number that also market "stem cell" products, offer them to patients. The Iowa and Nebraska lawsuits are also occurring in the context of Attorneys General initiating enforcement actions against companies alleging that they can cure or treat COVID-19.

Any business offering a product or service that claims to possess the ability to cure or prevent a disease should carefully ensure that these representations are supported by scientific evidence and approved by the FDA in order to avoid liability. By their nature, health claims require heightened substantiation and business cannot rely on "after the fact" testing to support prior claims. Businesses making general health and safety claims should also confirm they have sufficient scientific support backing their advertisements, given that Attorneys General are focusing their attention on this space.

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