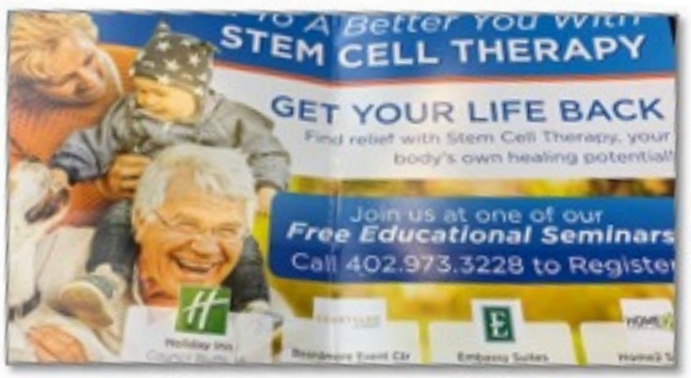
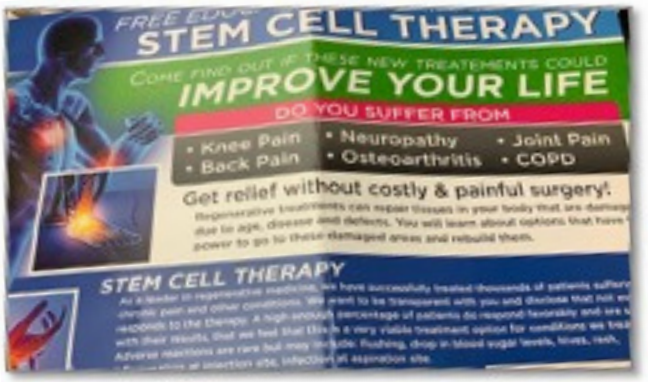
FACT SHEET

UNAPPROVED STEM CELL THERAPIES





Between 2004 and 2020, Unapproved Therapies have led to at least 360:

Infections
Disabilities
Deaths
Other adverse experiences

In 2019, Nebraskans were seriously injured by unsafe stem cell products.

- Many infections, like the ones in Nebraska, are caused by unsafe manufacturing practices.
- Some other infections are due to unsafe injection practices and people administering therapies outside of their scope of practice.

Other Harms

Large financial cost to consumers

Delay in seeking evidence-based treatments

Promises are made to treat:

Pain
Orthopedic conditions
Neurological diseases
Erectile dysfunction
Immunological conditions
Skin conditions
Autism
COVID-19
Hair Loss

https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2021/06/harms-linked-to-unapproved-stem-cell-interventions-highlight-need-for-greater-fda-enforcement

Nebraska Coalition for Lifesaving Cures

REGENERATIVE MEDICINE HAS TREMENDOUS POTENTIAL

Therapies are in development that address some of the most difficult diseases and medical conditions such as diabetes, spinal injury, macular degeneration and Parkinson's disease. They are now in later stages of clinical trials.

While some unapproved stem cell therapies have potential, they need to go through clinical trials where effectiveness is proven and adverse experiences can be thoroughly documented.

STATE ACTIONS

Informed consent laws are on the books in CA, WA, and FL. Providers must notify consumers that the treatment is not FDA approved.

The NY Attorney General won a $5.1 case against a stem cell clinic chain in Nov. 2021 on the grounds of false advertising.

The NE and IA Attorneys General have a similar pending case against a clinic operator.

FDA ACTIVITY

Stem cell therapies are under the jurisdiction of the FDA. The FDA gave businesses three years to file for proper approval or discontinue the use of unapproved therapies. That grace period ended in summer 2021. The FDA has taken action against a handful of clinics nationally and has sent out 400 letters alerting clinics that some of their products are in violation of FDA policies.

Sources

"The American stem cell sell in 2021: U.S. businesses selling unlicensed and unproven stem cell interventions." Cell Stem Cell 28, November 4, 2021. https://doi.org/10.1016/j.stem.2021.10.008

FDA: Important Patient and Consumer Information About Regenerative Medicine Therapies. July 9, 2021. https://www.fda.gov/vaccines-blood-biologics/consumers-biologics/important-patient-and-consumer-information-about-regenerative-medicine-therapies

https://ago.nebraska.gov/news/attorney-general-peterson-files-lawsuit-against-stem-cell-therapy-clinic-omaha?fbclid=IwAR0AOWorCLWsG86_5ZakrTponDu4QG12Wdo85DLgdTcEgul84_1_4KpGcAU
subheading