ARE STEM CELL TREATMENTS SAFE?

A Data-Driven Answer

At Auragens, one of the questions we hear most often is simple:

“Are stem cell treatments actually safe?”

The honest answer is this:

When regenerative medicine is performed correctly — with rigorous manufacturing standards, validated science, medical oversight, and uncompromising quality controls — the data overwhelmingly supports that these therapies are both safe and highly effective.

But the opposite is also true.

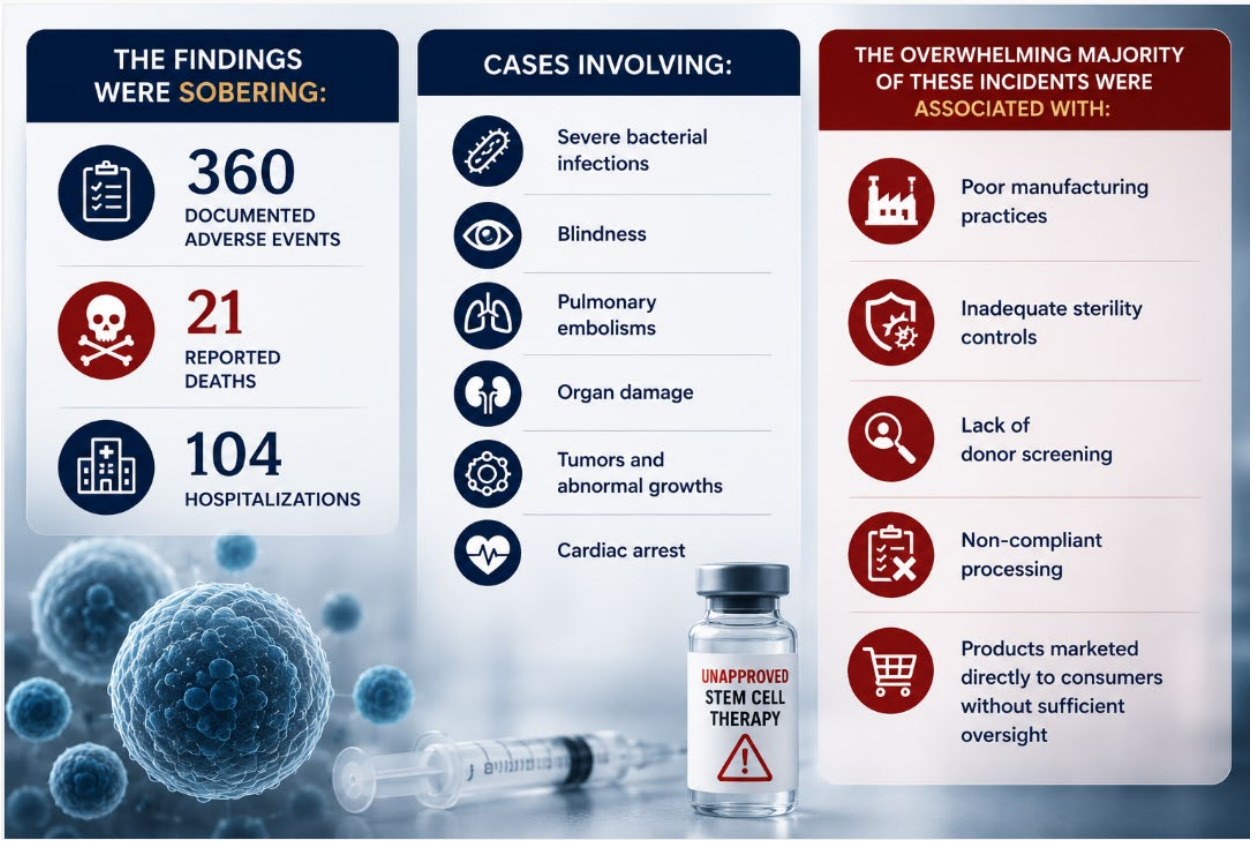
When shortcuts are taken, when products are poorly sourced, improperly manufactured, contaminated, or administered without adequate expertise and oversight, the consequences can be catastrophic.

That distinction matters.

And it is exactly why Auragens was built differently from the beginning.

The Data Behind the Concern

A recent review titled *"Documented Injuries and Adverse Events from Unapproved Stem Cell Therapies in the United States"* highlighted a growing number of injuries tied to unregulated and improperly administered stem cell products.



The findings were sobering:

- **360 documented adverse events**
- **21 reported deaths**
- **104 hospitalizations**
- Cases involving:
  - Severe bacterial infections
  - Cardiac arrest
  - Organ damage
  - Blindness
  - Pulmonary embolisms
  - Tumors and abnormal growths

The overwhelming majority of these incidents were associated with:

- Poor manufacturing practices
- Inadequate sterility controls
- Lack of donor screening
- Non-compliant processing
- Products marketed directly to consumers without sufficient oversight

In other words:

The issue is not regenerative medicine itself. The issue is how it is performed.

Why Auragens Took the Harder Path

At Auragens, we made a decision early on that if we were going to participate in advancing regenerative medicine, we would do it at the highest level possible — even when it meant moving slower, investing more, and holding ourselves to standards many others do not.

That is why Auragens pursued and achieved accreditation through the AABB — one of the most respected standards bodies in biologics, cellular therapies, and transfusion medicine.

That accreditation was not a marketing exercise.

It was a commitment to patients.

What “Done Correctly” Actually Looks Like

At Auragens, every cellular therapy protocol is built around a system of repeatability, validation, and patient safety.

That includes:

Rigorous Donor Screening

Every donor undergoes extensive medical, infectious disease, and eligibility screening before tissue is ever accepted into the process.

Chain of Custody & Traceability

We maintain full chain-of-custody oversight from donor sourcing through administration, follow-up, and long-term quality review.

Third-Party Laboratory Validation

Independent laboratories validate:

- Sterility
- Viability
- Identity
- Endotoxin levels
- Contamination screening
- Potency markers

Controlled Manufacturing Standards

Our production environment follows strict protocols designed to minimize contamination risk and preserve product integrity.

Extended Production Timelines

At Auragens, it takes approximately **15 months** to produce a patient-ready dose.

That timeline exists for a reason.

Because quality biologics cannot be rushed.

Shortcuts in regenerative medicine often happen behind the scenes:

- Poor tissue handling
- Insufficient expansion controls
- Inadequate sterility testing
- Weak quality assurance programs
- Improper storage and transport

These are precisely the kinds of failures that have contributed to the injuries documented in the report.

Expertise Matters

Cellular medicine is not simply about obtaining cells.

It is about:

- Understanding immunology
- Understanding inflammatory signaling
- Understanding manufacturing science
- Understanding administration protocols
- Understanding patient selection
- Understanding follow-up and safety monitoring

This is why outcomes can vary dramatically between facilities.

The difference between excellence and danger in regenerative medicine is often invisible to the patient — but critically important behind the scenes.

The Future of Regenerative Medicine Is Bright — But Standards Must Lead

Regenerative medicine remains one of the most exciting frontiers in healthcare today.

The ability to support the body's healing response through advanced biologics has enormous potential across orthopedics, autoimmune conditions, inflammatory disorders, neurodegenerative disease research, and longevity science.

But the future of this field will belong to organizations that prioritize:

- Scientific rigor
- Compliance
- Patient safety
- Repeatable outcomes
- Transparency
- Quality systems
- Data collection

Not hype.

Not shortcuts.

Not marketing claims unsupported by science.

Our Commitment to Patients

At Auragens, our mission has never been to simply participate in regenerative medicine.

Our mission is to help define what responsible regenerative medicine should look like.

That means:

- Building systems patients can trust
- Investing in oversight and accreditation
- Utilizing third-party validation
- Prioritizing safety above speed
- Creating predictable and repeatable outcomes
- Continuing to elevate standards across the industry

Because when regenerative medicine is done correctly, responsibly, and ethically, the data tells a very different story:

One of extraordinary promise.

And we believe the future deserves nothing less.