

# **Direct-to-consumer businesses promoting unproven stem cell and gene-based interventions, researchers warn**

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While stem cell therapy has been used to successfully generate and repair tissues that have been damaged due to certain conditions and diseases, such as leukemia, it is far from a cure-all.

Direct-to-consumer businesses, however, have increasingly been promoting unproven stem cell and gene-based interventions to unsuspecting members of the public across the globe as the answer to a litany of problems.

Through slick websites, television advertisements, and social media postings, the businesses frame their so-called therapies as a legitimate treatment for conditions ranging from musculoskeletal diseases and injuries to neurological disorders, said Laertis Ikononou, Ph.D., associate professor of oral biology at the University at Buffalo School of Dental Medicine.

"These presumed therapies do not have substantive evidence of safety or efficacy," he said.

As the immediate past chair of the International Society for Cell & Gene Therapy (ISCT) Committee on the Ethics of Cell and Gene Therapy (ECGT), which is composed of [academic researchers](#), clinicians, and regulatory policy and bioethics experts, Ikononou has studied this unsavory practice for several years.

He recently served as the lead author in a guide on direct-to-consumer businesses that offer these unproven therapies. It was published in

### Cytotherapy.

"We broke down what is legitimate and what is not," Ikonomou said.

"We also provided an overview of reporting mechanisms for patients who believe they have been harmed by these unapproved and unproven products and suggested practical strategies to address and counteract the widespread marketing of such products."

## **Desperate consumers seek unregulated interventions**

Examples of interventions that direct-to-consumer clinics offer include cell-based products and cell-derived products such as extracellular vesicles and perinatal tissue products, and rarely, gene-based therapies, including gene-modified cell therapies.

The clinics offer treatments for numerous conditions, including progressive ones such as Parkinson's or Alzheimer's disease, that can significantly diminish quality of life. Often, patients come to the clinics from a place of desperation.

"When a physician has told them, 'This is all we can do for you, and you're not going to get better,' people are absolutely within their rights to look for alternative treatment," Ikonomou said. "The problem is what a lot of these clinics offer is a total scam."

In some cases, after undergoing unregulated interventions, patients have ended up with physical harm, such as infections, or worsened conditions, including blindness.

Some of the clinics are led by [medical doctors](#), and some aren't.

For instance, a clinic for orthopedic care may offer interventions for other conditions in which the providers are not trained.

"We have seen chiropractors and homeopathic doctors who decide to make [stem cell therapy](#) part of their business," Ikonomou said. "Some businesses claim that the products they are selling are safe and effective. Others acknowledge the investigational nature of what they are selling but charge patients to access products in pay-to-participate studies. These purported studies are generally poorly designed, unblinded, unrandomized, and uncontrolled."

Typically, such studies have not been reviewed and authorized by national regulators, such as the U.S. Food and Drug Administration (FDA).

Ikonomou and his colleagues have been monitoring letters the FDA is addressing to these clinics.

"The products that they offer don't fall within their practice of medicine," he said. "For instance, you can't use umbilical cord tissue to treat all kinds of conditions, yet certain clinics advertise it as if you can."

## **Clinics often sell 'pricey placebo effect'**

Quick financial gain is often the primary motivator behind this nefarious practice, he said.

"Sometimes the clinic operators receive letters from [regulatory agencies](#) and then stop and switch to something else," Ikonomou said. "There is a lot of movement in and out of this marketplace."

Some musculoskeletal conditions, including unproven treatments for pain, are often offered in academic centers as a kind of auxiliary treatment to other types of treatments, he said.

"The mentality is that it won't hurt, and it may help," he said. "The

motive is a bit murkier than the private clinics."

Ikonomou pointed out it isn't just people diagnosed with serious illnesses or those in pain who are seeking therapy; clinics also target individuals wanting to just feel better as part of the "total wellness" trend.

"It's very expensive treatment," he said. "Even if it's safe, there's no evidence of any efficacy. Most of the time, it's just a very pricey placebo effect."

## **Aggressive marketing tactics in Sunbelt states**

As an experiment, Ikonomou put his name on the mailing list of one clinic, saying he wanted to sign up for the newsletter.

"Within minutes," he said, "I started getting calls."

The practice mirrors that of predatory loans.

"Some people say it's a buyer-beware situation," he said. "I don't agree with that. We don't espouse that approach for tobacco products or predatory lending. There is regulatory action, legislation, and pushback. We should follow the same approach with these businesses."

Consumers in some states experience more aggressive marketing from these clinics than others. The worst offenders are primarily found in California, Florida, Texas, and Arizona, according to published studies, Ikonomou said.

"There is a heavy concentration of retirees in those states, but it's more complicated than that," he said. "More research is needed to find out why."

## Not an easy fix

There is no easy solution to this situation, Ikonomou noted. Even if a patient is harmed, the clinics are not bound to report it. Also, it's hard to prove causality, especially if enough time has passed, and some businesses require patients to sign non-disclosure agreements.

While the FDA and Federal Trade Commission (FTC) have issued numerous warnings to the offending clinics, the U.S. marketplace has become way too big, and it's hard to contain, he said.

"Even if they're threatened with lawsuits, the clinics get their own legal representation and fight back," he said. "This can take years."

This is why creating the consumer guide was so important.

"We're trying to make this a starting point to reach out to patients and their families so that they can make informed decisions," he said. "It's important to reach out to health practitioners, too, because they can also inform patients of these practices and warn them."

**More information:** Laertis Ikonomou et al, International Society for Cell & Gene Therapy Position Paper: Key considerations to support evidence-based cell and gene therapies and oppose marketing of unproven products, *Cytotherapy* (2023). [DOI: 10.1016/j.jcyt.2023.03.002](https://doi.org/10.1016/j.jcyt.2023.03.002)

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