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Experts: Unproven stem cell procedures need more oversight

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Federal officials need to do more to prevent for-profit stem cell clinics from exploiting and potentially injuring patients, according to an article published in a leading medical journal.

The *New England Journal of Medicine* commentary follows a May article by The Associated Press that identified 170 U.S. clinics that charge between $5,000 and $50,000 for stem cell procedures that purport to treat dozens of diseases and conditions, including Alzheimer's, arthritis, erectile dysfunction and hair loss.

The journal authors highlight the risks of unproven stem cell procedures, a burgeoning field that has flourished despite little evidence of its safety or effectiveness. They also call on the Food and Drug Administration to clarify rules governing the space and to work with state medical boards to penalize physicians pushing bogus therapies.

The FDA said in a statement Wednesday that it "understands the need for clear guidance and has issued three draft guidance documents to specifically address this area."

Such draft guidance documents serve as recommendations, not legal requirements. There is no deadline for when they must be finalized.

Currently, none of the procedures offered by clinics are approved by the FDA, which oversees new and experimental medical products. Yet doctors routinely describe their offerings as "healing" or "regenerative"

medicine, suggesting their potential to cure patients.

"Their language is intentionally imprecise and exploits the vulnerability of patients with debilitating diseases," notes the commentary by Professors Hermes Taylor-Weiner and Joshua Graff Zivin, of the University of California, San Diego.

The largest stem cell chain in the U.S., the Cell Surgical Network, has more than 100-affiliated physicians operating in 24 states. It advertises procedures for more than 30 diseases and conditions, including Lou Gehrig's disease, multiple sclerosis and congestive heart failure.

Yet fine print on the network's websites states that its physicians are conducting experimental research: "We do not claim that these treatments work for any listed nor unlisted condition, intended or implied."

Dr. Mark Berman, the group's co-founder, called Wednesday's commentary "misleading and of no significance."

"There are laws against fraud and if this weren't a safe and even effective procedure, we would have quit doing it long ago," he wrote in an emailed statement. "We are moving forward. The train has left the station."

While the FDA has regulations governing human cells—including the fat-derived stem cells used by most clinics—they are vague and rarely enforced by the agency. When questioned, most stem cell doctors claim they are not subject to FDA regulation because they are practicing in-office surgery, which falls under the oversight of state medical boards.

The two Journal professors recommend that the FDA clarify which kinds of procedures cannot be performed in the office, and collaborate

on investigating clinics with state medical boards, which have the ability to revoke doctors' licenses.

"The added risk of an audit by a medical board might even be enough to discourage many physicians from offering unapproved procedures in the first place," the commentary states.

The journal authors also suggest the Federal Trade Commission has a role to play in policing unsupported or misleading advertising about stem cells. The agency already does this in the case of dietary supplements, where companies must collect specific scientific evidence before advertising a claim for their products.

An FTC spokesmen said the agency has no comment on the authors' proposal.