

FDA issues warning to clinics that offer unproven stem cell therapies

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Federal regulators are preparing to crack down on scores of clinics across the United States that offer pricey stem cell therapies for conditions ranging from autism to multiple sclerosis to erectile dysfunction without any scientific evidence that they work.

As many as 200 stem cell clinics have cropped up in recent years, peddling injections, facelifts, and treatments for a number of devastating conditions. They have avoided heavy regulation, in part because they use cells extracted from a patient's own body and because they don't do much to those cells before reinjecting them.

But the Food and Drug Administration recently issued draft guidelines clarifying that the stem cells used in most clinics are drugs and require a rigorous approval process before they can be used in patients. A [public hearing](#) is set for April.

The FDA underscored the new approach in a warning letter it sent at the end of December to a network of stem cell clinics in California, New York, and Florida. Regulators advised the owner that he needed FDA licenses and approval to sell and use stem cells, which the agency classified in the letter as biological drugs. Such licenses would require evidence that stem cell treatments are both safe and effective — the sort of proof that takes drug companies many years of clinical trials to obtain, at a cost of millions of dollars.

Read full, original post: [FDA moves to crack down on unproven stem cell therapies](#)