FDA Regulation of Adipose Stem Cell Therapies: Separating Fat from Fiction

Mary Ann Chirba
Boston College Law School

Internet marketing of stem cell treatments epitomizes the public health risks and regulatory dilemmas of misinformation gone viral. Discovering that fat holds an abundance of multipotent stem cells has fueled therapeutic innovations and created serious public health risks. Adipose-derived stem cells (ASCs) are easy to harvest and use and, via internet, easy to promote as curing everything from balding to macular degeneration to an eager audience of patients with serious conditions and few treatment options. Patient testimonials make no mention of those who paid for false hope with dollars or disability. More clinics mean better odds of evading FDA notice. The ensuing trifecta of therapeutic promise, limited treatments and widely disseminated misinformation pressures the FDA to permit more treatments for more patients, more quickly.

To promote innovation while protecting the public health, the FDA recently issued its "Comprehensive Framework" for regulating regenerative medicine and also ramped up enforcement against high risk clinics (with most using adipose in some form). The Framework consists of four Guidances: two address § 361 v. § 351 classification; two fulfill Cures Act directives to improve evaluation of regenerative products. This article focuses on the first two.

Although the FDA routinely draws lines between permissible and impermissible uses under § 361 and § 351, it has struggled to figure out where and how to draw those lines for ASCs. In the process, it has faced criticism for lagging behind rapid advances in adipose science - primarily because, despite acknowledging adipose's structural and nonstructural functions, it limits § 361 v. § 351 evaluation to structural functions.

This article explores the ramification of the FDA's solely structural evaluation of adipose concerning:

a) 361 v. § 351 Guidances applied to ASCs;
b) definitional ambiguities and factual inaccuracies;
c) impact on public health when evaluating whether ASCs are safe and effective for an intended use; and
d) limits of regulating cell-based risks as a means of curtailing provider-based risks to the public health.

Proposed organization:

1. HCT/P framework, § 361 v. § 351 criteria.
2. Guidance, § 351's "same surgical procedure" (SSP) exemption: definitions, problems.
3. Guidance, § 361's "minimal manipulation" (MM), "homologous use" (HU): definitions, more problems.
4. Apply MM/HU and SSP Guidances to ASCs – inaccuracies, even more problems.
5. ASC's structural and nonstructural functions; FDA acknowledges, but…
6. Solely structural evaluation is biologically inaccurate.
7. Precludes meaningful evaluation of safety and efficacy for nonstructural uses (SVF?).
8. FDA correctly prevailed in U.S. Stem Cell Clinics; likely to and should win pending cases.
9. However, lawsuits' bad facts obscure problems of solely structural evaluation.
10. Is provider-risk the true object of rigid categorization? If so, discuss limits of over-regulating cell-based risks to curtail provider-based risks.