

Are Stem Cells Over?

by Rick Jaffe, Esq.

Notes

1. Jaffe R. *Galileo's Lawyer*. Thumbs UP Press; 2008. Available at <http://www.amazon.com/Galileos-Lawyer-Alternative-Complementary-Experimental/dp/0980118301>.
2. This exemption from full drug regulation for stem cells and tissue (in FDA parlance "HCT/P's") is found at 21 CFR 1271.15. See <https://www.law.cornell.edu/cfr/text/21/1271.15>).
3. US Food and Drug Administration. Untitled letter to Regenerative Sciences Inc. [online document]. July 25, 2008. <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/Enforcement/UntitledLetters/ucm091991.htm>.
4. United States v. Regenerative Sciences LLC. Decided Feb. 4, 2014. Available at [https://www.cadc.uscourts.gov/internet/opinions.nsf/947528CDDA0B9A5A85257C7500533DF4/\\$file/12-5254-1478137.pdf](https://www.cadc.uscourts.gov/internet/opinions.nsf/947528CDDA0B9A5A85257C7500533DF4/$file/12-5254-1478137.pdf).
5. US Food and Drug Administration. Warning letter to IntelliCell Bioscience Inc. [online document]. March 13, 2012. <http://www.fda.gov/iceci/enforcementactions/warningletters/2012/ucm297245.htm>.
6. US Food and Drug Administration. Warning letter to Irvine Stem Cell Treatment Center [online document]. Dec. 30, 2015. <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm479837.htm>.
7. US Food and Drug Administration. Same surgical procedure exception under 21 CFR 1271.15(b): questions and answers regarding the scope of the exception. Draft guidelines [online document]. <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/UCM419926.pdf>.
8. US Food and Drug Administration. Homologous use of human cells, tissues, and cellular and tissue-based products. Draft guidance for industry and FDA staff [online document]. <http://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/tissue/ucm469751.pdf>.
9. US Food and Drug Administration. Minimal manipulation of human cells, tissues, and cellular and tissue-based products: draft guidance [Web page]. <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/ucm427692.htm>.
10. US Food and Drug Administration. Human cells, tissues, and cellular and tissue-based products (HCT/Ps) from adipose tissue: regulatory considerations; draft guidance [Web page]. <http://www.fda.gov/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/tissue/ucm427795.htm>.