The Biologics Paradigm: Wharton's Jelly Mesenchymal Exosomes as a Section 351(a) Drug vs. the Section 361 HCT/P pathway

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Summary

Section 361 covers HCT/Ps that meet all four 21 CFR 1271.10(a) criteria, including minimal manipulation and homologous use. Products that fail any criterion are drugs and biologics under Section 351(a) and need an IND to study and a BLA to market. This paper argues Wharton's jelly MSC exosomes are more than minimally manipulated and belong on the 351(a) path.

Exosome and mesenchymal stem cell-derived extracellular vesicle products are not approved by the FDA for any indication. This paper describes published scientific literature. It does not describe an available treatment.

Questions this paper covers

• What is the difference between FDA 351(a) and 361 HCT/P regulation for stem cell and exosome products?

• What is a 361 HCT/P?

• What are the four criteria in 21 CFR 1271.10(a)?

• Are exosomes regulated as 361 HCT/Ps or as biologics?

• Which federal pathways allow access before approval?

Sources

1. 21 CFR 1271.3(f) (minimal manipulation), 1271.10(a), 1271.20

2. FDA guidance, Regulatory Considerations for HCT/Ps: Minimal Manipulation and Homologous Use

3. 42 U.S.C. 262 (Section 351) and 42 U.S.C. 264 (Section 361)

4. FDA Public Safety Notification on Exosome Products, Dec 6, 2019

5. 21 U.S.C. 356(g) (RMAT); 21 U.S.C. 360bbb-0a (Right to Try)

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