FDA’s new stem cell guidelines receive both praise and criticism

The [FDA’s] new guidelines…clarify existing regulation by outlining what uses of human tissue can be offered to patients without FDA approval.

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The major points in the new guidelines specify that: the function of these cells in the recipient’s body must be the same as in the donor; the treatment cells don’t affect the whole body of the recipient; and manufacturers can only manipulate the cells “minimally”; along with which chemicals manufacturers can use to treat cells and prevent disease transmission.

The FDA notes the revised guidelines are meant to help manufacturers navigate regulations…[b]ut many interpret them as a crackdown on clinics offering patients experimental procedures.

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[S]everal doctors, researchers and nurses who spoke at the hearings said that patients are the ones who suffer in an unregulated system.
…

In the other camp, clinicians and industry representatives pushed back on the FDA’s restrictive wording in the guidelines…Some told the FDA to scrap its draft completely whereas others commended the agency on its more restrictive wording with only minor edits.

The GLP aggregated and excerpted this blog/article to reflect the diversity of news, opinion and analysis. Read full, original post: Stem Cell Advocates and Critics Push Back on FDA Guidelines