



# Issues with Biobanking

Mahendra Rao- Q Therapeutics & NYSCF



**Unregulated**

Medical Tourism

Cosmeceuticals

Medical Practice

- ADSC
- Legal in a country but regulated in another
- Not considered a medical product

**Devices**

- Retina
- Synthetic Glucose sensor
- Cornea compsoite
- Skin
- etc

**Allogenic/auto logous**

Cultured

Selected

Engineered

Combination

**HSC & derivatives**

**Cord Blood & ancillary tissue**

**MSC & MSC like**

**NSC & derivatives**

**All other cells**

- Marrow
- Cartilage
- T cells
- NK cells
- Cord Blood HSC
- Endothelial cells

- NSC
- Oligos
- Astrocytes
- Neurons
- OEG
- Schwann cells
- Pancreatic Islet
- Cardiomyocytes
- Hepatocytes
- Skeletal muscle
- etc

**Composite/Tis sue/organoids**

- Skin full thickness
- Valves & Vessels
- Ureter, Bladder, Urethra
- Trachea, Oesophagus
- Cardiac sheets / RPE sheets
- Pancreatic islets, liver organoids
- etc



# Autologous processed therapy

Each lot is a single product and is processed by different groups with different protocols

Very hard to consider a clinical trial as in a standard model

In the absence of guidance cell products are already being stored

Recent advances suggest that gene editing may enhance the utility of the cells



# Banking and Storage of Cells

Companies now storing bone marrow from cadaveric donors

Expanded bone marrow with variability

Placental cell products

iPSC banks

The people storing cells are not the ones getting an IND



**Bank  
Public/Pvt**

Bank other cells  
Ship and distribute  
Collect and process other samples  
Support development of novel uses



**Non stem cells**  
RBC's  
Plateletes  
T  
B  
Monocytes  
NK cells  
**Stem & Progenitor cells**  
CD34+  
EBC (< 1x10<sup>6</sup>)  
MSC (<1x10<sup>8</sup>)  
others

Plasma  
EBV transformed lines  
Immortalized progenitors  
**iPSC**



**Cord derived**  
MSC-Like  
**Placenta derived**  
Membranes-  
Matrix-  
Cells- MSC-like, others

Commercial products  
available





# Cord, Cord Blood and Placenta

- 1: Amniotic Fluid cells
- 2: Amniotic membranes
- 3: Placental cells (maternal and Fetal)
- 4: Placental tissue
- 5: Wharton Jelly
- 6: Cord Tissue derived stem cells
- 7: Cord Blood
- 8: Growth factors harvested from placenta
- 9: Plasma

## **Commercial Products**

- 1: CelGene
- 2: Cytomedix- Nuo Therapeutics
- 3: Reliance- Placental membranes
- 4: CBR and other private cord blood banks
- 5: Cultured or expanded derivatives- Cytomatrix



# Issues

Each lot is a single product and is processed by different groups with different protocols

Each group has received IND approval for a a single indication and now cells are being used for multiple additional indication

What happens to units that are stored

What happens to autologous processed cells



# Suggestions and Questions

Biobanks which supply processed samples need to be regulated and draft guidances be developed

Can the FDA advise us as to how they expect Biobanks to be regulated?

Are there any recommendations or guidances that are being considered for public comment

Does the FDA consider state licenses for establishing a banking facility akin to blood banks to be sufficient?





# Possible Recommendations

Separate and update tissue and cell procurement and processing for therapeutic use are needed

Comparability by end product should be considered

Autologous processed cells should be treated somewhat differently than allogeneic processed cells and these differences should be clarified

The FDA should consider harmonizing state licenses for establishing a banking facility akin to blood banks

Please consider a role for accreditation organizations

# Summary



Thank You  
[mrao@qthera.org](mailto:mrao@qthera.org)

