

Homologous Use Working Group

Cell Therapy Liaison
Meeting

January 4, 2007



Homologous Use Working Group

- Working Group: Academic and Industry representatives
- Advisory Group: responsible representatives from other organizations with vested interest in cell therapy
 - AABB
 - AATB
 - ASBMT
 - ASFA
 - ASH
 - CBER
 - FACT

Homologous Use Working Group

- Appearance of inconsistent application of *homologous use* determinations based on stated intent.
- Develop a written guidance to clarify to the scientific/academic/industry community how *homologous use* will be interpreted and the type of data required to support the decision criteria.

Homologous Use Working Group

- Unknown process to recognize and apply to the regulatory process the continuing advancements in the scientific understanding of biological properties of cells.
- Develop an open, public process for periodic re-evaluation of the *homologous use* determination based on increasing scientific data.

Homologous Use Working Group

- Next Steps:
- Cell Therapy Liaison Meeting
- Collaboration for proposed solutions
- Publish White Paper