Some comments about the Stakeholders Conference from J. Martorell (Barcelona)

Dear Dr. Bouis,
First of all tank you very much for inviting me to the conference.
Please find enclosed some personal comments that came to my mind after the conference. Those are personal ideas but they may be of help for you.

- A important part of the know-how about cells modification procedures are still in the hands of hospitals and universities.
- Some important hospitals have developed "Cell Therapy Units" that in part had been developed from Bone Marrow Transplantation Units those units are entering, at least at research levels in to other fields:
    - Bone Marrow Progenitors expansion.
    - Immune cell therapies: Citotoxic cells against cancer cells or even CMV (Cytomegalovirus), dendritic cells therapies etc.
    - Olfactory Bulb Nervous Tissue transplantation in to spinal cord to correct paraplegic patients.

All this procedures will need elementary transformations: basically: purification culture and expansion of cells. And the majority of them are single use preparation for a single receptor. A this moment probably to ask for costly certification procedures to this experimental projects is not the best way to help the field to develop.

By this reason I hope is better to **maintain the word substantial modification** in the text (not to remove it as has been proposed in the meeting) and in any case try to define it, ex. : "**Simply culture, expansion, and purification are not considered substantial modifications"**. Or Subtantial modifications are: Genetic modifications or modifications that modifie the biological programme in the cell offspring.

If differentiation between "autologous" and "alogenic" differentiation is not accepted, I will suggest a differentiation between:
"Preparations devoted to be used in a single patient (Decentralized Procedure) from preparations to be used in more than one patient (Centralized Procedure)".
From a Philosophical point o view, for the patients it will be difficult to accept (or understand) that cells prepared: from and for himself had become a "Commercial Product" due to a EU legislation.

Obviously companies had to make profits, but specially if cadaveric tissues are involved it will be necessary to be extremely careful with the public opinion otherwise the willingness to donated organs can be precluded at that would be a "Greek Drama". The companies had to understand that public opinion concerning, dead relatives and money, is very different in USA and in the European Union.
It will be necessary to clarify from the first moment that **"privet companies sell the services to transform the tissue not the cadaveric tissue it self "** otherwise they can create serious public opinion problems in the willingness to donate organs.

Finally I strongly support the point that "The **implantation** of tissues should only be possible ... in **centres authorized by the Member States.**.." This really protects the patient, not the costly and sometimes bureaucratic centralized accreditation procedures.

I hope to have been of help to you.

Best regards
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