



European Genetic Alliances' Network

*"working together for a voice in research & health policies
and benefiting from genetics, genomics & biotechnology"*

Press Release

News release

Immediate Release: 1st February 2007

Patients thank members of the ENVI committee for supporting their views.

The European Genetic Alliances Network (EGAN) is pleased to hear the results of the ENVI committee's vote on Advanced Medicinal Therapy Products. **We would like to thank all members of the ENVI committee who voted in accordance with patient's wishes.** All conservative amendments on ethics, which had the potential to severely limit the scope of this regulation, were rejected; the patient groups we represent are thankful for this.

Alastair Kent, President, EGAN commented, *"We are grateful that the majority of ENVI members have taken note of patient views. A centralised regulatory framework for the development of advanced therapies is the best way to deliver high-quality, safe, cutting-edge products to patients, and we're pleased to take a further step in this direction. This process is far from over and we're looking forward to pursuing the remaining points of difference at the plenary stage"*.

This debate continues: the proposed regulation will now be voted on by all MEPs in March in a plenary session, where some of the rejected amendments are likely to be resubmitted. EGAN looks forward to the continued support of ENVI members at this stage. *"Amendments passed by the JURI committee, removing therapies derived from stem cells, germ cells, and fetal cells from the scope of the regulation concern us greatly. We hope for the support of ENVI members in reversing these decisions at the plenary stage"*. Said Alastair Kent.

Patients and their families want to see a fair, transparent, appropriate and proportionate regulatory system. This will ensure the results of cutting edge biological research are translated quickly and equitably into safe, effective products that will improve patient's lives. The Regulation on Advanced Therapy Medicinal Products has the potential to do this, and create an EU-wide regulatory framework, overseen by experts, that will facilitate and ensure the safety of new developments in these fields.

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Notes to Editors

EGAN is an alliance of national genetic alliances and European disease specific patient groups with a special interest in genetics, genomics and biotechnology. EGAN is working for a voice in research and health policy and seeks a world in which genetic diseases are understood, effectively treated, prevented and the people affected supported.

www.egaweb.org

Amendments voted on by ENVI:

[Amendments 1-52](#)

[Amendments 53-137](#)

Stem Cells

Stem cell research offers the promise of effective therapy for a range of currently untreatable or incurable conditions. Much research will be needed before it will be possible to know if this promise can be fulfilled, and as yet we believe that it is not possible to rule out the use of stem cells for any particular source without running the risk of prematurely fore-closing options that might otherwise benefit patients.

EGAN supports high quality well regulated stem cell research using stem cells derived from all sources – embryonic, foetal, cord blood or adult to be carried out within a framework that is transparent and which promotes public understanding of the importance and potential of this work.

Gene, Cell and Tissue Therapy

Innovative therapies involving the manipulations of genes, cells and tissues are at an early stage of development. In some cases they are showing considerable benefits for defined disorders and EGAN supports the investment of resources in further research and development, and the creation of a regulatory regime that is likely to secure the speedy development of safe effective innovative therapies and their becoming available to patients in a timely and affordable manner. Regulatory mechanisms for gene, cell and tissue therapy should be proportionate to the risks and benefits associated with such interventions and the unmet health needs they are designed to address. Such frameworks should be endorsed by patients and families as sufficient and necessary, with the cost of prevention or delay appropriately factored in.