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Stem Cells, Gene Therapies, and Tissue Engineering: How do we Put Advanced Therapies into Practice in Europe?

16 March 2015

Multiple Product Candidates in Clinical Development

Product[1]	Cell Type	Indication	Preclinical	Phase I	Phase II	Phase III	Market
Cx601 (local)	Allogeneic Adipose-Derived Stem Cells	Complex Perianal Fistulas in Crohn's Disease	**Orphan Drug (EU)**				
Cx611 (intravenous)	Allogeneic Adipose-Derived Stem Cells	Rheumatoid Arthritis					
		Severe Sepsis					
Cx621 (intralymphatic)	Allogeneic Adipose-Derived Stem Cells	Autoimmune Disorders					
ChondroCelect	Characterized Autologous Chondrocytes	Knee Cartilage Lesions	**Partnered[2]**				

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[1] Covered by 24 patent families
[2] Distributed through Swedish Orphan Biovitrum ('Sobi') and the Finnish Red Cross Blood Service

Barriers for growth of ATMP industry in EU

- **Fragmented market**
  - Fragmented capital markets: National programs and several stock markets
  - Reduction in number of specialized biotech investors through the whole cycle: VCs, growth capital and investors in public stocks
  - Access to market and reimbursement to be negotiated market by market with different appraisals
- **Local interpretation of European ATMP legislation**
  - Hospital Exemption allows for two standards (Germany and Spain as examples)
  - Tissue procurement (Belgium as an example)
  - Legal uncertainty with potential reopening of ATMP legislation
- Need for further **harmonization of regulation** from FDA/EMA/Japanese authorities

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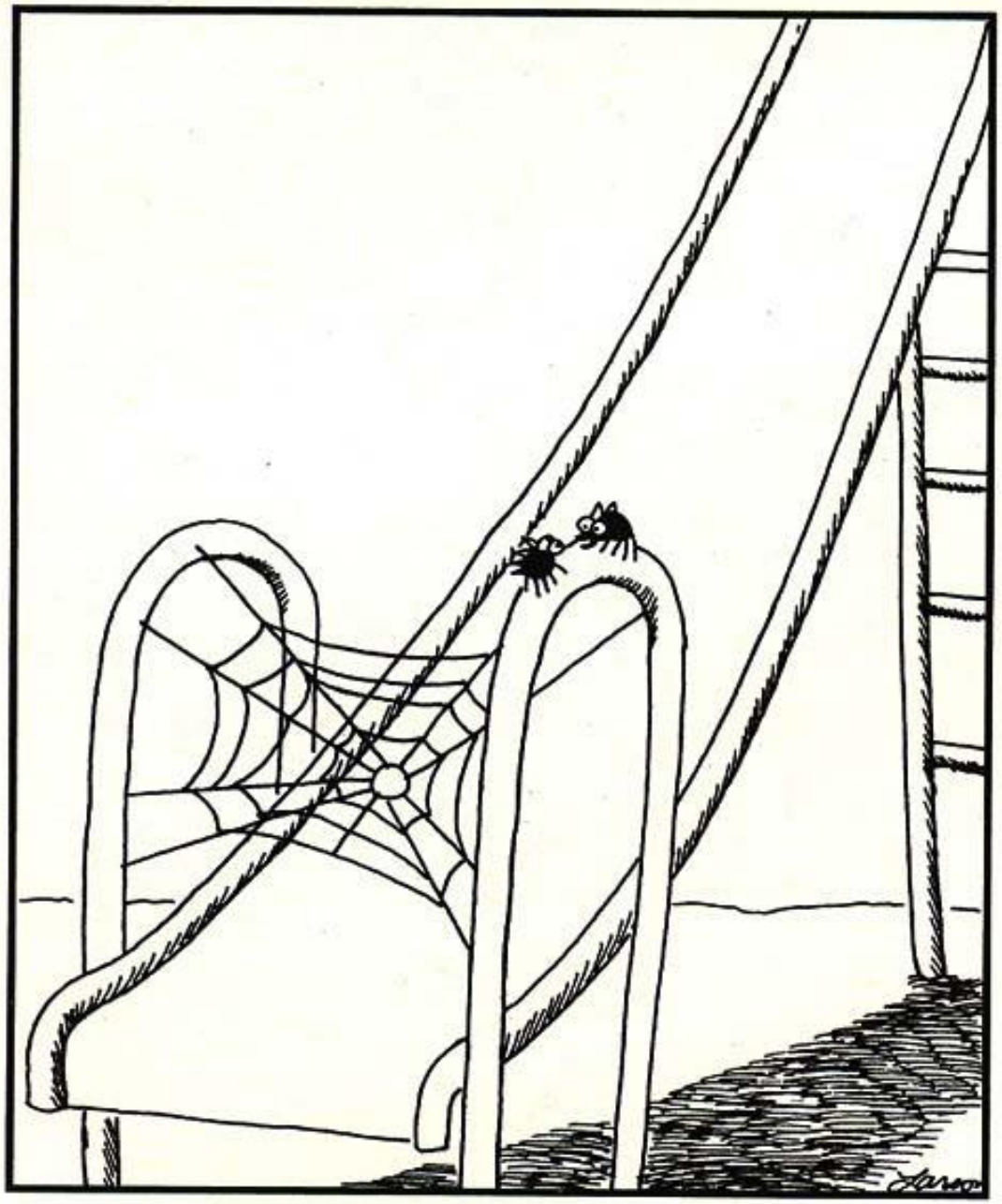
[1] Investigational New Drug
[2] Adipose Derived Mesenchymal Stem Cells for Induction of Remission in Perianal Fistulizing Crohn's Disease

Positive Measures being implemented

- Centralized Marketing Approval
- Centralized approval of clinical trials
- European Patent Protection
- Conditional Marketing Authorization
- Adaptive development



"If we pull this off, we'll eat like kings."

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