

Business models for tissue and eye banks

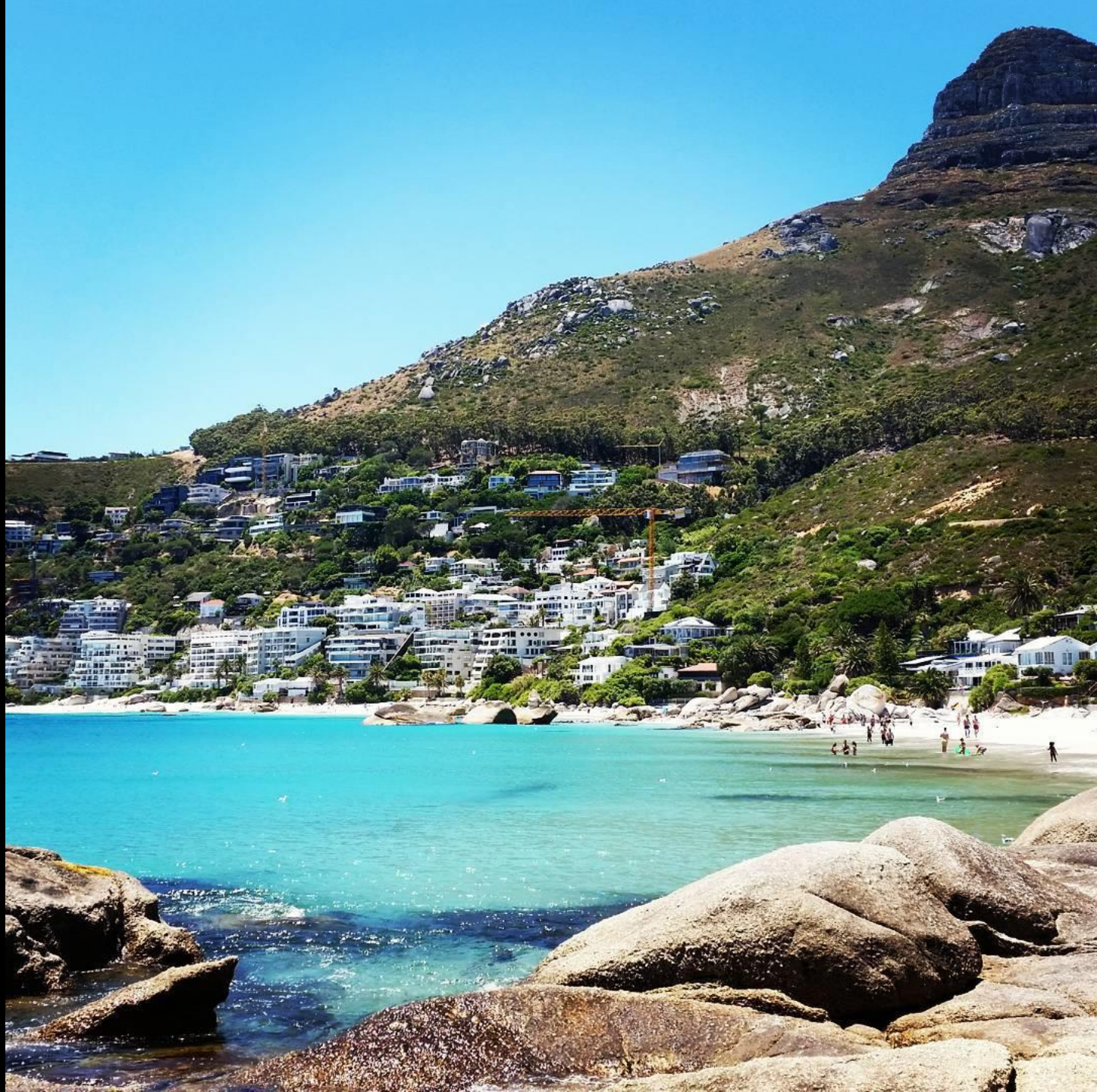
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South Africa – a country of contrasts

- Rich in mineral resources and high biodiversity
- The first heart transplant (1967)
- Legacy of oppression and discrimination
- High Gini co-efficient
 - World Bank report on SA March 2018
 - 55.5% of South Africans live below the national poverty line
 - 27.7% unemployment in Q3 of 2017; 38.6% youth unemployment
 - 1% of South Africans own 70.9% of the country's wealth
 - Groups most affected by poverty: black South Africans, unemployed, less educated, female-headed households, large families, children

Universal Health Coverage

- WHO definition
 - “all people and communities can use the promotive, preventive, curative, rehabilitative and palliative health services they need, of sufficient quality to be effective, while also ensuring that the use of these services does not expose the user to financial hardship” http://www.who.int/health_financing/universal_coverage_definition/en/
- Twitter: Universal Health Coverage means ensuring all people receive the health services they need without being pushed into poverty by paying for them

Universal right to healthcare

- Distributive justice
 - a just allocation/distribution of goods among members of society
- In practice:
 - access to and quality of healthcare are directly proportional to socioeconomic status
 - quality of healthcare is adversely affected in a resource-poor setting

Human tissue legislation

- Complex
 - ever-changing landscape in which advances in science and medicine need to be accommodated
 - high degree of technical expertise is required to ensure that the legislation is accurate, appropriate and unambiguous
- Generally accepted that the law has struggled to keep pace with advances in science and technology (Parker, 1986: 1028)

Legislation - objectives

- Protect the individual from harmful and unethical practices
- Respect the individual's right to determine how to use her/his own organs/tissues/cells
- Make provision for all South Africans
- Allow all South Africans to benefit from the advances in medical science
- Should not be unduly restrictive so as to avoid stifling basic and clinical research and biotechnological innovation

Legislation

Level	Legally-binding	Human tissues
Constitution	Yes	
Policy	No	Limited
Act	Yes	Yes
Regulations	Yes	Incomplete
Guidelines Standards	No	None officially

Acts

- National Health Act No. 61 of 2003
- ~~Human Tissue Act No. 65 of 1983~~
- Medicines and Related Substances Control Act No. 101 of 1965 (Medicines Act)
- Children's Act No. 38 of 2005
- Inquest Act No. 58 of 1959
- Consumer Protection Act No. 68 of 2008

Areas covered by Chapter 8 of the NHA

- Blood and blood products
- Assisted reproductive technology
- Cell-based therapy
- Transplantation
- DNA and genetic services
- Tissue banks
- Examination, allocation and disposal of human bodies and tissues

Regulations published in Government Gazette no. 35099 on 02 March 2012

Regulation no.	Title	Pages
No. R. 175	Regulations relating to artificial fertilization of persons	GG 35099 pages 3-21
No. R. 176	Regulations regarding rendering of clinical forensic medicine services	GG 35099 pages 22-30
No. R. 177	Regulations relating to the use of human biological material	GG 35099 pages 31-38
No. R. 179	Regulations relating to blood and blood products	GG 35099 pages 62-74
No. R. 180	Regulations regarding the general control of human bodies, tissue, blood, blood products and gametes	GG 35099 pages 75-96
No. R. 181	Regulations relating to the import and export of human tissue, blood, blood products, cultured cells, stem cells, embryos, foetal tissue, zygotes and gametes.	GG 35099 pages 97-124
No. R. 182	Regulations relating to tissue banks	GG 35099 pages 125-141
No. R. 183	Regulations relating to stem cell banks	GG 35099 pages 142-158

Regulations

- Lack of regulations
 - transplantation
 - cell and gene therapy
 - biobanks
- Redundancy/overlap
- Definitions
 - not harmonized
 - between regulations
 - relative to NHA

Human tissue definition

- National Health Act (no. 61 of 2003)
 - human tissue, and includes flesh, bone, a gland, an organ, skin, bone marrow or body fluid, but excludes blood or a gamete
- Regulations relating to tissue banks (No. R. 182 of 2010)
 - a functional group of cells. The term is used collectively in Regulations to indicate both cells and tissue

Human tissue bank definition

Regulations relating to tissue banks (No. R. 182 of 2010)

- ***"tissue bank"*** means an organisation, institution or person that provides or engages in one or more services involving cells and/or tissue from living or deceased individuals for transplantation purposes and is registered in terms of regulation 3 of these regulations

Payment: NHA section 60

Payment in connection with the importation, acquisition or supply of tissue, blood, blood products or gametes

- (1) No person, except—
 - (a) a hospital or an institution contemplated in [section 58 \(1\) \(a\)](#), a person or an institution contemplated in [section 63](#) and an authorised institution or, in the case of tissue or gametes imported or exported in the manner provided for in the regulations, the importer or exporter concerned, may receive payment in respect of the acquisition, supply, importation or export of any tissue or gamete for or to another person for any of the purposes contemplated in [section 56](#) or [64](#);
 - (b) a person or an institution contemplated in [section 63](#) or an authorised institution, may receive any payment in respect of the importation, export or acquisition for the supply to another person of blood or a blood product.
- (2) **The amount of payment contemplated in [subsection \(1\)](#) may not exceed an amount which is reasonably required to cover the costs involved in the importation, export, acquisition or supply of the tissue, gamete, blood or blood product in question.**
- (3) This section does not prevent a health care provider registered with a statutory health professional council from receiving remuneration for any professional service rendered by him or her.

Guidelines and Standards

- No official guidelines
 - i.e. emanating from or recognized/endorsed by the DoH
- Several professional bodies have established their own guidelines

Professional bodies: human tissues

Area	Professional body	Guidelines
Transplantation	Southern African Transplantation Society (SATS)	Yes http://www.sats.org.za/Guidelines.asp
Assisted reproductive technology	Southern African Society of Reproductive Medicine and Gynaecological Endoscopy (SASREG)	Yes http://www.fertilitysa.org.za/TreatmentGuidelines/ReproductiveMedicine.asp
Blood and blood products	National Blood Committee (not in operation since 2008)	Yes SANBS and WPBTS websites & other
Cell-based therapy	South African Stem Cell Transplantation Society (SASCTS)	Yes; none on website http://www.stemcell.org.za/index.htm
Genetic Services	Southern African Society of Human Genetics (SAHGS)	Yes http://www.sashg.org/documents.htm
Tissue banks	South African Tissue Bank Association (SATiBA)	Yes http://www.satiba.org.za/index.php
Forensic pathology and medicine	National Forensic Pathology Services Committee	Yes No website
	National Clinical Forensic Committee	In progress

South African Tissue Bank Association

- SATiBA
 - not-for-profit; established in 2015
 - members: tissue banks and others
 - industry representative (lobbying function)
 - projects
 - regulatory matters
 - capacity building
- Stem cells and gametes
 - not within the definition of human tissues in the NHA
 - SATiBA philosophy to be inclusive rather than exclusive
 - industry in SA is relatively small and resources are limited
 - opportunity to increase awareness and surveillance among members
 - self-regulation and limited oversight

Human tissue donation in SA

- Human tissues and cells donated in SA
 - heart valves, stem cells, cornea & sclera, amnion, blood & blood related products, skin, gametes, bone & tendon, bone marrow, femoral heads, cord blood & tissue
- Sources of human tissue donors
 - State and private hospitals
 - Forensic Pathology services
 - Funeral homes

Defining the need

- Difficult to determine the size of the market
 - no registry for tissue use in South Africa and the continent
 - no formal waiting lists for any tissues
- Decreasing supply of tissues in SA
- Demand >>> supply
 - Corneas
 - 3 000 patients in need of corneal transplant in South Africa
 - 2016: 150 local corneas transplanted nationwide
 - 2017: private ophthalmologists imported 1800 corneas from the USA and Europe
 - Cost results in exclusion of people unable to afford payment

Impediments to growth

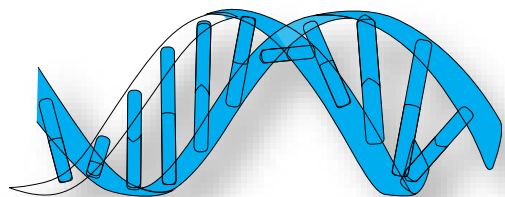
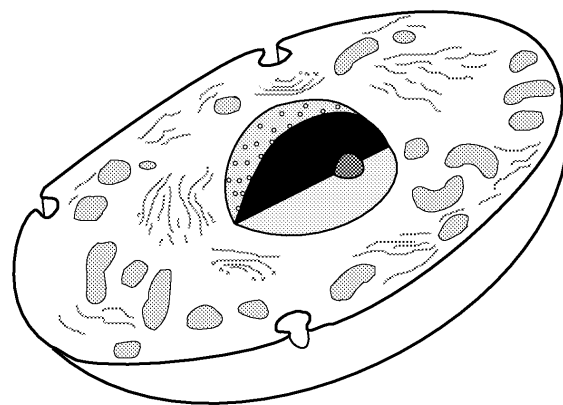
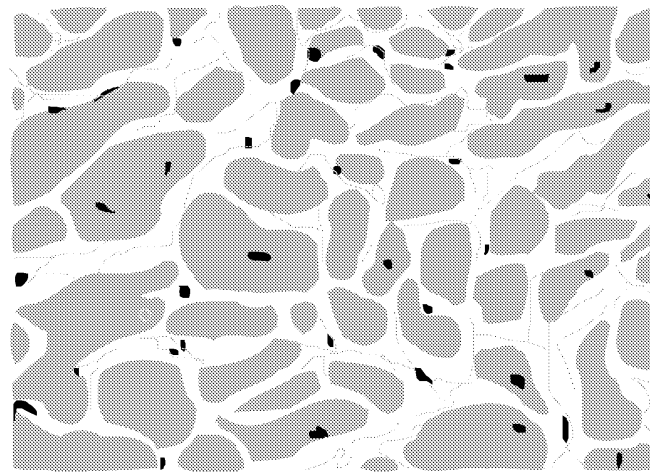
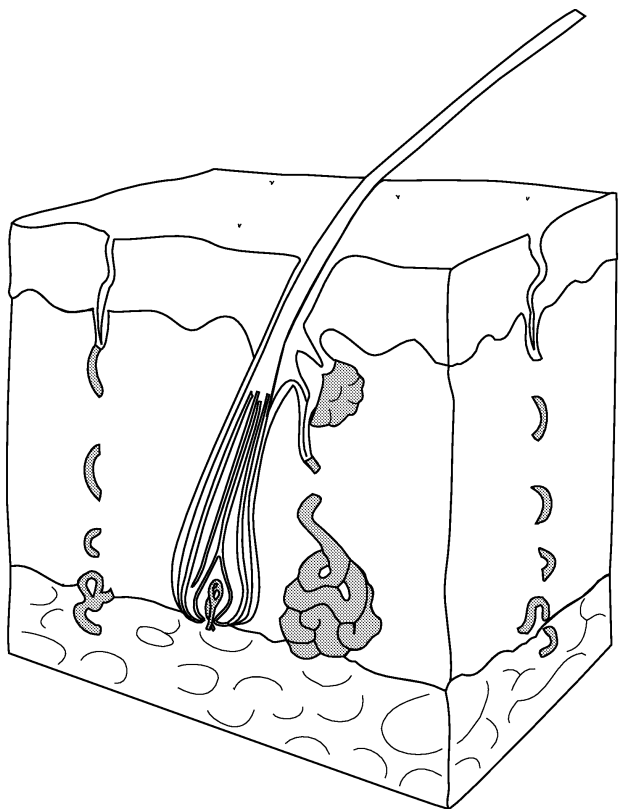
- Lack of sufficient/appropriate legislation and government support
 - NHA and regulations
 - Protection of Personal Information Act (pending)
 - Change of responsibility for Government mortuaries in 2006
 - SA Police Service to Forensic Pathology Services (DoH)
- Lack of a formal death-referral system which could support and facilitate the process
- Limited funding opportunities
- Lack of new entrants into the industry, no changes in leadership, no new expertise
 - Industry has become stagnant over the last 10 years

Impediments to growth

- Insufficient education in all sectors of society
 - medical fraternity
 - fragility of public opinion
- Cultural sensitivities around human tissue related to traditions and belief systems
- Issues of literacy and language
- HIV & AIDS
 - stigmatization
 - access to patient medical records

Business model

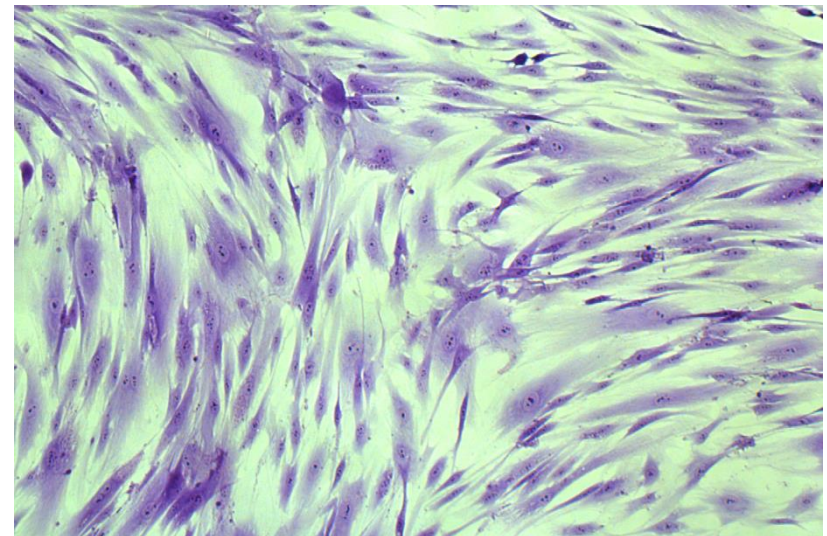
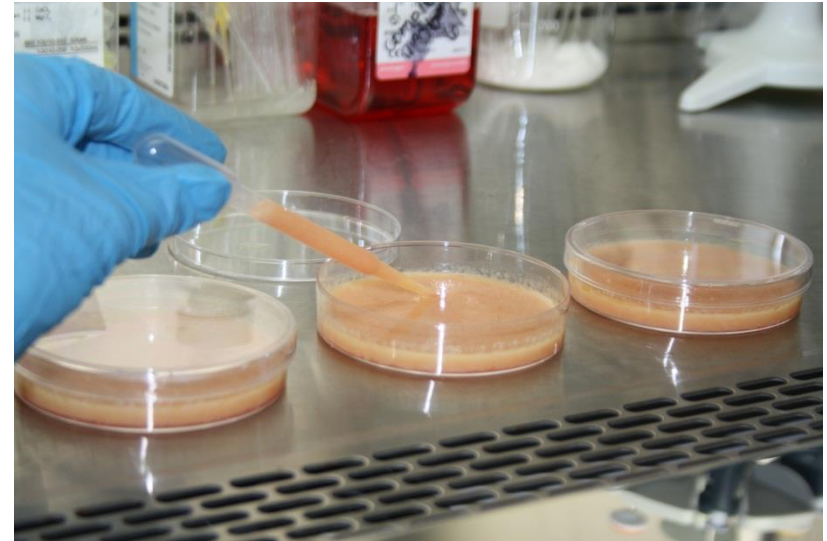
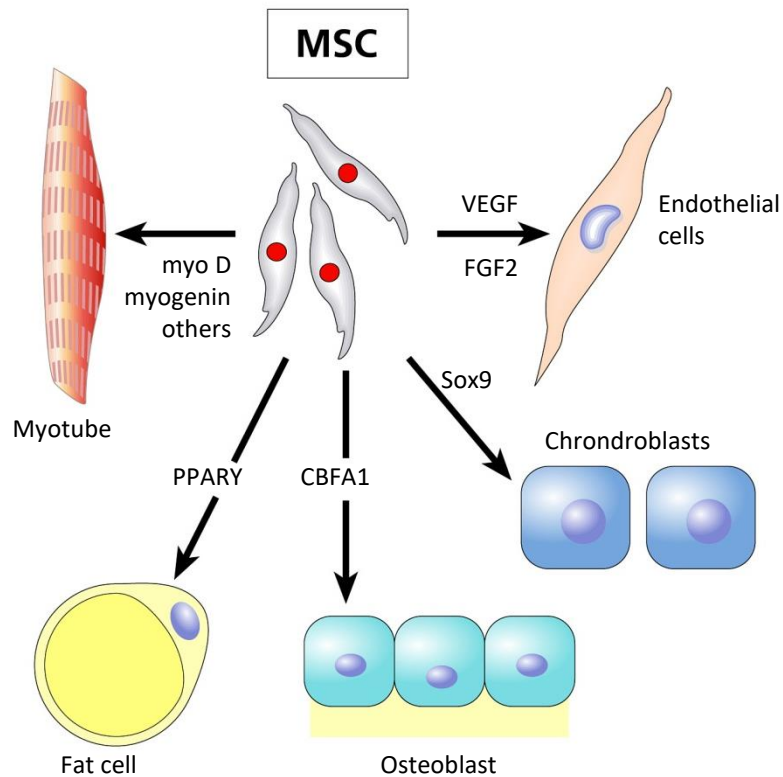
- Cost recovery
 - Not for profit
 - Surplus: capacity development, innovation
- Sustainability
 - Increase donor numbers
 - Enabling regulatory framework
- Innovation
 - Generate own IP
 - In-license
 - Reverse integration



Innovation

- Cell-based therapy
 - Hematopoietic stem cell transplantation
 - Mesenchymal stromal cells
- Tissue and organ engineering
 - Hard tissues (cartilage/bone)
 - Soft tissues (skin/veins/arteries)
 - Organs
- Gene therapy
 - Ex vivo
 - In vivo

Mesenchymal stem cells



Induced pluripotent stem cells

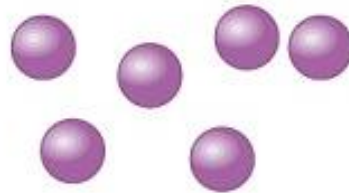
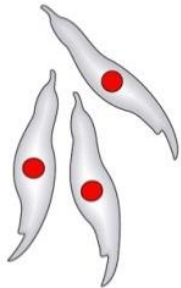
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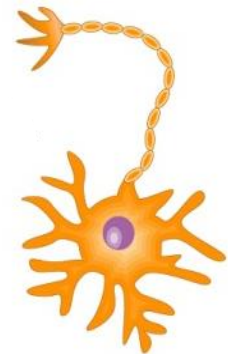
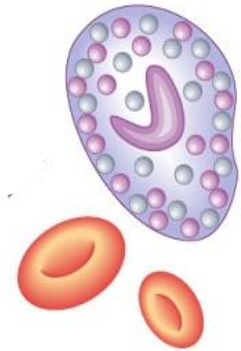
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c-Myc

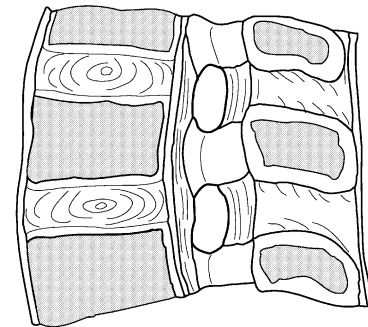
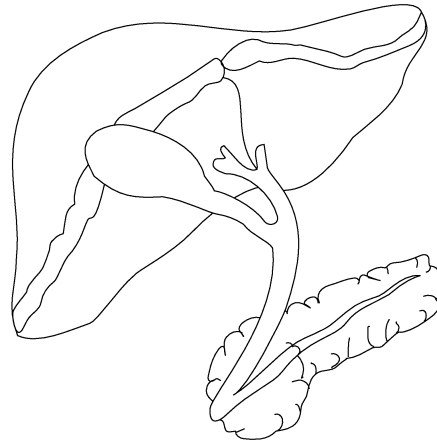
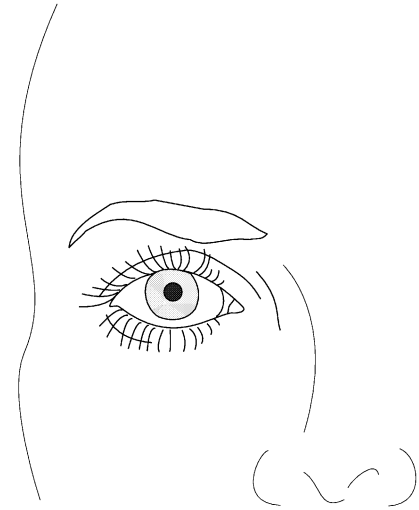
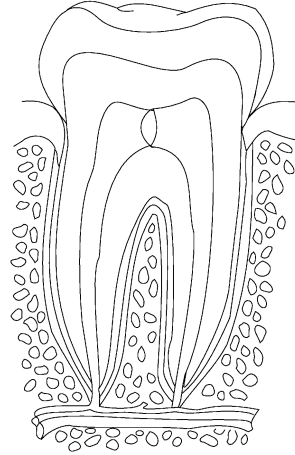
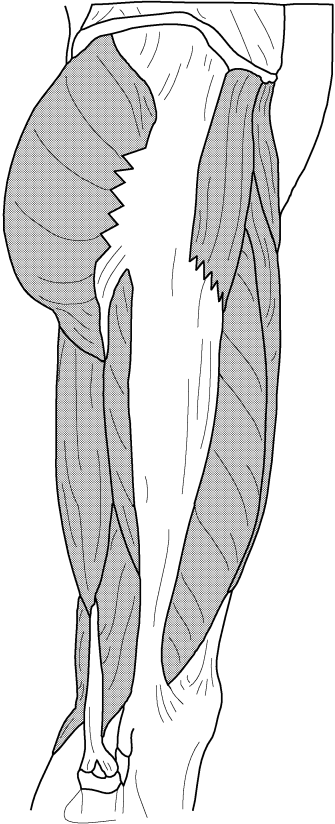


Pluripotent
stem cells

Differentiation
factors



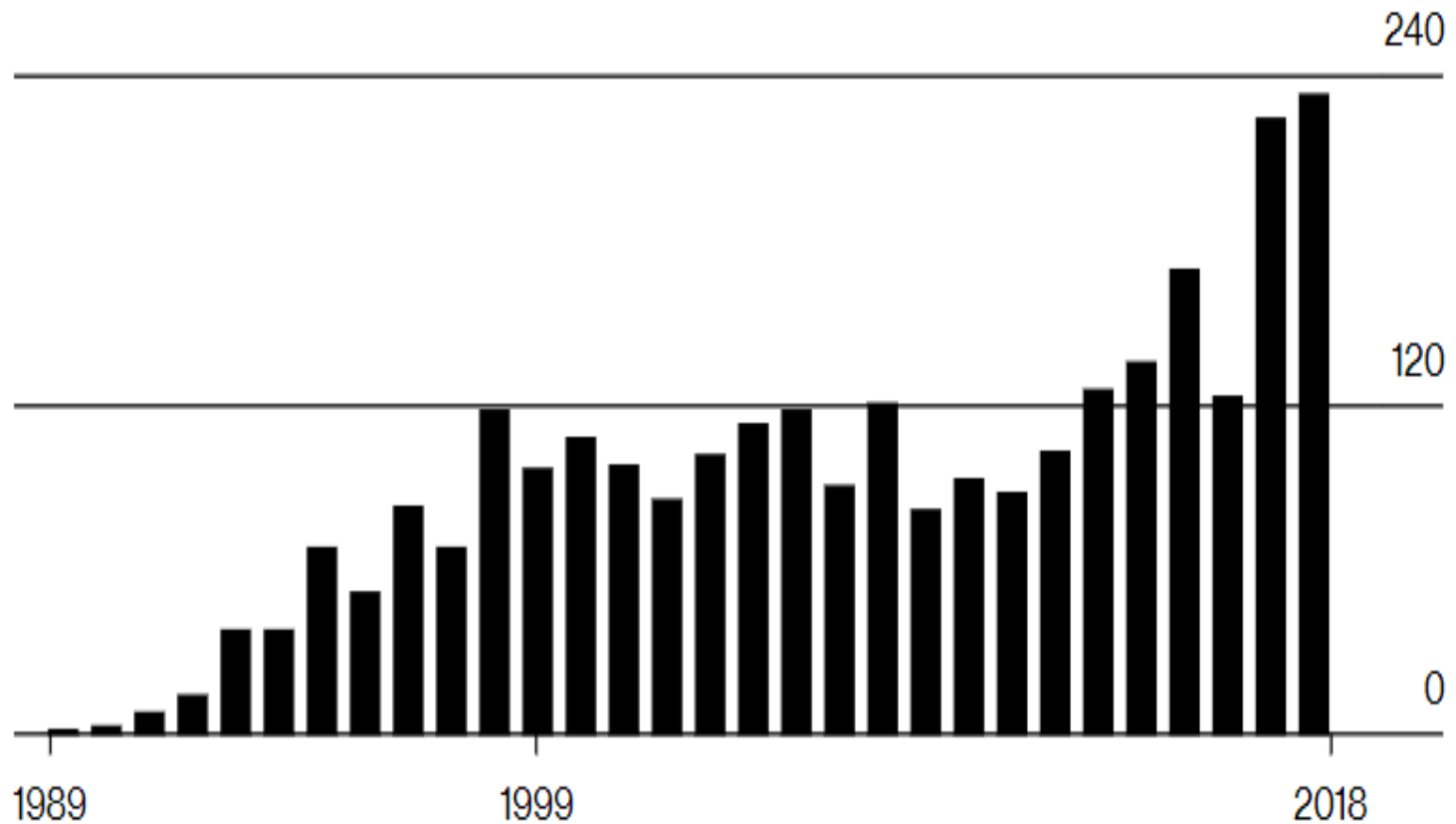
Tissue engineering opportunities



Gene therapy

- Definition (ASCGT)
 - modification of gene expression in an individual
- Objectives
 - replace a missing gene
 - correct an abnormal gene
 - add a therapeutic gene
- Methods
 - administration of a specific DNA (or RNA)
 - genome editing
- Somatic vs. germline

Number of gene therapy clinical trials approved worldwide



Data: The Journal of Gene Medicine

Health economics

- Healthcare resource allocation decisions
 - Maximize healthcare delivery within the limits of available resources
 - Must be clinically beneficial
 - Cost effective
 - Relative to existing practice (notion of dominance)
 - Cost savings
 - Money saved as a result of implementation of a given policy

Sustainable healthcare

- Universal access
 - No single life is better than another
 - Need to ensure that UHC is enhanced and not undermined by new scientific frontiers
- Need to embrace local factors
- Health economics
 - Cost-benefit and cost savings approaches
 - Cost reductions as economies of scale come to bear
- If it makes sense from both
 - a clinical and
 - an economic perspective,

then everyone stands to benefit