



LEGISLATIVE FRAMEWORKS AND ETHICS OF DONATION

Jeff Szer, Royal Melbourne Hospital, Australia

Donation of HPC



Autologous

HPC-A

HPC-M

Allogeneic

Family member

Volunteer Unrelated

HPC-A

HPC-M

HPC-C

Ethical Issues of Donation

- ▣ Nature of consent
 - Children as donors
- ▣ Coercion
 - Especially for family member donors
 - Risk
- ▣ Independent advocate
 - Especially for family member donors



Issues of donor safety



- WMDA Standards (2008)
 - ▣ Individual choice
 - ▣ Unpaid
 - ▣ Fully informed about risks of donation
 - Potential for multiple requests
 - Haemopoietic growth factor
 - ▣ Signed consent

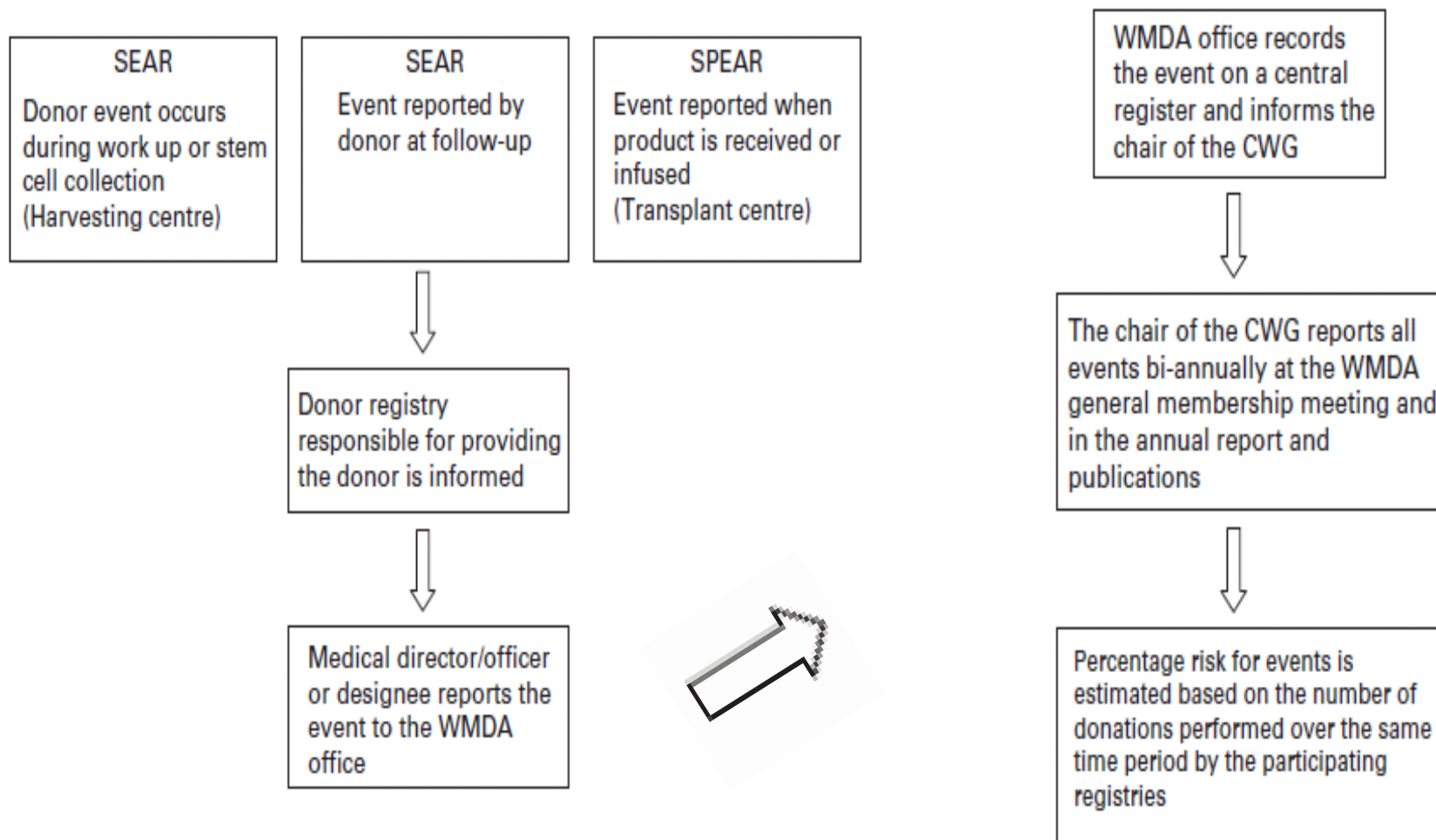
Issues of donor safety



- WMDA Standards (2008)
 - ▣ Independent medical assessment of suitability
 - (3rd party haematologist)
 - ▣ Issue of donors as research subjects
 - ▣ Donor follow-up
 - ▣ For VUD, accreditation and reaccreditation with WMDA

WMDA WHITE PAPER: Donor safety: the role of the WMDA in ensuring the safety of volunteer unrelated donors: clinical and ethical considerations. Shaw B et al BMT 2010;45:832–838

Adverse events

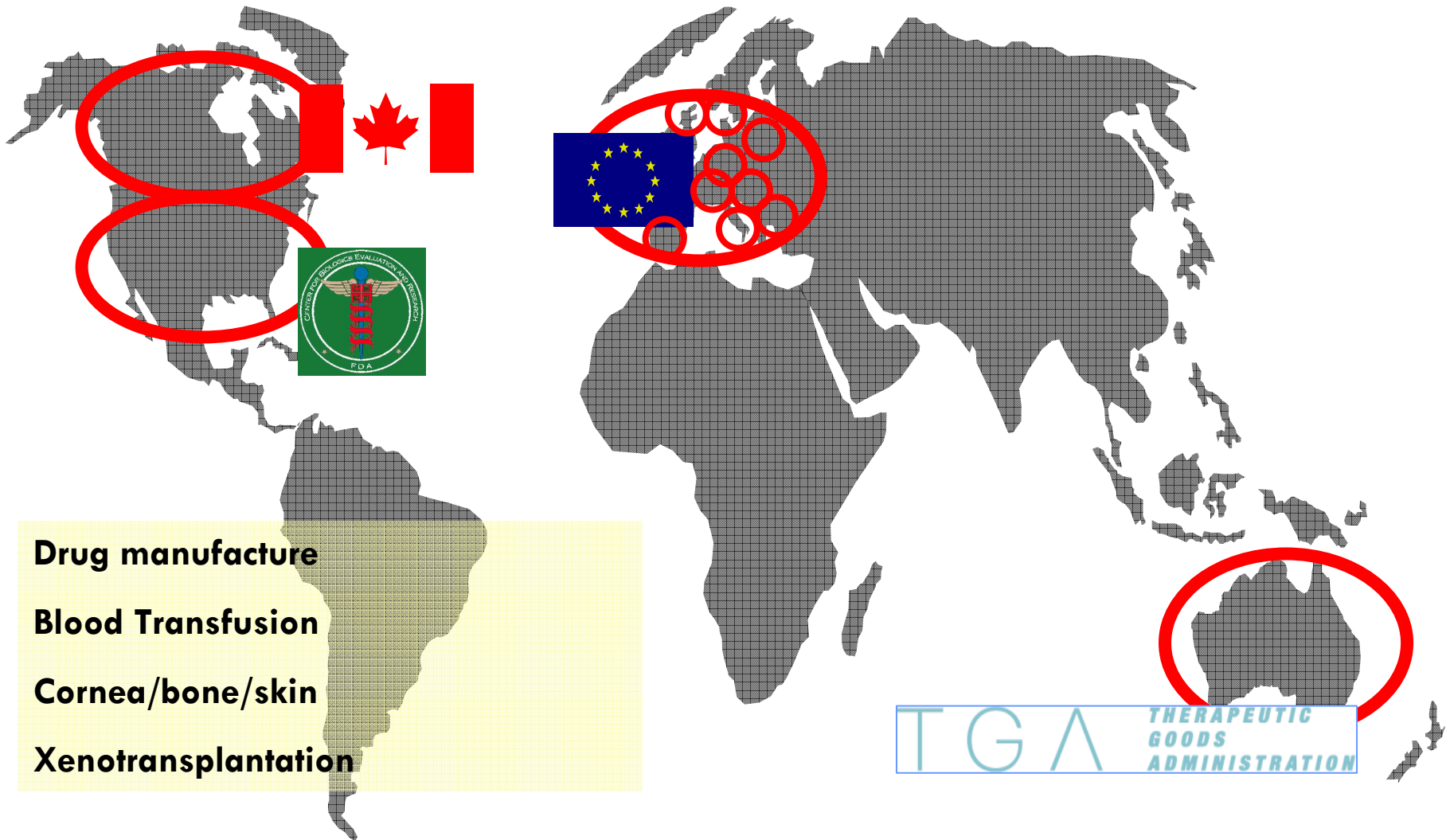


Adverse events



- Family member donors
 - ▣ Same duty of care
 - ▣ Possibly greater due to greater potential for subtle coercion
 - ▣ Traditionally managed in transplant centres more-or-less formally
 - ▣ Accreditation

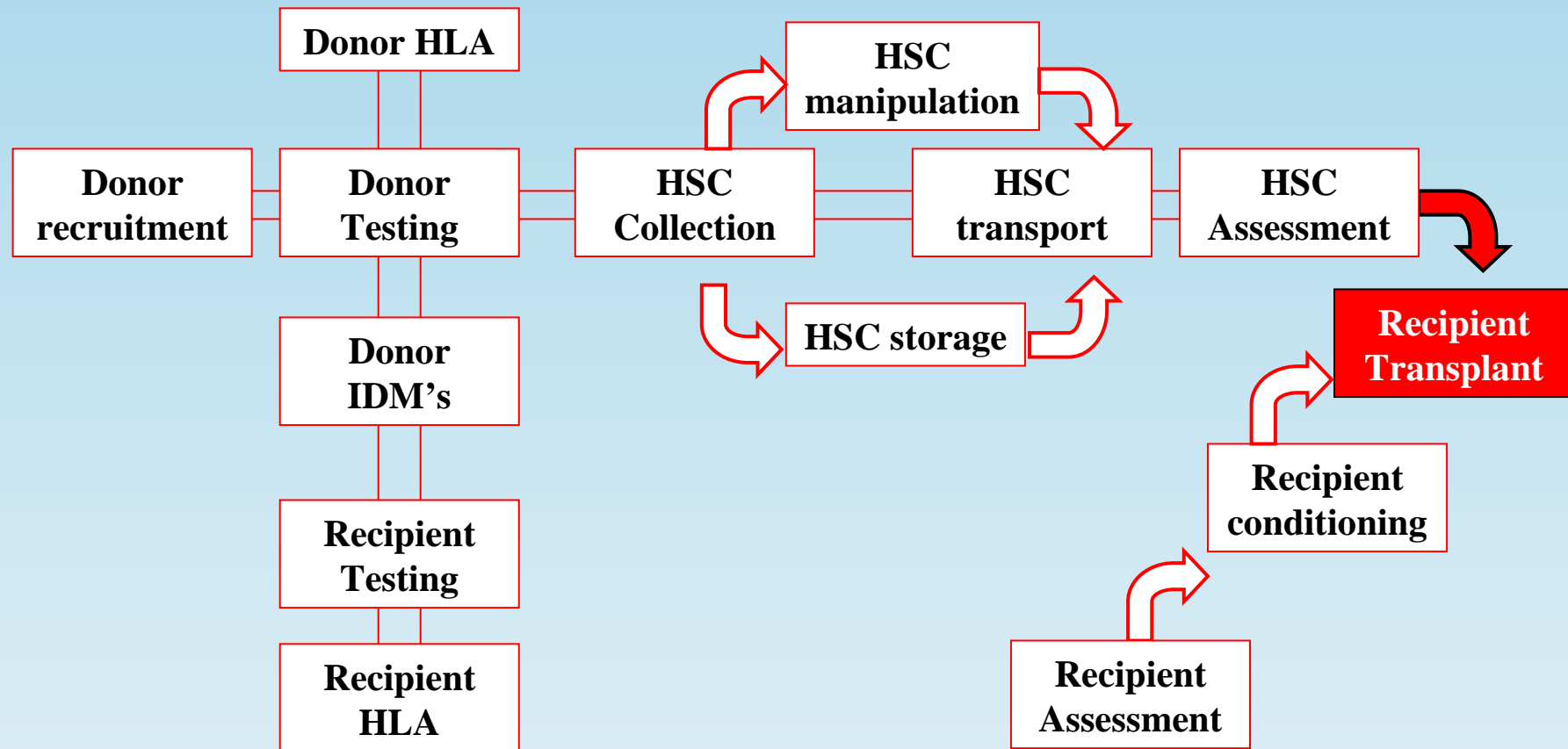
Barriers



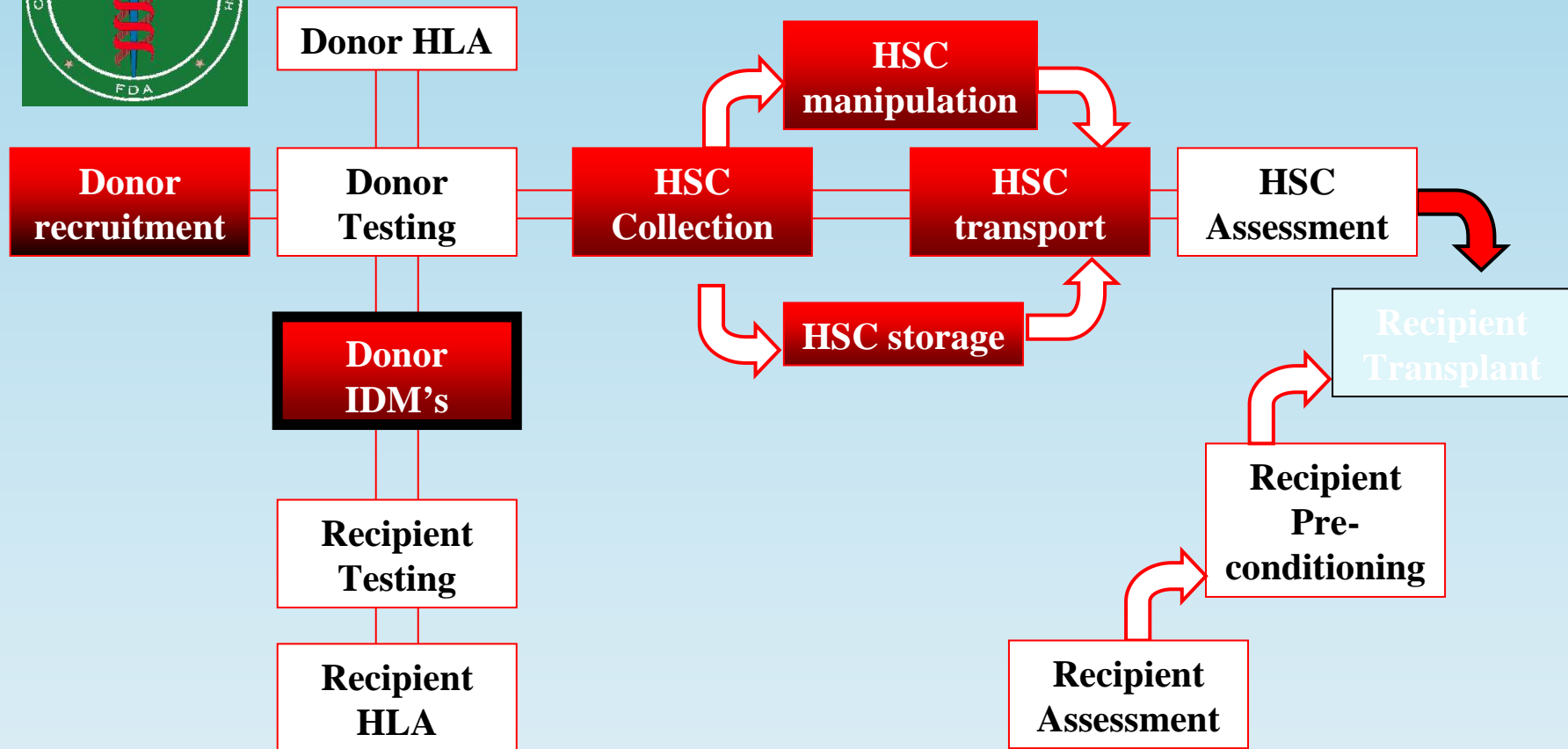
Drug manufacture
Blood Transfusion
Cornea/bone/skin
Xenotransplantation

TGA THERAPEUTIC
GOODS
ADMINISTRATION

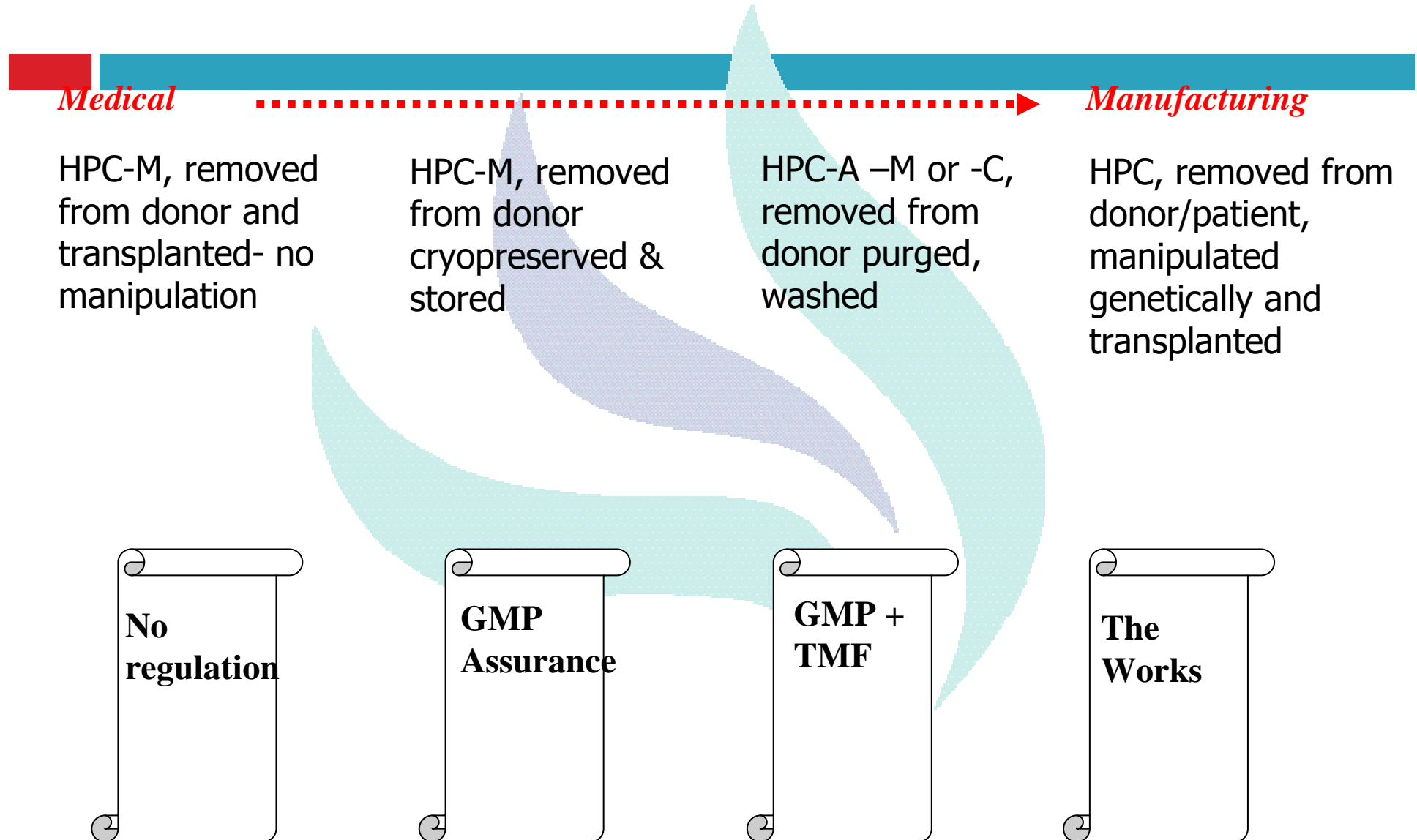
What is subject to regulation?



What is subject to regulation?



From Medical to Manufacturing Practice (TGA)



ROLES & RESPONSIBILITIES

Donors

Recipients

Registry

- Donor/cord unit database & search algorithm
- Coordination of process at national & international level

Donor Center

- Recruitment volunteer adult living donors
 - Education & counseling of donors
 - Health screening of volunteers
- Follow-up on donor health after donation

Collection Center

- Medical screening of selected donors
 - Harvest of HPC

Cord Blood Bank

- Collection, processing & storage of cord blood
 - Consenting of maternal donors
 - Health screening of mother and unit

Cell Processing Laboratory

- Protocol specific processing of HSC

Transplant Center

- Care & treatment of patient
 - Selection of donor
 - Transplantation

Registry Databases

- Outcomes of Transplantation
- Factors in safety and efficacy

ROLES & RESPONSIBILITIES

Donors

Recipients

Registry

- Donor/cord unit database & search algorithm
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Donor Center



• volunteer adult donor
• selection & counseling of donor
• screening of volunteer donor health after



Cell Processing Laboratory

- Protocol specific processing



HSC

Selection Center



• screening of selected donor
• Harvest of HPC



Transplant

• & treatment of recipient
• selection of donor
• Transplant



Blood Bank

• processing & storage of maternal donor blood
• processing of mother's milk



Registry Database

- Outcomes of Transplant
- Factors in safety and efficacy



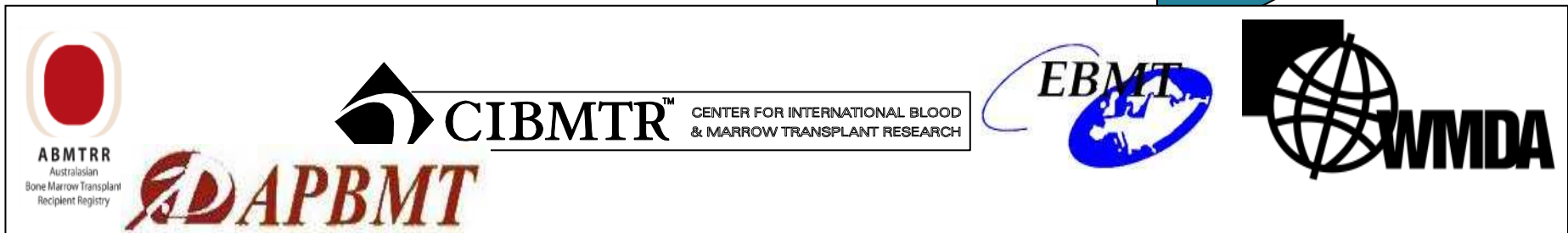
STANDARDS



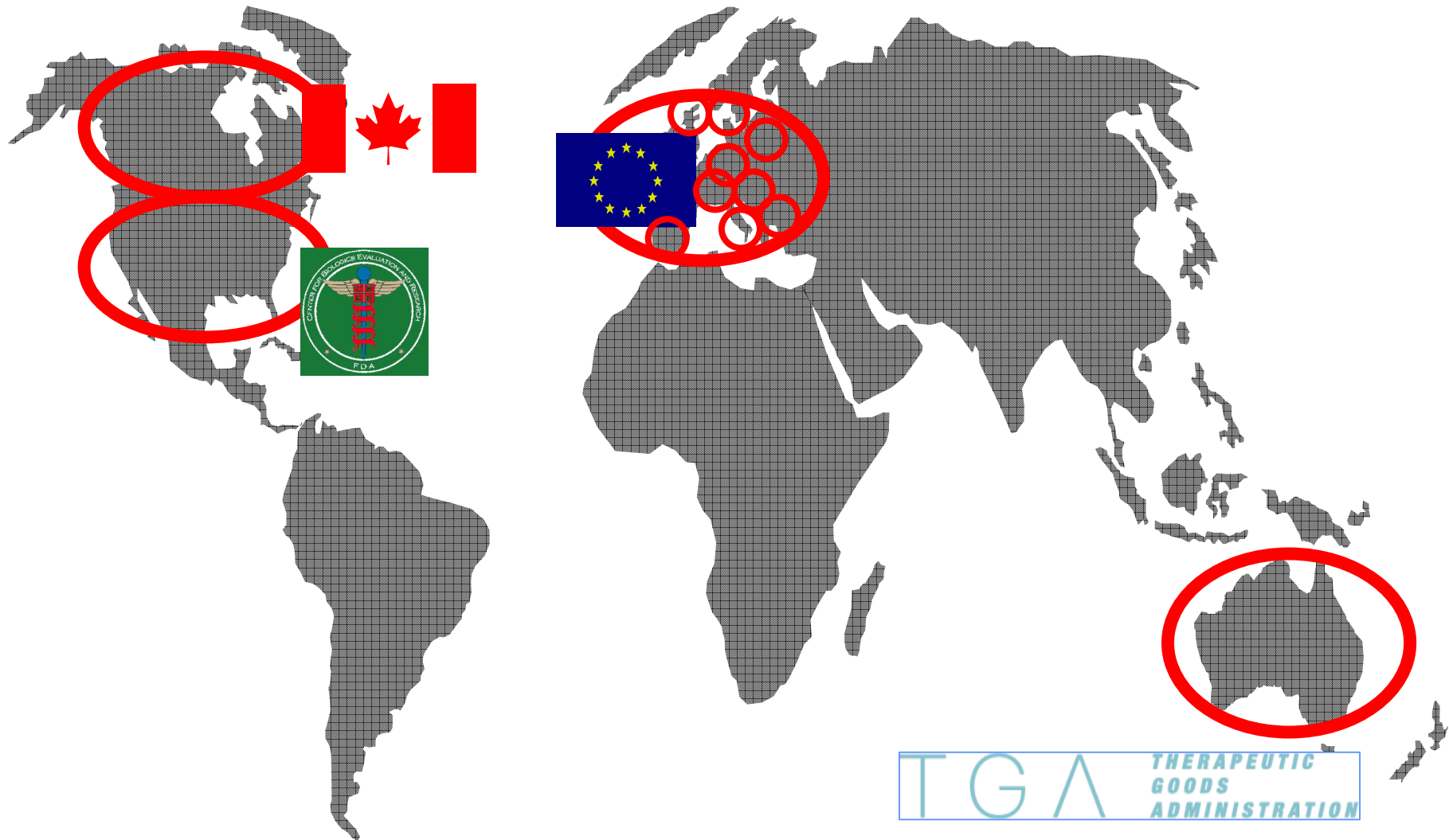
REGISTRATION/ACCREDITATION



OUTCOMES



If the barriers go up?



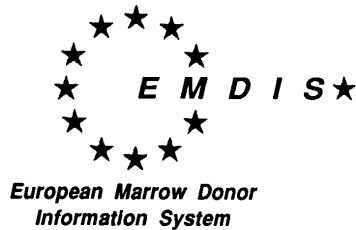
INTERNATIONAL CO-OPERATION: the solution not the problem



BMDW



WMDA



EMDIS



EBMT



NETCORD

CIBMTR



FACT



JACIE

Conclusions



- ❑ The ethical issues around HPC donation should be universal and apply equally to family and volunteer donors
- ❑ Safety reporting is vital
- ❑ Regulation in different parts of the world should be based on common-sense and safety and enhance rather than obstruct donation in an international collaborative.



9th International Donor Registry Conference and
WMDA Group Meetings

1– 5 May 2012
Sydney, Australia

Mark your calendar



science/ research/ donation/ cord blood banking/
transplantation/ bioethics/ regulation

Join us in Sydney 2012

wmdasydney2012.com

