Blood and Tissue: Products Liability Risks and Implications
Overview

- How are tissue products regulated?
- Human Tissue: Product or Service?
- State Statutes and Blood Shield Laws
- Case Study
- What happens in litigation?
- Mitigating the Risks
What are examples of HCT/Ps?

- Bone
- Skin
- Corneas
- Ligaments
- Tendons
- Dura mater
- Heart valves
- Stem cells
- Oocytes
- Semen
The Food and Drug Administration's Center for Biologics Evaluation and Research (CBER) regulates human cells, tissues, and cellular and tissue-based products (HCT/Ps) intended for implantation, transplantation, infusion, or transfer into a human recipient.

The FDA has published comprehensive requirements (current good tissue practice, donor screening and testing requirements) to prevent the introduction, transmission, and spread of communicable disease through tissue transfer, as well as numerous guidance documents on HCT/Ps.
Relevant FDA Regulations

**Current Good Tissue Practices (CGTPs):**

- Establishment registration and listing of the firm’s HCT/Ps
- Screening and testing of all donors to prevent spread of communicable disease
- CGTP Core Requirements and Quality System
- Contracting: Does your business partner comply with CGTPs?
- Which requirements apply if the end product is a combination product (i.e. also a biologic, drug, or device)?
- What is meant by “where appropriate”? 
The American Association of Tissue Banks (AATB) and the American Association of Blood Banks (AABB) are standard-setting organizations.

Establish standards and policies for record-keeping, quality control, donor screening, testing, and suitability determinations.

The AATB examines tissue banks for compliance with standards and policies.

Relevance for Products Liability?

The organizations help establish a standard of care to which blood and tissue banks/processors will be measured against in a products liability action.
Human Tissue: Product or Service?

Contracts between product manufacturers and distributors of human tissue (e.g., tissue banks) usually take the form of conventional supplier agreements, regarding tissue as a “product”

However:

- Strong public policy grounds for protecting human tissue distributors from products liability
- Every state has some form of blood shield laws, deeming the sale, distribution, and processing of blood (and, usually, tissue) as a “service”
- The Uniform Commercial Code (UCC) (as adopted by states) governs commercial transactions (generally, the sale of products)
- UCC specifically rejects conception of human tissue as a product
  - “Blood, blood plasma or tissue shall not be considered commodities subject to sale or barter, but shall be considered as medical services.”
Implications of “Service” Designation for Life Sciences Companies

- **Strict liability is not applicable**
  - “Human blood and human tissue, even when provided commercially, are not subject to [strict liability]” (Restatement 3d of Torts)

- **No implied warranties**
  - “The implied warranties of merchantability and fitness shall not be applicable to the furnishing of human blood, blood plasma, or other human tissue or organs...” (UCC)

- **Standard supplier/commercial contracts are not satisfactory**
  - Instead, contracts with “suppliers” must be structured as *service agreements*
But: Statutes Vary by State

The distribution of any human-derived products for any purpose by any party constitutes a service to which products liability does not apply.

Any person or firm providing blood or tissue for medical purposes will not be liable under products liability.

Any person or firm distributing blood or tissue on a not-for-profit basis does a service, and will not be liable under products liability.

Medical professionals utilizing human blood and blood derivatives for medical purposes are conducting a service.
Blood Shield Laws Not a Panacea

Life sciences companies handling human tissue cannot assume a state’s blood shield law will protect them.

What claims remain?

- Negligence based on non-compliance with FDA (and/or applicable state) regulations regarding practices for handling human tissue
- Negligence in selecting a tissue bank with a record of non-compliance and/or knowable contamination issues
- Products liability theories in some states:
  - When human tissue is sold *for profit*
    - Some states only provide protection for non-profit tissue banks and/or medical professionals
  - When distributed by parties other than tissue banks and/or medical professionals
    - Some states only provide immunity for these parties
Case Study

- John Smith has suffered from poor teeth quality and gum disease for a number of years and has recently lost a few teeth. He consults with his dentist regarding repair options.

- Dentist recommends a dental implant, wherein a permanent denture-like device is attached to his jaw bone, replacing the lost teeth. Dentist explains that testing is needed to ensure that John is a good candidate.

- Tests revealed that John’s jaw bone decay is much worse than expected and that there is not enough healthy tissue to properly secure the implant.
Case Study

- Dentist recommends performing a bone graft, in which donor tissue is transplanted into John’s jaw prior to placing the implant. The donor tissue is allowed time to heal and fuse with John’s existing jaw bone tissue before the dental implant device is introduced.

- John agrees and is scheduled for the bone graft procedure.

- Several months later, John returns for more tests. Dentist deems the graft to be sufficiently mature and performs the dental implant procedure.
Case Study
Case Study – Scenario #1

- Several months later, John is enjoying a meal out.
- While taking a bite of his sandwich, he feels something in his jaw shift, causing tremendous pain.
- Dentist determines that the screws holding the dental implant in place were stripped and unable to bear the proper amount of force.
- The implant must be removed and the graft evaluated to see if it is strong enough to hold a replacement device.
The Players – Scenario #1

Who are the potential parties to a lawsuit?

Hospital
- Employs, supervises, and trains the persons assisting in the procedure
- May store blood/tissue

Doctor
- Selects product
- Discusses risks/benefits with patient
- Implants or uses product

Tissue/Blood supplier
- Provides blood/tissue to hospital
- Provides blood/tissue to manufacturer

Manufacturer
- Designs and manufactures product
- Designs specifications for blood/tissue
Several months after his dental implant surgery, John awakens to realize that he has terrible jaw pain and that his gums feel inflamed.

He sees Dentist that day, and Dentist diagnoses an infected bone graft. Given the extent of the infection, the implant and graft must be removed.

John may not be a candidate for a replacement graft and dental implant, depending upon the degree of damage caused by the infection.
The Players – Scenario #2

Who are the potential parties to a lawsuit?

**Hospital**
- Employs, supervises, and trains the persons assisting in the procedure
- May store blood/tissue

**Doctor**
- Selects product
- Discusses risks/benefits with patient
- Implants or uses product

**Tissue/Blood supplier**
- Provides blood/tissue to hospital
- Provides blood/tissue to manufacturer

**Manufacturer**
- Designs and manufactures product
- Designs specifications for blood/tissue
Product Liability Theories

- Strict products liability
- Negligence
- Breach of warranty
- Battery
- IIED/Medical monitoring
Strict Liability & Negligence

- **Strict Liability**: “One engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect.”


- **Negligence**: One is liable for failure to exhibit ordinary care to any party who suffered an injury that was proximately caused by negligent conduct.

  - Manufacturing Defects — when the product departs from its intended design, even if all possible care was exercised.
  - Design Defects — when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design, and failure to use the alternative design renders the product not reasonably safe.
  - Inadequate Instructions or Warnings Defects — when the foreseeable risks of harm posed by the product could have been reduced or avoided by reasonable instructions or warnings, and their omission renders the product not reasonably safe.
Breach of Warranty & Battery

- **Breach of Warranty** – Dependent on classification of blood/tissue as product
  - Claims sounding in contract; Plaintiff still must establish some defective condition of the “product”

- **Battery** – a tort cause of action arising from a harmful or offensive contact with plaintiff’s person
  - In the blood and tissue context, the plaintiff must show exposure to some disease-causing factor as a result of the transplant

- **Intentional Infliction of Emotional Distress/Medical Monitoring** –
  - Attempts to hold supply chain liable for exposure in absence of manifestation
“Body Snatcher” Litigation

- In 2005, it was found that Biomedical Tissue Services (NJ) had criminally stolen and harvested corpses from funeral homes without permission of deceased families.
- Estimated that 1000 patients received skin, tissue, and bone from these wrongfully-harvested cadavers.
- BTS did not screen corpses; used cancerous and diseased cadavers.
- None of the 5 companies BTS sold to verified consent or quality of cadavers.
- Duties?
Mitigating the Risk

- Adhere to FDA’s applicable Guidances and Current Good Tissue Practices:
  - 21 CFR § 1271
  - Guidance for Industry: *Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products* (June 2014)

- Ensure that the tissue bank from which you are obtaining the tissue is registered with the FDA and is in good standing.

- Structure contracts with tissue banks (vendors) and hospitals/doctors (customers) as *service agreements* rather than contracts for goods or products.
  - Ensure that these service agreements contain provisions regarding indemnification in the event of a tissue product problem and a requirement that the tissue bank carry sufficient insurance to meet its indemnification obligations.
Thank you!

Kathryn T. Klaus, Esq.
Loss Control
Medmarc Insurance Group
703-652-1330 | kklaus@medmarc.com

Courtney A. Stevens, Esq.
Loss Control
Medmarc Insurance Group
703-652-1385 | cstevens@medmarc.com