Stem Cell and Regenerative Treatment Task Force Meeting

Medical Board of California
September 18, 2019

CDPH
CEH
DFDCS

Food and Drug Branch
Role in Stem Cell Product Regulation and Investigations
FDB: Role in Stem Cell Product Regulation

Drugs ∩ Biologics

Biologic Drugs

FDB: Who Needs A License

DRUG MANUFACTURERS
Manufacturing defined in H&SC §109970
FDB: Activities

**Regulatory**
Environmental Scientists
- Inspection
- Embargo
- Condemnation
- Administrative Penalty

**Investigative**
Investigators
- Criminal Case
- Civil Penalty
- Injunction

CDPH
OSPHLD

Laboratory Field Services Branch
Role in Stem Cell Product Regulation and Investigations
LFS: Role in Stem Cell Product Regulation

Human Blood
Biologics License

Human Tissue
Tissue Bank License

LFS: Who Needs A License

BIOLOGICS and TISSUE BANK
Specified in H&SC §§ 1600 - 1648.

Collection
- Donor qualification
- Donor testing
- Donor consent

Processing
- Preparation
- Testing
- Labelling

Storage
- License required unless exempted by law

Distribution
- Advertising
- Sale
- Exchange
LFS: Activities

**Regulatory**
- Inspection
- Investigation

**Enforcement**
- Injunction
- Suspension or revocation of licensure
- Fines
- Civil penalties

CDPH CHCQ

Healthcare Associated Infections Program
Role in Stem Cell Product Regulation and Investigations
HAI: Role in Disease Investigations

HAI Program
- Provides guidance to local health departments for infection control breaches, outbreaks, and unusual infectious disease occurrences associated with receiving healthcare.

Local Health Department
- Performs epidemiological investigations
- Recommends follow up actions to healthcare facilities

Licensing and Certification
- Ensures facilities follow laws and regulations
- If regulatory deficiencies are identified, ensures facilities implement the approved plan of correction

Multistate Outbreak of Umbilical Cord Blood-Derived Stem Cell Injection-Associated Infections

- **September, 2018**: Reports of bacterial infections following injections of an umbilical cord blood-derived stem cell product from the ReGen Series® (produced by Genetech, distributed by Liveyon, LLC)
  - ReGen Series® product recalled in late September 2018

- **As of December, 2018**: 12 cases in 3 states (Texas, Florida, Arizona)
  - Multiple California providers received the product
CDC Recommendations for Patient Notification

- **January 28, 2019**: CDC recommended that all patients who received the recalled ReGen® series product be notified
  - Risk of bacterial infection
  - Low, but potential risk of HIV, HBV, HCV; need to consider bloodborne pathogen testing

- **February 2019**: HAI Program convened 20 local health departments to discuss 140 California providers who received shipments of the ReGen Series® product
  - Determined CDPH or local health department to notify providers, who should, in turn, notify patients of the risks and recommend they discuss testing with their regular healthcare providers
Patient Notification in California

- Stem cell providers notified: 139
  – Estimated number of patients notified: 754
- Bacterial infections: 3 in CA residents (20 nationwide)
- No reports of bloodborne pathogen infections
THANK YOU