
Stem Cell and Regenerative Treatment Task Force Meeting

Medical Board of California
September 18, 2019



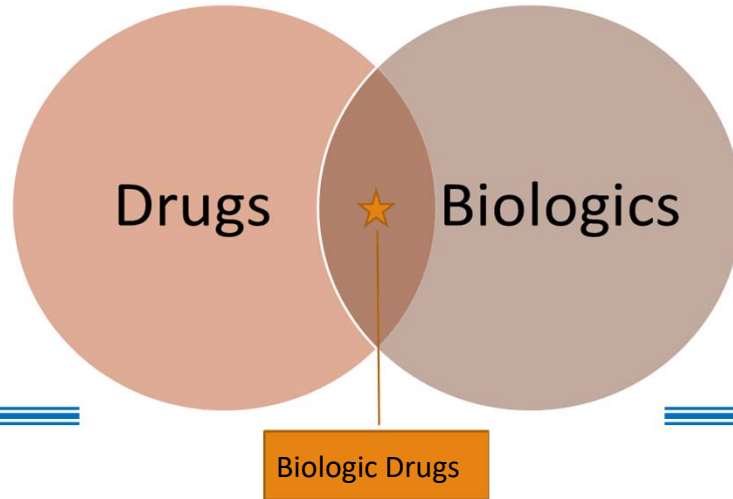
CDPH
CEH
DFDCS

Food and Drug Branch

Role in Stem Cell Product Regulation and
Investigations

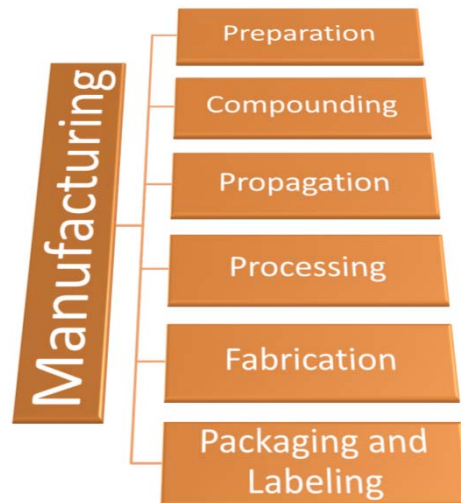


FDB: Role in Stem Cell Product Regulation



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

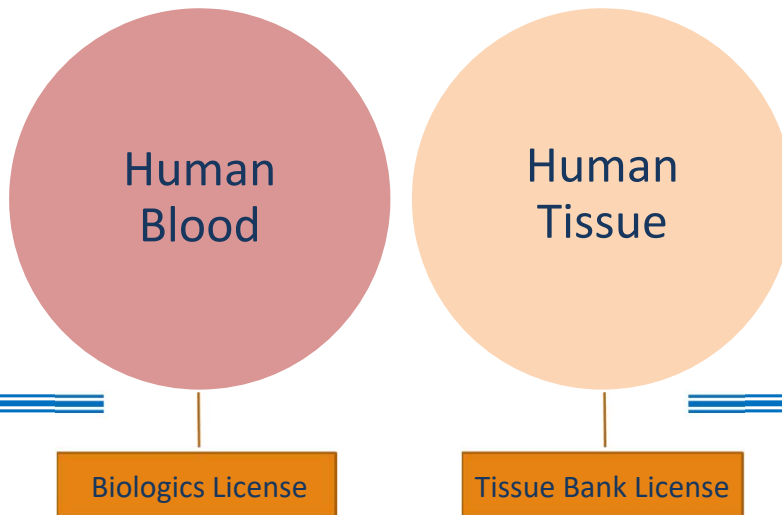
Laboratory Field Services

Branch

Role in Stem Cell Product Regulation and Investigations



LFS: Role in Stem Cell Product Regulation



LFS: Who Needs A License

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

Collection	<ul style="list-style-type: none">• Donor qualification• Donor testing• Donor consent
Processing	<ul style="list-style-type: none">• Preparation• Testing• Labelling
Storage	<ul style="list-style-type: none">• License required unless exempted by law
Distribution	<ul style="list-style-type: none">• 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 Morbidity and Mortality Weekly Report – December, 2018

Notes from the Field

Infections After Receipt of Bacterially Contaminated Umbilical Cord Blood–Derived Stem Cell Products for Other Than Hematopoietic or Immunologic Reconstitution — United States, 2018

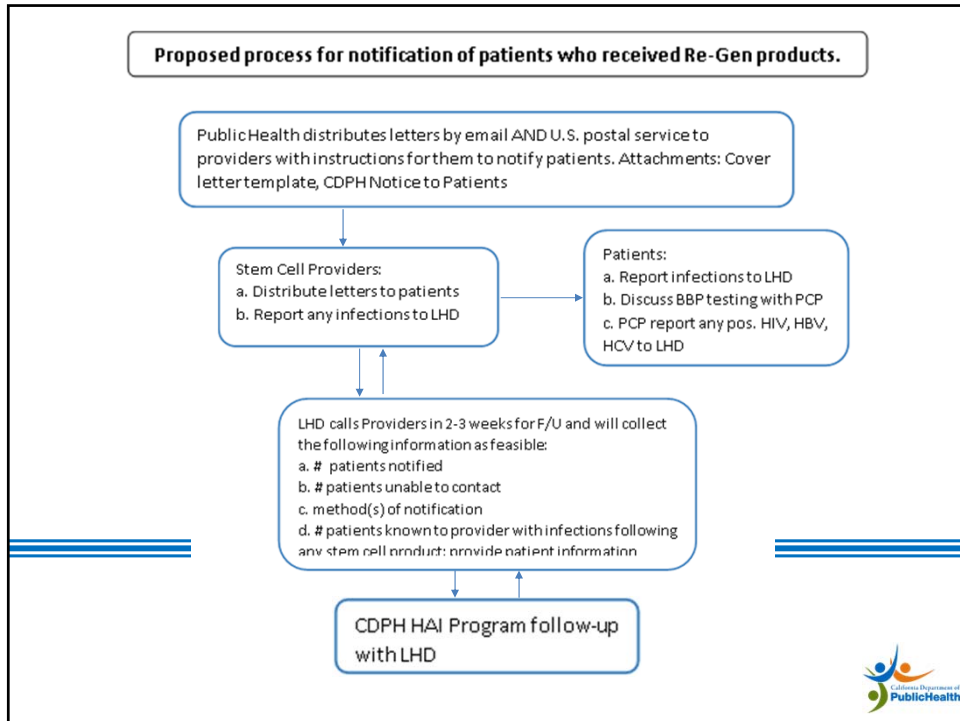
Kiran M. Perkins, MD¹; Samantha Spoto, MSPH²; Danielle A. Rankin,
MPH²; Nychie Q. Dotson, MPH²; Mary Malarkey³; Melissa Mendoza,
JD³; Lorrie McNeill³; Paige Gable¹; Krista M. Powell, MD¹



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



Harlan Loui
Chief of the Drug and Medical
Device Safety Section
Harlan.Loui@cdph.ca.gov
(916) 341-7358.

Robert Thomas
Chief of Laboratory Field
Services Branch
Robert.Thomas@cdph.ca.gov

Lynn Janssen
Chief of Healthcare
Associated Infections
Program
Lynn.Janssen@cdph.ca.gov



THANK YOU

