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# Stem Cell and Regenerative Treatment Task Force Meeting

Medical Board of California  
September 18, 2019

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**CDPH**  
**CEH**  
**DFDCS**

## Food and Drug Branch

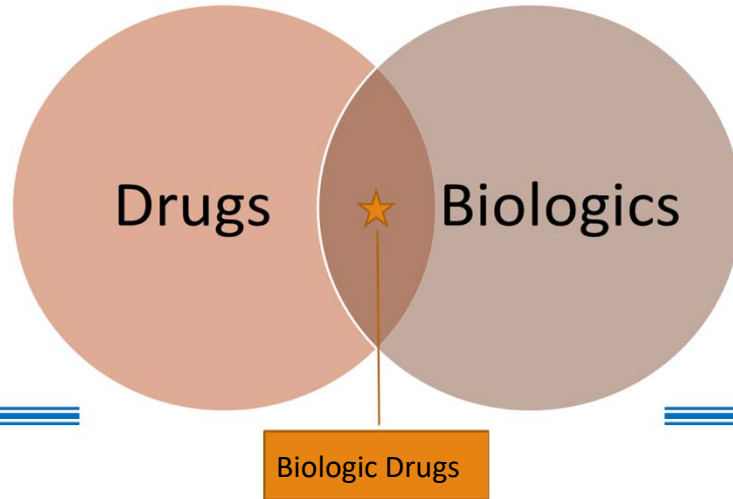
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Role in Stem Cell Product Regulation and  
Investigations

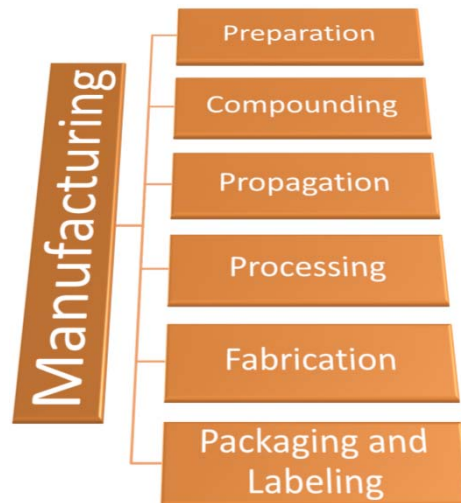


## FDB: Role in Stem Cell Product Regulation



## 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

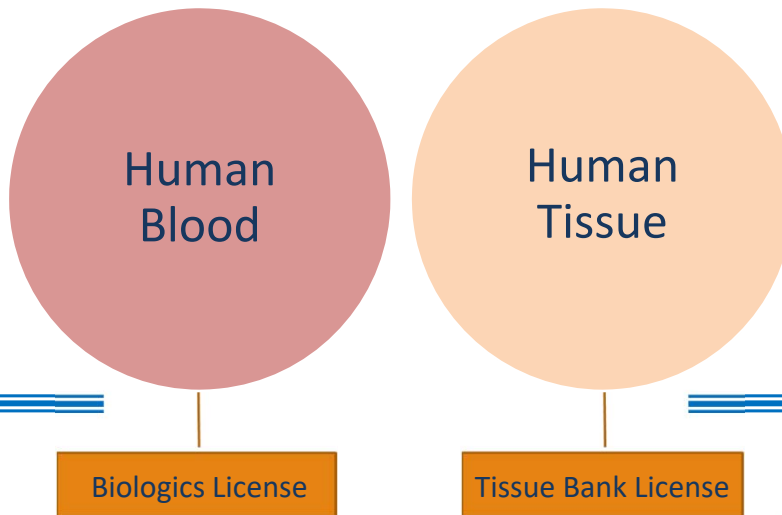
## Laboratory Field Services

### 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"><li>• Donor qualification</li><li>• Donor testing</li><li>• Donor consent</li></ul>
Processing	<ul style="list-style-type: none"><li>• Preparation</li><li>• Testing</li><li>• Labelling</li></ul>
Storage	<ul style="list-style-type: none"><li>• License required unless exempted by law</li></ul>
Distribution	<ul style="list-style-type: none"><li>• Advertising</li><li>• Sale</li><li>• Exchange</li></ul>



## 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

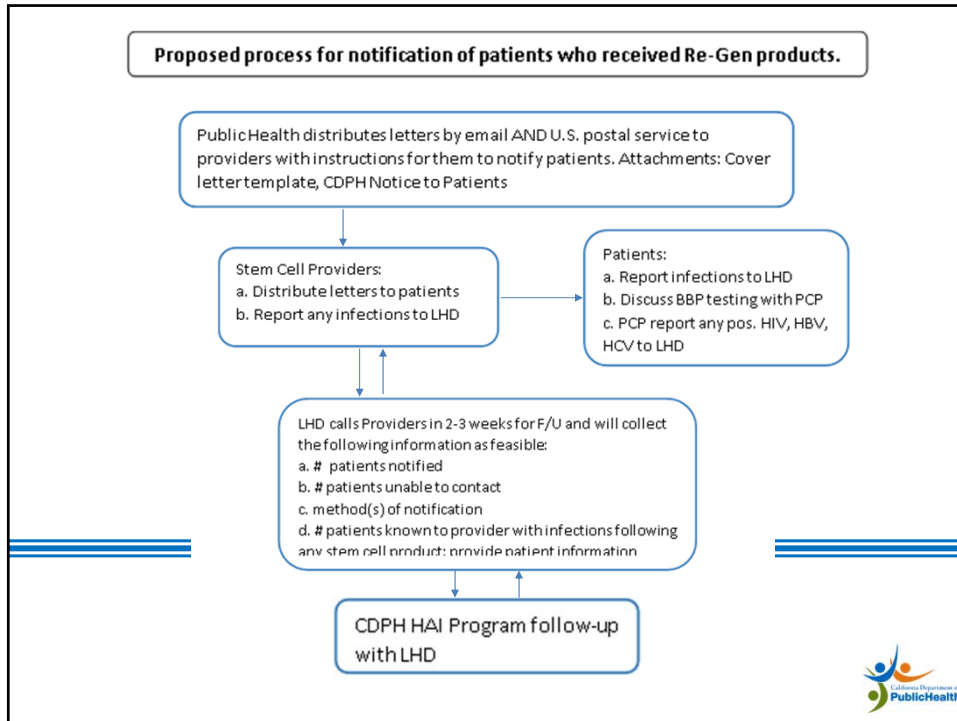
Kiran M. Perkins, MD<sup>1</sup>; Samantha Spoto, MSPH<sup>2</sup>; Danielle A. Rankin,  
MPH<sup>2</sup>; Nychie Q. Dotson, MPH<sup>2</sup>; Mary Malarkey<sup>3</sup>; Melissa Mendoza,  
JD<sup>3</sup>; Lorrie McNeill<sup>3</sup>; Paige Gable<sup>1</sup>; Krista M. Powell, MD<sup>1</sup>



### CDC Recommendations for Patient Notification

- **January 28, 2019:** CDC recommended that all patients who received the recalled ReGen<sup>®</sup> 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<sup>®</sup> 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





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THANK YOU

