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
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

<table>
<thead>
<tr>
<th>Role</th>
<th>Responsibilities</th>
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<tr>
<td><strong>HAI Program</strong></td>
<td>• Provides guidance to local health departments for infection control breaches, outbreaks, and unusual infectious disease occurrences associated with receiving healthcare.</td>
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<td><strong>Local Health Department</strong></td>
<td>• Performs epidemiological investigations</td>
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<td>• Recommends follow up actions to healthcare facilities</td>
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<td><strong>Licensing and Certification</strong></td>
<td>• Ensures facilities follow laws and regulations</td>
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<td>• If regulatory deficiencies are identified, ensures facilities implement the approved plan of correction</td>
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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
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
Public Health distributes letters by email AND U.S. postal service to providers with instructions for them to notify patients. Attachments: Cover letter template, CDPH Notice to Patients

Stem Cell Providers:
- a. Distribute letters to patients
- b. Report any infections to LHD

Patients:
- a. Report infections to LHD
- b. Discuss BBP testing with PCP
- c. PCP report any pos. HIV, HBV, HCV to LHD

LHD calls Providers in 2-3 weeks for F/U and will collect the following information as feasible:
- a. # patients notified
- b. # patients unable to contact
- c. method(s) of notification
- d. # patients known to provider with infections following any stem cell product: provide patient information

CDPH HAI Program follow-up with LHD
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