DSHS LRN RESPONSE TO THE 2015 DEPARTMENT OF DEFENSE ANTHRAX INCIDENT

Erin Swaney

MEMORIAL DAY WEEKEND– FRIDAY 5.22

- Just before midnight
- CDC contacted DSHS to notify that a company in San Antonio had received potentially active *Bacillus anthracis* sample material

MEMORIAL DAY WEEKEND – SATURDAY 5.23

- The CDC provided an overview during a conference call:
- They had been notified by a company on 5.22.15 that an unknown sample known as "Antigen 1" thought to be inactivated had not been accompanied by a certificate of inactivation.
- To check viability, 100 ul of that sample had been plated and incubated under BSL3 conditions, and resulted in the growth of 2 colonies. The appearance of the colonies was consistent with *Bacillus anthracis*.
- PCR was performed and gave positive results for all three *Bacillus anthracis* DNA sequences tested, including pX01 and pX02 targets.
- This indicated that it contained a virulent strain of *Bacillus anthracis* and that it was not inactivated. "Antigen 1" had been sent from the DoD to this facility as well as 4 other facilities.
- The names of those other facilities had been provided to the CDC and they were in the process of reaching out to the state public health departments

MEMORIAL DAY WEEKEND – SATURDAY 5.23

- The original company had been using the "Antigen 1" material to test a LFA, or Lateral Flow Assay. The testing process required the sample to be aliquotted by pipette, diluted then applied to the LFA.
- The company secured the sample pending further recommendations.
- The CDC suggested that the Laboratory Response Network (LRN) laboratories should perform culture confirmation of all samples. They recommended that a risk assessment should be performed
- The FBI WMD Coordinators had determined that no criminal activity was suspected.
- It was noted that states might have difficulty reaching the companies due to the holiday weekend, and a follow-up CDC conference call was scheduled for the next day.
- DSHS was contacted because a laboratory in Texas had been identified as one of the original 5 labs to receive "Antigen 1."

MEMORIAL DAY WEEKEND – SATURDAY 5.23

- Second conference call was held to update San Antonio staff on the situation. The next step identified was to have local personnel attempt to contact Company A.
- It was identified that the San Antonio LRN is not a Tier 1 Select Agent Program Registered Facility, so if anthrax was identified they would have to transfer it to CDC or DSHS.
- In the afternoon Company A was reached and informed of the situation. Company A identified two employees who had worked with the specimens up through 5.22.15. Interviews with them were scheduled for 5.24.15.
- The CDC provided a Risk Assessment tool that included questions about centrifugation, vortexing, splashes, and other potentially aerosol generating procedures.

CDC RISK ASSESSMENT TOOL

Brief risk assessment tool that you can use when you interview the people who worked with the samples. If you check items in the Potential Risk column, you cannot rule out possible exposure. Therefore, that group should be considered to receive PEP in consultation with an occupational health physician. We are available for consultation if you wish.

	Procedure	*Potential* Risk	Risk Very Unlikely
1.	If you centrifuged…		
a.	was it in an aerosol-tight rotor?	____No	____Yes
a.	was it centrifuged in a BSC?	____No	____Yes
a.	if not centrifuged in a BSC, was the rotor opened in a BSC?	____No	____Yes
1.	If you vortexed		
a.	were the vials sealed with an O-ring?	____No	____Yes
a.	was the vortex outside of a BSC?	____Yes	____No
a.	did you then open a flip-top tube?	____Yes	____No
1.	Did you create a splash or drop/break a tube?	____Yes	____No
1.	Did you do any other potentially aerosol-generating procedures (dry specimens by blowing nitrogen across them, vaporize them in a mass spec)	____Yes	____No

MEMORIAL DAY WEEKEND – SUNDAY 5.24

- CDC conference Call #2:
- "Antigen 1" was part of a panel of 25 specimens that had been distributed. All were 1 ml vials containing 150 µl of a suspension. CDC reported that two site visit teams would travel on 5.25.15 to visit the inactivation facilities where the material originated. They requested that the companies that received the potentially inactivated materials cease work and secure the samples.
- Revised the previous recommendation and asked that "Antigen 1" samples should be directly transferred to the CDC and samples 2-25 should be transferred to the local LRN labs.
- They provided Fact Sheets on Doxycycline and Ciprofloxacin, two antibiotics effective against *Bacillus anthracis*, and a list of questions to use during onsite visits that covered decontamination of materials and surfaces and disposal of PPE.

TUESDAY 5.26

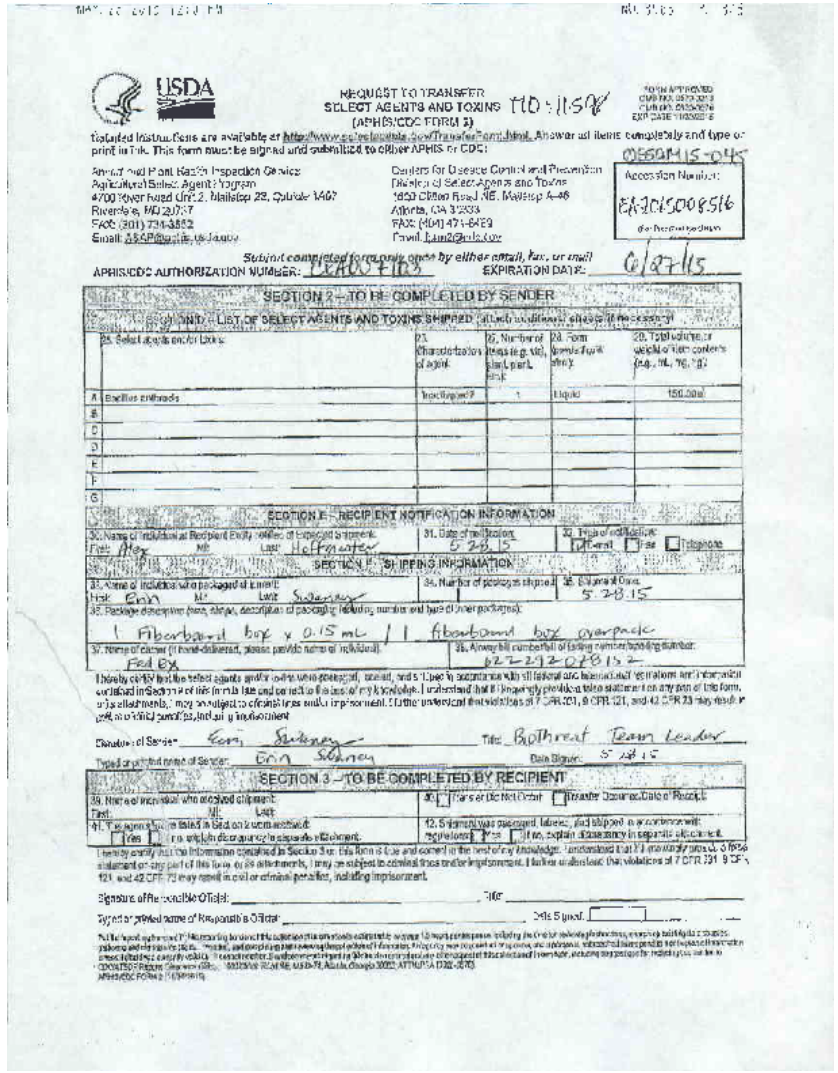
- The number of laboratories identified as having been shipped Antigen 1 rose to 9.
- DSHS was notified that a laboratory in Austin, TX was one of those 9.
- Further investigation revealed that Company B had received the shipment but not opened it. It has been secured in a freezer for future testing.
- Six specimens were transported to DSHS Laboratory and were secured in a Tier 1 SA registered facility pending CDC recommendations.

WEDNESDAY 5.27

- CDC Conference Call #3 was held.
- It informed participants that low concentrations of Bacillus anthracis were identified in “Antigen 1,” at 15 cfu/ml.
- They recommended that laboratory exposures could be assumed and any labs that had handled samples outside of BSL3 containment were recommended to shut down until decontamination procedures could be determined and performed.
- The total number of laboratories that were shipped material rose to 18, including a laboratory outside the US. A second lot of potentially viable material was also identified at that time.
- DSHS Laboratory was advised by the CDC to ship the material from Company B so a Form 2 was submitted to request approval for transfer to CDC.

THURSDAY 5.28

- Form 2 was received approved for the Select Agent transfer from Company B.
- A single vial containing 150 µl of “Antigen 1” sample was shipped overnight to the CDC in Atlanta.



USDA

REQUEST TO TRANSFER SELECT AGENTS AND TOXINS (APHIS/CDC FORM 2)

APHIS/CDC AUTHORIZATION NUMBER: EAP057125 EXPIRATION DATE: 6/27/15

SECTION 2 – TO BE COMPLETED BY SENDER

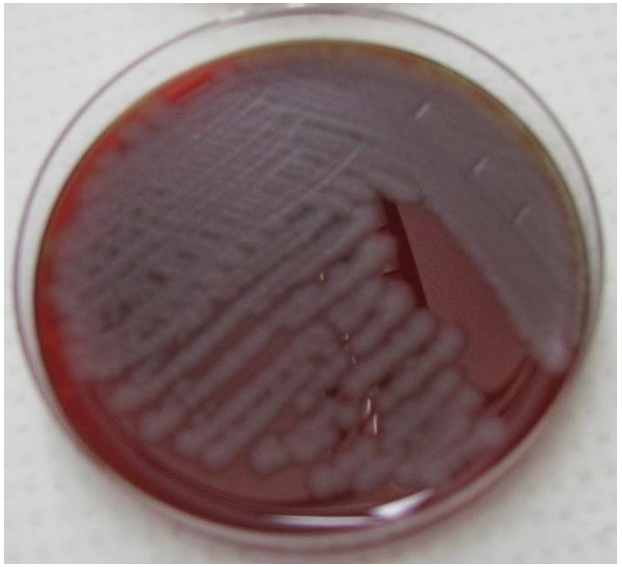
SECTION E – RECIPIENT NOTIFICATION INFORMATION

SECTION F – SHIPPING INFORMATION

SECTION 3 – TO BE COMPLETED BY RECIPIENT

SATURDAY 5.30

- The CDC test result became available and showed that the sample had 226 cfu/ml, a low concentration of *Bacillus anthracis* detected.

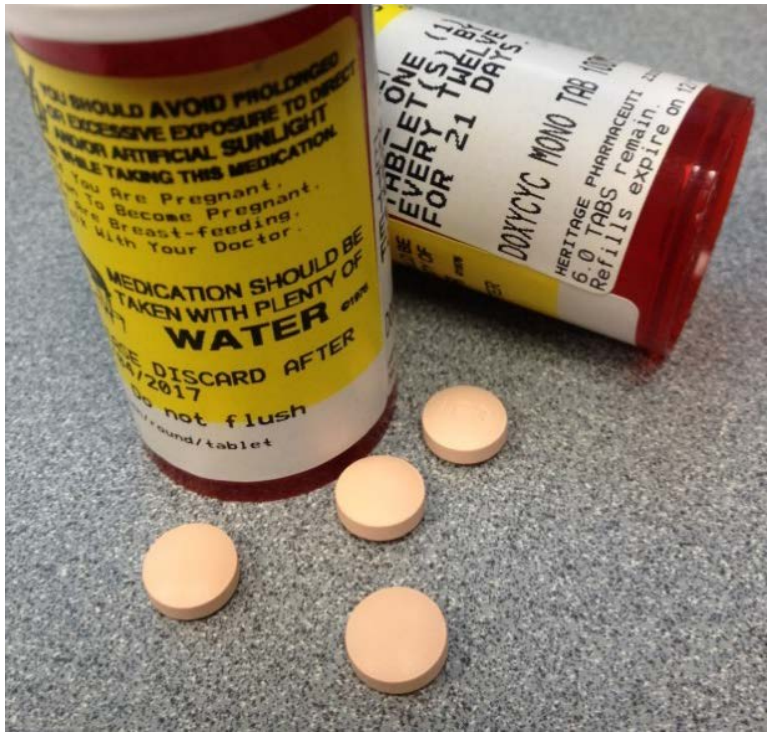


TUESDAY 6.2

- Conference calls were held to continue to coordinate response efforts.
- An additional 4 military and non-military laboratories in Texas were identified as having received a shipment of the material.
- Two laboratories no longer existed, and another Austin area company was identified that had received the material in 2006. That laboratory had used or destroyed all material and was out of the incubation period of disease.

THURSDAY 6.4

- CDC antimicrobial susceptibility testing results on Antigen 1 were finalized. The bacteria was susceptible to Ciprofloxacin and Doxycycline among other antibiotics.



TUESDAY 6.9

- DSHS was notified that Company B possessed materials from the additional lots identified as being potentially viable.
- DSHS Laboratory assisted Company B with initiating the SAP Form 2 process to transfer the material to CDC. They offered assistance such as providing packaging materials, dry ice, and knowledge of labeling requirements for shipping the material to CDC.

THURSDAY 6.18

- Company B's Form 2 was returned approved. DSHS Laboratory Staff arrived onsite and assisted Company B in packaging and shipping the shipment of 93 items to the CDC.
- Container was 25"x 22"x 20"
- Weighed 40 pounds

MONDAY 6.22

- DSHS Laboratory performed supplemental autoclave spore test for quality assurance of instrument parameters.
- 10 vials of potentially inactivated material were received from Company C in Austin and securely stored at -70C for eventual destruction.
- Military Laboratory A initiated the Form 2 process to transfer potentially inactivated material to DSHS.

MONDAY 6.22

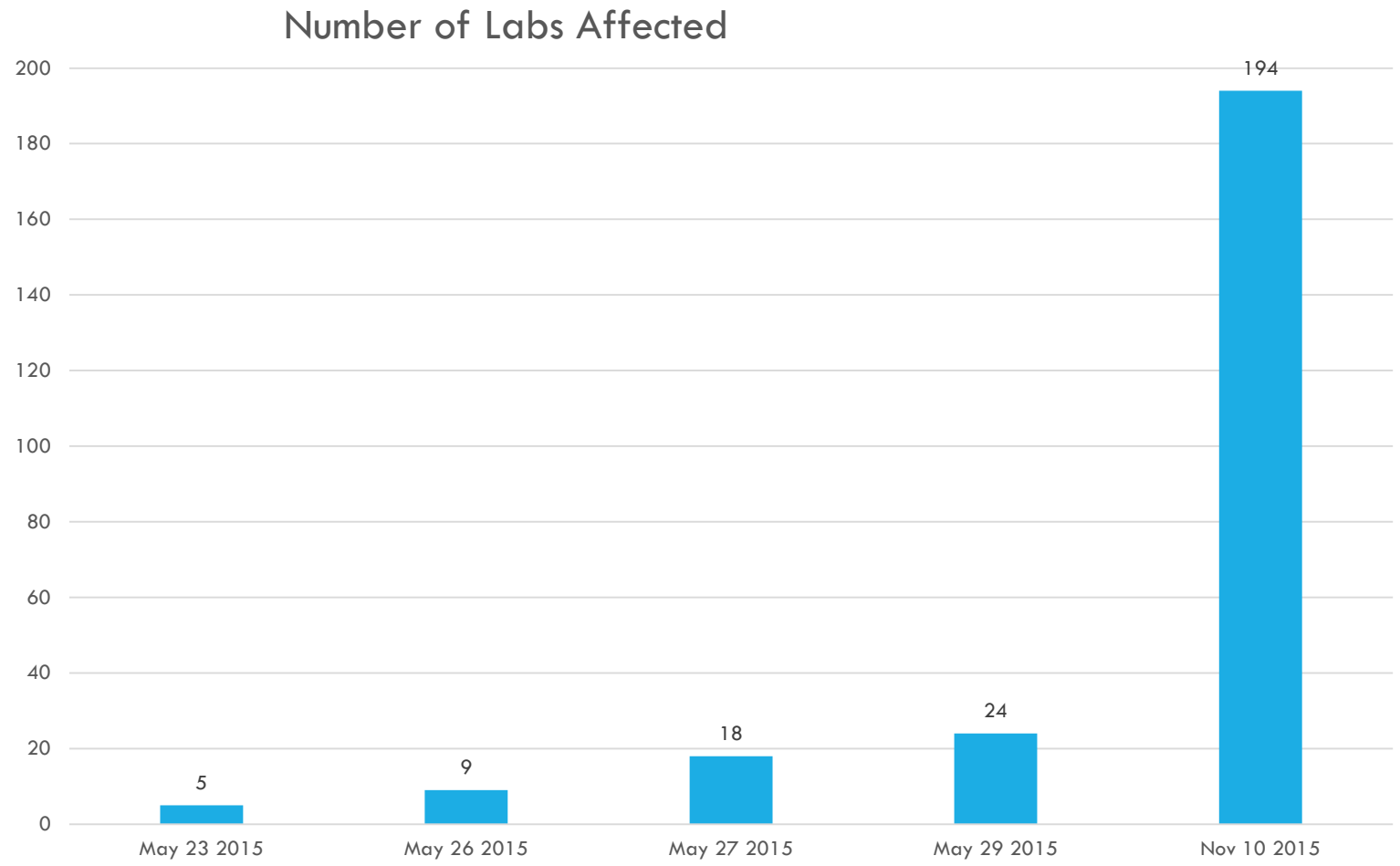
- Military Laboratory A delivered 18 samples to DSHS Lab.

- 10 samples from Company C and
  18 samples from Military Laboratory
  A were autoclaved and destruction
  was documented.

FRIDAY 7.10

- Additional testing on DoD samples produced from 2004-2015 identified another lot of viable *Bacillus anthracis*.
- Texas was notified that 5 laboratories in Texas received material from this lot including Company C in Austin TX.
- That material had already been destroyed.

The investigation revealed a total of 194 laboratories that had received the non-inactivated *Bacillus anthracis* material. This affected 9 foreign countries and all 50 states.



LESSONS LEARNED

- LRN was well equipped to provide assistance with:
  - Packaging and Shipping guidance
  - Providing shipping materials
  - Advising on Form 2 completion
  - Securing/storing agents
  - Destruction of materials

AFTERMATH

- Moratorium on production facility
- SAP surveys of inactivated material use
- FedEx no longer ships SAs