

**ORAL PRESENTATION BY RICHARD M. JACOBS
BEFORE THE SUB COMMITTEE ON OVERSIGHT AND
INVESTIGATIONS
COMMITTEE ON ENERGY AND COMMERCE
WASHINGTON, D.C.
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Good morning. My name is Richard Jacobs, and I am a chemist with the Laboratory Branch of the San Francisco District. I have 44 years of government service, 40 of those have been with the FDA. Most of my career has involved the work with the essential and non-essential elements.

Thank you this opportunity to bring to your attention those critical capabilities and functions that the San Francisco District Laboratory Branch provides not only the agency, but to our partners in public health, to the public in general, and to our local commercial industry.

The San Francisco lab is:

- ISO 17025 accredited.
- Lab scientific staff includes 10 chemists, 14 microbiologists, 3 biologists, and 1 technician. Many of our scientists have advanced degrees. Some have doctorates.
- While laboratory management staff includes a Science Branch Director, 3 supervisory analysts, and a district quality assurance manager, the laboratory is currently lacking a sample custodian, a safety officer, glassware washer, and 2 media preparation technicians. Those duties are presently being performed by scientific staff. Additionally, we have lost several journeyman scientists in the last year that haven't been replaced.
- With the exception of filth analysis, drug analysis, mycotoxin analysis, and pesticide analysis our lab covers the rest of the field program areas.
- Our lab houses two specialty functions for the Pacific Region: Toxic Elements (in foods and ceramicware) and Food and Color Additives.

I believe that the closure of our laboratory facility will lead to a loss of critical expertise, functionality, and capacity in certain critical programs, some of which may never be regained. Critical relationships with the State of California will be lost without having certain FDA analytical experts nearby:

- Our lab has been a pioneer in introducing many new technologies to the field. Examples include elemental analysis techniques such as ICP-MS, XRF techniques, and methods to accurately measure mercury and methylmercury in seafood.
- Our group is piloting the use of X-Ray Fluorescence by investigators in the field to detect potentially hazardous levels of toxic elements in foods and Asian herbal and patent medicines. This device can detect certain elements in a matter of seconds with little or no preparation of the product.
- Together with the state of California our group was instrumental in developing information to support new policy regarding lead in candy.
- The laboratory performs seafood sensory analysis, widely used for detection of spoilage in imported seafood, as well as analyzing for histamine and indole, two compounds indicative of microbial spoilage. A local analytical presence and the participation of analysts in inspections are essential for having impact on the local domestic and the import seafood industry.
- San Francisco district laboratory also has unique expertise in enteric viral analyses, especially Norwalk Virus and Hepatitis A. Analytical methods for these two viruses are in preparation for inter-laboratory validation. Over recent years, numerous outbreaks of Norwalk Virus indicate a need for a sensitive analytical method for detection of this virus on foods and in food handling environments.

- The San Francisco district laboratory contributed very importantly to the detection of *Escherichia coli* O157:H7 in last year's investigation of the incidence of clinical infections due to this organism traced to spinach, and later, in a different outbreak, to lettuce. This laboratory performed about half of the approximately 900 samples analyzed in the San Francisco Bay Area and found several strains which were linked to clinical cases using PULSENET. Indeed, one isolate matched about 63 clinical cases that had not previously been identified by the CDC as an outbreak and which occurred during the previous summer. Outbreak investigations would be severely hampered by not having analysts and an analytical activity available, locally. Moreover, many microorganisms, e.g. *E. coli* O157:H7, can be negatively affected by commercial shipping practices. So having a nearby lab where the samples can be delivered in a few hours is critical.
- The Microbiology section is capable of handling all food related pathogen detections and it is the only laboratory in the Pacific Region able to analyze drugs and medical devices for sterility and endotoxins.

The laboratory is well equipped for many analytical programs. It is “state of the art” equipped for Microbiology and Toxic Elements:

Aside from the typical equipment the lab is equipped with:

- Clean room facilities for sterility testing for drugs and medical devices and toxic element testing.
- Specialized sample preparation rooms and equipment.
- Room for specifically studying viral analytical methods
- A BSL2+ suite and ten analysts trained to CDC standards for work with several select agents.
- Possession of analytical chemistry equipment allowing flexibility in adapting to novel analytes, such as, currently, melamine and related compounds (cyanuric acid, ammeline and ammeline).

The lab is a member of FERN (microbiology, toxic elements) and CDC's Laboratory Response Network. San Francisco analysts have participated in training elemental analysis, *E. coli* O157:H7, FERN (Food Emergency Response Network) methods, Select Agent analytical methods, basic microbiology FDA analytical methods and Mobile Laboratory Training.

The laboratory actively collaborates or maintains contacts with the California Department of Health Services, USDA, the Lawrence Livermore National Laboratory and the University of California at Davis.

Thank you again Mr. Chairman for this opportunity, I will be glad to answer any questions that you or the other committee member might have.