

- Good morning, it's nice to be back at WO, and with you science writers today, my name is Brian Baker and with me is Dr. Pat Regan.
- It seems like just yesterday when I spent nearly 2 years here at HQ serving as the acting Director, Office of Regulatory Science within ORA.
- Our presentation today, is intended to do two things:
- First, tell you a little about ORA, providing insights to the cutting edge science we're doing in our field labs, and
- Second, to provide some examples of how we are innovating, using new technologies, developing new analytical tools--portable, hand-held detection devices-- which allow us to do our work faster, that we believe will save American lives and protect public health.

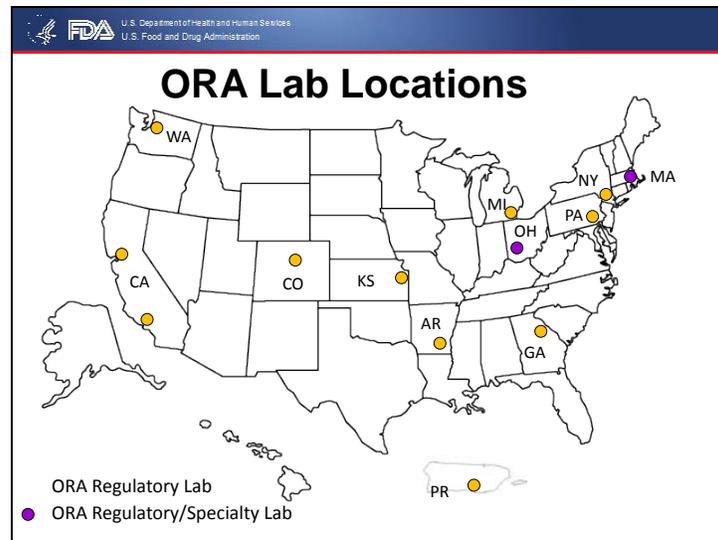


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### About FDA's Office of Regulatory Affairs (ORA)

- Lead office for all Agency field activities
- 227 offices & 13 laboratories spread across the nation
- 4,600+ inspectors, analysts, compliance officers & staff
  - Inspects regulated products & manufacturing facilities in the US and abroad
  - Analyzes samples of regulated products
- Reviews imported products offered for entry into the U.S.

- ORA is often referred to as “the Directorate” or “Enforcement Arm” of the Agency
- We represent approximately one-fourth of the agency’s approximately 15,000 employees and
- Of particular note for today’s presentation, we have approximately 1,000 scientists, engineers, and staff assigned to one of 13 field labs



- Of our thirteen field labs, two, colored in purple are considered specialized labs with unique science portfolios.
- The one in Cincinnati, Ohio, is our Forensics Chemistry Center – and our designated crime lab supporting the Office of Criminal Investigations in collaboration with DOJ, and sister federal law enforcement agencies including the FBI, DEA, and others.
- The one we will report on today is the Winchester Engineering and Analytical Center – referred to as WEAC located 8-miles north of Boston, MA.
- I lead this lab as Director, and Dr. Pat Regan serves as Analytical Branch Director; he also acted in my stead as lab director, for nearly 2-years while I was here at HQ leading ORAs national laboratory portfolio.



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## ORA Lab Program Work

Analytical capabilities in chemistry, microbiology, radiochemistry, and engineering

Performs testing of FDA regulated products:

Product	Areas of Testing/Analytical Activities Performed by ORA
Foods & Feeds	Pesticides, dioxins, mycotoxins, chemotherapeutics, color additives, toxic metals, filth, select radioisotopes
Pharmaceutical Products	Active pharmaceutical ingredient testing, dissolution testing, sterility
Devices	Risk-identified products such as infusion pumps, catheters, surgical tools
Tobacco Products	Flavor compounds in cigarettes, contaminants testing, substantial equivalence
Nanotechnology	Method development and research activities
All products	Private lab package reviews Analysts-on-inspections

ORA works closely with all of our FDA Product Centers, beginning with CFSAN and on down the line:

Two ongoing foodborne outbreak examples with intensive field lab involvement include:

- Cyclospora in cilantro associated with 546 laboratory-confirmed cases from 31 states between May and September 2015 and while there have been no deaths reported by the CDC thus far, there are 21 hospitalizations
- Salmonella in cucumbers associated with 488 cases in 32 states, 2 deaths and 102 hospitalizations

Both of these foodborne outbreak examples illustrate intense ORA field lab involvement, sample analysis, genotyping, and trace back.

Moving down the chart to Pharmaceutical Products, one example you may be familiar with would be the 2012 meningitis outbreak related to contaminated injectable steroids at compounding pharmacy in Massachusetts associated with more than 60 deaths in 20 states.

We'll cover examples from some of the other product Centers that reside within ORA's lab portfolio later in the presentation.

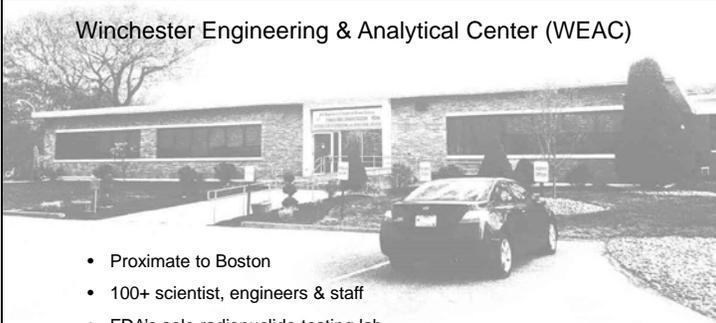


Our ORA field scientists, chemists, microbiologists, physicists, engineers are at work doing bench tests, conducting sample analyses, methods development and research activities germane to critical FDA priorities.

Slide 6

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### Winchester Engineering & Analytical Center (WEAC)

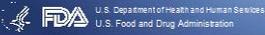


- Proximate to Boston
- 100+ scientist, engineers & staff
- FDA's sole radionuclide testing lab
- FDA's sole medical device testing lab
- FDA's sole radiation emitting electronic product testing lab

I'm happy to report design activities are nearing completion to provide new state-of-the-art facilities infrastructure investments for our work at WEAC.

We are:

- Proximate to Boston
- 100+ scientists, engineers, and staff
- FDA's sole radionuclide testing lab
- FDA's sole medical device testing lab
- FDA's sole radiation emitting electronic product testing lab



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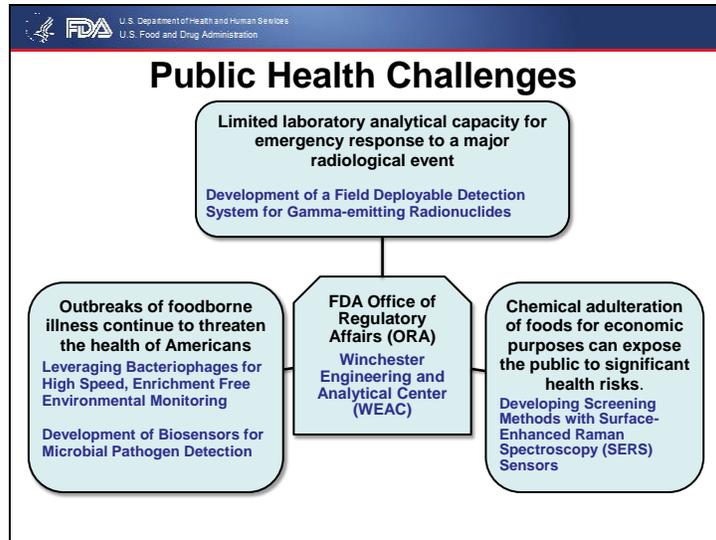
## FSMA...calls for faster analytical tools

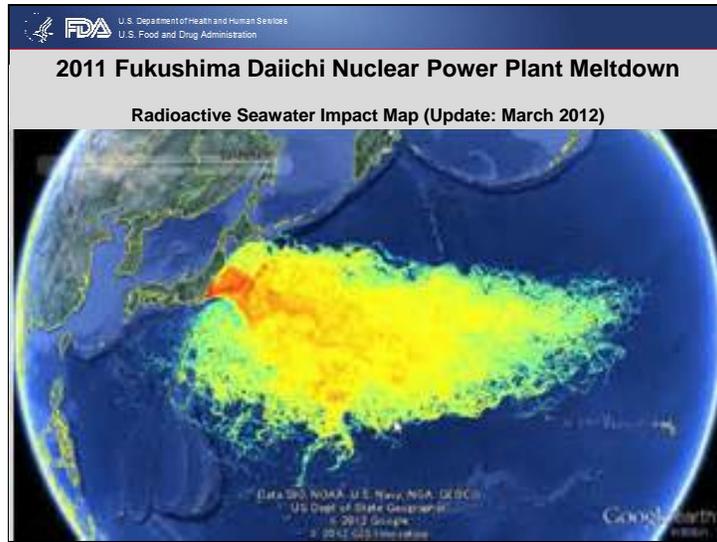
**FDA Food Safety Modernization Act (FSMA)**

- Improve Capacity to Prevent Food Safety Problems
- Increase Capacity to Undertake Analyses of Food Samples Promptly After Collection
- Identify New and Rapid Analytical Techniques, Including Commercially-available Techniques that can be Employed at Ports Of Entry

The FDA Food Safety Modernization Act of 2010 (FSMA) was signed into law by President Obama on January 4, 2011. It aims to ensure the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing it.

Allow me to introduce you to my colleague, Dr. Pat Regan who will reflect upon some of the public health challenges we face, and showcase some of the innovative responses underway.





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**U.S. NRC**

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## FOOD

### Food Defense

### Emergency Response

Radionuclides in Food  
Nuclear Surveillance

### Map of Power Reactor Sites

List of Power Reactor Units

#### U.S. Commercial Nuclear Power Reactors—Years of Operation

The map shows the distribution of commercial nuclear power reactors across the United States. Reactors are marked with triangles of varying sizes and colors, corresponding to their years of commercial operation. The legend indicates that the size of the triangle represents the number of reactors (0, 10, 42, 52) and the color represents the years of commercial operation (0-9, 10-19, 20-29, 30-39).

Years of Commercial Operation	Number of Reactors
0-9	0
10-19	10
20-29	42
30-39	52

Reactor: U.S. Nuclear Regulatory Commission

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## Radio-analytical Challenges

- Limited radio-analytical capacity nationwide due to:
  1. Resources required for establishing and sustaining laboratory infrastructure and expertise
  2. Global shortage in radio-analytical expertise
- Traditional analytical methods require laboratory setting



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## Preparedness and Solutions

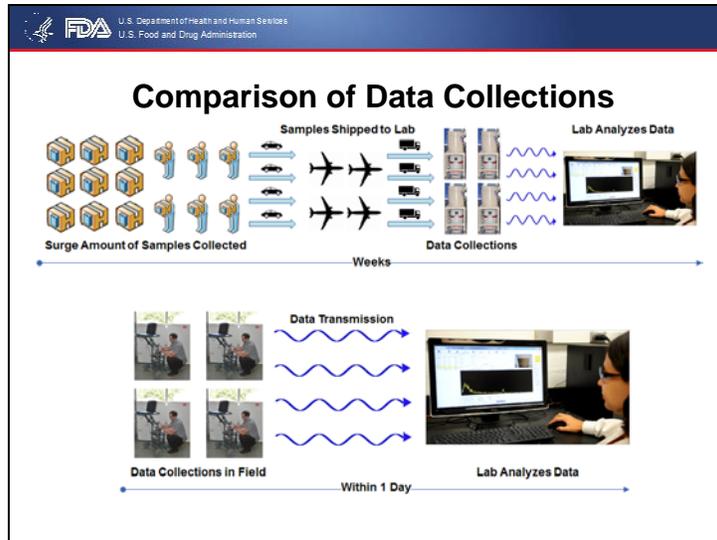
Leverage novel ideas, advanced technologies, collaborations with industry:

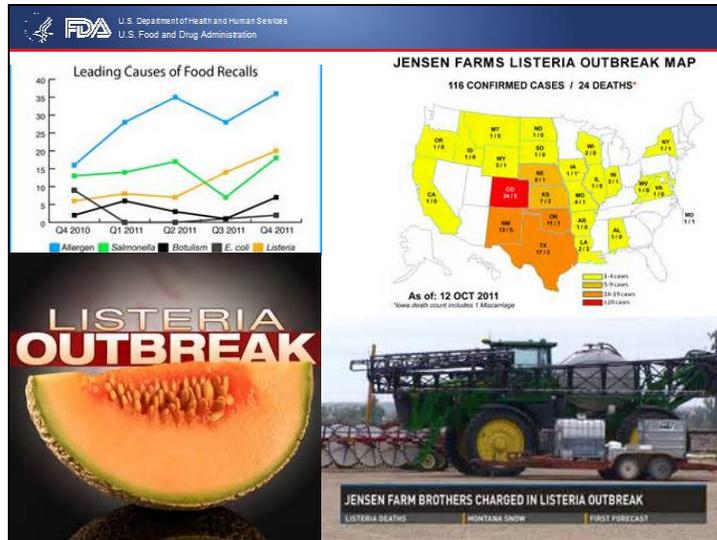
- Develop & build analytical systems addressing expertise shortage
- Increase nation's radio-analytical capacity

Design & build features:

- Enabling field applications portability
- Free of knowledge and experience requirement of end-user
- Light-weight, modular, scalable, mobile
- Robust
- User-friendly
- Laboratory analytical data quality
- Real time in-situ high throughput sample data collections







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sample6

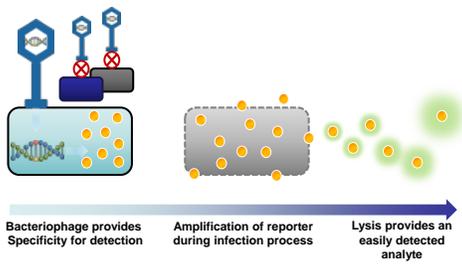
### Leveraging Bacteriophages for High Speed, Enrichment-free Environmental Monitoring

**Current Practice**

- Sample collection and off-site shipping (12–24h)
- Existing lab microbiological tests require enrichment (24–48 hours)
- Process lengthens the feedback cycle and increases risk

**Benefits of this System**

- Detects environmental *Listeria* contamination
- Time to result < 8 hrs
- Automatic live/dead discrimination



**Bacteriophage provides Specificity for detection**

**Amplification of reporter during infection process**

**Lysis provides an easily detected analyte**

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## Development of Biosensors for Microbial Pathogen Detection

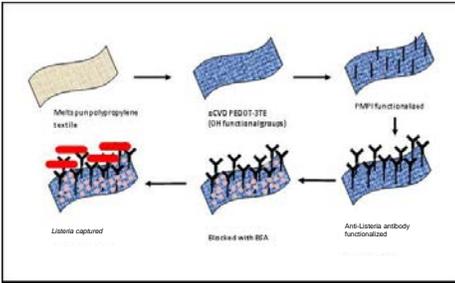
**Current Practice**

- Conventional methods require *several days* to obtain a result.
- Process lengthens feedback cycle & increases risk.



**Benefits of this System**

- Nanomaterial being utilized to create a variety of biosensor types *to decrease assay time*.
- Reduced assay time, amenable to detection of other pathogens.



The diagram illustrates a six-step process for developing a biosensor for microbial pathogen detection. It starts with a 'Melt spun polypropylene textile' (represented by a yellow fabric). This is followed by 'sCVD PEDOT-3TE (OH functional groups)' (represented by a blue textured fabric). The next step is 'PMP functionalized' (represented by a blue fabric with small black dots). This is followed by 'Anti-Listeria antibody functionalized' (represented by a blue fabric with Y-shaped antibodies). The next step is 'Blocked with BSA' (represented by a blue fabric with red Y-shaped antibodies). The final step is 'Listeria captured' (represented by a blue fabric with red Y-shaped antibodies and small red dots representing captured bacteria).

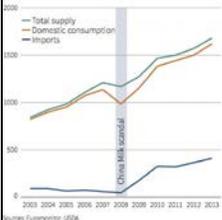
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### China's formula for milk

Baby formula made by foreign brands is in great demand in China after the 2008 scandal when six infants died. Since then whole milk powder imports have jumped almost 800 percent.

#### DAIRY WHOLE MILK POWDER

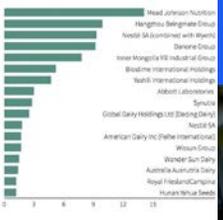
Thousand tonnes



Year	Total supply	Domestic consumption	Imports
2003	~100	~100	~0
2004	~150	~150	~0
2005	~200	~200	~0
2006	~250	~250	~0
2007	~300	~300	~0
2008	~350	~350	~0
2009	~400	~350	~50
2010	~450	~350	~100
2011	~500	~350	~150
2012	~550	~350	~200
2013	~600	~350	~250

#### CHINA'S \$12.5BLN INFANT FORMULA SECTOR

Top players - percent



Company	Percentage
Mei Johnson Nutrition	~15%
Hangzhou Baiguate Group	~12%
Nestlé SA (owned) with Weyu	~10%
Danone Group	~8%
Inner Mongolia Yili Industrial Group	~7%
Beilme International Holdings	~6%
WuXi International Holdings	~5%
Amkor Laboratories	~4%
Synutra	~3%
Global Dairy Holdings Ltd (Dairy Dairy)	~2%
Nestlé SA	~1%
American Dairy Inc (Dairy International)	~1%
WuXi Group	~1%
Wonder Sun Dairy	~1%
Aurinia Australia Dairy	~1%
Royal FrieslandCampina	~1%
Human Nutrit Seeds	~1%



**MELAMINE**





Source: Euromonitor, USDA  
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### Developing Screening Methods Using Surface-Enhanced Raman Spectroscopy (SERS) Sensors

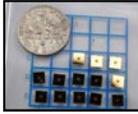




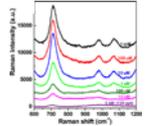


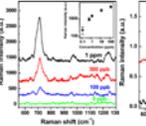
- Methods are simple; target user is non-scientist
- Sample preparation is simple, user friendly, green solvents

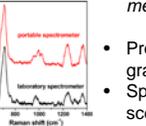




- Instrumentation: small/portable







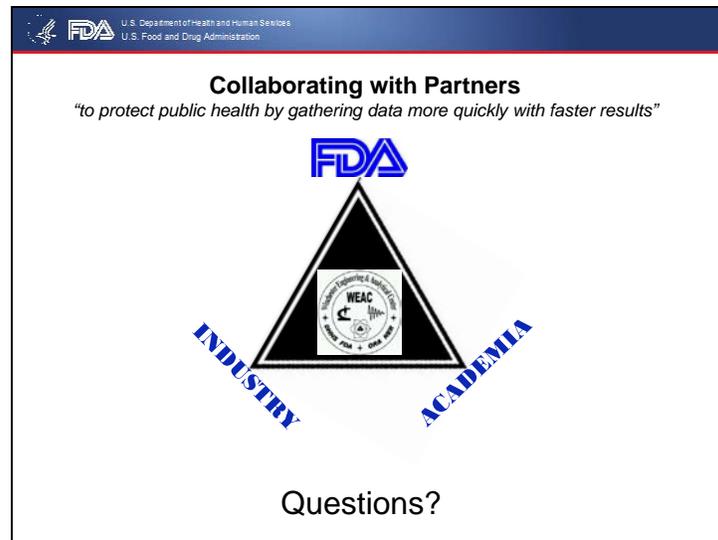
- Initial focus: adulteration of milk, milk products with small molecule(s) containing a high nitrogen content; e.g. *melamine in infant formula*







- Provide end user with graphic/text interface
- Spectral data behind the scenes



In conclusion, allow me to emphasize a few points:

First, that we are proud of our contributions to promoting and protecting public health in ORA at our Boston-based WEAC lab.

Second, that we partner with some of the brightest intellects and best academic minds of our day, together with established and emerging start-ups from the private sector, often spin-offs from our MIT and Harvard collaborators in what many of you have written about ...as a burgeoning BioTech and innovative science space in the Greater Boston Area.

This Triumvirate, developed in Boston over the past eight-years, portends to aid in propelling these and other new testing and diagnostic platforms out of the lab and into U.S. commerce, some of which, I believe will be "game changers" in terms of saving lives and protecting public health.

To accomplish this, we work closely with Alice Welch and her Technology Transfer team in the Office of the Chief Scientist.

For information on additional work underway, not presented here today, I refer you to a YouTube video created by the National Archives and Records Administration (NARA) - Your Federal Government cable TV series "telling the good government story" EPISODE 5 - Interview with FDA Director Brian Baker.

Thank you, and when next visiting Boston, do consider working with the FDA Office of Media Affairs to request a tour of our lab.