FDA Science Board Sub-Committee: Food Emergency Response Laboratory Network (FERN)

November 15, 2016

FERN Sub-committee

- FDA Science Board established subcommittee to evaluate current investments in:

  1) FERN cooperative agreement funding program (CAP)

  2) funding for state laboratories to achieve International Organization for Standardization (ISO) accreditation.

- Goal was to ascertain how ORA can advance and establish an effective integrated laboratory network among ORA, FDA Center, and state public health and food- and feed-testing laboratories.

Sub-committee Members

- **Barbara Kowalcyk, PhD,** *RTI International*
- Mark McLellan, PhD, *Utah State University*
- Lynn Goldman, MD, *George Washington U*
- David Goldman, MD,MPH, *USDA*
- Harvey Holmes, PhD, *CDC*
- Connie Weaver, PhD, *Purdue University*

Charge to Sub-committee

An evaluation/recommendations report that:

- Evaluates existing cooperative agreements with APHL, AFDA and AAFCO to further regulatory lab integration.
- Identifies how the Agency can continue to build a sustainable integrated laboratory network that meets the public health and regulatory needs under an integrated national food safety system.
- Assesses technical areas of data sharing, proficiency testing, method harmonization, quality and reporting of analytical results.
- Provides recommendations to facilitate the rapid and efficient interchange of laboratory results in an integrated laboratory network.

Sub-committee Questions

1. How can we further promote and build an integrated laboratory network among the food regulatory laboratories of ORA, FDA Centers and state health departments as part of developing a stronger system of mutual reliance in the food and feed program?
2. What are the appropriate scientific and technical capabilities required to facilitate the sharing of laboratory data between public health and regulatory agencies in a timely and efficient manner to enhance consumer protection?
3. What are the realized benefits and limitations to these FERN Network, laboratory accreditation, and Laboratory Associations cooperative agreements and how can we improve upon the current utilization of the results of these agreements?
4. How impactful to public health has this building of an integrated laboratory network and promotion of our state labs been to date?
5. What would be appropriate metrics to measure effectiveness of integration strategies in promoting national integrated laboratory system?

Evaluation Process

- Reviewed background materials.
- Interviewed FDA, staff from state and local laboratories, and others.
- Conducted site visit.
- Met regularly via conference call to review documents and conduct interviews.

FERN Mission and Objectives

- Created in 2004.
- Mission is to integrate nation's food testing laboratories at federal, state, local, tribal levels into network that is able to respond to emergencies involving biological, chemical, or radiological contamination of food.
- Objectives
  - Detect threat agents in food supply;
  - Prepare nation's laboratories to be capable of responding to food-related emergency events;
  - Provide surge capacity that allows nation to respond to food emergency events; and
  - Enhance the ability of nation to restore confidence in food supply after emergency or in response to a threat.

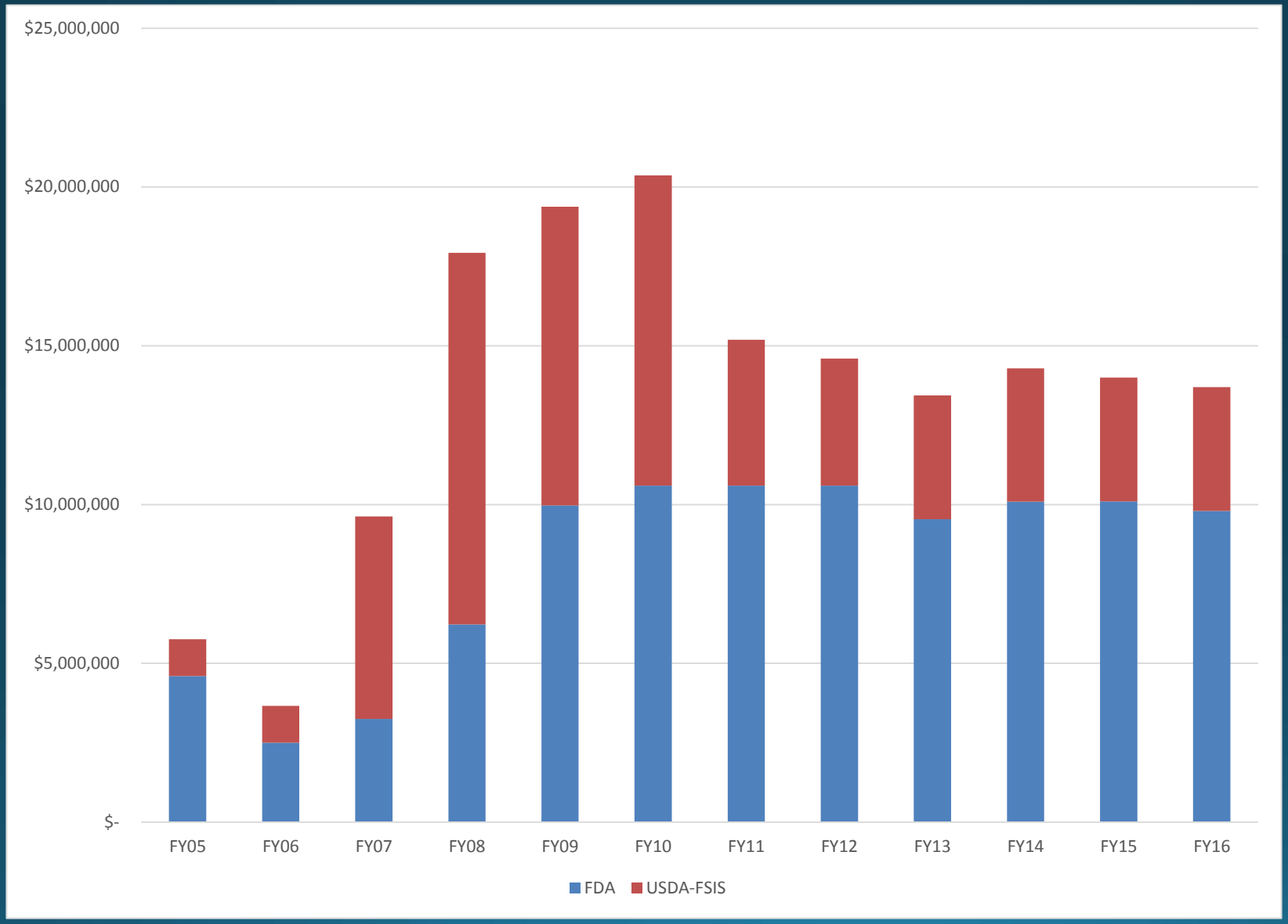
FERN Activities

- Activities
  - Conduct laboratory testing and targeted surveillance programs;
  - Develop standardized food testing methodologies;
  - Provide chemical, microbiological, and radiological training activities;
  - Conduct proficiency testing; and
  - Facilitate communication among member laboratories.
- Federal, state, local, tribal, and territorial government food-testing laboratories that have chemical, biological, and/or radiological analytical capabilities can apply.
- Coordinated by FDA and USDA-FSIS.

FERN Participation and Funding

- 170 member laboratories; 33 laboratories are funded
- $200 million has been invested in FERN since 2004.
  - FDA: $95.8 million
  - USDA-FSIS: $69 million
- Competitive cooperative agreement funding mechanism
  - (FDA FERN Cooperative Agreement Continuation Program, U18 ($10.1M, 26 awards);
  - ISO/IEC 17025:2005 Accreditation for State Food Testing Laboratories, U18 ($9.3M, 46 awards);
  - Building an Integrated Laboratory System to Advance Safety of Food and Animal Feed, U18, ($1.1M, 1 award).

FERN Funding 2005 - 2016



Building an Integrated Laboratory Network

Finding: FDA has the opportunity to continue to develop and expand the FERN network.

- **Efforts to date have resulted in stronger, more integrated food regulatory laboratory system but more needs to be done.**
- **Existing network could be leveraged to provide a higher level of training and technical support.**
- **FERN funding should be expanded to include more states and additional resources for training and travel.**
- **Important to critically evaluate how funds can best be utilized to build sustainable integrated laboratory network.**

Data Sharing

Finding: FDA should modernize its food safety information architecture to ensure safe and secure transmission of data, while encouraging and facilitating efficient data sharing.

- **FERN's data analytical capability requires an efficient sharing of the range of data types among multiple network partners.**
- **Existing data-analytics infrastructure lacks well-designed features and is impediment to full utilization of cooperative agreements.**
- **Redesign should be done within context of long-range strategic planning process as well as implementation of near-term fixes.**
- **Stakeholder engagement should be used in planning and redesign.**

Benefits and Limitations to Funding FERN

Finding: FDA's commitment to provide future funding opportunities to FERN will be required to sustain and ensure a fully integrated multilevel food-testing laboratory network.

- Increased expansion of diagnostic capacity.
- Increased capability through training, recruitment, method extension and enhancement studies.
- Loss of FDA funding would be extremely detrimental.
- Insufficient funding to replace/upgrade instruments.
- Expectation to accommodate unanticipated increases in testing without budget increases for supplies, reagents, and labor costs cause undue financial burden.
- Foundational level of support that would allow development of core competencies across laboratories.

Public Health Impact

Finding: FERN has a significant public health impact, and it is vital to maintaining public health preparedness and response.

- FERN CAP laboratories have been involved in every large food event in the United States since 2006.
- Reduced FDA's reaction time by providing improved rapid methods, analytical capacity and capability to define scope.
- Rapid recovery also provides economic benefits (e.g. reopening of Gulf waters for commercial fishing).
- Facilitated coordination and sharing of expertise and essential resources, such as technical capabilities and analytical instrumentation among laboratories.
- Could engage FERN more proactively in surveillance efforts.

Appropriate Metrics

Finding: FDA and USDA-FSIS should develop a broader range of metrics that more directly assess public health impacts, functionality of the network as a system, and other goals.

- Measuring effectiveness of FERN and national integrated laboratory system is critical for informing funding decisions as well as protecting public health.
- Choosing metrics that more specifically assess the public health impact will permit cost-benefit analyses that can show the return on this investment.
- Network- or national-level metrics could be developed around the requirements used for individual laboratories under cooperative agreements.

Recommendations

1. Developing a basic level of capability/capacity across the network is a worthwhile goal that should be supported by the federal government.
2. Efforts to build and sustain capabilities and capacities across FERN need consistent, multi-year funding.
3. FDA should develop a plan for FERN that would consider the advantages of a tiered approach designed to avoid unnecessary duplication.
4. FERN funding agencies should continue to improve their engagement with the CDC/LPRB-LRN Program Office to discuss areas of common interest and combine efforts to improve testing capacity and capability within and across networks.

Recommendations

5. FDA should develop a technology-management plan to anticipate the eventual replacement of existing instrument platforms that employ newer and more advanced diagnostic methodologies.

6. FDA should assume a holistic approach to addressing the IT and data-sharing needs of FERN partners. There is a strong public health need for an integrated information infrastructure that allows seamless transmission of data in a secure environment that facilitates rapid analytics.

7. FERN leadership should develop clear objectives and adopt metrics for both individual laboratories and the network, with appropriate targets and consensus as to what constitutes success and reflects the objectives.

Recommendations

8. FDA should convene an annual conference for FERN to engage scientists in professional education and development activities and facilitate sharing of information.

9. FERN should have the capacity to support professional travel to conferences and/or for training and development.

10. FDA and its sister agencies should work with states on best practices for hiring and retaining scientists who are needed to perform this mission-critical work.

11. FDA should regularly communicate with all eligible laboratories to increase public health preparedness and participation in FERN training efforts.

Conclusions

- FERN represents one of best national investments in:
  - Improving responsiveness of our combined federal, state, local and territorial governments;
  - Development of IFSS; and
  - Prevention of foodborne disease.
- Recommendations of this report be accepted with the utmost urgency and the specific recommendations be considered as a means of ensuring the maintenance of a safe and secure food system.

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