Partnerships to Address Global Product Safety in Public Health

Dr. Katherine Bond
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I. FDA and Globalization

II. FDA and PPPs: the Power of Collaboration

II. FDA Public Private Partnership (PPP) Case Studies
   - Global Curriculum
   - CDx
   - Global Food Safety Partnership (GFSP)

III. Challenges and Lessons Learned
FDA Regulated Products

- FDA is responsible for over $2 trillion in medical products, food, cosmetics, dietary supplements and tobacco.
- FDA-regulated products account for about 20 cents of every dollar of annual spending by U.S. consumers.
- The agency has approximately 15,700 full-time employees located around the world.
- FY 2014 budget is $4.38 billion.
Globalization by the Numbers

Volume of FDA Products Imported into the U.S.

Food
- 15% of food
- 50% of fresh fruits and 20% of fresh vegetables
- 80% of seafood

Devices
- At least 30% of all medical devices

Drugs
- 40% of drugs
- 80% of Active Pharmaceutical Ingredients (API) manufacturers are located outside the U.S.
Tracking and tracing a product is complex due to the increased number of involved individuals, producers, and companies, many of which are geographically dispersed.

Growing availability of distribution channels for products – think “Internet.”

Always the bad actors: Counterfeiting of products for economic or other reasons.
Power of Collaboration

Why does FDA partner?

- Meet regulatory challenges posed by globalization – regulatory cooperation and systems strengthening
- Leverage existing resources
- Enhance international engagement to achieve mutual programmatic goals
- Collaborative approaches to shared problems
Three Partnerships for Global Product Safety

Global Curriculum

CDx

Global Food Safety Partnership

Developing a Global Curriculum for Regulators

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Promoting and Protecting Public Health
The Challenge

- Currently, there is no curriculum that we know of that underlies education and training of regulatory professionals that can be applied in locations throughout the world.

What is the Global Curriculum?

- A set of fundamental regulatory competencies and a curriculum that defines a scope of work and body of knowledge required to effectively carry out regulatory duties, targeted at low and middle income countries.

Partners

- Lead Partners: The International Food Protection Training Institute (IFPTI) and the Regulatory Affairs Professionals Society (RAPS)
- Other Partners: Critical Path Institute, Drug Information Association (DIA), FDA, Bill and Melinda Gates Foundation, Pan American Health Organization (PAHO), and World Health Organization (WHO)
Global Curriculum: 2 Phases

Phase 1

Started
September 2013

1. Identification and selection of two expert panels
2. Draft and validate competency framework
3. Develop global curriculum framework
4. Develop gap assessment tool
5. Draft final report; transfer to WHO

Phase 2

Ends
September 2015

1. Expert Panel Review of Curriculum
2. Continued Maintenance, Publication, and Dissemination to WHO Member States
3. Coordination with Steering Committee
4. Gap Assessment Tool Alignment
5. Develop Training Course
6. Develop Training Alignment Tool
7. Pilot and Refine Tool
8. Final Report
## Global Curriculum: Competency Framework

**Audience:** A government official at the basic/fundamental level (minimally competent)

A government official at this level should be able to:

<table>
<thead>
<tr>
<th>Basic Level</th>
<th>Food (farm-to-fork) (BF)</th>
<th>Medical Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>BF 1</td>
<td>Identify the indicators of out-of-control conditions (hazards and risks) in food facilities.</td>
<td>BI 1</td>
</tr>
<tr>
<td>BF 2</td>
<td>Explain the importance of good practices along the food chain e.g., GAPs and GMPs, sanitation controls, and prerequisite programs.</td>
<td>BI 2</td>
</tr>
<tr>
<td>BF 3</td>
<td>Interpret scientific data within the framework of a risk-based approach and regulatory requirements.</td>
<td>BI 3</td>
</tr>
<tr>
<td>BF 4</td>
<td>Describe the biological and chemical hazards commonly associated with food and their public health impacts.</td>
<td>BI 4</td>
</tr>
<tr>
<td>BF 5</td>
<td>Describe the potential sources of biological and chemical hazards and how the sources change along the value chain.</td>
<td><strong>Pre-Approval/Approval (BA)</strong></td>
</tr>
<tr>
<td>BF 6</td>
<td>Articulate the importance of inspections carried out under food safety regulatory authority. BF 6.1 Facilities (sanitation, design, equipment, etc.) BF 6.2 Primary production BF 6.3 Import</td>
<td>BA 2</td>
</tr>
<tr>
<td>BF 7</td>
<td>Discuss transmission of foodborne illnesses.</td>
<td>BA 3</td>
</tr>
<tr>
<td>BF 8</td>
<td>Describe controls developed from a hazard analysis.</td>
<td><strong>Post-Approval (BP)</strong></td>
</tr>
<tr>
<td>BF 9</td>
<td>Explain the seven principles of HACCP.</td>
<td>BP 2</td>
</tr>
<tr>
<td>BF 10</td>
<td>Describe how to construct, implement, and reevaluate HACCP-based systems.</td>
<td><strong>Regulatory Information and Strategy (BI)</strong></td>
</tr>
<tr>
<td>BF 11</td>
<td>Describe processes or procedures necessary for food safety for unprocessed or minimally processed ready-to-eat foods.</td>
<td>BA 5</td>
</tr>
<tr>
<td>BF 12</td>
<td>Discuss preventive control measures that can be utilized to minimize allergen hazards in foods.</td>
<td>BA 6</td>
</tr>
<tr>
<td>BF 13</td>
<td>Describe food allergens and related regulatory provisions.</td>
<td>BA 7</td>
</tr>
</tbody>
</table>

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Promoting and Protecting Public Health
Counterfeit Detection Device (CDx)

The Challenge
- Global public health threat posed by substandard and falsified medical products

What is CDx?
- Innovative detection technology to *inexpensively, rapidly and non-destructively* screen pharmaceutical product packaging and dosage forms
  - Developed by FDA’s Forensic Chemistry Center
  - Uses variety of wavelengths of light, including UV to IR
  - Additional benefits: handheld, portable, minimal scientific or technical background required, minimal training required

Partners
- Skoll Global Threats Fund, U.S. Pharmacopeial Convention (USP), National Institutes of Health (NIH), Centers for Disease Control (CDC), U.S. Agency for International Development (USAID) President’s Malaria Initiative (PMI), Corning Inc., Reagan-Udall Foundation
CDx: Three Phases

1st Piece

PPP created to conduct field tests of CDx in Ghana
1. Skoll Global Threats Fund, USP, NIH, CDC, PMI through USAID
2. Field tests concluded in September, currently evaluating data

2nd Piece

Cooperative Research and Development Agreement (CRADA) signed with Corning, Inc., to optimize CDx design

3rd Piece

Reagan-Udall Foundation hosted stakeholders meeting to discuss building a potential partnership and:
1. Share lessons learned from past/ existing Product Development Partnerships (PDPs)
2. Define aspects that lend to making a PDP successful
3. Identify appropriate models and partners for CDx deployment
The Challenge

- Unsafe food sickens billions of people each year; compounds threats of hunger, malnutrition and poor health; causes major economic loses; and, poses barriers to trade.

What is GFSP?

- An innovative public private partnership est. in 2012 with the World Bank dedicated to improving the safety of food worldwide, focusing on middle income and developing countries to:
  - improve public health;
  - reduce health and economic risks to consumers and economic losses to businesses;
  - create economic opportunity; and
  - facilitate trade.
## GFSP Current Partners

### Governments *(Donors in red)*
- Canada
- Denmark
- Netherlands
- Food Standards Australia New Zealand (FSANZ)
- United States *(FDA & USAID)*

### Multilateral & International Organizations
- COMESA
- FAO
- Network of Aquaculture Centers in Asia-Pacific (NACA)
- UNIDO
- WHO
- World Bank/IFC

### Governments (Pilot countries)
- China
- Indonesia
- Kazakhstan
- Malaysia
- Vietnam
- Zambia

### Industry and Associations
- Mars Inc.
- Waters Corporation
- Cargill
- Food Industry Asia (FIA)
- General Mills
- Grocery Manufacturers Association (GMA)
Benefits of Partnering

- Scales up the world’s response to food safety challenges

<table>
<thead>
<tr>
<th>Private Sector</th>
<th>Public Sector</th>
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<tr>
<td>✓ Reduce Risks and Lower Costs</td>
<td>✓ Protect Public Health</td>
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<tr>
<td>✓ Contribute to Global Thought Leadership</td>
<td>✓ Advance Trade</td>
</tr>
<tr>
<td>✓ Have a “Seat at the Table”</td>
<td>✓ Enhance Food Security</td>
</tr>
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</table>
Challenges and Lessons Learned

• Clarity of goals and shared objectives

• Space to cultivate trust and confidence with a diverse group of stakeholders

• Sustainability of partnerships through new models

• Mechanisms for strategic coordination among partners to avoid duplication and reduce gaps
Questions?

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