Science Board Subcommittee Report on “Ensuring Safe Foods and Medical Products through Stronger Regulatory Systems Abroad” from the Institute of Medicine

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Background

The number and amount of products brought into the US has increased threefold between 2002 and 2011 (Gill, 2011). It is estimated that 80% of pharmaceutical ingredients and 40% of finished drugs come from abroad. Similarly, around 85% of the seafood, 39% of the fruits and nuts, and 18% of the vegetables that Americans buy are imported from abroad (proportion of US consumption - IOM, 2012). Many of these products are coming from emerging markets with limited regulatory environments.

A recent IOM report, Ensuring Safe Foods and Medical Products through Stronger Regulatory Systems Abroad, highlighted several regions with emerging economies, including China, India, Latin America/Brazil, and sub-Saharan Africa/South Africa. Product importation numbers are dynamic and vary by region. Enclosed are examples of major product lines from specific regions (see Appendix A). Of note, most of imported vegetables come from Mexico; while India is a major exporter of human drugs; and China provides a significant portion of animal feeds, biologics (i.e. vaccines and blood products), and seafood. (Appendix) These represent a sample of the myriad of products coming into the United States and overseen by different regulatory systems.

In addition there are other emerging factors that add to the challenges of regulating imported products such as the complexity of the global food and medicinal product supply chain and the call for changes in the American diet. The complexity of our food system has increased enormously in recent decades. For example, a simple cup of soup may contain as many as 40 different ingredients, which may have been handled, processed and packaged by as many as 500 different companies located all over the world. It would only take a problem in one of these 500 chain members’ processes to damage the entire supply chain (Miller, 2009).

Also, the Department of Agriculture (USDA) and the Department of Health and Human Services (HHS) revises the Dietary Guidelines for Americans every 5 years (USDA and HHS, 2010). The 2010 “Health Plate” Dietary Guidelines focus on balancing calories with physical activity, and encourage Americans to consume more healthy foods like vegetables, fruits, whole grains, fat-free and low-fat dairy products, and seafood, and to consume less sodium, saturated and trans-fats, added sugars, and refined grains. Currently, US agricultural production cannot address this demand in the medium term. In order to fulfill the US dietary guidelines, imported products are necessary but potentially have safety risks. Similarly, the demand for medicinal products for a variety of chronic disease conditions such as hypertension, diabetes, and cancer will increase due to an aging U.S. population. The expansion of emerging pharmaceutical markets globally is expected to account for 30% of the global spending on medicines by 2016 (IMS Institute, 2012).

FDA recognizes that its mission objectives are linked to the success and capacity of counterpart agencies in the emerging economies to fulfill their mandates. Several common problems may impair the regulatory environment in these countries and include lack of adherence to international standards, inadequate or non-existent legal foundations, competing or overlapping governmental responsibilities, poor surveillance systems, and inadequately trained personnel.
The recent IOM report, Ensuring Safe Foods and Medical Products through Stronger Regulatory Systems Abroad (IOM, 2012), identified several strategies to bridge these gaps:

1. Identify gaps in regulatory infrastructure and invest in strengthening the capacity of regulatory systems in developing countries
2. Focus and strengthen surveillance systems
3. Strengthen the regulatory workforce, particularly with respect to the development of a global curriculum for regulatory professionals

The charge of this Global Health subcommittee was to review the Institute of Medicines (IOM) Report “Ensuring Safe Foods and Medical Products through Stronger Regulatory Systems Abroad” and generate enthusiasm and momentum among partners external to the FDA to strengthen regulatory systems especially in low and middle income countries. To address this issue, we attempted 1) to understand the burden of disease and export challenges from major exporting countries to the US, 2) to consider ways to increase awareness of product safety and quality in these countries, and 3) to identify promising approaches to encourage and strengthen regulatory systems in these exporting countries.

1. Global Burden of Disease and Export Challenges

There has been a series of attempts to characterize the burden of disease by region. One recent attempt noted that the three leading risk factors for global disease burden were high blood pressure, tobacco smoking, and alcohol use (Lim, Vos, Flaxman et. al., 2012). In 1990, the leading risks were childhood underweight, household air pollution from solid fuels and tobacco smoking. From the 2012 global burden of disease study, the magnitude of risk for childhood communicable diseases (i.e. unimproved water and micronutrient deficiencies) decreased. These risks varied by region. For example with the increased urbanization in China over the past two decades, there has been a rapid rise in non-communicable diseases attributed to poor diet, high blood pressure, tobacco use, and cholesterol. Characterizing the disease burden risk has highlighted significant changes in diseases and public health interventions over time. Overall, there is a shift away from communicable diseases of children toward more non-communicable diseases in adults. These epidemiologic shifts likely reflect improving conditions often driven by improving economies in impoverished areas. That said, there are still significant areas of poverty in various regions, with the majority of the world’s poor residing in middle income countries. Many countries where the global burden of disease is significant have limited infrastructure and support for food and medical product regulatory oversight.

These initial attempts to characterize the disease burden provide a needed baseline to assess progress and highlight additional areas for study. One of the challenges with these macro-level studies is the inability to quantify some exposures that are either not routinely measured or are difficult to measure. With these changing economies, there is now a need to study the impact of ineffective regulatory and government infrastructures on public health in developing countries. Three general aspects need attention: the ability of governments to monitor food and medical product safety and quality issues at source (role of our FDA); a thorough analysis of the causes of food borne outbreaks and adverse events associated with medical product use with the needed epidemiological and laboratory support for
disease surveillance (role of our CDC); and lastly, the need to strengthen public health law across the legislative-enforcement spectrum. In particular, many developing countries might have laws on their books that are never backed by “law on the streets”. Reasons for this latter discrepancy require attention. Are there resources or models from wealthier countries that can encourage the building of legal infrastructures that would support the oversight of the food and medical product sectors? Ultimately, there is a need for global cooperation and information sharing in the global marketplace.

China, India, South Africa, and Brazil/Mexico were identified as key US import regions in the IOM report. The report also highlighted a number of critical issues from these various countries and regions. These critical areas included: 1. adherence to international standards, 2. controlling food supply chains, 3. infrastructure, 4. laws, 5. workforce, 6. Fragmentation of regulatory infrastructure, 7. surveillance, 8. communication, and 9. political will. In an attempt to understand these critical areas and the regulatory challenges across these important export countries, we tried to summarize the common elements (Appendix B). Knowing these elements will help identify intervention strategies from the IOM report.

a) Adherence to international standards

Three of the four regions had difficulty adhering to Food Standards. As measured by border rejections, the economic impact of adherence ranged from 1.8 billion dollars in Latin American (Jaffee and Henson, 2001) countries to $8 billion in China (Lu, 2005). Lack of adherence has been attributed to too few scientists to develop in-country standards and the difficulty of overseeing an enormous number of farmers and industries in these developing regions. Unfortunately, there is limited data on the specific number of regulators by country. Often these individuals are part-time and serve as generalists. Using surrogate available data from OECD the number of researchers per 1000 employed workers was 1.6, 0.9, 1.4, and 9.5 for China, Mexico, South Africa and the United States respectively (OECD, 2013).

b) Controlling Supply Chains

Three of the four regions have food supply chain issues and two of the four regions had medical product supply chain challenges. This included inadequate refrigeration, food spoilage, and separate supply chains for export and domestic markets, market dichotomy. For medical products, poor inventory or cold chain issues were cited. This is a clearly recognized issue with some organizations such as the Grocery Manufacturers Association providing resources such as the “Food Supply Chain Handbook” to improve supply chain integrity for companies (GMA, 2008).

c) Infrastructure

Two of the four regions were identified as having insufficient laboratory, manufacturing and market infrastructure. This included lack of food testing laboratories and quality assurance laboratories. Recent efforts by FDA have strengthened laboratory capacity through scientific exchanges and sharing of technologies. This is evident with recent collaborations with Mexico National Service of Health, Food Safety and Agro-Alimentary Quality (SENASICA) officials (FDA, 2013)Efforts to improve pharmovigilance or surveillance of medical products are being attempted as well.
d) Laws

In IOM workshops held in China and India, participants felt that their countries had adequate legal regulatory frameworks in place. The challenge was enforcing existing laws because of limited staffing, inadequate infrastructure, and lack of political will. In most of the regions, there was limited civil liability due to concerns about corruption and affordable access to legal representation.

e) Workforce

All four regions reported that they had insufficient regulatory/technical staff either through lack of training or ability to retain. In response to this gap, the FDA has supported a multi-stakeholder group, through a contract to the International Food Protection Training Institute (IFPTI) and the Regulatory Affairs Professionals Society (RAPS), to lead the development of a global curriculum for regulators with the goal of ultimately creating a global regulatory professional identity and competency trained workforce. This can contribute to sustainable regulatory capacity development around the globe and ultimately help protect and promote global public health by ensuring the safety of medicines.

Determining optimum workforce numbers is contingent on several factors including infrastructure, training, salary, and legal framework. Recently the U.S. has tried to document food safety epidemiologic and public health laboratory capacity (MMWR, 2011; Jones TF, 2013). This includes efforts that support the development of performance standards for foodborne disease outbreak response (CSTE 2010). As expected there is variability among states and a recommended need for more trained epidemiologists working in food safety (MMWR, 2011; Jones TF, 2013). Unfortunately, there is no matching data from the key importing countries. A recent report on food safety issues in China highlights a couple of key issues. In 2012, 6,685 major food poisoning incidents were officially reported in China. Conversely, the number of incidents reported just among FoodNet sites (representing 15% of the US population) was over 19,000 cases (Lam 2013). Globally, there is an underreporting of events or incidents. As is the situation in China, the magnitude of the food sector is huge as well as the variability of size of the various manufacturing and processing enterprises.

f) Fragmentation of Regulatory Infrastructure

In two regions, there are regulatory authorities at multiple levels of government (federal, provincial and municipal). Sometimes the regulatory authorities would have overlapping or conflicting regulatory authority.

g) Surveillance

Three of the four regions identified deficiencies in drug and device surveillance. This included lack of infrastructure for reporting or what to report and to whom. This is especially true for combating substandard, falsified and counterfeit drugs and medical products and supply chain threats. FDA leverages and helps promote information sharing platforms such as the WHO Global Surveillance and Monitoring System which can facilitate real-time information sharing during investigations of counterfeiting incidents enabling developing countries to become more vigilant about reporting and taking regulatory action against a product. Most regions identified deficiencies in vaccine surveillance
programs and an inability to convey trust in vaccine safety and efficacy. In addition, broad efforts are underway to improve food borne disease surveillance through endeavors as PulseNet International, the Global Foodborne Infections Network, the Global Microbial Identifier, and the 100k Foodborne Pathogen Genome Project from a variety of partners such as WHO, FAO, CDC, FDA, USDA, and academic institutions. These efforts are largely hampered by limited funds and existing infrastructure. Efforts to improve foodborne disease surveillance include regional efforts to support laboratory training, inter-country communication, and exportation of novel identification techniques. Additionally, the rapid developments in biotechnology have raised concerns about “dual-use” issues and the potential for food or product adulteration or contamination. Improved epidemiologic and molecular surveillance activities are needed to address these concerns.

h) Communication

Most regions identified insufficient communication between regulatory agencies and the public as an issue. Government transparency in identifying or revealing potential regulatory issues or problems with products was also cited as an issue. Some regions also noted lack of communication with counterpart regulatory agencies in neighboring countries.

i) Political Will

As expected, most regions cited competing priorities and limited budgets as an issue affecting regulatory oversight of food and medicinal products. Some regions acknowledged ongoing problems with corruption and government accountability, which have been highlighted by several high-profile cases in China. The most prominent case was the 2008 scandal involving the contamination of milk and baby formula with melamine that resulted in several infant deaths and thousands of illnesses. Corruption played a key role and a former State Food and Drug Administration (SFDA) commissioner was sentenced to death and several other high ranking officials were sentenced to jail for taking bribes. At local level, the most significant example was related to the contamination of medical products including drugs, biologics, and medical devices. In 2012, the former heads of Zhejiang FDA were sentenced to jail for taking bribes and corruption.

The Transparency International’s Corruption Perceptions Index measures the perceived levels of public sector corruption in countries worldwide. Based on expert opinion, countries are scored from 0 (highly corrupt) to 100 (very clean). Worldwide, the average score is 43 and 70% of countries score less than 50 out of 100. The index scores of the major global partners highlighted are in the associated table.
Table 1. Highlighted Country Information:

<table>
<thead>
<tr>
<th>Rank</th>
<th>Country/Territory</th>
<th>Score</th>
</tr>
</thead>
<tbody>
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<td>19</td>
<td>United States</td>
<td>73</td>
</tr>
<tr>
<td>69</td>
<td>South Africa</td>
<td>43</td>
</tr>
<tr>
<td>69</td>
<td>Brazil</td>
<td>43</td>
</tr>
<tr>
<td>80</td>
<td>China</td>
<td>39</td>
</tr>
<tr>
<td>94</td>
<td>India</td>
<td>36</td>
</tr>
<tr>
<td>105</td>
<td>Mexico</td>
<td>34</td>
</tr>
</tbody>
</table>

Transparency International Corruption Perceptions Index 2013

This table measures the perceived levels of public sector corruption in six countries in 2013 (United States, South Africa, Brazil, China, India and Mexico) on a scale of 0-100, where 0 means that a country is perceived as highly corrupt and 100 means it is perceived as very clean. In this table, the U.S. is ranked the highest at 19, with a score of 73, South Africa and Brazil are ranked at 69, with a score of 43, China is ranked 80, with a score of 39, India is ranked 94, with a score of 36, and Mexico is ranked 105, with a score of 34.

In summary, there is a shifting global burden of disease in many potential export countries. This is largely due to economic improvements in these countries. Continued improvement need the support of responsive regulatory systems.

2. Consumer Awareness of Food Safety or Product Safety in Countries Exporting to the U.S.

It has been observed that, as countries develop, the emerging middle class have higher expectations for product quality and safety. Evidence of this can be found by examining the number of media reports related to outbreaks and product quality. A review of Factiva media reports (a full text source for global news and business information) from May 2012 through May 2013, identified 4,871 reported documents of “salmonella” and “outbreak” mentioned worldwide (Andre Nault, information specialist, personal communication, University of Minnesota).

Table 2. Reported documents in the media by selected Countries

<table>
<thead>
<tr>
<th>Select Countries</th>
<th>Document Count</th>
<th>Country Population 2009 (estimated, 000)</th>
<th>Rate*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Netherlands</td>
<td>444</td>
<td>16,592</td>
<td>2676</td>
</tr>
<tr>
<td>Canada</td>
<td>360</td>
<td>33,573</td>
<td>1072</td>
</tr>
<tr>
<td>United States</td>
<td>1798</td>
<td>314,619</td>
<td>571</td>
</tr>
<tr>
<td>Malaysia</td>
<td>27</td>
<td>27,468</td>
<td>98</td>
</tr>
<tr>
<td>Mexico</td>
<td>45</td>
<td>109,610</td>
<td>41</td>
</tr>
<tr>
<td>Brazil</td>
<td>36</td>
<td>193,734</td>
<td>19</td>
</tr>
<tr>
<td>Thailand</td>
<td>17</td>
<td>67,764</td>
<td>17</td>
</tr>
<tr>
<td>India</td>
<td>186</td>
<td>1,198,003</td>
<td>16</td>
</tr>
<tr>
<td>China</td>
<td>116</td>
<td>1,345,751</td>
<td>9</td>
</tr>
</tbody>
</table>

* Document/Country population x 100,000
This table shows the number of reported documents in the media where “salmonella” and “outbreak” are mentioned by nine select countries (Netherlands, Canada, United States, Malaysia, Mexico, Brazil, Thailand, India and China). The first column represents the selected countries, the second column shows the total document count, the third column shows the estimated country population (multiplied by 100,000) in 2009, and the four column shows the rate which represents the document divided by the country population, multiplied by 100,000. The table ranks the countries by the rate in the fourth column. In this table, the Netherlands ranks first, with a rate of 2676, then Canada, with a rate of 1072, United States, with a rate of 571, Malaysia, with a rate of 98, Mexico, with a rate of 41, Brazil, with a rate of 19, Thailand, with a rate of 17, India, with a rate of 16 and then China, with a rate of 9.

In reviewing these reports by region, the vast majority (>70%) were from Europe, United States, and Australia. This likely reflects transparency and availability of media in the respective regions. Further, these regions have the infrastructure to detect and respond to potential public threats. There is often a cyclic relationship where detection and public engagement (e.g. media) promotes prevention and potential regulatory mechanisms. This raises several sociological questions. How and when do societies develop citizen advocacy organizations? What platforms are needed to develop this citizen advocacy?

![Figure 1. Cycle of disease detection, public advocacy, and support for regulatory infrastructure](image)

This diagram shows four circles that represent the four different components needed for regulatory infrastructure. The components are the following: (1) Disease Detection/Product Contamination, (2) Surveillance and Detection, (3) Public Awareness and Engagement, and (4) Support for Regulatory Infrastructure. The arrows between the four circles represent a cyclic relationship between these four components to improve regulatory infrastructure.
As an example, the PEW Charitable Trusts were founded on the motto of “Tell the truth and trust the people” and has three broad goals:

- Improve public policy by conducting rigorous analysis, linking diverse interests to pursue common cause and insisting on tangible results;
- Inform the public by providing useful data that illuminate the issues and trends shaping our world;
- Stimulate civic life by encouraging democratic participation and strong communities.

There appears to be an evolution as countries develop to create a “culture of safety” for their populace. The question remains on how to support public advocacy for emerging economies that export to the U.S., especially in the area of food and medical product safety. In many developing countries there appears to be a dichotomy of product availability and quality to in-country citizens versus to what is exported. This lack of domestic and export harmonization maybe an important indicator of this disequilibrium and lack of public advocacy within these countries. There are likely other regulatory measures that may indicate this disequilibrium such as limited land rights and public health laws.

In addition, there is value in supporting public-private partnerships especially in the area of drug development and manufacturing. The following is a case study supporting in country drug manufacturing and distribution.

**The Value of Public-Private Partnerships in Drug Manufacturing and Distribution**

In 2013, a new kind of public-private partnership began to produce the antiretroviral drug, atazanavir sulphate. The partnership is based on a recent agreement with New York-based drug maker Bristol-Myers Squibb. This technology transfer agreement will take effect until the patent expires in 2017. The drug will be made by Farmanguinhos, a technical-scientific unit of the Oswaldo Cruz Foundation (Fiocruz) and the Health Ministry’s largest pharmaceutical laboratory. It will be distributed in the public health network as part of the antiretroviral (ARV) cocktail therapy that is provided free of charge. This program stems from an interest by Brazil to be independent in the production of key medicines for its 194 million people and save money. Additionally, Brazil, through Farmanguinhos, has agreed to supply medication to other developing countries, in Latin America and Africa. Inter Press Service News Agency. [http://www.ipsnews.net/2012/12/brazil-enters-new-era-of-co-production-of-anti-aids-drugs/](http://www.ipsnews.net/2012/12/brazil-enters-new-era-of-co-production-of-anti-aids-drugs/)

This example demonstrates in country initiatives to support local populations as well as their export markets.

**3. Approaches to Encourage and Strengthen Regulatory Systems in Exporting Countries**

The FDA is actively engaging partner agencies in various countries to promote capacity building and ultimately improve public health. This is typified in the FDA “Global Engagement” document outlining current challenges and strategies (FDA, 2012). This includes the documented increase in clinical trials done abroad, the lack of unique identifiers for medical devices, and the dramatic number of ingredients sourced outside the U.S. FDA clearly recognizes the need to engage a broad range of stakeholders including government agencies, industries, academia, and NGO’s. This includes early detection, assessment, and management of global supply chain risks and identification of risk drivers through more
preventive, strategic approaches. This is an over-arching priority of external partnerships (see Appendix B - China Safety Initiative). In addition, there are a number of in-country and regional FDA efforts in key emerging economies. See recent examples in Appendix B. A specific example is the Disease Control Priorities Project (DCPP), which is designed to mainstream the notion that regulatory systems are an important component of in-country health systems.

Defined strategies include building and strengthening international offices, harmonizing regulatory standards, improving surveillance and response efforts, and promoting risk-based monitoring and inspection. These capacity building efforts include outreach and educational programs, such as Global forums for regulatory authorities, online educational tools (i.e. CDRH Learn), and scientific exchanges. To support international regulatory efforts, FDA is active in informational network development such as the Medical Products “Informational Hub” for the Americas. This tool is designed to effectively regulate across the Americas. The following is a case study highlighting this strategy:

**Case Study: The Importance of Regulatory System Strengthening to Mexico**

A compelling case for regulatory system strengthening was made in the plenary session by Mikel Arriola, the Commissioner of Mexico’s regulatory authority, COFEPRIS. Like many emerging economies, Mexico’s desire for regulatory reform is in part rooted in the need to respond to trade and economic development imperatives in Mexico. Arriola’s presentation was specifically organized to respond to IOM recommendations by showing what Mexico was doing in that particular area. He noted that these were important recommendations to heed because the IOM is housed in the United States, and the United States is Mexico’s largest trading partner.

Arriola affirmed the characteristics of successful regulatory systems put forward by IOM, including the need for rapid and appropriate response based on risk analysis, swift adjustment to innovative scientific discoveries and ideas, consistent application of regulations to all economic agents, and independence from external influences. He said Mexico had made great strides in these areas and touted a recent Pan American Health Organization assessment of its regulatory system, which accorded it the highest level of functionality—level IV, a regulatory system of “regional reference”.

Some of the policy changes that led to these improvements included reforms on reliance, third party auditing, and deregulation. For example, on reliance, COFEPRIS now recognizes the GMP certificates of 5 foreign agencies (FDA, ANVISA (Brazil), Health Canada, Pharmaceutical and Food Safety Bureau (Japan), TGA (Australia), and EMA (European Union)). On one-way equivalence (a form of reliance), it recognizes medical devices approved in the US, Canada, and Japan. Regarding third party audits, third parties are now allowed to do pre-verification of administrative paperwork on drugs and devices. Finally, the reclassification of medical devices has meant that 1,700 products no longer meet the definition of a medical device and thus do not need regulatory scrutiny.

The subsequent results of these policies have been dramatic. There have been large savings in administrative cost, and a decrease in the regulatory burden. Specifically, because of third party pre-verification, there has been a reduction in application waiting times from 1 year to less than a month. In total, the issuance of 11,618 market authorizations from March 2011 to August 2012 represented a market value of close to $1.8 billion, and a growth in the rate of approvals of 7,645% since 2010. This speeding of approvals has seen the release of 157 new generic medications and 31 innovator drugs.
With the savings derived from the strategy to liberate generics, COFEPRIS estimates that an additional 750,000 patients can be treated in 4 years. Arriola Peñalosa, M. 2012. Regulatory system successes and challenges in Mexico. Presentation at Dissemination Meeting for the IOM Report Ensuring Safe Foods and Medical Products Through Stronger Regulatory Systems Abroad, Washington, DC.

In promoting harmonization of standards, FDA has actively participated in a number of International and Regional harmonization efforts. This includes standards for pharmaceuticals, food, medical devices, and animal welfare. This includes participation in the International Codex Alimentarius Commission (Codex). In addition, exporting regions see the benefits to support regional harmonization efforts such as African Medicines Regulatory Harmonisation Initiative (AMRHI) (http://www.amrh.org/). Specifically, PEPFAR funds are used to carry out regulatory capacity building in East African communities through AMRHI (Appendix B – 9). International efforts to support regulatory authorities is also promoted at international conferences such as the International Conference of Drug Regulatory Authorities http://www.who.int/medicines/areas/qualitysafety/regulationlegislation/icdra/en/ and the Global Food Safety Partnership (GFSP) which provides capacity building on international standards rather than regional or private standards (http://blogs.fda.gov/fdavoice/index.php/tag/global-food-safety-partnership/) (see Appendix B).

In addition, Federal partners such as the Centers for Disease Control and Prevention have promoted global surveillance of foodborne pathogens. PulseNet has been exported globally as an example to help detect and respond to multi-country outbreaks. This cannot be understated as we seek to improve global food supplies. Additionally, with the recent concerns about product and food adulteration or contamination, national and global epidemiologic surveillance efforts need to be strengthened. Other recent examples to promote transparency and improve public health infrastructure include the recently revised International health regulations (WHO, 2005) and the WHO led initiative the international food safety authorities network (INFOSAN), a collaboration to promote inter-country collaboration.

Summary Comments

The Institute of Medicine report “Ensuring Safe Foods and Medical Products through Stronger Regulatory Systems Abroad” stated that the “FDA cannot do its job well without substantive improvements in the capacity of its counterpart agencies in emerging economies.” There are several challenges that these emerging markets face in promoting their regulatory infrastructure. This includes

- Adherence to international standards
- Controlling food supply chains
- Regulatory infrastructure and support
- Sufficient laws
- Trained workforce
- Fragmentation of their regulatory infrastructure
- Disease and product surveillance
• Interagency communication
• Political will

To address these issues, it is important to first understand the export challenges and the global burden of disease in these emerging markets. Continued efforts to reduce disease burden and improve economic conditions in these countries is paramount. This would hopefully address the dichotomy of within country access to food and medical products vs. product exports.

Additionally, efforts should support the in-country populace through public advocacy and public health laws. It is possible that FDA could engage and encourage external partners such as the food and pharmaceutical industry, non-governmental organization, and academia to aid in these efforts. Collective and interdisciplinary efforts could provide reasonable incentives to promote these public advocacy programs and strengthen public health and land right laws.

Private companies play a key role in ensuring that imported foods, pharmaceuticals and devices and their derivative products, meet the highest standards of quality and safety. It is in their material interest to do so as well as required under the law. Over decades, companies engaged in such imports, have acquired advanced knowledge and skills about how best to protect their consumers’ and the nation’s health, and further, have invested substantially in technical expertise and capabilities to monitor and assure safety across the various supply chains involved. That knowledge and expertise could be invaluable to the FDA as it enhances its abilities in these areas. Private-public partnerships focused on sharing knowledge about new and innovative ways of using advances in biotechnology and information technology to better protect health in a nonproprietary way could aid the public sector accelerating the use of the “best” available tools. Additionally, closer collaboration with industry experts could allow the FDA to have a greater, flexible and timelier impact in areas related to global surveillance and food and product monitoring.

Continued programs by the FDA to provide expertise and training exchanges will support and strengthen these efforts. In addition, further promotion of harmonization of standards in testing, inspection methods, good agriculture and manufacturing practices are needed. Case studies highlighting successes in promotion of interagency cooperation need to be documented and disseminated. Together these approaches will encourage and strengthen the regulatory systems in these exporting countries.
References

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Presented at Strengthening Core Elements of Regulatory Systems in Developing Countries: Meeting One, Institute of Medicine, Washington, DC. March 2, 2011


Council of State and Territorial Epidemiologist. 2010 Council to Improve Foodborne Outbreak Response. www.cste.org


Appendices

A. Product importation from major export markets
B. Update on FDA Global Regulatory Systems Strengthening efforts, December 2013.

Appendix A. Product importation from major export markets

Antibiotics Product Line Importation by Country Fiscal Year 2010 - 2012

The horizontal line graph presents antibiotic product line importation by country for FY 2010 through FY 2012. The vertical scale is in increments of 500 with a range from 0 to 4500. The horizontal scale is by fiscal year. The legend shows six different colored lines that represent the countries – Brazil (blue), China (red), India (green), Kenya (purple), Mexico (sky blue), and South Africa (orange). The graph shows the country trends for the number of total antibiotic product lines imported between FY 2010 through FY 2012: Brazil (154 in FY 2010 to 168 in FY 2011 to 182 in FY 2012), China (2,399 in FY 2010 to 2,879 in FY 2011 to 2,855 in FY 2012), India (3,533 in FY 2010 to 4,042 in FY 2011 to 4,098 in FY 2012), Kenya (4 in FY 2010 to 0 in FY 2011 to 4 in FY 2012), Mexico (259 in FY 2010 to 256 in FY 2011 to 277 in FY 2012), South Africa (17 in FY 2010 to 9 in FY 2011 to 8 in FY 2012).
Antiretroviral Drug Product Lines Importation by Country Fiscal Year 2010 - 2012

The horizontal line graph presents antiretroviral drug product lines importation by country for FY 2010 through FY 2012. The vertical scale is in increments of 200 with a range from 0 to 1200. The horizontal scale is by fiscal year. The legend shows six different colored lines that represent the countries – Brazil (blue), China (red), India (green), Kenya (purple), Mexico (sky blue), and South Africa (orange). The graph shows the country trends for the number of total antiretroviral drug product lines imported between FY 2010 through FY 2012: Brazil (2 in FY 2010 to 7 in FY 2011 to 12 in FY 2012), China (66 in FY 2010 to 115 in FY 2011 to 214 in FY 2012), India (733 in FY 2010 to 892 in FY 2011 to 953 in FY 2012), Kenya (0 in FY 2010 to 2 in FY 2011 to 0 in FY 2012), Mexico (32 in FY 2010 to 33 in FY 2011 to 82 in FY 2012), South Africa (9 in FY 2010 to 9 in FY 2011 to 16 in FY 2012).
Animal Food Product Line Importation by Country Fiscal Year 2010 - 2012

The horizontal line graph presents animal food product line importation by country for FY 2010 through FY 2012. The vertical scale is in increments of 5000 with a range from 0 to 25000. The horizontal scale is by fiscal year. The legend shows six different colored lines that represent the countries – Brazil (orange), China (red), India (light green), Kenya (brown), Mexico (grey), and South Africa (brown). The graph shows the country trends for the number of total animal food product lines imported between FY 2010 through FY 2012: Brazil (7,472 in FY 2010 to 4,547 in FY 2011 to 3,696 in FY 2012), China (16,251 in FY 2010 to 19,357 in FY 2011 to 23,154 in FY 2012), India (1,036 in FY 2010 to 988 in FY 2011 to 1,030 in FY 2012), Kenya (N/A), Mexico (7,404 in FY 2010 to 11,210 in FY 2011 to 10,184 in FY 2012), South Africa (19 in FY 2010 to 7 in FY 2011 to 11 in FY 2012).
The horizontal line graph presents biologics product lines importation by country for FY 2010 through FY 2012. The vertical scale is in increments of 500 with a range from 0 to 4000. The horizontal scale is by fiscal year. The legend shows six different colored lines that represent the countries – Brazil (blue), China (red), India (green), Kenya (purple), Mexico (sky blue), and South Africa (orange). The graph shows the country trends for the number of total biologics product lines imported between FY 2010 through FY 2012: Brazil (347 in FY 2010 to 22 in FY 2011 to 36 in FY 2012), China (1,510 in FY 2010 to 3,008 in FY 2011 to 3,667 in FY 2012), India (565 in FY 2010 to 508 in FY 2011 to 358 in FY 2012), Kenya (3 in FY 2010 to 0 in FY 2011 to 1 in FY 2012), Mexico (164 in FY 2010 to 156 in FY 2011 to 257 in FY 2012), South Africa (54 in FY 2010 to 28 in FY 2011 to 27 in FY 2012).
Human Drug Product Lines Importation by Country Fiscal Year 2010-2012

The horizontal line graph presents antiretroviral drug product lines importation by country for FY 2010 through FY 2012. The vertical scale is in increments of 10000 with a range from 0 to 60000. The horizontal scale is by fiscal year. The legend shows six different colored lines that represent the countries – Brazil (blue), China (red), India (green), Kenya (purple), Mexico (sky blue), and South Africa (orange). The graph shows the country trends for the number of total human drug product lines imported between FY 2010 through FY 2012: Brazil (799 in FY 2010 to 864 in FY 2011 to 919 in FY 2012), China (16,611 in FY 2010 to 19,768 in FY 2011 to 23,451 in FY 2012), India (37,705 in FY 2010 to 47,408 in FY 2011 to 56,431 in FY 2012), Kenya (45 in FY 2010 to 34 in FY 2011 to 24 in FY 2012), Mexico (26,667 in FY 2010 to 34,274 in FY 2011 to 49,636 in FY 2012), South Africa (726 in FY 2010 to 893 in FY 2011 to 1,003 in FY 2012).
Seafood Product Lines Importation by Country Fiscal Year 2010-2012

The horizontal line graph presents seafood product lines importation by country for FY 2010 through FY 2012. The vertical scale is in increments of 10000 with a range from 0 to 70000. The horizontal scale is by fiscal year. The legend shows six different colored lines that represent the countries – Brazil (blue), China (red), India (green), Kenya (purple), Mexico (sky blue), and South Africa (orange). The graph shows the country trends for the number of total seafood product lines imported between FY 2010 through FY 2012: Brazil (8,689 in FY 2010 to 6,873 in FY 2011 to 5,841 in FY 2012), China (55,661 in FY 2010 to 57,333 in FY 2011 to 57,731 in FY 2012), India (8,409 in FY 2010 to 11,615 in FY 2011 to 13,188 in FY 2012), Kenya (78 in FY 2010 to 110 in FY 2011 to 50 in FY 2012), Mexico (46,494 in FY 2010 to 51,747 in FY 2011 to 59,691 in FY 2012), South Africa (1,773 in FY 2010 to 1,522 in FY 2011 to 1,467 in FY 2012).
Vegetable Product Lines Importation by Country Fiscal Year 2010 - 2012

The horizontal line graph presents vegetable product lines importation by country for FY 2010 through FY 2012. The vertical scale is in increments of 200000 with a range from 0 to 1400000. The horizontal scale is by fiscal year. The legend shows six different colored lines that represent the countries – Brazil (blue), China (red), India (green), Kenya (purple), Mexico (sky blue), and South Africa (orange). The graph shows the country trends for the number of total vegetable product lines imported between FY 2010 through FY 2012: Brazil (621 in FY 2010 to 378 in FY 2011 to 503 in FY 2012), China (46,180 in FY 2010 to 44,956 in FY 2011 to 46,176 in FY 2012), India (17,899 in FY 2010 to 18,142 in FY 2011 to 21,813 in FY 2012), Kenya (8 in FY 2010 to 32 in FY 2011 to 19 in FY 2012), Mexico (1,031,272 in FY 2010 to 1,059,141 in FY 2011 to 1,170,656 in FY 2012), South Africa (330 in FY 2010 to 262 in FY 2011 to 203 in FY 2012).
Appendix B

Global Health Sub-Committee of the Science Board
Update on FDA Global Regulatory Systems Strengthening Efforts
December 2013

This FDA update describes the (1) purpose and (2) how agency activities will strengthen regulatory systems.

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1. Background

This FDA/OIP Compendium of Global Regulatory Systems Strengthening Efforts provides an overview of regulatory-systems strengthening activities and approaches that FDA/OIP has taken in the global environment. This compendium intends to inform the Global Subcommittee on in-country or regional FDA efforts for China, India, Brazil South Africa, Kenya and Mexico. Additional background documents and direct links to sources are also provided for reference to address the Subcommittee’s following requests for information:

- In-country or regional FDA infrastructure and capacity parameters for six countries – China, India, Brazil, South Africa, Kenya, and Mexico
- Summary of workforce and regulatory curriculum development activities
- What types of regulatory-systems strengthening approaches that they have taken this past year (e.g. training, curriculum and workforce development, other oversight) to engage their respective regions.
- How would the offices characterize those interactions and rate those countries comparatively?
- Do the offices have country background assessments or other documents that could inform the committee?
2. Global Information-Sharing Platforms

Purpose:
FDA has been working with multilateral partners to develop data and information sharing platforms in support of global regulatory cooperation and capacity. These platforms are now in or have completed their pilot phases.

How It Will Strengthen Regulatory Systems Strengthening Efforts
FDA continues to work intensively with our partners to maximize these investments; to ensure that FDA is contributing to and leveraging data and information; and to work with our multilateral and other partners to develop sustainability plans.

3. WHO Global Surveillance and Monitoring System

Purpose:
In 2010, the Food and Drug Administration (FDA) and the World Health Organization (WHO) entered into a cooperative agreement in support of building a global surveillance and monitoring system for combating SSFFC medical products and supply chain threats. The agreement recognized that data is lacking in significant ways, preventing public health regulators from comprehensively addressing the issues surrounding them in a systematic, sustainable manner. The purpose is to establish the following on SSFFC medical products: 1) the scale of the issue; 2) the geographic extent; 3) the medicines affected; 4) the harm caused; 5) the value of the market; and 6) supply chain vulnerabilities.

How It Will Strengthen Regulatory Systems Strengthening Efforts
OIP leverages & helps promote the WHO Global Surveillance & Monitoring System to facilitate real-time information sharing during investigations of counterfeiting incidents which enables developing countries to have the tools & information necessary to become more vigilant about reporting & taking regulatory action against the product. To date, more than 73 incidents, 140 batches/lots of medical products & 56 different API’s have been reported into the system. By the end of September 2013, over 60 Member States will have been training in the use of the system.

4. FDA Global Pharmacovigilance Activities

Purpose:
FDA is engaged in a number of activities to strengthen global PV systems, including the funding and dissemination of studies on PV capacity in Sub-Saharan Africa and Asia (see the link to the study below). To help guide its future efforts, FDA has catalogued its current activities in global PV in support of a broader strategy development process.

How It Will Strengthen Regulatory Systems Strengthening Efforts
Because FDA’s involvement in global PV is growing, FDA continues to develop a broader strategy in order to coordinate and leverage existing work with key partners, and to harness new opportunities in the context of global health programs.
For more information, we have included the FDA Global Activities Matrix in the ‘FDA Global Pharmacovigilance’ folder. The link to the ‘Safety of Medicines in Sub-Saharan Africa: Assessment of Pharmacovigilance Systems and their Performance’ report is: http://www.msh.org/projects/sps/SPS-Documents/upload/SPS-FDA-PV-Report-March-2012.pdf

5. Global Curriculum

Purpose:
FDA recently commissioned an Institute of Medicine (IOM) report, entitled Ensuring Safe Foods and Medicines through Stronger Regulatory Systems Abroad. The report identified lack of high quality and consistent training for food and drug regulatory staff in ensuring food and drug safety across the globe, particularly in low and middle income countries (LMICs), and recommended developing a global curriculum of fundamental regulator competencies.

In 2012, the IOM, with the FDA and other key stakeholders including WHO, PAHO, the Bill and Melinda Gates Foundation, and DIA, began a discussion about how to begin to take on the task of developing a global curriculum and published a Stakeholder Discussion Paper on the IOM website in June 2013.1

With funding received from the FDA in 2013, the International Food Protection Training Institute (IFPTI) and the Regulatory Affairs Professionals Society (RAPS) are now partnering to lead this important effort with the FDA, WHO, PAHO, the Critical Path Institute, and others.

This effort will take place over the next year and will include five key deliverables:
1. Identification and selection of expert panel
2. Development and validation of competency framework
3. Development of global curriculum framework
4. Gap assessment tool
5. Final report and transfer

Once completed, the goal is to transfer the global curriculum to WHO for integration in global capacity-building plans and to serve as the owner and access point for these materials.

By defining essential competencies, and then developing curricula, the outcomes of this project can meet the needs of different countries and regions, and can be updated with changing science and technology.

How It Will Strengthen Regulatory Systems Strengthening Efforts
We are hopeful that the results of this effort will ultimately create a global regulatory professional identity and competency trained workforce. This can contribute to sustainable regulatory capacity development around the globe and ultimately help protect and promote global public health by ensuring the safety of medicines. We are further hopeful that future work that will build from this project will lead to the development of training modules that will be readily available to countries in their own regulatory capacity building efforts.

1 http://www.iom.edu/Global/Perspectives/2013/GlobalCurriculum.aspx
6. China Safety Initiative

Purpose:
The early detection, assessment, and management of global supply chain risks and risk drivers through more preventive, strategic approaches before they can result in harm to the public is the overarching priority. The FDA, through external partnerships, will undertake the following efforts to accomplish these goals:

With Epidemico, the FDA is looking to use social media data mining in certain regions (specifically in China) to establish a novel supply chain surveillance system. These efforts, planned over 3 years, will involve:

- Identifying social media data sources for monitoring foods, finished drugs, and API
- Pulling live data from FDA systems on field and adverse event information to establish correlation and a comparative baseline (validation)
- Developing web-crawling techniques
- Refining statistical analytics
- Designing and enhancing the user interface experience for either stand-alone system delivered to FDA, or integration into FDA system (and potentially sharing risk information with external regulatory partners through FDA cloud computing)

With the Massachusetts Institute of Technology (MIT), the FDA is looking to gain a better understanding of the socio-economic, geo-political and environmental risk drivers which contribute to an unsafe supply chain from certain regions (specifically China), and how the FDA can best anticipate and react to early warning signals. These efforts, planned over 3 years, will involve:

- Preliminary identification of risk drivers using previous and current FDA case studies
- Preliminary database and technical solutions options and development
- Assessment of relevant sources of data for risk drivers (public, semi-public, industry-based and FDA-internal)
- Refinement of risk management approach and integration into FDA systems

With the United States Pharmacopeia (USP), the FDA is looking to create global spectral library of materials which will uniquely describe an API or drug product against other substances. The spectra in question will be identified based on risk factors (such as volume traded, easily counterfeited, adulterated, etc.) and will help industry and FDA to better detect and manage any supply chain incidents. These efforts, planned over ~1 year will involve:

- Establishing a coalition of partners (other national/regional pharmacopeias, including Chinese institutes) to establish a benchmark of existing spectra and ensuring consistency in approach and methodology
- Developing and harmonizing the spectra
- Developing the platform for the library

With FIDES (Focused Integration of Data for Early Signals) and through an existing Cooperative Agreement with NCFPD (the National Center for Food Protection and Defense) managed by the
Department of Homeland Security, the FDA is looking to rapidly identify and mitigate harm from food supply chain events originating from China. These efforts, planned over ~1 year will involve:

- Creating an inventory and assessment of existing data and surveillance systems
- Developing a severity scale and alerting criteria
- Developing and refining analytics and informatics tools
- Transition of real-time analysis into the online FIDES dashboard

**How It Will Strengthen Regulatory Systems Strengthening Efforts**

A diagram of the 4 partners of the China Safety Initiative is below. The partners are USP, MIT, Epidemico and FIDES. Each circle shows how each partner provides different ways in which the agency can enhance its global supply chain safety net. The arrows between the circles provide a visual representation of the synergies that exist between the partners. There are also two background colors that represent two strategic approaches that the partners are driving towards. Green represents the ‘Prevent/Detect’ approach which USP and MIT drive towards and Red represents ‘Detect/Respond’ which FIDES and Epidemico drive towards. (Diagram – China Safety Initiative Partner Synergies - provides a visual representation of these synergies).
7. Disease Control Priorities Project (DCPP)

Purpose:
The Disease Control Priorities Project (DCPP) is an ongoing effort to assess disease control priorities and produce evidence-based analysis and resource materials to inform health policymaking in developing countries. In the late 1990's the World Bank initiated work to inform priorities for control of specific diseases and to generate comparative cost-effectiveness estimates for interventions addressing the full range of conditions important in developing countries. In 1993, the World Bank published the first edition of Disease Control Priorities in Developing Countries (DCP1) with contributions from the World Health Organization, developing- an developed-world scholars, practitioners, and public health specialists. In April 2006, DCPP released the second edition of Disease Control Priorities in Developing Countries (DCP2) that includes updated information about the global burden of diseases brought about by tobacco, alcohol, psychiatric disorders, and injury, which account for an increasing proportion of deaths. DCP2 highlights cost-effective interventions based on careful analysis of health systems, the costs of disease burden, treatment, and prevention for a comprehensive range of diseases and conditions. The third edition is currently being written and as regulatory systems are now being recognized for their importance to health systems, the new edition will feature a chapter on regulatory systems. To spearhead this chapter, FDA and the IOM convened a meeting of key stakeholders to discuss what a regulatory chapter would look like in September of 2013.

How It Will Strengthen Regulatory Systems Strengthening Efforts
The idea is that this project will improve regulatory system strengthening efforts because it will help to mainstream the notion that regulatory systems are an important part of health systems.

8. Global Food Safety Partnership (GFSP)

Purpose:
The World Bank Group launched the Global Food Safety Partnership (GFSP) in December 2012 as a unique opportunity to work with international stakeholders to promote a new paradigm of capacity building for food safety as a global public good and global food markets and opportunities for developing countries. The GFSP builds on the initial work undertaken by the Asia Pacific Economic Cooperation (APEC) Food Safety Cooperation Forum and its Partnership Training Institute Network as well as other organizations, with the objective to support improved food safety systems as demonstrated by enhanced agri-food value chains and improved public health outcomes. Initial donors include private and public sector organizations; GFSP will also aim to align with international organizations including WHO and FAO.

How It Will Strengthen Regulatory Systems Strengthening Efforts

2 Note: This information is from the website http://www.dcp2.org/page/main/About.html
The GFSP will build capacity in developing and middle income countries on a needs driven basis through advisory services, education and training in the use of science based international standards and best practices for food safety. GFSP activities encompass local, regional, and online trainings for regulators in areas such as risk-based decision-making and GMPs. Partnering with FAO, GFSP is conducting food safety systems needs assessment in select countries to identify gaps and weaknesses across a country’s entire food safety system, and best direct limited capacity building resources. By improving coordination amongst capacity building efforts and organizations, the GFSP will ensure the resources are being leveraged to have the greatest impact on food safety systems strengthening.

9. PEPFAR

**Purpose:**
As PEPFAR transitions to country ownership, the regulatory functions that have traditionally been performed by outside entities (e.g. FDA tentative approval), will need to be undertaken by countries themselves. The HHS office that provides leadership on PEPFAR, the Office of Global Affairs, has sought to involve FDA as a key partner in helping to implement this transition because of its recognized expertise in the regulatory domain.

**How It Will Strengthen Regulatory Systems Strengthening Efforts**
In response, FDA has become increasingly interested in engaging on projects designed to build regulatory capacity with PEPFAR resources. This is especially true where there are clearly stated project objectives and appropriate roles for FDA staff. One project involves implementing a Center for Biologics Evaluation and Research (CBER) proposal to develop better regulatory frameworks for HIV test kit regulation because PEPFAR carries out millions of tests every year, and there have been a few high profile test kit failures. Another project entails using PEPFAR funds to carry out regulatory capacity building in the East African Community through the African Medicines Regulatory Harmonization Initiative. More specifically, FDA is very interested in assisting countries in the development of better pharmacoepidemiology capacity through approaches like hospital-based surveillance systems, and in leveraging investments made in substandard and falsified medical product monitoring platforms and detection devices.

10. Examples from FDA Sub-Saharan Africa Post, located in Pretoria, South Africa

**Example of Training Contributing to Academic Curricula**
As part of a PEPFAR mandate for FDA to provide drug registration training for African regulators, FDA, in collaboration with the Kilimanjaro School of Pharmacy and Purdue and Howard universities, provided a five-day course on the review of generic drug applications and PEPFAR drug reviews.

**Participants:** 37 regulators and academicians from 17 African countries

**Purpose:**
- Aimed at enabling regulators and pharmaceutical school faculty to familiarize themselves with regulatory and scientific methods applied by FDA
- Introduce the value of integrating regulatory science training into the curricula of schools of pharmacy and other academic institutions in Africa
**How It Will Strengthen Regulatory Systems Strengthening Efforts**
FDA and its partners believe that this training course can eventually be turned into a teaching module for use in academic curricula throughout Africa. Such curricula can support a cadre of regulatory affairs professionals to work in government agencies. This would further the availability and the manufacture of quality, safe and effective drug products for the African population.


**Example of Training Contributing to Strengthening Regulatory Capacity for GCPs and Clinical Trial Inspections**

FDA, in collaboration with the Southern Africa Development Community (SADC), which represents 15 African nations, is strategically engaging in strengthening regulatory capacity in the area of Good Clinical Practices (GCPs) and Clinical Trial Inspections. The SSA Post conducted a successful FDA/SADC Good Clinical Practice Inspection Training from August 24-28, 2012, in Lusaka, Zambia. This was the third in an FDA training series which is typically offered in three to four phases.

**Participants:** 36 drug regulators from 13 SADC countries participated, including Angola, Botswana, Lesotho, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, Tanzania, Zambia and Zimbabwe

**Purpose:**
- Aims to develop trainers who have expertise in clinical practices and inspection. These individuals will also be prepared to train others within their agencies and the regulated community.
- This particular workshop was designed to reinforce lessons learned and provide additional inspectional experience for those who completed workshops in the first two training phases in Botswana in 2010 and in Pretoria in 2011.

**How It Will Strengthen Regulatory Systems Strengthening Efforts**
These countries continue to make substantial progress in the oversight of clinical trials. For example, at the onset of our first training, only three of 13 participating countries were involved in how clinical trials are conducted. We now have an additional two countries conducting oversight, with others poised to start soon. Other milestones from our training include important advances towards systematic oversight in Botswana, Mauritius, Swaziland, Tanzania, Zambia and Zimbabwe.


**11. Examples from FDA Latin America Office, which consists of posts in San Jose, Costa Rica; Santiago, Chile; and Mexico City, Mexico**

**Example of Training Contributing to Strengthening Regulatory Capacity**

For its “train-the-trainer” programs, FDA’s Latin America Office invites officials to participate who have the capacity and authority to widely disseminate training in their home countries.
12. Examples from FDA China Office, which consists of posts in Beijing, Shanghai, and Guangzhou

Example of Training Contributing to Academic Curricula

The China Office and FDA have collaborated with Peking University to establish a world-class graduate degree program in pharmaceutical engineering management. This model program trains future leaders in China’s pharmaceutical industry, while accelerating modernization of the industry itself.

Source: Page 11 of FDA Global Engagement Report

Example of Training Contributing to Cooperation and Collaboration with other Regulatory Authorities

As part of the FDA International Scientist Exchange Program (ISEP), three scientists from China’s State Food and Drug Administration spent more than four months at FDA’s National Center for Toxicological Research applying bioinformatics technologies to regulatory data. This program ensured that the scientists could return to facilitate development of a bioinformatics infrastructure in China.

Source: Page 18 of FDA Global Engagement Report

13. Examples from FDA India Office, which consists of post in New Delhi and Mumbai

Example of Training Contributing to Strengthening Regulatory Capacity for GCPs and Clinical Trial Inspections

In response to Indian regulators’ request for a multi-year “train-the-trainers” program on good clinical practices/clinical research inspections, FDA worked to adapt a program for delivery in India. As a direct result, the Indian drug regulatory authority now certifies inspectors for clinical trial inspections, as well as trainers to expand future capacity.

Source: Page 13 of FDA Global Engagement Report

14. Example of FDA Training Supporting Local Universities in China, Latin America, and India

One of FDA’s requirements is that, with few exceptions, manufacturing supervisors at canneries must have taken an appropriate training course to understand how to make a safe commercially-sterile product. FDA must approve these so-called Better Process Control Schools (BPCS), which numerous large universities throughout the United States offer. Until recently, it was a challenge for foreign
manufacturers to send persons to attend BPCS in the United States because of travel and language barriers.

Participants:

- **China:** In September 2011, the first-ever, locally sponsored BPCS course in China was conducted at China Ocean University. Attendees were able to obtain the content of the course in Mandarin Chinese from local food technology professors, while an FDA technical advisor was available for questions. This June, the university held its second course, with eager attendees coming from mainland China as well as Taiwan.

- **Latin America:** The Latin America Office has identified three universities as having the knowledge base and infrastructure to conduct BPCS courses: Costa Rica’s Center for Food Technology Research (CITA), Guatemala’s Del Valle University, and Peru’s National Agrarian University- La Molina. In addition, FDA’s Latin America Office worked with the Inter-American Developmental Bank to obtain funding to provide the approved course materials for the universities in Guatemala and Peru to conduct their own BPCS. In Peru, the university recently completed their first BPCS on August 17th, 2012. Representatives from FDA were present to answer questions and assist with the delivery of the class. In Costa Rica, CITA has scheduled their first BPCS for August 27-31, 2012, and expects attendees from the Caribbean and Central America region. These are pilot programs, and we have already heard from other countries and institutions that want to participate in similar efforts.

- **India:** Before 2011, no in-country BPCS was available for these manufacturers. In March 2011, local faculty at Bhaskaracharya College of Applied Sciences in New Delhi taught a BPCS course for the first time. The course cost each student only about $200—this sum paid for instruction, catering for meals and course materials. Students came from throughout India to attend the course. A FDA technical advisor’s participation in the course allowed students to ask questions about process filings and engage in technical discussions with FDA. This year, the college held a second class in Sri Lanka for LACF and AF producers located in that country. A third class is planned for later this year.

Purpose:

- Support local universities throughout the world with the capability to host approved BPCS trainings right where they are needed
- Support these universities in order to provide these courses at a low cost, with capable instructors who speak the local language and understand the local realities of the industry.

How It Will Strengthen Regulatory Systems Strengthening Efforts

The FDA overseas offices are proud to have helped stand up these important training events in various parts of the world, and to support local universities as they develop the capacity to put on these courses.