



# Journal of the Association of Food and Drug Officials

*Serving the regulatory community since January 1937*

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## From the Executive Director

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### AFDO = True Collaborators

Collaboration is the practice where organizations work together with a common purpose and goal. It relies on openness and the willingness to share assignments, accountability, and achievement. AFDO has a long history of promoting collaboration dating back to our origin when the states of Michigan and Ohio recognized they could better achieve common objectives by forming collaborative partnerships. This belief soon spread to other states and the Association was formed. Today, perhaps more than any other time, we need to remind ourselves of the value of collaboration as we strive to meet the challenges of new comprehensive regulatory requirements and the advancement of a nationally integrated food safety system. To attempt these efforts independently is a sure prescription for disaster and only the most conceited would actually try.

AFDO is most proud of our collaborative efforts we currently have with the Association of Public Health Laboratories (APHL), American Association of Feed Control Officials (AAFCO), and the National Association of State Departments of Agriculture (NASDA). The work we are doing to standardize our nation's laboratories and address the complexity of implementing the Produce Safety rule is truly exceptional.

Our work with the Food Safety Preventive Control Alliance (FSPCA), Produce Safety Alliance (PSA), Sprout Safety Alliance (SSA), and the Seafood HACCP Alliance [SHA] will impact industry and regulators for many years to come. These Alliances set the foundations of education and understanding that will help to enable our food safety system to become one based on prevention and not reaction.

Our Manufactured Food Regulatory Program Alliance serves as a collaborative mechanism for state food protection programs to improve their regulatory programs and establish equivalence nationally among all regulatory bodies. The achievements of this Alliance are well recognized.

We may have come to take our commitment for collaboration for granted as we look at 119 years of it as testimony of our firm support for working with others. Remember it was AFDO that worked side by side with Dr. Harvey Wiley to promote those earliest of food safety laws. Remember it was AFDO that first pushed FDA to develop the Office of State Cooperation that today has become the FDA Office of Partnerships. And finally, remember it was AFDO that first offered the vision of a nationally integrated food safety system.

We did it not for money or fame, but because it was the right thing to do.



Joseph Corby  
AFDO Executive Director

## 2015-2016 AFDO Board of Directors

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<i>President*</i> <sup>∇</sup> .....	Stan Stromberg
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<i>CASA Regional Affiliate Director</i> <sup>∇</sup> .....	Erik Bungo
<i>MCAFDO Regional Affiliate Director</i> <sup>∇</sup> .....	Steve Moris and Steven Mandernach
<i>NCAFDO Regional Affiliate Director</i> <sup>∇</sup> .....	Katherine Simon
<i>NEFDOA Regional Affiliate Director*</i> <sup>∇</sup> .....	Darby Greco
<i>WAFDO Regional Affiliate Director</i> <sup>∇</sup> .....	Randy Treadwell

*\* Member of Executive Committee*

*∇ Voting Board Member*

## 2015-2016 AFDO Board-Appointed Advisors

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Cynthia Culmo, Abbott Laboratories

Gerald Wojtala, International Food Protection Training Institute

Doug Saunders, The Coca-Cola Company

## 2015-2016 AFDO Committee Chairpersons

### Administration Committee

*Angela Montalbano\** (718) 722-2876  
NY Department of Agriculture & Markets  
angela.montalbano@agriculture.ny.gov

*Joe Corby* (518) 860-2838  
Association of Food & Drug Officials  
jcorby@afdo.org

### Alumni Committee

*Dan Sowards\** (512) 282-2300  
rsowardsjr@austin.rr.com

### Associate Membership Committee

*Cynthia Culmo\** (512) 694-5575  
CC Consulting  
ctculmo@gmail.com

### Drugs, Devices & Cosmetics Committee

*Thomas Brinck\** (512) 834-6755  
TX Dept. of State Health Services  
tom.brinck@dshs.state.tx.us

*Dennis Baker* (214) 253-4904  
FDA/U.S. Food & Drug Administration  
dennis.baker@fda.hhs.gov

### Food Committee

*James Melvin\** (919) 733-7366  
NC Dept. of Agriculture & Consumer Svcs.  
jim.melvin@ncagr.gov

*Byron Beerbower* (517) 241-0934  
MI Dept. of Agriculture  
beerbowerb@michigan.gov

### Food Protection & Defense Committee

*Gary W. Elliott\** (803) 896-0640  
SC Dept. of Health & Environmental Control  
Garyw.elliott@gmail.com

*John Martin* (803) 896-0640  
U.S. Dept. of Homeland Security  
John.D.Martin@hq.dhs.gov

*Keith Payne* (202) 690-6522  
U.S. Dept. of Agriculture  
Keith.payne@fsis.usda.gov

*John D. Tilden* (517) 373-1503  
MI Dept. of Agriculture  
tildenj@michigan.gov

### Foodborne Outbreak & Emergency Response Committee

*Darby Greco\** (518) 402-7600  
New York State Department of Health  
djg11@health.state.ny.us

Mark Sestak (334) 206-5375  
Alabama Department of Public Health  
mark.sestak@adph.state.al.us

### International & Gov't. Relations Committee

*LaTonya Mitchell\** (303) 236-3016  
FDA/U.S. Food & Drug Administration  
Latonya.mitchell@fda.hhs.gov

*Ken Moore* (204) 983-3004  
Health Canada  
ken.moore@hc-sc.gc.ca

### Laboratory, Science & Technology Committee

*Yvonne Salfinger\** (904) 233-6710  
FL Dept. of Agriculture & Consumer Svcs.  
yhale@aol.com

*Dirk Shoemaker* (402) 471-8150  
Nebraska Dept. of Agriculture  
Dirk.shoemaker@nebraska.gov

*Dan Rice* (518) 457-4477  
NY State Dept. of Agriculture & Markets  
daniel.rice@agmkt.state.ny.us

### Laws & Regulations Committee

*Steven Mandernach\** (515) 281-8587  
IA Dept. of Inspection & Appeals  
Steven.mandernach@dia.iowa.gov

*Gary W. Elliott* (803) 896-0640  
SC Dept. of Health & Environmental Control  
Garyw.elliott@gmail.com

### Professional Development Committee

*Craig Nielson\** (404) 656-3627  
Georgia Dept. of Agriculture  
Craig.nielson@agr.georgia.gov

Laura Van Wagenen-Birdsill (303) 692-3649  
Colorado Dept. of Public Health & Environment  
Laura.vanwagenen-birdsill@state.co.us

### Seafood Committee

*Rita Johnson\** (813) 929-1097  
FL Dept. of Agriculture & Consumer Services  
rita.johnson@freshfromflorida.com

*Courtney Mickiewicz* (757) 363-3905  
VA Dept. of Agriculture & Consumer Services  
Courtney.mickiewicz@vdacs.virginia.gov

## AFDO Regional Affiliates

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### **Association of Food and Drug Officials of the Southern States**

**AFDOSS President.....Natalie Adan**  
Georgia Department of Agriculture  
(404) 657-4801  
Natalie.adan@agr.georgia.gov

### **Central Atlantic States Association**

**CASA President..... Danielle Stapleton-Bytheway**  
New Jersey Department of Health  
(609) 947-8597  
Danielle.stapleton@doh.state.nj.us

### **Mid-Continental Association of Food and Drug Officials**

**MCAFDO President.....Ellen Dettman**  
Missouri Department of Health & Senior Services  
(573) 751-6095  
Ellen.dettman@health.mo.gov

### **North Central Association of Food and Drug Officials**

**NCAFDO President..... Kirsten Knopff**  
MN Department of Agriculture  
(651) 201-6271  
Kristen.knopff@state.mn.us

### **North East Food and Drug Officials Association**

**NEFDOA President..... Lisa Silva**  
Maine Department of Health & Human Services  
(207) 287-5691  
lisa.roy@maine.gov

### **Western Association of Food and Drug Officials**

**WAFDO President..... Kimberly Stryker**  
Alaska Department of Environmental Conservation  
(907) 269-7583  
kimberly.stryker@alaska.gov

## 2015 AFDO Award Recipients

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The **Harvey W. Wiley Award** is AFDO's most prestigious award. This year's recipient, **Charlene Bruce**, was honored for her outstanding service and devotion to the administration of food, drug and consumer protection laws of our country. Ms. Bruce served more than thirty years with the Mississippi State Department of Health. For the past twenty years she served as the Director of the Food Protection Program for the state-wide Food Retail and Food Processing Programs. Prior to becoming the Director of the Food Program, she served as an FDA Rating Officer for both the Milk and Food Programs.

The **Associate Member Award** was presented to **Andrew Bonanno**, recently retired as a healthcare executive whose career spanned over 40 years, including 34 years at the U.S. Food and Drug Administration and 7 years at Abbott Laboratories. Within his tenure with FDA, Mr. Bonanno was the Deputy and Acting Regional Director for FDA's Central Region, where he was responsible for FDA's compliance and regulatory operations in a 15 state area.

The 2015 **Achievement Award** was presented to **Sara Kingland**, Food Safety Specialist with the Iowa Department of Inspections and Appeals. The Achievement Award is annually bestowed to individuals who have demonstrated exemplary performance within their field in their first five years of service.

AFDO awards three scholarships annually in the amount of \$1,500 each. The "**George M. Burditt Scholarship**", "**Betsy B. Woodward Scholarship**" and the "**Denise C. Rooney Scholarship**" are each awarded to an undergraduate student in their third year of college who has demonstrated a desire to serve in a career of research, regulatory work, quality control, or teaching in an area related to some aspect of foods, drugs or consumer product safety. This year's recipients were:

**Alexis Cordero**, University of Georgia, B.S. in Environmental Health Science

**Avery Becker**, Cornell University, B.S. in Food Science

**Laura Hayes**, University of Minnesota - Twin Cities, B.S. in Human Nutrition and B.S. in Horticultural Science

# 2015 AFDO Resolutions

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## **RESOLUTION NUMBER 2015-01**

**Submitted by:** AFDO Food Protection & Defense Committee

**Date:** March 19, 2015

**Concerning:** Functional Food Defense Plans

**Whereas,** food defense continues to be a priority for the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), and

**Whereas,** FSIS promotes mitigation of food defense vulnerabilities in FSIS-regulated establishments by encouraging these establishments to voluntarily adopt a functional food defense plan, and

**Whereas,** a functional food defense plan can be accomplished through tools and resources available on FSIS' website at [www.fsis.usda.gov/fooddefense](http://www.fsis.usda.gov/fooddefense) where establishments of any size can write, implement, and test their food defense plan and ensure it is functional, and

**Whereas,** in 2006, USDA/FSIS began measuring the status of industry's voluntary adoption of food defense plans via annual surveys to determine whether each FSIS-inspected establishment has a functional food defense plan (i.e., the plan is documented; measures are in place to address outside security, inside security, personnel security, and incident response; the plan was tested in the last year, and the establishment reviewed their plan in the past year), and

**Whereas,** the voluntary adoption of food defense plans has been included as a performance measure in USDA's Strategic Plan that sets a target for 90 percent of establishments to have a functional food defense plan, and

**Whereas,** AFDO strongly supports the implementation of functional food defense plans in all food processing establishments regardless of the size of the company, and

**Whereas,** AFDO recognizes that functional food defense plans contribute to a safer and more secure food supply by reducing the risk of unsafe product and economic loss, reduce theft, reduce the need for additional regulation on food defense, and reduce company liability, therefore be it

**Resolved,** that the AFDO Food Protection & Defense Committee, recommends that AFDO endorse the tools and resources provided by USDA/FSIS for FSIS-inspected establishments and support USDA's target goal of having 90% of these establishments having a functional food defense plan, and be it further

**Resolved,** that AFDO advise state food safety program managers and the National Association of State Meat & Food Inspection Directors of its support for FSIS's efforts with functional food defense plans and ask that they support this as well.

## **RESOLUTION NUMBER 2015-02**

**Submitted by:** AFDO Board of Directors

**Date:** March 19, 2015

**Concerning:** Date Labeling of Food

**Whereas**, the Food and Agriculture Organization of the United Nations [FAO] estimates that the amount of food loss and waste on a global scale is about one-third of the food produced for human consumption, which translates into 1.3 billion metric tons of food produced for human consumption or \$1 trillion wasted per year (FAO 2011), and

**Whereas**, the United States Department of Agriculture Economic Research Service (USDA/ERS) estimated that in the United States in 2010 about 133 billion pounds of food estimated at \$161.6 billion in retail value, which is about a third (31 percent) of the 430 billion pounds of edible food available at the retail and consumer levels, was not eaten as a result of being wasted (Buzby and others 2014), and

**Whereas**, the inconsistent use of date labeling terms such as sell-by, best-by, best-before, and use-by dates contributes to a general misunderstanding about how or whether dates on labels relate to food quality or safety, and

**Whereas**, this general misunderstanding of date labeling also leads to significant food waste, misapplication of limited government resources, and unnecessary financial burden for the consumer and the food industry, and

**Whereas**, this general misunderstanding may also lead to potential food safety risk in regards to perishable foods (Newsome and others 2014), detrimental impacts on the environment (e.g., land, water, energy, and climate change) and a weakened ability to address food security (Buzby and others 2011; FAO 2011; FAO 2013a,b; FAO 2014), and

**Whereas**, there are an estimated 805 million hungry people worldwide (FAO, IFAD and WFP 2014) and an estimated growth in the world's population from about 7 billion to nearly 9.6 billion by 2050 (UN 2013) creating a demand for food that will be 70% greater than it is today (FAO 2009), and

**Whereas**, AFDO participated in a Committee that developed a research paper entitled "Applications and Perceptions of Date Labeling of Food" that called for collaboration to address the challenges that food manufacturers, retailers, government officials, consumers and other stakeholders face as a result of the current date labeling situation, and

**Whereas**, AFDO supports the recommendations from the research paper that include:

### **Establish Date Labeling Uniformity**

- A simple workable solution needs to be developed to alleviate the challenges that date labeling causes for food manufacturers, retailers, government officials, and consumers, and other stakeholders.
- The food industry should align to develop a more consistent or single best practices date-marking system that takes into consideration on-package storage instructions.

### **Educate Consumers**

- Providing clear, simple consumer direction on food quality and safety and the meaning of date labeling would improve food waste behavior.

### **Reexamine Regulatory Enforcement**

- Regulatory agencies should revisit the emphasis placed on the issue of food date labeling at retail and, where appropriate, shift excessive resources placed on food quality date labeling to more significant health and safety risks.
- Coordination of Federal and State approaches to date labeling, while allowing for collaborative industry-led development of a solution to achieve uniformity, would increase consistency across labels and decrease confusion, including at the regulatory level.

### **Conduct More Research on Indicator Technologies**

- Additional research to evaluate and further develop indicator technologies, such as time – temperature monitoring devices, and implement other improvements along the supply chain to monitor temperature handling and storage information could help better gauge true shelf life and reduce food waste, especially that of fresh produce.

**Therefore be it resolved,** that AFDO inform FDA, USDA/FSIS, and state food safety programs of its support of the recommendations from the research paper entitled “Applications and Perceptions of Date Labeling of Food” and of our desire to seek uniform date labeling requirements for this country, and be it further

**Resolved,** that AFDO inform FDA and USDA/FSIS of our willingness to work with them in order to develop uniform date labeling requirements.

## **RESOLUTION NUMBER 2015-03**

**Submitted by:** AFDO Board of Directors

**Date:** June 19, 2015

**Concerning:** FDA support for research on compliance assistance approaches to food safety inspections in order to enhance FSMA implementation

**Whereas,** food safety investigator competencies in educating and communicating with firms will become critical as FDA adopts an “educating before regulating” enforcement strategy in implementing the Food Safety Modernization Act; and

**Whereas,** FDA is developing new compliance tools under FSMA that include “Voluntary correction of problems at the facility level, achieved immediately during the course of an inspection through communication with firm management by investigators and, as needed, Center technical staff”

(<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm395105.htm>); and

**Whereas,** some state- and local-level food safety agencies employ a compliance assistance approach that encourages investigators to educate and communicate with firm personnel, providing models on which the FDA may base this strategy and that may inform investigator training; and

**Whereas,** research in the state of Michigan (Buckley 2015) suggests 1) that firm compliance increases when investigators adopt a compliance assistance approach and 2) that competencies in educating and communicating are shaped by individual investigator traits, supervisor styles, and agency culture; therefore, be it

**Resolved,** that AFDO recommends that FDA support research on compliance assistance as it is employed by food safety agencies, with the objectives of 1) characterizing ways in which investigators educate and communicate with firms; 2) identifying outcomes for firm compliance; 3) characterizing personality and other traits of individual investigators, the styles their supervisors employ, and the culture of the agency; 4) investigating correlations among these variables; and 5) making training and guidance recommendations based on findings.

*Reference: Buckley, Jenifer A. 2015. Food safety regulation and small processing: A case study of interactions between processors and inspectors. Food Policy 51: 74-82.*

## **RESOLUTION NUMBER 2015-04**

**Submitted by:** AFDO Laboratory Managers Steering Committee

**Date:** June 21, 2014

**Concerning:** The Partnership for Food Protection, Laboratory Task Group, Food/Feed Testing Laboratories, Best Practices Manual (Draft)

**Whereas,** the AFDO Laboratories Managers Steering Committee was established through a U.S. Food and Drug Administration (FDA) Cooperative Agreement with the Association of Public Health Laboratories (APHL), Association of Food & Drug Officials (AFDO) and the Association of American Feed Control Officials (AAFCO), which is intended to promote Laboratory Accreditation to ISO 17025 Standards. The Laboratory Managers Steering Committee provides leadership for facilitating state food and feed laboratory accreditation and integration with state and federal food safety surveillance, compliance, and enforcement programs.

**Whereas,** The Partnership for Food Protection (PFP) was established by the FDA, as a group of officials representing federal, state, local, and tribal governments to build the foundation of the integrated food/feed safety system in the United States, and

**Whereas,** The PFP established the Laboratory Task Group (LTG), led by FDA and state laboratory professionals and comprised of members from multiple federal, state, and local agencies to document best practices and procedures for food/feed laboratories to support confidence in the integrity and scientific validity of laboratory analytical data and facilitate the acceptance of laboratory analytical data by regulatory agencies, and

**Whereas,** the LTG developed the Food/Feed Testing Laboratories, Best Practices Manual (Draft), published by the PFP in November 2013, which is a set of tools, definitions, and references, that laboratories can use to improve their operations, and

**Whereas,** LTG included members of the AFDO Laboratory Managers Steering Committee and Steering Committee has reviewed and endorsed the use of the manual by food/feed laboratories to support confidence in the integrity and scientific validity of laboratory analytical data and facilitate the acceptance of laboratory analytical data by regulatory agencies, therefore be it

**Resolved,** that the AFDO Laboratory Managers Steering Committee, recommends that AFDO endorse the use of the Best Practices Manual to support confidence in the integrity and scientific validity of laboratory analytical data and facilitate the acceptance of laboratory analytical data by regulatory agencies.

## About the Authors

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**Stephen Baker**, has been the Vice-President, Operations, at the Canadian Food Inspection Agency (CFIA) since July 4, 2011. Over the past few years, Stephen has achieved significant changes in the Branch, becoming a key driving force in implementation of the Agency's transformational, Change Agenda.

He joined the CFIA on September 16, 2008, as Vice-President, Finance, Administration and Information Technology (FAIT) Branch, later renamed to Corporate Management Branch from the Translation Bureau where he was Vice President, Corporate Services.

Stephen has more than 35 years of experience in a variety of operational settings including government and the private sector covering accounting and financial management, information technology, business administration and project management. He has held a number of senior level positions in Service Canada, Human Resources and Development Canada and the Treasury Board Secretariat.

Mr. Baker holds a Masters of Business Administration from the University of Ottawa and is a Certified Management Accountant (CMA).

**Paul Dezendorf, Ph.D.**, has worked as a university faculty member for the past twenty years. His current responsibilities include teaching research methods in a Master of Health Sciences program where he mentors early career professionals working to complete their master's research project and publication. He also teaches grant writing and public sector public relations in a Masters of Public Administration program. He has completed twenty-four grant-funded trips abroad, primarily to Russia, including a Fulbright Scholar year in Moscow. His academic background includes a doctorate in Public Health, an MBA in Entrepreneurship, an MSW, and a graduate certificate in gerontology.

**Dr. Jerry Elliott**, Director of the Compliance & Investigations Division (CID), Food Safety and Inspection Service, USDA, has over 25 years of experience with FSIS – a career that has included time with the Office of Field Operations as well as Director of the Import Inspection Division. As Director of CID he is responsible for managing the surveillance, investigation, and enforcement of regulated meat, poultry and processed egg products in-commerce; investigation of foodborne illness outbreaks; and response to natural disaster and intentional contamination events. Dr. Elliott is a graduate of Purdue University School of Veterinary Medicine.

**Craig Kaml, Ed.D.**, Vice President of Curriculum, International Food Protection Training Institute (IFPTI): Dr. Kaml is responsible for all development and delivery of curriculum at IFPTI. Prior to IFPTI, Dr. Kaml was Associate Dean of Extended University Programs, Director of the Distance Education Department, and Interim Associate Provost of Extended University Programs at Western Michigan University. Prior to that, he was Assistant Director of Distance Learning East Carolina University. He holds an Ed.D. in Educational Leadership, an M.A. in education (M.A.Ed) in Instructional Technology Specialist-Computers, both from East Carolina University, and a BS in Computer Information Systems from North Carolina Wesleyan College.

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**Denise Miller**, since 2011 has served as the Instructional Design Manager, the Quality Assurance Manager, and, currently, the Staff Writer at IFPTI. She is currently spearheading IFPTI's latest book project based on the Advanced Level of the Main Curriculum Framework for food and feed protection professionals; writing internal Standard Operating Procedures and the Annual Report; and collaborating with IFPTI leadership to write journal articles focusing on IFPTI's thought leadership and knowledge generation.

For nine years Ms. Miller served in the programming department at Grand Rapids Opportunities for Women (GROW) in Grand Rapids, Michigan. As the Program Manager for the Minding Your Own Business (MYOB) program and later as the Program Director at GROW, she provided business training and counseling, facilitating seminars and overseeing the development, marketing, and delivery of GROW's business programs targeting socio-economically disadvantaged women in west Michigan.

Previously, she served as the Assistant Director of International Programs at Kalamazoo College, overseeing the Africa-based study abroad programs (Kenya, Sénégal, and Zimbabwe), as well as marketing Kalamazoo College's study abroad programs nationwide. Ms. Miller delivered pre-departure and re-entry workshops and programs and edited the journal of students' study abroad reflections and photography, *The Atlas*, as well as the program-specific "Cultural Guidebooks." She directed the implementation of an Andrew W. Mellon Foundation grant to establish three consortium-based study abroad programs in Ecuador, England, and South Africa, through the collaboration of Bowdoin, Bates, and Colby Colleges in Maine.

**Melinda Plaisier**, is Associate Commissioner for Regulatory Affairs at the Food and Drug Administration. She has responsibility for over 4,000 staff and operations in the Office of Regulatory Affairs (ORA), Global Regulatory Operations and Policy. ORA has responsibility for imports, inspections and investigations, compliance and enforcement, and field laboratory operations.

ORA supports FDA's product centers by inspecting regulated products and manufacturers, analyzing samples of regulated products, reviewing imported products offered for entry into the United States, and responding to public health emergencies. ORA also works with other Federal, State, Local, Tribal and Territorial, as well as foreign regulatory counterparts to further FDA's mission.

Mrs. Plaisier began her career in public policy, working in the U.S. Congress for over a decade. She joined FDA in 1995, spending more than 13 years in the Office of the Commissioner, where she served as the Associate Commissioner for Legislation, providing executive leadership in directing and managing the agency's congressional relations and legislative activities. She also served as the Associate Commissioner for International Programs, where she focused on negotiating international agreements and working with developing nations.

Prior to becoming Associate Commissioner for Regulatory Affairs, she served as the Regional Food and Drug Director (RFDD) for the Central Region. As the RFDD, she

provided executive leadership in directing and managing the programs of FDA within the 15 states of the Central Region. Throughout her tenure in government she has been recognized for her leadership and management contributions with numerous agency honor awards, including FDA's highest award, the Award of Merit. In 2004 and again in 2009, Mrs. Plaisier was awarded the Presidential Meritorious Rank Award for exceptional long-term accomplishments in the Senior Executive Service.

**Stephen Stich** started his career with the New York State Department of Agriculture and Markets, Division of Food Safety and Inspection in 1987 as a Food Inspector. In 1992 Steve was promoted to a supervisory position in Albany where he progressed through the ranks and was named Director in 2010.

Steve is a current member of several food associations, including the Association of Food and Drug Officials where he is the current President. Steve also participates in several multi-state, and federal food safety working groups and alliances.

**Dr. Steven Solomon**, was appointed as the Deputy Associate Commissioner for Regulatory Affairs within the Food and Drug Administration's Office of Regulatory Affairs (ORA) in April 2014. Prior to this appointment, he served as the Associate Director for Global Operations and Policy in the Office of Global Regulatory Operations and Policy where he provided leadership on issues related to trade, global public health policy, global supply chain and specific issues related to China, India, and the G-8. He has also served as the Deputy Associate Commissioner for Compliance Policy in ORA, where he was responsible for domestic and international compliance policy as well as furthering the development of risk management within the organization. He has worked at FDA since 1990 in various capacities including in the Center for Veterinary Medicine as a veterinary medical reviewer and in the Office of Enforcement and Office of Regional Operations within ORA. Dr. Solomon has a DVM degree from Ohio State University and a Masters of Public Health from Johns Hopkins University. Prior to joining FDA, he owned and operated a private veterinary practice.

**Dan S. Smyly**, formerly held a position of Scientific & Regulatory Affairs Director with The Coca-Cola Company, North America Group in Atlanta, Georgia. Dan retired on March 31, 2013.

Prior to joining the Company in 1998, Dr. Smyly served as the Director of the Division of Food Safety in the Florida Department of Agriculture and Consumer Services in Tallahassee, Florida. He also held the position of State Chemist and Director of the Division of Chemistry, as well as other scientific and administrative positions during his 28-year career with that state agency.

Dr. Smyly remains active and has served in leadership roles in several scientific and professional organizations. He served as president of the Association of Food and Drug Officials of the Southern States (AFDOSS) in 1993 and was a key player in the establishment of the Seafood HACCP Alliance. In 1998, he served as president of the national Association of Food and Drug Officials (AFDO), and during his tenure as president of AFDO he initiated the dialogue for a fully integrated national food safety system. He currently serves as a member of the AFDO Associate Members

Committee, the AFDO Endowment Foundation Board of Trustees, and is a past industry representative to the AFDO Board of Directors. Dr. Smyly also served as Chair of the Science and Technology Council (Council III) of the Conference of Food Protection (CFP) in 1996, as Vice Chair of the CFP in 2000-2002 (the highest office allowed for industry representatives), and as a past long-term member of the CFP Executive Board of Directors (term expired in 2008).

Dr. Smyly received a Bachelor of Science degree in chemistry from Mississippi College in 1964 and a Ph.D. in analytical chemistry in 1970.

**Christopher Weiss**, Christopher Weiss, Ph.D., has been working in the non-profit sector over the past 15 years in areas related to food safety and consumer education and advocacy. Weiss spent 12 years with a non-profit association devoted to food allergy and anaphylaxis awareness, where he served as Vice President of Advocacy and Government Relations. During his tenure there, he helped enact significant laws such as the Food Allergen Labeling and Consumer Protection Act, which mandated allergen labeling requirements on the food manufacturing industry, and Section 112 of the Food Safety Modernization Act (FSMA), which called for the creation of national food allergy management guidelines for schools and early childhood education centers in the U.S. For the last three years, Weiss has worked at the International Food Protection Training Institute (IFPTI) in Battle Creek, Michigan, where he has played a key role in helping the U.S. Food and Drug Administration use the IFPTI curriculum development process to create a competent regulatory workforce across the U.S. in furtherance of the integrated food safety system as envisioned by FSMA. Weiss has also contributed to the development and dissemination of a variety of IFPTI publications, including peer-reviewed journal articles, organization annual reports, newsletter articles, and IFPTI's first book, *Regulatory Foundations for the Food Protection Professional*, which represents the first time that all food safety content areas necessary for Entry Level Food Protection Professionals have been covered in one publication. During his career, Weiss has collaborated with federal agencies such as FDA, USDA, and CDC; international organizations such as WHO; and representatives from the food industry and consumer groups.

## **President's Address**

**Steve Stitch**

**New York Department of Agriculture & Markets**

**AFDO 119<sup>th</sup> Annual Educational Conference**

**Indianapolis, IN – Sunday, June 21, 2015**

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Welcome, and thank you all for joining us at AFDO's 119<sup>th</sup> annual educational Conference in beautiful Indianapolis, IN. Our theme this year is "In Motion: Science Transforming Policy in Food, Drugs, and Medical Devices." I think you'll find our agenda matches that theme. As many of you know, the Past President is the Chair of the Conference committee for the following year, something I've unfortunately been unsuccessful in changing during my Presidency. So thank you Dave Read and the entire committee for putting this year's program together.

We continue to be in an interesting and transformative time, many would say the greatest in at least a few generations. We continue to focus on FSMA rules, only now it has shifted from review and comment to implementation. We continue to focus on integration of the food safety system, something AFDO has been talking about since 1998. And now, more and more we can see several seemingly separate initiatives beginning to link together. Manufactured and Retail Food Program Standards, lab accreditation, Rapid Response Teams, standardized training, the Partnership for Food Protection, and integrated FSMA phase 2 implementation workgroups; all starting to come together, toward the same end. Implementation and Integration are a connected long term process that AFDO Presidents will continue to talk about for many years to come.

For me it's been an incredibly interesting and busy year that has virtually flown by. I never got to the point where I woke up and didn't know what town I was in, but I did have a few panic attacks wondering at the last minute if I made hotel reservations, plugged in my TSA known traveler numbers, or had my precious jump drives with me.

I had the great pleasure of attending all 6 of AFDO's affiliate meetings, starting with WAFDO hosting last year's AFDO Conference in Denver. Then NCAFDO in Cleveland, MCAFDO in OKC, CASA in VA Beach, NEFDOA in S. Burlington, VT, and finally AFDOSS in Savannah, GA just a few weeks ago. In between were sprinkled travel to Vermont for the annual fall NASDA Meeting, with IFPTI to Costa Rica to meet with IICA (the Inter-American Institute for Cooperation on Agriculture), then in January to San Antonio, TX to meet with USDA, FSIS. And of course the usual meetings in my government role, PFP, MFRPA, RRT, FDA's Public meeting on implementation of the FSMA rules and a few others.

At the Wiley Awards banquet in Denver last year, I stated that my agenda, or focus as incoming President, was AFDO's agenda. In other words, we must continue to push forward on our short and long term agendas; including integration of the food safety system, implementation of the FSMA rules, and our training objectives. There's too much at stake to stray too far.

I'm amazed and very proud of the AFDO initiatives and accomplishments that have occurred in just this past year, and I'd like to highlight a few of them:

1. In October of 2014 the AFDO Board presented its training proposal to FDA leadership. The proposal is based on the ever increasing need for training of state and local inspectors, and fiscal responsibility. The key elements include
  - AFDO's proposal to survey states to determine training needs
  - Development of a system to determine training qualifications
  - And train the trainer courses so states can provide their own training at home
  - I'm happy to report that FDA agrees with the key elements of this proposal, and much of it has been put in motion.
2. On April 28<sup>th</sup> of this year, AFDO hosted a pre-conference forum on integration of the food safety system at the Food Safety Summit in Baltimore. The first time AFDO has provided a full day session at the Summit. The forum provided an overview of FDA-State integration efforts, where we were, where we are, success stories, and where we want to be down the road. Despite the social unrest in Baltimore that week, the forum was a rousing success with about 200 attendees. In fact, the Summit has already expressed their interest in having us back.
3. When NASDA applied for a cooperative agreement from FDA to develop an implementation plan for state adoption of the FSMA produce safety rule, they included AFDO as a partner. This agreement was awarded to NASDA in September of last year. AFDO's short term role is surveying states to determine current authorities, farm inventory, and adoption plans. Long term, AFDO will continue to be involved in the development of the implementation plan, and the development of standards.
4. In 2013 AFDO President Dave Read and Executive Director Joe Corby began monthly phone calls with Jeff Ferrar and Barbara Cassens with FDA's Office of Partnerships. And we've continued those calls. But, when we met with USDA leadership last fall, we realized we should also be in regular communication with them on integration efforts. So we're now also having calls with USDA on a regular basis. The topics of discussion include USDA's proposed retail beef grinding records, challenges of the local foods movement; joint outreach, training, and surveillance, and the recognition of USDA's important contributions to AFDO's Food and Meat Committees. Thanks to Keith Payne, our USDA Advisor to the AFDO Board for helping to make that happen.
5. And finally new AFDO scholarships to increase participation in our annual conference. 13 new scholarships for state and local officials, and one scholarship for each affiliate for future leaders. Together with the IFPTI fellowship program, AFDO is building its capacity, and in effect, establishing a succession plan. It's been refreshing to see the new talent coming into AFDO the past few years.

Although I've been involved to some extent in each of these initiatives, in the end, they are all AFDO's accomplishments; the collective product of AFDO staff, Officers and Board members, Committee Chairs, and involved membership. I have always said that

the members attending and actively participating in this conference represent some of the most talented and passionate food and drug safety advocates in the country. If it's possible, I'm both humbled, and proud to be associated with all of you. As current President I've had the honor of publicly sharing AFDO's accomplishments. In a way, my most important job as President has been to champion AFDO's agenda, and keep it moving forward. I hope I have done a worthy job.

Before I finish, I want to briefly mention a few folks who I have especially relied on over the past few years: AFDO staff, especially Denise, Krystal and Randy for taking care of me; Joe Corby, esteemed mentor and friend; my colleagues and friends on the AFDO Board, who I will greatly miss; my Department, including my two Assistant Directors Erin Sawyer and John Luker who supported me throughout the year; and finally, my wife Cathy who has always supported my involvement with AFDO. She's also been able to share in much of my travels, managing logistics, visiting with our friends, and taking pictures of everything I couldn't see while I was in another meeting room, at another hotel, in another city, and even in another country.

It has been an extreme honor and privilege to serve you, AFDO's members; and represent this fine association as President.

Thank you all

**Glenn W. Kilpatrick Address**  
**Steven Solomon DVM**  
**Deputy Associate Commissioner for Regulatory Affairs**  
**U.S. Food and Drug Administration**  
**Glenn W. Kilpatrick Memorial Address**  
**AFDO 119<sup>th</sup> Annual Educational Conference**  
**Indianapolis, IN – June 21, 2015**

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It is my pleasure to be here with you today. I am deeply honored to have been asked to give the Glenn W. Kilpatrick Memorial Address at this year's conference.

Mr. Kilpatrick began working for the U.S. Food and Drug Administration (FDA) in 1960, after serving as the Director of Food and Drugs and Weights and Measures for the State of Utah for seven years. In 1972 he was appointed FDA's Associate Director for Federal-State Relations. One of the Consumer Safety Officers who worked for him for almost ten years was a man that some of you may remember—Bob Tucker. Bob was the former Chief of Hazardous Products right here in the State of Indiana; he came to work at FDA's Federal-State Relations office in 1962.

Bob described Glenn as "perhaps one of the most committed zealots for federal-state relations" that the agency has seen and said that Glenn was known to frequently chime in at meetings saying, "Well, what about the states?" Glenn was gifted in his ability to bring the state perspective to many agency issues and influence decisions, and helped to further develop a number of new FDA-state cooperative programs.

Glenn Kilpatrick's remarkable career included many noteworthy accomplishments, such as enhancing communication between FDA and the states through the use of a rapid electronic system called the National Regional State Telecommunications Network, (or NRSTEN). It was observed at the time that some of our own FDA districts were in fact jealous of the speed with which information was being shared between FDA headquarters and our state partners, because they claimed they were not getting it as quickly.

Mr. Kilpatrick is also credited with instituting our state contract program, whereby state agencies assumed responsibility for inspectional activities, thus eliminating duplication of work. Today's contract program has been enhanced and expanded upon and we now have over 100 food and feed contracts with state programs in place.

He instituted and coordinated planning and informational conferences between FDA and associations of state and local officials, and he is recognized as having increased the number of state officials commissioned as officers of what was then the Department of Health, Education and Welfare in the execution of mutual responsibilities. Today we have 4,220 state officials commissioned, with well over half of these for food and feed.

In fact, in reflecting upon Mr. Kilpatrick's accomplishments, I feel quite comfortable making the statement that Glenn Kilpatrick was responsible for laying the early foundation for what we now know as the Integrated National Food Safety System (or IFSS). I know that many of you have built upon that foundation through the years.

Kilpatrick may have been described as a zealot for the states, but this, in essence, was borne of his desire to improve the system that protects consumers. As a fellow zealot for public health, I am a strong advocate for an integrated national food safety system. Only through our collaborative efforts and relationships with each other can we form the food safety net that is needed to protect consumers.

Glenn Kilpatrick was aware, long ago, of a very important principle: No one agency--- neither FDA, nor our partner federal, state and local regulatory and public health agencies-- can protect public health alone. We *need* each other.

To give some background of our journey to date, I wanted to share with you some of the more recent history of building an integrated national food safety system and to assess where I see us now.

### **Integrated Food Safety System: Vision**

In 2009, working with the Partnership for Food Protection Coordinating Committee, FDA drafted a white paper outlining the strategic vision for establishing a fully integrated, national food safety system. This system would be built upon existing collaboration with federal, state, territorial, tribal, and local regulatory and public health partners to provide comprehensive and well-coordinated food safety coverage.

The challenges to the food safety system identified at that time included a lack of resources, outdated food safety laws, insufficient strategic planning and inadequate coordination of operations and activities.

Outside reports issued about our food safety system noted additional concerns including variations in standards, lack of interoperable data systems and legal impediments to sharing data.

Following the review of these system challenges, I presented a webinar in June 2010 entitled, “Establishing a Fully Integrated National Food Safety System” on behalf of the Partnership for Food Protection Coordinating Committee. The foundational concepts of the Integrated Food Safety System included:

- Developing standards to ensure consistency;
- Training and certifying a highly skilled workforce;
- Working across jurisdictions to ensure protection of the entire food supply;
- Creating mechanisms for data sharing;
- Ensuring the use of quality systems;
- Building oversight and accountability; and
- Constructing an adequate infrastructure, resources and funding mechanisms to build and sustain the program.

In June of 2010, an Institute Of Medicine report entitled, “Enhancing Food Safety: The Role of the Food and Drug Administration”, was issued. This report stated, “To be fully successful, national food safety systems must be built with continuous input from FDA’s regulatory and public health partners.”

As a student of history I enjoy expounding upon it, but its value is not to recite it, but to make sure we learn from it. I want to focus on what we have accomplished to date in addressing these issues, and what the future looks like.

### **Integrated Food Safety System - Present**

Since 2009, much work has been completed to assemble the various components of this vision. Various federal and state workgroups, which included many of you through the Partnership for Food Protection or PFP, the Association of Food and Drug Officials, and other venues, have volunteered time outside of their usual responsibilities to get us to where we are today.

### **New Laws**

The Food Safety Modernization Act (or FSMA), passed in January 2011 to update the outdated food safety laws. Many of these new regulations will be finalized and issued over the coming months. FSMA does many things to help an integrated food safety system; it legislates many of the actions that we have had underway, but now with a stronger mandate. We face both considerable opportunity to improve food safety through these preventive measures, and considerable challenges in implementing these new regulations into our federal and state regulatory programs.

### **Standards**

Our regulatory programs are closer than ever to becoming standardized, thanks to the program standards which have been jointly developed by FDA and state and local partners including the Manufactured Food Regulatory Program Standards (or MFRPS), the Voluntary Retail Food Regulatory Program Standards and the Animal Feed Regulatory Program Standards (or AFRPS).

A significant milestone is the establishment of a process to continually assess and revise these standards based upon changes in our regulatory environment. Improvements in the retail food standards are made through a process that includes the Conference for Food Protection. The MFRPS Alliance, earlier this year, completed revisions of their standards and forwarded their recommendations to the PFP Governing Council for approval. These revisions to the program standards allow for constant program enhancement and promotion of national uniformity. We are looking for a similar standards improvement process to be developed under AFRPS.

## **Quality Systems**

One of the premises of a systems approach is the recognition that no regulatory system is perfect. A key objective is to have a robust quality management system so that we can incorporate a process of continuous improvement in meeting our public health mission. We each have built our respective federal and state quality management systems, however, an area we need to focus on is making these quality management systems more interactive to allow for enhancement in the entire system so that feedback and corrective actions take place both locally and nationally.

## **Oversight and accountability**

Following joint development of the standards there is a need for time, investment, and assistance to adopt the standards within our respective regulatory systems; which is currently happening. There must be an internal and external assessment process for each party to determine the success in meeting the standards. We continue to improve this process. I would also note that our integrated national food safety system is increasingly being audited by foreign governments. Just in the past few months we have been audited by the European Union, Australia, Canada, China and Indonesia.

As many of you are aware, the Government Accountability Office, or GAO, initiated an oversight study earlier this year focused on our progress in integrating federal, state and local food safety. Some of you in this audience may be asked by GAO for input and I encourage you to be open to this request. Please provide your candid position so that we have a record of both the strengths and challenges of our integrated national food safety system.

## **Strategic Planning and input from regulatory and public health partners**

To address the challenges that were noted regarding lack of strategic planning in our domestic food safety system, the PFP developed and released a strategic plan for the next six years. This plan was developed jointly and feedback was incorporated from the last 50 state meeting. The PFP governing council has also agreed to become part of a newly formed FSMA state strategy workgroup under the umbrella of the FDA Food and Veterinary Medicine Executive Council. To enhance collaboration on strategic planning we have embedded state officials in our implementation groups for FSMA, and are working with the National Association of State Departments of Agriculture, NASDA, who has taken a leading role in helping the states implement the produce regulation.

## **Training**

We all recognize the critical role of training in assuring the competency of a well skilled work force. We have come a long way since the “bubble schematic” that some of you may recall that Gary German, former head of our training division, put together to describe the vision for an “integrated food safety training and certification system.” Since that time, FDA and the states have been working together to carefully describe and analyze the job functions of both state and federal food safety professionals to complete what is known as a “Job Task Analysis” or “JTA”.

This JTA was then examined further to determine the core competencies for various positions—that is to say, what is the essential knowledge, and what are the skills and abilities—that are necessary and required to be successful at doing the job. Once these core competencies are identified, we can then develop the curriculum needed to ensure that we have a highly skilled work force. In doing this work we are collaborating with the PFP Training work group, the International Food Protection Training Institute (IFPTI), academia, and other partners to develop the training needed for our professional food safety employees.

We are hosting an inaugural food safety training summit later this year and have invited key partners to participate in this process, which will continue over the following months.

While State, local and tribal officials have had access to the same online courses and training modules as FDA for some time, we are implementing FSMA training in new ways to encourage federal and state staff training together whenever possible. In this way, staffs learn the same thing, at the same time, whether it is in the classroom or on the job.

### **Working across jurisdictions**

I have observed an increase in working relationships across the food safety system, for example, states mentoring other states, development and sharing of best practices, collaboration on IT systems, leveraging of laboratory capability and expertise, and many more instances. These are outstanding examples of our collective desire to not only build our individual program, but to construct a system that works across jurisdictions. We have been extremely successful in expanding our food safety response activities through our Rapid Response Teams (or RRTs). These teams demonstrate integration among the various disciplines and agencies necessary to improve response to food borne outbreaks and protect consumers.

These collaborations between our state and federal partners have been so successful that two states, on their own accord, have decided to build RRTs with their district offices.

Another cross-jurisdictional effort has been our Food Protection Task Forces. Task force membership includes local FDA districts, academia, law enforcement, local health departments, state regulatory and health officials, and industry among others. In order to collaborate and leverage you need to know your partner. These task force meetings have allowed the establishment of the relationships needed to enhance cooperation and information sharing between all partners within a geographical area. We all recognize the need to build a larger community of food protection stakeholders and these task forces can serve as a potential local model for the future of food protection that fits into a nationally integrated food safety system.

### **Information Sharing**

While we have not resolved all the legal impediments to information sharing, we have built new disclosure mechanisms using section 20.88 of Title 21 of the Code of Federal

Regulations. This allows for a single-signature authorization of all officials within a state agency.

We currently have 89 single-signature 20.88 agreements in place for agencies doing food and feed work. We continue to focus on improving information sharing through multiple channels such as the 50-state informational calls, the Reportable Food Registry, recent enhancements to our IT systems such as the inclusion of recalls in eSAF, development of a portal for state access to real-time food registration information, and enhancements to eLEXNET and FoodShield. We have also incorporated the PFP IT Workgroup and other state members into the planning process for the development of our Observation and Corrective Action Report (OCAR) system that is currently under construction.

## **Resources**

On our end, FDA has significantly increased its investments in state and local regulatory and public health agencies to further the effort. We have almost tripled our investment for contracts, grants and cooperative agreements from 2009 – 2015. Additionally, the President has proposed in the FY16 Budget a \$32M increase in funding to help support IFSS. Recognizing that one size does not fit all, we are working with our partners to look at new funding models that have greater flexibility and impose less administrative burden on FDA and the states. We must create a sustainable model, and we believe that one way we can facilitate this is by consolidating funding for programs with interrelated activities and goals while ensuring equitable funding based upon mutually acceptable criteria.

FDA has also invested in our state liaisons, district emergency response coordinators (ERCs), regional emergency response coordinators (RERCs), our cooperative program staffs, and others that are critical to integrate our food safety activities. States are also using dedicated staff to support the IFSS. Resources will always be a challenge for us collectively, so together; we must do a better job of telling our food safety story and highlighting the value and successes of an IFSS to our appropriators and stakeholders.

## **Looking toward the future**

There is a deep commitment to sustain these efforts not only by FDA, but by our state and local regulatory and public health partners as well. Our greatest strength is our collective commitment to our food safety and public health mission. So many of you have contributed your own time, intellect, and energy to working on these activities, and for that we are truly appreciative.

The PFP strategic plan has a vision of “Mutual reliance for a safer food supply” and has established guiding principles and key components that define the seamless operation of the integrated national food safety system. Mutual reliance can mean different things to different people, so I will elaborate what it means to me and to us, the FDA. FDA sees mutual reliance as building upon our existing relationships with regulatory and public health partners through increasing the exchange of information that is critical to making decisions that protect the public health. When I speak of mutual reliance with respect to our local, state and other federal food safety partners, I’m talking about reaching a level

of confidence such that we can fully rely on each other's work to make and implement public health decisions and controls.

To continue to move forward, over the next 12 – 18 months, FDA is teaming up with a couple of partners on “mutual reliance” pilots which we believe will help practically inform the practices, policies, and further investments needed to advance an integrated national food safety system. These pilots will be conducted by federal and state field staff representing various geographical areas of the country. Once completed, their evaluation and lessons-learned will be shared with a broader audience through the Partnership for Food Protection.

There are many quantitative outputs and measures to look at in determining our progress in developing an integrated national food safety system. For example, the number of jurisdictions enrolled in and inspections done under standardized programs; how rapidly we identify, trace back to source and remove contaminated product from the market; number of laboratories and volume of sample analyses conducted by accredited labs; number of joint or complimentary enforcement actions taken; and many other measures I am sure you can think of. However, a significant challenge is that we do not have, at this time, a single metric to tell us our progress in integrating the national food safety system.

The most integral aspects of any partnership are trust, respect and open communication. Partnerships are dependent upon the ability and willingness of the partners to work through problems and roadblocks in the sharing of a common goal. While a qualitative measure, I offer the following: I attend a fair number of joint FDA/State conferences. I historically came back from each conference with a “laundry list” of complaints and issues that various parties raised to my attention.

This past year, I have been to multiple meetings and not only have I not walked away with that list, but for the first time, folks have stood up and affirmatively complimented the partnerships. Do I think that this is because there are no problems? NO! But what that tells me is that there has been a fundamental shift in our institutional cultural attitudes that allows these problems to be worked out at lower levels. To me this is a significant measure of our progress.

In closing, I offer that what started out as Glenn Kilpatrick's original vision of shared responsibility, close collaboration and rapid communication, and then evolved into a vision of having seamless partnerships and operations to better protect public health, is no longer just a vision—it has taken root and grown. It is the reality of what we are doing every day. We need only look around us to see that this is true. Not only has it taken form, but it is the envy of many of our international partners, who have been auditing us, observing what we are doing and taking back aspects of our IFSS to their own countries. Are we done? No, and let me be clear, we will never be done.

We will continue to be tested by new and repeat public health, fiscal, political and logistical challenges. And we will continue to rise to these challenges and move forward for the greater public good.

I would like to thank each of you for what you have accomplished. I commend you for your perseverance, dedication and resiliency in advocating for and creating an

integrated national food safety system. Never forget that our strength is in the unity of our collective mission. What we have done to build the IFSS has improved food safety and established a stronger safety net to protect consumers and will continue to do so for generations to come. The vision is now a reality.

And while we will work together to improve and sustain this reality, I want to remind you that it is the work that each of us does in our daily lives to protect the American public that truly honors the spirit of Glenn Kilpatrick.

It has been my privilege to be a part of this effort, and to speak with you today.

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**U.S. Food and Drug Administration Associate Commissioner for  
Regulatory Affairs Update  
Melinda Plaisier  
Associate Commissioner for Regulatory Affairs  
U.S. Food and Drug Administration  
AFDO 119<sup>th</sup> Annual Educational Conference  
Indianapolis, IN – June 22, 2015**

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*(Transcribed)*

Good morning, everyone. I want to thank the Association of Food and Drug Officials (AFDO), for this opportunity to provide you with an update on the Food and Drug Administration's Office of Regulatory Affairs (ORA). I also appreciate the opportunity to be back home again in Indiana. I'm a proud Hoosier and Indianapolis is my hometown.

In keeping with this year's conference theme, I'm going to talk with you this morning about how FDA and ORA are in motion: Transforming ORA's organization and operations.

For anyone new to AFDO or FDA, ORA is the agency's field organization. We're often referred to as the "field", or the "eyes and ears" of FDA. We are approximately 5,000 men and women across the U.S. grouped into 20 districts, five regions and over 270 offices, resident posts or home domiciles, and we have investigators in three foreign offices. We cover a wide range of enterprise-wide responsibilities. We are:

The investigators, including criminal investigators who carry out inspections and investigations;

Compliance officers who work with the investigators and center offices of compliance to translate inspections into actions, where warranted;

Imports staff who protect our borders, screening FDA-regulated products offered for import into the U.S. working with U.S. Customs and Border Protection and other federal agencies with border safety and security responsibilities;

We have a national network of 13 laboratories, and an office of regulatory science, who provides the regulatory science foundation for the work we do;

We leverage and collaborate with federal, state and local partners through our state cooperative programs, state liaisons, district collaborations, and staff in the office of partnerships who oversee standards programs, contracts, grants and other cooperative arrangements;

We also leverage increasingly with foreign regulatory counterparts;  
We have a communications staff focused on improving transparency internally and externally;

We have a network of recall coordinators, consumer complaint coordinators, emergency response coordinators, establishment inventory coordinators, and quality systems managers;

We have an expanding group of policy and risk management experts; a training staff; and of course a robust infrastructure of administrative and mission support staff – all whom work across ORA.

I am extremely honored to be leading this extraordinary organization. It is an exciting time to be at FDA, and particularly to be in ORA. We are on the cusp of perhaps the most significant change, ever, to our operations and organization.

### **Drivers for Change**

In a 2012 speech to the Food and Drug Law Institute, then-Commissioner Margaret Hamburg spoke of several things driving change and driving our work:

New legislation;  
Compelling public health imperatives;  
Advances of science and technology; and  
Globalization

Those drivers are as salient now as they were nearly three years ago, and they remain the drivers of our change efforts today.

While the agency overall is undergoing a transformation at many levels, I will focus on the change I'm leading in ORA, and the work we have underway — much of which are collaborative efforts across the agency with our colleagues in programs and centers— and, with foreign, federal, state, local, tribal and territorial partners, as well as associations such as AFDO.

### **FDA and ORA's Change Initiatives**

We have three main streams of change underway. While they are not mutually exclusive, they are complimentary, and ultimately together will result in significant organizational and operational change in ORA.

Program Alignment;  
Center Initiatives – some driven by legislation, some self-driven change initiatives; and,  
ORA's fiscal year strategic priorities.

I'll start with Program Alignment.

#### **1. Program Alignment**

In September 2013, Dr. Hamburg issued a charge to FDA's senior leaders to transition to distinct commodity-based and vertically integrated regulatory programs with well-defined leads, coherent policy and strategy development, well-designed and coordinated implementation and a de-layered management structure.

She also charged us to look at specialization of investigations and compliance, training, new work planning models, compliance policy and enforcement strategies, laboratory optimization, and “best business processes”.

In February 2014, she issued a second memorandum, referred to as the “decisions” memo, which outlined and then affirmed a common set of recommendations the leadership had submitted to her in response to her charge. That decision memo has provided the framework for how we are collectively advancing Program Alignment across the agency, and certainly within ORA.

I’ll briefly walk through these decisions.

We agreed to establish commodity-based and vertically integrated regulatory programs in:

Pharmaceutical Quality

Food and Feed

Medical Devices and Radiological health

Products regulated by CBER (Center for Biologics Evaluation and Research)

Tobacco

Bioresearch Monitoring

And we added Imports as a specialized program area

Each program will be led by an ORA senior executive or senior manager, and over time, we will move from our current geographically-based management model to a program-based management model.

Our current regional management structure will be transitioned into ORA programs in fiscal year 2017, and ultimately be dissolved. No offices or laboratories will be closed due to alignment, nor will any regional staff be asked to move, but we will of course, continue to assess locations as leases come up as we always do.

The Regional Food and Drug Director (RFDD), positions are being transformed into the program executive positions.

Program Alignment – Program Directors & RFDDs

We are in the final stages of hiring program executives for food and feed, medical devices, and pharmaceuticals, and we have recently posted the vacancy for Biologics. In the interim, we have named people to act in these positions:

Joann Givens is the Acting Food and Feed Program Director. Previously she had been the Acting Regional Food and Drug Director for the Central Region and the FDA Food Safety Modernization Act (FSMA) Implementation co-lead with Roberta Wagner, Associate Director for FSMA Operations, in FDA’s Center for Food Safety and Applied Nutrition.

Alonza Cruse is the Acting Pharmaceutical Quality Program Director. He has been at headquarters serving as the Acting Director of the Office of Medical Products and Tobacco Operations since 2013, and is also currently the director of ORA’s Los Angeles District Office.

Captain Mutahar Shamsi, United States Public Health Service, is the Acting Medical Device Program Director. He is currently the District Director of ORA's New England District Office, and has served as the Acting Regional Food and Drug Director for the Northeast Region.

Kay Lewis is the Acting Biologics Program Director. She is currently the Director of ORA's San Francisco District Office.

Our current cadre of Regional Food and Drug Directors includes:

Dennis Baker, in the Southwest Region, and the only remaining permanent Regional Food and Drug Director

Anne Reid, Acting Regional Director for Southeast Region

Charles Becoat, Acting Regional Director for Northeast Region

Diana Amador-Toro, Acting Regional Director for Central Region

Dr. Bill Martin, Acting Regional Director for Pacific Region

During the transition year of fiscal year 2016, the Regional Food and Drug Directors will continue to run the regions, while the new Program Directors lead the development and establishment of the program staffs and new infrastructure that we intend to stand up in fiscal year 2017. Once the new management model is in effect, we will no longer use the Regional Food and Drug Director position.

## **2. Increase Specialization.**

ORA will increase specialization of investigators, compliance officers and operational managers to enable FDA to mirror and adapt to the increased specialization, sophistication and complexity of our regulated industries.

ORA is already highly specialized, but not exclusively specialized in a single program. This initiative will take us to a new level of expertise, whereby investigators, compliance officers and operational managers will specialize in a single program area with subspecialties in that same program.

As we move to increased specialization, we anticipate not only increasing the technical knowledge of our specialized inspectorate, but also hiring differently, bringing different skill sets and disciplines to our work force. For example, under the Food Safety Modernization Act Produce Safety Standards, we envision recruiting, training and retaining a cadre of produce safety experts to work closely with the states. For other programs, devices for example, we expect to hire more engineers, statisticians or nurses; or for drugs, more pharmacists or other medical professionals.

Strategies for combination products and cross-cutting specialties are still to be determined. And, strategies to afford one to switch programs during one's career will also be developed.

While we will be moving away from our current geographic management model to a program-based management model for investigations and compliance, we will also be retaining the district offices and their local functions.

The District Directors will still have all of their current responsibilities and duties for their district and states, including the important function of leading district/state/local collaborations. What will change is their operational oversight of investigations and compliance as it will be within a single program.

For state, local, tribal and territorial partners, we would expect your local District Director to remain a principal point of contact, but as we specialize, he/she may also work to triage any issues you may have specific to a program for which they may not have operational oversight. We will work closely with all partners when the time comes, to ensure we have clear and current contact information available for both local issues as well as program issues.

We are also taking this opportunity to look across ORA as an enterprise and assess any other changes that would benefit our staff, the organization, and ultimately provide enhanced public health protection. For example:

State Cooperative Programs will be aligned in the Food and Feed program, established as its own office, and then specialized by program – shellfish, dairy, and retail. The specialists' scope of work will not change but what will change is that all specialists within a given program will be established as a single specialized staff. A new director position will be established to lead State Cooperative Programs overall, and if the staffing ratios warrant it, additional program director positions will also be added; Our regional and district emergency response coordinators will be established as a staff, reporting into operations, but they will retain their current cross-cutting and geographic responsibilities, and continue to assist responding to emergencies with the Rapid Response Teams and other state and local emergency response planning, exercises, or other activities.

I am still considering other critical positions, such as the state liaisons, consumer complaint coordinators, recall coordinators, quality system managers, and our ever important administrative and mission support staff.

The goal is not to change for the sake of changing, it is to meet the charge of Program Alignment, creating efficiencies of operations, increased opportunity for our staff, but also preserving and enhancing the significant investments we have made at the state and local level, and ensuring we have the most effective and rational processes possible to best position us to protect public health.

### **3. Training**

In training we have committed to expand, enhance, and modernize our approach. ORA University- our internal training and development provider will remain the foundation for ORA's training programs, but we are developing new partnerships and models to establish curricula and sustainable ways to build, deliver and evaluate training, while dedicating the resources needed to meet the training needs of the future.

We have to ensure that all training provides the correct content, has high quality instruction and is transferable to the skills needed to build and retain the competency of our collective field staff – FDA, state and local partners.

Revamping and expanding a sustainable training program is critical to our ability to effectively implement and maintain Program Alignment as well as much of the new legislation.

#### **4. Compliance policy and enforcement strategies**

The agency is committed to ensuring we have clear, current, outcome-based, and effectively communicated compliance policies and enforcement strategies. We agreed to address barriers to efficiency such as many layers of case review, or lack of prioritization. We agreed that the centers lead the development and communication of compliance policy and enforcement strategies, in partnership and consultation with ORA, and we then take the lead in executing those policies and strategies.

Specializing our compliance officers and staff, and aligning them with the programs will also foster greater efficiency and effectiveness as we work to enhance the agency's compliance and enforcement infrastructure.

#### **5. Imports**

We have reviewed our import operations and determined that ORA needs to increase import specialization and focus on national import strategies. We are working with the centers to better define risk modeling, and establish import strategies by commodity.

Internally, we are looking at establishing additional import districts. The Southwest Import District, which sits across the southern U.S. border, serves as a model for future additional districts on the other borders.

And, we have infrastructure work to do in terms of pay grades, training, and other work force investments - treating imports as the specialization it already is.

#### **6. Lab Optimization**

As I previously mentioned, ORA has a national network of 13 laboratories. Many are "full service labs", others more focused in one or two program areas, and two "specialty labs" – the Forensic Chemistry Center, our only lab accredited to do forensic work, and the Winchester Engineering and Analytical Center, our only lab doing engineering and device work.

We are working on a plan that increases laboratory specialization, fosters Program Alignment and collaboration between ORA and the centers, and enhances our capabilities and promotes efficiency within the current laboratory configuration.

Organizationally, we will establish the labs as a single lab resource under a senior scientist. We recently announced the appointment of Dr. Paul Norris, as the senior

scientist to lead ORA's labs. While not specific to Program Alignment, Dr. Norris will also lead our collaborations with all of our science partners to advance our shared goals.

Like the AFDO theme of science transforming policy, science is the absolute foundation of all of the work we do.

## **7. New work planning**

We committed to revamp work planning – it is our internal process - the mechanics of how we work with each center to establish our annual “contract” for field activities.

We need to modernize the work-planning process and work with the centers to ensure we are truly basing it on risk factors, public health outcomes, past inspectional history, and operational experience. And work towards strategic long-term planning;

And, again, while not directly related to Program Alignment, enhancing and improving our processes of work planning with our state partners, remains a priority.

And, lastly, of course, we continue to have a FSMA inspection frequency mandate that has to be covered between FDA and our state partners.

## **8. Delaying/streamlining**

ORA and the centers also agreed we should de-layer management and review levels, where feasible, and push decision-making down to the lowest level practicable, in order to take timely and appropriate action, avoid duplication, improve efficiency, and enhance accountability. This effort will cut the layers of review that hinders our ability to protect the public health in a timely fashion.

In terms of delaying the number of managers, it is likely that we will need more managers and supervisors than we currently have, once we finalize our new management models. So, any further assessment of delaying management will focus more on the decision-making part of managing and supervising, than the actual number of positions.

## **9. The final area of decision is Business Processes Improvement**

While we are exploring new organizational structures, it needs to be recognized that business processes will need to be updated and enhanced to maximize efficiency regardless of organizational changes. Just the nomenclature alone, will require updates and changes to a wide range of documents – our SOPs, Field Management Directives, and the Investigators Operational Manual, to name a few. There will be significant “housekeeping” to do to ensure our business processes and procedures are current with the new structures and operations.

That's a very brief and high-level overview of Program Alignment. So how are we doing all of this?

From the onset, I committed to ORA that we would have a transparent and inclusive process, and we would take as much time as we needed to be thoughtful, thorough, and work to get this right.

We have employed a range of engagement tools:

Last year, I held town hall meetings in every district, I visited every laboratory, and met with each regional staff; We launched a SharePoint Engagement site, as the “go to” site for all ORA employees to get information, but more importantly as a portal for submitting information – ideas, questions, concerns, considerations. We’ve received over 600 submissions, and I am reading them all, as are my key leadership team. It has and continues to provide a wealth of great information to inform the decisions; We have held focus groups, “chats” formed after the “FSMA Chats”, and video messages. I’ve held All-Hands, and our managers have held brown bag meetings at the district level.

Aligning investigations, compliance and operational managers alone is a huge task. We have spent months gathering and analyzing data on all of our investigators, compliance officers, and operational managers to try to align individual proficiency, with preference and operational need. We are beginning to map out scenarios of programs to ensure it makes operational sense.

We are also beginning to calculate the number of districts and management teams we will need for each program, based on the work plan. We have made initial calculations which I rolled out at a March All-Hands, but we continue to revise them, which is why I did not present them here. They continue to evolve as we work to ensure we got it right before we finalize and make alignment assignments.

Also, there are dozens of working groups – ORA and the centers – working together on the action plans to design and begin to map implementation plans under each decision element – program-by-program. This first year, ORA alone, had 240 individual action items to complete on Program Alignment alone. We are working to get them all done by the end of this fiscal year, while also beginning to develop longer term action plans for FY16 and beyond.

It is fair to say Program Alignment does not only represent significant change, but also a Herculean task that will be ongoing for some time to come.

My goal is to determine alignment by the end of the summer, and make the remaining decisions by the end of this fiscal year, roll them out within ORA in early October, and then begin to transition throughout FY16. The overall goal remains standing up this new paradigm in FY17.

### **Legislation/Center Initiatives**

The second change effort, and perhaps the largest changes operationally, are being driven by center initiatives and legislative mandates. Some examples include:

For food and feed, as everyone here should know, the FDA Food Safety Modernization Act or FSMA is driving transformational operational change. Given FSMA has been the

major driver of our resources and focus since its passage in 2011, and the significant investments the agency has made to engage publicly about FSMA, I won't spend time discussing it but will mention this:

The FSMA Operational Strategy, released in May 2014, sets a framework for promoting widespread industry compliance, enhancing our operational partnerships with states and other government counterparts, and expanding the oversight tool kit to promote and verify compliance.

Examples include:

Changing how we approach inspections. We've all heard Deputy Commissioner Mike Taylor reference "educate before and while we regulate" which I recently learned was cribbed from a quote "educate before you regulate" from Secretary of Agriculture, Chuck Ross of Vermont. Regardless of the genesis of the quote, it has become somewhat of a mantra for us, and we recognize the importance of education first, when implementing new regulations.

We are also working on new approaches, new tools and tactics; We will put more emphasis on data analysis and targeted risk factors including risks associated with the product or industry and using the overall compliance history of the firm to determine our focus; We are exploring how we might provide firms incentives for compliance such as reduced scrutiny of firms with a proven track record; and, we will assess the compliance of individual firms and industries through a range of inspection and sampling techniques.

We are also focused on establishing a new staffing and training model which is also a goal under program alignment.

As we modernize our training model, AFDO, the International Food Protection Training Institute, and others will continue to be valued partners for providing training and education.

For medical products, particularly pharmaceuticals, there are multiple legislative mandates guiding our work, and one for tobacco.

And then center initiatives, like the Center for Drug Evaluation and Research's pharmaceutical quality initiative or the Center for Devices and Radiological Health's Case for Quality are also driving change in these product areas.

I'll highlight a few key changes underway:

The Food and Drug Administration Safety and Innovation Act (or FDASIA) provided a range of new authorities, and gives us tools to inspect firms in a more risk-based fashion.

We can now request records in lieu of or in advance of an inspection. And, the new law gives us the power to block imports in the event we are kept from inspecting an

overseas facility, or when companies refuse to provide full and complete information on their products.

We can also now detain drugs that an investigator believes to be adulterated or misbranded, and once the rule is finalized, we will be able to destroy drugs refused entry into the U.S. that are valued at \$2,500 or less. This new power will be important tools for our investigators in international mail facilities where they often see previously refused shipments, show up repeatedly, hoping to get through.

FDASIA also allows FDA to enter into agreements with foreign governments to recognize inspections. While work on this provision is ongoing, once realized, it will be a significant advancement in global integration.

Under the Generic Drug User Fee Act (or GDUFA), among the commitments, FDA will conduct risk-adjusted biennial surveillance inspections of active pharmaceutical ingredient and generic finished dosage form manufacturers with a goal of achieving parity of inspection frequency and depth of inspection between foreign and domestic in FY17.

Since 2012, we have conducted over 2,900 GMP inspections of generic manufacturing facilities, and almost 60 percent of these inspections were conducted overseas.

Another new law is the Drug Quality and Security Act (or DQSA), which contains important provisions relating to the oversight of compounding of human drugs.

DQSA was passed by congress on the heels of the fungal meningitis outbreak in late 2012, and it describes the requirements for compounded human drug products either as a manufacturer or outsourcer.

FDA anticipates that state boards of pharmacy will continue their oversight and regulation of the practice of pharmacy, including traditional pharmacy compounding. And, we will continue to cooperate with state authorities to address pharmacy compounding activities that may be volatile of the Food Drug and Cosmetic Act.

Since the fungal meningitis outbreak began, we have been conducting inspections of compounding pharmacies for cause (in response to serious adverse event reports and reports of quality problems) and proactively to identify pharmacies with deficient sterile compounding practices.

To date, ORA has completed well over 200 inspections, exercised oversight over at least 20 recalls by compounders, issued over 30 warning letters, issued nine state referral letters, obtained two consent decrees and three criminal prosecutions, and our work continues.

We are also working with the Center for Drug Evaluation and Research, on a new inspection protocol pilot to develop a new paradigm for inspections and reports that will advance pharmaceutical quality.

This represents a move away from our historic approach of looking for violations, to one of looking for a state of quality. Certainly, if we find a problem or risk to public health, we would execute a thorough inspection, and take action if warranted.

But through this pilot we hope to add to our approach and focus on measuring and ascertaining the state of quality production and quality systems in an inspected facility.

The general principles for the pilot include:

Standardized approach to inspection;  
Data gathering to inform “quality intelligence” of sites and products;  
Risk based and rule based process, using expert questions; Semi-qualitative scoring that allows for comparisons within and between sites; More common inspection report structure; and Recognize and reward positive behaviors in cases where facilities exceed basic compliance.

We are also working closely with the Center for Devices and Radiological Health (CDRH) on several key initiatives:

Under the Case for Quality initiative – which was launched in 2011, after consistently seeing a high volume of the same inspectional findings year after year, CDRH asked the question, “Are we using the right approach to improve device quality?” Several efforts were launched and ORA is actively engaged in two key activities:

### **1. The Voluntary Compliance Improvement Pilot.**

The objective is to assess the viability of achieving voluntary compliance using root-cause methodology with device firms that have self-identified as having issues that could subject them to a violated determination if FDA inspected.

For the pilot four device manufacturers (two foreign and two domestic) were identified. Expert consultants are working with the firms and certifying to FDA that the participants have defined the problems, analyzed root causes, and taken appropriate corrective action.

### **2. The Medical Device Innovation Consortium.**

It is a public-private partnership between industry, FDA, and non-profits. It was launched in 2012 with three goals:

Align resources, by working cooperatively to re-engineer pre-competitive technology innovation;

Accelerate progress by reducing the time and resources needed for new technology development, assessment, and review; and,

Achieve results by helping patients benefit by gaining access to new medical technologies sooner.

Workgroups are currently advancing a number of specific initiatives.

ORA continues to work closely with the Center for Tobacco Products (CTP) as CTP continues to implement the Family Smoking Prevention and Tobacco Control Act. We have established a small dedicated tobacco cadre in ORA, which we expect to expand as the need expands; and we are focusing tobacco lab work in our Southeast Regional Lab as well as the Forensic Chemistry Center.

These are just a few examples of change efforts being driven by legislation or center-led initiatives, but all represent significant operational change.

ORA's Strategic Priorities is the third change effort and it focuses on internal efforts to continuously improve.

### ORA's Strategic Priorities

In fiscal year 2015 we set four Strategic Priorities for ORA.

The first is to recruit, train, develop and retain a diverse world-class work force. We are working to ensure we are using all recruitment and retention tools available, and we're working to establish career ladders for all positions, and elevate our grade structure by strategically raising the floor and ceiling.

We are also working to enhance the culture of our organization and redefine our values, particularly in the face of change;

The second is Core Process Improvements – these range from big to smaller but with big impact. Examples of significant change include: lab optimization and import operations – both of which are direct overlaps with program alignment. In both areas I mentioned, we are working to assess the structures and functions overall, to create efficiencies in operations, and increase opportunities for our work force.

The smaller effort with a huge impact is working to enhance and improve foreign inspection trip planning. For anyone who has traveled globally, you know the work that goes into planning the logistics for a single trip. Last year, ORA completed over 3,000 foreign inspections, and as those numbers continue to increase, we must have a trip planning process that is seamless, provides timely and outstanding customer service to our travelers, while also ensuring the trip planning staff has the infrastructure, training and resources they need to manage the travel.

The third priority is to enhance our leveraging of partnerships – which I'll come back to - strengthening our relationship with federal, state, local, tribal and territorial public health and food safety partners remains a priority.

Improve infrastructure – facilities and IT. ORA staff work in more than 270 facilities located around the U.S., some are FDA owned facilities, others leased. These facilities are in varying states of repair or disrepair. We are working with FDA's budget office to establish a long-range strategic plan for addressing our facility's needs.

In addition, ORA is nearly completely dependent on IT to get our jobs done, and we simply have to have a modern, reliable, effective, and accessible IT infrastructure – programs and systems. On the large scale, we are working to assess our overall architecture, and on the smaller, but equally important end is our work to get modern tools into the hands of our employees including more tablets and hand-held devices.

And, we are very mindful of and working on developing an effective two-way IT system for information sharing with our regulatory and public health partners.

I'd like to close by talking about our partnerships.

### Investments in Partnerships

While it is one of our strategic goals, building and maintaining effective partnerships permeates everything we are doing in ORA to advance FDA's public health mission.

All of the changes we are working to achieve in ORA organizationally and operationally will create efficiencies and opportunities for our employees. But, the bottom line is regardless of how much we improve efficiency of operations, our partnerships are critical to our collective ability to ensure an effective public health safety net.

Partnerships with our foreign, federal, state, local, tribal and territorial partners, and partnerships with key associations are critical to the strength of that safety net.

And, in our future state, we will have new ways to work with industry.

Regardless of your role, it takes all of us, and we each bring different knowledge, skill, ability, and responsibility to the food and feed safety and public health table.

For ORA, this commitment has translated into real investments of time, effort, and money.

We continue to invest in our Office of Partnerships to expand their staff and role.

We are in the process of adding an "integration staff" to better support and help advance an integrated food safety system through additional support and staff assistance for the Partnership for Food Protection governing council, various workgroups and several cooperative agreements;

We are adding an "international & federal relations" staff to better support ORA's investments and contributions to international and federal collaborations;

And, I am very hopeful we can soon announce our permanent director. The delay is due to an "executive slot" human resources issue that has come up, more a technicality than a problem, but it is resulting in a delay in making a long-awaited announcement. I want to acknowledge and thank Barbara Cassens for her strong and invaluable leadership, serving in an acting capacity for a prolonged time.

We continue to invest in District/State collaborations. Some are very successful and models for others. And, others are still evolving. Regardless, these collaborations are invaluable and we will continue to work to make this a successful part of the way we do business.

We are heavily invested with many of you in the Partnership for Food Protection. Together, we have advanced work towards achieving an integrated food safety system through the development and adoption of “best practices documents”. We’ve issued them for:

Food/Feed Testing Labs;

Principles for Information Technology; and,

A Model for Local, Federal, State Planning and Coordination of Field Operations and Training.

We are working with key associations in new ways such as with:

AFDO through a cooperative agreement for retail foods and another for the Manufactured Foods Regulatory Program Standards Alliance – both intended to advance the Integrated Food Safety System;

The Association of Public Health Labs, AFDO and the American Association of Feed Control Officials through a cooperative agreement on labs and science to advance and improve our scientific collaborations and laboratory network;

The National Environmental Health Association through an agreement on training and we also partner on training with the International Food Protection Training Institute, and universities – Auburn, the University of California, North Carolina University, and the University of Tennessee.

The National Association of State Departments of Agriculture (NASDA) with whom we have a cooperative agreement for implementation of the FSMA produce rule to help us Establish the number of farms impacted,

The state agencies that want to take a leadership role in implementing this rule, and, To develop novel ways such as pre-inspection assessments to help educate the industry to be in compliance with the rule.

And, AFDO is also engaged in this work with us and NASDA.

We also partner with the National Egg Regulatory Officials, the Interstate Shellfish Sanitation Conference, and the Conference of Interstate Milk Shippers, all intended to enhance our collaborations in these important programs.

ORA has also increased our fiscal investment through our contracts, grants and cooperative agreements programs – going from a \$25 million investment in 2009 to over \$60 million last year – a total of \$240 million over the last six years. This represents investments in:

Contracts – We contract about 23,000 inspections per year, including about 15,000 in food/feed, just under 7,000 Mammography Quality Standards inspections, and just under two dozen medical device inspections – a relatively new area of inspection collaboration.

Cooperative Agreements – We have our cooperative agreements programs that support the three regulatory program standards, as well as supporting the Rapid Response Teams.

The Manufactured Foods Regulatory Program Standards (MFRPS) (10 foundational standards) were first released in 2007 in response to an Office of the Inspector General report recommending that we take steps to promote equivalency among federal-state food safety entities. There are now have 40 states enrolled, representing 89 percent of our contract inspections.

And, I am very pleased to announce that the Wisconsin Department of Agriculture Trade and Consumer Protection is the first state to meet the MFRPS standards; Animal Feed Regulatory Program Standards – launched in 2014, like MFRPS intend to establish a uniform foundation for the design and management of state programs responsible for the regulation of animal feed. Our first year goal of enrolling five states was surpassed by enrolling 12 states, with additional states in the queue.

Retail Foods Regulatory Program Standards is a good example of new ways of partnering. These standards provide a guide to design and manage state, local, tribal, and territorial retail food programs. There are approximately 2,300 jurisdictions eligible to enroll and as of April of this year 649 or approximately 28 percent were enrolled.

The scope of managing this program is extensive and the cooperative agreement with AFDO has provided a vehicle through which retail programs can apply for the funding they need to build their capacity and infrastructure.

Rapid Response Teams began in 2008 to develop multi-jurisdictional teams that operate using Incident Command System principles of a Unified Command structure for all-hazard preparedness, response, mitigation and recovery within the integrated food safety system. We now have 18 states and 14 FDA districts participating.

Other Federal-State Cooperative Efforts include investments like:

Investing in the Food Emergency Response Network or FERN – an integrated, secure lab network with federal, state and local partners. We work on methods development, training, proficiency testing, surveillance assignments, and electronic communications and collaborations;

Food Protection Task Force (FPTF) grants – which provide funding for task force meetings with stakeholders to execute food protection projects, foster communication and cooperation, and collaboration among state, local, and tribal food protection, public health and agriculture regulatory agencies. Currently 15 states and the District of Columbia have FPTF grants.

Association agreements, scientific conference cooperative agreements, innovative food defense cooperative agreements, a milk drug residue database contract, investing in Food Shield, funding for partner training, and supplies, and we've funded studies and workshops – all intended to advance integration as we work to shore up that safety net.

FSMA is a game changer. We will be working with all of our partners to ensure these investments continue and that we continue to make the right investments for the times.

We also have partnership investments beyond food and feed. We participate in and fiscally support the Pharmacy Compounding 50-state meetings and co-lead and support with funds the Case for Quality in the Medical Devices Innovation Consortium.

Globally, our partnerships are focused on building a foundation for increased collaboration and trust. FDA's Office of International Programs (OIP) leads the portfolio, but ORA has a seat at the table on all of the key initiatives.

We continue to work in multilateral forums, and bilaterally, in a more strategic way. I'll share just a few examples with you.

Bilaterally we are working with OIP and the Centers on:

Comparability assessments with key partners – we continue to work with New Zealand, the first partner with whom we concluded a Food Safety Systems Recognition Agreement. Now we are working on comparability assessments with Canada and Australia;

FDA has established a Produce Working Group with Mexico intended to focus on preventive practices and verification measures for the production of safe produce.

And, we are invested in FDA's Mutual Reliance Initiative, launched in May 2014. It is a strategic collaboration between FDA and the European Union to evaluate whether we have comparable regulatory and procedural frameworks for inspections of manufacturers of human pharmaceuticals with a goal of relying on each other's inspectional information.

As part of the Mutual Reliance collaboration, we will analyze whether the differences and variability matter in terms of the quality of the oversight and our ability to receive information that each system could confidently rely on to make regulatory decisions.

Multilaterally,

We participate in the Pharmaceutical Inspection Cooperation Scheme or PICS is intended to facilitate networking between participating authorities and the maintenance of confidentiality commitments, exchanges of information and experiences in the field of GMP, and the mutual training of GMP inspectors.

FDA became a member in 2011, and PICS now includes 46 countries. FDA is an active member with the newly developing PICS Training Academy, which will serve as a virtual training resource for inspectors. PICS allows for a more effective use of inspection resources through sharing lists of planned inspections and access to reports of inspection.

Lastly, the joint inspection initiative supports our relationship building efforts, and we make every effort to have the competent authority join us, whether as an observer, training, or a true joint inspection. Thus far we have done about 56 drug inspections and 26 medical device inspections where a competent authority has joined us in some capacity.

These are just a few examples of the valuable investments ORA has and is making to support the advancement of effective partnerships. I have been saying “our partnerships are more important now than ever” for the last decade – and it is still true. It will simply take all of us – working together to ensure an effective public health safety net.

I am mindful that I have just shared with you a lot of information, and I’ve kept it pretty high level, but I wanted to be able to give you a good sense of the scope of work and change underway in ORA.

Program Alignment – driving significant organizational change and some operational change;

Center Led Initiatives and Legislation – driving significant operational change; and, ORA’s Strategic Priorities – which go to the core of our organization.

And, I didn’t even mention our “day jobs” and the work we do every day to meet our obligations to the agency and public health.

I welcome you to ask questions, submit comments or suggestions. Please submit them to ORA’s Division of Communications via the website provided.

I’ll close where I began – this is an exciting time to be at FDA and in ORA. We are in the midst of transformative change across our entire enterprise. Change that will provide increased opportunity for our work force, improved strategic approaches across the programs, efficiencies of operations, new tools and tactics, new and improved partnerships, and all of it should position us to provide enhanced public health protection.

I want to thank AFDO for the opportunity to share this update and the work underway in ORA.

To all of my ORA colleagues here, thank you for the work you do every day. And to all of our partners, thank you for your collaboration and commitment to public health. We look forward to the exciting work ahead.

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Applied Nutrition Update  
Dr. Susan Mayne, Director  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
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*This article is based on comments by Dr. Susan T. Mayne, Director of FDA's Center for Food Safety and Applied Nutrition at AFDO's Annual Educational Conference, June 22, 2015, Indianapolis, IN.*

When introducing myself for the first time, I often start with a quote from one of my professors at the University of Colorado, Dr. Morris Massey: "What you are is where you were when."

If you want to understand someone, you need to understand where they came from and what factors in their life have shaped their core values and how they think about things. I am a scientist by training. I started my scientific training as a chemist. During my undergraduate studies, I had an internship in a human performance laboratory that changed the direction of my career. In this laboratory we studied exercise science and nutrition and how to optimize human physical performance. This experience led to my passion for a career in preventive nutrition. I went on to earn a Ph.D. in nutritional sciences, with minors in biochemistry and toxicology from Cornell University. For the next 25 years I conducted research and studied the role of diet and nutrition in chronic disease risk while serving in various capacities at Yale University, most recently, as Chair of the Department of Chronic Disease Epidemiology at the Yale School of Public Health, and Associate Director of the Yale Cancer Center. In this setting I was immersed in an environment that taught me to think as a population scientist. I realized the enormous impact that health interventions, including policy, can have on improving the lives of people around the world. As my career has matured, so has my passion for translating scientific knowledge into improved public health.

I was attracted to the FDA by the potential to use science to impact public health in a way that was difficult in an academic setting. We need to translate cutting edge science in a way that improves health, and policy is one of the best levers we have to do that. To me, it's not just about studying potential health benefits and risks, but finding out how to make and communicate policy changes to enable the benefits and reduce the risks.

Being appointed as the Director of FDA's Center for Food Safety and Applied Nutrition (CFSAN) has been a wonderful privilege. I have learned so much since January 2015, when I arrived at FDA. There is a remarkable depth and breadth of scientific expertise in CFSAN, including toxicologists, biologists, chemists, nutritional scientists, food technologists, behavioral scientists, medical officers and epidemiologists. Working with the scientists are policy and communications experts, economists and lawyers. The scope of expertise needed at the intersection of policy and science at CFSAN is extraordinary. What is so fascinating is to see how these different disciplines work

together to integrate science, policy and the law to address public health concerns. CFSAN's mission is broad; we are responsible for protecting the safety of the nation's food supply, ensuring that cosmetic products are safe and properly labeled, fostering the reformulation of food towards healthier products and ensuring that consumers have access to accurate and useful information to make healthy food choices. It is truly an exciting environment for me to be in.

Another thing I have learned that I did not appreciate coming from academia is how closely CFSAN works with its stakeholders. One of the very unique things about CFSAN is the diversity of stakeholders. I couldn't possibly meet with them all, so in my first three months on the job I made it a point to meet with stakeholder groups -- consumer groups; professional and scientific organizations; medical and patient groups; and representatives of the food, cosmetic, animal products, biotechnology and specialty foods industries. These were very informative meet-and-greet sessions and gave me the opportunity to hear about the issues most important to each group, how the groups characterize their interactions with CFSAN, and suggestions for improved future interactions. I enjoyed the stakeholder meetings and having the opportunity to learn everyone's perspectives, especially perspectives on what CFSAN can do better. I continue to meet with stakeholder groups and take that information back with me. As I think about new program initiatives moving forward, I remember those conversations and think, "How is this going to affect this stakeholder? What are some of the sensitivities we need to be aware of?"

### **FDA Food Safety Modernization Act**

I'd like to provide an update on some of the exciting activities ongoing in CFSAN. First and foremost, this year, we made huge progress in implementing the FDA Food Safety Modernization Act (FSMA). FSMA is one of the most sweeping food safety laws in history and it addresses a critical public health problem. Every year, 48 million people, or 1 in 6 Americans, get sick from foodborne diseases. Approximately 128,000 are hospitalized, and 3,000 die. Enactment of FSMA was based on the recognition that the solution to the problem of foodborne illness is a comprehensive prevention strategy that involves all participants in the food system, domestic and foreign, doing their part to minimize the likelihood of harmful contamination. This shift in approach to preventing foodborne illness rather than solely reacting to foodborne illness is an enormously big effort within FDA's Foods and Veterinary Medicine Program (FVM), which spans CFSAN and the Center for Veterinary Medicine (CVM). FVM works closely with the Office of Regulatory Affairs (ORA) and the Office of International Programs (OIP), located in the Office of Global Operations and Regulatory Policy (GO). Accordingly, successful implementation of FSMA depends, in large part, on close partnership, collaboration, and decision-making.

This year, five final regulations were issued to implement FSMA. The preventive controls regulations require food facilities to develop and implement written food safety plans that indicate the possible problems that could affect the safety of their products and outline steps the facility would take to prevent or significantly minimize the likelihood of those problems occurring. The Produce Safety rule establishes science-based standards for growing, harvesting, packing and holding produce in areas such as water quality and employee health and hygiene. The FSMA rules also require importers

of human and animal food to ensure that overseas suppliers are taking these same food safety steps. They also establish a program for the accreditation of third-party certification bodies to conduct food safety audits and to certify that food produced by such facilities meets FDA food safety requirements. The rules addressing imports will give consumers confidence that the food they eat is safe, whether it's produced domestically or imported.

We developed these rules through a transparent and participatory process, working closely with all of the stakeholders that will be affected by the rules. FDA experts travelled across the country to meet with farmers, for example, to ensure that the produce safety rule addressed the diversity of operations.

But finalizing the rules is just one part of building a modern, effective food safety system. For a long time now, our work has moved forward on parallel tracks. We have had teams working on finalizing the rules, integrating the information received in response to both the original proposals and to revisions outlined in the supplemental proposals. Concurrently, we have teams designing the strategies and developing the operational plans that will be needed to implement these rules when they become effective. We have included state representation on all of the working groups to make sure that the different sectors that are going to be impacted by implementation of FSMA have a voice at the table.

We are not just expecting industry to do things differently under FSMA. FDA will be doing things differently as well. Our inspection and compliance staffs will be trained to be specialists in one area, rather than covering a broad range of products. Members of these staffs will be teamed with subject matter experts across the agency. They will work together to drive correction of problems and help implement preventive approaches. We are developing targeted, risk-based inspection models that guide inspection priority, frequency, depth and approach on the food safety performance of firms. We will develop performance goals and metrics to enable us to deploy our resources in the most effective way.

Our training strategy for the food industry recognizes that one size doesn't fit all when it comes to training. We will use a variety of training options and delivery formats for the industry, including public-private alliances. We have made a firm commitment to educate before and while we regulate. That means providing education and technical assistance resources to support compliance with these new regulations.

We will be relying heavily on state public health and agriculture departments and other state and tribal departments as we implement FSMA. This partnership is multi-faceted. The States will help educate industry and will conduct the majority of inspections domestically. It is important that FDA take advantage of the States' food safety commitment and their knowledge of local conditions and practices. We have been building a National Integrated Food Safety System to fully integrate the more than 3,000 state, local and tribal government agencies involved in food safety in FDA's work to meet the FSMA mandate. The states will need inspector training programs, information sharing capacity with FDA and other states, and state laboratory enhancement and coordination.

Fiscal years (FY) 2015 and 2016 are crucial years for doing the upfront work that is needed to implement FSMA. FDA must be equipped to lay the foundation to ensure smooth and effective implementation in late 2016 and 2017. FDA must be prepared to make improvements in a number of areas, including inspection modernization and training; development of a national, integrated food safety system; industry education and technical assistance; technical staffing and guidance development; modernized import safety programs; and risk analytics and evaluation.

## **Risk Analysis**

An important aspect of preventive control systems under FSMA is that industry has the responsibility to identify hazards as it designs and implements preventive controls programs. But in some cases, CFSAN has information through risk assessments and other means to provide guidance or set requirements for specific pathogens in foods that it knows could adversely affect public health. This is the case within the FSMA framework but also for foods that fall outside the FSMA framework. A good example is our requirement for achieving a specific log reduction for pathogens in juice.

It will continue to be our job to conduct risk assessments and study specific food safety issues to bring the best science available to consideration of food safety hazards and appropriate actions, such as guidance or other standards. To that end, FDA is updating its 2002 Risk Analysis Framework document, which describes the processes for initiating, selecting, and conducting safety and risk assessments.

*Listeria monocytogenes (Lm)* is one food safety hazard to which CFSAN has devoted attention recently, bringing the issue to the FDA Food Advisory Committee. This year, an outbreak of *Lm* was associated with single-serve ice cream manufactured by Blue Bell Creameries. The Centers for Disease Control and Prevention (CDC) have reported a total of ten patients infected with *Lm* in four states. All ten patients were hospitalized. Three deaths were reported. This outbreak presented a public health challenge in that we do not often see *Lm* outbreaks associated with shelf-stable products maintained at temperatures that are low enough to prevent *Lm* from growing. The vast majority of *Lm* outbreaks involve foods that are perishable, even if refrigerated. We will consider the input of the Food Advisory Committee in determining whether any changes are needed in guidance provided to the industry on this pathogen.

Chemical contaminants are another important area for work in CFSAN. Several initiatives are underway. CFSAN is updating the "Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food" -- this is more commonly known as "The Redbook." The Redbook is a valuable resource used to guide FDA's assessment of the safety of chemicals added to food. FDA held a public meeting on this issue in December 2014 and a public docket was opened to receive comments. To maintain its value and usefulness to FDA's mission, the Redbook is being updated to reflect current science and the often multidisciplinary aspects of chemical safety and risk assessments.

Another chemical contaminant issue is arsenic. Arsenic is present in the environment as a naturally occurring substance. It is found in water, air, food, and soil in both an organic and inorganic form (the latter is the more toxic form). Arsenic can be found in many

foods, including grains, fruits, and vegetables, due to absorption from the soil and water. Because long-term exposure to high levels of arsenic is associated with higher rates of skin, bladder, and lung cancers, FDA has for many years monitored the presence of total arsenic in foods. More recently, FDA has begun using more sophisticated analyses of samples to specifically quantify the presence of inorganic arsenic. FDA's sampling and risk analysis efforts have focused on rice and rice products, because rice has higher levels of inorganic arsenic than any other food measured by FDA, and it is an ingredient in a variety of foods and beverages, including foods for infants and young children. FDA continues to work with other federal agencies, stakeholders, and scientists to understand and address the risks associated with arsenic in food.

FDA also has a role in providing advice to the public related to food hazards. For example, FDA is working with the Environmental Protection Agency to revise joint advice issued in 2014 encouraging pregnant women, those who may become pregnant, breastfeeding mothers, and young children to eat more fish, particularly fish lower in mercury. This is a complicated issue as fish have both beneficial effects when consumed during pregnancy but also can include the chemical contaminant methylmercury. So the challenge is to take into account the benefits as well as the risks and translate that information into consumer advice about eating fish.

### **Nutrition Initiatives**

CFSAN also is involved in a number of exciting nutrition-related activities. CFSAN's public health mission includes implementing initiatives to reduce the rates of nutrition-related risk factors for chronic disease; optimizing health through improved nutrition; fostering the development of healthier foods; and ensuring that consumers have access to accurate and useful information to make healthier food choices.

One major initiative is the updating of the Nutrition Facts label on food packages to promote healthy dietary practices. As a result of advances in science, we now know more about the association between nutrient consumption and disease. For example, we now know that the type of fat is more information than the amount. We are also updating serving sizes because people are eating different portions than they did 20 years ago. And we are updating the format of the label to draw attention to important information like calories. We accepted public comment on the proposals and hope to issue a final rule soon.

We also published a final rule on menu labeling to make calorie information available on chain restaurant and other menus. Calories also will be required on certain vending machines. Americans eat and drink about one-third of their calories away from home, and making calorie information available will help consumers make informed choices for themselves and their families. The menu labeling rule applies to restaurants and similar retail food establishments if they are part of a chain of 20 or more locations, doing business under the same name and offering for sale substantially the same menu items. The menu labeling final rule also requires covered establishments to provide, upon consumer request, other written information about nutrient content.

FDA also published a final determination that partially hydrogenated oils (PHOs), which are the primary source of industrially-produced *trans* fats in the food supply, are no

longer considered “Generally Recognized as Safe” (GRAS) (80 FR 34650). Publication of this determination does not mean that trans fat will be completely eliminated from food because trans fats also occur naturally in meat and dairy products. Trans fat is also present at very low levels in other refined edible oils, where it is unavoidably produced during the manufacturing process. In addition, companies can petition FDA for specific uses of certain PHOs. We know that trans fat increases the levels of low density lipoprotein or LDL cholesterol, which contributes to coronary heart disease. Reducing consumption of PHOs will prevent thousands of coronary heart attacks and deaths each year.

In other rulemaking, as of August 2014, foods labeled as “gluten-free” must contain less than 20 parts per million. This level is the lowest that can be reliably detected in foods using scientifically validated analytical methods. The definition provides consumers—especially those with celiac disease—the assurance that “gluten-free” claims on food products are consistent and reliable across the industry, and gives them a standardized tool for managing their dietary intake. In November 2015, we proposed a rule to establish requirements for fermented and hydrolyzed foods, or food that contain those ingredients, and bear the “gluten-free” claim.

FDA is also continuing efforts to achieve a gradual reduction of added sodium in the food supply.

One important internal initiative that warrants mention is elevating the prominence of CFSAN’s dietary supplement program by making it an independent office instead of a staff within the Office of Nutrition, Labeling and Dietary Supplements. Separating the nutrition and dietary supplement programs will provide each with separate leadership and accountability, enabling a strengthening of the programs’ ability to identify and achieve goals. With expanded prominence, the new Office of Dietary Supplement Programs can be more strategic in how it uses its resources to ensure the integrity of product identity; enhance compliance with Good Manufacturing Practices through more enforcement and additional education; increase attention to products with acute health hazards; find efficiencies in the New Dietary Ingredient review process; and devote greater attention to substantiation of claims.

### **International Food Safety**

Given the increasing globalization of the food supply, CFSAN has a very broad and diverse portfolio of international responsibilities. First and foremost, FDA ensures the safety of imported foods, and under new rules recently issued to implement the FDA Food Safety Modernization Act, importers are accountable for verifying that imported food meets U.S. safety standards.

FDA also participates in the activities of the Codex Alimentarius Commission. The major emphasis of Codex’s work is on developing international food safety standards, codes of practice, and guidelines. CFSAN provides the delegate or alternate delegate to 16 of 18 active Codex Committees/Task Forces. Apart from the international trade agreement implications, the value of Codex standards lie in their providing a set of sound internationally recognized standards that countries can use to improve the safety of

food (important for food imports) and use in facilitating trade (important for food exports).

Another important initiative in the public health and trade venue is providing leadership and oversight to ensure that FDA's food and cosmetic programs meet international obligations such as those under the World Trade Organization (WTO). The advent of new "WTO-plus" trade negotiations requires that CFSAN staff devote more time and attention to public health and trade activities. CFSAN employees represent FDA in trade discussions with the Department of Health and Human Services, the Office of Management and Budget, and the U.S. Trade Representative.

CFSAN employees work to promote and provide oversight of capacity building efforts, which aim to support efficient and sustainable improvements to countries' oversight of food safety systems and, thereby, increase the safety of food imports to the U.S. These efforts involve substantial coordination with partners to leverage resources, to avoid duplication of efforts, and to broaden the reach of food safety capacity-building efforts.

FDA also is working on systems recognition with countries with mature, robust food safety systems that are similar to that of the United States for FDA-regulated food products. The process involves assessing a foreign country's food safety system to determine if it is comparable to that of the U.S. food safety system. That means that the foreign country's food safety system may be different, but it provides the same level of public health protection. FDA has recognized New Zealand's system in this manner and is now evaluating the systems of Canada and Australia. Systems recognition provides a new level of regulatory cooperation while facilitating trade between the countries.

## **Outbreaks and Recalls**

Over the past few years, high-profile outbreaks related to various foods, from spinach to peanut butter to ice cream, have underscored the need to make continuous improvements in food safety, and many of the activities described here work toward that goal. However, FDA must remain vigilant when food safety problems occur despite everyone's best efforts, and the Agency plays a significant role in responding to outbreaks of foodborne illness and working with companies to recall products when appropriate.

Several years ago, FDA created a Coordinated Outbreak Response and Evaluation (CORE) Network to manage not just outbreak response, but surveillance and post-response activities. CORE takes a three-pronged effort: detection, response and prevention. This way, as an outbreak is contained, CORE determines what steps need to be taken to prevent the problem from happening again. CORE members work with regulatory, public health and agricultural agencies at the federal, state and local levels on this important mission.

In fiscal year 2014, there were 557 food-related recalls representing 2549 food products. The main reasons for food recalls in 2014 were by far microbial pathogens including *Salmonella*, *Lm*, and various strains of Shiga toxin-producing *E. coli* (STECs) and undeclared allergens. These two categories of recalls were followed by recalls due to

allergen cross-contact, allergen labeling and undeclared non-allergenic ingredients including sulfites and colors.

## **Research Initiatives**

CFSAN's research helps to inform the Center's regulatory role as it applies to food and cosmetic safety, food defense, and applied nutrition. A significant area of work is whole genome sequencing (WGS), a cutting-edge technology that FDA has put to use in supporting investigations of outbreaks of foodborne illnesses. Researchers created and deployed Genome Trakr, the first integrated network of laboratories to use WGS for pathogen identification. The Genome Trakr network consists of 14 federal labs, 14 state health and university labs, one U.S. hospital lab, five labs located outside of the U.S., and collaborations with independent academic researchers. The network, which regularly sequences over 1,000 isolates each month, produces comprehensive libraries of genomic information for a variety of foodborne pathogens (e.g., STECs, *Salmonella*, *Listeria*, *Vibrio*, *Cronobacter*), including parasites and viruses.

Other current areas of research include DNA sequencing to quickly identify seafood species; development of improved methods for determining sulfites in foods; development of mass-spectrometry based methods for detection of gluten in foods; cardiotoxicity of dietary supplements; development of rapid molecular methods for improved throughput screening of foodborne pathogens; analysis of foods that list live microbes as an ingredient (probiotics); and the use of metagenomics. These are just a few examples of foundational research in CFSAN that we undertake to support our public health mission.

What I have learned about the applied research laboratories within CFSAN is that they have a broad range of expertise. They can be called upon as needed to develop new assays and methods in order to make sure that we're protecting the safety of the U.S. food supply and that we have the analytical capacity to respond as needed when called to do so.

## **Closing**

In closing, my new leadership position at CFSAN has been a wonderful learning experience. I have observed an amazing array of public health issues coming across my desk. I am energized by the diverse breadth and depth of activity, and look forward to the challenges and opportunities ahead.

I feel privileged to be leading CFSAN and championing the very important work that is carried out by CFSAN employees each and every day. The work commitment that I see in CFSAN employees every single day is astounding. I have enjoyed meeting with CFSAN's many stakeholders and working together to address growing challenges and opportunities to protect and promote public health. One of the most exciting and gratifying things about my job is that we all share the same goal – a safe food supply. Industry wants this. Consumers want this. State and local governments want this. We all want this. I am very much looking forward to working together in partnership to make sure that we're meeting our public health mission.

# The Impact of the IFPTI Fellowship on the Food Regulatory Arena

Craig Kaml, Ed.D., Vice President of Curriculum

Christopher Weiss, Director, Evaluation and Publications

International Food Protection Training Institute

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The International Food Protection Training Institute (IFPTI) Applied Science, Law, and Policy: Fellowship in Food Protection program (Fellowship Program) was designed to prepare future leaders in the food regulatory arena. Three cohorts, each comprising 10-12 individuals, have successfully completed the program. The purpose of the following study was to measure the extent to which the Fellowship Program has achieved its objectives. An electronic survey consisting of five open-ended questions related to professional development, job responsibilities, and leadership activities was sent to members of the first three cohorts, with 23 individuals (70%) completing the survey. More than half of the respondents reported having presented at a conference or workshop since completing the Fellowship; just under two-thirds indicated having an increased leadership role in professional associations or work-related committees since completing the Fellowship Program; 70% indicated that they had assumed more responsibilities at work since completing the Fellowship Program, with ten former Fellows (43%) reporting a new job title or job promotion within their regulatory agency. Over half of the respondents reported being more active in professional associations or work committees, while 78% of the former Fellows reported using the designation "IFPTI Fellow" in various professional settings. These results demonstrate that the Fellowship Program is accomplishing the primary objective of enhancing the leadership skills of food regulators at various levels of jurisdiction.

## Background

The International Food Protection Training Institute (IFPTI) Applied Science, Law, and Policy: Fellowship in Food Protection (Fellowship Program) was created to help support the national, integrated food safety system (IFSS) as envisioned by the Food Safety Modernization Act (FSMA) and federal regulatory agencies such as the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA). The ANSI-accredited program provides future leaders with an intense professional development experience focused on critical thinking, problem-solving, writing original research projects, and delivering presentations, all within the framework of food regulatory science, law, and policy.

The Fellowship Program is offered to select food regulatory professionals at the federal, state, local, tribal, and territorial levels with two to ten years of experience, and who wish to pursue a long-term career in food protection. As a prerequisite, Fellows are required to complete the FDA Office of Regulatory Affairs University (ORA-U) online courses identified in Standard 2 of both the FDA retail and manufactured foods program standards, as well as FD 170, the Application of Inspection and Investigation Techniques course (or equivalent). To be accepted into the program, applicants must also submit letters of recommendation, a letter of support from their agency, a letter of commitment to complete the program, and must also go through an exhaustive vetting process involving the Fellowship Program Selection Committee.

During the year-long program, the Fellows: 1) participate in three week-long discussion-based sessions (generally held at the IFPTI global headquarters in Battle Creek, MI); 2) design and develop an original research project under the guidance of IFPTI mentors and subject matter experts (SMEs); and 3) present their research findings at the annual conference of the Association of Food and Drug Officials (AFDO). Additionally, final articles based on the Fellows' research projects are published in a special edition of the AFDO Journal.

The Fellowship welcomed its first cohort in late 2010, Cohort II in 2011, and Cohort III in 2012. A total of 35 individuals have completed the Fellowship, with an additional 10 individuals participating in Cohort IV in 2014-2015. However, due to slight attrition, the pool for the present research was reduced from 35 to 33 individuals.

As part of the overall Fellowship Program evaluation strategy, IFPTI started conducting an alumni survey of past Fellows beginning in 2012, and feedback from the survey is used to continuously improve the program. Survey questions are designed to gauge any impact(s) the Fellowship Program has had on the Fellows' careers. In 2012, IFPTI reported on the results of the alumni survey conducted of Cohort I, and although the survey results were favorable, the methodology was limited to a small participant pool (just seven members of Cohort I responded to the alumni survey). In 2014, however, IFPTI was able to survey Cohorts I through III, and able to garner a respondent size of 23 (70% of the available Fellowship alumni).

## **Methodology**

The 2014 Fellowship Program alumni survey was developed and posted on the IFPTI-branded Learning Management System (LMS), a secure online learning environment overseen by IFPTI staff. Individuals, including Fellowship participants, created a username and password, which allowed them access to the LMS. An initial email with instructions for taking the survey through the LMS was sent to the thirty-three individuals representing Cohorts I, II, and III of the Fellowship Program. Individuals who did not take the survey were sent a series of reminder emails encouraging them to do so.

The survey questions inquired as to whether the Fellows, since completing the Fellowship Program:

- 1) Had a paper published or had presented at a conference or workshop;
- 2) Increased their leadership role in professional associations or workshops;
- 3) Became more active in professional associations or work committees;
- 4) Changed positions or were given more responsibilities at work; and/or
- 5) Used the designation "IFPTI Fellow" in any capacity.

Each question also contained an open-ended section that allowed the Fellows to elaborate on their responses.

## **Results**

Twenty-three of the thirty-three available Fellows completed the survey, yielding a response rate of 70%. Five of the respondents were members of Cohort I; eight were members of Cohort II; and ten were part of Cohort III.

***Publishing a Paper/Presented at a Conference or Workshop***

None of the Fellows indicated having published a paper since completing the Fellowship. However, thirteen respondents (57%) reported presenting at a conference or workshop. The conferences specifically named by the respondents included AFDO and regional AFDO affiliates (Southern States/AFDOSS, North Central/NCAFD, Western/WAFDO), state environmental health association annual conferences (Texas, California), the Manufactured Program Standards (MFRPS) Alliance conference, an FDA Central Region retail food seminar, and the Interstate Environmental Health Seminar (which comprises eight states in the Mid-Atlantic/Southern parts of the U.S.).

***Increased Leadership Role***

Fifteen of the Fellows (65%) indicated having an increased leadership role in professional associations or work-related committees since completing the Fellowship Program. Ten of the respondents (43%) became Co-Chairs, Chairs, Junior Board Members, Senior Board members, or Secretaries of AFDO (and/or regional AFDO affiliates) professional committees; one had become President of a regional AFDO affiliate; one former Fellow reported being elected Vice President of a regional Conference for Food Protection; another reported becoming Co-Chair of the Manufactured Program Standards and the Retail Program Standards (VNRFRPS) Committees; and one indicated serving on a local board of the National Environmental Health Association.

***More Active in Professional Associations or Work Committees***

Thirteen of the survey respondents (57%) reported being more active in professional associations or work committees since participating in the Fellowship Program. Associations and committees mentioned were national in scope (the National Environmental Health Association/NEHA, AFDO, the International Association for Food Protection/IAFP, the U.S. Public Health Service, the Conference for Food Protection, the Partnership for Food Protection, the Seafood HACCP Alliance, and the American Water Works Association); regional AFDO affiliates (AFDOSS, Mid-Continental/MCAFD, Central Atlantic/CASA, WAFDO); state-specific (Georgia Environmental Health Association, Georgia Association of Food Protection, Texas Environmental Health Association); and local in nature, including the Lubbock (TX) Restaurant Association, and a small onsite sewage conference.

***More Responsibilities at Work***

Sixteen of the respondents (70%) indicated that they had assumed more responsibilities at work since completing the Fellowship Program. Ten respondents (43%) reported being given a new job title, or being promoted within their regulatory division, department, or agency to positions such as Division/Department Director, Bureau Chief, Program Manager, Sanitarian III, Supervisor, and Coordinator. One of the Fellows reported a new management job in the private industry sector, while five of the Fellows

indicated they had taken on more responsibilities related to items such as FDA contracts, plan reviews of food service establishments, the Incident Command Team, and FSMA.

### ***Use of the IFPTI Fellow Designation***

When asked whether the Fellows have used the designation “IFPTI Fellow” since completing the Fellowship Program, a total of eighteen (78%) responded in the affirmative. Numerous instances of the designation usage were provided, including using the designation in their bios or resumes (9), when attending conferences/workgroups or in other professional settings (7), when presenting at conferences or during other speaking engagements (4), in job applications (2), in conversation (2), and when helping to recruit future Fellows (1).

### **Conclusion**

The results of this survey clearly demonstrate IFPTI Fellowship participants have increased their job responsibilities and professional activities and have advanced in their positions. In other words, the Fellowship has helped position these individuals as true future leaders in the food safety realm.

Since completing the Fellowship Program:

- Approximately seven out of ten respondents reported having an increased leadership role through professional associations and/or work committees, and had also taken on more responsibilities at work;
- More than half of the former Fellows indicated having presented at a conference or workshop;
- Close to half reported a new job title or job promotion within their regulatory agency.

These results support the program’s primary objective of properly training a new cadre of engaged food safety leaders. “IFPTI Fellows represent the next generation of leaders in food protection at a time when huge reform and change is taking place,” according to Joseph Corby, Executive Director of AFDO. “The program couldn’t be timelier, and will help assure that a national, integrated food safety system becomes a reality.”

The next Fellowship Program alumni survey will be distributed during mid-2015, again to the first three Cohorts. Cohort IV will be surveyed beginning in 2016.

### **Recommendations**

Based on the survey results, the IFPTI Fellowship Program should be continued, and even expanded. Regulatory agency directors and managers should recommend participation in the Fellowship Program to identify future leaders in food safety. Future alumni surveys will aid IFPTI leadership in reviewing the program content and experience, and aligning the program with current regulatory philosophy and direction.

# AFDO Past Presidents: Reflections on the Past and Challenges for the Future

Paul Dezendorf, Christopher Weiss, and Denise Miller  
International Food Protection Training Institute

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## Background

Given the profound culture shift brought on by the Food Safety Modernization Act (FSMA) and current retirement of a cohort of experienced food protection professionals, gathering the perspective of AFDO Past Presidents regarding past and future food protection trends is potentially of great value to the food protection community. To meet this need, the International Food Protection Training Institute (IFPTI) elicited the thoughts and opinions regarding the changing food protection landscape from AFDO Past Presidents via an online survey and a face-to-face focus group discussion. IFPTI also elicited comments regarding the Past Presidents' comments from individuals participating in Cohort IV of the IFPTI Fellowship in Food Protection.

## Premise

AFDO Past Presidents have extensive years of service in the food protection field and their expertise offers the potential to benefit the profession and its practitioners. The IFPTI project represents the first attempt to garner this expertise and share it with food protection professionals.

## Survey Questions

The online survey contained the following six open-ended questions:

1. What have been the significant changes related to food safety during your career in food safety?
2. What have been the most noteworthy challenges to food safety during your career in food safety?
3. If you had a crystal ball at the time, what is one thing that you wish you had known about the field of food safety that you didn't know during your career in food safety?
4. What changes related to food safety do you see occurring in the future?
5. What will be the most significant challenges to food safety in the future?

6. What words of wisdom do you have for new persons entering the food safety profession now?

**Method**

In early 2015, IFPTI sent out an electronic survey via Survey Monkey® to approximately 30 AFDO Past Presidents. The survey contained a brief set of open-ended questions related to changes and challenges in food safety during their career in food safety, along with open-ended questions related to future challenges in the field. The results of the survey were shared with a face-to-face focus group of 13 Past Presidents during the June 2015 Annual AFDO Conference in Indianapolis. During the focus group, the Past Presidents commented on the survey results and added additional thoughts and opinions related to the survey questions. The focus group (which lasted approximately one hour) was recorded, and a transcript was created in order to help analyze the discussion. The identity of Past Presidents has been withheld from this narrative. IFPTI also shared the survey results with participants in Cohort IV (2014-2015) of the Applied Science, Law, and Policy: Fellowship in Food Protection, an annual program designed to foster future leaders in the food protection arena. Comments from the Cohort IV Fellows are interwoven into the narrative which follows.

**Results**

Fourteen AFDO Past Presidents responded to the online survey, for a response rate of approximately 48%. One Past President opted out of the survey, while the remaining fifteen Past Presidents did not respond.

**Significant Changes During Your Career**

With respect to the first question regarding significant changes related to food safety during their professional careers, the Past Presidents’ concerns centered on legislation such as FSMA, politics, partnerships, technology, and globalization. In particular, FSMA was noted in three responses. As one survey respondent said, “FSMA will increase implementation of the Integrated Food Safety System (IFSS) to meet the global challenges of a safe food supply.” The table below lists a summary of the responses (obtained through both the survey and focus group) to question number one.

<b>Q1. What have been the significant changes related to food protection during your career?</b>	
Globalization of the food supply, consolidation of food industry	Quantum leap in use of technology (in online training and in the field—food production and supply chain)
FSMA, Food Code (and the Conference for Food Protection), NLEA, DSHEA, juice and seafood HACCP, shell egg regulations, LACF, and Acidified Food regulations	Increased importance of marketplace and personal beliefs on food safety field (i.e., “buy local” and organic movements promoted as improving food safety)
Whole genome sequencing soon—impact on policy, know which firms have specific products	FDA Cooperative Agreements to associations = improvements in regulatory effectiveness
Program standards (retail, manufactured	Risk-based inspections vs. more traditional

<b>Q1. What have been the significant changes related to food protection during your career?</b>	
food)	approaches
Integrated food safety system (IFSS) (AFDO had major role)	Major outbreaks that led to significant changes
AFDO board’s decision to make education a primary focus	Ever-shrinking budget; no money at state level
Eggs designated as a “potentially-hazardous food”; listeria issues with soft cheese and cold cuts; produce associated with foodborne illness	

Clearly, much has changed throughout the period that these food safety leaders were actively employed in the field. At the beginning of their careers, food protection professionals (FPPs) turned to the Food, Drug, and Cosmetic Act of 1938 (rather than FSMA) as the main source of food safety-related legislation (with the exception of commodity-specific regulations, such as the Poultry Products Inspection Act), imports and exports accounted for a much smaller percentage of the overall food supply, the integrated food safety system was nothing more than an idea (if that), inspectors focused on “walls, floors, and ceilings,” Facebook and Twitter held no sway in the marketplace, technology was not as advanced nor as pervasive as it is now, and program standards were non-existent. As one Cohort IV Fellow noted, “The overarching theme ...is the shift to a more risk-based approach to food inspections through the establishment of new food safety laws and regulations.”

### **Noteworthy Challenges During Your Career**

With regard to the second question regarding the most noteworthy challenges during the history of their careers, AFDO Past Presidents mentioned a wide variety of topics, including politics, finance/budget, integration (federal-state, epi-regulatory, etc.), social media, pseudoscience, change management, intentional contamination, training gaps, and moving targets in the form of emerging and evolving pathogens. A summary of these topics collected through the survey and the focus group appear in the table below.

<b>Q2. What have been the most noteworthy challenges to food safety during your career in food safety?</b>	
Politics (including Uniformity Legislation of 2005 that would have undermined states’ and locals’ authority); regulators seen by some legislators as “the enemy”	Recognition of HACCP as a valuable tool to control hazards (processed and retail foods)
Federal-state cooperation	People’s ability to change
Cooperation between epidemiology and regulatory fields; independence of agencies and lack of information-sharing	Some states used to have rules that are now statutes; others have no new regulations
Pseudoscience, misinformation, and “chemophobia”	Consistent, equal access of FPPs to training
Budgets	Intentional contamination
Lack of resources and coordination of available resources	Obtaining compliance from habitually poor operators
FSMA and PCA	Emerging and evolving pathogens

One Cohort IV Fellow added an additional perspective:

“The resounding challenge seems to be budget/resource maintenance and the failure of regulatory agencies to keep up with technology. As more and more is expected of food safety regulatory agencies without commensurate increases in resources and funding, it’s impossible to maintain an *effective* preventive emphasis on food safety. With lack of resources, agencies seem to triage what needs to be accomplished and priorities shift from preventive public health activities to reactionary. This reactionary emphasis seems to cost more in the long run, thereby worsening the funding/resource challenge.”

### Crystal Ball

Question number three of the survey asked the Past Presidents what they wish they had known at the start of their careers. Not surprisingly, the former AFDO Presidents returned to some of the same themes of politics, technology, change management, social media, and cooperation and collaboration that were identified by the first two survey questions. In other words, they wish they’d known more about some of the changes and challenges that they would ultimately face in their careers at the beginning of their careers—and understandably so. A summary of the responses to question three appear in the table below.

<b>Q3. If you had a crystal ball at the time, what is one thing you wish you had known about the field of food protection that you didn’t know during your career in food protection?</b>	
The impact of politics	How fractured the regulatory system is
How quickly technology would advance in food safety and defense	Foods we thought were safe turned out to be unsafe (e.g., peanut butter, cantaloupes, inside of shell eggs)
How long it takes for some things to change or to achieve consensus	That food safety is not a “one size fits all” solution; there are many ways to accomplish our goals
Risk of low-moisture foods; cottage foods	That it would take an act of Congress to change our attitudes about food safety
The rise of genomics and genomic sequencing	How prevalent/impactful social media and misinformation would turn out to be
Equivalency vs. harmonization	Reliance on imports (logarithmic increase)

For people who are up-and-coming leaders, however, some of the unanticipated challenges that the AFDO Past Presidents faced during their careers are now “givens” with respect to the food safety arena, such as the impact of social media: “[...] regulatory agencies need to be open to using social media to share the correct information,” responded another Cohort IV Fellow.

### Changes In The Future

In the second half of the survey, Past Presidents were asked to consider the *future* of food safety. Specifically, question four asked what changes the Past Presidents predicted for the future in the arena of food safety. A summary of the responses to question four appear in the table below.

<b>Q4. What changes related to food protection do you see occurring in the future?</b>	
Need for a push for entire food industry to embrace food safety culture	Focus on prevention (early intervention) and regulatory assistance and consultation
Improvements in and use of technology (smart phones for inspections, tracebacks, and consumer tracking of foods' origins)	State-federal-industry partnerships and consumer education along w/in-depth analysis of huge data sets to identify problems/trends before they become crises
More politics and less funding	More imported foods
More funding and emphasis on food safety issues from federal to local levels, with states all using uniform systems	Emergence or identification of new food safety risks or outbreaks concerning foods not previously known as high hazard foods
Food safety of worldwide distribution of food	More reliance on 3 <sup>rd</sup> -party inspections
Improved lab techniques and improvements in prevention	Increased ability to detect pathogens and outbreaks
More training delivered electronically (webinars, apps, online)	Higher standards (more professional staff, program standards)
Additional allergens (sesame seeds, mustard, spices such as cumin, bananas)	Edibles (marijuana and other novel ingredients)

Many of the topics mentioned by the Past Presidents in response to their past careers surfaced again when asked about the future of food safety. These topics included technology, globalization, increased partnerships, funding challenges, emerging pathogens, and the political arena. One of the Cohort IV Fellows emphasized the challenge of creating the integrated food safety system, by noting “[...] the integration of food safety practices into an organizational culture—whether in industry or regulatory—takes a sustained and conscious effort which is being accomplished in varied degrees among the different partners.”

### **Challenges for the Future**

Question five asked the Past Presidents about food safety *challenges* they anticipate in the future. Again, many of the same topics/issues were mentioned, including technology, globalization, politics, funding, and pseudoscience. A summary of the responses to question five appear in the table below.

<b>Q5. What will be the most significant challenges to food protection in the future?</b>	
More intentional contamination and terrorism	“We’ve always done it that way” thinking and behaviors
Food-altering technologies	Globalization pressure on domestic food supply to match availability, quality, and price of imports
Globalization and global food safety verification; imported foods (and surveillance of them)	Rapid analytical methodologies and genome sequencing to detect pathogens (and identify specific ones); big data analysis to determine food safety trends
Continued widespread distribution of	Ever-increasing public food safety

<b>Q5. What will be the most significant challenges to food protection in the future?</b>	
pseudoscience and misinformation due to social media	expectations and the loss of public's confidence in the effectiveness of government in ensuring a safe food supply
Food security—being able to supply the amount of food we'll need	Politics and politicians
Funding, budgets, adequate training	Education assistance for small firms for FSMA implementation
True uniformity	Integration
Collaboration	Actual sharing of information

### Words of Wisdom

The final survey question asked Past Presidents to offer advice to new people entering the food safety profession. The respondents say it best in their own words (edited for clarity and brevity):

Work in a food processing plant for practical experience; study basics of crisis management; learn all you can about food pathogen and controls.

Be involved and open to new ideas and ways of doing things and embrace change.

Use every opportunity to see many different aspects of the food chain—we are all on the same side (regulators, industry, consumers)—we may need some help seeing the full picture.

Participate in national organizations such as AFDO to stay abreast of global issues that impact your agency. The contacts and collaborations will be valuable in recognizing roles and responsibilities in future food protection efforts.

Learn how to operate in the political arena and how to align yourself with the winning side—you'll need that skill set.

Gain true mentors, give back to those coming after you, and seek partnerships with others (feds, industry, medical field, IT field).

Read all you can about national and international food safety news; jump at all training opportunities; listen to others and learn; spend some time in a food lab.

Stay focused on potential emerging food safety issues.

Keep up with science; be aware of popular beliefs; view yourself as a problem-solver; become a critical thinker; focus your priorities on food safety risk; keep an open mind; believe in what you do; pick your battles.

Have a tremendous passion to work in an area that protects the American public and have a network that you can go to, to get feedback on ideas.

Understand that evolution will continue to change many concepts that we believed to be unquestionable.

Seek balance between science, decision-making, policy-making, and how people think and act.

Be passionate and patient; be a good listener; be ready for surprises; develop language skills; and share your profession whenever you can.

## Discussion

The results of this survey and focus group discussion indicate that AFDO Past Presidents are willing to share their expertise with emerging food safety leaders. This willingness to “pass the torch” on to the next generation of leaders was appreciated by Cohort IV Fellows, as indicated by one response: “[...] the majority of the responders appeared to be still actively involved with [...] food protection and were eager to share their experience in order to ensure that the field continues on the correct path.”

The results also point to the fact that there are recurring themes (politics, budgetary issues, accelerated technological advances, emerging pathogens, new regulations and guidance, and a new approach to inspections) in terms of both changes *and* challenges that, if conveyed to people just entering the field, could help streamline the acculturation process of making them aware of previous and anticipated concerns. This sharing of information and lessons learned between previous generations and the next could help cut down on the need to “reinvent the wheel,” as well, and allow the next cohort of leaders to build on best practices.

## Recommendations

The food protection professional field can benefit from regular, periodic dialogues with Past Presidents of AFDO. Continued dialogue with food protection leaders can help ensure that lessons are shared with and assimilated by new leaders, facilitating continuity of vision. The IFPTI survey and focus group results can lay the foundation for further collaboration among past, present, and future members of the food safety profession. Such collaborations can involve online or print media, editorials, and panel presentations where past or current food safety leaders can “pass the torch” to a future generation of food safety leaders. And, finally, IFPTI’s Applied Science, Law, and Policy: Fellowship in Food Protection program is another vehicle by which experienced food protection leaders who serve as instructors (many of whom are AFDO Past Presidents) can share their insights, experience, and knowledge with future food safety leaders.

Correspondence concerning this article may be addressed directly to [pdezendorf@email.wcu.edu](mailto:pdezendorf@email.wcu.edu).

## From the AFDO Archives (1997)

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### **“Regulatory Cooperation Over The Next Five Years”**

**Regulatory Affairs Professional Society  
1997 Annual Conference**

**Presented by**

**Dan S. Smyly, Ph.D, President**

**Association of Food and Drug Officials**

**Washington, D.C.**

**September 9, 1997**

Good Morning. First, I would like to thank George Burditt for inviting the Association of Food and Drug Officials (AFDO) to participate on this panel today and to provide input from the states’ perspective on the topic of “Regulatory Cooperation Over the Next Five Years”. Of course, I may be a little biased, but if one considers the cumulative total of all of the resources committed at the state and local levels of government to assure consumers of the safety of food, drugs, cosmetics, medical devices, and other consumer products, one should come to the conclusion that collectively the states are a major regulatory stakeholder in these areas. And, again, if I may continue to be a little biased, I firmly believe that AFDO will play a key role over the next five years and beyond because the Association is in the best position to represent the regulatory interests of the states. In my view, AFDO must make sure that the states are programmed, up front and not after the fact, in all federal initiatives and activities or this vast available resource will be wasted.

As George indicated, I am Dan Smyly and am currently serving as President of AFDO – this probably explains my biased opinions. In my “day job” I am the Director of Food Safety with the Florida Department of Agriculture and Consumer Services.

For those of you who have not had the opportunity to have at least a ten to fifteen minute chat with Mr. Burditt, you may be saying to yourself “What is or Who is AFDO?” That is a legitimate question, and since George has not had a chance to talk with each of you, I cannot hold him responsible.

AFDO is a professional association consisting of state, federal and local regulatory officials as members, with industry representatives as associate members. From its very inception over 101 years ago, AFDO has recognized the need to balance a state’s right, and indeed its ultimate obligations, to protect its citizens in the areas of food, drugs, cosmetics, and other consumer product safety which impact public health with the need for uniform laws and regulations to prevent regulatory chaos for national and international corporations, AFDO’S primary purpose has been to promote, as its motto states, “Uniformity through Cooperation and Communication”. Through the efforts of its membership of volunteers who also have “day jobs”, AFDO has fostered uniformity by drafting the Model Food and Drug Act many years ago that has been adopted by virtually every state with only

minor deviations. This model state law is basically Florida, we have been “eliminating fat, duplication and government waste” for the past decade. Actually, we have been extricating bones over the past two to three years. If we continue down this road for five more years, our budget will make the “Skull and Crossbones” look fat.

With the dwindling resources available for government services and with the current taxpayer attitude of no new taxes, no increases in user fees and reduction in regulations, it is critical that government at all levels develop effective ways to pool all available resources and to work smarter and more cooperatively in regulating food, drugs, cosmetics, medical devices, and other consumer products. Our elected policy makers must clearly articulate to the public that a significantly reduced government will ultimately provide significantly reduced services. We, as citizens in this great country, can certainly continue to expect and demand the best protection that modern technology can provide. But, we must understand that our expectation should coincide with our willingness to pay for these services. Also, I believe that industry must be willing to go beyond government mandates and then be allowed to find ways to advertise and market the extra efforts incorporated into their products in an effective and honest manner. Government’s “consumers” are industry’s “customers”. Industry’s “satisfied customers” are government’s “content consumers” and usually “content consumers” do not continue demand increasingly burdensome regulations.

All major stakeholders at the federal-state-industry regulatory interface must continue to work toward the development of a truly vertically integrated national system for regulating food, drugs, medical devices, cosmetics, and other consumer products. In some quarters this may be referred to as “seamless regulations”. By properly inserting a good word beginning with “e”, we could call this system, “VINES”. Through continued communication, we must sort through all activities or functions needed to establish the most effective nationally integrated regulatory system. We should then determine which level of government is best equipped to carry out each function and assure that adequate resources are provided at all levels of government to implement the system.

The Congress and the Clinton Administration are encouraged to critically reevaluate the vast resources available in the state and local levels of government. The federal agencies’ human resources are and will continue to be limited. Instead of looking inward to federal resources, I strongly suggest an outward evaluation of the most effective way to use federally generated funds to enhance, strengthen, and unify the existing state and local agency infrastructure and resources. All inspection, laboratory testing, and enforcement activities at all levels of government to effectively regulate the hundreds of thousands of establishments at the retail level. We must pool our resources and we must work together.

The states and federal agencies have a long history of working together through various cooperative agreements, contracts, grants, memoranda of understanding and, most recently, partnerships. In my view, we must get beyond partnerships which some states still view with identical to the Federal Food, Drug and Cosmetic Act of 1938. AFDO has also taken the lead role in promoting the adoption of

uniform state rules and interpretations of laws and rules by drafting model codes for states to adopt. The Association continues to work with the U.S. Food and Drug Administration (FDA) to resolve controversies and to build consensus among the states and the food industry in our joint efforts to get the modern version of the FDA Food Code adopted by the states.

Over the years, the interest of AFDO's membership migrated predominately toward food regulatory issues and the drug, cosmetics and medical devices interests waned. Since about 1990, my predecessors and I recognized this shortcoming of the Association and have made a concerted effort to re-emphasize the "D" (for Drug) in AFDO. By offering split sessions on Food and Drugs during our annual educational conferences, by co-sponsoring with the FDA numerous workshops on drugs and medical devices, and through the efforts of our Drugs, Devices and Cosmetics Committee under the active leadership of Cynthia Culmo with the Texas Department of Health, we have made great strides in turning this situation around.

In reviewing your 1997 Annual Conference program and seeing topics dealing with biologics, pharmaceuticals, medical devices, clinical efficacy, blood products and technologies, etc., I realize that, with my career background in chemistry and in a food regulatory program, I will not be able to address issues specific to your industries from my personal experiences. However, the topic for this panel is a pretty large umbrella which casts a shadow over a vast array of issues involving all regulatory programs and industry interfaces.

In speaking from the states' perspective, each of the 50 states has a vision and expectation of what it thinks the federal-state-industry regulatory relationship should be over the next five years. This vision is keenly impacted by the specific stresses and issues being experienced at the time by each state, i.e what are the "hot bottoms" in each state?? And almost always, they will be slightly different. My comments today are in no way an attempt to provide a consensus opinion of the states. As a matter of fact, when I requested input and assistance for this presentation from my Board of Directors, I was advised that "They trusted me and that I was on my own". So my comments are based upon my view of the world, steeped in 27 years of regulatory experience at the state level and tempered by recent events and trends.

Obviously, barring no catastrophic outbreak of food borne illness or injuries from drugs, cosmetics and medical devices, the number one driving force impacting the regulatory/industry interface over the next five years will continue to be the efforts to balance the federal budget. Five years from today will be 2002, and we will be only a few days away from the federal government entering its FY 02 operations with a balanced budget!!!

I know Mary Pendergast and Ron Chesemore are very aware of the adverse impacts the drive to balance the federal budget has had and will continue to have over the next five years on resources available to the FDA. However, I do not believe that federal agencies have as keen an appreciation for the magnitude of the negative impact this activity is having on states' budgets. In skepticism since

many partnerships seem to favor the federal agency over the states. For us to have a truly nationally integrated regulatory system, we must involve Congress, State Legislators, Governors, and other state executive leaders to adequately fund and jointly plan nationally integrated programs. The funding commitment by all stakeholders is absolutely essential to formalize such a national system.

I would be remiss if I did not leave one final thought with you today regarding legislation currently before the Congress that has the potential to gravely damage the federal-state-industry regulatory interface and the ability for government and industry to effectively respond to emerging consumer concerns in a timely manner. That legislation deals with sweeping federal preemption under the guise of National Uniformity. AFDO has raised its concerns numerous times in many different forums. I will do so again today by attempting to state AFDO's position as succinctly as I possibly can, AFDO is opposed to any preemptive legislation that takes away the states' ability to protect its citizens in the areas of food, drugs, cosmetics and other consumer products safety which impact public health. We feel we have made some progress in this debate as it relates to food, but not as it relates to drugs and cosmetics.

AFDO, in its role of promoting regulatory uniformity, agrees that when a national standard exists it should be the law of the land as long as practical mechanism is in place for a state to petition the federal agency for a different standard in situations that are unique to that state. It should then be incumbent upon the federal agency to adopt the new standard as a national standard if warranted by the situation. When there are no federal laws, regulations. Interpretations or standards, the states must be free to take whatever action deemed appropriate and be restricted only by the states, statutory authorities and administrative rulemaking procedures. Again, if appropriate, the federal agency should promptly initiate the federal process for adoption as a new national standard.

I hope these few thoughts and comments have been provocative enough to cause you to join those of us who lay awake at night pondering over possible solutions to the many challenges that we must face together over the next five years. Again, George, thank you for inviting me here to participate.

# **Dr. Dan Smyly Statement from the Proceedings of the Third Annual Federal/State Conference on Food Safety**

November 20-21, 1997

Mr. Smyly

Dan Smyly

Department of Agriculture, State of Florida

Thank you, Tom. When I saw my name on the program I thought I was going to get to ride free on this particular topic today.

But while I was out with my coworkers last night partnering at the Sacramento Brewery I did jot down a few notes and I carry them around with me just in case I get called up to do something like this.

I don't know, it's kind of frightening in a way, I guess you and I have been in too many meetings together over the last five years, we're starting to sound and think alike, and I don't know whether that's good or bad.

But before I got into that I would like to follow your comments of yesterday and really commend Stu Richardson and his staff, the FDA and the USDA staff that worked together with some of the industries here over the last day and a half.

I think this has been a very good meeting. I think we've seen a lot of possibilities that we can take back to our work on our jobs, and maybe come to some resolution to some of the problems we have to deal with.

You mentioned AFDO two or three times this morning, and I'm not sure everyone in the room knows what AFDO really is. But AFDO is a professional association consisting of state, federal and local representatives as regular members. And the industry is represented in this association as associate members.

From its very inception 101 years ago AFDO has recognized the need to balance the state's right, and indeed the ultimate obligation to protect its citizens in the public health areas of food, drugs, medical devices, cosmetics and other consumer product safety with the need to have uniform laws and regulations to prevent regulatory chaos for the national and international corporations.

AFDO's primary role or purpose has been to promote, as its motto says, uniformity through cooperation and communication. Through the efforts of its membership of volunteers, who also have day jobs, AFDO has sponsored uniformity by drafting the Model Food and Drug Act many years ago which has been adopted by virtually every state with only minor deviations. This model law is basically the same as the Federal Food, Drug and Cosmetics Act of 1938.

AFDO also has taken the lead role and promoted uniform state rules and interpretation of laws and rules by drafting model codes for states to adopt.

The Association continues to work with the U.S. Food and Drug Administration to resolve controversies and to build consensus among the states and the food industry in our joint efforts to get the modern FDA food code adopted by the states.

During our 1997 annual conference at Minneapolis, Minnesota we actually adopted a resolution that encourages the adoption of the 1997 Food Code, and we also wanted to continue working with the FDA to resolve about three key controversial issues that still exist. And those involve the demonstration of knowledge, consumer advisories, and variances.

Now, to me, barring a catastrophic foodborne illness outbreak the number one driving force that's going to impact on regulatory and industry interface over the next five years is going to be the effort to continue to balance the federal budget.

Five years from today will be 2002, and we will be into the second month of the federal government's FY02 budget, which is the year of the balanced budget. And I know people like Carl Reynolds that was here yesterday and Richard Barnes and John Turner with the FDA, and Tom Billy with the USDA, are very aware of the adverse impacts the drive to balance the federal budget has had on, and will continue to have on, for the next five years, the FDA and USDA budgets.

However, I do not believe the federal agencies have as keen an appreciation for the magnitude this negative impact of this activity is having on the state budgets. In Florida we have been reducing fat, cutting duplication, eliminating waste, government waste for the last two years. And as a matter of fact, we just gave up the state meat inspection program. It will be referred to the USDA at the end of business on December 1st of this year. I kind of hate that because I was looking forward to working with Tom and his staff as we moved forward into the future and a different way of handling the meat and poultry regulatory programs between the federal and state agencies.

With our dwindling resources we have very few options except to work very closely together, pool our resources, and work toward a common goal. We've got to work smarter, as Tom said yesterday, and more cooperatively in the regulation of foods in this country.

I also believe that all major stakeholders in the federal/state/industry/regulatory interface must continue to work towards its development, or what I call a truly vertically integrated national food regulatory system. In some quarters, as Tom mentioned again yesterday, this is referred to as seamless regulations.

The Congress and Clinton Administration should critically reevaluate the vast resources available in the state and local levels of government. The federal agencies' human resources are, and will continue to be, limited.

Indeed, or instead of looking inward, I strongly suggest that an outward evaluation of the most effective way that federally generated funds to enhance, strengthen and unify the existing state and local agencies' infrastructure and resources for regulating food in this country at the retail level.

All inspections, laboratory testing, and enforcement activities on all levels of government must be captured in an overall focused national food regulatory system. No level of funding increase will give sufficient resources for the federal government to effectively regulate the hundreds of thousands, and I think you mentioned million, retail establishments. We must pool our resources, and we must work together.

12/18/2014 Federal/State Partnerships to Improve Food Safety A Vision of the Future  
<http://www.fsis.usda.gov/OPPDE/animalprod/Proceedings/Federal.html> 8/18

The states and the federal agencies have, in my opinion, a long history of working together. Through various cooperative agreements, contracts, grants, memorandum of understanding, and most recently the buzzword is "partnerships."

"Partnerships" are certainly a central piece of the current strategy that we must use as we move from where we've been for the last several decades to where we ought to be in the very near future. Again, I think the lack of, our dwindling resource base leaves us no option except to do that. And for us to have a truly national integrated regulatory food system we must involve the President, Congress, governors, state legislators, and other state executive leaders to provide adequate resources at all levels of the government to implement the national system.

Just recently we had an AFDO Board meeting in Washington the first week of November. And I mentioned to the board the need to get beyond partnerships and to look at a framework, I call it a blueprint, of a national system where we get key individuals from the appropriate federal agencies, the associations that have some impact or some involvement in food safety from farm to the table.

As a result of those discussions the Board asked me to pursue that idea with our federal counterparts.

And, Tom, earlier this week has sent letters to Michael Friedman, the lead Deputy Commissioner for FDA, and to Catherine Woteki, the Under Secretary for Food Safety at USDA.

In those letters I requested their support to convene a select group for one and a half to two days, to work with a facilitator to craft the blueprint for the future of vertically integrated national food regulatory system in this country.

The goal of this meeting should be to determine all of the functions and activities required to have a state of the art national food regulatory system; To determine the level or levels of government best equipped to carry out each function or activity; And to obtain funding, or funding commitment from all stakeholders to provide adequate resources at all levels of government to implement the system.

I suggested that the select group include key members from federal agencies, four or five members from each of the associations that have involvement, the participants of the key consumer advocacy groups, and possibly participation from one of the think tanks to serve as a facilitator.

If they concur that the timing is right for such a visionary meeting, AFDO stands ready to partner with them to make this meeting a reality. And I think what you just mentioned about the National Academy of Sciences, if we can get some good thoughts together, it might be even helpful to that process, as they evolve with that.

Thank you very much.

**ASSOCIATION OF  
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**AFDO FOOD CODE  
POCKET GUIDE**

A POCKET GUIDE FOR REGULATORS  
(Based on the 2013 FDA Food Code)

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# Mark Your Calendar

*With these important dates:*

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**February 1 - 4, 2016**

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## **MCAFD0**

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## **CASA 2016 Annual Education & Training Seminar**

**April 25 - 28, 2016**

Philadelphia, PA

## **NEFDOA**

**May 4 - 6, 2016**

Saratoga, NY

## **Food Safety Summit**

**May 10 - 12, 2016**

Chicago, IL

## **NEHA**

**June 14 - 16, 2016**

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## **AFDO 120<sup>th</sup> Annual Educational Conference**

*Hosted by* **CASA**

**June 25 - 29, 2016**

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# JOURNAL



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